MILLIMAN WHITE PAPER

Measuring the impact of proposed changes from the Prescription Drug Pricing Reduction Act of 2019 in the Part D benefit design for key stakeholders

Including the impact of extending manufacturer rebates to beneficiaries

Commissioned by the West Health Policy Center

Matthew Hayes, FSA, MAAA
Pedro Alcocer, FSA, MAAA
Sara Yi, ASA, MAAA

NOTE: This analysis was performed on the original language of The Prescription Drug Pricing Reduction Act prior to the updated language released on December 6, 2019.

Proposed changes to the Medicare Part D benefit design have significant financial implications for all Part D stakeholders, including the federal government, Part D beneficiaries, and pharmaceutical manufacturers.

On July 25, 2019, the U.S. Senate Finance Committee approved the Prescription Drug Pricing Reduction Act (PDPRA[1]), which would create an out-of-pocket (OOP) maximum for Part D beneficiaries. These proposed plan modifications are expected to have significant impacts on the costs of all Part D stakeholders. The West Health Policy Center has commissioned Milliman to estimate the financial impacts of these potential benefit design changes, as well as several plausible alternatives.

Furthermore, earlier in 2019 proposed changes to the anti-kickback statute from the U.S. Department of Health and Human Services (HHS) would have required manufacturer rebates to be applied to prescription drug prices at the pharmacy during a beneficiary's point-of-sale (POS) transaction. This would have been a departure from the current approach of accounting for manufacturer rebates after the transaction at the pharmacy.

Under this current approach, manufacturer rebates are used by plans to reduce the cost of prescription drugs in the pricing of benefit plans. Therefore, manufacturer rebates are currently not directly shared with beneficiaries and other stakeholders. While these proposed changes were ultimately not implemented by HHS, discussions among PDPRA sponsors have centered on adding similar language to PDPRA.[2] As a result, the West Health Policy Center has requested that Milliman include in our analysis the impact of two PDPRA alternative scenarios in which manufacturer rebates are extended to beneficiaries at the point of sale.

Background

One of the most impactful changes proposed in PDPRA is modification of the standard Part D plan design. Figures 1 and 2 below provide a comparison of the current Part D benefit design for non-low-income beneficiaries and the revised defined standard plan design under PDPRA. Applicable drugs are those drugs that are subject to the manufacturer payment and are based off of U.S. Food and Drug Administration (FDA) filing status. Applicable drugs include most brand drugs. As Figure 2 shows, PDPRA would remove the current coverage gap, create a hard OOP maximum for Part D beneficiaries, and move the Part D manufacturer payment to the catastrophic phase. Just as importantly, PDPRA would require that manufacturer payments be made on low-income (LI) beneficiaries in addition to non-LI beneficiaries. By comparison, the current plan requires manufacture payments only on non-LI beneficiaries.

Additionally, changes to the reinsurance and plan liability portions in the catastrophic section of the proposed PDPRA plan design would be phased in from 2022 to 2024, with the design fully implemented by 2024. Note for figure 2 we are showing the estimated 2024 Deductible and True Out-of-Pocket thresholds. These values have been indexed based on estimated per capita Part D spending increases.

[1] The full text of the PDPRA is available at https://www.finance.senate.gov/imo/media/doc/FINAL%20Description%20of%20the%20Chairman's%20Mark%20for%20the%20Prescription%20Drug%20Pricing%20Reduction%20Act%20of%202019.pdf.

[2] Haseley, D. (July 25, 2019). Inside Drug Pricing: Grassley, Wyden Consider Reviving Trump's Defunct Drug Rebate Plan. Inside Health Policy. Retrieved November 25, 2019, from https://insidehealthpolicy.com/inside-drug-pricing-daily-news/grassley-wyden-consider-reviving-trump's-defunct-drug-rebate-plan (subscription required).

FIGURE 1: CURRENT 2020 PART D DEFINED STANDARD BENEFIT DESIGN

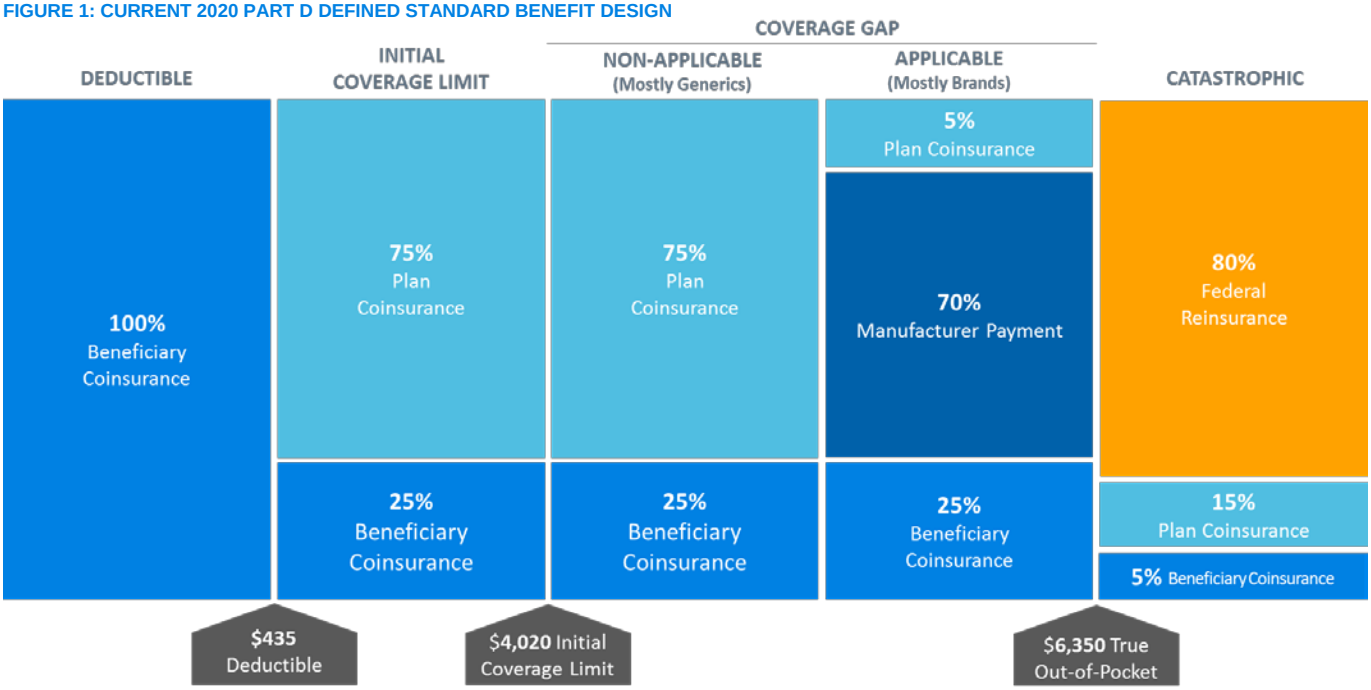
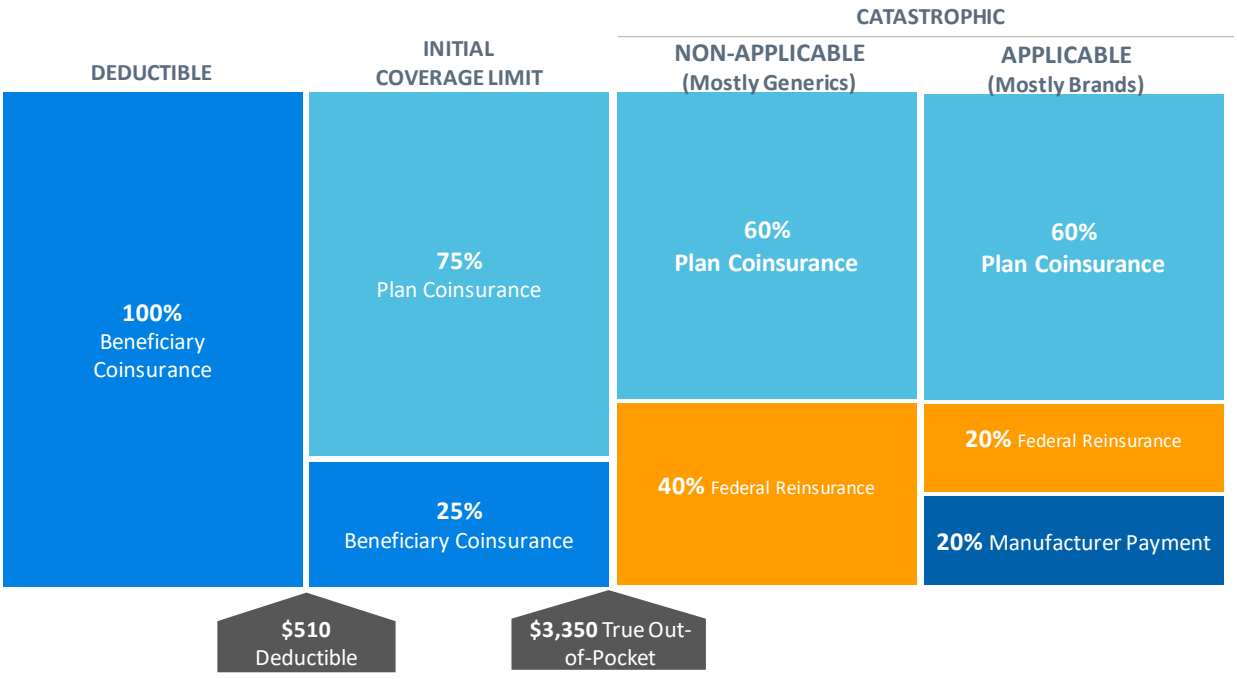


FIGURE 2: PROPOSED PART D DEFINED STANDARD BENEFIT DESIGN UNDER PDPRA FOR 2024



In our analysis of both the current and PDPRA projections (Scenario 1 and Scenario 2), we assumed current Part D rules for manufacturer rebates, and thus treated them as direct and indirect remuneration (DIR). Under this assumption, rebates are

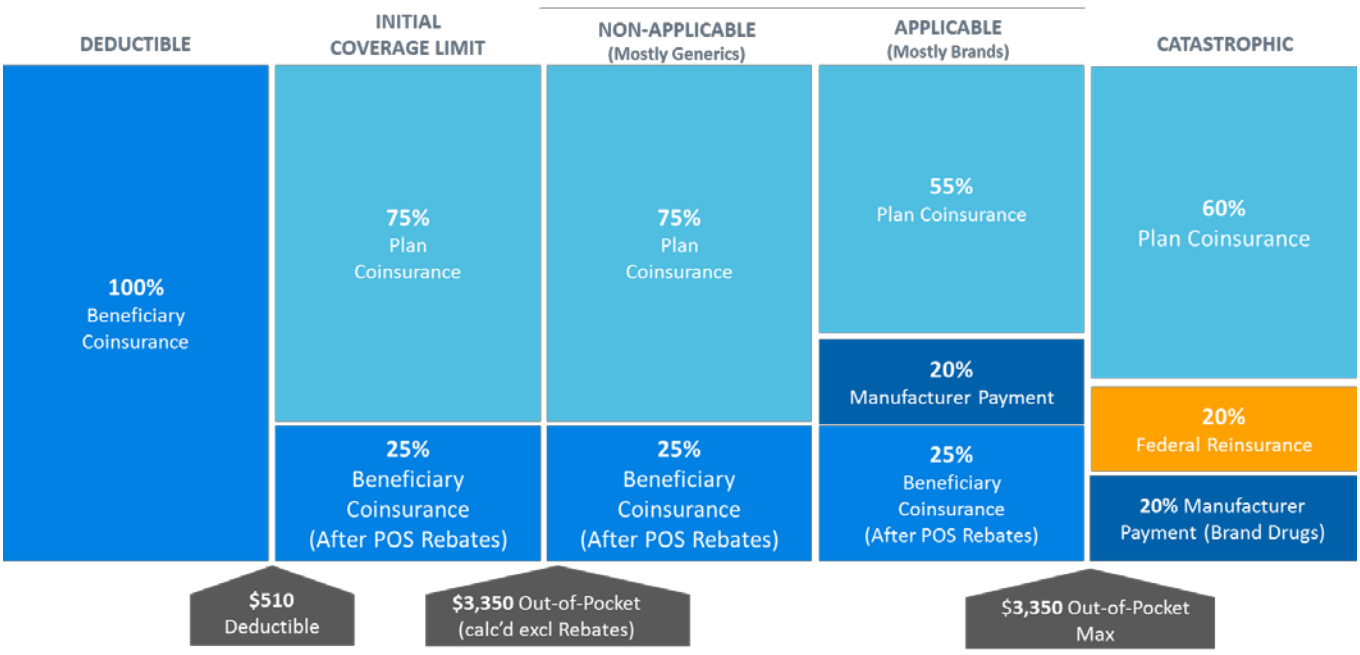
paid by manufacturers after the POS transaction and reduce premiums rather than the pharmacy reimbursement on which beneficiary out-of-pocket cost sharing is based. As the Part D program is run under a competitive bidding process, lower premiums are a valuable incentive to drive membership growth. Many Part D plans prefer to receive rebates as DIR instead of at the point of sale, as more of the savings can be used to lower premiums.

Our analysis included two alternative PDPRA scenarios per West Health's request, under which rebates affect the beneficiary portion of the POS price of rebated prescription drugs. For the first of two alternative scenarios (Scenario 3), we assumed the same benefit design as PDPRA, but moved the rebates to the POS transaction. As our analysis shows, this scenario would lead to substantially higher costs for the federal government as member cost sharing is reduced and that member cost-sharing reduction would lead to an increase in the net cost that Part D plans would cover. An increase in costs for Part D plans generally leads to an increase in the direct subsidy paid to plans by the federal government. Furthermore, beneficiaries with lower costs would spend less time in the catastrophic phase, which would substantially lower the plan design payments made by manufacturers in the catastrophic phase. Media reports have suggested that the projected increases in federal Part D spending under this scenario may have contributed to the withdrawal of the proposed changes to the anti-kickback statute earlier in 2019.[3]

As an alternative way to extend rebates to beneficiary cost sharing at the POS while mitigating increased federal spending, the West Health Policy Center asked us to analyze an alternative Part D benefit design (Scenario 4). Under this alternative design, rebates would be applied at the point of sale for the purposes of determining member cost sharing only. This means rebates would not apply to either manufacturer or federal reinsurance payments. Unlike in Scenario 3, where full POS rebates delayed the start of manufacturer catastrophic payments and increased federal spending, this scenario would start the manufacturer catastrophic payment at the point it would have happened without rebates at the POS, the same starting point as envisioned under PDPRA. Figure 3 details this potential benefit design, which includes a separate accumulator for when a beneficiary meets the threshold necessary to start the manufacturer payment, as well as the member OOP maximum, after which federal reinsurance payments would start. This design would keep manufacturer payments at the same level as PDPRA, based on the defined standard benefit, but would lower member cost sharing.

In our analysis, we only looked at the basic benefit and thus utilized the defined standard benefit design shown above. Because any supplemental benefits that Part D plans provide must be paid for by member premium, we have excluded them from our analysis.

FIGURE 3: ALTERNATIVE PDPRA PART D DEFINED STANDARD BENEFIT DESIGN WITH REBATES AT POS (SCENARIO 4)



[3] Drug Channels (July 12, 2019). Six reasons why the rebate rule failed—and what's next. Retrieved November 25, 2019, from https://www.drugchannels.net/2019/07/six-reasons-why-rebate-rule-failedand.html.

The light blue portions in the figures above represent the plan net liability, which is paid for by government and member premiums. The government premium is paid with the direct subsidy, while member premiums make up the rest of the cost for a plan to offer a benefit.

Results

We evaluated the financial impact of each scenario to the federal government, Part D beneficiaries, and manufacturers between 2022 (the implementation date of the revised Part D design in PDPRA) and 2029. The components comprising each stakeholder category are described below:

- **Federal government** includes federal reinsurance, direct subsidy payments, low-income cost-sharing subsidy (LICS), and low-income premium subsidies (LIPS)
- **Part D beneficiary** includes member premiums and member cost sharing
- **Manufacturer** includes rebates and Part D manufacturer payments, including the current Coverage Gap Discount Program (CGDP) payment and the catastrophic payment required under PDPRA

Although plan sponsors can be expected to react to potential changes in PDPRA, our stakeholder analysis excludes them, as changes in the financial risk to sponsors will be funded through direct subsidy payments and member premiums.

Figure 4 shows the financial impact of moving from the current Part D benefit design to the Part D benefit design as described in PDPRA. As shown below, we have estimated a reduction in federal spending of over $60 billion over the eight-year period from 2022 to 2029. These reduced costs are driven by an increase in the manufacturer payment and a reduction in LICS. While federal reinsurance is expected to be reduced, this reduction would be offset by an increase in direct subsidy payments, as the government funds 74.5% of the total cost of the Part D program, defined as the cost of both the plan bid amount and federal reinsurance. This means that if program costs were moved between reinsurance and plan liability there should be theoretically no change in federal government spending. Therefore, under our model the increase in federal savings is attributable to the reduction in direct subsidy and reinsurance payments resulting from increased manufacturer payments. Additionally, the federal government funds 100% of the LICS program, but the LICS liability would be reduced because the coverage gap would be eliminated. Moving LICS spending to plan liability in turn would lower federal government spending, as an increase in plan liability would be spread to higher member premiums.

FIGURE 4: IMPACT OF PDPRA PART D BENEFIT REDESIGN, 2022-2029 (IN BILLIONS)

	COST (SAVINGS)
Fed Gov't	-$63
Member	-$4
Pharma	$67

Part D beneficiaries would be expected to see lower costs overall, but this reduction in costs would be skewed toward higher-cost utilizers because member premiums would be expected to increase. This means that low utilizers would see increased overall costs while higher-cost utilizers would see lower costs. These reduced costs for high utilizers would likely more than offset an increase in their premiums. Overall, we estimate that beneficiaries would experience a reduction in costs of $4 billion over the eight-year period. Figure 5 shows how these reduced costs would be realized between member premium and member cost sharing.

FIGURE 5: IMPACT OF PDPRA PART D BENEFIT REDESIGN ON MEMBERS, 2022-2029 (IN BILLIONS)

	COST (SAVINGS)
Premium	$20
Cost Share	-$24

According to a statement from PDPRA sponsor, Sen. Chuck Grassley, the catastrophic manufacturer payment percentage was set higher than the current manufacturer payment in the coverage gap. We see this in our modeling, as the manufacturer payments are projected to increase by over $60 billion over the eight-year period. This means the majority of the projected federal government savings would come from the catastrophic manufacturer payments.

We have included additional details in the appendix showing how each of the components move for each stakeholder.

There are two important caveats of note in the analysis above that could affect actual results. First, we have left plan administrative costs and profit margins flat on a dollar basis between the scenarios. However, plans may set premiums to retain the same percentage of profit over the larger liability that comes with PDPRA, which could increase total costs. However, the competitive nature of Part D plans may limit these increases.

Although plans may have additional costs managing the new benefit design, we have not included any changes in member behavior prompted by the new benefit design, which could lead to higher plan costs. Under the new benefit design, some members may be incentivized to utilize more heavily in the catastrophic phase, as they would no longer have a 5% coinsurance for these drugs. In turn, plans may have incentives to implement stronger utilization management and leaner formularies in order to manage any additional catastrophic risks they could incur. As well, these changes may alter beneficiary behavior as well. The actual results if PDPRA is implemented will vary depending on how these offsetting forces play out.

It should be noted that we have not considered any potential impacts to Part C benefits and premiums for Medicare Advantage Part D (MAPD) plans. As these plans often buy down the Part D premium, any increases to the Part D premium could result in higher MAPD premiums, or lower overall MAPD benefits. As well, we have excluded Employer Group Waiver Plans (EGWP) from this analysis. Changes to certain assumptions in our analysis, including trend assumptions, could produce different results. For more information regarding the assumptions in this analysis, see the "Methodology" section.

Figure 6 details how the results change from PDPRA if rebates were to be applied at the point of sale (Scenario 3). As seen with the earlier rebates to POS analyses from various publications, moving rebates to the POS can be expected to increase total Part D costs for the federal government. As well, savings overall are expected for drug manufacturers. These large savings are due to beneficiaries taking longer to get to the catastrophic phase. Furthermore, the manufacturer payment would no longer include a double payment on rebates. With rebates as DIR, manufacturers make the 20% catastrophic payment based on a pre-rebated amount, whereas when rebates go to the POS, manufacturers make the catastrophic payment based on the drug price after rebates, which leads to significant savings for manufacturers. Members would also see savings, but these savings would be skewed toward members utilizing highly rebated drugs.

FIGURE 6: IMPACT OF PDPRA REDESIGN AND MOVING REBATES TO THE POS (SCENARIO 3) (IN BILLIONS)

	COST (SAVINGS)	
	VS CURRENT DESIGN	VS. PDPRA DESIGN
Fed Gov't	$0	$63
Member	-$23	-$19
Pharma	$23	-$44

Figure 7 shows the impact of Scenario 4, in which rebates would only reduce beneficiary costs at the POS. Furthermore, the benefit design under this scenario would have separate accumulators to determine when the manufacturer and catastrophic payments begin. Figure 3 above details how this new design would be structured, with the manufacturer payments starting earlier than the catastrophic limit. Compared to the scenario above that moved rebates to the POS (Scenario 3), this design mitigates the increases in federal spending by sharing rebates only with members through reduced cost sharing. Recently, administration officials and members of Congress have expressed a desire to extend more of the savings associated with PDPRA with beneficiaries at the POS; applying rebates only to the beneficiary contribution at the POS (Scenario 4) would achieve the same reduction in cost sharing as application of full rebates at the POS (Scenario 3), with a smaller impact on beneficiary premiums and without reducing manufacturer payments.[4] See the appendix for more details.

FIGURE 7: IMPACT OF PDPRA REDESIGN AND MOVING REBATES TO THE POS, ALTERNATIVE DESIGN, SCENARIO 4 (IN BILLIONS)

	COST (SAVINGS)		
	VS. CURRENT DESIGN	VS. PDPRA DESIGN	VS. PDPRA POS REBATES (SCENARIO 3)
Fed Gov't	-$38	$25	-$38
Member	-$29	-$25	-$6
Pharma	$67	$0	$44

Methodology

To calculate our estimates of the current Part D benefit design, we started with 2018 claims from Milliman's proprietary Part D claims database. Members were split by low-income status for our projections. We first projected claims from 2018 to all study years using utilization and unit cost trends consistent with our expectation for the Part D market and annual Milliman research. We adjudicated these claims on a seriatim basis for both the LI and non-LI populations, utilizing the Part D defined standard benefit to determine member cost sharing and other Part D phase distributions. We then blended the LI and non-LI cohorts based on the expected member distribution to create the total expected claims. We then estimated rebates based on expected Part D rebates in the Medicare Trustees report.[5] To calculate the plan bid amount, the net plan liability was calculated from these results for each year. We applied a 15% retention load for non-benefit expenses and profit margin and utilized the risk scores in our underlying data to normalize the costs to a 1.0 risk score. The plan bid amount was then assumed to be the projected

[4] Wilkerson, J. (November 11, 2019). White House, Senate want more seniors to benefit from drug price bill. Inside Health Policy. Retrieved November 25, 2019, from https://insidehealthpolicy.com/daily-news/white-house-senate-want-more-seniors-benefit-drug-price-bill (subscription required).

[5] 2019 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds. Retrieved November 25,

National Average Bid Amount. The National Average Reinsurance was determined in a manner similar to the plan reinsurance amount. The National Average Member Premium and direct subsidy were then calculated for each year, using Centers for Medicare and Medicaid Services (CMS) prescribed formulas. We then calibrated our results by comparing our projections to the 2020 Part D National Average Bid Amount and National Average Reinsurance.

The other scenarios utilized the same claims as the current benefit design, but with claims adjudicated at a seriatim level using each scenario's unique benefit design. Scenario 3 had the allowed cost of each brand drug reduced before the claims adjudication. Because of this, the allowed claims amount in Scenario 3 matches the allowed claims amount minus manufacturer rebates from the other scenarios. In Scenario 4, the rebates are only included in reducing the member cost sharing and not other stakeholder payments. Therefore, in this scenario rebates are still applied after the POS in terms of sharing rebates with CMS through reinsurance.

Enrollment for our projections came from the Medicare Trustees report, with our distribution of LI members estimated from an earlier Congressional Budget Office (CBO) analysis on the impact of the proposed rule to eliminate the anti-kickback safe harbor.[6] We then adjusted that membership to account for the expected number of enrolled months per member in each year.

For rebates, we allocated higher rebates to the top 10 rebated drug classes, and assumed no rebates for protected class drugs and a lower rebate level for specialty drugs. We then backed into the rebate level for other brand drugs to match the total level in the 2019 Medicare Trustees report for plan year 2018. We then allowed these rebates to adjust with trends for future years. We assumed that manufacturer rebates make up 85% of total rebates in the Medicare Trustees report. For the rebates to POS scenarios, we left 15% of rebates as DIR and did not move them to POS scenarios, to isolate the impact of just moving manufacturer rebates to the POS. If rebates paid by pharmacies to Part D plans were also moved to POS, the results would be impacted.

We assumed risk scores would stay at 2018 levels in this analysis. Lastly, the defined standard benefit parameters of each year were determined by starting with the 2020 parameters and trending to future years based on the historical trends of each component of the benefit design. It should be noted that the projected results may be particularly sensitive to certain assumptions, including the selection of specialty trends. Although in recent years specialty drug trends haven been higher than trends for other brand drugs, we set both specialty and other brand drug trends at the same levels in our analysis. We assumed specialty trends moderate to the level of other brand trends for the entire duration of our projections. Leaving specialty trends at the same historically higher levels would lead to higher costs in the reinsurance phase of PDPRA, and thus would show that PDPRA would lead to a larger cost reduction for the Federal government.

Caveats

We prepared this work for the specific purpose of providing analysis on the Prescription Drug Pricing Reduction Act of 2019 (PDPRA) and alternative scenarios requested by West Health Policy Center. This information should not be used for any other purpose. Milliman does not intend to benefit or create a legal duty to any third-party recipient of its work. This work was performed under the existing Consultant Services Agreements with the Gary and Mary West Health Policy Center. Milliman does not endorse any specific policy proposals discussed in this analysis.

In performing this analysis, we relied on public data and other information provided by CMS and other entities. We did not audit this data and other information. If the underlying data or information is inaccurate or incomplete, the results of our analysis may likewise be inaccurate or incomplete. We performed a limited review of the data used directly in our analysis for reasonableness and consistency and have not found material defects in the data. If there are material defects in the data, it is possible that they would be uncovered by a detailed, systematic review and comparison of the data to search for data values that are questionable or for relationships that are materially inconsistent. Such a review is outside the scope of this work.

In order to provide the information requested by the West Health Policy Center, we have constructed several projection models. Differences between our projections 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.

We do not provide legal advice, and recommend that readers consult with legal advisors on legal matters. This report provides objective quantification of potential legislative changes and is not advocating for these changes.

[6] 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. Retrieved November 25, 2019, from https://www.cbo.gov/system/files/2019-05/55151-SupplementalMaterial.pdf.

APPENDIX: IMPACT OF PDPRA PART D BENEFIT REDESIGN BY STAKEHOLDER FROM CURRENT DESIGN, 2022-2029 (IN BILLIONS)

	VS. PDPRA	VS. PDPRA POS REBATES (SCENARIO 3)	VS. PDPRA BENEFICIARY POS REBATES ALTERNATIVE DESIGN (SCENARIO 4)
Member - Premium	$20	$38	$31
Member - Cost Share	-$24	-$61	-$60
Pharma Pay	$67	$23	$67
CMS – Reinsurance	-$324	-$329	-$347
CMS – LICS	-$164	-$194	-$194
CMS – LIPS	$14	$23	$19
CMS – Direct Subsidy	$412	$499	$485

Milliman

Milliman is among the world's largest providers of actuarial and related products and services. The firm has consulting practices in life insurance and financial services, property & casualty insurance, healthcare, and employee benefits. Founded in 1947, Milliman is an independent firm with offices in major cities around the globe.

milliman.com

CONTACT

Matthew Hayes
Matthew.Hayes@milliman.com

Pedro Alcocer
Pedro.Alcocer@milliman.com

Sara Yi
Sara.Yi@milliman.com