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Potential IRA Interactions with Medicare Part D Risk Adjustment

Model Considerations

Commissioned by PhRMA

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The passage of the Inflation Reduction Act (IRA) marks one of the largest changes to Medicare Part D in the program's history. Key provisions in the IRA include[1]:

- A requirement for the HHS Secretary to negotiate maximum fair prices for single-source drugs in Medicare Part D (beginning in 2026) and Medicare Part B (beginning in 2028)
- Re-design of the Part D benefit, including a beneficiary maximum annual out-of-pocket cap of $2,000, replacement of the Coverage Gap Discount Program with the Manufacturer Discount Program, and significant shifts in claim liabilities between stakeholders (beginning fully in 2025, following removal of beneficiary catastrophic cost sharing in 2024)
- Beneficiary cost sharing for all covered insulins limited to a $35 per month supply and $0 beneficiary cost sharing for Part D vaccines (beginning in 2023)
- Manufacturer rebates paid to CMS if the price of a drug increases faster than inflation (beginning in 2023)

The re-design of the Part D benefit, in particular, significantly shifts responsibility for drug costs among beneficiaries, the federal government, pharmaceutical manufacturers, and plans. Notably, plan liability increases from 15% to 60% in the catastrophic phase, representing a 4-fold liability increase. The benefit re-design corresponds to a shift in two of the primary government funding mechanisms – federal reinsurance, which pays a portion of actual claim costs, and the direct subsidy, which is a risk-adjusted monthly payment to compensate plans for the average risk of their members. Under the IRA, federal reinsurance decreases, and the direct subsidy is expected to materially increase to compensate plans for their larger share of claims cost. The direct subsidy is used to reduce member premiums, so this increase in direct subsidy will be critically important to mitigating premium increases.

In order to appropriately distribute direct subsidy payments among plans, the Centers for Medicare and Medicaid Services (CMS) uses a Part D risk adjustment model (i.e., the RxHCC model) to estimate the relative risk score of each member, which is then used to adjust the monthly member-level Part D direct subsidy payments that plans receive. While CMS has acknowledged it plans to recalibrate the Part D risk adjustment model to account for the new plan liabilities,[2] at present, the new model is not available, and the details and timing of the recalibration are unknown. The change in the Part D benefit design, as well as other limitations of the RxHCC model, may lead to material disconnects between risk scores and expected plan liability if not appropriately accounted for. This disconnect could lead plans to adopt benefit designs or formularies that attract beneficiaries with conditions overpredicted by the RxHCC model (for which plans are generally compensated more than actual costs) and discourage enrollment of beneficiaries with conditions that tend to be underpredicted by the model. PhRMA engaged Milliman to analyze how the IRA changes to the Part D benefit may impact risk scores and highlight areas of importance for consideration when CMS updates the RxHCC model.

Risk Adjustment Model Overview

CMS uses the RxHCC model to predict plan liability for prescription drugs under the Part D program to adjust the direct subsidy payments made to each plan to reflect the relative risk of each plan's beneficiaries. The model assigns this beneficiary-level risk through a score based on medical diagnosis codes from the prior year and demographic information from the current year. The risk score then adjusts a plan's monthly member-level Part D direct subsidy payments, which are calculated as the plan's bid multiplied by the beneficiary's risk score, less the plan's basic member premium.

[1] https://www.milliman.com/-/media/milliman/pdfs/2022-articles/8-17-22_weathering-the-reform-storm.ashx
[2] CY 2024 Advance Notice and Rate Announcement, p. 69 https://www.cms.gov/files/document/2024-advance-notice-pdf.pdf

The 2023 RxHCC model is the most recent calibration,[3] which uses 2018 Medicare Fee-For-Service and MA encounter data for diagnoses and 2019 Prescription Drug Event expenditure data (i.e., using 2018 medical diagnoses to predict 2019 prescription drug costs). In other words, CMS determines 2023 direct subsidy payments using a model calibrated to claim experience from four to five years prior. While CMS accounts for cost trends, this lag does not capture other factors that may influence claim expenditures, such as new drug launches, patent expirations, or other market shifts between the calibration year and the payment year.

Analysis

While CMS' specific calibration methodology is not publicly known, CMS has historically made explicit adjustments to its calibration methodology to reflect material changes to the Part D program (such as the closing of the coverage gap). Given the materiality of the IRA's impact on plan liability, we expect CMS to make some adjustments to the RxHCC model. However, the timing and details of such updates are unknown at this time.

This paper discusses several elements for CMS to consider when updating the RxHCC model to reflect the IRA's provisions. To assess their importance, we examine how these elements could impact plan payments prior to CMS making a model adjustment. This discussion is intended to illustrate the materiality of the IRA's impact on plan costs and does not imply that we expect the current RxHCC model will be in place in 2025 without a material calibration.

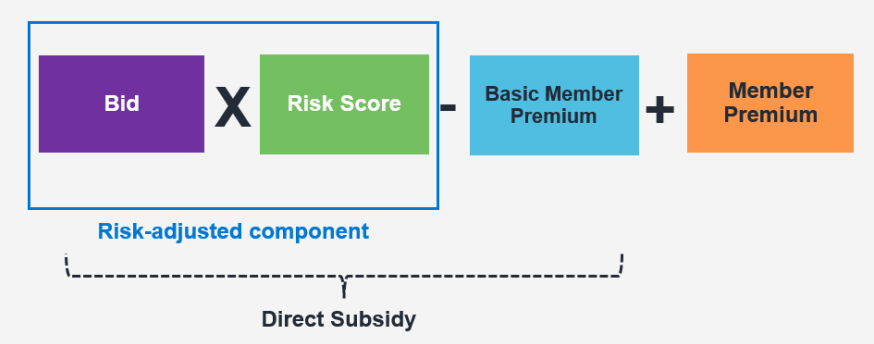
Receiving guidance on planned model updates with enough time to react is of critical importance to plans as they make strategic decisions for 2025 given the material impact of risk adjustment on plan revenue.

As with all risk scoring models, the current RxHCC model has certain limitations. The IRA benefit re-design represents a significant structural change to the Part D benefit and necessitates model adjustments to account for the new structure. However, even with an appropriate re-calibration, the model will still maintain many of its current limitations.

The Significance of the Direct Subsidy

In the Part D program, plan revenue is comprised of the following components:

Figure 1: Plan revenue calculation



Using 2019 and 2020 claims and risk score data for FFS and MA beneficiaries with Part D coverage from the CMS 100% Research Identifiable (RIF) dataset, we created a comparison of plan paid amounts[4] to risk scores to understand which conditions are over- or under- predicted under various scenarios. We compared the relativity of plan paid amount gross of rebates to the market to the relativity of risk score to the market ("paid-to-risk score ratio"). A ratio less than 1.0 indicates the RxHCC model over-predicts plan costs, while a ratio greater than 1.0 indicates an under-prediction of plan costs.

[3] 2023 Medicare Advantage and Part D Rate Announcement Fact Sheet | CMS

[4] Throughout this paper "plan paid" or "plan liability" refer to gross drug costs less beneficiary cost sharing, coverage gap discount payments (status quo) / manufacturer discount payments (IRA), federal reinsurance, and low income cost sharing subsidies. This amount is gross of manufacturer rebates unless explicitly noted. Costs are trended to 2025 and reflect actual benefit designs for status quo scenarios and are adjudicated under the IRA defined standard design for IRA scenarios.

Figure 2 displays an example of an over-predicted RxHCC:

Figure 2: Example plan-to-risk score ratio calculation

Component	Value	Annotation
RxHCC risk score relativity	2.25	*a*
Actual plan liability for beneficiaries with this RxHCC	$2,000	*b*
Average plan liability for the market (across all conditions)	$1,000	*c*
Relativity of actual plan liability to the market average	2.00	*d = b/c*
Paid-to-risk score ratio	**0.89**	***e = d/a***

In this hypothetical example, the actual plan liability for a beneficiary with this RxHCC is $2,000, compared to an assumed average liability of $1,000 for the market across all conditions. In other words, the plan's liability for a beneficiary with this RxHCC is 2.0 times higher than the market average. However, the risk score is 2.25 times higher than the market average, and therefore, greater than the ratio of actual plan liability to the market average, which results in a paid-to-risk score ratio of less than 1.0 (0.89). As noted above, a paid-to-risk score ratio below 1.0 indicates the RxHCC model over-predicts plan costs, such that the plan would be compensated more than necessary to cover actual claim costs.

Please note, this analysis focuses on a comparison between relative risk scores and relative costs before and after the IRA and not on total plan compensation. Because we anticipate the direct subsidy to increase considerably, risk scores will become a significantly more material component in the plan revenue equation. **It is important to keep in mind that "over / under prediction" is not necessarily synonymous with plan "over / under compensation."**[5]

In the following sections, we assess the RxHCC model limitations and discuss implications for the plan and its beneficiaries.

Timing of Data Used to Calibrate the RxHCC Model

A significant data lag in the RxHCC model calibration leads to differences in risk model coefficients relative to expected plan costs. The RxHCC model does not effectively capture all major market events affecting plan liability (e.g., new drug launches, expanded indications, significant price changes, patent losses, and regulatory changes) that occur during the gap between calibration and application, which is typically a period of three or four years. This leads to a discrepancy between the data used to calibrate the model and projected costs in all years. This difference between the experience period and the projection period becomes more pronounced when there is a market event as significant as the IRA.

Based on past models, the 2025 payment year model will presumably be based on 2021 or 2022 expenditure data, which represents a significantly different benefit design than the one that will be in place in 2025 once the IRA's redesign policy changes are implemented. Assuming a three-year lag[6], a model calibrated using claims experience representing the full Part D redesign would not be incorporated into the model calibration until 2028. Similarly, a model capturing claims experience reflecting 2026 maximum fair prices (MFPs) would not be incorporated until 2029. Even if CMS re-adjudicates claims under a 2025 defined standard benefit design to calibrate the 2025 payment year model, this may not capture changes in utilization patterns or beneficiary behavior resulting from the significant changes to cost sharing under the IRA.

EXAMPLE

The IRA impacts plan economics for specialty drug patients in particular, as the majority of spend for these patients occurs in the catastrophic phase (where plans will see the largest increase in liability). This dynamic is shown in the example in Figure 3.

- Based on our analysis, under the current RxHCC model applied to 2020 claims data, the cost to the plan for the average patient with HIV / AIDS (RxHCC 1) is $799 per month, which is 5.83x greater than the market average plan liability (for all conditions). The beneficiary is assigned a relative risk score of 4.82, on average, resulting in a paid-to-risk score ratio of 1.21. That is to say, actual plan liability is 1.21x the predicted costs for this condition, meaning that the model underpredicts plan liability for beneficiaries with HIV / AIDS by 21 percent.

[5] For example, for a condition with a risk score relativity of 1.50 and a plan liability relativity of 2.00, we would say the condition is "underpredicted" because the risk score is less than the plan liability on a relative basis. However, if this condition has significant rebates, the plan liability relativity may decrease to 1.25, meaning that the plan actually receives more (1.50) than its liability (1.25). Rebates and the magnitude of the bid, basic member premium, and member premium impact ultimate plan compensation, outside of risk scores. Rebates, in particular, may materially reduce plan liability but are not accounted for in risk scores.
[6] The current model reflects a 4 year lag, which is atypical due to COVID-related legislation

- Under the IRA, plan liability significantly increases to $2,654 per month for beneficiaries with HIV / AIDS, or 9.33x the expected market average plan liability. Prior to RxHCC model changes, the paid-to-risk score ratio would increase to 1.94, suggesting the actual plan costs are almost twice the predicted costs.

With a model change, RxHCCs could more appropriately capture plan liability, leading to a paid-to-risk score ratio under the IRA that is similar to the status quo. Because of the interaction between the risk adjustment model and financial outcomes—no matter which form the model takes—plans must incorporate the expected cost / risk score relationship into their pricing strategies and decisions.

Figure 3: Paid-to-risk score ratios for a beneficiary with HIV / AIDS (RxHCC 1)

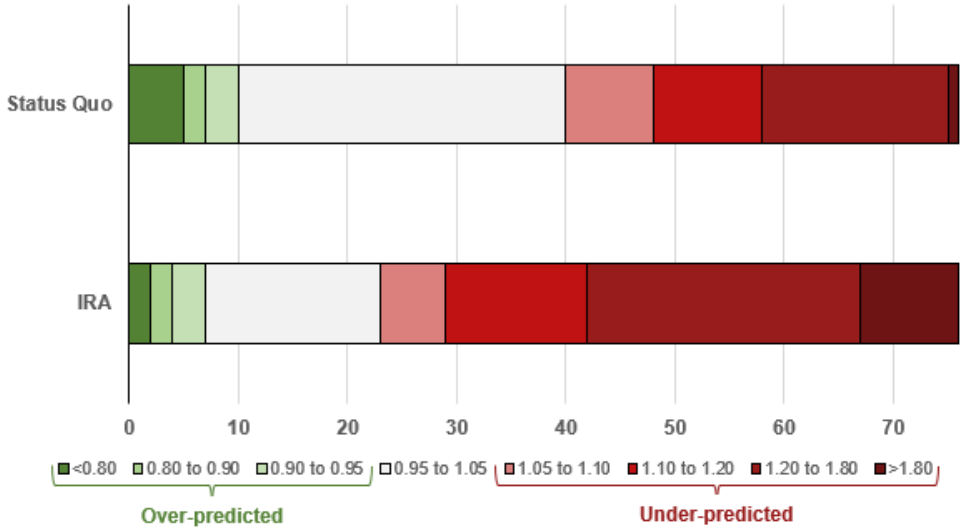
	Status Quo Adjudication Under Current Model	IRA Adjudication Under Current Model
Plan Paid – RxHCC 1 Beneficiary	$799	$2,654
Plan Paid – Market Average	$137	$284
Plan Paid Relativity	5.83	9.33
Risk Score – RxHCC 1 Beneficiary	5.03	5.03
Risk Score – Market Average	1.04	1.04
Risk Score Relativity	4.82	4.82
Paid-to-Risk Score Ratio	1.21	1.94

ANALYSIS

Based on our analysis of Medicare data, the current RxHCC model applied to 2020 claims data “accurately" predicts 30 conditions (out of 76), as measured by a paid-to-risk score ratio between 0.95 and 1.05. In other words, the relative risk scores for these conditions are within 5% of the actual relative plan liability.

Prior to model changes made to account for the changes in IRA policy and plan liability that take effect in 2025, the number of "accurately" predicted conditions drops to 16 (out of 76). The reduction in this scenario is the result of the IRA plan redesign placing increased liability on the plan without a corresponding increase in risk score to offset the change. We estimate 18 conditions are currently underpredicted by more than 20%, while 34 conditions (out of 76) would be underpredicted by more than 20% under the 2025 IRA benefit design prior to a model change. The underprediction is also estimated to occur to a greater degree under the IRA. While only one condition is currently underpredicted by more than 80%, 9 conditions would fall in that bucket under the IRA prior to a model change.

Figure 4: Distribution of RxHCCs by paid-to-risk score ratio for members with each RxHCC



Generally, over-predicted conditions are treated by generics or no drugs at all, so gross Part D spend is relatively low. Therefore, plan cost for beneficiaries with these conditions decreases relative to the higher market average plan cost. Under-predicted conditions are typically treated by high-cost specialty drugs, so gross Part D spend is relatively high. Further, the plan cost of these conditions drastically increases under the IRA due to the increased catastrophic plan liability. Note, risk scores are calculated at the beneficiary level so comorbidities and differences in demographics impact results.

Similarly, today, non-low income beneficiaries (i.e., beneficiaries not eligible for the Part D low income subsidy program) tend to be over-predicted while low income beneficiaries (i.e., beneficiaries eligible for the Part D low-income subsidy program) tend to be under-predicted. Under the IRA, the magnitude of over / under prediction increases. Non-low income beneficiaries tend to have ***lower*** costs than average, so their relativity ***decreases*** as the market average plan liability increases. Conversely, low income beneficiaries tend to have ***higher*** costs than average, so their relativity ***increases*** as the market average plan liability increases.

PLAN IMPLICATIONS

Prior to a recalibrated payment year 2025 RxHCC model, plans would be more significantly undercompensated for high-cost beneficiaries and overcompensated for low-cost beneficiaries until a model change is made.

Changes to risk score model coefficients, and therefore, the risk-adjusted direct subsidy payments, could meaningfully affect plan decisions, such as benefit design, formulary design, and even the business decisions about participation in the Medicare Part D market. In particular, plans may adjust benefits and formularies to avoid enrolling beneficiaries taking high-cost medications, as plans will not be able to offset the significant expected cost without a sufficient number of beneficiaries with lower costs. And, if plans cannot maintain some level of profitability, on average, they may consider leaving the Part D market.

PATIENT IMPLICATIONS

To the extent plans begin restricting formularies, beneficiaries reliant on specific medications may have limited plan options or may have to pay a higher premium for a richer (more enhanced) plan. The patients most likely impacted by any formulary reductions are those with conditions underpredicted by the RxHCC model and those taking non-protected or low rebate drugs. Under the IRA, 53 of 76 conditions would be underpredicted by the current RxHCC model, with 34 of those conditions underpredicted by more than 20% and nine conditions underpredicted by more than 80%. The conditions underpredicted by more than 80% include:

- HIV / AIDS (RxHCC 1)
- Multiple Myeloma and Other Neoplastic Disorders (RxHCC 16)
- Secondary Cancers of Bone, Lung, Brain, and Other Specified Sites; Liver Cancer (RxHCC 17)
- Immune Disorders (RxHCC 97)
- Multiple Sclerosis (RxHCC 160)
- Primary Pulmonary Hypertension (RxHCC 185)
- Cystic Fibrosis (RxHCC 225)
- Major Organ Transplant Status, Except Lung, Kidney, and Pancreas (RxHCC 396)
- Pancreas Transplant Status (RxHCC 397)

POTENTIAL MITIGATION STRATEGIES

Currently, CMS calibrates the RxHCC model by re-adjudicating claims under a payment year benefit and "using a multiple regression analysis of actual expenditures" to predict Part D plan liability.[7] Given the significant change in expected plan liability resulting from the IRA, we expect CMS will re-adjudicate to the new standard IRA benefit but could also consider adjusting its re-adjudication process to account for potential changes in beneficiary utilization. Given the materiality of the change in benefit design and importance of risk scores, CMS could consider releasing a preliminary model or early guidance on expected changes to allow plans to understand expected impacts while CMS finalizes model changes.

Assignment of Health Conditions

CMS may also consider other strategies for improving model accuracy, such as including drug claims for condition imputation and severity. The current RxHCC model uses medical diagnoses to predict Part D plan liabilities, which does not capture differences in costs for drugs treating the same condition, particularly when there is a wide range in costs of treatment options. Incorporating drug claims in the RxHCC model would allow for the imputation of missing diagnoses, as well as an indication of condition severity that can be reflected in the model's coefficients, similar to the HHS-HCC risk adjustment model in the Affordable Care Act (ACA) Exchange market. In particular, incorporating drug claims could improve the model's predictive accuracy for conditions that may be treated with a wide array of therapies, ranging from low cost generics to high-cost specialty medications, resulting in heterogeneity in spending within the RxHCC. In such

[7] https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c07.pdf

instances, patients who are treated with high-cost medications will likely drive higher plan liabilities than patients not treated with the high-cost medications, all else equal. But both patient cohorts receive the same coefficient in today's RxHCC model. Using pharmacy utilization data would allow for the identification of high-cost medication patients and adjustment of their assigned model coefficients to reflect the plan liability more accurately.

Additionally, some beneficiaries may not have a medical diagnosis that aligns with their drug spend, and the RxHCC model will not recognize a condition for them. This dynamic incents plans to ensure proper medical coding, but that may not be feasible in all cases—particularly for PDPs that do not have access to their beneficiaries' medical information. There are also other instances where a beneficiary may have significant drug spend to treat a condition but will lack an associated medical diagnosis, such as:

- The beneficiary has a well-managed condition and has not visited a doctor in the calendar year but continues to take maintenance medication. Examples may include beneficiaries with asthma, migraine headaches, or hypertension
- The provider miscoded or did not code the beneficiary's diagnosis.

The assignment of RxHCCs does not consider which drugs, if any, the beneficiary is taking in the diagnosis year, as risk score assignment is based on medical diagnoses. As such, RxHCC coefficients reflect the average Part D plan liability across all spend for beneficiaries with the given condition.

EXAMPLE

To illustrate this dynamic, Figure 5 below displays differences in risk scores and plan liability for beneficiaries with a chronic pancreatitis diagnosis either using a pancreatitis drug[8] or not. Since the RxHCC model assigns risk scores from medical diagnoses, both groups of beneficiaries have very similar risk scores. However, the non-drug users have 3.5 times lower plan costs than the drug users.

Figure 5: Average Risk Score and Cost for Members with Chronic Pancreatitis (RxHCC 65)

	Risk Score[1]	Plan Liability
Pancreatitis Drug User	2.11	$1,840
Non-Drug User[2]	1.98	$530

[1]Risk scores are calculated at the beneficiary level and reflect all of the beneficiary's conditions leading to slight differences between drug users and non-drug users.
[2]These patients do not use drugs indicated for chronic pancreatitis but may use unrelated drugs.

ANALYSIS

We modeled paid-to-risk score ratios separately for different types of drug users within each RxHCC under an IRA benefit design. As an example, looking at ratios separately for generic, brand, and non-drug users under the IRA, brand users are underpredicted more often and to a greater degree than lower-cost users. We separate generic and brand users as a proxy of the cost variation for a given condition, although some conditions may have significant cost variation even amongst brand drugs.

For many conditions, the vast majority of beneficiaries have lower spend and a small number of beneficiaries have higher spend. The coefficient is an average and, therefore, largely reflects the costs of the lower spend patients. The lower spend patients are slightly overpredicted while the small number of high spend patients are significantly underpredicted.

One notable exception is cystic fibrosis (RxHCC 225). Beneficiaries with this condition are split roughly evenly between patients taking cystic fibrosis drugs[9] (generally higher cost patients) and those taking only unrelated drugs (generally lower cost patients). Note, all cystic fibrosis drug use in the data was from branded products. As a result, the risk score falls roughly halfway between the relative cost for these two groups.

- In aggregate, our analysis found the average plan liability for beneficiaries with RxHCC 225 was approximately $14,000 per month, and the average risk score was around 5.0.
- We found the average plan liability for cystic fibrosis drug users with RxHCC 225 was approximately $34,000 per month, while these beneficiaries had a risk score around 6.0.

[8] We identified pancreatitis drug users as beneficiaries with at least one script for a drug related to pancreatitis in 2020, based on a clinician-developed mapping to assign drugs to RxHCCs.
[9] We identified cystic fibrosis drug users as beneficiaries with at least one script for a drug related to cystic fibrosis in 2020, based on a mapping we developed using clinical judgement to assign drugs to RxHCCs.

- On the other hand, the average plan liability for non-cystic fibrosis drug users with RxHCC 225 was approximately $800 per month, while these beneficiaries had a risk score around 4.0.
- While the risk score for beneficiaries using generics was 33% lower, plan liability for these beneficiaries was over 97% lower.

This example highlights how lower cost beneficiaries can be significantly overpredicted while higher cost beneficiaries can be significantly underpredicted, since the current RxHCC model does not account for differing drug use within a condition.

PLAN IMPLICATIONS

Since risk scores do not consider specific drug utilization, risk scores are overpredicted for beneficiaries taking less expensive drugs and underpredicted for beneficiaries taking more costly drugs. Some conditions have an extremely wide range of treatment costs, even though lower cost drugs may not be interchangeable for all patient types. This dynamic may incent plans to avoid beneficiaries taking high cost drugs for conditions with a wide range of treatment options, particularly in classes with relatively low rebates on brand or specialty drugs.

PATIENT IMPLICATIONS

To the extent plans adjust formularies to favor low cost options in classes treated by products with a wide range of costs, beneficiaries reliant on specific medications may have limited plan options or may have to pay a higher premium for a richer plan. This would be most impactful for a condition like cystic fibrosis, as discussed above, given roughly half of cystic fibrosis patients are treated by cystic fibrosis drugs and the other half are not. For most other conditions treated by drugs with large variation in cost, such as Myasthenia Gravis, Inflammatory and Toxic Neuropathy, and Aplastic Anemia, a higher proportion of utilization comes from lower cost users.

POTENTIAL MITIGATION STRATEGIES

CMS may consider incorporating drug utilization to help identify conditions, similar to the methodology used in the HHS-HCC risk adjustment model in the ACA market. CMS may need to consider using a new enrollee adjustment for beneficiaries with medical-only coverage in the diagnosis year, but pharmacy coverage in the payment year.

Assumptions and Methodology

BENEFICIARY IDENTIFICATION AND DATA CONSIDERATIONS

We relied on the CMS 100% RIF dataset, which includes all Medicare Parts A, B, and D paid claims and Medicare Part C encounter data for Medicare beneficiaries. We included beneficiaries meeting one of the following criteria:

- Continuous non-Medicare Advantage enrollment in Part A and B in 2019 and 2020, and continuous enrollment in Part D in 2020

  OR

- Continuous Medicare Advantage enrollment in Part C in 2019 and 2020, and continuous enrollment in Part D in 2020

We relied on a dataset that excluded employer group waiver plan (EGWP) data and beneficiaries with ESRD. These members represent approximately 12% of total Part D enrollment and could affect our results, but we do not expect the impact to be significant.

We did not assume any behavioral changes as a result of the IRA benefit redesign or price negotiations.

RISK SCORES

We calculated Part D risk scores by applying 2020 CMS RxHCC model and EDS filtering methodology to diagnosis year 2019 RIF claim data.

COST METRICS

We trended costs to 2025 using estimated industry trends. We based the “status quo” cost metrics on the current Part D benefit design, and we re-adjudicated claims under the 2025 IRA Part D benefit design to calculate the IRA cost.

Caveats and Limitations

This information was developed to help PhRMA understand how the Medicare Part D risk adjustment model may be impacted from the benefit redesign provisions in the IRA. This information may not be appropriate, and should not be used, for other purposes.

This report is intended for PhRMA. PhRMA may share this information with external parties with Milliman's prior written consent. We do not intend this information to benefit, and assume no duty or liability to, any third party that receives this work product. Any third-party recipient of this report that desires professional guidance should not rely upon Milliman's work product, but should engage qualified professionals for advice appropriate to its specific needs. Any releases of this report to a third party should be in its entirety.

We relied upon the 2019 and 2020 CMS 100% Research Identifiable datasets, as well as other publicly available information. We accepted these items without audit. To the extent the data and information is not accurate or is not complete, the values provided in this report may, likewise, be inaccurate or incomplete.

Milliman developed certain models to estimate the values included in this report. The intent of the models was to project plan liability and summarize risk scores assigned using the 2020 CMS RxHCC model. We reviewed the models, including the inputs, calculations, and outputs for consistency and reasonableness. We believe they are appropriate for intended purpose and in compliance with generally accepted actuarial principles and relevant actuarial standards of practice (ASOP).

Michelle Klein, Nikki Haddock, and Jason Petroske are actuaries for Milliman and members of the American Academy of Actuaries. They 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.

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