# CIGNA'S TAKE: DRUG REBATE RULE

## Response to HHS OIG on Proposed Rule to Remove Safe Harbor Protection for Drug Rebates

Cigna strives to be a constructive voice in the health care dialogue. We advocate for change that fosters innovation, demands quality, and drives choice and affordability to better enable treatment and support of the whole person. In our April 2019 response to the Office of Inspector General (OIG) of the Department of Health and Human Services (HHS) Notice of Proposed Rulemaking on the safe harbor protection for drug rebates, we communicate our concerns about the likely impacts of the proposed rule and indicate a desire to work with the agency and Congress to advance reforms that we believe accomplish the goal to make prescription drugs more affordable for beneficiaries.

Key topics and issues in the proposed rule and our responses are below.

### The role of rebates

- There is widespread misunderstanding about the role rebates play in improving overall affordability and choice for beneficiaries.
- Rebates are a critical tool to help reduce drug spending.
  - Plan sponsors use rebates to lower premiums and cost-sharing, expand access, enhance benefits, or provide discounts to enrollees at the point of sale (POS).
- Pharmacy Benefit Managers (PBMs) typically reduce prescription drug costs by 30% off of list prices by using aggregate purchasing power and leveraging competition among pharmacies to create savings without sacrificing patient access or high quality pharmacy services.
- Many studies show rebates do not lead to higher list prices. The actuarial firm Milliman found that, on average, the highest cost drugs have the lowest manufacturer rebates (as a percentage of gross drug cost), for brand drugs with rebates.[1]
- Not all drugs are rebated; only 36% of brand (sole-source/innovator) drugs have rebates.[1]
  - Manufacturers of specialty drugs do not typically provide rebates because their products face almost no competition.
  - Manufacturers have no incentive to offer rebates on drugs included in any of the Part D program's six protected classes because plan sponsors are required to include those drugs on their formularies.
  - Non-rebated drugs continue to see double-digit increases, burdening patients, plan sponsors, and taxpayers.
- Beneficiaries have improved access to, and reduced costs for, prescription drugs because PBMs negotiate aggressive discounts with manufacturers, allowing plan sponsors to structure benefits to keep premiums low, despite rising drug prices.
  - According to the Medicare Trustees, between 2011-2017, Part D drug costs increased by 8% annually from about $67 billion to more than $100 billion, while average premiums increased by only $3.29, a little more than 1% annually, helped in part by increased rebates negotiated on behalf of beneficiaries and the program.[2]
  - A 2018 study by actuarial firm Oliver Wyman found that rebates have saved beneficiaries $34.9 billion in premium costs from 2014-2018 and without rebates, premiums would have been 52 percent higher in 2018.

### Proposed rule provisions

- OIG proposes to: (1) Alter the existing rebate safe harbor to exclude the Medicare Part D and Medicaid managed care programs; (2) Create a new safe harbor to protect rebates if the discount is passed through to the dispensing pharmacy; and (3) Create a second safe harbor to protect certain fees paid by a manufacturer to a PBM for services rendered.

1. Milliman, Prescription Drug Rebates and Part D Drug Costs. July 16, 2018.
2. 2018 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds.

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## Potential impacts of the proposed rule

*Medicare Part D*

- The proposed changes will increase premiums for the vast majority of current Part D enrollees, while providing only limited relief on out-of-pocket (OOP) costs for the subset of beneficiaries whose prescriptions carry rebates. Mandating POS rebates does nothing to reduce the high list prices of the approximately 64% of prescription drugs that do not carry rebates.[1]
- According to a projection by the CMS Office of the Actuary (OACT), only one in five Part D enrollees would see savings from the proposed changes, while premiums would increase for all beneficiaries by 25% over the next 10 years.
  - Relatively few beneficiaries would see a positive effect, and the reduction in OOP costs would vary by disease category.
- Low-income subsidy (LIS) eligible enrollees will not benefit from POS rebates, but premiums for plans most attractive to them will likely see very large increases due to lower generic dispensing rates in these plans.
- Beneficiaries who use generic drugs or who have no alternative options except high-cost brand drugs are unlikely to benefit and may end up worse off financially under the proposal.
- The most significant cost implication would be the cost to taxpayers; OACT estimates Part D program costs would go up by 14% if the rule were to take effect, putting an additional $196 billion on the taxpayer tab over the first 10 years.
- Furthermore, should healthier enrollees elect to drop Part D coverage because of increased premiums, it will only exacerbate the problem of rising premiums and discourage younger and healthier beneficiaries from enrolling in Part D going forward, threatening the stability of the entire program.
- The proposed rule is silent as to how it should be applied to Employer Group Waiver Plans (EGWPs), which are generally designed to mirror active workers' benefit designs or set by collective bargaining agreements.
  - We urge OIG that it must exempt EGWPs from a final rule as it would be especially disruptive to require these changes.

*Medicaid*

- Cigna urges OIG to exempt Medicaid managed care in the event it finalizes the proposed rule.
- Most Medicaid managed care organization (MCO) enrollees already pay low, flat copays for their prescriptions, and it is not clear if any enrollees who pay a percentage of drug costs for non-preferred products will benefit from the proposal.
- In Medicaid, the largest portion of rebates manufacturers pay is mandated under the Medicaid Drug Rebate Program. As those requirements are set by statute, the proposed rule does not change them and makes removing the protection of the discount safe harbor for Medicaid MCOs very complicated.
- The proposed rule will increase overall drug spending in Medicaid as states will likely require the use of preferred drug lists to maximize the supplemental rebates they receive in an effort to minimize the impact of losing the Medicaid MCO rebates.

*Value-based arrangements*

- It is essential to bring the concepts and lessons of value-based arrangements (VBAs) to spending on pharmaceuticals to ensure payments are driven by the link between service delivery, clinical outcomes, and patient well-being.

**Cigna Note** – Cigna and Express Scripts have been leaders in developing and implementing VBAs in the commercial market. By measuring pharmacy data, we hold drug manufacturers accountable for expected health outcomes from medications and use these insights to inform future affordability strategies and cost improvements. Clients enrolled in our value-based programs have seen significant improvements in both patient adherence and decreased spending.

- It remains unclear if VBAs could operate effectively without rebates, which function as a means to reconcile payment for the drug against the past performance of the plan sponsor and manufacturer under the terms of a contract arrangement.
- We suggest OIG create a new safe harbor or modify the proposed rule to account for VBA contracts.

*Patient access*

- Creating and maintaining a POS rebate system would impose a new financial burden that dispensing pharmacies do not have today, which could have the unintended consequence of reduced access for beneficiaries.

## Summary and recommendations

- If OIG opts to finalize the rule, Cigna and Express Scripts are prepared to make the new system work.
  - Operationally, the proposed rule provides little guidance on how rebates would be applied at the POS. HHS must provide clear guidance on open issues and collaborate with stakeholders to ensure they are addressed.
- A better path forward would be to reform the Part D program by limiting beneficiary out-of-pocket costs enhancing plan tools to manage the program, requiring plan sponsors to offer a POS rebate option as one enhanced plan, and introduce the power of PBM negotiation and formulary management to Part B drugs.