PART D CATASTROPHIC COVERAGE - FINANCIAL IMPLICATIONS OF RESTRUCTURING TO INCLUDE MANUFACTURER'S LIABILITY

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1. Executive Summary

As prescription drug prices continue to rise, many stakeholders have debated how to slow the trend and who should pay for it. The Medicare Advantage and Part D programs remain at the center of this discussion. Organizations such as the Medicare Payment Advisory Commission ("MedPAC") and the American Action Form ("AAF") as well as Congress have put forth proposals to redistribute the liabilities within the Part D program in response.

Under current Part D program rules, the CMS covers 80% of prescription drug costs (less an adjustment for rebates and other forms of Direct and Indirect Renumeration ("DIR")) above a certain threshold, known as the True Out of Pocket cost ("TrOOP"). Claims above the TrOOP are commonly referred to as catastrophic claims. In the catastrophic phase of the Part D benefit, the member is liable for 5% of costs and the health plan covers the remaining 15% (plus an adjustment for DIR). Prescription drug manufacturers ("manufacturers") currently share a portion of the liability in the "Gap" phase for brand drugs but have no liability in the catastrophic phase.

Oliver Wyman Actuarial Consulting, Inc. ("Oliver Wyman") has modeled four scenarios related to the redistribution of liabilities within the catastrophic phase. Each of the scenarios involve keeping the current manufacturer's liability in the Coverage Gap Discount Program ("CGDP") intact under its current 2020 parameters but introducing additional liability for manufacturers in the catastrophic phase, while also altering government and plan liability in the catastrophic phase. Each scenario is outlined below and makes no changes to any benefit phase other than catastrophic:

- **Scenario 1**: In the catastrophic phase, the revised liabilities would be as follows: 50% manufacturer, 30% Federal Reinsurance, 15% plan, and 5% member.
- **Scenario 2**: In the catastrophic phase, member liability would be reduced to 0% and the revised liabilities would be as follows: 50% manufacturer, 30% Federal Reinsurance, and 20% plan.
- **Scenario 3**: In the catastrophic phase, the member liability would stay at 5%, and the remaining 95% would be split evenly as follows: 31.7% manufacturer, 31.7% Federal Reinsurance, and 31.7% Plan.
- **Scenario 4**: In the catastrophic phase, the member liability would be reduced to 0%, and the revised liability would be split evenly as follows: 33.3% manufacturer, 33.3% Federal Reinsurance, and 33.3% Plan.

In the scenarios described above, it's important to note the following:

- Payments from the Federal Reinsurance program would be reduced by a percentage of the DIR received by a plan, similar to the current process.
- Manufacturer's would only be liable for Non-Low Income members' brand and biosimilar claims, similar to the current CGDP program.
- For Low-Income and generic drug claims, we assumed that plans would be subject to the combination of the new plan liability plus the manufacturer's share. For example, in Scenario 1, the plan liability would be 40%, made up of the original 15% plus the 25% the manufacturer isn't paying on these types of claims.

- For the scenarios which include 5% member cost sharing, Low-Income cost sharing subsidies would remain equal to the difference between what the member actually paid, and the 5% they otherwise would have paid.

Oliver Wyman evaluated the effect over a 10-year period (2021 through 2030) of restructuring the liabilities in the catastrophic phase of the Part D program to include manufacturer's liability as described under the scenarios outlined above. Exhibit 1 shows the net change separately by Scenario for total government liability (Direct Subsidy, Federal Reinsurance, Low-Income Cost Sharing ("LICS"), and Low-Income Premium Subsidy ("LIPS")), Member Premium, Member Cost Sharing, and Manufacturer's Liability:

Exhibit 1 – Estimated (2021 through 2030) Total Cost of Restructuring the Part D Catastrophic Liabilities to include Manufacturer's Liability

	Change (In Billions)			
Scenario*	Government Liability	Member Premium	Member Cost Sharing	Manufacturer's Liability
1 (50/30/15/5)	($173.8)	($39.2)	$0.0	$213.0
2 (50/30/20/0)	($94.3)	($20.5)	($59.3)	$219.4
3 (31.7/31.7/31.7/5)	($110.1)	($24.8)	$0.0	$134.9
4 (33.3/33.3/33.3/0)	($34.6)	($7.0)	($59.3)	$146.3

*(Manufacturer / Reinsurance / Plan / Member)

We have separated the net change to government liability over a 10-year period (2021 to 2030) in each of the scenarios into each of the separate Part D subsidies. As noted above, Federal Reinsurance payments decrease significantly as liability is decreased from 80%, but that is partially offset by increases to Direct Subsidy payments as a plan's catastrophic liability cost of coverage increases. There are additional savings to the government as the LIPS payments decrease in all scenarios, and the LICS payments decrease in scenarios where the 5% member cost sharing is eliminated.

Exhibit 2 – Estimated (2021 through 2030) Government Cost of Restructuring the Part D Catastrophic Liabilities

	Change (In Billions)			
Scenario	Direct Subsidy	Federal Reinsurance	LICS	LIPS
1 (50/30/15/5)	$423.3	($582.1)	$0.0	($15.0)
2 (50/30/20/0)	$503.8	($569.2)	($22.7)	($6.2)
3 (31.7/31.7/31.7/5)	$462.1	($562.7)	$0.0	($9.5)
4 (33.3/33.3/33.3/0)	$518.1	($529.0)	($22.7)	($1.0)

*(Manufacturer / Reinsurance / Plan / Member)

It is important to note that in the absence of any plan behavior changes, the net impact of restructuring the catastrophic liabilities is $0 in the scenarios where the 5% member cost sharing is not changed; there is solely a shifting of dollars between stakeholders, with no net increase to the program. For the scenarios which include eliminating member cost sharing, we have modeled increased utilization as members no longer have a financial incentive to forego less important drug treatments, which produces a net increase to the program across all stakeholders.

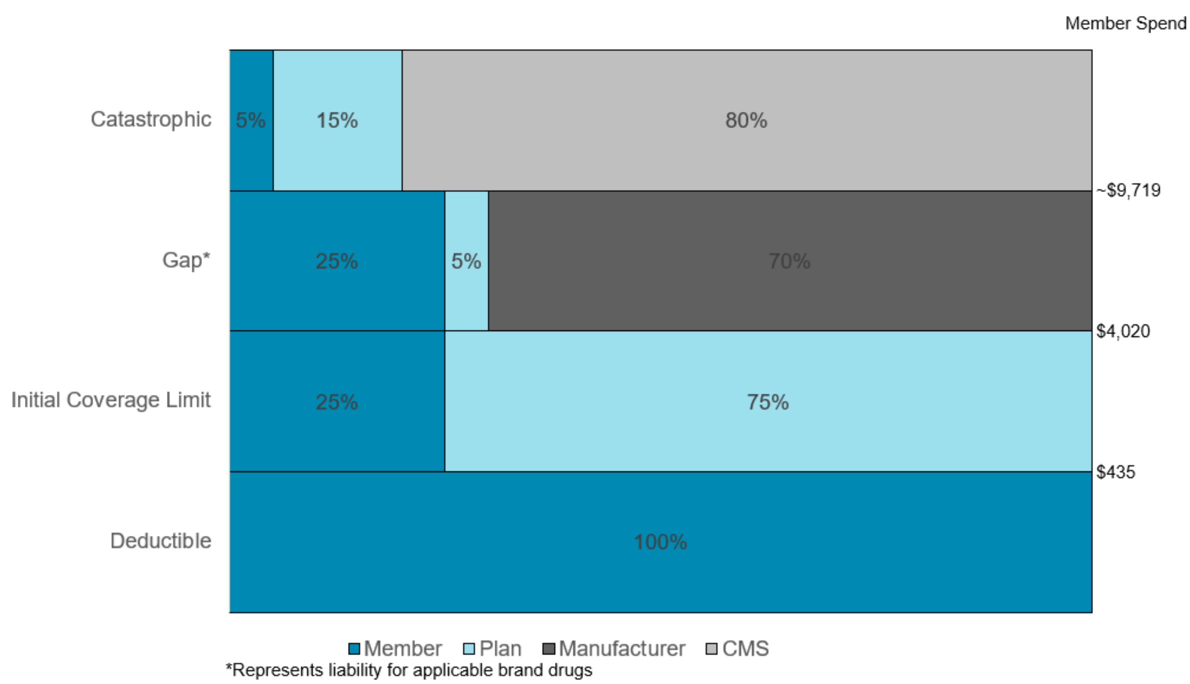
In all scenarios in the analysis, we have assumed that manufacturers make no additional changes to drug pricing (in excess of the inflation trend already assumed) in response to their increased liability. We have also assumed that plans make no significant formulary changes in response to the increased risk and liability under the proposal, and lastly that administration and profit margins remain the same. As such, these results could be viewed as an upper limit.

The remainder of this report provides background information on the proposed restructuring of the catastrophic phase of the Part D benefit to include manufacturer's liability, outlines the analysis undertaken by Oliver Wyman, and presents the details of our analysis.

2. Background

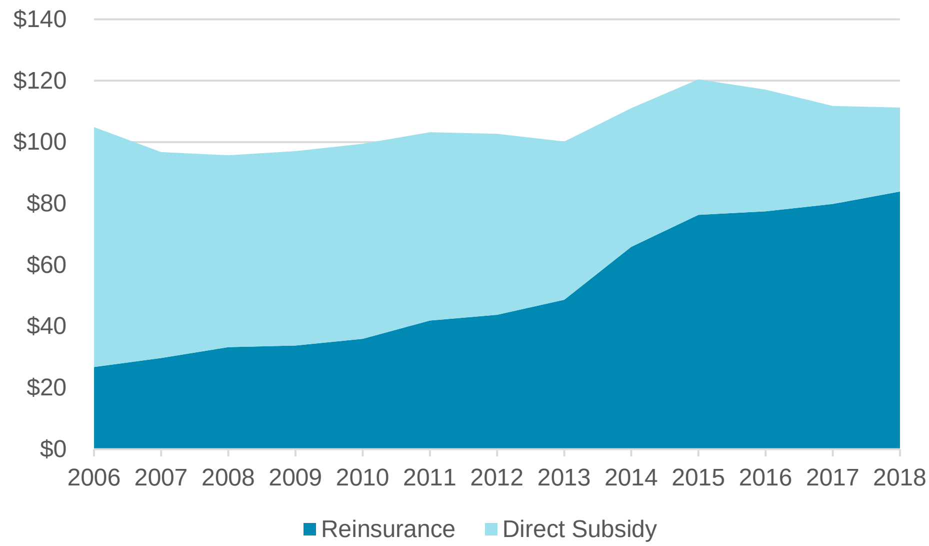
With the passage of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), Congress authorized Medicare coverage of outpatient prescription drugs beginning in 2006. The MMA established the minimum standard benefit Part D plans must offer. The benefit structure adjusts each member's liability as their cumulative drug expenditures grow. After moving through the deductible, Initial Coverage Limit, and Coverage Gap phases, a member's OOP costs would eventually reach the annual true out-of-pocket threshold, or TrOOP ($6,350 in 2020). Once a member reaches the TrOOP, their cost-sharing would be reduced to 5% and CMS would pay 80% of the drug cost after adjustments for rebates. Exhibit 3 highlights the Part D benefit structure and stakeholder liability in 2020.

Exhibit 3 – 2020 Part D Benefit Design



In the years since inception of the Part D program, the thresholds for exiting and entering the different benefit phases, as well as the structure of the Coverage Gap have changed, but the catastrophic phase still features the same liability percentages as they were originally outlined in the MMA. Reinsurance payments from the government have increased significantly over time, primarily due to expensive specialty medications, but there has been some leveling off of reinsurance payments in the most recent years. Exhibit 4 shows the change in the CMS Direct Subsidy and Part D Reinsurance since 2006 based on the 2019 Medicare Trustees Report.

Exhibit 4 – 2006 through 2018 CMS Average Actual Reinsurance and Direct Subsidy Payments Per-Member Per-Month (PMPM)



This exhibit illustrates that CMS reinsurance payments have increased significantly, which is driven heavily by the introduction of Hepatitis C medications starting in 2014. Concurrent with the reinsurance increase, there have been offsetting reductions in risk-adjusted capitation payments PMPM. In tandem, the increasing reinsurance payments and decreasing capitation payments result in the overall combined cost of the two items increasing only slightly over time. Proposals to restructure the liability in the catastrophic phase would significantly alter this trajectory of increasing Federal Reinsurance payments, but would also increase Direct Subsidy payments, resulting in an increased total cost to the federal government.

3. Analysis

Using data sources made public by CMS, the 2019 Medicare Trustees Report, and data proprietary to Oliver Wyman, we projected 2021 drug costs, rebates, and member cost sharing, as well as government and plan liabilities associated with the Medicare Part D program.

As defined by statute, the CMS Direct Subsidy payment is equal to the difference between the National Average Bid Amount ("NABA") and the National Average Member Premium Amount ("NAMPA"). The NAMPA is calculated as 25.5% of the "total cost", or the sum of the NABA and the National Average Federal Reinsurance Amount. The program changes modeled in this report would increase the NABA, while moderately decreasing the sum of NABA and Federal Reinsurance, resulting in an increase in the Direct Subsidy. LICS payments would decrease in the scenarios where the 5% member cost sharing in the catastrophic is eliminated. Lastly, the overall LIPS payments will decrease slightly as the Low-Income bid amount would increase by less than the direct subsidy. It is important to note that this result would vary by State.

We are modeling one factor that will bring additional costs into the program (as opposed to shifting liabilities between stakeholders): Induced utilization due to removal of member cost sharing above the TrOOP. **This change is modeled only in the scenarios where the 5% member cost sharing is eliminated.**

We have assumed that Low-Income members exhibit no behavioral changes as a result of removing any nominal cost sharing in the catastrophic phase. For Non-Low-Income members, we have assumed that the current cost sharing level of 5% causes some implicit reduction in their utilization. Many members in the catastrophic phase of the Part D benefit are utilizers of very expensive brand and specialty medications. The current 5% cost sharing forces some members to opt for the least expensive version of the drug, or to forego non-essential drugs all together. If that cost sharing is removed, there would be additional utilization as member financial incentives change.

In the 2019 Medicare Trustees Report, the Board estimates that Part D enrollment will increase from 45.8 million enrollees in 2019 to 59.1 million enrollees in 2028. Using this membership data, we projected that Part D enrollment will reach 61.7 million enrollees in 2030. Using these membership projections, we have estimated the net cost to the government, the change in member premiums and cost sharing, and the net impact to manufacturers over the 10-year period in Exhibits 5 through 8 below.

Exhibit 5 – Estimated Cost of Restructuring the Catastrophic Phase to include Manufacturer's Liability as Described in Scenario 1 (50% / 30% / 15% / 5%)

		Change (In Billions)			
Year	Members (In Millions)	Government Liability	Member Premium	Member Cost Sharing	Manufacturer's liability
2021	49.1	($11.2)	($2.5)	$0.0	$13.7
2022	50.8	($12.6)	($2.8)	$0.0	$15.4
2023	52.3	($13.8)	($3.1)	$0.0	$17.0
2024	53.8	($15.0)	($3.4)	$0.0	$18.4
2025	55.2	($16.3)	($3.7)	$0.0	$19.9
2026	56.5	($17.7)	($4.0)	$0.0	$21.7
2027	57.8	($19.2)	($4.3)	$0.0	$23.5
2028	59.1	($20.8)	($4.7)	$0.0	$25.5
2029	60.4	($22.6)	($5.1)	$0.0	$27.7
2030	61.7	($24.5)	($5.5)	$0.0	$30.1
All years		($173.8)	($39.2)	$0.0	$213.0

Exhibit 6 – Estimated Cost of Restructuring the Catastrophic Phase to include Manufacturer's Liability as Described in Scenario 2 (50% / 30% / 20% / 0%)

		Change (In Billions)			
Year	Members (In Millions)	Government Liability	Member Premium	Member Cost Sharing	Manufacturer's liability
2021	49.1	($6.2)	($1.3)	($3.7)	$14.2
2022	50.8	($6.9)	($1.5)	($4.2)	$15.8
2023	52.3	($7.6)	($1.6)	($4.7)	$17.5
2024	53.8	($8.2)	($1.8)	($5.1)	$19.0
2025	55.2	($8.8)	($1.9)	($5.5)	$20.5
2026	56.5	($9.7)	($2.1)	($6.0)	$22.4
2027	57.8	($10.4)	($2.3)	($6.5)	$24.2
2028	59.1	($11.2)	($2.5)	($7.1)	$26.3
2029	60.4	($12.1)	($2.7)	($7.8)	$28.5
2030	61.7	($13.2)	($2.9)	($8.5)	$31.0
All years		($94.3)	($20.5)	($59.3)	$219.4

Exhibit 7 – Estimated Cost of Restructuring the Catastrophic Phase to include Manufacturer's Liability as Described in Scenario 3 (31.7% / 31.7% / 31.7% / 5%)

		Change (In Billions)			
Year	Members (In Millions)	Government Liability	Member Premium	Member Cost Sharing	Manufacturer's liability
2021	49.1	($7.1)	($1.6)	$0.0	$8.7
2022	50.8	($8.0)	($1.8)	$0.0	$9.7
2023	52.3	($8.8)	($2.0)	$0.0	$10.7
2024	53.8	($9.5)	($2.2)	$0.0	$11.7
2025	55.2	($10.3)	($2.3)	$0.0	$12.6
2026	56.5	($11.2)	($2.5)	$0.0	$13.8
2027	57.8	($12.1)	($2.7)	$0.0	$14.9
2028	59.1	($13.2)	($3.0)	$0.0	$16.2
2029	60.4	($14.3)	($3.2)	$0.0	$17.5
2030	61.7	($15.6)	($3.5)	$0.0	$19.0
All years		($110.1)	($24.8)	$0.0	$134.9

Exhibit 8 – Estimated Cost of Restructuring the Catastrophic Phase to include Manufacturer's Liability as Described in Scenario 4 (33.3% / 33.3% / 33.3% / 0%)

		Change (In Billions)			
Year	Members (In Millions)	Government Liability	Member Premium	Member Cost Sharing	Manufacturer's liability
2021	49.1	($2.3)	($0.5)	($3.7)	$9.4
2022	50.8	($2.6)	($0.5)	($4.2)	$10.6
2023	52.3	($2.8)	($0.6)	($4.7)	$11.7
2024	53.8	($3.0)	($0.6)	($5.1)	$12.7
2025	55.2	($3.2)	($0.7)	($5.5)	$13.7
2026	56.5	($3.6)	($0.7)	($6.0)	$14.9
2027	57.8	($3.8)	($0.8)	($6.5)	$16.1
2028	59.1	($4.1)	($0.8)	($7.1)	$17.5
2029	60.4	($4.4)	($0.9)	($7.8)	$19.0
2030	61.7	($4.7)	($0.9)	($8.5)	$20.6
All years		($34.6)	($7.0)	($59.3)	$146.3

As shown in the subsequent exhibit, each scenario would result in a decrease of total government payment and more of the total government payment would be made up of the risk-adjusted direct subsidy when compared to the Status Quo Scenario.

Exhibit 9 – Estimated Direct Subsidy and Federal Reinsurance Payments PMPM from CMS under Status Quo vs Proposed Restructuring under Scenarios 1 (50% / 30% / 15% / 5%)

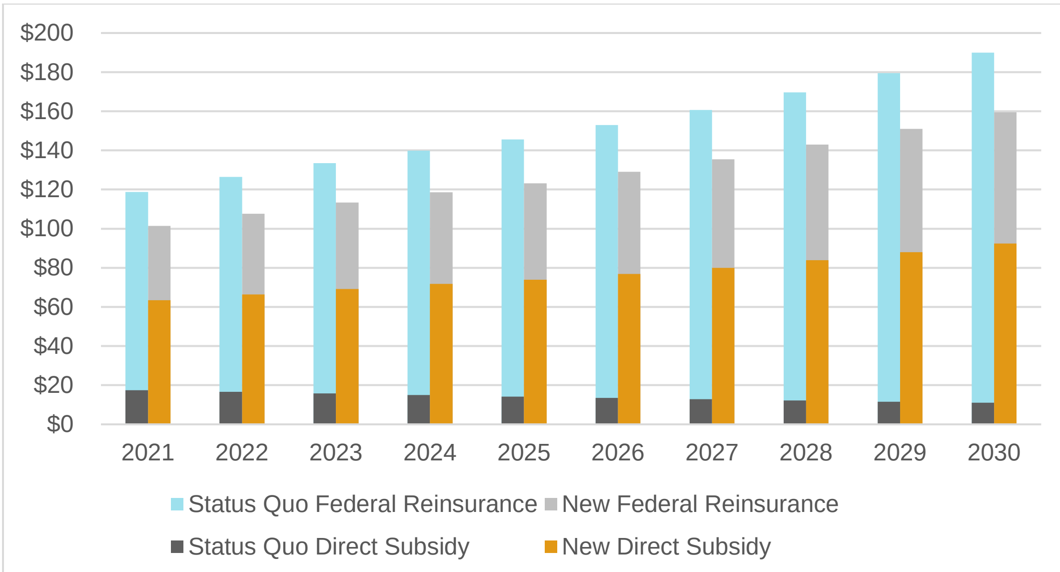


Exhibit 10 – Estimated Direct Subsidy and Federal Reinsurance Payments PMPM from CMS under Status Quo vs Proposed Restructuring under Scenario 2 (50% / 30% / 20% / 0%)

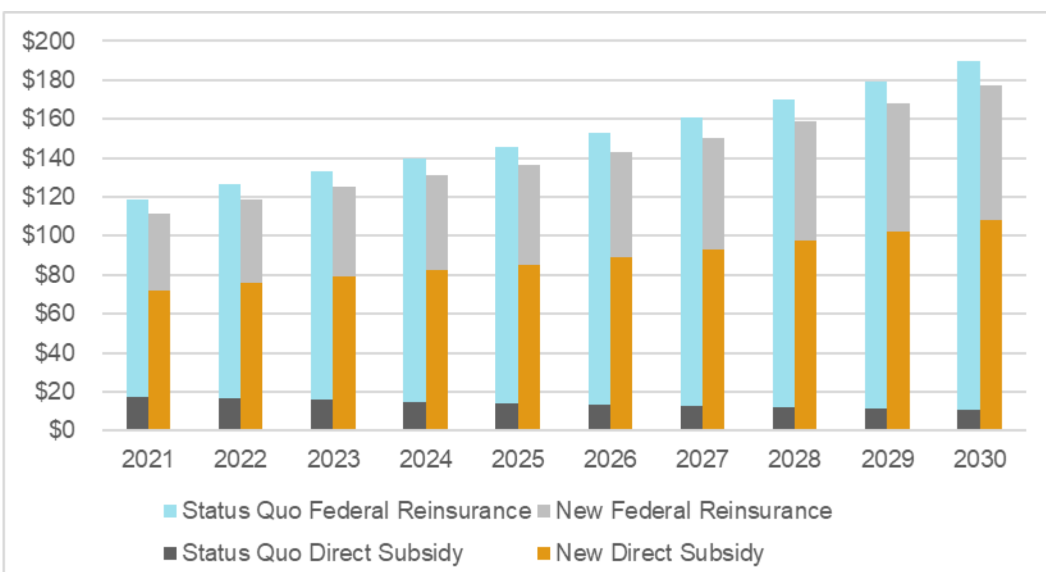


Exhibit 11 – Estimated Direct Subsidy and Federal Reinsurance Payments PMPM from CMS under Status Quo vs Proposed Restructuring under Scenario 3 (31.7% / 31.7% / 31.7% / 5%)

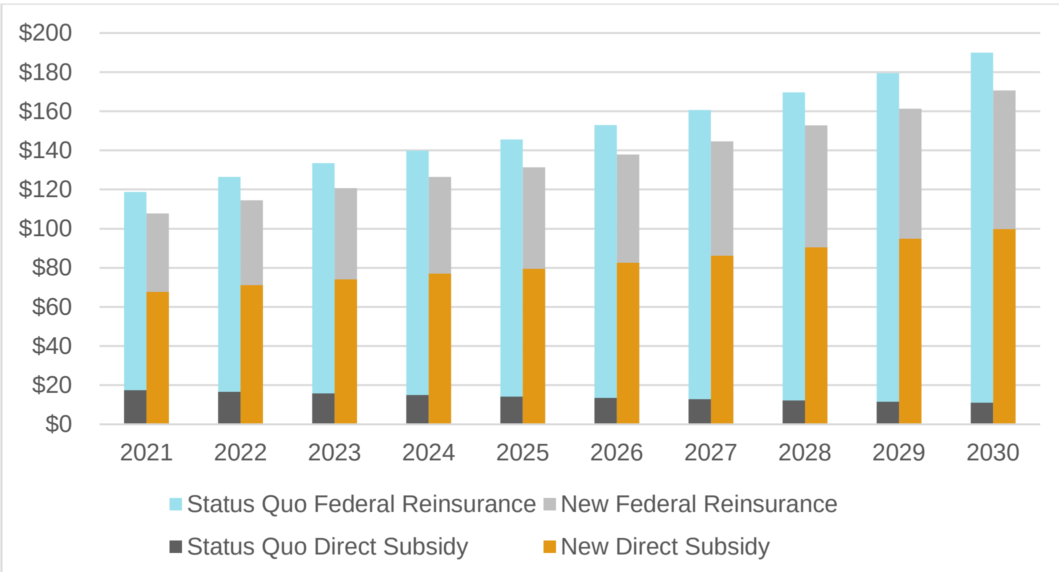
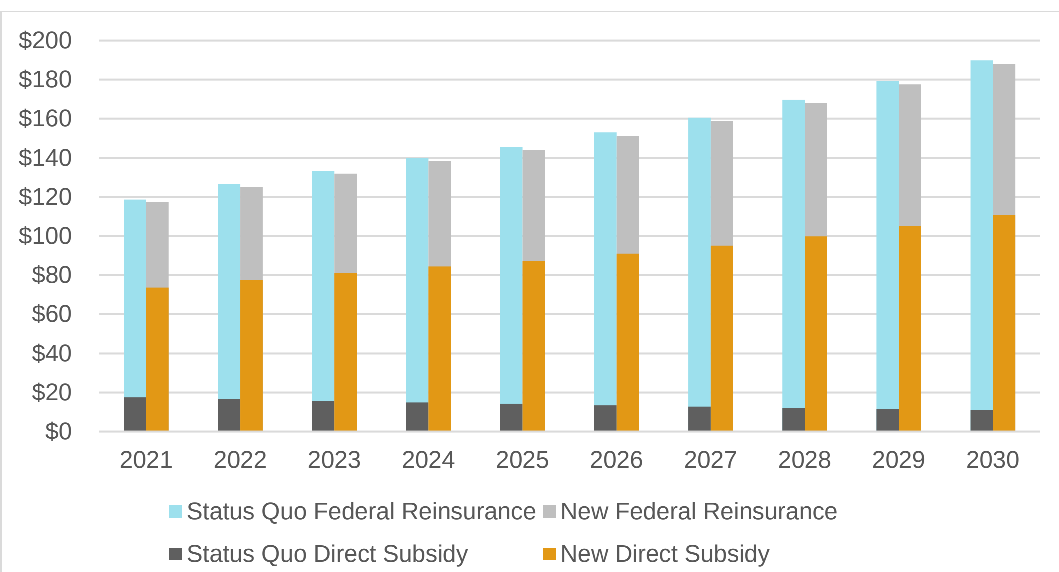


Exhibit 12 – Estimated Direct Subsidy and Federal Reinsurance Payments PMPM from CMS under Status Quo vs Proposed Restructuring under Scenario 4 (33.3% / 33.3% / 33.3% / 0%)



Additional Considerations

In the analysis, we have assumed that manufacturers make no additional changes to drug pricing (in excess of the inflation trend already assumed) in attempt to recover some of their increased liability in the catastrophic phase.

These results do not reflect an assumption that plans will respond to these policies with significant changes to formularies to offset the impacts of their increased liability in the catastrophic phase. We have also not assumed that plans will charge additional risk premiums as a result of their increased liability in the catastrophic phase.

We have not included any transitional period from the current 80% Federal Reinsurance to the proposed Federal Reinsurance amounts outlined in the paper. It is possible that CMS would implement this change over a number of years, similar to other major historical programmatic changes. In that case, our estimates for the net impact would be overstated.

In January 2019, the Department of Health and Human Services ("HHS") proposed that rebates after the point of sale will no longer be excluded under Federal anti-kickback statutes. This would have a meaningful impact on the CMS direct subsidy, federal reinsurance payments, and member cost sharing amounts estimated in this analysis. We have not included any adjustments for this rule, and the results presented in this paper would need to be revisited should this rule be finalized.

Lastly, as the CMS RxHCC model is calibrated based on health plan liability, it would require significant recalibration as a result of this proposal. The impact of this recalibration on revenue has not been considered as part of this analysis.

REPORT QUALIFICATIONS/ASSUMPTIONS AND LIMITING CONDITIONS

Oliver Wyman was commissioned by Campaign for Sustained Rx Pricing to analyze the impact of restructuring the CMS Federal Reinsurance program would have on members, health plans, and the federal government.

Oliver Wyman shall not have any liability to any third party in respect of this report or any actions taken or decisions made as a consequence of the results, advice or recommendations set forth herein.

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While this analysis complies with applicable Actuarial Standards of Practice, users of this analysis should recognize that our projections involve estimates of future events and are subject to economic and statistical variations from expected values.

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