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VIA Electronic Delivery to: www.regulations.gov

March 1, 2024

The Hon. Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: Docket CMS-2024-0006
Baltimore, MD 21244-8010

Re: Advance Notice of Methodological Changes for Calendar Year (CY) 2025 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies

Section III G. Part D Risk Adjustment Model (RxHCC), p. 91

CMS proposes updates to the RxHCC to reflect the impact of the new 2025 Part D benefit structure per the Inflation Reduction Act (IRA).

CMS proposed the following modifications to the risk adjustment model, which are likely to significantly impact plan payment adequacy under the IRA:[1]

- Update the model to reflect the new 2025 IRA benefit structure
- Apply separate normalization factors to MA Prescription Drug Plan (MA-PD) vs. standalone Prescription Drug Plan (PDP) risk scores
- Remove 95 diagnosis codes
- Update data years to reflect 2021 diagnoses and 2022 expenditures, which would reflect the most recent year of complete spending data available.

BIO Comment: BIO agrees that the risk adjustment changes CMS is proposing to account for IRA benefit changes will improve Part D payment accuracy and hopefully assure access to needed medicines,. Given increased plan liability under the IRA, particularly in the catastrophic phase and for low-income subsidy (LIS) enrollees, the accuracy of the risk adjustment model will become even more critical for plan payments.[2] We encourage the agency to be as accurate as it can with risk-based plan payment so that plans have appropriate incentives to enroll all beneficiaries and cover needed medications. Given increased pressure on standalone PDP bids in particular under the IRA, we urge the agency to finalize its proposal to apply separate normalization factors to PDPs vs. MA-PDs.

[1] Avalere, "Proposed Revisions to Part D Risk Adjustment Model in 2025," February 5, 2024. https://avalere.com/insights/proposed-revisions-to-part-d-risk-adjustment-model-in-2025
[2] Ibid.

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Adjusting RX-HCC Model for IRA Part D Redesign

CMS's proposal in the CY 2025 Advance Notice is to update the Part D risk adjustment model to reflect the expected increase in plan liability associated with the IRA and other changes to the Part D standard benefit.

> **BIO Comment**: BIO believes it is necessary to, as CMS is proposing, update the Part D risk adjustment model to reflect the redesign of the Part D benefit as required by the IRA, including the increase in plan liability given the $2,000 cap on annual out-of-pocket spending for CY 2025 and the new Manufacturer Discount Program. We believe these updates to the Part D risk adjustment model are essential for plan sponsors to develop accurate bids for CY 2025 and to keep the Part D benefit working for its enrollees. Especially given that a larger portion of plan payment will be subject to risk adjustment, it is even more critical to pay plans accurately to reflect their enrolled populations.[3]
>
> We also support the adjustments to the RxHCC model to reflect Part D plans' additional financial liability during the phase-in period for specified manufacturer and specified small manufacturer drugs. As expressed in our November 8, 2023 letter, we are concerned that the increased costs on Part D plans during the phase-in period will create perverse incentives for plans to restrict access to the very medicines that Congress intended to protect. While we commend CMS for recalibrating the RxHCC model to reflect the phase-in, it is not clear that this recalibration will fully cover plans' increased costs. Therefore, we continue to urge CMS to carefully scrutinize discrimination against drugs subject to the phase-in during the annual formulary review process. We believe is important that CMS take steps to ensure that these small biotech protections are implemented as Congress intended.

Different Risk Score Normalization Factors for PDPs vs. MA-PDs

CMS has proposed to apply separate normalization factors for PDPs and MA-PDs ; previously, CMS has used a single normalization factor for both populations. CMS believes that, given the growing divergence in risk scores between fee-for-service (FFS) and MA populations and higher plan liability under the IRA, the separate normalization factor will lessen increased pressure on PDP bids relative to MA-PD bids under the IRA and will more accurately predict payments for these different plan types.

> **BIO Comment**: BIO supports the Agency's proposal to calculate separate normalization factors for MA-PDs and PDPs. Recent years have seen a growing divide in the Part D plan market between standalone PDPs, where the number of plans has generally been

[3] Medicare Payment Advisory Commission, "Realigning Incentives in Medicare Part D," June 2020. https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun20_ch5_reporttocongress_sec.pdf

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trending downward over time in conjunction with a reduction in PDP enrollment, and MA-PDs, where plan availability and enrollment have experienced steady growth. MA-PD sponsors can use rebate dollars from Medicare payments to lower or eliminate their Part D premiums, so the average premium for drug coverage in MA-PDs is heavily weighted by zero-premium plans.

In 2024, the average monthly PDP premium is substantially higher than the enrollment-weighted average monthly portion of the premium for drug coverage in MA-PDs ($40 vs. $10), according to KFF.[4] This premium imbalance between PDPs and MA-PDs could be exacerbated as plans assume greater liability for costs above the catastrophic threshold in 2024 and 2025. The increasing availability of low or zero-premium MA-PDs, while PDPs charge substantially higher premiums, could tilt enrollment even more towards MA plans in the future and undermine choices for patients who prefer original Medicare.

And while provisions in the IRA to make the Part D benefit more generous will help enrollees, especially those with high drug spending, the benefit design changes could also make it harder for some plan sponsors to continue to offer competitively priced coverage, particularly sponsors of standalone drug plans.

Given the upwards pressure on PDP bids and higher plan liability for LIS beneficiaries under the new benefit structure relative to today, BIO is particularly concerned that plans will have less incentive to offer LIS benchmark plans or to provide appropriate coverage for medications commonly used by these enrollees. While MA-PDs cannot be LIS benchmark plans, MA-PD bids are included in CMS's calculation of the LIS benchmark by statute. Lower MA-PD bids relative to PDPs depresses the LIS benchmark premium, making it more difficult for PDPs to achieve benchmark status.[5] This dynamic can already be seen in 2024, even before the most substantial IRA benefit design changes have gone into effect. The number of LIS benchmark plans has decreased by 34%, from 191 plans in 2023 to 126 plans in 2024. Furthermore, in 18 states there are 3 or fewer LIS benchmark plan options in 2024.[6] This reduction in LIS benchmark plan options may force LIS beneficiaries switch to a plan that may not cover all of their needed medications or to enroll in a non-benchmark plan and pay a premium they cannot afford.

Understanding how well Part D continues to meet the needs of people with Medicare as the various provisions of the IRA are implemented will be informed by ongoing analysis

[4] KFF, "**An Overview of the Medicare Part D Prescription Drug Benefit," Oct 17, 2023.** https://www.kff.org/medicare/fact-sheet/an-overview-of-the-medicare-part-d-prescription-drug-benefit/

[5] Avalere, "How May the IRA Shift Part D Market Dynamics," August 24, 2023. https://avalere.com/insights/how-may-the-ira-shift-part-d-market-dynamics

[6] Avalere, "Part D Premium Increases, Market Disruption Expected in 2024," October 11, 2023. https://avalere.com/insights/part-d-premium-increases-market-disruption-expected-in-2024

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of the Part D plan marketplace, formulary coverage, and costs for new and existing medications, and trends in Medicare beneficiaries' out-of-pocket drug spending. We therefore encourage the Agency to pay close attention to these phenomena, to ensure that the MA-PD and PDP markets do not cleave any further and that their parameters and populations begin to more resemble one another once again. We believe doing so will help ensure all Part D enrollees continue to receive access to the treatments they need.

While CMS's proposal to apply separate PDP and MA-PD normalization factors is a positive step in stabilizing the Part D market, we strongly encourage the agency to ensure that risk adjustment is as accurate as possible in predicting liability for PDPs and the LIS population. We also urge CMS to consider other tools at the Agency's disposal to help further stabilize the PDP and LIS benchmark plan markets in 2025 and beyond, such as considering changes to the de minimis policy. Additionally, given increased pressure on plans under the IRA, the Agency should closely monitor and take necessary steps to protect against formulary erosion that hinders beneficiary access to needed medicines.

Years of Data to Calibrate the Part D Risk Adjustment Model

CMS proposes to calibrate the 2025 Part D risk adjustment model based on 2021 diagnoses and 2022 expenditures. According to the Agency, the updated model being proposed uses the most recent available data for model calibration, which it believes best reflects what the patterns in drug spending will be in 2025. The Agency believes these data will more accurately predict costs relative to 2018-2019 data.

BIO Comment: BIO agrees with the Agency that the more recent data set should be used. Nevertheless, we encourage the Agency to always look for ways to improve Part D risk adjustment to continually improve accuracy of payment and ensure access for all Part D enrollees. To that end, we encourage the Agency to incorporate an assumption in the RxHCC model to account for likely increases in beneficiary utilization, especially of innovative and rare disease drugs from the newly instituted annual $2,000 OOP cap or to consider this for 2026 risk adjustment given there will be one year of data on utilization but only pre-IRA data would be available for the model update.

Additionally, today CMS uses diagnoses submitted for the prior year to identify a beneficiary's health status in the payment year. Thus, if a beneficiary is diagnosed with a high-cost condition in the payment year, that diagnosis is not reflected in the determination of the beneficiary's health status in the payment year. We therefore encourage the Agency to explore the use of diagnoses submitted in the payment year to determine a beneficiary's health status for payment purposes. BIO believes such an approach would better marry current beneficiary health status to payment in the long run.

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Conclusion

BIO appreciates the opportunity to provide feedback to CMS through the Advance Notice. We look forward to continuing to work with the Agency to ensure all Medicare Part D enrollees get the drugs and treatments they need. If you have and questions, please contact us at 202-962-9200.

Sincerely,

/s/
Crystal Kuntz
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/s/
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