MILLIMAN REPORT

Medicare Part D Pharmacy Price Concessions at the Point of Sale

Potential Impacts on Stakeholder Costs

Commissioned by the Pharmaceutical Care Management Association (PCMA)

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Executive Summary

BACKGROUND

Under the current Part D structure, plan sponsors may negotiate point of sale (POS) and post-POS price concessions with pharmacies. POS price concessions, such as discounts off average wholesale price (AWP), reduce the drug cost at the pharmacy counter. Post-POS price concessions are based on metrics that cannot be reasonably determined at the POS and are reported to the Centers for Medicare and Medicaid Services (CMS) as direct and indirect remuneration (DIR).[1,2]

Pharmacy DIR is often tied to preferred network participation and structured as performance-based arrangements between pharmacies and plan sponsors. In 2022, approximately 98% of standalone Prescription Drug Plans (PDPs) and 66% of Medicare Advantage Prescription Drug plans (MA-PDs) have a preferred network arrangement.[3]

On January 6, 2022, CMS and the Department of Health and Human Services (HHS) issued a proposed rule that would require pharmacy DIR to be reflected in the negotiated price used at the POS for most drugs. The negotiated price would be based on the "lowest possible reimbursement" the pharmacy could receive from the plan sponsor.[4,5] If finalized, this policy would be effective beginning January 1, 2023. No changes to the treatment of pharmaceutical manufacturer rebates have been proposed for 2023 Medicare Part D bids.

KEY FINDINGS

The Pharmaceutical Care Management Association (PCMA) requested we estimate the ten-year (2023 to 2032) financial impact of reflecting pharmacy DIR at the POS to key stakeholders in the Medicare Part D individual market. Typically, pharmacy DIR is applied as post-POS price concessions. Our modeling reflects shifting these post-POS price concessions to the POS.

- On average across all beneficiaries, this proposed policy could reduce cost sharing and increase premiums. We estimate the cost sharing reduction would outweigh the premium increase for beneficiaries in aggregate. For individual beneficiaries, net impacts will vary by income, health status, plan choice, pharmacy choice, drug use, benefit design, and other factors.
    - We estimate approximately two-thirds of beneficiaries would experience minimal change or a net increase (premium increases outweigh cost sharing savings) to their overall costs.
    - Many of the remaining one-third of beneficiaries may realize a net decrease (cost sharing savings outweigh premium increases), while some will experience a net increase depending on the factors above.
- This change may increase overall federal government costs between 2% and 5% over 10 years. This increase is primarily driven by increases to the risk-adjusted direct subsidy.
- This change could reduce pharmaceutical manufacturer coverage gap discount program (CGDP) payments between 7% and 11% as fewer beneficiaries reach the coverage gap phase and payments are based on lower POS costs.

We assumed contracts would be structured such that current DIR levels would be reflected in the new negotiated price and otherwise assumed no behavioral changes. We expect stakeholders may change behaviors in response to the rule if finalized, which could result in material changes to our estimated stakeholder impacts.

It is possible that overall price concessions could increase or decrease with this proposed rule as stakeholders change their behavior. If overall price concessions decrease, our estimated total program costs could increase, and any estimated

[1] CMS (April 28, 2021). Final Medicare Part D DIR Reporting Guidance for 2020. Retrieved January, 26, 2022, from: https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/2020_DIR_Reporting_Guidance_Memo.pdf

[2] Bell, Deana and Margiott, Tracy (January 2018). Medicare Part D DIR: Direct and Indirect Remuneration Explained. Retrieved February 8, 2022, from: https://www.milliman.com/en/insight/medicare-part-d-dir-direct-and-indirect-remuneration-explained

[3] Drug Channels (November 2, 2021). Consolidation and Preferred Pharmacy Networks in 2022's Medicare Part D Plans: Cigna, CVS Health, Humana, UnitedHealthcare, WellCare, and More. Retrieved January 26, 2022, from https://www.drugchannels.net/2021/11/consolidation-and-preferred-pharmacy.html

[4] CMS (January 12, 2022). Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs. Retrieved January 24, 2022, from: https://www.federalregister.gov/documents/2022/01/12/2022-00117/medicare-program-contract-year-2023-policy-and-technical-changes-to-the-medicare-advantage-and

[5] This would not necessarily apply to applicable drugs in the coverage gap phase. For applicable drugs in the coverage gap phase, plans could determine the proportion of price concessions applied at the POS relative to post-POS.

stakeholder savings could be reduced. If overall price concessions increase, our estimated total program costs could decrease, and any estimated stakeholder savings could be increased. We do not opine on the likelihood of any particular change or behavioral response occurring in the future.

ESTIMATED FINANCIAL IMPACT

Figure 1 illustrates the estimated financial impact from 2023 through 2032 of reflecting pharmacy DIR at the POS. Impacts are shown as a range based on two different modeling approaches for applying DIR at the POS. These approaches are described in more detail below.

FIGURE 1: ESTIMATED TEN-YEAR (2023-2032) FINANCIAL IMPACT OF REFLECTING PHARMACY DIR AT POS FOR THE INDIVIDUAL PART D MARKET

	BENEFICIARY PREMIUM	BENEFICIARY COST SHARING	FEDERAL GOVERNMENT	PHARMACEUTICAL MANUFACTURER CGDP
Dollar Change (Billions)	$11.6 - $21.7	($19.7) - ($71.4)	$25.4 - $60.7	($11.0) - ($17.2)
Percent Change	6% - 11%	(5%) - (19%)	2% - 5%	(7%) - (11%)

Impacts are relative to a baseline scenario in which pharmacy DIR is applied after the POS. Appendix I includes baseline values.
Beneficiary premium excludes the low income premium subsidy (LIPS), and beneficiary cost sharing excludes the low income cost sharing subsidy (LICS).
The federal government impact includes the risk-adjusted direct subsidy, federal reinsurance, LIPS, and LICS.
The individual Medicare Part D market includes PDPs and MA-PDs and excludes Employer Group Waiver Plans (EGWPs).
This modeling reflects the defined standard benefit design.
Lower bound and upper bound of ranges for each stakeholder do not necessarily align with the same approach for applying DIR at the POS.

The Figure 1 stakeholder cost estimates reflect the following:

- **Beneficiary.** The overall beneficiary impact is the sum of the beneficiary premium and cost sharing components. Beneficiary premium excludes the low income premium subsidy (LIPS), and beneficiary cost sharing excludes the low income cost sharing subsidy (LICS). These are subsidies paid by the federal government for low income (LI) beneficiaries and are included as federal government costs.
- **Federal government.** The federal government impact includes the risk-adjusted direct subsidy, federal reinsurance, LIPS, and LICS. The direct subsidy is a risk-adjusted payment from CMS to plan sponsors to cover the portion of a plan sponsor's costs related to the defined standard benefit. The federal government covers 80% of allowed costs in the catastrophic phase of the Part D benefit through federal reinsurance, reduced for a portion of post-POS price concessions that the plan sponsor collects on all drugs.
- **Pharmaceutical manufacturer CGDP.** The pharmaceutical manufacturer CGDP covers 70% of the cost of applicable drugs in the coverage gap phase of the Part D benefit for non-low income (NLI) beneficiaries.

Beneficiaries, the federal government, and pharmaceutical manufacturers (manufacturers) through the CGDP fund the Medicare Part D program. This report estimates the financial impact to these stakeholders specifically. There are other entities that do not directly fund the program that may be affected by potential program changes, including plan sponsors, pharmacy benefit managers (PBMs), wholesalers, pharmacies, and manufacturers through items other than the CGDP.

The estimates in Figure 1 reflect the overall estimated cost or savings for the entire individual Part D market. Market-wide costs or savings do not imply most beneficiaries would realize that impact. The financial impact for a particular beneficiary may differ from the overall impact shown above. The effects on beneficiaries with different characteristics are described in the next section of this report.

The results of this analysis may change if stakeholders or other entities change their behavior. We do not opine on the likelihood of any particular change or behavioral response occurring in the future.

Appendix I provides additional detail on the estimated impact for each cost component for Part D stakeholders.

Stakeholder Impacts and Considerations

Pharmacy DIR is currently applied as post-POS price concessions, meaning the DIR amounts are paid after drugs have been dispensed. This modeling instead reflects the use of pharmacy price concessions to directly reduce drug costs at the

POS. CMS' stated reasons for the proposed change include reduced beneficiary out-of-pocket costs and increased drug pricing transparency and market competition in Part D.[6]

To estimate the impact of reflecting pharmacy DIR at the POS, we modeled replacing post-POS pharmacy DIR, including DIR for applicable coverage gap scripts, with equivalent POS price concessions. Plan sponsors contract pharmacy DIR on different bases. We used two different approaches for modeling pharmacy DIR:

- **POS DIR applied per script**. Pharmacy DIR is applied as a fixed per script dollar amount across all drug types (generic, brand, and specialty).[7] This results in a greater assumed percentage reduction in cost per script for generics compared to brand and specialty drugs.
- **POS DIR applied as a percent of allowed cost**. Pharmacy DIR is applied as the same percent of allowed cost across all drug types (generic, brand, and specialty). This results in a greater assumed absolute reduction in cost per script for brand and specialty drugs compared to applying POS DIR per script.

These modeling approaches are meant to represent a range of impacts for reflecting pharmacy DIR at the POS that accounts for the actual mix of contracting bases. A given plan sponsor may use both approaches at different pharmacies, and/or contract different DIR amounts for generic, brand, and specialty drugs. There are other ways in which plan sponsors contract pharmacy DIR, and these approaches could impact the results of this analysis.

CMS' proposed rule would require the negotiated price used at the POS to be based on the "lowest possible reimbursement" the pharmacy could receive from the plan sponsor. That is, all possible pharmacy DIR that could be paid by the pharmacy would be reflected in the POS price. The proposed rule would still allow for pharmacy incentive payments from plan sponsors to pharmacies (i.e., negative pharmacy DIR) after the POS, although we expect most plan sponsors would not have negative DIR.[8] Our modeling assumes DIR contracts would be restructured to reflect current DIR levels as the lowest possible reimbursement with no negative DIR.

STAKEHOLDER IMPACTS

In Medicare Part D, DIR paid after the POS is typically used by plan sponsors to reduce beneficiary premiums and government subsidies (including federal reinsurance, LIPS, and the direct subsidy) as a result of reduced plan liability. While post-POS DIR is sometimes also used by plan sponsors to enhance benefits, it does not typically directly reduce a beneficiary's drug cost at the POS.

Unlike post-POS price concessions, DIR reflected at the POS would be shared among all stakeholders paying a portion of POS drug costs. This includes beneficiaries through cost sharing, the federal government through federal reinsurance and the LICS, and manufacturers through the CGDP. Any remaining drug costs (plus any non-benefit expenses and profit margin) are reflected in the plan sponsor's claim liability and are ultimately funded through the direct subsidy, LIPS, and beneficiary premium.

- **Beneficiaries.** We estimate reflecting pharmacy DIR at the POS would increase premiums on average across all beneficiaries. Individual beneficiaries would experience an increase or decrease in premium, depending on the plan in which they are enrolled. We estimate reflecting pharmacy DIR at the POS would decrease cost sharing for certain beneficiaries, and in aggregate, the cost sharing savings would outweigh the beneficiary premium increase. Figure 2 includes additional detail on how beneficiaries may be financially impacted if pharmacy DIR was reflected at the POS.
    - We estimate that approximately one-third of Part D beneficiaries are considered LI and would experience a small or no financial impact if pharmacy DIR were reflected at the POS. We expect full subsidy eligible LI beneficiaries to experience little impact because most of their premium and cost sharing is subsidized through LIPS and LICS. We estimate the majority (>97%) of LI beneficiaries are full subsidy eligible.[9]

[6] CMS (January 6, 2022). CY 2023 Medicare Advantage and Part D Proposed Rule (CMS-4192-P). Retrieved January 25, 2022, from https://www.cms.gov/newsroom/fact-sheets/cy-2023-medicare-advantage-and-part-d-proposed-rule-cms-4192-p

[7] Our modeling categorizes drugs as applicable and non-applicable. Applicable drugs are typically brands and are subject to the CGDP. Non-applicable drugs are typically generics and do not apply to the CGDP.

[8] Positive pharmacy DIR at the POS is the most likely outcome of the proposed rule and thus, we did not model any negative pharmacy DIR scenarios for this analysis.

[9] CMS (August 31, 2021). 2021 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Insurance Trust Funds. Retrieved February 1, 2022, from https://www.cms.gov/files/document/2021-medicare-trustees-report.pdf

- We estimate that approximately one-third of beneficiaries may experience a net increase in their overall costs if pharmacy DIR were reflected at the POS. These are beneficiaries who are NLI and either have no drug claims or end the year in the deductible phase of the Part D benefit. For these beneficiaries, we estimate premium increases typically outweigh potential cost sharing reductions.
- The remaining approximately one-third of beneficiaries are NLI and end the year with claims above the deductible. The estimated net impact on NLI beneficiaries that end the year with claims above the deductible is sensitive to the way in which pharmacy DIR is contracted and the beneficiary's characteristics. Some of these beneficiaries will experience overall higher costs (premium increases outweigh cost sharing savings) and some will experience lower overall costs (cost sharing savings outweigh premium increases).
  - If pharmacy DIR is contracted on a per script basis across all scripts, we estimate most of the one-third of NLI beneficiaries that end the year with claims above the deductible may experience lower overall costs (cost sharing savings outweigh premium increases).
  - If pharmacy DIR is contracted as a percentage of allowed cost, we estimate the majority of the one-third of NLI beneficiaries that end the year with claims above the deductible may experience higher overall costs (premium increases outweigh cost sharing savings).

FIGURE 2: ESTIMATED BENEFICIARY FINANCIAL IMPACT OF REFLECTING PHARMACY DIR AT THE POS FOR THE INDIVIDUAL PART D MARKET

BENEFICIARY CATEGORIZATION	PERCENTAGE OF BENEFICIARIES[1]	ESTIMATED FINANCIAL IMPACT OF REFLECTING PHARMACY DIR AT THE POS
Low Income	33%	Small or no effect on premiums and cost sharing
Non-low income, end year with no claims or in deductible phase	35%	Typically experience net increase in costs (potential premium increases typically outweigh potential cost sharing reductions)[2]
Non-low income, end year above deductible phase	32%	Could experience net increase or decrease in costs[3] • If pharmacy DIR is contracted on a per script basis, NLI beneficiaries who end the year in the initial coverage limit (ICL) or coverage gap phases (29%) may typically experience lower overall costs, and NLI beneficiaries who end the year in the catastrophic phase (3%) may typically experience higher overall costs • If pharmacy DIR is contracted as a percentage of allowed cost, NLI beneficiaries who end the year in the coverage gap or catastrophic phases (10%) may typically experience lower overall costs, and NLI beneficiaries who end the year in the ICL phase (22%) may typically experience higher overall costs.

[1] Projected 2023 baseline scenario in which pharmacy DIR is applied after the POS.
[2] The impact to plan premium depends on the current level of pharmacy DIR. Plans with little or no pharmacy DIR may experience premium decreases.
[3] Percentages are of total individual Part D market (i.e., additive to the 32% who are NLI and end the year above the deductible phase)

The potential cost or savings for each beneficiary will vary based on an individual's income, health status, drug use, benefit design, pharmacy choice, plan choice, how the beneficiary's plan contracts pharmacy DIR, and other factors. For example:

- Benefit Design. Beneficiaries taking drugs subject to coinsurance (as opposed to fixed dollar copays) could realize savings when reflecting pharmacy DIR at the POS, because their cost sharing could be based on a lower POS cost. Beneficiaries taking drugs with fixed dollar copays could realize an increase in premium without realizing a decrease in cost sharing. Both copays and coinsurance amounts could change if plan sponsors need to adjust benefits to meet actuarial equivalence requirements.
- Pharmacies. Beneficiaries that fill drugs that are not subject to pharmacy DIR could see an increase to premium without the benefit of lower cost sharing. For plans with pharmacy DIR arrangements,

beneficiary cost sharing at non-DIR participating pharmacies could be reduced if the plan sponsor needs to adjust benefits to meet actuarial equivalence requirements. The magnitude of DIR often varies for different pharmacies in the same plan. Potential cost sharing savings could vary for beneficiaries in the same plan using the same drug but shopping at a different pharmacy.

- DIR amount. The impact to beneficiary premium may vary with the level of pharmacy DIR by plan. For a plan with no pharmacy DIR in place today, premiums may decrease as the plan will experience no change to the negotiated price but will benefit from an increase in the direct subsidy. Pharmacy DIR is less common among MA-PDs than PDPs.
- Part D plan type. Beneficiaries enrolled in MA-PDs with $0 Part D premiums may realize Part D savings if their cost sharing is reduced and the plan's Part D premium is kept at $0. In 2021, 65% of MA-PD beneficiaries were enrolled in $0 Part D premium plans.[10] MA-PDs may have flexibility to adjust medical benefits in lieu of Part D premium changes. This report does not consider how or if MA-PDs would maintain these $0 Part D premium plans under this proposal.

Figure 3 in Appendix I includes additional detail on the distribution of beneficiaries by phase and income level.

- **Federal government.** We estimate reflecting pharmacy DIR at the POS could increase federal government costs by approximately 2% to 5% over ten years compared to the current environment. This is driven primarily by estimated increases in the risk-adjusted direct subsidy as the plan sponsor covers a greater proportion of the claim costs. LIPS also increases, but to a lesser extent. These increases are partially offset by a decrease in LICS.

  The impact on federal reinsurance is sensitive to the way in which pharmacy DIR is applied in our modeling. There are three key factors that affect federal reinsurance when pharmacy DIR is reflected at the POS:

  1. Reinsurance *decreases* because the 80% catastrophic coverage is applied to a lower POS cost.
  2. Reinsurance *decreases* because fewer beneficiaries may reach the catastrophic phase due to the lower POS costs in other benefit phases.
  3. Reinsurance *increases* because it is no longer reduced for DIR that was previously shared with the federal reinsurance program.

  If POS DIR is applied as a fixed per script dollar amount across all drug types, we estimate that federal reinsurance could increase as the reduction in the portion of DIR shared with the federal reinsurance program (item 3) outweighs the effects of lower POS costs and fewer beneficiaries reaching the catastrophic phase (items 1 and 2).

  If POS DIR is applied as the same percent of allowed cost across all drug types, we estimate that federal reinsurance could decrease due to lower POS costs and fewer beneficiaries reaching the catastrophic phase (items 1 and 2), which outweighs the reduction in pharmacy DIR shared with the government (item 3). In practice, a combination of these DIR contract types exist, so the impact to federal reinsurance likely lies between these two results.

- **Pharmaceutical manufacturer CGDP.** We estimate manufacturer CGDP payments would decrease when reflecting pharmacy DIR at the POS, because the CGDP could be determined based on a lower POS cost and we project that fewer beneficiaries would reach the coverage gap phase of the Part D benefit due to the lower POS costs in other benefit phases.

KEY CONSIDERATIONS

- **Pharmacy DIR in the coverage gap.** Under the proposed rule, plan sponsors will have the flexibility to determine how much pharmacy DIR to reflect at the POS for applicable drugs in the coverage gap phase. This would create a second definition of "negotiated price" specific to applicable drugs in the coverage gap and may pose additional operational complexity. Plan sponsors will need technical direction from CMS for how to account for this in bid development if they choose to exercise this flexibility.

[10] Henry J Kaiser Family Foundation (November 2, 2021). Medicare Part D: A First Look at Medicare Prescription Drug Plans in 2022. Retrieved January 25, 2022, from: https://www.kff.org/medicare/issue-brief/medicare-part-d-a-first-look-at-medicare-prescription-drug-plans-in-2022/

For applicable coverage gap scripts, we reflected all pharmacy DIR at the POS in our modeling. Applying some or no DIR at the POS (i.e., keeping post-POS pharmacy DIR for applicable scripts in the coverage gap) may change our estimated stakeholder impacts. Manufacturer and federal government impacts may be reduced if plans reflect less or no pharmacy DIR at the POS for applicable scripts in the coverage gap.

Plan sponsors who choose to reflect some or no DIR at the POS for applicable drugs in the coverage gap may be able to attain a more competitive bid position relative to plans that reflect all pharmacy DIR at the POS for applicable drugs in the coverage gap. The amount of DIR plan sponsors choose to reflect at the POS for applicable drugs in the coverage gap may impact premium levels for beneficiaries.

- **Preferred network disruption.** Pharmacy DIR is often tied to preferred network participation.[11] The emergence of preferred pharmacy networks reduced Part D program costs, including federal government costs and beneficiary premiums, and provided beneficiaries access to reduced cost sharing at preferred pharmacies.[12]

  The elimination of DIR payments from pharmacies to plan sponsors could erode the value of preferred networks. When reflecting pharmacy DIR at the POS, preferred network arrangements might be based on discount differentials alone. Relative to DIR payments, discount differentials are less impactful on premiums. This could result in reduced cost sharing differentials between preferred and non-preferred pharmacies, though beneficiaries may still have reduced cost sharing through reduced POS drug costs. Given this, some plan sponsors may decide to no longer offer preferred network arrangements.

  Disruption to preferred pharmacy networks could also lead to reduced revenue for some pharmacies. In the current environment, participating pharmacies benefit from some beneficiaries purchasing non-pharmacy (and in many cases, higher margin) retail items when they fill prescriptions. Without (or with reduced) preferred pharmacy cost sharing differentials, utilization may shift to non-preferred pharmacies and preferred pharmacies may lose foot traffic from Part D beneficiaries. On the other hand, other pharmacies (i.e., those in fewer preferred networks currently) may benefit from increased sales if beneficiaries move their prescriptions and make retail purchases at new locations.

- **Pharmacy cash flow.** Most pharmacy DIR arrangements are currently structured such that the pharmacy is paid the full POS drug price when a drug is dispensed, and the pharmacy potentially reimburses the plan sponsor for a portion of the drug cost in a settlement after the POS. From a cash flow perspective, pharmacies may benefit from this arrangement. This is because there may be an opportunity to collect investment income on the float between the upfront POS reimbursement and the drug expense. With pharmacy DIR at the POS, the lower POS price could reduce this float, thus reducing this potential cash flow opportunity. However, having all pharmacy reimbursement occur at the POS could reduce uncertainty about the timing and amount of cash flow.

- **Operational challenges.** It may be difficult to structure POS price concessions such that the resulting net pharmacy reimbursement remains unchanged from that with the current DIR approach. When reflecting pharmacy DIR at the POS, we assume pharmacies experience revenue neutrality. If pharmacies are not revenue neutral, POS price concessions could result in higher or lower pharmacy reimbursement than in the current environment.

- **Pharmacy DIR contracting basis.** The potential impact of reflecting pharmacy DIR at the POS will vary by plan based on how DIR is contracted and applied at the POS. Different contracting approaches could change how stakeholders are affected. For example, we estimate that if pharmacy DIR were applied as a fixed per script dollar amount across all drug types, federal reinsurance could increase. However, we estimate that if POS DIR were applied as the same percent of allowed cost across all drug types, federal reinsurance could decrease. Changes in the treatment of pharmacy DIR could cause pharmacies and plan sponsors to restructure their current DIR contracts.

- **Competitive bid positioning.** Some plans do not have pharmacy DIR arrangements, and thus would not have changes to POS costs, but would benefit from the increase in direct subsidy revenue. These plans would be expected to have a decrease in member premiums and improved competitive bid positioning relative to plans collecting pharmacy DIR currently. A similar dynamic would apply to plans with lower-than-average pharmacy DIR

[11] Plans may also collect DIR from standard network pharmacies.

[12] Kaczmarek, S., Sheldon, A., Liner, D. (October 2013). The Impact of Preferred Pharmacy Networks on Federal Medicare Part D Costs, 2014-2023. Retrieved February 8, 2022, from: https://www.spcma.org/wp-content/uploads/2016/06/Milliman_Preferred_Pharmacy_Networks.pdf

amounts. MA-PDs may benefit from reflecting pharmacy DIR at the POS more than PDPs given that MA-PD pharmacy DIR is typically lower than that for PDPs.

- **Cost mitigation.** Due to the competitive nature of the Part D program, plan sponsors may look for new ways to mitigate the potential upward pressure on bids. This could include attempting to negotiate deeper discounts or DIR with pharmacies, attempting to negotiate increased DIR with manufacturers, or looking for ways to improve administrative efficiencies, among other strategies. Any attempt to negotiate deeper contracting terms would depend on the manufacturers' and pharmacies' willingness to negotiate. For MA-PD plan sponsors, there may be more emphasis on Part D quality metric reporting and adherence, as these items impact a MA-PD sponsors' star rating and revenue.
- **Beneficiary disruption.** Part D beneficiaries have the option to choose a new plan each year. For many beneficiaries, premium is a key consideration when selecting a Part D plan. If the current pharmacy DIR structure changes, some plan sponsors may experience higher-than-average enrollment changes to the extent their plan premium, benefits, or preferred pharmacies change relative to other plans in the market. This may lead to greater disruption in the PDP space, as these types of plans typically compete based on premiums and tend to have higher DIR than MA-PDs. In addition, some LI beneficiaries are automatically enrolled in Part D plans based on premium levels. Greater-than-average premium changes could result in more LI beneficiaries changing plans to the extent that carriers are unable to project and/or achieve low income benchmarks. Switching plans can be disruptive to beneficiaries, as they may need to navigate new drug formularies, pharmacies, and cost sharing structures, for example.
- **Benefit parameters.** CMS may need to reevaluate the Part D benefit parameters, which could result in a reduction to the defined standard deductible, ICL, and true out-of-pocket (TrOOP) threshold for catastrophic coverage following the implementation of reflecting pharmacy DIR at the POS. Our analysis does not reflect the impact of potential changes to the Part D benefit parameters due to reflecting pharmacy DIR at the POS.
- **Drug adherence.** Reflecting pharmacy DIR at the POS reduces POS costs, which may reduce cost sharing for certain beneficiaries. With lower cost sharing, beneficiaries may increase drug utilization and adherence. Increased drug adherence may result in improved clinical outcomes and reduced medical costs. It could also lead to increased government outlays in Medicare Advantage if the adherence increases drive star rating improvements and higher bonus payments. Our analysis does not reflect the impact of increased adherence or other potential beneficiary behavioral changes.

Methodology

Modeling detail: Our analysis begins with a cost model calibrated to the 2022 market-wide national average bid results under a defined standard benefit design. The 2022 national average bid amount, national average member premium, and federal reinsurance are $38.18, $33.37, and $92.68, respectively. Milliman's manual Part D data is used as the pricing basis. The manual rates, adjustment factors, assumed demographics, and risk scores in the model are based on recent Part D claims experience from over 61 million member months across 34 U.S. regions and Puerto Rico. Our approach relies on separate LI and NLI claim probability distributions (CPDs) that provide allowed spend levels based on the average price by formulary tier (preferred generic, non-preferred generic, preferred brand, non-preferred brand, and specialty) and distribution method (retail and mail order). We weight together separate CPDs for MA-PDs and standalone PDPs. We did not account for any potential risk adjustment model changes resulting from these proposed changes. 2022 reflects the expected effect of the COVID-19 pandemic to the extent plan sponsors reflected this in their 2022 bids.

2023 to 2032 projection: We based our impact analysis on the estimated nationwide average individual Medicare Part D market for a ten-year projection period (2023 to 2032). To develop our 2023 to 2032 baseline projections, we trended the 2022 results using enrollment and trend projections developed from the 2021 Medicare Trustees Report and Milliman Part D cost and utilization trends.[13] The 2023 to 2032 baseline projections assume no additional adjustment for potential impacts of the COVID-19 pandemic. Ten-year estimates are on an undiscounted basis and do not reflect any time-value-of-money adjustments.

Enrollment: Our enrollment estimates reflect the individual Medicare Part D market, including standalone PDPs and MA-PDs, and excluding EGWPs. We used the 2021 Medicare Trustees Report to estimate nationwide individual Medicare Part D average enrollment by income status.

Trend: The pricing projections for years 2023 to 2032 reflect allowed cost trends based on the Part D per capita cost trend from page 149 of the 2021 Medicare Trustees Report. Trends for 2031 and 2032 were assumed to equal those for 2030. The projections are based on separate non-applicable, applicable, and specialty trends. We calibrated to the Medicare Trustees Report trends by scaling non-applicable, applicable, and specialty unit cost and utilization using Milliman's standard Part D 2022 trend assumptions. We assumed applicable cost, specialty cost, and specialty utilization would be the primary drivers of changes in future trends.

Contracting terms and non-benefit expenses: Discounts off average wholesale price (AWP), dispensing fees, margin, and administrative fees were based on an annual survey of Part D sponsors conducted by Milliman and are representative of a typical individual Part D plan.

Benefit parameters: 2022 benefit parameters reflect those in CMS' Announcement of Calendar Year (CY) 2022 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies. Benefit parameters for years 2023 to 2030 are based on the projections on page 210 of the 2021 Medicare Trustees Report. In line with the 2021 CMS Medicare Part D Rate Announcement, 2031 and 2032 benefit parameters were projected using the same trends in Part D expenditures used for allowed costs or the consumer pricing index (CPI). We assume the LIPS program subsidizes 95% of the average premium for LI beneficiaries.

DIR: The estimates in this analysis are sensitive to the assumed level of DIR. Different DIR assumptions could lead to different results. We estimated total 2022 DIR (including manufacturer DIR and pharmacy DIR) based on Milliman's annual survey of Part D sponsors. We modeled manufacturer rebates as a percent of applicable allowed cost, before adjusting for federal reinsurance. We assumed 2022 manufacturer rebates to be approximately 29.2% of applicable allowed cost. For 2023 to 2032, we assumed the same manufacturer rebate as a percent of applicable allowed cost as estimated for 2022. We assumed manufacturer DIR would continue to be reflected after the POS. We assumed 2022 pharmacy DIR to be approximately 8.5% of allowed cost. For 2023 to 2032, we assumed the same pharmacy DIR as a percent of allowed cost as estimated for 2022. This equates to approximately $11.07 per script in estimated pharmacy DIR across all scripts, including non-DIR eligible scripts, in 2022.

[13] CMS (August 31, 2021). 2021 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Insurance Trust Funds, ibid.

Appendix I: Beneficiary and Stakeholder Detail

Figure 3 shows the projected distribution of beneficiaries by income and cost sharing phase.

FIGURE 3: PROJECTED 2023 INDIVIDUAL PART D MARKET WITH POST-POS PHARMACY DIR AND DEFINED STANDARD BENEFIT DESIGN BENEFICIARY ENROLLMENT BY END-OF-YEAR PART D CLAIM PHASE AND INCOME STATUS (AS A % OF TOTAL ENROLLMENT)

PHASE	NLI	LI	TOTAL
$0 Claimants	5%	3%	8%
Deductible	30%	9%	39%
ICL	22%	10%	32%
Coverage Gap	7%	5%	12%
Catastrophic	3%	6%	9%
Total	**67%**	**33%**	**100%**

Figure 4 provides the estimated financial impact from 2023 through 2032 by stakeholder component. Federal government cost components include the risk-adjusted direct subsidy, federal reinsurance, LIPS, and LICS. The beneficiary impact is the sum of the beneficiary premium and cost sharing components, excluding LIPS and LICS. Manufacturers fund the CGDP.

FIGURE 4: ESTIMATED TEN-YEAR (2023-2032) FINANCIAL IMPACT OF PHARMACY DIR AT POS FOR THE INDIVIDUAL PART D MARKET

STAKEHOLDER COMPONENT	BASELINE (BILLIONS)	DOLLAR CHANGE FROM BASELINE (BILLIONS)	PERCENT CHANGE FROM BASELINE
Federal Government	**$1,349.5**	**$25.4 - $60.7**	**2% - 5%**
Risk-Adjusted Direct Subsidy	$14.3	$56.0 - $77.0	391% - 537%
Federal Reinsurance	$786.4	($28.0) - $35.9	(4%) - 5%
LIPS	$77.2	$4.7 - $8.9	6% - 11%
LICS	$471.5	($28.3) - ($40.0)	(6%) - (8%)
Beneficiaries	**$562.4**	**($8.2) - ($49.7)**	**(1%) - (9%)**
Premium	$188.9	$11.6 - $21.7	6% - 11%
Cost Sharing	$373.5	($19.7) - ($71.4)	(5%) - (19%)
Pharmaceutical Manufacturer CGDP	**$152.3**	**($11.0) - ($17.2)**	**(7%) - (11%)**

Totals may not tie exactly with the sum of components due to rounding.
Lower bound and upper bound of ranges do not necessarily align with the same approach for applying DIR at the POS.

Tables 17, 18, and 19 in the proposed rule include CMS' estimated ten-year (2023-2032) stakeholder impacts (billions) of reflecting pharmacy DIR at the POS with application to applicable drugs in the coverage gap. CMS' estimates by stakeholder component in billions generally fall within the ranges in Figure 4, with the exception of the risk-adjusted direct subsidy and manufacturer CGDP. CMS projects the risk-adjusted direct subsidy will increase by $97.6 billion and manufacturers will save $17.9 billion over ten years if pharmacy DIR were reflect at the POS. In addition, CMS projects federal reinsurance would decrease, while our modeling estimates that federal reinsurance could decrease or increase, depending on the way in which pharmacy DIR is contracted.[14]

It is unclear how CMS' estimates were developed. CMS states their estimates assume pharmacies will retain 2% of existing price concessions. This, along with other potential differences in assumptions and approach, may explain differences

[14] CMS (January 6, 2022). CY 2023 Medicare Advantage and Part D Proposed Rule (CMS-4192-P), ibid.

between estimates. Potential financial impacts for each stakeholder cost component are sensitive to many factors, including the way in which plan sponsors contract pharmacy DIR, which is not publicly available. Our estimated ranges are not intended to reflect upper or lower bounds on the possible financial impacts of reflecting pharmacy DIR at the POS.

Appendix II: Medicare Part D Background

Medicare Part D was enacted as part of the Medicare Modernization Act of 2003 and took effect on January 1, 2006. The voluntary prescription drug benefits are offered through private plan sponsors who contract with CMS to administer the benefit. Costs are partially subsidized for Medicare beneficiaries, who may choose between enrolling in an MA-PD or PDP. In 2021, more than 48 million people are enrolled in a Part D plan,[15] with about 50% enrolled in PDPs and the other 50% enrolled in MA-PDs.

Medicare Part D bids are highly regulated and are subject to a bidding process. The program is funded through government subsidies, beneficiary premiums, and manufacturers. Plan sponsors are risk-bearing intermediaries that sell and administer subsidized plans to beneficiaries; they are not a primary source of funding for the program. Potential gains and losses for plan sponsors are limited due to risk-sharing arrangements with CMS.

THE DEFINED STANDARD DRUG BENEFIT

The Part D benefit is divided into four distinct cost sharing phases: the deductible phase, initial coverage phase, coverage gap phase, and catastrophic phase. Beneficiaries accelerate through the phases based on distinct spending amounts. Each stakeholder's liability changes throughout the benefit year as the beneficiary moves through the four phases.

Part D plan sponsors may offer a defined standard Part D benefit, actuarially equivalent benefit, or an enhanced benefit plan. CMS updates the defined standard benefit parameters each year. The defined standard benefit is outlined with the latest 2022 parameters:

Deductible phase: In the deductible phase, the beneficiary is responsible for 100% of drug costs up to the deductible ($480). Drug cost is defined as negotiated drug price after POS discounts and prior to application of post-POS rebates.

Initial coverage phase: After the deductible is met, the beneficiary pays 25% of drug costs until $4,430 in total drug costs, the 2022 initial coverage limit (ICL), is reached. The plan sponsor pays the remaining 75% of drug costs in this phase.

Coverage gap phase: Claim liability in the coverage gap phase is shared between the beneficiary, plan sponsor, and manufacturers, and varies for applicable (typically brand) and non-applicable (typically generic) drugs. Beneficiary liability in the coverage gap was closed under the Affordable Care Act (ACA). In 2022, beneficiaries pay 25% of drug costs for both non-applicable and applicable drugs. For non-applicable drugs, plan sponsors pay the remaining 75%. For applicable drugs, plan sponsors pay 5%, and manufacturers pay the remaining 70%, referred to as the CGDP payment. LI beneficiaries eligible for cost sharing subsidies do not receive the CGDP payments because the federal government pays subsidies through all phases of the benefit.

Catastrophic phase: Beneficiaries reach the catastrophic phase when their annual out-of-pocket expenditures reach $7,050, the 2022 TrOOP. CGDP payments also contribute toward the TrOOP. In the catastrophic phase, the beneficiary pays approximately 5% of drug costs, the federal government subsidizes 80% of drug costs, and the plan sponsor pays the remaining cost (approximately 15%).

MEDICARE SUBSIDIES

The federal government subsidizes Part D program costs through the direct subsidy, federal reinsurance, LIPS, and LICS.

Direct subsidy: The direct subsidy is a risk-adjusted capitated payment meant to cover the plan sponsor's costs related to the defined standard benefit. The remaining portion of a plan sponsor's costs is covered through beneficiary premium.

Federal reinsurance: The 80% of drug cost covered by the government in the catastrophic phase is referred to as the federal reinsurance subsidy. The federal reinsurance subsidy is net of the full calendar year rebates (i.e., that is collected for all claims during the four coverage phases for a beneficiary). The amount of rebates attributed to federal reinsurance is proportional to federal reinsurance as a share of annual drug costs.

LI subsidies: CMS subsidizes costs for LI beneficiaries through LIPS and LICS payments. LI beneficiaries pay no (or a reduced) premium or deductible and have minimal copays.

RISK SHARING PROGRAMS WITH PLAN SPONSORS

In addition to federal reinsurance payments, the Medicare Part D program provides the following ways to mitigate financial

[15] Henry J Kaiser Family Foundation (November 2, 2021). Medicare Part D: A First Look at Medicare Prescription Drug Plans in 2022, ibid.

risk for Part D plan sponsors:

Risk corridor payments: Risk corridors limit the gains and losses of Part D plan sponsors when actual claims differ from expected claims filed in Part D bids. Based on specific thresholds, a plan sponsor pays CMS if plan claims experience is better than expected and CMS subsidizes the plan sponsor if claims experience is worse than expected. No payments are made if actual experience is within 5% of the target amount. The payments cover 50% of claims in the 5% to 10% corridor and 80% of claims in excess of the 10% threshold. Administrative costs and projected gain/loss margin are excluded from the risk corridor calculations.

CMS-RxHCC risk adjustment: The direct subsidy payments are risk-adjusted to reflect the health status of the enrolled beneficiaries using CMS' Hierarchical Condition Category (HCC) risk adjustment model. Less healthy individuals are designated by higher risk scores. By design, the risk adjustment mechanism pays plan sponsors more for less healthy beneficiaries. One important element of the risk adjustment process in Part D is that the risk score coefficients are developed using plan liability prior to DIR. If POS drug prices are adjusted to reflect pharmacy DIR, CMS will need to adjust the RxHCC model to re-align risk-adjusted direct subsidy payments.

Disclosures

Tracy Margiott and Tory Carver are actuaries for Milliman. We are members of the American Academy of Actuaries and meet the Qualification Standards of the American Academy of Actuaries to render this opinion. To the best of our knowledge and belief, this information is complete and accurate and has been prepared in accordance with generally recognized and accepted actuarial principles and practices.

This Milliman report has been prepared for the specific purpose of estimating the effect of potential Medicare Part D program changes on stakeholder costs. This information may not be appropriate, and should not be used, for any other purpose. Milliman does not endorse any public policy or advocacy position on matters discussed in this report.

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Milliman has developed certain models to estimate the values included in this report. The intent of the models was to summarize Part D costs. We have reviewed the models, including their inputs, calculations, and outputs for consistency, reasonableness, and appropriateness to the intended purpose and in compliance with generally accepted actuarial practice and relevant actuarial standards of practice (ASOP).

The results presented herein are estimates based on carefully constructed actuarial models. Differences between our estimates and actual amounts depend on the extent to which future experience conforms to the assumptions made for this analysis. It is certain that actual experience will not conform exactly to the assumptions used in this analysis. Actual amounts will differ from projected amounts to the extent that actual experience deviates from expected experience.

Actual results will vary for specific Medicare organizations and other stakeholders due to differences in demographics, trends, discount arrangements, formulary, utilization patterns, and rebate arrangements, among other factors. Our analysis does not reflect possible changes in stakeholder behavior that could result from these potential program changes. Results will vary based on how beneficiaries and other stakeholders react to the changes, if implemented.

In performing this analysis, we relied on data and other information from the Centers for Medicare and Medicaid Services (CMS), the 2022 CMS & HHS proposed rule, the 2021 Medicare Trustees Report, and Milliman's Part D claims manual. We have not audited or verified this data and other information but reviewed it for general reasonableness. If the underlying data or information is inaccurate or incomplete, the results of our analysis may likewise be inaccurate or incomplete.

This report outlines the review and opinions of the authors and not necessarily that of Milliman. Milliman does not provide legal advice, and recommends that Pharmaceutical Care Management Association consult with its legal advisors regarding legal matters. The terms of Milliman's Consulting Services Agreement with Pharmaceutical Care Management Association dated August 2, 2013 and engagement letter dated January 13, 2022 apply to this report and its use.

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