WHITE PAPER

Medicare Part D 2020: Where, Oh Where, Should My Pharmacy Rebates Go?

Alison Pool, ASA, MAAA
727.259.7469 • alisonp@wakely.com

Julia Lambert, FSA, MAAA
727.259.7474• julial@wakely.com

Dagny Grillis, FSA, MAAA, CERA, PhD
727.259.6784 • dagny.grillis@wakely.com

Introduction

As the 2020 bid season gets underway, a critical question being asked is how to handle prescription drug rebates and pharmacy price concessions – will these Direct and Indirect Remuneration (DIR) amounts be allowed to be paid to the Part D plan sponsors as in the past? Alternatively, will the proposed rules suggesting that the manufacturer drug rebates and pharmacy price concessions (collectively referred to as 'rebates' for the balance of this paper) instead be credited against the cost of the drug at the point of sale be finalized with a January 1, 2020 effective date? The rules may not be finalized before the June 3, 2019 due date for filing 2020 benefits and pricing. Guidance from CMS and OACT on the preferred method of handling rebates in the 2020 bids given these uncertainties has not yet been provided.

This paper will provide why this change affects the Part D pricing, some options for handling rebates in the BPTs and the consequences of the actions.

Why do POS Rebates Matter?

The November 28, 2017[1] request for information concerning the application of manufacturer rebates and pharmacy price concessions followed by the November 30, 2018[2] and February 6, 2019[3] proposed rules are clear that the intention of the department of Health and Human Services (HHS) is to change the current methods that drug manufacturers and pharmacies use to provide manufacturer rebates and price concessions back to Part D sponsors. The current law allows these manufacturer rebates and price concessions to be paid to the plan sponsors retrospectively and to not be considered at the time the beneficiary receives the drug at the point of sale. Although plan sponsors must use these rebates to reduce member premiums and/or increase benefits, beneficiaries do not see the benefit of these rebates when they are at the pharmacy counter. The cost of drugs at the point of sale generally reflect the cost before reductions from rebates, and consequently, members' cost-sharing is also based on the cost of the drug before rebates. The new proposed rules have multiple provisions: prohibit the plan sponsor from

[1]See https://www.govinfo.gov/content/pkg/FR-2017-11-28/pdf/2017-25068.pdf
[2]See https://www.federalregister.gov/documents/2018/11/30/2018-25945/modernizing-part-d-and-medicare-advantage-to-lower-drug-prices-and-reduce-out-of-pocket-expenses
[3]See https://www.federalregister.gov/documents/2019/02/06/2019-01026/fraud-and-abuse-removal-of-safe-harbor-protection-for-rebates-involving-prescription-pharmaceuticals

receiving the manufacturer rebates, specifically allow for manufacturer rebates to be reflected at the point of sale, and require that pharmacy concessions be reflected at the point of sale. The combination of these rules results in the beneficiary seeing the lowest contracted cost at the pharmacy counter.

Moving rebate amounts to the point of sale significantly changes the actuarial projections of costs and premiums and likely means benefit plan changes from the current environment. Why does the point-of-sale (POS) drug cost matter so much to the Part D program? Many facets of the Part D program are tied to the drug costs recognized at the pharmacy counter. Some of the aspects of the Part D program that are modified by shifting rebates to POS drug cost reductions are listed below.

- Probably the most obvious impact is that beneficiary coinsurance amounts will be reduced when rebates are recognized at the point of sale. Copayments may also be reduced depending on the copay value compared to the POS drug cost.
- The Part D benefits vary by phases (deductible, initial coverage period, gap, and catastrophic phases). These phases depend on the accumulated total drug costs and the out-of-pocket costs that the beneficiary has incurred at the point of sale. The reduction in the POS drug cost will impact the rate at which beneficiaries move through the Part D drug phases. Lower POS drug costs mean beneficiaries move through the phases slower and hit the catastrophic phase later. Among other things, this means savings for CMS' federal reinsurance.
- The amount that drug manufacturers pay for applicable (brand) drugs in the gap are based on the POS drug cost and member cost-sharing. Lower POS drug costs and lower cost-sharing mean lower coverage gap discount amounts and savings for manufacturers.
- Some of the actuarial equivalence (AE) tests compare the offered benefit to the coinsurance-based defined standard benefit plan. These tests use the POS drug cost. For example, in the initial coverage period, the copays must be less than or equal to 25% of the projected drug cost. Under retrospective DIR settlement, a $25 copay would comply with a projected $100 average drug cost. However, if rebates were recognized at the point of sale, the $100 drug cost would be reduced, and the $25 copay would now reflect a percentage of allowed cost that is greater than 25%, indicating a needed reduction in the $25 copay in order to satisfy AE tests.

As you can see by the forgoing list, recognizing rebates at the point of sale will change beneficiary cost-sharing and projected costs by benefit phase. These changes, in turn, will result in changes to plan liability, revenue requirements and member premium in the Bid Pricing Tools (BPTs), ultimately affecting the national average bid amounts and subsidies paid by CMS.

The proposed rules indicate an effective date as soon as January 1, 2020. Because the rules are not final and may not be final in time for the BPT submissions, the lingering question is: What is the appropriate method for developing the bids for CY2020? To-date, no guidance has been provided to indicate CMS' expectation for the development of the bids. In the absence of guidance, MAOs have some options but none without risk. Our intention with this paper is not to provide guidance on BPT development but to provide the options as we see them.

The Proposed Rules

The CMS proposed rule published November 30, 2018 focuses on rebates stemming from performance-based pharmacy price concessions.

The proposed rule calls for a re-definition of 'negotiated prices' for prescription drugs.[4] Previously, negotiated prices represented all pharmacy payment adjustments *except those contingent amounts that cannot "reasonably be determined" at the point of sale* (italics added). The language allowed for a difference between the cost at the point of sale and the gross drug cost that the Part D plan sponsor ultimately achieved. Contracts between PBMs and plan sponsors include discounts, administration costs, and rebates from drug manufacturers. In addition, the agreements can also include performance based parameters that are measured over time that drive the amount of the price concessions from pharmacies. Because of the requirement to measure utilization or other parameters over time, these performance-based metrics could not be immediately determined and therefore could not be applied at the point of sale.

The new proposed definition of 'negotiated price' reflects the lowest possible reimbursement for the drug under the sponsor's contract. In other words, the lowest possible reimbursement including any price concession amounts will be reflected in the POS price at contracted pharmacies.[5]

On February 6, 2019,[6] HHS further supported the change in the definition of 'negotiated price' with a proposed rule which would remove manufacturer rebates to plan sponsors from the safe harbor protection in the anti-kickback statute (AKS) section 1128B(b) of the Social Security Act (SSA). Excluding rebates from the safe harbor protection further strengthens the push to eliminate the post-sale rebates in favor of POS rebates.

The HHS rule proposes a new safe harbor protecting discount arrangements that are determined to be beneficial and have a low risk of fraud and abuse. Certain arrangements between drug manufacturers and PBMs where the flat fee service payments (i.e., not tied to the cost of the drug or volume of drug expected to be dispensed) are retained by the PBM and not passed through would qualify for safe harbor protection.

Both proposed rules include the possible effective date of January 1, 2020.

The proposed rules acknowledged that changing the definition of 'negotiated price' impacts various groups associated with the Part D program differently. The rule referenced several analyses that studied these impacts. The following list details some of the changes that were observed in the supporting research completed by Wakely[7] for a defined standard benefit design:

[4] See https://www.federalregister.gov/documents/2018/11/30/2018-25945/modernizing-part-d-and-medicare-advantage-to-lower-drug-prices-and-reduce-out-of-pocket-expenses
[5] See https://www.federalregister.gov/documents/2018/11/30/2018-25945/modernizing-part-d-and-medicare-advantage-to-lower-drug-prices-and-reduce-out-of-pocket-expenses.
[6] See https://www.federalregister.gov/documents/2019/02/06/2019-01026/fraud-and-abuse-removal-of-safe-harbor-protection-for-rebates-involving-prescription-pharmaceuticals
[7] See https://aspe.hhs.gov/system/files/pdf/260591/WakelyImpactAllPartiesManufacturerRebatesPointSale.pdf.

- Average beneficiary[8] – Basic member premiums increase while cost-sharing decreases.
- CMS – Part D direct subsidy payments and low-income premium subsidies increase but federal reinsurance and low-income cost-sharing payments decrease.
- Drug Manufacturers – Coverage gap discounts decrease.
- Part D Sponsor – Basic plan liability costs increase which leads to increases in Part D premium.

Impact of POS Rebates on Bids

The impact of the proposed rules will vary by specific Plan Benefit Package (PBP) and therefore should be considered for each PBP separately. The following discussion is generalized and is intended to provide a non-exhaustive list of considerations.

Defined Standard (DS) Plan

If rebates are recognized at the point of sale, the plan liability of defined standard plans will be higher. The beneficiary cost-sharing for this type of plan is coinsurance-based, so the coinsurance percentage is applied to a lower amount at the point of sale. Whereas retrospective rebate application results in allocating rebates between the plan sponsor and CMS, reduced drug cost at the point of sale under a DS plan results in members gaining a portion of the rebate through reduced member cost-sharing. Essentially, the rebates that once were provided to the plan sponsor to share only with CMS are now also shared with the beneficiary, leading to increased costs for the sponsor and increased premiums.

Under the DS plan, the deductible phase may last longer as the POS rebates lower the cost of scripts requiring more scripts before the deductible is satisfied. Similarly, beneficiaries will move through the benefit phases at a slower rate, pushing scripts from later benefit phases into earlier benefit phases.

Enhanced Alternative (EA) Plan

The impact of the POS rebates to EA plans will depend on the enhancements to benefits and may result in different results than a DS plan. For slightly enriched plans with reduced deductibles and member coinsurance, a similar cost shifting of reduced cost-sharing by the beneficiary and increased costs to the plan sponsor is expected, driving up premiums.

Many EA plans offer copays on most tiers with coinsurance applied only to the high cost drugs on the specialty tier. The copay tiers will not see as great of an impact from the POS rebates, since the copay could be less than the net cost of the drug after recognizing the rebate. For copay plans, the reduction in member cost-sharing is limited. Preliminary pricing for richer EA plans that cover the deductible and offer copay coverage in the gap indicates that the total Part D member premium could actually decrease under a scenario where proposed rules are finalized before the 2020 bid deadline. In this scenario, it is important to note that the basic member premium for the EA plans still increases but is more than offset by the decreases in the supplemental premium.

[8] The average beneficiary here refers to a non-low-income (non-LI) and not a user of high cost/specialty drugs. The impact to low-income beneficiaries is expected to be minimal. The impact to non-LI beneficiaries with utilization of higher cost drugs is expected to have lower cost-sharing than under the current system, since the higher cost drugs are more typically on tiers using coinsurance for cost-sharing. The premium increase will impact all of the non-LI population.

DS and EA

For both DS and EA plans, the time to reach the Initial Coverage Limit (ICL) and True Out-of-Pocket Cost (TrOOP) threshold will be longer, since the POS drug costs will be reduced. Because the number of scripts and time needed to reach the ICL increases, the payments by manufacturers in the gap would decrease, meaning lower Coverage Gap Discount Program (CGDP) payments to sponsors. CGDP is also calculated as a percentage of allowed costs for brand drugs without enhanced gap coverage, further allowing manufacturers to save from the POS rebates on a proportional basis. Then, as the time to reach TrOOP increases, the liability under the Federal Reinsurance program also decreases.

Actuarial Equivalence Tests

Actuarial equivalence (AE) tests are required to verify that the prescription drug coverage provided by the sponsor is at least as good as the defined standard benefit. For plans that will be reducing the costs of drugs significantly at the point of sale, the lower drug costs will likely require lower copays under basic alternative, actuarially equivalent, or potentially even EA plans in order to meet the actuarial equivalence tests.

Direct Subsidy

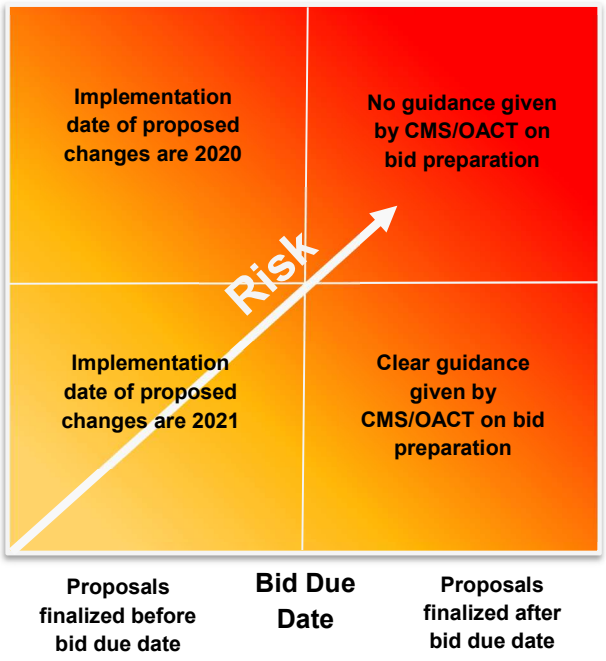
The direct subsidy is expected to increase under these rules. Both the Base Beneficiary Premium (BBP) and National Average Bid Amount (NABA) are expected to increase, due to the basic plan liability increasing. However, the NABA is expected to increase more than the BBP resulting in an increase in the direct subsidy that is paid to plan sponsors.

Guidance or No Guidance – What is the Risk?

Although many interest groups will be impacted by the change in the way rebates are handled, both PDP and MA-PD plan sponsors have particular interest in having a decision in time to complete Bid Pricing Tools (BPTs) prior to the June 3, 2019 bid deadline. For plan sponsors, the stakes are high as bidding inappropriately could result in the loss of market position or inadequate revenue.

The comment period on the proposal to change the AKS closes April 8, 2019, a few days after the publication of the Final Rate Notice and Call Letter for 2020 bids. It is unlikely the Final Rate Notice will address the status of either proposal. Additionally, it is questionable whether the proposals will be finalized before the bid due date.

The following diagram summarizes the risks that plan sponsors face, depending on the timing of the finalized proposals and released guidance:



The lowest end of the risk spectrum reflects finalized rules before the bid due date with a delayed implementation date. While this scenario is the easiest for bid preparation, plan actuaries are already using valuable resources needed for preparing 2020 bids for modeling scenarios under possible changes in regulations. This naturally puts the bidding process at risk.

If the proposed rules are finalized with an implementation date of 2020, the risks of the previous scenario still exist, but time does not permit plan sponsors to fully negotiate revised contracts with PBMs and manufacturers. It is likely bid projections will be inaccurate compared to actual results. This can then lead to greater risk corridor settlement amounts in either direction.

At the next level of risk is the scenario where the proposed rules are not finalized before the due date, but CMS/OACT gives clear guidance on how to bid. Ideally, guidance should include whether to prepare an alternate set of bids and assumptions to use in the alternate set. Also under this scenario could be guidance where plan sponsors are instructed to bid under the status quo, but a second round of bid development would be allowed after the bid submission date should the proposed rules be finalized effective for 2020.

The most worrisome of all scenarios is where the proposed rules are not finalized and CMS/OACT remains silent regarding the approach to the 2020 bid submission. In this scenario, plan sponsors will have to use judgment not only on how to submit their own bids, but also how the industry will submit their bids, as the direct subsidies CMS pays plan sponsors are based on the national averages of bid submissions. If either of these assumptions is incorrect (year of implementation or how the industry bids), plan sponsors could put their market position and or projected profitability at risk. A bid based on a 2020 implementation date has the risk of being non-competitive, but protects plans financially. A bid based on a later implementation date risks being underfunded. Either scenario can again lead to greater risk corridor settlement amounts.

Although many of the risks for stand-alone Part D plan sponsors and MA-PD plan sponsors are the same, some differences exist. For stand-alone Part D plan sponsors, there is an additional risk of losing auto assign membership if their bids are different than their industry counterparts. MA-PD plans have other considerations given that many use Part C rebates to cover all or part of the Part D premiums. The interaction between the Part C and Part D pricing impacts benefit choices MA-PDs offer. Given the significant possible swings in the direct subsidy, an inaccurate guess at the national average bid will mean finding significant concessions in benefits at rebate reallocation should the plan sponsor incorrectly assume the industry bids will be based on a 2020 implementation date.

For MA-PD plans offering EA plans, the pricing may indicate that total member premium does not change much between the current rebate approach and POS rebate assumptions. However, the risks at rebate reallocation are still very real. The basic premium could still change dramatically at rebate reallocation if the national average bid assumptions in the initial bid submission are incorrect.

What Else?

Thus far, we have concentrated on the impact of moving rebates from being retrospectively settled to being recognized at the point of sale, as well as the mechanical impact to 2020 bid preparation and results should the proposed

rules be effective January 1, 2020. However, other important topics should also be considered:

- **PBM contract changes.** Will rebates simply be transferred to the point of sale, or will there be a comprehensive change to the contractual discounts for rebate-able drugs or perhaps both rebate-able and non-rebate-able drugs? Could the rebate contracts for commercial plans also be affected?
- **Amount of manufacturer rebates and price concessions transferred to the point of sale**. One potential outcome of recognizing manufacturer rebates and price concessions at the point of sale is that competition between manufacturers will increase at the point of sale due to transparency of net drug costs and will drive drugs costs down further. However, others speculate that not all rebates and price concessions will be transferred to the point of sale and net costs of drugs will increase.
- **Operating changes**. Adjudicating rebates at the point of sale is significantly different operationally than retrospective settlements. Creating Prescription Drug Event data and adopting PBM reporting to accommodate rebates at POS will be a significant infrastructure change for those PBMs and plan sponsors who have never recognized rebates at the point of sale.
- **Formulary changes**. The proposed changes to the AKS also remove the incentives for preferred formulary placement based on the volume of drug consumption. This will change the dynamics of how plan sponsors build their formularies, perhaps resulting in an improved formulary placement of biosimilars and generics relative to high cost, highly rebate-able brand drugs.
- **Value-based contracting**: The proposed changes to the AKS preserve retrospective settlement of DIR under value-based contracts. This may result in an increased move toward contracting with financial terms based on outcomes.

We expect these topics will become front and center once the proposed rules are finalized.

The Bids – What to Do?

In the absence of guidance from CMS or OACT, Part D plan sponsors should consider the possible scenarios.

- **Review benefit plans**. Determine if actuarial equivalence will be an issue under POS rebates and be prepared to adjust Part D benefits if needed. Further, if an MA-PD, determine if the Part C rebate can support the higher cost of the Part D basic benefit or if changes to Part C benefits will be needed.
- **Consider the 2020 formulary**. Generally, formulary development considers manufacturer rebates by including drugs with higher rebates and/or placing them on lower formulary tiers. With net drug cost comparison transparency at POS, the incentive to maximize rebates may not apply in the same way.
- **Discuss the rebate contract(s)**. The PBM contract likely includes references to manufacturer rebates and/or price concessions. The change to POS rebates may require a redefinition of terms and agreements in the contract.
- **Prepare alternate sets of bids**. The nature of bid development requires many hours. The prospect of preparing multiple sets of bids with differing assumptions is daunting. However, if either rule is announced to be effective for the 2020 plan year at the eleventh hour, having a set of bids ready to go would be comforting.

Please contact Alison Pool at alisonp@wakely.com with any questions or to follow up on any of the concepts presented here.