MILLIMAN RESEARCH REPORT

Medicare Part D Rebate and Catastrophic Coverage Policy Changes

Stakeholder Analysis

March 2019

Commissioned By: The Drug Pricing Lab at Memorial Sloan Kettering Cancer Center

Michelle Angeloni, FSA, MAAA
Sean Hilton, FSA, MAAA
Tory Carver, ASA, MAAA

Milliman


Milliman

Table of Contents

Executive Summary

Medicare Part D is a complex program with multiple stakeholders. The government, beneficiaries, and drug manufacturers fund the program through various payment mechanisms taking place before, during, and following the point-of-sale (POS) purchase of prescription drugs. Plan sponsors negotiate with drug manufacturers, pharmacies, pharmacy benefit managers (PBMs), and other service providers to offer plans to beneficiaries at competitive premium levels. Recent drug pricing reform and policy change efforts would likely have financial and behavioral impacts on these stakeholders.

As legislators and market stakeholders evaluate potential changes to the Medicare Part D program[i,i,ii,iii,iv], and pharmaceutical drug pricing more broadly, The Drug Pricing Lab at Memorial Sloan Kettering Cancer Center (The Drug Pricing Lab) requested that we estimate the impact of certain proposed modifications to the Part D standard benefit design on stakeholder costs and the flow of payments within the program.

In this paper, we explore the potential impact of rebates shared at the POS as well as a redesign of catastrophic coverage, including changes to the federal reinsurance program and beneficiary cost sharing. We also study the possible impact of implementing a separate CGDP true out-of-pocket (TrOOP) spending accumulator under a system requiring POS application of rebates. We examined the potential costs, savings, and strategic considerations for key stakeholders.

Several organizations, including the Centers for Medicare and Medicaid Services Office of the Actuary (OACT), Wakely, and other Milliman consultants, have also released estimates of some of the potential policy changes included in our analysis. We believe our analysis is unique and adds to the discussion through the development of a seriatim model to perform a claim level evaluation of the 2020-2029 ten year impact of illustrative Part D policy changes. Using a seriatim model allowed for projecting the impact of rebate changes at the granular claim level using information from SSR Health, which importantly factors in rebate differences between therapy classes. **As a result of the fundamental differences in modeling technique and assumed rebate levels, the results of this study will vary from others released on this subject.**

Our analysis considered the impact of Part D program changes on the individual Part D market with the standard plan design. We modeled the Part D cost impact to (1) beneficiaries through premium and cost sharing, (2) drug manufacturers through Coverage Gap Discount Program[1] (CGDP) payments, and (3) the government through federal reinsurance, direct subsidy payments, low income premium subsidies (LIPS) and low income cost sharing subsidies (LICS). Our analysis is limited to the aforementioned spending impacts and does not consider other financial effects to stakeholders or the potential financial impacts of behavioral changes likely to be caused by these policy changes.[2]

We performed this analysis at the request of The Drug Pricing Lab.

PRESIDENT'S BUDGET: CATASTROPHIC COVERAGE REDESIGN AND CGDP TROOP EXCLUSION

We evaluated the impact of the following changes to catastrophic coverage from the President's 2019 budget proposal:

- Decreasing federal reinsurance in the catastrophic phase[3] to 20%,
- Eliminating beneficiary cost sharing above the TrOOP threshold, and

[1] ***Coverage Gap Discount Program****: Starting in 2011, drug manufacturers were required to cover 50% of ingredient drug cost for brand-name drugs taken by non-low income beneficiaries in the Part D coverage gap. The Balanced Budget Act of 2018 revised the coverage gap discount to be 70% of ingredient cost for brand and biosimilar products for non-low income beneficiaries. This program does not apply to drug spend for low income beneficiaries and only applies to the drug spend in the coverage gap phase.*

[2] ***Additional Stakeholders:*** *Our modeling assumes that the only stakeholders are the Part D beneficiaries, the government, and drug manufacturers. For example, we did not model the potential impact on pharmacies, Medicare Part D plans, or medical plans. We have assumed that all impacts on Medicare Part D plans are passed through to the other stakeholders through adjusted beneficiary premium, low income premium subsidy, and direct subsidy payments (e.g., we have assumed that plans will retain the same margin in all scenarios such that plans are "neutral" in all scenarios). Our modeling is limited to the defined standard plan design in the individual Medicare Part D market. Our modeling ignores group coverage through Employer Group Waiver Plans "EGWPs" and alternative and enhanced benefit designs. These exclusions could drive differences relative to other analysis on the subject.*

[3] ***Catastrophic Phase****: The spending phase of the Medicare Part D benefit above the TrOOP threshold. Under the current Part D plan design, the government pays 80% of gross drug cost through reinsurance and beneficiaries pay 5% of gross drug cost, subject to minimum copays. Plan sponsors cover the remaining liability, or approximately 15% of gross drug cost in this phase. In our modeling, we ignored the minimum copays in the catastrophic phase.*

- Excluding CGDP payments from beneficiaries' TrOOP accumulation.

Figure 1 summarizes the impact of combinations of these catastrophic coverage changes, as follows:

- **Catastrophic Coverage Redesign:** Column (A) summarizes the impact of all three catastrophic coverage changes: reducing federal reinsurance from 80% to 20%, eliminating beneficiary cost sharing above the TrOOP threshold, and excluding CGDP payments from beneficiaries' TrOOP accumulation.
- **Eliminating Cost Sharing above TrOOP Threshold:** Column (B) summarizes the impact of eliminating the cost sharing above the TrOOP threshold only and does not include the impact of the other two catastrophic coverage changes.
- **Excluding CGDP from TrOOP:** Column (C) summarizes the impact of excluding CGDP from TrOOP only and does not include the impact of the other two catastrophic coverage changes.

We note that the impact of reducing federal reinsurance from 80% to 20% is not shown as a standalone scenario in Figure 1. In our analysis, this scenario does not affect total spending by stakeholder as the reinsurance reduction translates to an increase in direct subsidy.

FIGURE 1: 2020-2029 IMPACT OF REDESIGNING CATATROPHIC COVERAGE AND EXCLUDING CGDP FROM TROOP

STAKEHOLDER	(A) CATASTROPHIC COVERAGE REDESIGN	(B) ELIMINATING COST SHARING ABOVE TROOP	(C) EXCLUDING CGDP FROM TROOP
Beneficiaries	-2%	-4%	+1%
Government	-6%	+2%	-7%
Drug Manufacturers (CGDP)	+80%	0%	+80%

Percentage changes are relative to the annual baseline spending for each specific stakeholder and scenario.
Each scenario is distinct and cumulative impacts will vary.

REBATE PASS-THROUGH

We evaluated the impact of another key element of the President's 2019 budget proposal and of the rule proposed by the Department of Health and Human Services (HHS) Office of Inspector General that would require manufacturers to apply some or all Part D prescription drug rebates toward POS drug prices. We considered the impact of passing through 33% of rebates, 66% of rebates, 90% of rebates, and 100% of rebates at the POS. Our analysis does not include policy changes affecting rebates paid to plans by pharmacies.

We estimate passing rebates through at the POS would decrease beneficiary and drug manufacturer spending, while increasing government spending primarily through increases in direct subsidy payments – these impacts are expected to produce greater spending changes as higher percentages of rebates are passed through. Figure 2 summarizes our findings.

FIGURE 2: 2020-2029 IMPACT OF REBATE PASS-THROUGH

	REBATE PASS-THROUGH PERCENT			
STAKEHOLDER	33%	66%	90%	100%
Beneficiaries	-1%	-3%	-4%	-4%
Government	+2%	+4%	+5%	+6%
Drug Manufacturers (CGDP)	-19%	-36%	-46%	-50%

Percentage changes are relative to the annual baseline spending for each specific stakeholder and scenario.

Rebate Pass-Through with Separate CGDP TrOOP

We also evaluated the impact of rebate pass-through using a separate "Beneficiary TrOOP" and "CGDP TrOOP" such that manufacturer payments are not affected by rebates passed through at the POS. This benefit structure is not a part of the existing proposals and is analyzed at The Drug Pricing Lab's request to inform the discussion in the event such a measure is proposed.

Introducing a separate CGDP TrOOP accumulation alongside rebate pass-through requirements is projected to decrease beneficiary spending compared to the current, single beneficiary TrOOP calculation, and would hold manufacturer CGDP spending constant. Government spending is expected to increase by smaller amounts in this rebate pass-through scenario. Comparing the 100% rebate pass-through with and without a separate CGDP TrOOP accumulator, beneficiary spending is estimated to fall by 6% compared to 4%, and government spending rises by 2% compared to 6%.

FIGURE 3: 2020-2029 IMPACT OF REBATE PASS-THROUGH WITH SEPARATE CGDP TROOP

	REBATE PASS-THROUGH PERCENT			
STAKEHOLDER	**33%**	**66%**	**90%**	**100%**
Beneficiaries	-2%	-4%	-5%	-6%
Government	+1%	+1%	+2%	+2%
Drug Manufacturers (CGDP)	0%	0%	0%	0%

Percentage changes are relative to the annual baseline spending for each specific stakeholder and scenario.

Rebate Pass-Through for Specific Therapeutic Classes

At The Drug Pricing Lab's request, we modeled the impact of POS rebate pass-through on diabetes, oncology, and Hepatitis C medications[4] separately (i.e., we modeled passing through rebates for one class while all other rebates are not passed through) to analyze the impact on the entire population.

Figure 4 summarizes the impact of passing through 100% of rebates on medications in each specific therapeutic class while rebates are not passed through at the POS for medications outside of the therapeutic class. We estimate that POS rebate pass-through for diabetes medications would have larger impacts on total spending than oncology or Hepatitis C medications due to the larger number of beneficiaries utilizing those medications and the significant rebates typically associated with diabetic treatments. Our results are sensitive to the level of rebates assumed by class and product (as provided by SSR Health), which can vary by organization based on the formulary composition and other factors.

FIGURE 4: 2020-2029 IMPACT OF 100% THERAPEUTIC CLASS-SPECIFIC REBATE PASS-THROUGH

STAKEHOLDER	DIABETES	ONCOLOGY	HEPATITIS C
Beneficiaries	-1%	~0%	~0%
Government	+2%	~0%	~0%
Drug Manufacturers (CGDP)	-20%	-1%	~0%

Percentage changes are relative to the annual baseline spending for each specific stakeholder and scenario.
Each scenario is distinct and cumulative impacts will vary.

Rebate Pass-Through for Specific Subpopulations

We analyzed the impact of market-wide rebate pass-through on specific subsets of the population taking drug treatments for the three aforementioned therapy classes (diabetes, Hepatitis C, and oncology).

Figures 5 and 6 summarize the impact on beneficiary spending of 100% rebate pass-through, shown independently for beneficiaries utilizing medications in the diabetes, oncology, and Hepatitis C therapeutic classes. For example, the "Diabetes" column of Figure 5 reports estimated percentage changes in total beneficiary spending (i.e., beneficiary cost sharing and premiums) when all beneficiaries taking diabetes medications receive full POS rebates on each rebate-able drug they utilize (including diabetes drugs). Figure 6 differs from Figure 5 by assuming manufacturer CGDP payments are unaffected by rebates passed through at the POS and remain at baseline levels (i.e., Beneficiary TrOOP and CGDP TrOOP are separate).

[4] *Diabetic, oncology, and Hepatitis C disease states were identified by flagging utilization for medications summarized in the Appendix of this report. Use of any medication within a disease's drug list codes a beneficiary to that specific disease state. Beneficiaries may belong to none or all of the disease states based on this methodology.*

FIGURE 5: 2020-2029 IMPACT OF 100% MARKET-WIDE REBATE PASS-THROUGH ON POPULATION SUBSET

STAKEHOLDER	DIABETES	ONCOLOGY	HEPATITIS C
Beneficiaries	-20%	-7%	-28%

Percentage changes are relative to the annual baseline spending for each specific stakeholder and scenario. Each scenario is distinct and cumulative impacts will vary.

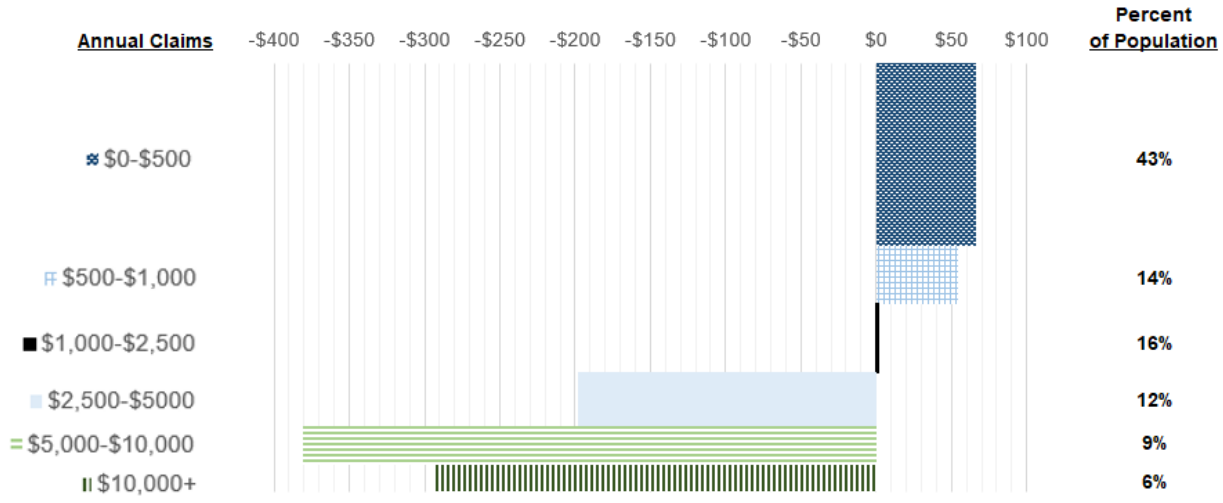
FIGURE 6: 2020-2029 IMPACT OF 100% MARKET-WIDE REBATE PASS-THROUGH ON POPULATION SUBSET (SEPARATE CGDP TROOP)

STAKEHOLDER	DIABETES	ONCOLOGY	HEPATITIS C
Beneficiaries	-21%	-8%	-28%

Percentage changes are relative to the annual baseline spending for each specific stakeholder and scenario. Each scenario is distinct and cumulative impacts will vary.

While we estimate that passing rebates through at the POS would decrease beneficiary-specific cost sharing and increase market-wide beneficiary premiums, the exact beneficiary impact is highly dependent on each beneficiary's pharmacy spend profile. We evaluated the impact of 100% rebate pass-through on beneficiaries' total costs by analyzing effects for beneficiaries at varying levels of drug spending. Figure 7 summarizes the projected change in annual beneficiary costs (i.e., cost sharing and beneficiary premiums) for beneficiaries with different levels of total prescription claims.

FIGURE 7: 2020-2029 IMPACT OF 100% REBATE PASS-THROUGH ON ANNUAL BENEFICIARY COSTS (COST SHARING + PREMIUM)



Distribution of beneficiaries by annual spending range is based on projections of 2020-2029 spending as outlined in the Methodology section

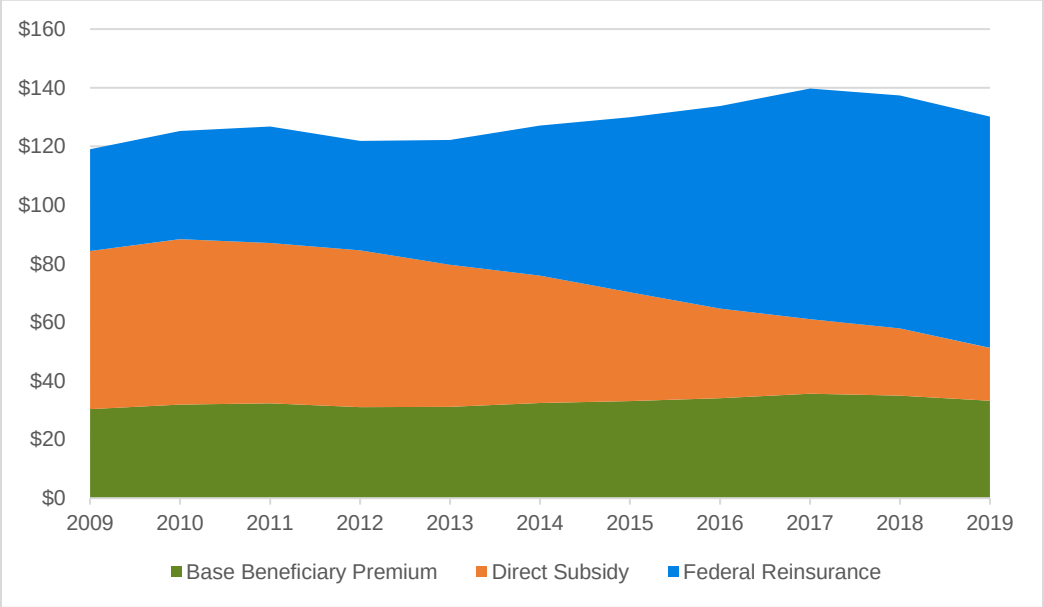
Figure 7 summarizes our estimate that over half of beneficiaries, those with between $0-$1,000 in annual prescription claims, would see increases in their costs on average as beneficiary premiums would rise more than the reductions in beneficiary cost sharing. The average amount of this increase is about $65 annually, or approximately $5 per month. We estimate that the 16% of beneficiaries with $1,000-$2,500 in annual prescription claims would see almost no change in their costs on average as increases in beneficiary premiums would be offset by reductions in beneficiary cost sharing. We estimate that the remaining 27% of beneficiaries with more than $2,500 in annual prescription claims would see reductions in their costs on average as increases in beneficiary premiums are more than offset by reductions in beneficiary cost sharing.

Background

Within the past several years, legislators and market stakeholders have taken steps to evaluate material changes proposed for the Part D program. Senator Ron Wyden of Oregon introduced a bill[i] in June of 2017 that if passed would amend the Part D program by removing beneficiary cost sharing in the catastrophic phase. In November of 2017, the Centers for Medicare and Medicaid Services (CMS) released a Request for Information (RFI) soliciting comments on reflecting a portion of direct and indirect remuneration (DIR) at the POS[ii]. The President's FY2019 budget proposal also included commentary on reflecting a portion of DIR at the POS, which reduces beneficiary out of pocket spending at the POS, as well as potential changes to the catastrophic phase of the Part D benefit. These changes include eliminating catastrophic beneficiary cost sharing and reducing federal reinsurance from 80% to 20%[iii]. On November 26, 2018, CMS issued a proposed rule to eliminate post-POS pharmacy DIR to Part D plans as early as 2020,[iv] and on January 31, 2019, the Department of Health and Human Services (DHHS) released a proposed rule[v] to change the Anti-Kickback Statute safe harbors and eliminate protections for the practice of drug manufacturers providing post-POS rebates to PBMs and plan sponsors. This paper analyzes the impacts of some of these proposals on the various affected stakeholders.

The changes above may have been proposed in part due to a history of increases in federal reinsurance spending and increases in manufacturer rebates. Since the inception of the Medicare Part D program, there has been a significant shift in the program's funding from direct subsidy[5] payments to net federal reinsurance[6] payments. Figure 8 summarizes the annual, historical direct subsidy amounts, calculated by CMS based on Part D plan sponsors' projections of the cost of providing defined standard coverage[7] as well as projected net federal reinsurance payments and the base beneficiary premiums as distributed in the Annual Release of Part D National Average Bid Amount and Other Part C & D Bid Information[vi].

FIGURE 8: ESTIMATED ELEMENTS OF DIRECT FINANCING OF PART D PROGRAM



[5] ***Direct Subsidy:*** *As defined in the 2018 Medicare Trustees Report, "The amount paid to the prescription drug plans representing the difference between the plan's risk-adjusted bid and the beneficiary premium for basic coverage."*

[6] ***Net Federal Reinsurance Payments:*** *Reinsurance subsidy as defined in the 2018 Medicare Trustees Report as "payments to the prescription drug plans in the amount of 80 percent of drug expenses that exceed the annual out-of-pocket threshold" net of rebates not retained by the plan and shared with the federal government.*

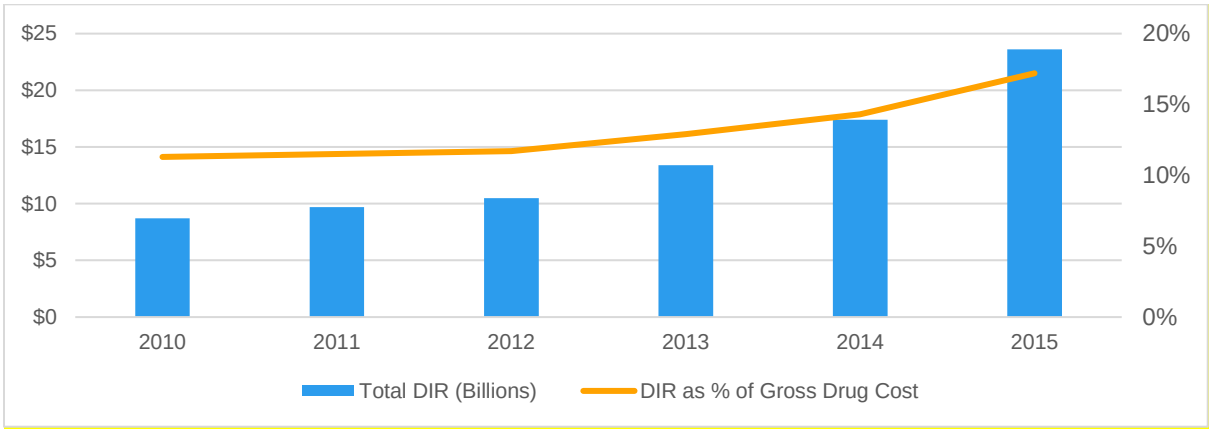
[7] ***Cost of Providing Defined Standard Coverage:*** *As defined in the 2018 Medicare Trustees Report, "The sum of the national average monthly bid amount and the estimated catastrophic reinsurance."*

The direct subsidy is set annually to target non-subsidized base beneficiary premiums at 25.5% of the cost of standard benefit coverage, defined as the sum of the National Average Bid Amount (NABA) and estimated federal reinsurance. Based on projections from plan sponsors, CMS establishes the direct subsidy such that it and estimated federal reinsurance fund 74.5% of the projected cost of standard coverage.

Between 2009 and 2019, the projected cost of the standard benefit coverage used to establish the direct subsidy increased from $119.06 per member per month (PMPM) to $130.16 PMPM (average of 0.9% annually). During this same ten-year period, the projected federal reinsurance increased from $34.73 PMPM to $78.88 PMPM (8.5% annually).

There are many drivers of this shift from direct subsidy payments to federal reinsurance payments including general price inflation and increased spending on high cost drugs, both of which increase the likelihood that beneficiaries reach the catastrophic phase where the federal government pays 80% of drug costs. While drug prices have increased, the market has also experienced significant increases in manufacturer rebates,[8] which are shared with the government based on federal reinsurance as a percentage of total Part D drug spend. In a study from the Office of Inspector General (OIG),[vii] the average unit cost of Part D drugs increased 29% from 2011 to 2015, while total rebate dollars increased 155%. The following graph published by CMS illustrates this increase[viii]:

FIGURE 9: DIR PAYMENT BY YEAR ($PMPM)



The CMS RFI, the President's FY2019 budget proposal, the CMS proposed rule to end post-POS pharmacy DIR, and the HHS-OIG proposed rule to eliminate rebate safe harbor protections may each aim to disrupt these historical federal reinsurance and DIR trends through modifications to the Part D benefits and stakeholder payment practices.

[8] ***Manufacturer Rebates:*** *A return of part of the prescription drug cost from the pharmaceutical manufacturer to the plan sponsor or PBM.*

President's Budget: Catastrophic Coverage Redesign and CGDP TrOOP Exclusion

We evaluated the impact of the following changes to catastrophic coverage from the President's 2019 budget proposal:

- Decreasing federal reinsurance in the catastrophic phase to 20%,
- Eliminating beneficiary cost sharing above the TrOOP threshold, and
- Excluding CGDP payments from beneficiaries' TrOOP accumulation.

We modeled modifications in the catastrophic phase cost sharing as outlined in Figure 10 below:

FIGURE 10: REDESIGNED CATASTROPHIC PHASE COST SHARING PARAMETERS

CATASTROPHIC PHASE PARAMETERS	CURRENT (2019)	2020	2021	2022	2023+
Federal Reinsurance Coinsurance	80%	65%	50%	35%	20%
Plan Liability Coinsurance	Approx. 15%	35%	50%	65%	80%
Beneficiary Coinsurance	Approx. 5%	0%	0%	0%	0%

Figure 11 summarizes the impact of combinations of these catastrophic coverage changes, as follows:

- **Catastrophic Coverage Redesign:** Column (A) summarizes the impact of all three catastrophic coverage changes: reducing federal reinsurance from 80% to 20%, eliminating beneficiary cost sharing above the TrOOP threshold, and excluding CGDP payments from beneficiaries' TrOOP accumulation.
- **Eliminating Cost Sharing above TrOOP Threshold:** Column (B) summarizes the impact of eliminating the cost sharing above the TrOOP threshold only and does not include the impact of the other two catastrophic coverage changes.
- **Excluding CGDP from TrOOP:** Column (C) summarizes the impact of excluding CGDP from TrOOP only and does not include the impact of the other two catastrophic coverage changes.
- **Eliminating Cost Sharing above TrOOP Threshold & Excluding CGDP from TrOOP:** Column (D) summarizes the combined impact of the changes to catastrophic coverage summarized in columns (B) and (C) and excludes the impact of decreasing federal reinsurance in the catastrophic phase to 20%.

We note that the impact of reducing federal reinsurance from 80% to 20% is not shown as a standalone scenario in Figure 11 as this standalone scenario does not affect total spending by stakeholder in our analysis. In isolation, reducing the reinsurance percentage has an offsetting increase in plan liability, which translates to increased direct subsidy. Please see the "Federal Reinsurance form 80% to 20%" section below for additional detail.

FIGURE 11: 2020-2029 IMPACT OF CATATROPHIC COVERAGE CHANGES ($ BILLIONS)

	(A) CATASTROPHIC COVERAGE REDESIGN	(B) ELIMINATING COST SHARING ABOVE TROOP THRESHOLD	(C) EXCLUDING CGDP FROM TROOP	(D) ELIMINATING COST SHARING ABOVE TROOP THRESHOLD & EXCLUDING CGDP FROM TROOP
2020 to 2029 Impact by Stakeholder ($b)				
Beneficiary	-$7.3 *(-2%)*	-$18.6 *(-4%)*	$6.3 *(+1%)*	-$7.3 *(-2%)*
Government	-$71.9 *(-6%)*	$18.6 *(+2%)*	-$85.6 *(-7%)*	-$71.9 *(-6%)*
Drug Manufacturers	$79.2 *(+80%)*	$0.0 *(0%)*	$79.2 *(+80%)*	$79.2 *(+80%)*
Total	**$0.0 *(0%)***	**$0.0 *(0%)***	**$0.0 *(0%)***	**$0.0 *(0%)***
2020 to 2029 Beneficiary Impact ($b)				
Cost Sharing	$1.1 *(~0%)*	-$28.5 *(-6%)*	$23.7 *(+5%)*	$1.1 *(~0%)*
Premium	-$8.5 *(-2%)*	$9.9 *(+2%)*	-$17.4 *(-4%)*	-$8.5 *(-2%)*
Total	**-$7.3 *(-2%)***	**-$18.6 *(-4%)***	**$6.3 *(1%)***	**-$7.3 *(-2%)***
2020 to 2029 Government Cost Impact ($b)				
Federal Reinsurance	-$477.0 *(-39%)*	$0.0 *(0%)*	-$67.9 *(-5%)*	-$67.9 *(-5%)*
Direct Subsidy	$439.3 *(+36%)*	$44.4 *(+4%)*	-$9.7 *(-1%)*	$30.2 *(+2%)*
Low Income Premium Subsidy	-$3.9 *(~0%)*	$4.5 *(~0%)*	-$7.9 *(-1%)*	-$3.9 *(~0%)*
Low Income Cost Sharing Subsidy	-$30.3 *(-2%)*	-$30.3 *(-2%)*	$0.0 *(0%)*	-$30.3 *(-2%)*
Total	**-$71.9 *(-6%)***	**$18.6 *(+2%)***	**-$85.6 *(-7%)***	**-$71.9 *(-6%)***

Each scenario is distinct and cumulative impacts will vary.
+/- Percentage changes are from baseline total expenditures for each stakeholder. Sums of values may differ from totals due to rounding.

While this analysis excludes the evaluation of financial impacts to Employer Group Waiver Plans (EGWPs), we note that the exclusion of CGDP from TrOOP for those plans would increase manufacturer costs as well. This would be true particularly for EGWP plans with low beneficiary cost sharing and/or with maximum out-of-pocket (MOOP) thresholds below the TrOOP threshold, where there may be no limit to CGDP payments within the annual benefit period.

FEDERAL REINSURANCE FROM 80% TO 20%

In the Catastrophic Coverage Redesign policy change scenario we modeled federal reinsurance decreasing from 80% to 20%. Reducing the reinsurance percentage with an offsetting increase in plan liability has no impact on aggregate government spending in isolation (i.e., ignoring the impact of plan changes such as increased risk loads or changes in high cost claims management). That is, an even shift between reinsurance and plan liability will have an offsetting impact on the direct subsidy such that government spending is neutral in aggregate.

If such a change in reinsurance and other regulatory changes incentivize plans to meaningfully improve high cost claims management, then there could be a reduction in total Part D spending, potentially reducing government spending. Conversely, this could encourage plans to purchase private reinsurance or apply additional risk margin, which might increase costs.

ELIMINATING CATASTROPHIC COST SHARING

We modeled eliminating beneficiary cost sharing above the TrOOP threshold by increasing plan liability in the catastrophic phase. This scenario reduces beneficiary spending while increasing government spending primarily through increases in the direct subsidy.

Excluding CGDP from TrOOP accumulation offsets this, by causing beneficiaries to stay in the coverage gap longer, increasing beneficiary and drug manufacturer spending. We estimate that this will also cause federal reinsurance to decrease as fewer beneficiaries hit the catastrophic phase.

POTENTIAL BEHAVIORAL IMPACT OF CHANGES IN CATASTROPHIC COVERAGE AND CGDP TROOP EXCLUSION

This catastrophic coverage redesign, as described in the sections above, may result in the following examples of behavioral changes:

- Plan bids[9] would reflect increased plan liability in the catastrophic phase. This may result in changes to plan formularies and management of higher cost drugs to the extent allowable under Part D requirements (e.g., generic-driven formulary).
- Increased plan liability in the catastrophic phase with decreasing federal reinsurance and beneficiary cost sharing would lead to increased direct subsidy payments. Because plan sponsors receive risk-adjusted direct subsidy amounts, the increase in direct subsidy may encourage a greater emphasis on risk score coding.
- Drug manufacturers would be subject to more CGDP payments in the coverage gap as beneficiaries require greater drug spending to transition from the coverage gap to the catastrophic phase. This may result in changes to drug manufacturer pricing and rebate strategies.
- Beneficiaries with high-cost medications would see a reduction in their out-of-pocket costs which could increase utilization of higher priced products. This could be the result of improved adherence as well as reduced incentives to find cost effective alternatives. This could affect medical claims[ix,x], which are not considered in this paper's analysis of Part D spending.

Behavior changes are highly unpredictable in the context of many potential changes to the Medicare Part D program, but stakeholders will certainly react to any potential regulatory changes. The estimation of impacts of these potential behavioral changes is beyond the scope of our analysis and is therefore not reflected in the figures we present.

[9] ***Plan Bids**: Medicare Part D plan sponsors are required to submit bid pricing tools (BPTs) to CMS for approval as part of rate development. Direct subsidy payments and beneficiary premiums are based on the bids plans submit annually.*

Rebate Pass-Through

We evaluated the impact of the OIG proposed rule[v] that would require manufacturer rebates on brand drugs to be passed through to consumers at the POS to reduce their out of pocket drug spending. We model this effect at the therapeutic class level, and we consider the impact of passing through 33% of rebates, 66% of rebates, 90% of rebates, and 100% of rebates at POS. Our analysis ignores rebates paid to plans by pharmacies.

We estimate that passing rebates through at the POS would reduce manufacturer CGDP payments and reduce average beneficiary spending, with reductions in cost sharing more than offsetting increases in premiums on average. We estimate this could increase government spending, with the increase in direct subsidy and LIPS more than offsetting reductions in federal reinsurance and LICS. We note that the impact on beneficiaries varies greatly depending on their medication profile, with both "winners and losers". Figure 12 summarizes our findings.

FIGURE 12: 2020-2029 IMPACT OF REBATE PASS-THROUGH ($ BILLIONS)

REBATE PASS-THROUGH PERCENTAGE	33%	66%	90%	100%
2020 to 2029 Impact by Stakeholder ($b)				
Beneficiary	-$5.7 *(-1%)*	-$12.0 *(-3%)*	-$17.0 *(-4%)*	-$19.3 *(-4%)*
Government	$24.2 *(+2%)*	$47.6 *(+4%)*	$63.0 *(+5%)*	$69.4 *(+6%)*
Drug Manufacturers	-$18.5 *(-19%)*	-$35.5 *(-36%)*	-$46.0 *(-46%)*	-$50.1 *(-50%)*
Total	**$0.0 *(0%)***	**$0.0 *(0%)***	**$0.0 *(0%)***	**$0.0 *(0%)***
2020 to 2029 Beneficiary Impact ($b)				
Cost Sharing	-$15.8 *(-3%)*	-$32.6 *(-7%)*	-$45.0 *(-9%)*	-$50.5 *(-11%)*
Premium	$10.1 *(+2%)*	$20.6 *(+4%)*	$28.0 *(+6%)*	$31.2 *(+7%)*
Total	**-$5.7 *(-1%)***	**-$12.0 *(-3%)***	**-$17.0 *(-4%)***	**-$19.3 *(-4%)***
2020 to 2029 Government Cost Impact ($b)				
Federal Reinsurance	-$17.9 *(-1%)*	-$33.5 *(-3%)*	-$42.4 *(-3%)*	-$45.6 *(-4%)*
Direct Subsidy	$63.1 *(+5%)*	$125.5 *(+10%)*	$167.5 *(+14%)*	$184.8 *(+15%)*
Low Income Premium Subsidy	$4.6 *(~0%)*	$9.4 *(+1%)*	$12.8 *(+1%)*	$14.2 *(+1%)*
Low Income Cost Sharing Subsidy	-$25.6 *(-2%)*	-$53.8 *(-4%)*	-$74.8 *(-6%)*	-$84.1 *(-7%)*
Total	**$24.2 *(+2%)***	**$47.6 *(+4%)***	**$63.0 *(+5%)***	**$69.4 *(+6%)***

+/- Percentage changes are from baseline total expenditures for each stakeholder. Sums of values may differ from totals due to rounding.

POTENTIAL BEHAVIORAL IMPACT OF REBATE PASS-THROUGH

The pass-through of rebates may result in the following examples of behavioral changes, which were not factored into our analysis. Behavior changes, while highly unpredictable, are inevitable to occur in some form:

- Beneficiaries could see reduced out-of-pocket costs which could increase utilization. This could be the result of improved adherence as well as reduced incentives to find cost effective alternatives. This could affect medical claims[ix,x] and is not considered in this paper's analysis of Part D spending.
- Depending on the pass-through percentage, drug manufacturers may have limited ability to use rebates to improve formulary placement. To compete for favorable tier placement drug manufacturers may reduce drug list prices. This could affect the commercial market and is not considered in this paper's analysis of Part D spending.
- Plan sponsors (or their PBMs) may attempt to negotiate for stronger rebates or other contracting terms (e.g., discounts) to improve competitiveness of bids in response to premium increases. In the absence of rebate improvements, plan sponsors may instead change formulary structures to eliminate or reduce favorable formulary placements of brand drugs, or to apply formulary restrictions in effort to more tightly manage brand utilization. Sponsors may then implement formulary strategies that rely on incentivizing the utilization of generics having the lowest net costs after rebates. The four or five tier formulary structures typically seen in Part D could therefore change based on the level of rebate pass-through.

LIMITING CHANGES TO CGDP DUE TO REBATE PASS-THROUGH

At The Drug Pricing Lab's request, we modified our rebate pass-through modeling to calculate CGDP payments using drug prices before POS rebates. This approach eliminates the impact of POS rebate pass-through on claim level CGDP payments through the creation of a "CGDP TrOOP". This benefit design is not included in the OIG proposed rule, and, as we are not lawyers, we have not opined on HHS's authority to implement this structure.

Under this approach, parallel CGDP payments are determined for each claim:

- The **theoretical CGDP** payment is based on the drug price net of POS rebates. This CGDP amount is used to determine beneficiary cost sharing and progress towards the beneficiary TrOOP.
- The **actual CGDP** payment is based on the drug price before POS rebates. This CGDP amount is the amount paid by drug manufacturers, which continues until the CGDP TrOOP threshold is met.

This approach requires an additional TrOOP calculation, which determines when CGDP payments end. The CGDP TrOOP is distinct from the beneficiary TrOOP:

- The **beneficiary TrOOP** is determined based on actual beneficiary cost sharing and theoretical CGDP payments. Both items are computed using the drug prices net of POS rebates. Beneficiary TrOOP is the point at which beneficiaries enter the catastrophic spending phase.
- The **CGDP TrOOP** is determined based on theoretical beneficiary cost sharing and actual CGDP. Both items are computed using the drug price before POS rebates. CGDP TrOOP is the point at which CGDP payments end.

Figure 13 below demonstrates how each TrOOP amount is determined under this approach.

FIGURE 13: KEY AMOUNTS COMPUTED WITH CGDP TROOP APPROACH

	Beneficiary TrOOP	**CGDP TrOOP**
Beneficiary responsibility	Actual cost sharing	Theoretical cost sharing
Drug manufacturer responsibility	Theoretical CGDP payments	Actual CGDP payments
Responsibility determined using	Drug price net of POS rebate	Drug price before POS rebate

Given that the CGDP payments reduce plan liability, we estimate that beneficiary premiums, LIPS, and direct subsidy payments are lower with the separate CGDP TrOOP accumulator. Comparing the 100% rebate pass-through with and without a separate CGDP TrOOP accumulator, beneficiary spending is estimated to fall by 6% compared to 4%, and government spending rises by 2% compared to 6%. Figure 14 summarizes our findings:

FIGURE 14: 2020-2029 IMPACT OF REBATE PASS-THROUGH WITH SEPARATE CGDP TROOP ($ BILLIONS)

REBATE PASS-THROUGH PERCENTAGE	33%	66%	90%	100%
2020 to 2029 Impact by Stakeholder ($b)				
Beneficiary	-$8.8 *(-2%)*	-$18.0 *(-4%)*	-$24.8 *(-5%)*	-$27.8 *(-6%)*
Government	$8.8 *(+1%)*	$18.0 *(+1%)*	$24.8 *(+2%)*	$27.8 *(+2%)*
Drug Manufacturers	$0.0 *(0%)*	$0.0 *(0%)*	$0.0 *(0%)*	$0.0 *(0%)*
Total	**$0.0 *(0%)***	**$0.0 *(0%)***	**$0.0 *(0%)***	**$0.0 *(0%)***
2020 to 2029 Beneficiary Impact ($b)				
Cost Sharing	-$15.8 *(-3%)*	-$32.6 *(-7%)*	-$45.0 *(-9%)*	-$50.5 *(-11%)*
Premium	$7.0 *(+1%)*	$14.6 *(+3%)*	$20.2 *(+4%)*	$22.7 *(+5%)*
Total	**-$8.8 *(-2%)***	**-$18.0 *(-4%)***	**-$24.8 *(-5%)***	**-$27.8 *(-6%)***
2020 to 2029 Government Cost Impact ($b)				
Federal Reinsurance	-$17.9 *(-1%)*	-$33.5 *(-3%)*	-$42.4 *(-3%)*	-$45.6 *(-4%)*
Direct Subsidy	$49.1 *(+4%)*	$98.7 *(+8%)*	$132.8 *(+11%)*	$147.0 *(+12%)*
Low Income Premium Subsidy	$3.2 *(~0%)*	$6.7 *(+1%)*	$9.2 *(+1%)*	$10.4 *(+1%)*
Low Income Cost Sharing Subsidy	-$25.6 *(-2%)*	-$53.8 *(-4%)*	-$74.8 *(-6%)*	-$84.1 *(-7%)*
Total	**$8.8 *(+1%)***	**$18.0 *(+1%)***	**$24.8 *(+2%)***	**$27.8 *(+2%)***

+/- Percentage changes are from baseline total expenditures for each stakeholder. Sums of values may differ from totals due to rounding.

REBATE PASS-THROUGH FOR SPECIFIC THERAPEUTIC CLASSES

At The Drug Pricing Lab's request, we modeled the impact of rebate pass-through on diabetes, oncology, and Hepatitis C medications[10] separately (i.e., we modeled passing through rebates for one class while all other rebates are not passed through) to analyze the impact on the entire population. These rebates were modeled at 100% pass-through levels assuming no behavioral changes (e.g., changes in rebate levels, formulary coverage, etc) and the estimated total dollar impacts are illustrated in Figure 15. The list of drug names included in each therapeutic class as defined for this analysis may be viewed in Table 1 of the Appendix of this report.

[10] *Diabetic, oncology, and Hepatitis C disease states were identified by flagging utilization for drugs contained within a list associated with each of the three diseases. Use of any drug within a disease's drug list codes a beneficiary to that specific disease state. Beneficiaries may belong to none or all of the disease states based on this methodology.*

FIGURE 15: 2020-2029 IMPACT OF 100% THERAPEUTIC CLASS SPECIFIC REBATE PASS-THROUGH ($ BILLIONS)

CLASS OF DRUG TREATMENT	DIABETES	ONCOLOGY	HEPATITIS C
2020 to 2029 Impact by Stakeholder ($b)			
Beneficiary	-$4.7 *(-1%)*	-$1.9 *(~0%)*	-$0.6 *(~0%)*
Government	$25.0 *(+2%)*	$2.5 *(~0%)*	$0.6 *(~0%)*
Drug Manufacturers	-$20.4 *(-20%)*	-$0.6 *(-1%)*	~$0.0 *(~0%)*
Total	**$0.0 *(0%)***	**$0.0 *(0%)***	**$0.0 *(0%)***
2020 to 2029 Beneficiary Impact ($b)			
Cost Sharing	-$16.3 *(-3%)*	-$2.8 *(-1%)*	-$0.9 *(~0%)*
Premium	$11.6 *(+2%)*	$0.9 *(~0%)*	$0.4 *(~0%)*
Total	**-$4.7 *(-1%)***	**-$1.9 *(~0%)***	**-$0.6 *(~0%)***
2020 to 2029 Government Cost Impact ($b)			
Federal Reinsurance	-$1.5 *(~0%)*	-$20.3 *(-2%)*	-$13.3 *(-1%)*
Direct Subsidy	$53.1 *(+4%)*	$24.5 *(+2%)*	$15.0 *(+1%)*
Low Income Premium Subsidy	$5.3 *(~0%)*	$0.4 *(~0%)*	$0.2 *(~0%)*
Low Income Cost Sharing Subsidy	-$31.9 *(-3%)*	-$2.1 *(~0%)*	-$1.3 *(~0%)*
Total	**$25.0 *(+2%)***	**$2.5 *(~0%)***	**$0.6 *(~0%)***

Each scenario is distinct and cumulative impacts will vary.
+/- Percentage changes are from baseline total expenditures for each stakeholder. Sums of values may differ from totals due to rounding.

We note that these results are highly sensitive to the assumed level of rebates by therapeutic class which we set using information from SSR Health. The SSR Health data is not specific to Medicare Part D and does not necessarily reflect the impact of Medicare Part D formularies and protected classes on rebates. For example, the antineoplastic therapeutic class is a protected class, which may drive lower rebate levels for oncology medications thus dampening the results presented for Oncology.

We compared the total dollar values shown in Figure 15 to the 100% rebate pass-through for all therapeutic classes in aggregate, found in the 100% column of Figure 12, to determine the impact of these therapeutic classes for the Part D market. Through this, we found these drug classes contribute to a significant portion of our estimated impact of the 100% rebate pass-through policy. In particular:

- When 100% of rebates are passed through on all drugs, the rebates passed-through for diabetes medications are expected to account for 25% of the overall resulting reductions in beneficiary costs. Rebates on diabetes medications have a large impact due to the significant out-of-pocket costs diabetes patients face and the large rebate amounts, particularly on insulins.
  - When 100% of rebates are passed through for all drugs, rebates passed through for diabetes medications account for 36% of the resulting increase to government costs, including 37% of the increase in LIPS and 38% of the decrease in LICS. This is due to the sizable proportion of the low income population taking diabetes medications.
  - Rebates passed through for diabetes medications accounted for 41% of the overall decreases to the CGDP when rebates are passed through for all drugs. The CGDP decrease is due to the passing through of rebates lowering POS drug costs. These list price reductions are sufficient to offset increases to CGDP from beneficiaries progressing more slowly through the Part D benefit phases when their out of pocket expenses are reduced at POS.
- When 100% of rebates are passed through for all drugs, rebate pass-through on oncology medications accounts for 10% of the overall resulting beneficiary cost decreases and 4% of government spending increases.
- Hepatitis C medications are responsible for another 3% of changes to beneficiary costs and 1% of government spending increases when 100% of rebates are passed through for all drugs.

  - The population cohort utilizing Hepatitis C drug treatments is a high-cost pool of beneficiaries with a majority of drug expenditures in the catastrophic phase compared to the Diabetes and Oncology subsets. Because most of their spending is in the catastrophic phase rather than in the coverage gap where CGDP is incurred, rebates passed through on drugs taken by the Hepatitis C medication-utilizing subset have a smaller impact on CGDP relative to rebates for other subsets.

- Combined, Oncology and Hepatitis C medications cause 74% of the overall resulting reduction in federal reinsurance when 100% of rebates are passed through. Due to the high cost of many of these medications, many beneficiaries taking them make it to the catastrophic phase and will remain in the catastrophic phase even with a 100% passing through of rebates. The reduction in allowed from rebate pass-through will significantly reduce federal reinsurance spending, with a smaller impact on beneficiary spending.

Figure 16 presents the estimated impact of 100% rebate pass-through for each therapeutic class under a policy scenario whereby manufacturer CGDP payments are held constant through a separate CGDP TrOOP accumulator. When drug manufacturer payments are held constant at spending levels prior to the rebate pass-through, CGDP amounts are no longer decreased by POS rebates and act to reduce the plan liability, which consequently leads to lower beneficiary premiums. These resulting premium reductions are estimated to limit the growth in government spending, compared to the case where drug manufacturer spending is allowed to decrease by rebates passed through at POS.

FIGURE 16: 2020-2029 IMPACT OF 100% THERAPEUTIC CLASS SPECIFIC REBATE PASS-THROUGH WITH SEPARATE CGDP TROOP ($ BILLIONS)

CLASS OF DRUG TREATMENT	DIABETES	ONCOLOGY	HEPATITIS C
2020 to 2029 Impact by Stakeholder ($b)			
Beneficiary	-$8.1 *(-2%)*	-$2.0 *(~0%)*	-$0.6 *(~0%)*
Government	$8.1 *(+1%)*	$2.0 *(~0%)*	$0.6 *(~0%)*
Drug Manufacturers	$0.0 *(0%)*	$0.0 *(0%)*	$0.0 *(0%)*
Total	**$0.0 *(0%)***	**$0.0 *(0%)***	**$0.0 *(0%)***
2020 to 2029 Beneficiary Impact ($b)			
Cost Sharing	-$16.3 *(-3%)*	-$2.8 *(-1%)*	-$0.9 *(~0%)*
Premium	$8.1 *(+2%)*	$0.8 *(~0%)*	$0.4 *(~0%)*
Total	**-$8.1 *(-2%)***	**-$2.0 *(~0%)***	**-$0.6 *(~0%)***
2020 to 2029 Government Cost Impact ($b)			
Federal Reinsurance	-$1.5 *(~0%)*	-$20.3 *(-2%)*	-$13.3 *(-1%)*
Direct Subsidy	$37.8 *(+3%)*	$24.0 *(+2%)*	$15.0 *(+1%)*
Low Income Premium Subsidy	$3.7 *(~0%)*	$0.4 *(~0%)*	$0.2 *(~0%)*
Low Income Cost Sharing Subsidy	-$31.9 *(-3%)*	-$2.1 *(~0%)*	-$1.3 *(~0%)*
Total	**$8.1 *(+1%)***	**$2.0 *(~0%)***	**$0.6 *(~0%)***

Each scenario is distinct and cumulative impacts will vary.
+/- Percentage changes are from baseline total expenditures for each stakeholder. Sums of values may differ from totals due to rounding.

REBATE PASS-THROUGH FOR SPECIFIC SUBPOPULATIONS

We modeled the impact of passing through 100% of market-wide rebates on the subsets of the population taking diabetes, oncology, and Hepatitis C, and all other medications. We note these populations are not mutually exclusive, with beneficiaries belonging to any or all of the disease state categories (including all other). Figure 17 summarizes the population subsets we considered and the estimated impact of rebate pass-through from the baseline spending amounts for those populations. Figure 18 summarizes the same information but for non-low income (NLI) beneficiaries only. The impacts on stakeholder spending levels illustrated in both figures were estimated at the 100% pass-through level. The entire drug usage for each of the four population subsets was analyzed, as opposed to analyzing only the disease-specific medications used to assign beneficiaries to the population subsets.

FIGURE 17: 2020 TO 2029 AGGREGATE IMPACT OF 100 % REBATE PASS-THROUGH BY NON-LOW INCOME MEDICATION USER

	AGGREGATE PROGRAM LEVEL			BENEFICIARY LEVEL		
MEDICATION USER	COST SHARING ($BILLIONS)	PREMIUM ($BILLIONS)	ANNUAL TOTAL SPEND ($BILLIONS)	ANNUAL COST SHARING PER BENEFICIARY	ANNUAL PREMIUM PER BENECIARY	ANNUAL TOTAL SPEND PER BENEFICIARY
Diabetes	-$17.0 *(-23%)*	$2.4 *(+3%)*	-$14.6 *(-20%)*	-$699.50 *(-23%)*	$97.70 *(+3%)*	-$601.80 *(-20%)*
Oncology	-$3.3 *(-11%)*	$1.1 *(+3%)*	-$2.2 *(-7%)*	-$298.40 *(-11%)*	$97.70 *(+3%)*	-$200.70 *(-7%)*
Hepatitis C	-$0.8 *(-29%)*	$0.0 *(+1%)*	-$0.8 *(-28%)*	-$3,489.70 *(-29%)*	$97.70 *(+1%)*	-$3,392.00 *(-28%)*
All Other	-$106.4 *(-14%)*	$30.4 *(+4%)*	-$76.0 *(-10%)*	-$341.70 *(-14%)*	$97.70 *(+4%)*	-$244.00 *(-10%)*

We define Medication User to mean any beneficiary who utilized that category of drug in an annual period. See Appendix Table 1 for drug lists. Each scenario is distinct and cumulative impacts will vary.
+/- Percentage changes are from baseline total expenditures for each medication user cohort. Sums of values may differ from totals due to rounding.

FIGURE 18: 2020 TO 2029 AGGREGATE IMPACT OF 100% REBATE PASS-THROUGH WITH SEPARATE CGDP TROOP BY NON-LOW INCOME MEDICATION USER

	AGGREGATE PROGRAM LEVEL			BENEFICIARY LEVEL		
MEDICATION USER	COST SHARING ($BILLIONS)	PREMIUM ($BILLIONS)	ANNUAL TOTAL SPEND ($BILLIONS)	ANNUAL COST SHARING PER BENEFICIARY	ANNUAL PREMIUM PER BENEFICIARY	ANNUAL TOTAL SPEND PER BENEFICIARY
Diabetes	-$17.0 *(-23%)*	$1.7 *(+2%)*	-$15.3 *(-21%)*	-$699.50 *(-23%)*	$71.20 *(+2%)*	-$628.30 *(-21%)*
Oncology	-$3.3 *(-11%)*	$0.8 *(+3%)*	-$2.5 *(-8%)*	-$298.40 *(-11%)*	$71.20 *(+3%)*	-$227.20 *(-8%)*
Hepatitis C	-$0.8 *(-29%)*	$0.0 *(+1%)*	-$0.8 *(-28%)*	-$3,489.70 *(-29%)*	$71.20 *(+1%)*	-$3,418.50 *(-29%)*
All Other	-$106.4 *(-14%)*	$22.2 *(+3%)*	-$84.2 *(-11%)*	-$341.70 *(-14%)*	$71.20 *(+3%)*	-$270.50 *(-11%)*

We define Medication User to mean any beneficiary who utilized that category of drug in an annual period. See Appendix Table 1 for drug lists. Each scenario is distinct and cumulative impacts will vary.
+/- Percentage changes are from baseline total expenditures for each medication user cohort. Sums of values may differ from totals due to rounding.

If 100% of rebates were passed through on all drugs market-wide, we estimate beneficiaries who take diabetes medications would see aggregate savings of $14.6 billion from 2020 through 2029, with a $17.0 billion savings in cost sharing, offset by a $2.4 billion increase in premiums. If drug manufacturer CGDP payments are held constant rather than allowed to decrease due to rebate pass-through amounts, beneficiaries taking diabetes medications are expected to see additional savings of $0.7 billion, driven by lesser premium increases.

Beneficiaries who take oncology medications would see smaller aggregate savings of $2.5 billion. Similarly, beneficiaries who take Hepatitis C medication will see an estimated $0.8 billion reduction in costs. Due to the high cost of these drugs, beneficiaries will likely still end in the catastrophic phase even with rebate pass-through. The reduction in allowed that would be seen would largely reduce federal reinsurance in the catastrophic phase and have minimal impact on beneficiary cost sharing.

Figures 19 and 20 illustrate the estimated impacts of passing through 100% of rebates for the full population of Medicare enrollees, but with results stated by grouping beneficiaries according to different levels of total annual beneficiary spending (i.e., total cost of premiums, out of pocket spending, and plan liability associated with the beneficiary's annual drug use). Projected changes in beneficiary cost sharing and beneficiary premiums from 2020 to 2029 as well as the percentage of Medicare enrollees in each spending range are shown below. We note that the annual, per beneficiary impact on premiums declines as the Annual Beneficiary Spending increases as the higher spending ranges have greater proportions of low-income beneficiaries, who receive premium subsidies.

FIGURE 19: 2020-2029 IMPACT OF 100% REBATE PASS-THROUGH BY RANGE OF ANNUAL SPENDING (ANNUAL AMOUNTS PER BENEFICIARY)

ANNUAL BENEFICIARY SPENDING RANGE (OUT-OF-POCKET COST + PLAN LIABILITY)	DISTRIBUTION OF BENEFICIARIES	IMPACT ON BENEFICIARY COST SHARING	IMPACT ON PREMIUM	TOTAL IMPACT ON BENEFICIARY COSTS	PERCENTAGE CHANGE IN ANNUAL BENEFICIARY COST
$0-500	42.5%	-$7.60	$74.20	$66.60	12%
$501-1,000	13.5%	-$19.30	$73.30	$54.00	6%
$1,001-2,500	16.0%	-$66.30	$67.60	$1.30	0%
$2,501-5,000	12.5%	-$262.60	$64.10	-$198.40	-14%
$5,001-10,000	9.0%	-$430.40	$49.70	-$380.80	-21%
$10,001-15,000	2.5%	-$276.60	$35.50	-$241.10	-13%
$15,001-25,000	2.0%	-$164.70	$30.60	-$134.10	-7%
$25,000+	2.0%	-$544.10	$38.10	-$506.10	-11%
Total	100%	-$108.60	$67.10	-$41.50	-4%

FIGURE 20: 2020-2029 IMPACT OF 100% REBATE PASS-THROUGH BY RANGE OF ANNUAL SPENDING ($BILLIONS)

ANNUAL BENEFICIARY SPENDING RANGE (OUT-OF-POCKET COST + PLAN LIABILITY)	DISTRIBUTION OF BENEFICIARIES	IMPACT ON BENEFICIARY COST SHARING	IMPACT ON PREMIUM	TOTAL IMPACT ON BENEFICIARY COSTS	PERCENTAGE CHANGE IN ANNUAL BENEFICIARY COST
$0-500	42.5%	-$1.5	$14.7	$13.2	12%
$501-1,000	13.5%	-$1.2	$4.6	$3.4	6%
$1,001-2,500	16.0%	-$5.0	$5.1	$0.1	0%
$2,501-5,000	12.5%	-$15.3	$3.7	-$11.6	-14%
$5,001-10,000	9.0%	-$17.7	$2.0	-$15.7	-21%
$10,001-15,000	2.5%	-$3.5	$0.4	-$3.0	-13%
$15,001-25,000	2.0%	-$1.3	$0.2	-$1.1	-7%
$25,000+	2.0%	-$5.0	$0.4	-$4.7	-12%
Total	100%	-$50.5	$31.2	-$19.3	-4%

Beneficiaries with elevated levels of annual spending are expected to see greater reductions in their overall Part D costs. These high utilizers benefit from rebates being passed through to directly reduce the allowed costs of their drugs on which cost sharing may be based (e.g., in the form of a percentage coinsurance). Beneficiaries with lower levels of annual beneficiary spending benefit less from the pass-through of rebates, since there are fewer rebates associated with their drug use; the increases in premium due to POS rebates exceed the cost sharing reductions for beneficiaries in the lower annual beneficiary spending ranges. We note that the impact to beneficiaries is not uniformly decreasing on an annual, per beneficiary basis between the $5,000 and $25,000 allowed spending ranges (see Figure 20) – we attribute this effect to beneficiaries taking longer on average to reach the catastrophic phase of the Part D benefit, where their cost sharing is reduced, due to the lower allowed costs of their drugs after POS rebates.

Methodology

MODEL APPROACH

We developed a seriatim model to project the impact of various Part D benefit design changes on the individual Part D market with the standard benefit design. We did not model effects for actuarial equivalent, basic alternative, and enhanced alternative plan designs or any EGWPs. The model uses claim specific data to adjudicate the changes to the defined standard benefit discussed in this report without consideration of potential behavioral shifts caused by these policies.

Our model allocates all claim costs, rebates, non-benefit expenses and margin between beneficiaries' premium and cost sharing; the government's federal reinsurance payments, direct subsidy payments, LIPS, and LICS; and drug manufacturers' CGDP payments.

First, the model's claim adjudication splits each claim into beneficiary cost sharing, LICS, gross plan liability, CGDP, and gross federal reinsurance. We then reduce the gross federal reinsurance amounts to reflect our projection of offsets from non-POS rebates. We also calculate the net plan liability as the gross plan liability less plan-retained, non-POS rebates plus our assumption for non-benefit expenses and margin. We split the projected net plan liability between beneficiary premium, direct subsidy, and LIPS.

CLAIMS DATA AND ASSUMPTIONS

The claim data underlying our analysis is 2017 claims data from Milliman's Part D Consolidated Database (PDCD). This is the data used to develop Milliman's Part D manual rates and is based on Medicare Part D experience including over 60 million member months across 34 regions and Puerto Rico.

We projected 2019 claims using trends and contracting terms consistent with our expectation for the 2019 individual Medicare Part D market. Our expectations for a typical individual Part D plan tie to the published 2019 NABA and National Average Member Premium (NAMP).

We projected 2020 through 2029 using trends, individual Part D enrollment, and Part D benefit parameters from the 2018 Medicare Trustees report[xi] with the following additional considerations:

- We projected the 2028 and 2029 enrollment, trends, and benefit parameters based on the rate of change between 2026 and 2027 in the 2018 Medicare Trustees Report.
- We scaled the 2018 Medicare Trustees Report trends when we applied the trends to generic, brand and specialty drugs to reflect that we expect cost increases to be driven by brand and specialty AWP increases and specialty utilization increases.
- We assumed no impact of the evaluated policy changes on aggregate risk scores in modeling results nationally. On a regional or plan-basis the impacts of risk adjustment could vary significantly depending on the variation of assumptions from averages assumed across the market.
- We did not adjust benefit parameters from publicly available sources (e.g., 2018 Medicare Trustees report) to reflect the potential impacts of these or other policy changes to the Part D program. In particular, benefit parameters could be materially reduced if rebates are passed through at the POS, which could significantly impact the results presented in this report.

ADDITIONAL ASSUMPTIONS

Our modeling reflects 2018 therapeutic class-level rebates as a percent of cost from SSR Health's US prescription brand net pricing data tool. We applied a uniform reduction to the SSR Health data to exclude additional discounts included in the SSR data that are not typically considered rebates. We validated the rebates in total against our extrapolation of published OIG estimates[xii]. We note that the SSR rebate information is not specific to Medicare Part D and does not necessarily reflect the impact of Medicare Part D formularies and protected classes on rebates. **Rebates may vary significantly by product and by plan; therefore, results produced by this analysis would likely differ materially across plans if performed at the plan level.** Rebate levels are unavailable to the majority of PBM clients. We assume plan sponsors are able to price accurately for POS rebates based on reliable information on

rebates, though in practice the lack of transparency regarding manufacturer rebate levels may present challenges to adequate bid development.

We informed our projections of pharmacy DIR, non-benefit expenses, and margin using Milliman's survey of Part D sponsors 2019 bids. Our projections represent our expectations for a typical individual Part D plan. We did not model pharmacy DIR at the seriatim level and instead applied pharmacy DIR at an aggregate per script level. These amounts were not included as pass-through rebates in any of the scenarios we modeled.

We modeled impacts on government spending, beneficiary spending, and drug manufacturer spending by estimating changes to the following components of each stakeholder's total costs:

- Government
  - Federal Reinsurance; Direct Subsidy; LIPS; LICS
- Beneficiary
  - Out-of-Pocket Costs; Beneficiary Premiums
- Drug Manufacturers
  - CGDP Payments

Our analysis does not estimate the impacts of policy changes on components of stakeholder spending not listed above, nor does it factor in behavior changes, which are highly unpredictable but inevitable.

Caveats and Limitations

This Milliman report has been prepared for the specific purpose of summarizing our estimates of the impact of various potential Part D benefit changes. This information may not be appropriate, and should not be used, for any other purpose.

Milliman does not intend to benefit, and assumes no duty or liability to, third parties who receive this work product. Any third party recipient of this work product who desires professional guidance should not rely upon Milliman's work product, but should engage qualified professionals for advice appropriate to its own specific needs. Milliman does not endorse any public policy or advocacy position on matters discussed in this report.

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.

The methodologies and assumptions underlying this analysis may produce estimates that differ from results prepared by other Milliman consultants and external organizations. The impact of provisions evaluated in this report were estimated using claim level modeling techniques and rebate information from SSR Health and other sources; our findings may vary from others released on this subject based on reasons including differences in information sources and modeling approaches.

In performing this analysis, we relied on data and other information provided by CMS and SSR Health. 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.

ACKNOWLEDGMENT OF QUALIFICATION

The authors are actuaries for Milliman, members of the American Academy of Actuaries, and meet the Qualification Standards of the Academy to render the actuarial opinion contained herein. To the best of their knowledge and belief, this information is complete and accurate and has been prepared in accordance with generally recognized and accepted actuarial principles and practices

Appendix

TABLE 1: THERAPEUTIC CLASS DRUG LISTS - DIABETES

ALOGLIPTIN/PIOGLITAZONE	HUMULIN 70/30 KWIKPEN
GLYXAMBI	HUMULIN 70/30 PEN
INVOKAMET	HUMULIN N
INVOKAMET XR	HUMULIN N KWIKPEN
JANUMET	HUMULIN N U-100 PEN
JANUMET XR	HUMULIN R
JENTADUETO	HUMULIN R U-500 (CONCENTRATED)
JENTADUETO XR	HUMULIN R U-500 KWIKPEN
KAZANO	NOVOLIN 70/30
KOMBIGLYZE XR	NOVOLIN 70/30 RELION
OSENI	NOVOLIN N
SYNJARDY	NOVOLIN N RELION
XIGDUO XR	NOVOLIN R
ALOGLIPTIN	NOVOLIN R RELION
FARXIGA	NOVOLOG
INVOKANA	NOVOLOG FLEXPEN
JANUVIA	NOVOLOG MIX 70/30
JARDIANCE	NOVOLOG MIX 70/30 PREFILLED FLEXPEN
NESINA	NOVOLOG PENFILL
ONGLYZA	
TRADJENTA	
BASAGLAR KWIKPEN	
LANTUS	
LANTUS SOLOSTAR	
LEVEMIR	
LEVEMIR FLEXPEN	
LEVEMIR FLEXTOUCH	
TOUJEO SOLOSTAR	
TRESIBA FLEXTOUCH	
AFREZZA	
APIDRA	
APIDRA SOLOSTAR	
BASAGLAR KWIKPEN	
FIASP FLEXTOUCH	
HUMALOG	
HUMALOG JUNIOR KWIKPEN	
HUMALOG KWIKPEN	
HUMALOG MIX 50/50	
HUMALOG MIX 50/50 KWIKPEN	
HUMALOG MIX 75/25	
HUMALOG MIX 75/25 KWIKPEN	
HUMULIN 70/30	

TABLE 2: THERAPEUTIC CLASS DRUG LISTS – HEPATITIS C

DAKLINZA
EPCLUSA
HARVONI
MAVYRET
OLYSIO
SOVALDI
TECHNIVIE
VIEKIRA PAK
VIEKIRA XR
ZEPATIER

TABLE 3: THERAPEUTIC CLASS DRUG LISTS – ONCOLOGY

ADRUCIL	CABOMETYX	ZELBORAF
ALIMTA	CALQUENCE	ZOLINZA
AZACITIDINE	CAPRELSA	ZYDELIG
CAPECITABINE	COMETRIQ	ZYKADIA
CLADRIBINE	COTELLIC	ANASTROZOLE
CYTARABINE AQUEOUS	FARYDAK	ARIMIDEX
DECITABINE	GILOTRIF	AROMASIN
FLUDARABINE PHOSPHATE	GLEEVEC	DEPO-PROVERA
FLUOROURACIL	IBRANCE	EXEMESTANE
GEMCITABINE	ICLUSIG	FARESTON
GEMCITABINE HCL	IDHIFA	FASLODEX
MERCAPTOPURINE	IMATINIB MESYLATE	FEMARA
METHOTREXATE	IMBRUVICA	LETROZOLE
METHOTREXATE SODIUM	INLYTA	MEGACE ORAL
PURIXAN	IRESSA	MEGESTROL ACETATE
TABLOID	ISTODAX (OVERFILL)	SOLTAMOX
TREXALL	JAKAFI	TAMOXIFEN CITRATE
VIDAZA	KISQALI	BICALUTAMIDE
XATMEP	KYPROLIS	CASODEX
XELODA	LENVIMA 10 MG DAILY DOSE	ELIGARD
ARZERRA	LENVIMA 14 MG DAILY DOSE	EMCYT
BLINCYTO	LENVIMA 18 MG DAILY DOSE	FIRMAGON
DARZALEX	LENVIMA 20 MG DAILY DOSE	FLUTAMIDE
EMPLICITI	LENVIMA 24 MG DAILY DOSE	NILANDRON
ERBITUX	LENVIMA 8 MG DAILY DOSE	TRELSTAR MIXJECT
GAZYVA	LYNPARZA	VANTAS
HERCEPTIN	MEKINIST	XTANDI
IMFINZI	NERLYNX	ZYTIGA
KADCYLA	NEXAVAR	LEUPROLIDE ACETATE
KEYTRUDA	NINLARO	LUPRON DEPOT (1-MONTH)
LARTRUVO	RUBRACA	LUPRON DEPOT (3-MONTH)
OPDIVO	RYDAPT	LUPRON DEPOT (4-MONTH)
PERJETA	SPRYCEL	LUPRON DEPOT (6-MONTH)
RITUXAN	STIVARGA	LYSODREN
TECENTRIQ	SUTENT	NILUTAMIDE
VECTIBIX	TAFINLAR	ZOLADEX
YERVOY	TAGRISSO	ACTIMMUNE
AFINITOR	TARCEVA	BEXAROTENE
AFINITOR DISPERZ	TASIGNA	DACARBAZINE
ALECENSA	TORISEL	HYDREA
ALUNBRIG	TYKERB	HYDROXYUREA
TARGRETIN	VELCADE	INTRON A
TICE BCG	VERZENIO	INTRON A W/DILUENT
TRETINOIN	VOTRIENT	MATULANE
BOSULIF	XALKORI	PROLEUKIN
ZEJULA		THALOMID
SYLATRON		REVLIMID
SYNRIBO		

[i] Sen. Wyden, Ron. Reducing Existing Costs Associated with Pharmaceuticals for Seniors Act of 2017 or the RxCAP Act of 2017. https://www.congress.gov/bill/115th-congress/senate-bill/1347

[ii] 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. Retrieved December 11, 2018, from: https://s3.amazonaws.com/public-inspection.federalregister.gov/2017-25068.pdf.

[iii] "2019 Budget Fact Sheet." March 2018. https: //www.whitehouse.gov/wp-content/uploads/2018/02/FY19-Budget-Fact-Sheet_Reforming-Drug-Pricing-Payment.pdf

[iv] Department of HHS, CMS (November 2018). Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses. Retrieved December 11, 2018, from: https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-25945.pdf.

[v] U.S. Department of Health and Human Services, Office of Inspector General (January 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 1, 2019, from: https://www.hhs.gov/sites/default/files/20190131_42-CFR-Part-1001.pdf

[vi] Department of HHS, CMS (July 2018). Annual Release of Part D National Average Bid Amount and Other Part C & D Bid Information. Retrieved December 11, 2018, from: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/PartDandMABenchmarks2019.pdf.

[vii] U.S. Department of Health and Human Services, Office of Inspector General. "Increases in Reimbursement for Brand-Name Drugs in Part D." June 2018. https://oig.hhs.gov/oei/reports/oei-03-15-00080.pdf

[viii] "Medicare Part D – Direct and Indirect Remuneration (DIR)." January 2017. https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-and-indirect-remuneration-dir.

[ix] Lopert, R., Shoemaker, J. S., Davidoff, A., Shaffer, T., Abdulhalim, A. M., Lloyd, J., & Stuart, B. (2012). Medication adherence and medicare expenditure among beneficiaries with heart failure. American Journal of Managed Care, 18(9), 556-563.

[x] Roebuck, M., Liberman, J., Gemmill-Toyama M., & Brennan T. (2011). Medication Adherence Leads To Lower Health Care Use And Costs Despite Increased Drug Spending. Health Affairs, Vol. 30, No. 1, https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2009.1087

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

Michelle Angeloni
michelle.angeloni@milliman.com

Sean Hilton
sean.hilton@milliman.com

Tory Carver
tory.carver@milliman.com