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VIA ELECTRONIC SUBMISSION — PartDPolicy@cms.hhs.gov; PartDBenefits@cms.hhs.gov

RE: CY 2025 Part D Redesign

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to submit comments on the *Calendar Year (CY) 2025 Part D Redesign.*[1] PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. Since 2000, PhRMA member companies have invested more than $1.1 trillion in the search for new treatments and cures, including $102.3 billion in 2021 alone. Consistent with that mission, PhRMA companies are committed to the continued success of the Medicare Prescription Drug Benefit Program (Part D).

It has been nearly two decades since enactment of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA). In that time, Medicare Part D has brought medical advances and breakthroughs to more than 50 million seniors and disabled persons, even as it holds down program costs. Beneficiaries have received a constantly evolving array of medicines, greatly improving treatment across a range of illnesses. Even as treatments have expanded, improved, and become more personalized, Medicare Part D costs have remained steadily in line with original projections, with annual spending growth smaller than other parts of Medicare. Moreover, medicine usage has been found to reduce other health care spending.[2] Major policy changes to Part D were included as part of the Part D redesign provisions of the Inflation Reduction Act (IRA), including the creation of the maximum out-f-pocket (MOOP) cap ,and a maximum monthly cap on cost sharing (also referred to as smoothing). All of these changes require careful policy development and thoughtful implementation of key operational details.

[1] HPMS Email, "Solicitation for feedback on IRA Part D Redesign," 4.11.2023
[2] De Avila, J. L. M., D.O.; Zhang, J.X. (2021). Prevalence and Persistence of Cost-Related Medication Nonadherence Among Medicare Beneficiaries at High Risk of Hospitalization. In JAMA Network Open (Vol. 4, pp. e210498).

We appreciate the opportunity to submit feedback on calendar year (CY) 2025 Part D redesign and other associated policies, in response to the recent Health Plan Management System (HPMS) email solicitation. In this communication, CMS seeks "feedback from interested parties on several annual programmatic policies for CY 2025 and beyond. These areas include, but are not limited to, how CMS should: (1) define standalone Prescription Drug Plan (PDP) meaningful difference to ensure a substantial difference exists between basic and enhanced benefit plans offered by a parent organization in a PDP region; (2) set non-defined standard tiered cost-sharing thresholds; (3) define parameters for what constitutes an enhanced benefit plan under the Part D Redesign; and (4) modify formulary Tier Models."[3]

To that end, we are providing feedback on a number of policies associated with Part D Redesign, including but not limited to the four issues highlighted in the HPMS email. This feedback is described in the table of contents that follows.

[3]HPMS Email, "Solicitation for feedback on IRA Part D Redesign," 4.11.2023

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I. CY 2025 REDESIGN

In response to CMS' specific requests in the HPMS email solicitation, PhRMA offers the following feedback.

Meaningful Difference

The IRA makes several policy changes to the Medicare Part D program, which will make the framework of the program differ significantly from the design of the Part D program when it was first created. Specifically, the standard benefit design will be more generous in 2025 compared to current law as a result of the establishment of maximum out-of-pocket (MOOP) limits, the ability of beneficiaries to spread cost sharing throughout the plan year, and other policy changes included in the IRA such as instituting a copay cap for insulins and eliminating Part D cost sharing for adult vaccines recommended by the Advisory Committee on Immunization Practices. Therefore, CMS needs to reassess/reevaluate various elements of the Part D program, including how CMS should define meaningful differences between basic and enhanced benefit plans.

CMS currently requires that basic and enhanced plans offered by the same Part D sponsor in a service area represent "meaningful differences," with enhanced plans representing "meaningful increases in value" over the basic plan offering.[4] CMS uses the Out-of-Pocket Cost (OOPC) model to evaluate annual bid submissions for meaningful differences and Total Beneficiary Cost (TBC). The OOPC model calculates the total monthly OOP cost (including premiums and estimated cost sharing) for the average Medicare beneficiary over a calendar year.[5]

The OOPC model has several known shortcomings that we have raised with CMS several times in the past. These well-documented shortcomings of the current OOPC model have created unintended consequences, such as use of lagged data that places certain medications (i.e., older medicines with high utilization in the base data) at a disadvantage over others in basic PDP formularies due to the long lag time between the data used in the OOPC model and the time period for which it is applied, and not accounting for members shifting from non-covered to covered products.[6] Given the significant changes to Part D redesign that take effect in 2025, it is even more crucial for CMS to move away from a model that has demonstrated inadequacies over time with risks to beneficiary access to medicine. As a result of the overall benefit improvements in patient affordability through the addition of the MOOP, the current OOPC model may no longer be useful to evaluate differences between basic and enhanced

[4] CMS. Medicare Prescription Drug Benefit Manual - Chapter 5, p. 24. Available here.
[5] CMS. CY 2023 Out-of-Pocket Cost (OOPC) Model. Available here.
[6] Milliman, "Impact on Formulary Design from Medicare Part D Meaningful Difference Regulations," Prepared for PhRMA, November 2014. *This report has been shared with CMS previously.*

plans based on beneficiary out-of-pocket (OOP) spending. ***PhRMA urges CMS to develop an alternative framework for assessing meaningful differences between plan offerings*** that accounts for these IRA policy changes***.*** CMS should also provide an opportunity for stakeholders to have input on an alternative framework.

Furthermore, in developing a new model for testing meaningful difference, ***CMS should evaluate how enhanced benefit designs should be structured to protect and maintain a variety of coverage levels and options for beneficiaries.*** To that end, CMS could consider various options for what constitutes enhanced benefit design under Part D redesign, looking carefully at policy changes like lower beneficiary cost sharing (e.g., reduced deductibles or copays) and pursuing additional "meaningful difference" evaluations, such as patient access metrics in terms of the comprehensiveness of a formulary and requiring greater coverage across all therapeutic areas or innovative treatments; or maintaining current utilization management (UM) for all plans and requiring demonstrably less restrictive prior authorization and step therapy standards for enhanced plans. CMS could also review exclusions (i.e., add coverage of excluded drugs for enhanced plans). Having enhanced plan options would still be valuable to beneficiaries under benefit redesign. A broader and well-constructed framework could ensure beneficiaries have adequate access and choice.

Formulary Tiering and Cost-sharing Thresholds

Over time, Part D coverage has shifted towards increased formulary tiering, with a growing number of medicines subject to coinsurance instead of fixed copays. Today, the vast majority (91 percent) of PDPs use formularies with five coverage tiers, and nine percent have expanded to include a sixth tier.[7] While most Part D plans have historically only applied coinsurance to specialty tier drugs, in recent years plans have increasingly extended coinsurance to drugs on lower cost-sharing tiers. As evidence of this, today, 65 percent of all drugs covered by PDPs are covered on a coinsurance tier.[8] The increased use of complex, multi-tiered formularies and growing prevalence of coinsurance exposes patients to a disproportionately high share of the cost of their medicines and increases the complexity of the Part D benefit-design structure. The proliferation of tiers on Part D formularies has made it confusing and difficult for beneficiaries to understand their plan designs and predict their cost sharing, which could result in patients selecting plans that may not best meet their health needs.

Moreover, CMS included additional tier models for CY 2017 with a non-preferred drug tier option, which allowed plan sponsors to offer a "blended" non-preferred drug tier, consisting of both brand and generic drugs.[9] Typical coinsurance on the non-preferred drug tier is 40 percent but can be as high as 50 percent. PhRMA has had long-standing concerns about this blended non-preferred drug tier, as the blended tier masks actual cost-sharing levels. Allowing plans to include many lower-cost generic drugs on the blended tier results in a significantly lower

[7] Avalere. 2022 Medicare Part D formularies: an initial analysis. November 2021.

[8] *Ibid.*

[9] See p. 193 of the 2017 Draft Call Letter.

average cost sharing across the tier, while in fact many patients' actual out-of-pocket costs for medicines on nonpreferred tiers are considerably higher than the non-discriminatory $100 threshold—creating an access barrier for patients. In fact, an Avalere analysis across all 2020 Part D plans with coinsurance on the blended non-preferred tier showed brand medicines on this blended tier with excessive cost-sharing levels. Specifically, brand medicines had cost sharing that resulted in beneficiary OOP costs greater than $100 on the non-preferred tier 75 percent of the time, brand medicines placed on these tiers had cost sharing exceeding $500 on the non-preferred tier 16 percent of the time, and brand medicine cost sharing exceeded $1,000 on the non-preferred tier more than five percent of the time.[10]

Further, CMS must continue enforcing statutory non-discrimination requirements[11] in evaluating plan benefit design for all medicines, both brand and generic. These provisions are important today and will become even more so in the coming years as plan incentives shift dramatically. Continuing to allow plans to include large numbers of lower-cost generic drugs on the non-preferred drug tier (which pulls down the computed average cost sharing across all drugs), implicitly endorses, and in fact encourages, plans to skirt the benefit parameters put in place by CMS intended to ensure that plan benefit designs are not discriminatory against beneficiaries that need higher cost therapies. As CMS notes, the Agency "sets forth certain benefit parameters, which are based on updated data analysis…[and] CMS will only approve a bid submitted by a Part D sponsor if … tiered cost sharing for non-defined standard benefit designs [do] not exceed levels annually determined by CMS to be discriminatory."[12] Therefore, ***CMS should reconsider blended tiers and monitor whether cost-sharing amounts paid by beneficiaries taking brand medicines on this tier exceed the discriminatory threshold.*** Such a change is even more urgent given the substantial benefit design changes happening in the Part D program; CMS must protect beneficiaries from harmful benefit design trends that are resulting in unreasonably high cost sharing for beneficiaries who rely on these medicines.

As CMS evaluates current formulary tiers under IRA changes, we request that CMS allow plans to offer all-copay plan designs and still meet actuarial equivalence. CMS could also require that under such copay designs, beneficiaries never pay more than their plan – thus, copays could never exceed the Part D negotiated price net of manufacturer rebates or any other direct or indirect remuneration.

Further, all CMS formulary review processes for existing plan designs should remain in place—e.g., ensuring adequate, non-discriminatory coverage for drugs across classes and appropriate tier placement and utilization management. CMS should monitor formulary access (including coverage, cost sharing, and utilization management) for plans offering all-copay designs versus more typical cost sharing/tiering structures.

[10] Analysis by Avalere for PhRMA. February 2020

[11] Social Security Act § 1860D-11(e)(2)(D).

[12] See p. 186 of the 2017 Draft Call Letter.

Specialty Tier

For more than a decade PhRMA has expressed particular concern with the specialty tier and its impacts on Medicare beneficiaries' ability to afford needed medicines that happen to meet the specialty tier criteria, which is merely based on an out-of-pocket cost threshold and not on clinical best practice. Our concerns increased when CMS finalized a policy to allow Part D plans to offer a second, preferred specialty tier with no additional beneficiary protections.

A substantial body of academic research also shows that high cost sharing for specialty tier medicines can adversely impact beneficiary access and adherence to needed therapies.[13] For example, among patients with chronic myeloid leukemia (CML), high-cost sharing is associated with reduced and/or delayed initiation of treatment.

Moreover, the Part D specialty tier runs counter to Part D's non-discrimination requirements, which require that a plan's design does not "substantially discourage enrollment by certain Part D eligible individuals."[14] PhRMA has repeatedly noted that allowing plans to have a specialty tier that imposes very high and non-appealable cost sharing – as much as 33 percent -- on certain beneficiaries whose health conditions require access to higher cost medicines is inherently discriminatory.

The intentional plan design of inordinately higher cost sharing for beneficiaries with higher cost health care needs is also unique to the pharmacy benefit. While patients may pay more for a visit to a specialist as compared to a primary care physician, this differential is usually minimal.[15] Although high-cost services, such as hospitalizations, can result in a wide range of incurred costs,[16] we are not aware of plan benefit designs in which patients with more costly hospital stays are charged a dramatically higher "specialty tier" hospital coinsurance percentage. Indeed, such practices run counter to the core purpose of insurance.

We acknowledge the affordability gains cost-sharing smoothing and the new out-of-pocket limit in Part D offer to beneficiaries with the highest OOP medicine costs. Nevertheless, we note that high coinsurance on medicines, as currently permitted in the specialty tier, could continue to impede access to medically necessary drugs for some Part D beneficiaries.

Therefore, we recommend that CMS reconsider policies like the specialty tier, which increase costs and barriers to access for beneficiaries. If CMS continues to permit plan sponsors to use a specialty tier in Part D, CMS should make clear that plan decisions to assign a medicine to the specialty tier cannot be based solely on reaching a specified cost threshold. Decisions should

[13] https://www.kff.org/medicare/issue-brief/the-out-of-pocket-cost-burden-for-specialty-drugs-in-medicare-part-d-in-2019/

[14] Social Security Act § 1860D-11(e)(2)(D).

[15] For example, CY 2021 in-network service category cost sharing requirements for Medicare Advantage plans limit primary care physician cost sharing to $35 and physician specialist cost sharing to $50 for plans subject to the voluntary and mandatory MOOP. Centers for Medicare & Medicaid Services, Contract year 2021 Part C benefits review and evaluation. February 6, 2020.

[16] Agency for Healthcare Research and Quality, Statistical brief #164: expenses for hospital inpatient stays, 2004. March 2007. https://meps.ahrq.gov/data_files/publications/st164/stat164.shtml.

also be based on clinical criteria, such as widely accepted guidelines indicative of clinical best practice, or for certain therapeutic classes demonstrating that there are non-specialty tier alternatives suitable for most patients with the condition. Failing to consider clinical factors may place beneficiaries in a situation where they lack a non-specialty tier therapeutic alternative and are also unable to request a cost-sharing exception for the specialty tier product given CMS regulations.

LIS Benchmark Plans

Under IRA's Part D benefit redesign, plan liability is expected to increase across various therapeutic areas and beneficiary groups.[17] Plan liability will increase more for low-income subsidy (LIS) enrollees than for non-LIS enrollees, and the ability for plans to offset this increase in liability will vary. Specifically, Medicare Advantage Prescription Drug Plans (MA-PDs) can benefit from medical cost offsets. Additionally, higher performing MA-PDs can use quality-related rebate dollars to offset increases in liability to mitigate premium impacts.[18] Conversely, lower-performing PDPs do not have these flexibilities. With a higher proportion of LIS enrollees than MA-PDs, PDPs will likely face more significant liability increases. As such, MA-PDs are likely to have more financial flexibility than PDPs to absorb higher costs under benefit redesign, which could lead to lower bids for the basic portion of the Part D benefit for MA-PDs relative to PDPs.

Because both MA-PD and PDP bids are used to calculate the LIS benchmark (but only PDPs are designated as benchmark plans), lower MA-PD bids relative to PDP bids can drive down the LIS benchmark, making it more difficult for PDPs to qualify as LIS benchmark plans. PhRMA is concerned that benefit redesign could exacerbate this dynamic, resulting in a significant number of current LIS benchmark PDPs losing benchmark status and creating instability for LIS beneficiaries who are auto-assigned to remaining benchmark plans. LIS beneficiaries who are auto-assigned to benchmark plans may be enrolled in plans that do not cover their drug or to a plan that has new UM requirements. Additionally, if the LIS benchmark is sufficiently low relative to PDP bids, this could result in only one PDP per region qualifying as an LIS benchmark plan. This would leave LIS beneficiaries in benchmark plans with no option to select an alternative benchmark plan if the assigned benchmark plan in their region does not cover their drug. This is further exacerbated by the fact that LIS beneficiaries may lack sufficient resources or information to navigate these plan changes and ensure they have appropriate coverage.

Existing beneficiary protections, such as transition fill requirements and the exceptions and appeals process, likely do not go far enough to protect beneficiary access if LIS benchmark offerings are significantly reduced following Part D redesign. CMS should consider additional beneficiary protections for formulary coverage such as a strengthened "grandfathering" period

[17] Avalere Health. "Risk Adjustment Under Part D Benefit Redesign." Available here.

[18] Avalere Health. "IRA Question of the Week: How Will the Law Impact Plans and PBMs?" Available here.

for LIS beneficiaries to maintain coverage for their drugs if they are forced to switch plans. This "grandfathering" period could apply for the entirety of the new plan year, and be applicable in situations in which:

1. Beneficiaries are forced to switch plans because their current plan loses benchmark status;
2. The benchmark plan they are re-assigned to does not cover their drug(s) or has new utilization management requirements; and
3. There are limited or no alternative benchmark plan options in their region for beneficiaries to select.

CMS could also consider other options to create stability in benchmark offerings, such as raising the de minimis amount or rethinking the structure of the benchmark more broadly.

Additionally, as plan liability for LIS beneficiaries is expected to increase significantly under Part D redesign,[19] CMS should closely scrutinize LIS benchmark plan formularies to ensure that these plans are not restrictive in terms of coverage or utilization management. Specifically, PhRMA recommends that CMS compare and perform outlier tests for LIS benchmark plan formularies relative to all other basic plan formularies under Part D redesign. CMS should consider comparisons of formulary management within therapeutic areas, as opposed to across all drugs in aggregate, with a specific focus on therapeutic areas that historically have high utilization by LIS beneficiaries. CMS should ensure that top drugs currently used by LIS beneficiaries in the Part D program continue to have appropriate coverage and access in LIS benchmark plans under Part D redesign.

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As mentioned in our opening comments, PhRMA appreciates the opportunity to submit feedback to CMS on CY 2025 Part D Redesign, and other associated policies, including those not limited to the specific items referenced in the recent HPMS email solicitation. While the Agency did not seek specific comments in these areas, we note that the IRA makes several significant changes to the Part D program's benefit structure and coverage. In addition to imposing government price setting for selected medicines and changing stakeholder liability under redesign, the IRA also makes other significant benefit changes such as establishing a MOOP limit, enabling beneficiaries to spread cost sharing throughout the plan year, instituting a copay cap for insulins, and eliminating Part D cost sharing for adult vaccines recommended by the Advisory Committee on Immunization Practices.

In light of these significant changes to Part D, ***CMS needs to reassess/reevaluate the interrelation between various elements of the Part D program, including maintaining historic formulary protections, implementing the smoothing program, and undertaking significant***

[19] Avalere Health. "Risk Adjustment Under Part D Benefit Redesign." Available here

updates and recalibrations of the Part D risk adjustment model. Our concerns focus on guarding against potential unintended access challenges for beneficiaries that could accompany these significant policy changes, as well as the need for strong oversight and efficient operationalization of the changes in Part D.

To that end, we appreciate the opportunity to provide proactive comments in the areas that follow and would be happy to engage with you on any issues raised in this letter.

II. PART D FORMULARY PROTECTIONS

The IRA requires Part D plans to assume greater financial risk while maintaining the program's nondiscrimination rule and all patient protections. Therefore, CMS' IRA implementation process should have as a key goal coverage, access, and affordability that is as good as or better than what is in place today – rather than allowing beneficiary coverage, access, and affordability to be eroded by more restrictions in coverage.[20] It is important for CMS to clearly specify how it will enforce current protections as IRA's changes are implemented.

While the intent of the IRA was to provide Medicare beneficiaries with increased affordability and access to medicines, unintended consequences of the law may emerge as CMS makes policy decisions throughout the law's implementation. Furthermore, we note that the government price setting provisions will not only impact those drugs but also other competitors in the class. Thus, CMS should review and update its formulary review standards to ensure beneficiaries continue to have access to a broad range of therapies. The standards should reflect the significant changes to the Part D benefit both due to redesign and also government price setting.

Under the IRA's Part D redesign, starting in 2025, plan responsibility in the catastrophic phase will increase from 15 percent to 60 percent of costs, while the government reinsurance obligation during the catastrophic phase will drop from 80 percent to 20 percent. This means that more of the Part D plan sponsors' expected costs must be anticipated in their annual Part D plan bids (which are reimbursed by the government as part of the Part D direct subsidy), and less will be recouped from the government after the fact through reinsurance payments. Additionally, the IRA Part D redesign will cap annual beneficiary out-of-pocket costs at $2,000 in 2025. While this is a long-needed improvement in patient affordability, it means that Part D plans will experience increased exposure to financial risk for catastrophic coverage, which could create incentives for plans to restrict access to medicines, leading to prescription abandonment and treatment discontinuation, ultimately resulting in worse outcomes for patients. We offer several recommendations to address this below.

[20] CMS Fact Sheet. IRA Lowers Health Care Costs for Millions Americans. https://www.cms.gov/newsroom/fact-sheets/inflation-reduction-act-lowers-health-care-costs-millions-americans

As implementation of the IRA moves forward, CMS should be on guard for the narrowing of formularies in Part D, which would be to the detriment of the nearly 50 million seniors and other individuals who rely on the program for access to medicines.[21] It is crucial that CMS and Part D plans educate seniors on the multitude of changes to Part D, including the implementation of the drug pricing provisions and other benefit changes, so that seniors understand potential trade-offs between lower premiums and limited access to more innovative treatments. This could be accomplished, for example, through a simpler, transparent scoring system highlighting variances between plans that include access to the latest biopharmaceutical innovations and those that do not.

Protect and Maintain Current Part D Coverage Standards

Since the beginning of the Part D program's implementation, there has been a recognized need for policies ensuring appropriate access to medicines. Due to concerns that some plans might otherwise design their formularies in ways that discriminate against certain beneficiaries, Medicare Part D plans are required to cover "all or substantially all" medications within six classes and categories that are of clinical concern (commonly known as the "protected classes"), which includes anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, immunosuppressants.[22] Plan formularies must also include drug classes covering all disease states, and a minimum of two chemically distinct drugs in each class.[23] Part D formularies must include drugs most used by Medicare beneficiaries (which CMS identifies using prior years' data on drugs and drug classes with the highest utilization in Part D) and must ensure that beneficiaries have access to a range of medically appropriate drugs to treat all disease states to ensure the formulary design does not discriminate or discourage enrollment by certain groups.

We continue to believe that the protected class policy offers valuable protections for vulnerable patients, particularly when the Part D program will be undergoing unprecedented changes due to enactment of the IRA. The six protected class policy has been integral to the Part D program's success, assuring broad formulary access for many of the nation's most vulnerable seniors and people with disabilities. Access to a broad range of treatment options and choice of medicines is important to Medicare beneficiaries. There is no one-size-fits all approach to treatment – each person is unique with genetic and molecular variations that may affect response to any particular therapy. Further, the statutory requirement that Part D plans cover "drugs" (thus, at least two drugs) in each class is a basic yet fundamental protection that ensures Medicare beneficiaries, who are more likely to be affected by multiple chronic conditions, have a broad range of therapies. According to a 2022 analysis by the CBO, per

[21] Kaiser Family Foundation. An Overview of the Medicare Part D Prescription Drug Benefit. 0ct. 19 2022. https://www.kff.org/medicare/fact-sheet/an-overview-of-the-medicare-part-d-prescription-drug-benefit/

[22] Centers for Medicare & Medicaid Services, Medicare Prescription Drug Benefit Manual Chapter 6—Part D Drugs and Formulary Requirements, Section 30.2.5 (2016) (emphasis added).

[23] Centers for Medicare & Medicaid Services, Medicare Prescription Drug Benefit Manual Chapter 6—Part D Drugs and Formulary Requirements, Section 30.2.1 (2016).

enrollee use of prescription medicines increased in Medicare Part D from an average of 48 prescriptions per year in 2009 to 54 in 2018,[24] a trend that will likely continue. PhRMA has long maintained that these formulary protection standards are important to protect Medicare beneficiaries, and we underscore the need for CMS to ensure that these beneficiary protections are maintained and strengthened under IRA changes. ***PhRMA recommends CMS should increase transparency of the Agency's formulary review processes and report on CMS' oversight and outcomes of the formulary reviews outlined in the Part D Benefits Manual to protect against discriminatory benefit designs that prevent access to new innovative medicines.[25]***

Robust Oversight of Beneficiary OOP Exposure

The increase in Part D plan responsibility for managing the catastrophic phase of the benefit may motivate plans to be even more aggressive when managing their formularies. Part D plans may expand upon current trends toward more formulary tiers and increasing the number of drugs subject to maximum coinsurance requirements, continuing to stratify their formularies and increasing the number of drugs placed on non-preferred and specialty tiers.

According to MedPAC's 2019 Report to Congress, in 2019 most Part D beneficiaries were enrolled in plans that utilized a five-tier formulary including a specialty tier for high-cost drugs, and the use of coinsurance was widespread.[26] Additional formulary tiers can result in access burdens for patients, as Part D plan sponsors typically impose up to 33 percent coinsurance for medicines on the specialty tier, and coinsurance for non-preferred tier medicines can be as high as 40 to 50 percent.[27] The trend towards increased use of complex, multi-tiered formularies and growing prevalence of coinsurance expose patients to a disproportionately high share of the cost of their medicines. Today, 65 percent of all drugs covered by PDPs are covered on a coinsurance tier.[28] Meanwhile, the share of brand medicines covered on a plan's preferred drug tier continues to decrease. In 2023, about one-quarter (26 percent) of brand medicines covered by PDPs are placed on the preferred brand tier, while 24 percent and 49 percent are placed on the non-preferred and specialty tiers, respectively".[29] Relative to the fixed-dollar copays commonly applied to medicines on the preferred drug tier, the increased use of coinsurance-based non-preferred and specialty tiers results in higher and less predictable cost

[24] January 2022 CBO Report "Prescription Drugs: Spending, Use, and Prices" accessed at https://www.cbo.gov/publication/57772#:~:text=Use%20of%20prescription%20drugs%20among,year%E2%80%94a%2013%20percent%20increase.

[25] Avalere Health. 2022 Medicare Part D Formularies: An Initial Analysis. November 2021.

[26] MedPAC. (March 2019). Report to the Congress: Medicare Payment Policy. Chapter 14. Available at: https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/mar19_medpac_entirereport_sec_rev.pdf

[27] MedPAC. (2022). July 2022 Data Book: Health Care Spending and the Medicare Program. Data Book Chart 10-15, p. 27-28. Available at: https://www.medpac.gov/document/july-2022-data-book-health-care-spending-and-the-medicare-program/.

[28] Cubanski J, Damico A, Neuman T. (May 2018). Medicare Part D in 2018: The Latest on Enrollment, Premiums and Cost-Sharing. Kaiser Family Foundation

[29] Unpublished Avalere Health analysis of 2023 Part D formularies.

sharing for beneficiaries who rely on brand medicines. Thus, ***PhRMA specifically recommends that CMS pay close attention to plans' tiering decisions, cost-sharing levels, and patient out-of-pocket exposure*** for both brand and generic medicines.

Further, PhRMA also would like to note our concerns that government price setting, layered on top of the significant changes in stakeholder liability from Part D redesign, will have significant impacts on the structure of Part D and could negatively impact patient access to medicines. Indeed, we believe that price setting will put the very nature of Part D's competitive system at risk. The price setting in the IRA will have impacts far beyond the drugs selected for initial price applicability year (IPAY) 2026, extending to other therapeutic competitors in the class.

To illustrate these concerns, new research from the Hayden Consulting Group suggests that it might be more difficult for non-selected drugs to be placed on preferred formulary tiers without accompanying significant levels of rebating. There is a danger this could lead to a general narrowing of Part D formularies, shrinking to those selected drugs with mandatory coverage. To the extent that CMS sets MFPs for selected drugs well below the ceiling price, these potential formulary dynamics could intensify further. To that end***, PhRMA recommends that CMS' process for arriving at a final MFP for selected medicines should seek to minimize effects within therapeutic classes that would result in narrower formularies and fewer choices for patients***. CMS should also be mindful and seek to limit the risk of perverse incentives that are more likely to result from MFPs set at levels well below the ceiling price. CMS should create sufficient safeguards to ensure that there is diversity across plan formularies to offer beneficiaries plan options that continue to meet their individual therapeutic needs. In practice, this calls for plan formularies that include both selected drugs and medicines that aren't subject to government price controls.

Additionally, given the potential for significant disruption stemming from government price setting layered on top of Part D redesign, ***PhRMA recommends that CMS examine trends in plan formularies pre- and post-IRA including the number of generic and brand drugs covered in each category/class, changes in formulary tiering, and utilization management for different classes of drugs.*** CMS should also examine coverage of selected versus non-selected drugs on plan formularies, including coverage, tier placement, and UM.

Rigorously Evaluate the Use of Utilization Management

Besides formulary limitations, insurers also use UM as a strategy to reduce their spending on covered medicines, which can have a negative impact on patient access. These insurance tactics, including prior authorization and fail first (also known as step therapy), may prevent or delay patients from accessing the medicines prescribed by their physicians. A recent report from GoodRx found that the average number of medicines covered by Part D that are subject to utilization management restrictions increased from 27 percent in 2010 to 47 percent in 2021.[30]

[30] Marsh, T. (2021). The Big Pinch: New Findings on Changing Insurance Coverage of Prescription Drugs. GoodRxHealth. Available at: https://www.medpac.gov/document/july-2022-data-book-health-care-spending-and-the-medicare-program/.

This confirms previous research published by MedPAC that found Medicare beneficiaries now face access barriers for nearly half of all medicines covered in Part D.[31]

In fact, prior authorization and step therapy can result in non-coverage, even if a drug is included on a Part D plan formulary. Prior authorization and step therapy requirements may effectively lead to coverage denials for failure to seek and obtain prior authorization or try and fail on a different therapy before the Part D plan will cover the patient's prescribed therapy. CMS has previously recognized that these types of utilization management impose barriers to patients' access to the treatment, which could adversely affect the progression of a patient's disease and overall health. For example, in its 2018 proposed rule CMS cited several studies that suggested step therapy may be costly, both economically and regarding patient health.[32] CMS acknowledged that "[s]everal studies show that enrollees become discouraged when step therapy is used" and that the delay caused by step therapy "may cause a worsening of conditions leading to increased medical costs."[33] This is not only harmful to beneficiaries, but it runs counter to Congress's goals in enacting the IRA: to help patients afford the medicines they need.[34]

Further, changing incentives from the IRA could result in plans choosing to cover medicines very differently. A recent payer survey conducted by Magnolia Market Access indicates that payers expect their plans to take a number of actions over the next year due to increased liability in Part D, such as tighter formularies and increased UM, including prior authorization and step therapy.[35] With changing formulary dynamics caused by government price setting, PhRMA is concerned that formulary restrictions are likely to increase, resulting in significant risk to patients needing innovative medicines to treat difficult to treat conditions such as cancer and autoimmune conditions.

Moreover, we note that therapeutically alternative medicines in a given class may not be appropriate for some patients who may need a particular medicine. If plans narrow access to certain medicines due to dynamics introduced by government price setting, patients who are stable on a given medication may lose access and be forced to switch to an alternative medicines that is not optimal for their unique circumstances, which could result in adverse health outcomes.[36,37] Numerous studies have found that switching stable patients to a new

[31] MedPAC. (2022). July 2022 Data Book: Health Care Spending and the Medicare Program. Data Book Chart 10-15, p. 27-28. Available at: https://www.medpac.gov/document/july-2022-data-book-health-care-spending-and-the-medicare-program/.
[32] See 83 Fed. Reg. 62152, 62187 (Nov. 30, 2018).
[33] *Ibid.*
[34] Senate floor speech by Senator Ron Wyden, August 6, 2022. https://www.finance.senate.gov/chairmans-news/wyden-delivers-floor-speech-in-support-of-the-inflation-reduction-act
[35] Magnolia Market Access IRA Payer Insights Survey, Winter 2023. Respondents (n=30) represent ~290M covered US lives.
[36] American College of Rheumatology. (2023). American College of Rheumatology Position Statement: Patient Access to Biologics. Available at: https://www.rheumatology.org/Portals/0/Files/Patient%20Access%20to%20Biologics%20aka%20Model%20Biologics.pdf .
[37] Atzeni, Fabiola et al. (2016). Switching rheumatoid arthritis treatments: an update. Autoimmunity reviews. 10,7: 397-403. DOI:10.1016/j.autrev.2011.01.001.

medicine for non-clinical reasons leads to poor side effects and increased nonadherence and is often associated with negative health outcomes.[38]

PhRMA recommends that CMS update its plan evaluation and oversight procedures and rigorously exercise its responsibility to enforce statutory non-discrimination requirements in Part D. Specifically, PhRMA urges CMS to conduct diligent formulary oversight to guard against increasingly aggressive utilization management restrictions or the narrowing of patient treatment options, including exclusion of medicines.

III. PART D APPEALS AND EXCEPTIONS PROCESS

Given the multitude of changes that will be taking place in the Part D program, it is crucial that the Part D coverage determination and appeals process is working effectively, and plans are making appropriate determinations for ensuring appropriate and timely access to needed medications. PhRMA urges CMS to consider ways to streamline and simplify the appeals and exceptions process for all Part D beneficiaries as well as provide appropriate access to data that could be helpful to shed light on Part D plan policies and practices. We also note that while well-functioning appeals are an essential safety net for patients, the availability of an appeal process cannot be a justification for systematically restricting access to care.

The current appeals process in Medicare Part D could create patient access barriers. A MedPAC analysis found that a "majority of beneficiaries were not aware they could ask for an exception or appeal a plan decision, nor could they understand how the appeals process works.[39] Even if a beneficiary has the understanding and inclination to file an appeal, the beneficiary typically will need to wait some time before an appeal decision is reached. It can take more than two weeks before a beneficiary can obtain a decision from an independent review entity.[40] While expedited determinations can be made within 24 hours, in practice, it can take much longer than a day for a beneficiary to receive a drug following an expedited review. This is because the clock does not begin to run when a beneficiary is denied coverage of a drug at the pharmacy counter, but only when the prescriber submits necessary information to the Part D sponsor, which may be days after the beneficiary attempted to fill the prescription.[41] If the Part D

[38] Nguyen E, Weeda E, Sobieraj D, et al. (2016). Impact of Non-Medical Switching on Clinical and Economic Outcomes, Resource Utilization and Medication-Taking Behavior: A Systematic Literature Review. Current Medical Research and Opinion. 32(7):1281-1290. Available at: https://pubmed.ncbi.nlm.nih.gov/27033747/.

[39] Medicare Payment Advisory Commission, "Report to the Congress: Medicare Payment Policy" (March 2014; pgs. 368-369). Available at: http://www.medpac.gov/docs/default-source/reports/mar14_entirereport.pdf.

[40] The standard timeframe for a standard determination is 72 hours, after which the Part D sponsor has 7 days to undertake the first level appeal, and then the independent review entity has another 7 days to undertake its review. 42 C.F.R. §§ 423.568(b), 423.590(a), 423.600(d).

[41] In the case of an exception request, the timeframe begins when the prescriber submits a statement explaining the medical necessity of the drug; where the beneficiary is seeking to satisfy prior authorization requirements the timeframe begins when the prescriber submits evidence demonstrating the prior authorization criteria has been met. Medicare Prescription Drug

sponsor denies the beneficiary's fill at the initial coverage determination, it can take another week to obtain a decision from an independent review entity, even when reviewed on an expedited basis.[42]

Moreover, CMS program audits have shown "unacceptably high rates of non-compliance" with certain coverage determinations and appeals requirements, which have resulted in inappropriate delays or denials of medications. CMS has previously reported that fewer than 17 percent of all negative coverage determinations in 2013 were appealed to Part D plans for redetermination, but that on appeal, nearly 80 percent of denials were overturned.[43] We are concerned that the relatively low proportion of coverage denials that are appealed reflects a lack of transparency in the appeals process or excessive administrative burden for beneficiaries and providers. Given the substantial changes in the Part D program, we urge CMS to continue exploring policy options to improve the current overly burdensome and complex appeals process in Medicare Part D to ensure beneficiaries' timely access to needed medicines.

Further, Part D plans must allow beneficiaries to request a tiering exception to obtain a non-preferred drug at the lower cost-sharing amounts applicable to drugs in the preferred tier. However, CMS permits plans to maintain a formulary tier for "very high cost and unique items" (the "specialty tier") which is exempt from tiered cost-sharing exceptions. A 2019 Office of Inspector General (OIG) report found that Part D beneficiaries experienced up to 84 million rejections when they tried to fill prescriptions at pharmacies, which is about a 3.5 percent overall rejection rate. The report also found that of the 744,987 appeals filed by beneficiaries in 2017, sponsors overturned 73 percent of drug coverage denials that were appealed, indicating that some denials could have been avoided. OIG notes that "The extra step of appeal represents friction in the program, and may create an administrative burden for beneficiaries, prescribers, and Part D sponsors." In this report, OIG recommended that CMS "provide beneficiaries with clear, easily accessible information about sponsor performance problems, including those related to inappropriate pharmacy rejections and coverage denials."[44]

Today, Part D plans design formularies that place an unacceptable number of drugs on the specialty tier without clinical justification for doing so. The new financial pressures resulting from the IRA reforms to Part D are likely to increase this trend. By imposing a very high and unappealable level of cost sharing, the specialty tier effectively discriminates against certain

Benefit Manual, ch. 18, §§ 30, 30.1, 30.2.2.2. While a beneficiary can obtain a transition fill while waiting for the appeal to resolve itself, doing so represents yet another hurdle for the beneficiary to navigate. Moreover, the transition fill is only available to those continuing a therapy, not new starts.

[42] A Part D sponsor has 72 hours to conduct the first-level appeal of an expedited case. Once the sponsor's decision has been reached, an independent review entity has another 72 hours to reach a decision. 42 C.F.R. §§ 423.572(a), 423.590(d)(1), 423.600(d).

[43] Centers for Medicare & Medicaid Services. Advance Notice of Methodological Changes for Calendar Year (CY) 2016 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2016 Call Letter. February 20, 2015. http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2016.pdf

[44] Office of Inspector General. Some Medicare Part D Beneficiaries Face Avoidable Extra Steps That Can Delay or Prevent Access to Prescribed Drugs. September 2019. https://oig.hhs.gov/oei/reports/oei-09-16-00411.pdf

patients based on their clinical needs or health status. Therefore, it is imperative for CMS to make the tiering exceptions process more accessible to beneficiaries by eliminating the tiering exceptions request exemption for the specialty tier.

Once again, PhRMA strongly urges a more patient-centered approach to the Part D specialty tier that would, at a minimum, remove the specialty tier's exemption from formulary exceptions and allow patients to appeal specialty tier cost sharing by demonstrating a medical need for the specialty tier drug. We find this policy change particularly urgent given the new incentives resulting from the IRA. It is neither fair nor reasonable to require patients to pay cost-sharing as high as 33 percent coinsurance when they can demonstrate that they must take a specific medicine and have no reasonable alternative.

To impose a very high and unappealable level of cost-sharing in such circumstances amounts to discrimination based on a particular patient's clinical needs or health status. At a minimum, patients who have previously undergone step therapy and/or have otherwise demonstrated that drugs on lower tiers are not clinically appropriate should pay cost sharing as if the drug were available on a more favorable tier. Requiring these patients to pay higher cost sharing singles them out based on their specific prescription drug needs or specific conditions without any clinical or utilization management rationale. Therefore, PhRMA recommends that CMS require Part D plans to allow medicines on the specialty tier to be eligible for tiering exceptions.

Moreover, CMS must not lose sight of the importance of strong beneficiary protections and appeals amidst so many fundamental changes to Part D. To that end, PhRMA encourages CMS to re-examine and update rules around coverage determinations, appeals, and tiering exceptions to allow beneficiaries to appeal for lower cost sharing or exceptions for clinical reasons, to require clear language in Part D plan materials/websites that explains the exceptions process, and to examine trends in exceptions and appeals requests and outcomes specific to selected and non-selected drugs and to enhance transparency and public reporting of these beneficiary protections and appeals outcomes.

IV. REDEFINE NEGOTIATED PRICE

The Part D program has changed significantly since the original beneficiary protections were created, as has the behavior of the Part D plans and PBMs. Part D plans have been increasing their market consolidation, with three insurers—UnitedHealth, Humana, and CVS Health—covering close to six in ten of all Part D beneficiaries in 2022.[45] The PBM market is also highly consolidated, with 80 percent of all U.S. prescription claims in 2021 being processed by just three firms: CVS Health, Express Scripts (Cigna), and OptumRx (UnitedHealth).[46] Such

[45] August 17, 2022 Kaiser Family Foundation Report "Key Facts About Medicare Part D Enrollment and Costs in 2022" accessed at https://www.kff.org/medicare/issue-brief/key-facts-about-medicare-part-d-enrollment-and-costs-in-2022/#
[46] April 5, 2022 Drug Channels "The Top Pharmacy Benefit Managers of 2021" accessed at https://www.drugchannels.net/2022/04/the-top-pharmacy-benefit-managers-of.html

consolidation gives the Part D plans and their PBMs outsized influence, leaving beneficiaries with fewer affordable choices.

Patient OOP burdens are exacerbated by current practices of Part D plan sponsors and PBMs to retain their substantial negotiated discounts and rebates, typically using rebate dollars to reduce premiums overall instead of lowering patient cost sharing on rebated medicines. Even if a Part D sponsor or its PBM has negotiated a rebate for the product, coinsurance is often based on a medicine's undiscounted list price. A recent analysis found that 92 percent of Part D beneficiaries' out-of-pocket spending is based on the list price rather than the discounted price their insurer gets.[47]

The drug price negotiation program will further distort patient access because the maximum fair price (MFP) of selected drugs will be equal to or lower than net price. In contrast, without a regulatory change to the definition of "negotiated price," the negotiated prices for competing non-selected drugs may continue to be based on the list price of the drug, even when the manufacturer provides rebates or other remuneration significantly reducing the net price to the plan. As a result, when a plan uses percentage-based coinsurance, cost sharing will differ significantly for selected versus non-selected drugs, exacerbating PBMs' current failures to pass rebates to patients. PhRMA recommends that CMS move to equalize cost-sharing differentials for patients, by redefining Part D negotiated price to take into account all manufacturer price concessions.

V. SMOOTHING OF PART D OOP COSTS

PhRMA has long supported increased affordability and predictability of patient OOP costs in an effort to increase access to medicines. Today beneficiaries who aren't eligible for low-income subsidies face multiple affordability challenges due to the way the Part D benefit is structured. Beneficiaries with high costs in Medicare Part D may struggle with paying for their medicines, as historically the benefit design of Part D did not include a cap on out-of-pocket spending or a way for enrollees who incur high costs over a short period to spread their costs out over time.

The IRA includes several patient affordability improvements to the Medicare Part D program – including the creation of a program to spread out or "smooth" beneficiary out of pocket costs over the course of the plan year. The smoothing of OOP costs, coupled with the $2,000 maximum out of pocket (for 2025), are meaningful improvements in patient affordability and we know that many patients will be protected from high OOP spending as these policies take effect beginning in 2025.

Research has shown that OOP costs for Medicare Part D beneficiaries can spike early in the year as a result of the annual deductible. Part D beneficiaries taking higher cost specialty medicines

[47] https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/S-U/Trends-in-Out-of-Pocket-Spending-for-Brand-Medicines-in-Medicare-Part-D_FINAL-Update-May-21.pdf

may see both deductibles and higher cost-sharing in the early months of the year, creating a significant financial burden for enrollees.[48] These high out-of-pocket costs for beneficiaries can result in increased nonadherence to medication[49] and reductions or delays in treatment initiation[50], which can lead to worsened health outcomes over time. Without the ability to spread out these high OOP costs frontloaded at the beginning of the year, health disparities could be exacerbated, as there is documented variability in income and assets of beneficiaries in the Medicare program, with Black and Hispanic beneficiaries having considerably lower median incomes than white beneficiaries.[51]

While the need for the program is well documented, PhRMA is concerned about implementation of the new program as enrollment in smoothing is voluntary, the features of smoothing are only described with broad parameters in the law, and many key operational and effectuation details have yet to be determined. Proper implementation of the program will be critical in meeting its underlying goals and providing the intended affordability relief to enrollees, which will improve access to medicines and adherence, and likely will also reduce health disparities. Further, we note that these affordability and adherence gains are important not just for those enrollees with the highest costs, but also for beneficiaries with lower and modest incomes, who could also benefit in some cases from the smoothing program.

PhRMA has given a great deal of thought to principles related to smoothing and key decision points CMS will face in implementing the program. We lay out our recommendations below.

Beneficiary Education and Outreach

As participation and enrollment in smoothing is voluntary, beneficiary education and outreach will be a critical factor in the success of the program and the uptake by enrollees, especially in the early years of implementation. The statutory formula will make smoothing of clear benefit to some, but, as PhRMA understands the formula, it may not offer the same benefit to all Medicare beneficiaries. Yet, all beneficiaries are eligible to enroll. As such, education and outreach will be critical to ensuring successful implementation and that beneficiaries have a clear understanding of how smoothing may impact their OOP costs.

The statute requires that both CMS and plans provide information on the smoothing program to prospective enrollees. CMS must provide such information within general informational

[48] Doshi JA, Li P, Pettit AR, Dougherty JS, Flint A, Ladage VP. Reducing out-of-pocket cost barriers to specialty drug use under Medicare Part D: addressing the problem of "too much too soon". Am J Manag Care. 2017;23(3 Suppl):S39-S45.
[49] Nekui F, Galbraith AA, Briesacher BA, et al. Cost-related Medication Nonadherence and Its Risk Factors Among Medicare Beneficiaries. Med Care. 2021;59(1):13-21. doi:10.1097/MLR.0000000000001458
[50] Li P, Wong YN, Jahnke J, Pettit AR, Doshi JA. Association of high cost sharing and targeted therapy initiation among elderly Medicare patients with metastatic renal cell carcinoma. Cancer Med. 2018;7(1):75-86. doi:10.1002/cam4.1262
[51] Jacobson G, Huang J, Neuman T, Smith K. Wide Disparities in the Income and Assets of People on Medicare by Race and Ethnicity: Now and in the Future. Kaiser Family Foundation. September 2013. https://www.kff.org/medicare/report/wide-disparities-in-the-income-and-assets-of-people-on-medicare-by-race-and-ethnicity-now-and-in-the-future/

materials on the Medicare program. Plan sponsors must notify prospective enrollees of the option for smoothing in promotional materials and include information within educational materials. Additionally, the statute requires tailored notification requirements. Specifically, Part D plans must have a mechanism in place to notify a pharmacy if a beneficiary has out-of-pocket costs that make it likely that the enrollee may benefit from smoothing. Such mechanism must ensure that pharmacies then inform the beneficiary of the notification. However, the statute is not prescriptive as to the content of the educational materials or notifications, nor how the information must be communicated. Therefore, ***PhRMA recommends that CMS take all actions within its authority to ensure robust communication and outreach, including that every Medicare beneficiary has consistent and clear education and outreach materials on smoothing, and that the program is accessible to Part D beneficiaries who most need it***.

CMS must have a strong role in the development and dissemination of beneficiary education and outreach materials. A comprehensive framework and detailed oversight will help ensure information is consistent and understandable to beneficiaries from various backgrounds and communities, as health insurance literacy is vital in enrollment among Medicare beneficiaries by giving them the ability to make an educated choice to enroll in a plan that best meets their needs and preferences.[52] Evidence has shown that individuals with poor health, low socioeconomic status, or racial and ethnic minorities are more likely to have lower health insurance literacy, which can pose challenges to a beneficiary's ability to understand the details related to smoothing.[53,54] Thus, patient education materials must clearly explain the enrollee's responsibilities in participating in the smoothing program. For example, education materials should explicitly spell out that if a patient chooses to smooth OOP costs over the remainder of the plan year, the patient could incur monthly costs for the medicine even if they don't take the medicine every remaining month of the year (e.g., in instances where an enrollee starts and then discontinues a higher cost specialty medicine, such as cancer or hepatitis C therapies where a prescribed course of therapy may be for a fixed duration of time).

Smoothing and the accompanying MOOP in Part D are major new benefits. ***CMS should launch an aggressive education and outreach campaign on changes to the Part D program, outside of the traditional annual beneficiary education and outreach activities, to ensure the new benefits and affordability improvements are well understood.*** To ensure that beneficiaries are receiving the necessary information about the program, CMS should partner with patient advocacy groups and other senior organizations like Area Agencies on Aging and State Health Insurance Assistance Programs (SHIPs) to leverage their proven ability to reach their communities, which can broaden beneficiary outreach and increase knowledge of smoothing and other Part D benefit changes. CMS should also extend outreach beyond beneficiaries, and target caregivers and providers. Caregivers and providers play a vital role in a beneficiary's

[52] Park S, Langellier BA, Meyers DJ. Association of Health Insurance Literacy With Enrollment in Traditional Medicare, Medicare Advantage, and Plan Characteristics Within Medicare Advantage. JAMA Netw Open. 2022;5(2):e2146792. Published 2022 Feb 1. doi:10.1001/jamanetworkopen.2021.46792

[53] *Ibid.*

[54] Villagra VG, Bhuva B, Coman E, Smith DO, Fifield J. Health insurance literacy: disparities by race, ethnicity, and language preference. Am J Manag Care. 2019;25(3):e71-e75. Published 2019 Mar 1.

health care team, especially in instances where beneficiaries do not solely direct their own interactions within the healthcare system. It is imperative that these team members are also made aware of the smoothing program, so they are better positioned to assist in navigating enrollment and managing a beneficiary's administrative needs.

CMS must also work to update current annual education materials associated with open enrollment (e.g., Medicare & You handbook, CMS websites, etc.) to ensure these materials include a robust, in-depth explanation in clear language with illustrative scenarios of the program changes in the IRA and how a beneficiary's OOP costs could change under the smoothing program.

In addition to CMS materials, Plan Finder will need to be updated to include information on smoothing, with careful attention to how the smoothing option is displayed and what impact it has on estimated beneficiary OOP costs. ***Specifically, we urge CMS to create a real-time calculator tool in Plan Finder that provides beneficiaries with estimated smoothing payments based on information they put into the available data fields.*** This calculator tool should also provide beneficiaries a comparison of their monthly costs with and without smoothing, thus allowing them to assess whether they would benefit from smoothing and make an informed decision about whether they want to enroll in the program. PhRMA recognizes that the incorporation of these changes to Plan Finder may require more lead time. We therefore urge CMS to start today, so that this tool can be incorporated into Plan Finder in time for the 2025 plan year.

Plan Education and Outreach

In an effort to provide beneficiaries with timely notice on the program, plans should be required to send out information about OOP smoothing and how to enroll in the program to all beneficiaries in their plan prior to the start of open enrollment (i.e., by the end of September prior to the start of the following plan year). Consistent with CMS' roll out of other IRA benefit enhancements like the insulin copay caps and zero copays for certain preventive vaccines, CMS should develop model education notices and language for plans to use, with specific requirements for marketing and plan enrollment materials and where in those materials explanatory language on the smoothing program must be displayed.

In addition, routine communications throughout the plan year, such as monthly explanation of benefit (EOB) notices, could include a projection of a patient's OOP cost-sharing to date, and projected cost-sharing obligations along with information on the smoothing option.

Due to the novel nature of the smoothing program, clear direction from CMS may be the most effective way to ensure that all beneficiaries are receiving identical language regardless of their plan. Differing language to describe the smoothing program across plans could confuse enrollees, hindering enrollee engagement with the program.

Pharmacy Education and Outreach

CMS should also establish standardized language for the specific notifications to beneficiaries, with particular focus on the beneficiaries with OOP costs that "make it likely the enrollee may benefit" from the program.[55] CMS should also work with pharmacies and pharmacists to understand how implementation of the program will impact workflow and identify any potential burdens that may be placed on pharmacies. This collaboration would also provide an avenue for CMS to educate pharmacists on the smoothing program and their anticipated role, so they may adequately and accurately communicate information on the program to Medicare beneficiaries.

The new smoothing program can make broad strides in making out of pocket costs more predictable from month to month for beneficiaries. However, its success is tied to the ability to broadly educate on and explain this new benefit.

Enrollment in Smoothing

A clear and consistent enrollment process in the smoothing program will be a strong determinant for how many and which beneficiaries enroll in the program. The statute notes that Medicare Part D beneficiaries may elect the smoothing option prior to the beginning of the plan year or any month during the plan year.[56] However, there are few specifications in the law on the mechanism(s) that will be made available for beneficiaries to enroll, and no discussion regarding whether enrollment in the smoothing program can happen concurrently with Part D's annual open enrollment and plan selection process. Due to the importance of enrollment in the program, ***PhRMA recommends that Medicare beneficiaries should be able to seamlessly enroll in smoothing as part of their annual Part D plan selection process and at the point-of-sale (POS), as appropriate. In addition, CMS should ensure beneficiaries have a standardized and consistent experience enrolling in and benefiting from smoothing, regardless of their selected plan or where they fill a prescription.***

The legislative language leaves much up for interpretation regarding the timing and mechanisms of enrollment in the smoothing program, however we note that the mechanisms through which beneficiaries can enroll in the program will be integral to uptake. Beneficiaries should have multiple mechanisms to enroll in the smoothing program, including as a part of the annual open enrollment process, at or simultaneous with the point-of-sale at the pharmacy, directly on the Part D Plan website, by calling their Part D plan and adopting smoothing, or by completing a mail-in form. The opportunities for these varying methods of enrollment in smoothing should be consistent across all plans and incorporated into current Part D enrollment processes through general requirements established by CMS. Research has shown that for Medicare beneficiaries, 30 percent of cancer prescriptions and over 50 percent of

[55] See SSA 1860D-2(b)(2)(v)(III)(dd) (OOP costs make it likely enrollee may benefit from election)
[56] The law allows an enrollee to elect smoothing either prior to the plan year, or in any month during the plan year. 1860D-2(b)(2)(E)(v)(II).

prescriptions to treat immune disorders or high cholesterol go unfilled.[57] Therefore, CMS should begin working to ensure there is opportunity for real-time enrollment and the ability to elect smoothing mid-plan year or at the start of a new plan year even if a beneficiary is not actively selecting a new plan, as most Part D beneficiaries don't switch Part D plans from year to year.[58]

Re-enrollment in the smoothing program should be automatic for beneficiaries who aren't switching plans from year to year, just as Medicare beneficiaries are automatically re-enrolled in their Part D plan. However, beneficiaries should have the ability to disenroll from smoothing once they determine enrollment is no longer beneficial (i.e., in instances where an enrollee starts and discontinues a medication or if their OOP cost with smoothing becomes unexpectedly high. SEE APPENDIX C). This enrollment should also be applied to beneficiaries who are crosswalked to another plan. However, if a beneficiary actively switches plans, regardless of whether it is a plan offered by the same plan sponsor, they should be prompted to re-enroll in smoothing through the available plan enrollment mechanisms.

We note that every Medicare beneficiary has different OOP exposure from medicines. While some individuals whose costs extend beyond the MOOP will clearly benefit from enrollment in the smoothing program, the benefits may be less direct for others. Further, every beneficiary's financial situation is distinct, so OOP exposure in one month that might be too great for one individual may be more manageable for another. See appendix A-D of how PhRMA reads the statutory formula as applied to illustrative examples of different Medicare beneficiary OOP exposures. To accomplish the statutorily required notification, CMS should clearly define parameters for when a beneficiary's out of pocket costs make it likely that they "may benefit." PhRMA has modeled the statutory formula and would be happy to meet with CMS regarding how levels and timing of cost sharing may affect smoothing. However, independent of a determination of who "may benefit," there should be broad outreach and education to all Medicare beneficiaries by the plan and the pharmacy on the existence of the smoothing program.

Pharmacies will be on the front line of interaction with Medicare beneficiaries and are specifically tasked by the law with notifying beneficiaries if the smoothing is likely to be beneficial to them. The ability to enroll in smoothing in real time at, or simultaneous with, the point-of-sale is essential to the program's ability to meet its goals of increasing affordability for patients. CMS should be involved in shaping this notification process to make POS enrollment an efficient avenue of uptake, particularly for Medicare beneficiaries who will most benefit from smoothing - those with the highest costs, including those who will reach the MOOP with one or just a few prescription fills. A delay in enrollment in smoothing for these patients could

[57] Dusetzina SB, Huskamp HA, Rothman RL, et al. Many Medicare Beneficiaries Do Not Fill High-Price Specialty Drug Prescriptions. Health Affairs. 2022; 41(4). https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2021.01742

[58] Biniek JF, Damico A, Cubanski J, Neuman T. Medicare Beneficiaries Rarely Change Their Coverage During Open Enrollment. KFF. Published November 2022. https://www.kff.org/medicare/issue-brief/medicare-beneficiaries-rarely-change-their-coverage-during-open-enrollment/

render the program unworkable for them. Moreover, enrollment in smoothing at the pharmacy may be a key avenue of uptake in the program.

We encourage CMS to provide clear guidance to Part D plans regarding the process for effectuation of POS election and enrollment in the smoothing program to ensure that it is an effective mechanism of enrollment to provide consistent access to beneficiaries. This guidance should include identification of the types of pharmacies that would be eligible to support POS enrollment in smoothing to provide consistent access to the program. In the alternative, CMS could provide guidance on telephone or online enrollment in smoothing that would take effect at the time the beneficiary is dispensed a medicine.

The calculation methodology for smoothing payments easily allows for POS enrollment. For example, the statute clearly lays out that plans could assess a beneficiary who enrolls into smoothing $0 when the medicine is dispensed, and then the plan bills the beneficiary the appropriate smoothed amount.[59] It should therefore be a relatively simple matter for Part D plans to work with network pharmacies to effectuate smoothing.

Specifically, PhRMA believes the process could work as follows:

1. The enrollee elects smoothing at the pharmacy counter;
2. The pharmacy charges such enrollee $0 when the medicine is dispensed, since the enrollee will be billed later;
3. The pharmacy notifies the plan of the election when submitting the claim to the plan;
4. The plan pays the pharmacy both the plan's share as well as the enrollee's cost-share (given that the pharmacy would have had to bill this cost-share in the absence of smoothing, both amounts should be easily calculated);
5. The plan bills the enrollee the smoothed amount at the end of the month, folding it into the existing EOB process, and for each subsequent month that smoothed amounts are owed during the plan year. (Note: at the point that the beneficiary's accrued OOP reaches the maximum out of pocket limit, the maximum monthly charge will become fixed at a set dollar amount. At such point, the plan should inform the enrollee of this set monthly charge.)

Although enrollment at the POS will greatly benefit beneficiaries and increase access to enrollment in the smoothing program, it is important to understand the implications on workflow and the potential burden that could be placed on pharmacies by having a role in facilitating enrollment into the smoothing program. Guidelines will need to be established by CMS on how this will be operationalized by pharmacies and the tools that will be made available to them to enroll beneficiaries in pharmacy settings, including community pharmacies, retail chains, mail order, and specialty pharmacies. It will be critical to collaborate with and obtain feedback from providers in pharmacy settings to ensure that the implementation of this

[59] See SSA 1860D-2(b)(2)(E)(iii) (enrollee is "billed" for the amount owed); 1860D-2(b)(2)(E)(v)(IV) (consequences for failure to pay amount "billed").

program does not place undue burden on them or inhibit their ability to effectively serve their communities.

Calculations of "Smoothed" Amounts

Smoothing, coupled with the new maximum OOP cap in Part D, is a significant step forward in improving affordability for beneficiaries with high OOP pocket costs, especially those taking higher cost specialty medications who may hit their MOOP with one or just a few fills. For these individuals, the statutory smoothing formula is a straightforward calculation that produces a consistent payment from month to month (SEE APPENDIX A and B).

However, the experience of other eligible beneficiaries seeking to smooth OOP cost sharing may be less straightforward. Specifically, Medicare beneficiaries with OOP costs that fall short of the $2,000 MOOP may encounter inconsistent monthly smoothing obligation amounts, based on how we read the statutory formula, resulting in confusion and unintended affordability challenges.

Under our modeling of the statutory calculation as applied to beneficiaries with total costs under $2,000, some enrollees may face smoothing obligations for a given month that may exceed the monthly incurred prescription cost-sharing, or calculations that result in paying very minimal smoothing obligations in early months but then result in significant monthly smoothing obligations in later months of the year. For example, under the calculations presented in Appendix D, an enrollee in smoothing with a $125 monthly incurred cost sharing for medicines would have smoothing obligations of $167 in January and have more minimal OOP smoothing obligations in February through July, but incur significantly higher smoothing obligations in November and December.

We note that depending on how CMS interprets the statutory formula, a Medicare beneficiary's experience in the smoothing program could also change dramatically over the course of the year, based on the level of monthly cost sharing, cost of the prescription, the point of enrollment in a given plan year, the number of prescriptions being smoothed, and other factors. Further, beneficiaries that start and stop a treatment or switch medicines over the course of a year could see significant variability in their smoothing obligations from month to month (SEE APPENDIX C). Due to the variability of current smoothing calculations based on individual beneficiary circumstances, ***PhRMA recommends that CMS provide clear procedures for the calculation of smoothing payments to ensure that calculations both advance patient affordability and are understandable across different beneficiary OOP scenarios and plan types.***

Additionally, we note that CMS' particular interpretation of the statutory calculation could have a significant impact on a beneficiary's monthly smoothing obligation. Based on PhRMA's

understanding of the calculation, as written in the statute, the "number of months remaining in the plan year" component of the formula[60] could be interpreted in two ways (SEE APPENDIX E):

- Option 1: **The current month of the plan year would count toward** the remaining months in the plan year (e.g., 12 "months remaining" in the plan year for costs incurred in January, 11 "months remaining" for costs incurred in February, etc.) or;
- Option 2: **The current month of the plan year would not be counted toward** the remaining months in the plan year (e.g., 11 "months remaining" in the plan year for costs incurred in January, 10 "months remaining" for costs incurred in February, etc.).

PhRMA recommends that CMS use the interpretation of the "months remaining in the plan year" to count the current month toward the remaining months in the use of the calculation. We view Option 1 as more patient friendly, since it results in lower monthly smoothing payments overall. However, we acknowledge that under the Option 1 approach, there is the possibility for enrollees to owe costs from December that would potentially be billed toward the end of December or in January of the following year. Under Option 2, the monthly OOP payments for enrollees in smoothing would be higher, as this interpretation results in a smaller divisor than Option 1 (SEE APPENDIX E).

Payments

The current statutory language describes few details on the process of smoothing payments from the enrolled beneficiary to the plan. Therefore, ***PhRMA recommends that CMS consider standardized procedures and rules to ensure that smoothed cost-sharing amounts are clear and that the process for invoicing enrollees is reasonable, patient-centered, and consistent across all Part D plans.***

Given the wide variety of smoothing calculations dependent on an enrollee's OOP expenses, there is a clear need for structured guidelines by CMS around the timing of billing mechanisms to provide clear rules across Part D plans regarding when enrollees can be billed for smoothing payments and for which prescriptions. CMS should determine both the invoicing mechanisms for smoothed payments from enrollees to the plan, as well as the enrollee's method of paying smoothed OOP costs, especially if it will differ from other payment processes for plan premiums. It may also be necessary to develop a way for enrollees to easily track their smoothing payments throughout the plan year, which will be especially important for beneficiaries taking multiple medications or those that start and stop a course of treatment during the plan year. As enrollees will still be responsible for smoothing payments even after discontinuing a medication, clear tracking could be a useful tool in helping enrollees understand what they are responsible for paying and also potentially reduce the likelihood for missed payments. Additionally, there needs to be an established procedure in the event of nonpayment, e.g., appropriate notices and determining how long after a bill is sent is payment

[60] SSA 1860D-2(b)(2)(E)(iv)(I)(bb) and (iv)(II)(bb).

considered missing. CMS should develop the language to be used in notices to enrollees in the event of nonpayment, so it is consistent across plans and provides the enrollee the information needed to address the missed payment. These procedures will be critical in providing all enrollees with a consistent experience in the smoothing program and prevent plans from implementing stricter or disparate guidelines around nonpayment for enrollees.

Disenrollment and Lock Out

The statute allows plans to disenroll beneficiaries from the smoothing program for failure to pay, but provides few details on how disenrollment can occur or the scope of disenrollment.[61] This could leave room for enrollees in the program who are disenrolled to be "locked out" of the smoothing program due to an error, unintentional missed payment, or potentially small unpaid amounts of money. ***PhRMA recommends that CMS establish clear procedures related to disenrollment and lockout that appropriately balance beneficiary access and patient protections with financial and operational considerations for plans. While disenrollment and lockout may be allowed in certain cases under the law, we implore CMS and plans to use this as a last resort, and to minimize the scale of lockout to only that particular plan.***

Given the lack of detailed language in the statute, CMS should implement strong and detailed guidelines and processes related to a plan's ability to disenroll for failure to pay that will provide appropriate protections for beneficiaries in the smoothing program. These guidelines should balance beneficiary protections against reasonable tools that limit plan financial losses from nonpayment. As CMS designs these policies and procedures, we encourage the Agency to consider established patient protections embedded in current disenrollment policies for failure to pay Part D premiums that should also be logically applied to the smoothing program. For example, these current procedures require a minimum grace period of at least two months, require a written notice from plans of nonpayment prior to disenrollment, and establish a set number of days after a bill is sent for it to be considered a late or missed payment.[62]

Specific to lock out, after a plan disenrolls a beneficiary from smoothing, plans are also able to "lock out" individuals from re-enrolling, which would force beneficiaries to change to a new plan if they need to enroll in smoothing in a future plan year. To prevent beneficiaries from being permanently "locked out" of smoothing, CMS should also establish a path to re-enrollment in smoothing. Again, CMS should consider establishing reasonable allowances similar to those in place in the program today for failure to pay Part D premiums. This might include a beneficiary repaying all or a certain portion of costs owed before re-enrolling in smoothing or establishing a "good cause" policy for inability to pay, such as based on illness, death, death of a spouse, or similar factors. CMS should strongly consider guidelines that

[61] See SSA 1860D-2(b)(2)(E)(v)(IV) (consequences for failure to pay amount "billed").

[62] Centers for Medicare & Medicaid Services. What Happens When a Plan Member Doesn't Pay Their Medicare Plan Premiums? April 2021. (Accessed May 2023). https://www.cms.gov/outreach-and-education/outreach/partnerships/downloads/11338-p.pdf.

prevent plans from enforcing overly restrictive disenrollment policies and providing beneficiaries with protections, reasonable notice prior to disenrollment, and the opportunity to re-enroll after disenrollment.

VI. UPDATES TO THE PART D RISK ADJUSTMENT MODEL FOR CY 2025

The Part D program has been in effect for more than 15 years, and during that time CMS has not undertaken a comprehensive update to the Part D risk adjustment model. Many fundamental aspects of the current Prescription Drug Hierarchical Condition Category (RxHCC) model impede its ability to accurately predict costs in Part D. These gaps between predicted plan costs and actual plan liabilities threaten patient access, particularly for those individuals with serious health conditions. To the extent that risk payments do not recoup the plan costs of care for beneficiaries with certain health conditions, it creates perverse incentives for plans to structure formularies and coverage in a way that discourages enrollment by these beneficiaries, creating potential barriers to care.

PhRMA implores CMS to undertake a thoughtful and complete review of the RxHCC model, factoring in both important updates resulting from the benefit design changes made by the IRA and also considering other misalignments where further refinements and improvements could be implemented.

The identified shortcomings and chronic underpredictions laid out below underscore the importance of a complete reassessment of the Part D RxHCC system, to modernize the risk adjustment system and account for current Part D benefit parameters. These updates are critical to ensure that Part D financing supports appropriate incentives for plans to design Part D benefits in a way that provides beneficiary access to a wide variety of medicines.

In addition, ***we request that CMS consider updates for the CY 2025 RxHCC model early enough to allow sufficient time for CMS to recalibrate the model appropriately and incorporate extensive stakeholder input and feedback as part of a traditional notice and comment rulemaking process.*** We also ask that CMS engage in active dialogue with stakeholders as it considers the development of updated RxHCC model parameters, and we are eager to share with CMS the results of our own actuarial work and modeling. In particular, understanding that the recalibration process is time-intensive, we request CMS provide written guidance, sharing the planned updates to the model with sufficient detail for plans to incorporate into strategic planning for 2025 (which is already occurring) even before completely finalized. We spell out detailed areas in need of reform and our specific recommendations below.

Background on the Part D Risk Adjustment Model

The Medicare Part D program is financed today through a combination of direct subsidy and reinsurance payments from CMS, as well as premium and cost-sharing contributions from

enrollees (or premium and cost-sharing payments made by the government on behalf of LIS enrollees). Part D plans submit bids to CMS each plan year to predict the expected cost of the drug coverage that is in their offered plans.

As part of this annual bid submission process, stand-alone PDPs and MA-PDs adjust their Part D bids using the Part D risk adjustment model, also known as the RxHCC model. The model works to predict plan liability based on the health status, medical diagnoses, and demographic characteristics (e.g., age, gender, low-income status, institutionalized status) of a plan's enrollees. This Part D risk adjustment model must have accurate and reliable data to ensure that plans have appropriate incentives to enroll beneficiaries in Part D plans regardless of their health status or other demographic characteristics and to provide appropriate access to prescription drug treatment options across health care conditions and therapeutic areas.

The RxHCC model is misaligned with plan costs for beneficiaries with certain health conditions

While the Part D risk adjustment model has a goal of accurately reflecting the varied plan costs of treating all health care conditions, it does not always deliver on this promise today. Analysis of the current RxHCC model shows that it chronically underpredicts plan liabilities for certain therapeutic areas and overpredicts for others. This gap between predicted and actual plan liabilities makes certain therapeutic areas disadvantageous for plans to cover. And while these problems are significant today, they could grow in the coming years if CMS does not recalibrate the RxHCC model appropriately or in time for the model to be implemented with sufficient time before major IRA changes take place.

A recent analysis by Avalere Health found that the current RxHCC model underpredicted Part D plan liability in 2019 for all 11 therapeutic areas analyzed, with the model's predicted plan liability ranging from 22 to 75 percent *lower* than actual plan liability.[63] Thus, in these therapeutic areas, plans were at risk for significant losses for each patient enrolled in their plan who took at least one medication in these analyzed therapeutic areas. Of those conditions analyzed, those with the widest discrepancy between predicted and actual plan liabilities in 2019 include oncology (underpredicted by 53 percent), multiple sclerosis (underpredicted by 64 percent), autoimmune conditions (underpredicted by 73 percent), and hepatitis C (with actual plan liabilities underpredicted by 75 percent).[64]

Current Misalignments in the Model are Exacerbated by the IRA

[63] Avalere Health analysis based on 2019 claims data. Therapeutic areas analyzed included anticoagulants, anticonvulsants, antipsychotics, asthma/COPD, autoimmune conditions, diabetes (insulin and non-insulin), HIV, hepatitis C, multiple sclerosis, and oncology.

[64] Avalere Health. Risk Adjustment under Part D Benefit Redesign. Feb 27, 2023. Found at: https://avalere.com/insights/risk-adjustment-under-part-d-benefit-redesign#:~:text=Avalere%20projects%20that%20the%20NAMBA,value%20than%20it%20does%20today.

Under Part D's original program design, plan sponsors were at risk for a large portion of the benefit costs and reimbursed largely through their risk adjusted annual bid amount. However, over time the share captured in the plan's up-front bid has steadily declined, with more costs and government spending shifting away from risk-based capitated payments and toward growing reinsurance payments and cost-sharing assistance for low-income subsidy beneficiaries. This financing shift over two decades led to calls for the benefit to be redesigned, which occurred in the IRA.[65]

Underpredictions in the current RxHCC model will likely grow in the coming years, as the redesign of the Part D benefit put in place by the IRA changes the financing of the Part D program. Therefore, CMS must undertake significant and timely changes to the model that extend beyond minor recalibration adjustments.

Specifically, significant changes in stakeholder contributions under Part D redesign will impact plan bids and financing, as plans will again be forced to account for the majority of Part D's cost through their annual risk adjusted bids.[66] This dramatic increase in the portion of plan payments subject to risk adjustment will further exacerbate any underlying misalignments in the current model, and to the extent the model underestimates spending for enrollees with specific diseases, the potential financial losses to plans could be significantly larger under redesign than under the existing benefit structure. While we expect CMS is anticipating the need to recalibrate the model under the new IRA benefit design, as plans take on a greater share of liability it will be even more critical to ensure the new model accurately captures plan costs across all conditions.

PhRMA has worked with two different consulting actuaries to better understand shortcomings in the current RxHCC model and potential solutions. These analyses suggest that the scale of misalignment is significant for some conditions and will only increase in the coming years. In terms of payments subject to risk adjustment, under redesign and the new changes in plan financing of Part D that takes place beginning in 2025, an Avalere analysis estimates the national average monthly bid amount (NAMBA)-adjusted amount of total Part D drug spending could account for 84 percent in 2025, a more than three-fold increase over the 27 percent of Part D drug spending subject to risk adjustment in 2023. Therefore, any underprediction in costs for 2025 and beyond could result in financial losses to plans that are much greater than today.[67] Another actuarial consultant's analysis of the RxHCC model similarly confirms this misalignment in costs, if recalibration and important updates that take into account changes in the IRA do not occur. Under a status quo benefit design, this analysis suggests that only 39 percent of conditions have plan costs that are accurately predicted,[68] however this drops to 21

[65] Inflation Reduction Act, P.L. 117-169, Section 11201.
[66] Avalere Health. Risk Adjustment under Part D Benefit Redesign. Feb 27, 2023. Found at: https://avalere.com/insights/risk-adjustment-under-part-d-benefit-redesign#:~:text=Avalere%20projects%20that%20the%20NAMBA,value%20than%20it%20does%20today.
[67] Avalere Health. Risk Adjustment Under Part D Benefit Redesign. Feb 27, 2023. Found at: https://avalere.com/insights/risk-adjustment-under-part-d-benefit-redesign#
[68] Internal actuarial analysis. Accurately predicted means a paid-to-risk score between 0.95 and 1.05.

percent of conditions accurately predicted after the IRA provisions take effect in 2025. Moreover, the analysis shows that in a post-IRA world, more RxHCCs will become both under-predicted and also to a greater degree than today. Specifically, the analysis shows that the RxHCC model will underpredict gross plan costs by more than 20 percent for nearly half (45 percent) of all conditions in 2025 and beyond.

Actuarial comparison of paid to risk score ratios show certain health conditions are overpredicted, meaning plans with beneficiaries with these conditions are typically paid more than plan costs, which tend to be those areas where Part D spending is low, such as those either treated primarily with generics or no drugs at all. In contrast, the RxHCC model is likely to underpredict conditions treated primarily with higher cost-specialty drugs, meaning plans will be *paid less than actual plan costs* to treat beneficiaries with these conditions.

The negative implications of chronic underpayment will grow in the future, as the IRA's programmatic changes alter plan incentives. For example, the plan cost of conditions treated with specialty medicines is likely to dramatically increase in a post-IRA world, particularly for high-cost patients, with the implementation of the MOOP and higher catastrophic plan liability under the IRA. In addition, accurate RxHCC prediction for LIS beneficiaries – whose costs tend to be underpredicted in the current RxHCC model -- is even more important in a post-IRA world, due to new and increasing plan liability for LIS beneficiaries under the IRA, and the fact that a greater share of LIS beneficiaries' total drug spending falls in the catastrophic phase of the benefit, compared to non-LIS beneficiaries.[69]

This could have significant implications for plan formulary and coverage designs. In particular, the underpredictions of LIS beneficiaries (who tend to be sicker, on average, and have higher prescription drug utilization than other Medicare beneficiaries) could result in plan design and bidding strategies that no longer seek to attract LIS beneficiaries, with PDP plans bidding intentionally above the expected LIS benchmark and Part D Special Needs Plans (DSNPs) cutting benefits to mitigate premium increases.

The Part D Risk Adjustment Model Needs Updating to Reflect Current Part D Benefit Design

To fix the chronic underprediction, CMS must recognize factors that lead to errors and make changes. First, CMS must align current benefit parameters in Part D with the RxHCC model.

As noted in PhRMA's comments on the 2024 Advance Notice, we remain concerned with the Agency's recent decision to maintain the 2023 RxHCC model exactly in its current form for calendar year (CY) 2024, despite IRA-related changes to the underlying Part D benefit that begin to take effect in 2024. In those comments, we expressed concern regarding the lack of

[69] Avalere Health. Risk Adjustment Under Part D Benefit Redesign. Feb 27, 2023. Found at: https://avalere.com/insights/risk-adjustment-under-part-d-benefit-redesign#

alignment between the 2023 RxHCC model and the 2024 Part D benefit parameters, which will lead to inaccurate plan payments for certain conditions and enrollees. In 2024, policies take effect that cap cost-sharing for Medicare beneficiaries taking insulin and add a transitional out-of-pocket cap for beneficiaries, with additional costs in catastrophic shifting from beneficiaries to plans. As a result of CMS' decision to change nothing in the RxHCC model for the 2024 plan year, the model will have clear errors, and risk payments will not reflect these policy changes in Part D.

While CMS has chosen to make no changes for 2024, in the 2024 Advance Notice and Rate Announcement the Agency states its intent to "recalibrate the RxHCC model based on the updated benefit structure and propose any changes for CY 2025."[70]

To that end, ***PhRMA urges CMS to proactively begin the process of making significant and widespread updates to the Part D risk adjustment model for the 2025 plan year, providing an opportunity for extensive stakeholder engagement***

Structural Problems in the RxHCC Model Undercut its Ability Predict True Plan Costs

There are a number of shortcomings of the underlying structure of the current RxHCC model that could lead to its inaccuracies in predicting plan costs, as compared to expected costs. Among these shortcomings are the significant lag in data and the use of medical diagnosis codes to adjust spending, which do not reflect severity of disease, actual prescription drug utilization, or fully account for rare diseases. ***CMS must go further than minor adjustments and incorporate more significant changes to address foundational misalignments in the model.***

At a minimum, CMS must update the model to account for the significant policy and financing changes in the new Part D benefit parameters that take effect in 2025. However, we also encourage the Agency to go further and update its model to account for a number of non-IRA considerations and misalignments described below.

The Part D Risk Adjustment Model uses Lagged Data

As noted earlier, timing limitations in the risk adjustment model result in mismatches between the base data plan liability and the plan liability for the payment year at hand. Specifically, the current RxHCC model has a significant data lag – typically between three to five years -- in time between the year of actual claims and the year's costs that are predicted. For example, the most recent calibration is the 2023 RxHCC model, which uses 2018 Medicare fee for service and MA encounter data for medical diagnostics that predict expenditures using 2019 PDE data.[71]

[70] CY 2024 Advance Notice and Rate Announcement, p. 69 https://www.cms.gov/files/document/2024-advance-notice-pdf.pdf
[71] CY 2023 Advance Notice, p 69. https://www.cms.gov/files/document/2023-advance-notice.pdf

This significant data lag in the model calibration can lead to differences in expected plan costs relative to the underlying model parameters. For instance, with data that old, the RxHCC model cannot capture important events in the marketplace that would impact changes in plan liability, such as new drug launches, expanded indications for current treatments, significant price changes of a medicine, loss of patents or generic and biosimilar entry, as well as any significant regulatory or statutory policy change that occurs during the intervening period of data lag.

Given this data lag, continued use of the current RxHCC model, particularly if used in combination with outdated Part D benefit parameters, will put CMS is in a position where it will be using pre-IRA data to predict plan costs for the new benefit designs that take effect in the coming years, as both the benefit design and plan liability in Part D were changed significantly in the IRA. Thus, the PDE data used in the near term will reflect a completely different Part D plan benefit design, and this mismatch will continue for years in the future. Even if CMS re-adjudicates claims on a 2025 defined standard basis, that would not capture any utilization or behavioral changes resulting from the significant changes to member cost sharing under the redesigned benefit.

As further context of the practical impact of this data lag, diagnostic data reflecting the IRA redesign changes (taking effect in 2025) will not be fully incorporated into the current RxHCC model until 2028, and the government-set MFP prices (which first take effect in 2026) will not be first reflected in the RxHCC model PDE data until 2029.

The implications of this data lag are also significant on Part D plan economics. Without significant changes to the RxHCC model, plans will continue to be undercompensated for higher cost members and overcompensated for lower cost members. These economic implications could meaningfully affect plan decisions about fundamental aspects of the program, including the design of their offered benefit, formulary coverage, UM restrictions, premium levels, and even whether a plan participates in Part D at all.

In keeping with our concern that no changes to the RxHCC model were made for 2024, when the benefit parameters changed, as CMS looks ahead to 2025, it should not continue to predict future years' costs using outdated and fundamentally flawed data sets. Given the significant discrepancy which will undermine the integrity and reliability of the RxHCC model, ***PhRMA recommends that CMS comprehensively and promptly recalibrate risk scores to address the timing and the data lag in the current model.*** To the extent that more recent data is not available, the Agency could alternatively institute a payment adjustment or agree to re-adjudicate claims when more accurate data becomes available. Furthermore, with the significant increase in costs subject to risk adjustment for higher cost-specialty medicines (where plan liability will increase the most dramatically under redesign), CMS should look to update its model so that it better predicts the cost of care for conditions that often require these medicines.

The RxHCC Model Should Consider Prescription Drug Utilization and Not Simply Rely on Medical Diagnosis

As designed today, the RxHCC model uses medical diagnoses in the prediction of prescription drug costs and plan liability, with RxHCC adjustments based on average plan liability for members with this condition. This current reliance on diagnosis codes creates a mismatch, as the diagnosed conditions of a particular patient do not automatically correlate with highly variable data on actual prescription drug utilization or costs; thus, plans could be overcompensated for members on lower cost drugs and undercompensated for members taking higher cost medicines to treat this medical diagnosis. Additionally, CMS has itself noted in the context of the individual and small group markets' risk adjustment model that in some cases health conditions are underreported and medical diagnosis data alone may miss cases where "a patient with a long-term chronic condition has not visited a provider for that condition during their plan enrollment."[72]

Adjusting payments based on diagnosis with no correlation with actual prescription drug utilization can be a problem for certain conditions because the prescription drug costs for a particular patient and related plan liability may vary widely based on severity of disease and on the prescribed treatment regimen. This could also exacerbate availability of medicines for patients with rare diseases, as treatments are often higher cost and may not be adequately captured in the model, leading to access issues. While plans employ many tools to drive patients to lower cost therapeutic options for a condition and generic drug utilization in Part D has held steady at approximately 90 percent,[73] there are clinical instances where a patient may need a brand medicine, including when there is no lower cost therapeutic alternative. Medicare beneficiaries generally only receive access to brand medicines with higher unit costs after navigating unfavorable formulary placement and aggressive UM restrictions, and adjustments to update the RxHCC model could be made in such a way to preserve plan incentives to control costs while increasing the accuracy of the model.

Furthermore, for the reasons stated above, actual drug cost and utilization have a significant bearing on plan liability, yet CMS has made the decision not to factor any prescription drug utilization into the Part D risk adjustment payments. ***CMS should institute reforms in the RxHCC model to be more granular and that include at least some drug utilization in addition to diagnosis codes (particularly in certain classes where otherwise the model would underpredict)****, similar to the ACA risk adjustment model****.*** This would allow average plan costs of medicines to be more closely aligned with actual plan costs, bringing the model's predicted plan liability more in line with actual plan liability and decreasing plan incentives to design formularies to discriminate against beneficiaries taking certain medicines. This could be particularly important for individuals taking medications for rare diseases, which may not be appropriately captured in the model today.

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[73] MedPAC Report to Congress, March 2022. p. 467. Found at: https://www.medpac.gov/wp-content/uploads/2022/03/Mar22_MedPAC_ReportToCongress_Ch13_SEC.pdf

Changes in the RxHCC Model are Needed to Protect Access to Medicines for Medicare Patients

Misalignments between predicted and actual costs, changes in benefit design and liability in the IRA, and chronic structural problems in the RxHCC model's design stand in the way of the model accurately predicting plan liability in Part D. As described above, these problems are significant today and will compound over time. Left unchanged, the delta between predicted and actual plan costs will increase in the coming years.

While these areas of misaligned financing are troubling on their own, in the Part D program, the implications on patient access are an area of significant concern, requiring action by CMS. To be clear, these financing inequities do not occur in a vacuum and any inequities between the payments plans receive and actual plan costs will have a direct impact on beneficiary access to medicines (or restrictions on that access). For example, for therapeutic areas where plan liabilities are overpredicted (a net gain to the plan), Part D plans may have incentives to design their plan benefits and formularies in such a way to attract more beneficiaries with these conditions. Conversely, if costs are consistently underpredicted for certain health care conditions, plans will find that it is not profitable to enroll beneficiaries with these conditions, and in an effort to mitigate losses, the plans may erect access barriers that make their plans less attractive to Part D enrollees with health conditions with less favorable risk scores. Specifically, as the Part D risk adjustment model fails to adequately cover plan liabilities for certain higher cost conditions, plans may have perverse incentives to design plans with coverage, tiering, or UM rules that that discourage enrollment of certain beneficiaries with these health conditions, including through narrower formularies or increased utilization management.[74] As a result, without significant updates to restore the accuracy of the model, it may happen that only the most enhanced plans continue to cover certain products associated with these high cost beneficiaries. Such a result would require these higher-cost, sicker Part D beneficiaries to pay higher premiums for enhanced plans in the future.

In addition, subpopulations of beneficiaries are chronically underpredicted by today's RxHCC model, making them less attractive (and less profitable) from the perspective of the health plan. An actuarial analysis by Milliman shows that underpredicted higher-cost subpopulations include LIS beneficiaries, as well as non-elderly and disabled Medicare populations (those under 65).[75] While these subpopulations are higher-cost today, the degree to which the current RxHCC model underpredicts plan liability for LIS and non-elderly Medicare populations increases dramatically in 2025 and beyond, which will make them even less attractive enrollees in the plan as redesign takes effect.

[74] Avalere Health. Risk Adjustment under Part D Benefit Redesign. Feb 27, 2023. Found at: https://avalere.com/insights/risk-adjustment-under-part-d-benefit-redesign#:~:text=Avalere%20projects%20that%20the%20NAMBA,value%20than%20it%20does%20today.

[75] Milliman. Medicare Part D risk and claim cost changes with the Inflation Reduction Act. Jan. 18, 2023. https://us.milliman.com/-/media/milliman/pdfs/2023-articles/1-18-23_part-d-risk-ira-article.ashx

CMS must approach the updates of the RxHCC model with the patient in mind, noting the direct link between the accuracy of the model and the overarching goal of protecting patient access to medicines in Part D. It is imperative that the model reflects the current program and also adequately compensates for the costs of the sickest Medicare beneficiaries. Any risk adjustment model used in Part D should, at a minimum, reflect new benefit parameters, account for changing plan liability, and correct for the largest gaps in predicted versus actual plan costs in certain therapeutic areas. Without such substantive updates, plans may face incentives to narrow formularies or restrict coverage in ways that disincent enrollment of the sickest and highest cost beneficiaries who most need care.

VII. CMS' CONTINUED USE OF HPMS FOR SOLICITATION OF FEEDBACK

Changes in the IRA related to redesign and associated policies in the Medicare Part D program are complex and have far reaching implications for all Part D stakeholders, including patients, caregivers, providers, health insurance plans, prescription drug manufacturers, and others. We note that CMS' continued use of the HPMS distribution list to call for input in these areas is not the usual way that the Agency seeks comment and input on Part D policy and programmatic changes. Thus, many stakeholders of the Part D program who are not health and drug plans, plan consultants, or pharmaceutical manufacturers that routinely use the HPMS system[76] may be unaware of this current opportunity to provide input.

In order to ensure robust engagement from all Part D stakeholders, the Agency should not limit stakeholder feedback requests to the HPMS system, but instead employ more traditional methods of soliciting comment and feedback that coincide with publication in the *Federal Register*, which is the notice of public record.[77]

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PhRMA appreciates the opportunity to provide feedback on CY 2025 Part D Redesign and other related issues.

Please feel free to contact Rebecca Jones Hunt at 202-835-3400 if we can provide any further information or if you have any questions about the topics discussed in our comments. We are happy to discuss these comments and provide any further details or supplemental materials that you may request.

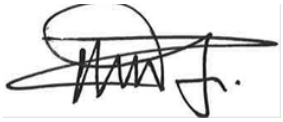
Sincerely,

[76] https://hpms.cms.gov/app/ng/home/
[77] 44 U.S.C. 1507 (publication in the Federal Register is constructive notice).

Rebecca Jones Hunt
Deputy Vice President, Policy & Research

/s/

Judy Haron
Deputy Vice President, Law



Meiti Negari
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Appendix A: Part D Beneficiary with $2,000 in Monthly OOP Costs Starting in January

The Part D beneficiary in this example is taking a higher cost medicine that reaches the maximum out of pocket (OOP) limit on the first fill. Under the IRA, this beneficiary would continue to fill their prescription, but incur no additional OOP costs in subsequent months of the year, however still face a monthly smoothing obligation as the $2,000 in total OOP costs are spread over the year.

Methodology: Calculations are rounded to the nearest dollar. Calculations assume no prior cost sharing contributed toward TROOP and implementation where month of incurred costs count toward "months remaining in the plan year." First month payment calculation from statute = $2,000 – costs incurred[78]/remaining months of the plan year.

Month	Months Remaining	Costs Remaining from Prior Months	Costs Incurred in Month	Smoothing Payment
January	12	-	$2,000 (OOP Cap)	**$167**
February	11	$1,818	$2,000	**$167**
March	10	$1,636	$2,000	**$167**
April	9	$1,455	$2,000	**$167**
May	8	$1,273	$2,000	**$167**
June	7	$1,091	$2,000	**$167**
July	6	$909	$2,000	**$167**
August	5	$727	$2,000	**$167**
September	4	$545	$2,000	**$167**
October	3	$364	$2,000	**$167**
November	2	$181	$2,000	**$167**
December	1	$0	$2,000	**$167**

[78] The statutory formula provides that for the first month, the maximum monthly cost is determined by calculating "the annual out-of-pocket threshold . . . minus the incurred costs of the enrollee as described in paragraph (4)(C)," divided by months remaining in the plan year. SSA 1860D-2(b)(1)(E)(iv)(I). Because the costs described in paragraph (4)(C) generally refer to "TrOOP," and because the $2,000 will be smoothed over the course of the year, no costs are deducted in the first month of smoothing.

Appendix B: Part D Beneficiary with $400 in Monthly OOP Costs for Several Months, Starting in January

The Part D beneficiary in this example is taking a higher cost medicine for several months of the year, with sufficient OOP costs to reach the maximum out of pocket limit in May. In the later months of the year, the beneficiary has ceased therapy and incurs no additional medicine costs, however still has a monthly smoothing obligation that continues for the remaining months of the year.

Methodology: Calculations are rounded to the nearest dollar. Calculations assume no prior cost sharing contributed towards TROOP and implementation where month of incurred costs count toward "months remaining in the plan year." First month payment calculation from statute = $2,000 – costs incurred[79]/remaining months of the plan year.

Month	Months Remaining	Costs Remaining from Prior Months	Costs Incurred in Month	Smoothing Payment
January	12	-	$400	**$167**
February	11	$233	$400	**$58**
March	10	$575	$400	**$98**
April	9	$878	$400	**$142**
May	8	$1,136	$400 (OOP Cap)	**$192**
June	7	$1,344	$0 (Cease Therapy)	**$192**
July	6	$1,152	$0	**$192**
August	5	$960	$0	**$192**
September	4	$768	$0	**$192**
October	3	$576	$0	**$192**
November	2	$384	$0	**$192**
December	1	$192	$0	**$192**

[79] See prior footnote – only costs that would count toward TrOOP are deducted to calculate the first month maximum cap. As $400 will be smoothed over the course of the year, it is not deducted from the $2,000 maximum out-of-pocket limit in calculating the smoothing payment for January.

Appendix C: Part D Beneficiary with $150 in Monthly OOP Costs from January to April and $250 in Monthly OOP Costs from September to December ($1,600 in Annual Cost Sharing)

The Part D beneficiary in this example consistently takes their medication from January to April but discontinues use of that medication in May. In September, the beneficiary is prescribed a new monthly medication for the remainder of the year, with total OOP costs from both medicines reaching $1,600 in this year. Under the statutory smoothing calculation, the enrollee has lower, more consistent payments in the beginning of the year and an ongoing smoothing obligation for May- August despite having no incurred OOP costs these months. When the beneficiary begins taking a new medication later in the year, it results in significantly larger, inconsistent smoothing payments.

Methodology: Calculations are rounded to the nearest dollar. Calculations assume no prior cost sharing contributed towards TROOP and implementation where month of incurred costs count toward "months remaining in the plan year." First month payment calculation from statute = $2,000 – costs incurred/remaining months of the plan year.

Month	Months Remaining	Costs Remaining from Prior Months	Costs Incurred in Month	Smoothing Payment
January	12	-	$150	**$167**
February	11	$(17)	$150	**$12**
March	10	$121	$150	**$27**
April	9	$244	$150	**$44**
May	8	$350	$0 (Cease Therapy)	**$44**
June	7	$306	$0	**$44**
July	6	$263	$0	**$44**
August	5	$219	$0	**$44**
September	4	$175	$250 (Start New Therapy)	**$106**
October	3	$319	$250	**$190**
November	2	$379	$250	**$315**
December	1	$315	$250	**$565**

Appendix D: Part D Beneficiary with $125 in Monthly OOP Costs Starting in January ($1,500 in Total Annual Cost Sharing)
The Part D beneficiary in this example consistently takes prescription medicines totaling $125 in monthly cost sharing, with total annual OOP costs reaching $1,500. If the beneficiary does not elect smoothing, they would pay $125/month in cost sharing. If the beneficiary does elect smoothing, the statutory smoothing calculation results in smaller OOP costs in the early months of the year, however smoothing obligations would exceed monthly incurred costs for the medicine at the end of the year.

Methodology: Calculations are rounded to the nearest dollar. Calculations assume no prior cost sharing contributed towards TROOP and where month of incurred costs count toward "months remaining in the plan year." First month payment calculation from statute = $2,000 – costs incurred/remaining months of the plan year.

Month	Months Remaining	Costs Remaining from Prior Months	Costs Incurred in Month	Smoothing Payment
January	12	-	$125	**$167**
February	11	$(42)	$125	**$8**
March	10	$75	$125	**$20**
April	9	$180	$125	**$34**
May	8	$271	$125	**$50**
June	7	$347	$125	**$67**
July	6	$405	$125	**$88**
August	5	$441	$125	**$113**
September	4	$453	$125	**$145**
October	3	$434	$125	**$186**
November	2	$372	$125	**$249**
December	1	$249	$125	**$374**

Appendix E: Impact of Different Interpretations of the IRA Statutory Smoothing Calculations

Based on PhRMA's understanding of the calculation, as written in the statute, the "number of months remaining in the plan year" component of the formula could be interpreted in two distinct ways:

- Option 1: The current month of the plan year **would count towards** the remaining months in the plan year; or
- Option 2: The current month of the plan year **would not be counted towards** the remaining months in the plan year

The Part D beneficiary starts taking a medication with $2,000 in monthly cost-sharing starting in August that triggers the maximum OOP limit on the first fill. This example demonstrates how the OOP exposure of the beneficiary changes based on the different interpretations of the language "number of remaining months in the plan year." There is a $100 difference in the enrollee's monthly smoothing payment between the two options/statutory interpretations.

Month	Costs Incurred in Month	"Months Remaining" Under Option 1	Smoothing Payment Under Option 1	"Months Remaining" Under Option 2	Smoothing Payment Under Option 2
January	$0	12	**$0**	11	**$0**
February	$0	11	**$0**	10	**$0**
March	$0	10	**$0**	9	**$0**
April	$0	9	**$0**	8	**$0**
May	$0	8	**$0**	7	**$0**
June	$0	7	**$0**	6	**$0**
July	$0	6	**$0**	5	**$0**
August	$2,000(OOP Cap)	5	**$400**	4	**$500**
September	$2,000	4	**$400**	3	**$500**
October	$2,000	3	**$400**	2	**$500**
November	$2,000	2	**$400**	1	**$500**
December	$2,000	1	**$400**	0	**$0**