MILLIMAN WHITE PAPER

Possible Outcomes of Potential Disclosure Requirements in Medicare Part D

Commissioned by the Pharmaceutical Care Management Association

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Background

Legislators at the state and federal level have introduced proposals that could require pharmacy benefit managers (PBMs) to publicly disclose financial and business information, including rebates. In Medicare Part D, pharmaceutical manufacturers pay rebates to PBMs or plan sponsors in exchange for preferred formulary coverage of their products. Rebate contracting terms between pharmaceutical manufacturers and PBMs or plan sponsors are considered confidential. Disclosure requirement legislation could require PBMs to publicly release contracted manufacturer rebate amounts.[1,2,3,4]

The Pharmaceutical Care Management Association (PCMA) has requested Milliman to review potential outcomes of disclosure requirements on Medicare Part D. PBM disclosure requirements could affect many aspects of the pharmacy supply chain. This white paper specifically focuses on the potential impacts to manufacturer rebates if PBMs were required to publicly release contracted rebate amounts.

Potential outcomes of PBM disclosure requirements on manufacturer rebates

Public release of manufacturer rebate amounts may result in a shift in competitive dynamics and a subsequent change in manufacturers' contracting strategies. This may include changes to rebate amounts. As manufacturer rebate amounts change, Part D stakeholders may change their behavior accordingly. The analysis described in this white paper does not take these behavioral changes into account.

The Federal Trade Commission (FTC) has suggested that public disclosure of competitively sensitive information "can blunt a firm's incentive to offer customers better deals by undercutting the extent to which such a move would win business away from rivals" and "can enhance a firm's incentive to raise prices by assuaging the fear that such a move would lose customers to rivals."[5] Several states have considered legislative proposals that include PBM disclosure requirements to which the FTC expressed concerns regarding pharmaceutical manufacturer rebate arrangements:

- In response to proposed PBM disclosure requirements under California Assembly Bill (AB) 1960 (2004), the FTC commented, "If pharmaceutical manufacturers learn the exact amount of the rebates offered by their competitors (either because the safeguards on subsequent disclosure by purchasers and prospective purchasers are insufficient or because the mandated disclosure to prescribers provides sufficient information for pharmaceutical manufacturers to calculate these amounts) then tacit collusion among manufacturers is more feasible. Consequently, the required disclosures may lead to higher prices for PBM services and pharmaceuticals."[6]

- In response to Virginia's House Bill (H.B.) 945 (2006), the FTC commented that public disclosure of proprietary information can "undercut vigorous competition on drug pricing" by allowing pharmaceutical manufacturers to learn detailed information about their competitors' rebates and other incentives. The FTC explains that "knowledge of rivals' prices can dilute incentives to bid aggressively," resulting in increased prices for both PBM services and pharmaceuticals.[7]

- In 2007 and 2009, the states of New Jersey (Assembly No. 320) and New York (Senate Bill 58) considered proposals requiring PBMs to disclose potentially sensitive and proprietary contract information. The FTC provided commentary to both state legislatures, stating its concerns that the public disclosure of manufacturer rebate contracts may influence the bidding practices of pharmaceutical manufacturers. The FTC highlights that "Absent such knowledge [regarding competitors' rebate arrangements] manufacturers have powerful incentives to bid aggressively for formulary position, because preferential formulary treatment offers the prospect of substantially increased sales." The FTC goes on to say that if the disclosure of this information is required and not properly protected, then the elimination of these incentives would ultimately raise pharmaceutical costs for consumers.[8,9]

In the context of the Medicare Part D program, the Congressional Budget Office (CBO) cites the FTC's concerns around public disclosure of manufacturer rebates and notes the potential for rebates to decrease and drug prices to increase with disclosure requirements in place.[10]

A prior study performed by the Centers for Medicare and Medicaid Services (CMS) Office of the Actuary (OACT) assessed the impact of a proposed rule to remove the safe harbor exemption for post-point-of-sale rebates.[11] In that study, OACT assumed that manufacturers might reduce rebates by 15% as a result of the proposed requirement. If finalized, this could effectively make manufacturer rebate amounts available to competitors. As one potential result of the public disclosure of manufacturer rebates in

Medicare Part D, we estimated the 10-year (2024 to 2033) impact to Part D stakeholders of pharmaceutical manufacturers reducing rebate levels by 15% (Figure 1). We estimate that reducing manufacturer rebates by 15% could increase federal government costs by $134 billion, or 10%, over 10 years, assuming no resulting behavioral changes.

FIGURE 1: ESTIMATED 10-YEAR (2024-2033) IMPACT OF A 15% REDUCTION TO MANUFACTURER REBATES IN THE INDIVIDUAL PART D MARKET

	BENEFICIARY PREMIUM	BENEFICIARY COST SHARING	FEDERAL GOVERNMENT	PHARMACEUTICAL MANUFACTURER DISCOUNT PROGRAMS
Dollar Change (Billions)	$3.1	$0.0	$134.4	$0.0
Percent Change	1%	0%	10%	0%

Impacts are relative to a baseline scenario in which pharmaceutical manufacturer rebates are approximately 26% of allowed cost in 2023. See Methodology section below for more detail.

The individual Medicare Part D market includes standalone prescription drug plans (PDPs) and Medicare Advantage plans providing drug coverage (MA-PDs) and excludes Employer Group Waiver Plans (EGWPs).

See the Stakeholder Detail section below for a description of the components for each stakeholder.

- The national average member premium (NAMP) cap provision under the Inflation Reduction Act (IRA) caps annual premium increases at 6% through 2029, with some additional limitations beginning in 2030. With the NAMP cap in place, reducing manufacturer rebates has a minimal impact on beneficiary premium, as we estimate the 6% cap has already been met through 2029 due to the implementation of other IRA provisions. The impact on beneficiary premium could be different in other markets in which the NAMP cap does not exist.

- Reducing manufacturer rebates in Part D could increase federal government costs. The NAMP cap shifts additional liability to the federal government through the direct subsidy. Additionally, federal reinsurance payments could increase because rebates attributed to federal reinsurance would decrease if total rebates decreased. Beneficiary cost sharing and pharmaceutical manufacturer discount program payments are not impacted, as manufacturer rebates are a post-point-of-sale price concession.

While the FTC and OACT have written that public disclosure of rebates could reduce rebate levels, there are instances and scenarios in which public disclosure of rebates may increase rebate levels. For example, rebates may increase if manufacturers learn what their competitors are contracting and seek to offer more competitive rates, or if plan sponsors push for rebate levels offered to competitors.[12] Higher rebate levels could reduce costs for consumers.

Additional considerations

Administrative costs: Disclosure requirements may increase PBM costs as PBMs prepare and submit the required information to the designated entity.[13] As a result, PBMs may pass these increased administrative fees through to plan sponsors.

Stakeholder behavior changes: Other than OACT's assumed 15% reduction in manufacturer rebate levels, our estimates assume no changes in stakeholder behavior as a result of public disclosures of manufacturer rebates. Additionally, our estimates assume no changes in stakeholder behavior as a result of the 15% reduction in manufacturer rebates. For example, plan sponsors may adjust contracting strategies and formularies to improve competitive positioning, and beneficiaries may switch to different plans based on premium changes, cost sharing changes, or other factors. The results of this analysis may change if stakeholders or other entities change their behavior. The likelihood of any particular change or behavioral response occurring in the future was considered out of scope for this analysis.

Stakeholder detail

Beneficiary: The 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: 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. In 2024, the federal government covers 80% of beneficiaries' allowed costs in the catastrophic phase of the Part D benefit through federal reinsurance, reduced for a portion of post-point-of-sale price concessions that the plan sponsor collects on all drugs. Beginning in 2025, federal reinsurance decreases to 20% for applicable drugs and 40% for non-applicable drugs above the maximum out-of-pocket (MOOP).[14]

Pharmaceutical manufacturer discount programs: In 2024, the Medicare Coverage Gap Discount Program (CGDP) covers 70% of the cost of brand and biosimilar drugs in the coverage gap phase of the Part D benefit for non-low income (NLI) beneficiaries. Beginning in 2025, the CGDP will be replaced with the Manufacturer Discount Program (MDP), which covers 10% of applicable drug costs above the deductible and below MOOP, and 20% of applicable drug costs above MOOP for all beneficiaries (LI and NLI).

Methodology

Modeling detail: Our analysis begins with a cost model calibrated to the 2023 market-wide national average bid results. The 2023 national average bid amount, national average member premium, and federal reinsurance are $34.71, $32.74, and $93.68, 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 claim experience from over 55 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).

2024 to 2033 projection: We based our impact analysis on the estimated nationwide average individual Medicare Part D market for a 10-year projection period (2024 to 2033). To develop our 2024 to 2033 baseline projections, we trended the 2024 results using enrollment and trend projections developed from the 2022 Medicare Trustees Report and Milliman's Medicare Part D cost and utilization trends. We reflect the changes to the Part D benefit design as outlined in the IRA. 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 2022 Medicare Trustees Report to estimate nationwide individual Medicare Part D average enrollment by income status.

Trend: The pricing projections for years 2024 to 2033 reflect allowed cost trends based on the Part D per capita cost trend from page 198 of the 2022 Medicare Trustees Report. Trends for 2032 and 2033 were assumed to equal those for 2031. The projections are based on separate generic, brand, and specialty trends. We calibrated to the Trustees Report trends by scaling generic, brand and specialty unit cost and utilization using Milliman's standard Part D 2023 trend assumptions. Our projections do not reflect Part B and Part D price negotiations as set forth in the IRA.,

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: The 2023 benefit parameters reflect those in CMS's calendar-year (CY) 2023 Medicare Advantage and Part D Advance Notice and the IRA. Deductibles for years 2024 to 2033 and the initial coverage limit (ICL) for 2024 are based on the projections on page 198 of the 2022 Medicare Trustees Report. In line with the 2023 CMS Medicare Part D Rate Announcement, 2032 and 2033 deductibles were projected using the same trends in Part D expenditures used for allowed costs or the annual percentage increase (API).

The 2025 MOOP reflects the value provided in the IRA. MOOPs for years 2026 to 2033 are based on the methodology provided in the IRA and were projected using the API. We assume the LIPS program subsidizes 98% of the average premium for LI beneficiaries.

Rebates: We modeled pharmaceutical manufacturer rebates as a percentage of brand allowed cost, before adjusting for federal reinsurance. We estimated total 2023 rebates (including manufacturer rebates and pharmacy rebates) based on Milliman's annual survey of Part D sponsors. We assumed 2023 manufacturer rebates to be approximately 26% of allowed cost. For 2024 to 2033, we assumed the same manufacturer rebate as a percentage of brand allowed cost as estimated for 2023, adjusted for changes in allowed costs due to pharmacy rebates being reflected at the point of sale. This results in projected manufacturer rebates equal to approximately 30% of allowed cost by 2033. Future rebates could vary depending on behavior changes resulting from proposed program changes. Different rebate assumptions could lead to different results.

Disclosures

This report has been prepared for the specific purpose of estimating the effect of disclosure requirements on Medicare Part D 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. The information presented in this report is provided for PCMA. PCMA may share this information with outside entities with Milliman's permission. Milliman does not intend to benefit, and assumes no duty or liability to, other parties who receive this work product. Any third party recipient of this work product who desires professional guidance should not rely upon Milliman's work product, but should engage qualified professionals for advice appropriate to its own specific needs. Any releases of this report to a third party should be in its entirety. This report must be read in its entirety and specialized knowledge of the industry is necessary to fully understand the report and its conclusions.

In performing this analysis, we relied on data and other information from CMS. 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.

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.

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. This report outlines the review and opinions of the authors and not necessarily those of Milliman.

The terms of Milliman's Consulting Services Agreement with Pharmaceutical Care Management Association dated August 2, 2013, and its associated contract "State Law and Part D Study_Phase 2 proposal_20220920.pdf," dated September 20, 2022, apply to this report and its use.

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ENDNOTES

[1] The full text of California Assembly No. 1960 (2004) is available at http://leginfo.ca.gov/pub/03-04/bill/asm/ab_1951-2000/ab_1960_bill_20040825_enrolled.pdf.

[2] The full text of Virginia House Bill 945 (2006) is available at https://lis.virginia.gov/cgi-bin/legp604.exe?061+ful+HB945+pdf.

[3] The full text of New Jersey 212th Legislature, Assembly No. 320 (2006) is available at https://pub.njleg.state.nj.us/Bills/2006/A0500/320_U1.PDF.

[4] The full text of New York Senate Bill 58 (2009) is available at https://assembly.state.ny.us/leg/?default_fld=&bn=S00058&term=2009&Summary=Y&Actions=Y&Text=Y&Committee%26nbspVotes=Y&Floor%26nbspVotes=Y.

[5] FTC (August 19, 2010). Horizontal Merger Guidelines, p. 24. Retrieved February 15, 2023, from https://www.ftc.gov/sites/default/files/attachments/merger-review/100819hmg.pdf.

[6] FTC (September 7, 2004). Letter to California Assembly Member Greg Aghazarian regarding the FTC staff's comments on California Assembly Bill No. 1960. Retrieved February 15, 2023, from: https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-comment-hon.greg-aghazarian-concerning-ca.b.1960-requiring-pharmacy-benefit-managers-make-disclosures-purchasers-and-prospective-purchasers/v040027.pdf .

[7] FTC (October 2, 2006). Letter to Virginia General Assembly Member Terry G. Kilgore regarding the FTC staff's comments on Virginia House Bill No. 945. Retrieved February 15, 2023, from: https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-hon.terry-g.kilgore-concerning-virginia-house-bill-no.945-regulate-contractual-relationship-between-pharmacy-benefit-managers-and-both-health-benefit/v060018.pdf .

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[9] FTC (March 31, 2009). Letter to New York Senator James L. Seward regarding the FTC staff's comments on New York Senate Bill 58. Retrieved February 15, 2023, from: https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-honorable-james-l.seward-concerning-new-york-senate-bill-58-pharmacy-benefit-managers-pbms/v090006newyorkpbm.pdf.

[10] CBO (March 12, 2007). Letter to U.S. Representatives Joe Barton and Jim McCrery regarding the Committee on Oversight and Government Reform's request for comment on imposing reporting requirements on prescription drug plans. Retrieved February 15, 2023, from: https://www.cbo.gov/system/files/2018-10/03-12-drug-rebates.pdf.

[11] CMS Office of the Actuary (August 30, 2018). Proposed Safe Harbor Regulation. Retrieved February 15, 2023, from: https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/ProposedSafeHarborRegulationImpact.pdf.

[12] Klaisner, J., Holcomb, K., & Filipek, T. (January 31, 2019). Impact of Potential Changes to the Treatment of Manufacturer Rebates, p. 1. Milliman Client Report commissioned by Assistant Secretary for Planning and Evaluation (ASPE). Retrieved February 15, 2023, from: https://aspe.hhs.gov/system/files/pdf/260591/MillimanReportImpactPartDRebateReform.pdf.

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[14] Applicable drugs are subject to the Coverage Gap Discount Program (CGDP) or Manufacturer Discount Program (MDP) and are typically brand drugs. Non-applicable drugs are not subject to the CGDP or MDP and are typically generic drugs.