How current Part D risk scores could interact with point-of-sale rebates

Recalibration of RxHCCs for POS rebates could have disparate impacts on plan sponsors

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On November 20, 2020, the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) finalized a proposal to lower prescription drug costs by removing the safe harbor protection of drug manufacturer rebates under the Anti-Kickback Statute (AKS) and creating a new safe harbor for price reductions reflected at the point of sale (POS).

In practice, one of the effects of this rule would be to reduce the out-of-pocket costs for beneficiaries. While the rule is the subject of litigation and implementation has been delayed to January 2023, this rule as it currently stands would shift the financial responsibilities among the beneficiary, government, manufacturer, and health plan in their share of drug costs. Such changes in the Medicare Part D reimbursement landscape will impact Part D plans in many ways. In this paper, we focus on the implications of potential changes to the Part D risk score mechanisms.

When Part D started in 2006, the Centers for Medicare and Medicaid Services (CMS) implemented a risk adjustment program that adjusts each member's capitation rate to pay more for sicker beneficiaries and less for healthier ones using the RxHCC risk adjustment model.² The RxHCCs helped counter plan sponsors' incentive as insurers to prefer healthier

beneficiaries over sicker ones. The RxHCC model prospectively estimates the gross plan liability, before rebates, based on the beneficiaries' demographic, diagnostic, and other characteristics. Each year, each member's risk score is determined using a prior base year of claims. The RxHCC is formulaically determined by the diagnoses found in the member's medical claims. Each member's RxHCC is multiplied by the chosen Part D plan's standardized bid amount (at risk factor of 1.0) to arrive at the Part D plan payment for that member.

Because of changes in the use, price, and availability of drugs, from time to time CMS recalibrates or updates the RxHCC model using regression techniques. Changing Part D to POS rebates may impact the coefficients for RxHCC categories by varying degrees. Here we will examine the potential impact of POS rebates on the plan year 2019 RxHCC model³ by using the case of two disease states well-known to be associated with drug manufacturer rebates: diabetes and multiple sclerosis.

How RxHCC risk scores are developed today

Risk scores are designed to predict the plan liability (excluding federal reinsurance, manufacturer payments, and member cost sharing) of each beneficiary under defined standard benefits before rebates. Through regression analysis, CMS has developed the RxHCC model to reflect beneficiaries' age, sex, low-income status, disability status, and medical diagnoses using coefficients that reflect expected additional plan liability for each variable before rebates are applied.

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¹ Pharmaceutical Care Management Association v. U.S. Department of Health and Human Services, et al. (2021). Civil Action No.21-95. Retrieved February 18, 2021, from https://www.pcmanet.org/wp-content/uploads/2021/01/2021-01-30-D.E.-19-Order.pdf.

² CMS (July 31, 2018). Risk Adjustment. Retrieved February 18, 2021, from http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Risk-Adjustors.

³ Plan year 2019 used the 2018 RxHCC model.

In 2007, drug manufacturer rebates (commonly known as direct and indirect remuneration, or DIR⁴) were estimated to offset 20% of plan liability. In recent years, rebates have grown substantially and are estimated to offset 50% of gross plan liability (before rebates) or 28% of total drug costs in 2018.⁵ Therefore, rebates have a growing impact on net plan liability. Rebates vary widely among therapeutic classes, but within a therapeutic class they are often similar due to competitive pressures. Because CMS uses gross rather than net plan liability to calibrate the RxHCC model, the growth of rebates means that Part D risk scores less accurately reflect plan liability for beneficiaries with certain conditions for which heavily rebated drugs are frequently used.

Using gross plan liability to create the RxHCC model will generate a higher or lower gain for certain categories of patients. This is caused by a mismatch between risk-adjusted plan revenue and net expenses. The mismatch means that risk adjustment might not adequately compensate plans for adverse selection or adequately penalize plans for favorable selection, both of which can lead to market destabilization.

How current RxHCCs may lead to mismatches between plan revenue and plan liabilities

Today, a dollar of rebate is worth more to a plan than a dollar of discount. This is because, according to Part D program rules, a plan shares rebates with the federal government, but not directly with beneficiaries. However, a dollar of discount is shared among beneficiaries, the federal government, the manufacturer, and the health plan. Compared to the current rebate environment, POS rebates will likely increase plan liabilities if the plan sponsor does not make changes to how the Part D plan operates.

Because rebates vary across drugs and therapeutic classes, POS rebates will cause plans' liabilities to increase more for patients in certain condition categories than for others. Plan liability will increase more for condition categories that are often treated with highly rebated drugs.

To offset such changes, CMS may eventually recalibrate the RxHCC model and reflect changes in plan liability. This recalibration would mean RxHCC risk scores will better match the net plan liability for most condition categories. As of the publication of this paper, CMS has not recalibrated RxHCC risk score to reflect POS rebates for the 2022 plan year. It may take CMS several years to recalibrate the model using emerging prescription drug event (PDE) data with POS rebates. In the interim, CMS may apply approximate adjustments to final calculated risk scores.

A case study

To illustrate the variation in plan financial results by condition category due to POS rebates, we estimated 2019 revenue and claims for non-low-income subsidy (NLIS) Prescription Drug Program (PDP) patients with diabetes and multiple sclerosis, who use brand and generic drugs, under baseline and POS rebates scenarios—assuming no change in the risk scores. In the baseline scenario, the revenue reflects national benchmarks for plan year 2019 and the claims reflect the defined standard for plan year 2019. In the POS rebate scenario, national average bid amount (NABA) and average federal reinsurance have been adjusted based on estimated impact from the Federal Register due to 100% POS rebates combined with Part D plans exerting greater formulary control.⁷

For illustration, we selected beneficiaries with diabetes and multiple sclerosis who used brand and generic drugs, as they are disease categories with different drug costs and rebate patterns. Beneficiaries with diabetes often utilize medium-cost drugs with high rebates. Beneficiaries with multiple sclerosis often utilize high-cost drugs with lower rebates. The figures we use should be regarded as illustrative.

⁴ Bell, D. & Margiott, T.A. (January 2018). Medicare Part D DIR: Direct and Indirect Remuneration Explained. Milliman White Paper. Retrieved February 18, 2021, from http://us.milliman.com/en/insight/medicare-part-d-dir-direct-and-indirect-remuneration-explained.

⁵ Suzuki, Shinobu (November 9, 2020). Effects of pharmaceutical manufacturer rebates on Part D's risk adjustment. MedPAC. Retrieved February 18, 2021, from http://medpac.gov/docs/default-source/meeting-materials/rebates-and-part-d-rxhcc-medpac-nov-2020.pdf?sfvrsn=0.

⁶ CMS (January 15, 2021). 2022 Medicare Advantage and Part D Rate Announcement Fact Sheet. Retrieved February 18, 2021, from http://www.cms.gov/newsroom/fact-sheets/2022-medicare-advantage-and-part-d-rate-announcement-fact-sheet.

⁷ HHS (November 30, 2020). Final Rule: 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. Federal Register. Retrieved February 18, 2021, from http://www.federalregister.gov/documents/2020/11/30/2020-25841/fraud-and-abuse-removal-of-safe-harbor-protection-for-rebates-involving-prescription-pharmaceuticals.

As shown in Figure 1, currently the RxHCC is calibrated using the \$266 per member per month (PMPM) gross plan liability for beneficiaries with diabetes, but the actual net liability is \$76 PMPM after rebates. Although the standardized bid amount (at risk factor of 1.0) accounts for total rebates for all Part D beneficiaries, this example illustrates that revenue and claims are not aligned by condition group. In this example, if the RxHCC model were recalibrated for POS, it would use \$207 PMPM as an input and produce closer alignment between revenue and claims.

Additionally, the plan margins of diabetic and multiple sclerosis patients have decreased under the POS rebates scenario because the plan retained rebates have decreased to zero, as shown in Figure 1. This results in higher plan liability in the POS rebates world.

Figure 1 shows the net plan liability impact for the NLIS PDP population. NLIS Medicare Advantage Part D (MAPD) plans tend to have higher risk scores, but lower claims and rebates, compared to NLIS PDP plans. As a result, the reductions in PDP plan margins are potentially more than if we had simulated an MAPD plan.

Health plans with significant LIS members may face even more volatility in financial results due to higher brand utilization in the LIS population compared to NLIS. Because the RxHCC model assigns different coefficients for LIS, NLIS, and institutional populations, the RxHCC recalibration for POS rebates may impact LIS coefficients more than the NLIS coefficients.

FIGURE 1: FINANCIAL RESULTS UNDER BASELINE AND POS REBATE SCENARIOS FOR TWO CONDITIONS

	Diabetes Brand Users		Multiple Sclerosis Brand Users	
	Baseline*	POS Rebates**	Baseline	POS Rebates**
2019 Parameters—CMS Provided or Estimated POS				
Direct Subsidy	\$18	\$44	\$18	\$44
National Average Bid Amount (NABA)	\$51	\$82	\$51	\$82
National Average Member Premium (NAMP)	\$33	\$38	\$33	\$38
Average Federal Reinsurance	\$79	\$65	\$79	\$65
019 Revenue PMPM				
Average Patient RxHCC Risk Score	1.275	1.275	3.373	3.373
Risk Adj. Direct Subsidy PMPM	\$32	\$67	\$140	\$238
Basic Member Premium	\$33	\$38	\$33	\$38
Total Revenue	\$65	\$104	\$173	\$275
019 Claims PMPM				
Total Allowed Claims***	\$791	\$791	\$6,131	\$6,131
POS Rebates	\$0	\$283	\$0	\$1,687
Plan Liability (Net of POS Rebates for POS Scenarios)†	\$266	\$207	\$1,060	\$819
Plan Retained Rebate	\$189	\$0	\$1,130	\$0
Net Plan Liability	\$76	\$207	(\$70)	\$819
019 Margins PMPM				
Plan Margins††	(\$11)	(\$103)	\$243	(\$544

Notes:

^{*} Baseline scenario reflects plan financials using 2019 RxHCC model and benchmarks under current rebate rules.

^{**} POS scenario reflects the plans' margins without RxHCC recalibration under POS rebate rules.

^{***} This includes beneficiaries' brand and generic drugs.

[†] After cost- sharing, manufacturer discounts, federal liability in catastrophic coverage, and POS rebates (for POS scenarios).

^{††} Plan margins equal total revenue minus net plan liability and does not account for pharmacy rebates and non-benefit expenses.

RxHCC model recalibration

CMS uses historical claims data to develop the RxHCC model. CMS finalized a new RxHCC model for plan year 2022 in the 2022 Rate Announcement and it did not reflect POS rebates.⁸ Historically, CMS used data with a lag of four to five years to update RxHCCs. It will be several years before CMS will be able to use data generated under POS rebates to recalibrate the RxHCCs, so CMS may use a modeling approach instead.

A recalibrated risk score model could include changes to the structure of the RxHCCs, adding or deleting RxHCC categories as well as changing the RxHCC coefficients. The resulting coefficients for conditions often treated with highly rebated drugs may show significant decreases compared to those for conditions mostly treated with generics. We note that RxHCC coefficients for conditions with no or low rebates may increase to offset decreases in other coefficients, assuming the RxHCC model would be recalibrated to a 1.0 risk score. Plans should consider how the CMS recalibration process may introduce uncertainty into their financial results.

Methodology and data sources

We identified NLIS beneficiaries taking type 2 diabetes or multiple sclerosis (MS) drugs from Milliman's 2019 Prescription Drug Consolidated Database (PDCD) to model the impact of point-of-sale rebates on plan liability. To estimate plan revenue, we applied the 2019 national average monthly bid amount and

national average base beneficiary premium to the empirical risk scores. To estimate net plan liability, we applied the 2019 defined standard benefit design to these NLIS beneficiaries' claims assuming post-sale rebates (baseline) and point-of-sale rebates. We assumed 50%, 30%, and 20% of allowed rebates for diabetic, MS, and other brand drugs. Additionally, we assumed a 67% rebate plan retention ratio for the baseline scenario. The margin reflects the differential between the plan revenue and net plan liability.

Caveats and limitations

The findings reflect the research of the authors. Estimates in this report represent national averages. Differences between our projections and actual amounts depend on the extent to which future experience conforms to the assumptions made for this analysis. For any particular condition and Part D plan sponsor, results may vary substantially due to formulary design, rebate amounts, and benefit phase distribution of drug spend, among other factors. We note that the actual implementation and interpretation of the rule is subject to government action.

Bruce Pyenson and Amy Kwong are members of the American Academy of Actuaries and meet the qualification standards for performing the analyses in this report.



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⁸ CMS, 2022 Medicare Advantage and Part D Rate Announcement Fact Sheet, op cit.