Value of Rebates in Federal Healthcare Programs

Presentation to OMB-OIRA

August 8, 2018

Agenda

- **Introductions**
- **Policy & Legal Concerns** with Restricting or Eliminating Rebates
- Success of Rebates in **Lowering Costs** for Federal Healthcare Programs
- Implications for EO 12866 **Cost/Benefit Analysis**
- **Questions**

Why We Are Here

Why We Are Here

1. We understand OIRA is currently reviewing a proposed rule which could limit or otherwise restrict the use of rebating arrangements in Federal healthcare programs
2. PCMA believes rebates are a critical tool in controlling drug costs and that eliminating or restricting the discount safe harbor would do more harm than good
3. **As OIRA reviews this rule, we ask that you consider: (1) the significant legal barriers to implementation; (2) the overwhelming costs that would be imposed on the system; and (3) the agency's obligations to comply with existing Executive Orders**

Origin of Current Rebating Arrangements

- Drug manufacturers' expanded use of rebates for pharmacy-dispensed prescription drugs paid by insurers is the result of the settlement of a class action antitrust lawsuit in the mid-1990s.*
- Under the settlement, manufacturers agreed to pay more than $408 million in damages and to offer the same types of discounts to all entities that could "demonstrate an ability to affect market share."
- Determining market-share movement can only be done retroactively through rebates. **Manufacturers are unlikely to risk further litigation by giving higher up-front discounts to payers than to pharmacies.**

* In re Brand Name Prescription Drugs Antitrust Litig., No. 94 C 897, 1996 WL 167350, at *10 (N.D. Ill. Apr. 4, 1996), opinion modified on reconsideration, No. 94 C 897, 1996 WL 351178 (N.D. Ill. June 24, 1996), and rev'd, 123 F.3d 599 (7th Cir. 1997).

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Legal Concerns with Eliminating or Restricting Rebates

Statutory/APA Concerns

- The wording of the statutory exception for discounts (42 U.S.C. 1320a-7b(b)) to the AKS is broad – protecting from scrutiny any "discount or other reduction in price," so long as it is properly disclosed and appropriately reflected in the costs claimed or charged made by the provider
  - This interpretation is supported by both the legislative history of the AKS, as well as by the OIG itself, which has previously taken the position that the safe harbor regulations merely replicate, and do not expand, the statutory language of the discount exception
- There is a strong argument that the underlying language of the AKS (exempting from scrutiny any "discount or other reduction in price,") unambiguously indicates that Congress did not intend that rebates be subjected to AKS scrutiny

Non-Interference Concerns

- Section 1860D-11(i) very clearly prevents HHS from inserting itself into the negotiations between Part D plan sponsors and manufacturers
  - Indeed, CMS has long taken an appropriate view of the non-interference clause's applicability to negotiations between Part D plan sponsors and pharmacies and manufacturers, reflecting the understanding that the Part D program's success is built upon free market competition

- A policy which specifies the very methodology by which plans, their contracted PBMs, and manufacturers negotiate over and pay for drug products is precisely the type of interference Congress intended to avoid, and which HHS has, since the creation of the Part D program

Role of Rebates in Lowering Drug Costs

Rebates Benefit the Medicare Program

- In the very same month that HHS released its Blueprint targeting manufacturer rebates, CMS released its 2018 Annual Medicare Trustees report crediting rebates with lowering costs in the Part D program
  - CMS said, "[t]his upward revision to projected rebates is a major reason for decreases in overall Part D costs compared to 2017"

- On July 31st CMS announced that – for a second year in a row – Part D premiums continued to decline (down to $32.50 for 2019)
  - Note that CMS' proposal to require rebates be passed through at POS would have *increased* premiums

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Elimination of the Discount Safe Harbor Would Tie the Hands of Payers

- Price concessions negotiated by PBMs, most of which are in the form of rebates, significantly lower the cost of drugs to insured patients.
- According to a study by Visante Inc. on Part D costs, PBMs help patients and payers save $941 per enrollee per year in prescription drug costs.
- Without the use of rebates, payers would have little ability to drive competition among brand drug manufacturers. Payers would not be able negotiate up-front discounts or after-the-fact discounts through rebates.
- It is illogical to think that manufacturers would simply lower their prices to all payers across the board in the absence of rebates.

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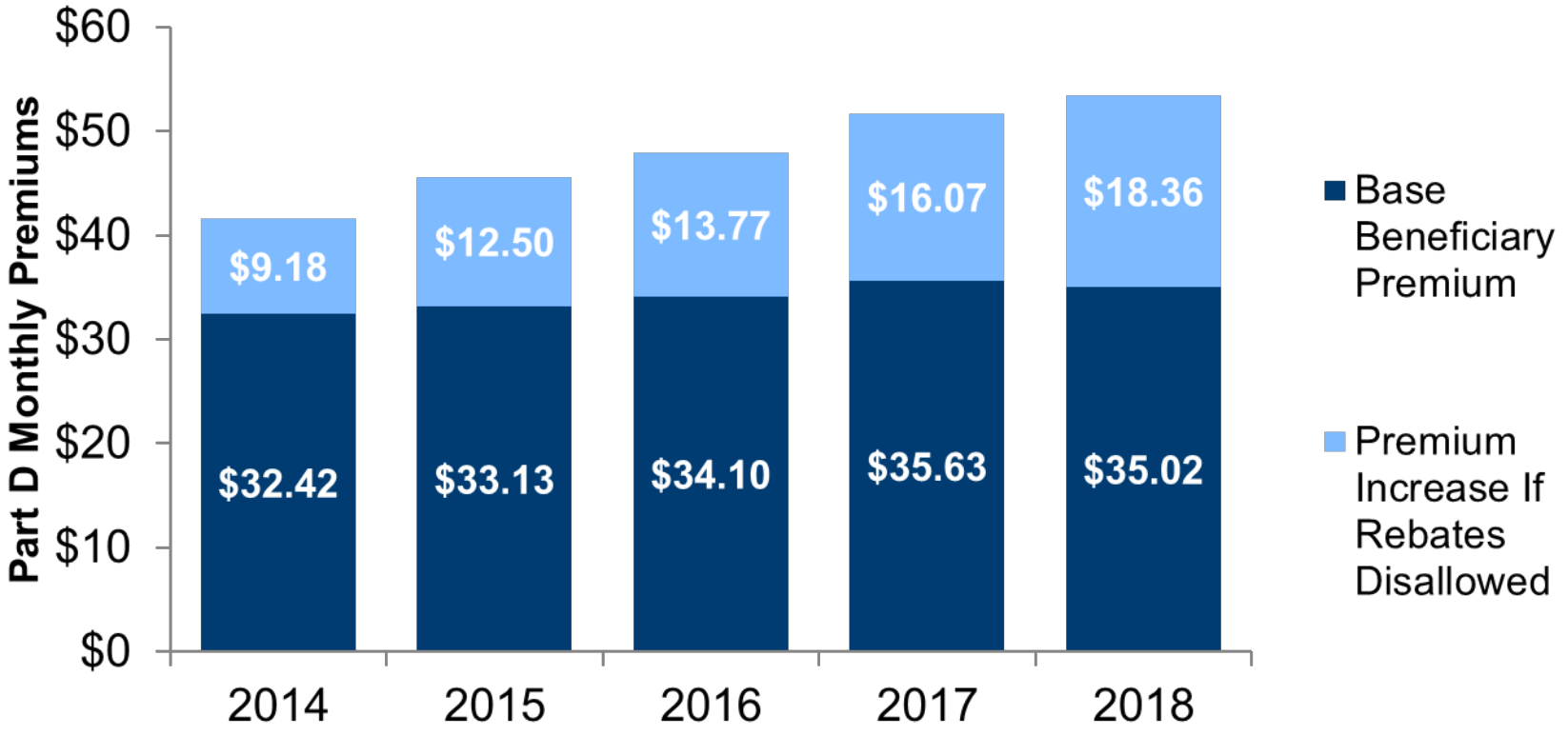
Premium Impact of Disallowing Rebates in Part D



Source: Oliver Wyman, "Premium Impact of Removing Manufacturer Rebates from the Medicare Part D Program, July 2018.

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Eliminating Rebates Fails to Address High Drug Costs

- If rebates were limited to a certain percentage of list price, that would also limit competition. Manufacturers would know they could raise prices and not be subject to competition beyond a certain point.
- If rebates were eliminated, PBMs and other payers could be forced to institute narrower formularies with more restrictions to try to attain more reasonable costs

Cost/Benefit Analysis Considerations

Implementation Concerns

- Restricting rebates would require a major effort, including re-contracting, revising bids, and a major overhaul of the Part D regulations
  - Over the course of nearly 15 years, plans, PBMs, manufacturers and other key drug supply chain actors (wholesalers, GPOs, etc.) have developed systems, processes, and contracts built and reliant upon back-end rebates based on volume and formulary placement. Any efforts to restrict or undermine this underlying system must be seriously analyzed for both known and unintended costs
  - Given that both manufacturers and PBMs – and Part D plan sponsors and PBMs – operate under contracts based on a rebate-driven system, a complete restructuring of these arrangements would require a significant investment in time and dollars
  - Part D regulations would also need to be reviewed and updated – assuming they can be without a statutory change - including a review of: the definition of negotiated price, formulary tiers including specialty tiers, cost-sharing and actuarial soundness, permissible mid-year changes, exceptions and appeals etc. Beneficiary materials would also need to be revised to reflect the new construct.

Restricting Rebates Has Far-Reaching Implications Across Federal Programs – and Beyond

- Rebates are used as a **tool** to negotiate drug prices across both **Federal** and **commercial/employer** marketplaces.
  - Rebates play key a key role in Part D, Part B, Medicaid, FEHB, TRICARE – as well as in commercial and employer marketplaces.

- Restricting the use of rebates in only Federal programs — will still cause ripples across the entire drug supply chain.

Additional EO Obligations

- Executive Order (EO) 13771, *Reducing Regulation and Controlling Regulatory Cost* (January 20, 2017)
- Executive Order (EO) 13813, *Promoting Healthcare Choice and Competition Across the United States* (October 12, 2017)

Questions