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The Return of POS Rebates

Pricing Impacts That Would Disrupt the Part D Marketplace

On November 20, 2020, HHS finalized three rules regarding Medicare.

- Rule eliminating manufacturer rebates after the point-of-sale from the safe harbor of anti-kickback legislation
- Rule implementing "Most Favored Nation" pricing rules on Part B drugs.
- Rule adding language to anti-kickback legislation to enable Value-Based Insurance Design

This paper will focus specifically on the point-of-sale (POS) rebates rule. Please note – these rules are final with no comment period and are scheduled to become law in 60 days from promulgation (January 19, 2021). If nothing changes, CMS and OACT will likely instruct Part D plans to follow the law, which means manufacturer rebates need to be reflected at point-of-sale only.

Elimination of Manufacturer Rebates after Point-of-Sale

The same rule eliminating rebates after the point-of-sale was considered for the 2020 payment year and did not move forward. This rule was not originally expected to pass into law because the associated executive order[1] was contingent on a requirement that it "is not projected to increase Federal spending, Medicare beneficiary premiums, or patients' total out-of-pocket costs."[1] Prior analysis developed by OACT[2], Wakely[3], and other consulting firms projected that Federal spending and Medicare beneficiary premiums would increase if post-sale rebates were to be recognized at point-of-sale. However, Health and Human Services Secretary Alex Azar affirmed[4] his belief that the rule will not increase premiums, member costs, or federal spending, thereby setting the rule in motion.

[1] July 24, 2020 Executive Order on Lowering Prices for Patients by Eliminating Kickbacks to Middlemen https://www.whitehouse.gov/presidential-actions/executive-order-lowering-prices-patients-eliminating-kickbacks-middlemen/
[2] https://www.federalregister.gov/documents/2019/02/06/2019-01026/fraud-and-abuse-removal-of-safe-harbor-protection-for-rebates-involving-prescription-pharmaceuticals
[3] https://aspe.hhs.gov/system/files/pdf/260591/WakelyImpactAllPartiesManufacturerRebatesPointSale.pdf
[4] https://www.hhs.gov/about/news/2020/11/20/secretary-azar-confirmation-in-response-to-executive-order-on-lowering-prices-for-patients.html

This rule[5] will prevent rebates from being applied after point-of-sale, which will have a significant impact on the pricing of Part D bids for 2022. An example of the impact of point of service rebates to plan liability is included below under the current (PPOS) and possible future (POS) scenarios:

Table 1 – Point of Sale Rebates Example

Component	Post Point of Service	Point of Service
Drug Price	$100	$100
Rebate	27%	27%
Amount Used to Buy down Premiums	$27	$0
Amount Used to Buy down Drug Cost	$0	$27
Net Price	$73	$73
Member Coinsurance	25%	25%
Member Pay	$25	$18.25
Plan Pay	$48	$54.75

The rule will go into effect on Jan. 1, 2022 (pending legal action or potential decisions by the next Administration). There is some[6] debate[7] over whether the rule was officially withdrawn from consideration, meaning that the current "final" rule would be nullified on procedural grounds. Rebates offered from pharmaceutical manufacturers directly to Medicaid managed care organizations and rebates on Part B drugs are not impacted by this rule.

Wakely has written extensively about this topic in previous whitepapers[8]. Some of the key pricing, benefit, and PBM contracting considerations of this change include:

- Drug prices
    - Instead of negotiating based on the most favorable rebate arrangements, plans and PBMs will be forced to reprioritize lower drug prices. Point-of-sale drug costs will likely fall as plans attempt to recapture rebate savings at point-of-sale, and incentives to increase drug prices are reduced.
- Formularies

5 https://www.hhs.gov/sites/default/files/rebate-rule-discount-and-pbm-service-fee-final-rule.pdf
6 https://www.yalejreg.com/nc/going-through-regulatory-withdrawal/
7 https://healthpolicy.usc.edu/evidence-base/are-we-gearing-up-for-a-drug-rebate-rule-instant-replay/
8 https://aspe.hhs.gov/system/files/pdf/260591/WakelyImpactAllPartiesManufacturerRebatesPointSale.pdf
https://www.wakely.com/sites/default/files/files/content/pos-white-paper-3272019_1.pdf
https://www.wakely.com/sites/default/files/files/content/medicare-part-d-2020-pharmacy-rebates.pdf

  - Plans and PBMs may be less incentivized to include high-cost, high rebate drugs if they are retaining less of that rebate savings, and therefore we may see significant changes to formularies.

- Risk adjustment

  - The proposed Part D risk adjustment model for payment year 2022 was developed using basic benefit costs prior to any reductions for rebates. If plans are required to apply rebates at the point-of-sale, then the risk adjustment model will not accurately reflect the basic benefit costs when it is applied in 2022 under a POS rebate setting. In the absence of any CMS action to correct this inconsistency, this will create opportunities for risk selection that are unlikely to be resolved before the 2022 bid submission deadline in June 2021.

- Plan benefits

  - Basic alternative (BA) and actuarially equivalent (AE) plans may have to lower cost-sharing amounts to maintain benefit adequacy with the Defined Standard benefits in order to pass the bid's actuarial equivalence tests.

- Benefit phase

  - Members will progress more slowly through their benefit, with potentially fewer reaching the coverage gap phase altogether, others remaining in the coverage gap phase longer, and fewer members and/or less spend in the catastrophic phase.

- Premium levels

  - Basic Part D premiums will likely rise as plans retain less of the manufacturer rebates and other stakeholders (e.g. members, federal government, and drug manufacturers themselves) share in rebate savings at the point-of-sale. On the other hand, supplemental Part D premiums may decrease depending on the richness of the benefit, which in some cases may even lead to a decrease total Part D premiums for the richest enhanced alternative plans.

- Enrollment

  - This change in the treatment of rebates could encourage continued movement to MA-PD plans, as standalone PDP plans are less able to absorb the premium shock likely to be experienced in a POS rebate setting.

- Trend

  - Unit cost before rebates will likely grow at a slower rate or fall (especially for brands) because increases in drug prices will more directly result in increased plan premiums.

  - Utilization will rise as drugs become more affordable for members

- Manufacturer coverage gap discount program (CGDP) payments
    - Manufacturer CGDP payments in the gap will be reduced significantly as drug prices fall and fewer people reach the coverage gap.
- Pharmacy DIR
    - Will likely become more important as plans seek new ways to reduce premiums. Agreements and payment norms may have to be restructured to comply with the new safe harbor definitions.
- Bid components
    - The National Average Direct Subsidy and National Average Reinsurance are likely to flip directions (higher plan liability, lower reinsurance amounts), creating significant uncertainty in the expected level at which to bid.
- Impact on Commercial Marketplace
    - Commercial plans may voluntarily shift to POS rebates or turn to broader forms of re-contracting as PBMs and plans seek consistent contracting terms across lines of business.
- CMS Guidance
    - CMS will likely issue additional guidance for plans if this rule remains, which could be impactful for bid preparation.
- Adherence
    - If POS rebates succeed in lowering member cost-sharing, then members may be more likely to fill their prescriptions, resulting in increased adherence, which has significant impacts on Star scores as well as medical costs.

The implementation of Point-of-Sale rebates would have drastic and far-reaching impacts on the Part D marketplace. It will be important for the incoming administration to quickly and clearly signal their intent with regards to this rule so that plans, PBMs, and manufacturers have adequate time to prepare if a change is in the works.

Please contact Drew McStanley at drew.mcstanley@wakely.com or Casey Gardner at casey.gardner@wakely.com with any questions or to follow up on any of the concepts presented here.