WHITE PAPER

Medicare Part D 2020: Pharmacy Rebates – So Many Options, So Little Time

Tim Courtney, FSA, MAAA
727.259.7480 • timc@wakely.com

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

Introduction

With the 2020 bid submission deadline only about a month away, there are still uncertainties regarding the proposed rules for Part D rebates moving to point-of-sale (POS). Wakely recently released a white paper on this topic describing why these proposed changes affect Part D pricing, some potential options plans had at that time for handling rebates in the BPTs, and some of the consequences of these actions.[1]

Since then, the Centers for Medicare & Medicaid Services (CMS) has released guidance on how plans should bid for 2020 given the uncertainty of whether these proposed rules will be finalized. Also, CMS has announced a two year voluntary risk corridor demonstration to help Medicare Part D plans make this transition if rebates do end up moving to point-of-sale. Following this guidance, CMS held a call that clarified questions related to POS rebates and the risk corridor demonstration.

This paper will describe how these proposed changes, if implemented, would affect health plan sponsors' financial results, and will discuss the guidance CMS and OACT have released regarding how plans should bid for 2020 as well as some preliminary information about the Part D risk corridor demonstration. We also provide our thoughts on strategic considerations for 2020 bidding.

Which Proposed Rules?

There are two similar rules that are important for health plans to be monitoring.

First, on November 30, 2018,[2] CMS published a proposed rule which, if finalized, would redefine the term "negotiated price". The proposed rule states that "negotiated price" currently means all pharmacy payment adjustments except those contingent amounts that cannot ''reasonably be determined'' at the point of sale. The rule proposed eliminating the exception for contingent pharmacy price concessions. We will refer to this as the "Pharmacy Concessions" rule in this paper. If finalized, the rule would also redefine "negotiated price" to mean the lowest amount a pharmacy could receive as reimbursement for a covered Part D drug under its contract with the plan sponsor. The comment period for this rule has already ended, and it could potentially be adopted as soon as 2020.

Second, on February 6, 2019,[3] the Department

[1] See https://www.wakely.com/blog/medicare-part-d-2020-where-oh-where-should-my-pharmacy-rebates-go

[2] See https://www.federalregister.gov/documents/2018/11/30/2018-25945/modernizing-part-d-and- medicareadvantage-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- safeharbor-

of Health and Human Services (HHS), Office of the Inspector General proposed a rule that would remove the safe harbor protection in the anti-kickback statute section of 1128B(b) of the Social Security Act (SSA) regarding manufacturer rebates to plan sponsors. This change would be made in an effort to eliminate post-sale rebates and reduce drug costs at point of sale, either via chargebacks or point-of-sale (POS) rebates. We will refer to this as the "Safe Harbor" rule in this report. The comment period for this rule ended on April 8, 2019, and it is proposed to be effective as early as January 1, 2020.

What are the 2020 Bid Requirements?

As explained in the prior Wakely paper, significant impacts to costs and bid components result from these rules. It is possible that both the Pharmacy Concession and Safe Harbor rules could be finalized before the 2020 bid submission deadline of June 3, 2019. Plans need to know how to bid for 2020 rather than gambling whether the rules will be finalized and trying to guess how the rest of the market will bid.

To address this issue, CMS recently released guidance for how plans should bid for 2020 in an April 5, 2019 memo.[4] CMS specifically focused only on guidance regarding the Safe Harbor rule affecting manufacturer rebates. For 2020 bids, CMS specified in the memo that plan sponsors should submit bids consistent with the current anti-kickback statute law and regulations that are in effect as of the bid submission deadline of June 3, 2019.

The specification that plan sponsors should bid in accordance with the current laws in effect as of June 3, 2019 means that all plan sponsors should submit

2020 bids assuming the current safe harbor protection for manufacturer rebates is still in place. Even if the Safe Harbor rule is finalized before the bid submission deadline, there is not enough time left for them to legally go into effect. That takes at least 60 days once the rule is finalized, so no matter what happens, all plans should bid under current safe harbor rules. Since 2020 revenue will be set according to the bid submission, bidding under current rules will mean that basic revenue is under-estimated if the Safe Harbor rule is implemented for 2020.

Bidding requirements related to the Pharmacy Concession rule are less clear. The Office of the Actuary (OACT) recently responded to a live question during their May 2, 2019 User Group call that OACT's expectation is that plan sponsors would submit bids in a manner consistent with any pharmacy concession rule in place before the bid submission deadline. We interpret this to mean that plans should submit bids consistent with the pharmacy concession rule as soon as it is published. While pharmacy concessions are a much smaller portion of overall direct and indirect remuneration, this guidance still creates challenges for plans in determining how to bid and how to judge the impact on the national average bid. OACT also called out sections 3.4.5 and 3.4.6 of Actuarial Standard of Practice 41, which provide guidance on the report date and "subsequent events" that become known to the actuary after the date of the report.

protection-for-rebates-involving-prescription-pharmaceuticals

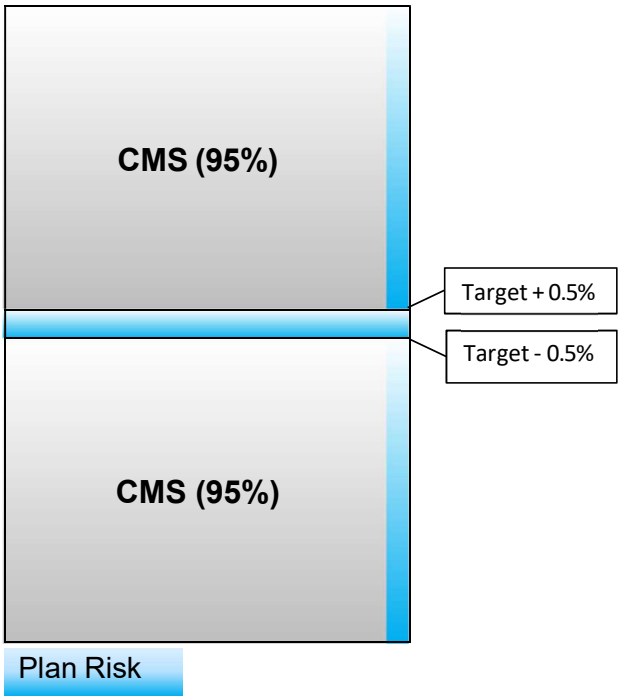
[4] See https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/Downloads/HPMS-Memos/Weekly/SysHPMS-Memo-2019-Apr-5th.pdf

What is the Risk Corridor Demonstration?

The April 5, 2019 memo also introduced a contingent risk corridor demonstration program that provides plans an opportunity to transfer a significant portion of Part D basic coverage risk to CMS, should the effective date for the Safe Harbor rule be January 1, 2020. Since CMS has stated that plans should be bidding for 2020 assuming the current treatment of rebates is in effect, there is increased financial risk for plans if the Safe Harbor rule is ultimately finalized for 2020. As explained later in this paper, we expect basic plan sponsor liabilities to increase as manufacturer rebates are shifted to point of sale. These increased costs will not be reflected in the bid, so CMS payments to plans will be inadequate if the Safe Harbor rule is effective for 2020.

The demonstration modifies the Part D risk corridors for plans that participate by significantly narrowing the risk corridors and increasing the share of risk borne by CMS. More specifically, the government would be responsible for 95% of the deviation between the target amount and the actual incurred costs beyond the first 0.5%. See Figure 1 below.

Figure 1: Risk Corridor Demonstration



Based on the April 5, 2019 memo and a follow-up April 8, 2019 call hosted by CMS, the following details were clarified regarding the demonstration:

- **How long is the demonstration?** It is a two year program for 2020 and 2021.
- **Is the demonstration mandatory or voluntary?** It is voluntary, but if a plan participates in the first year, they are required to participate in the second year as well. It is unclear whether the same risk-sharing terms would apply in 2021.
- **How is the demonstration triggered?** It is only triggered if the Safe Harbor rule is finalized as effective for 2020. Otherwise, the demonstration will not occur.
- **Is there another demonstration for the Pharmacy Concession rule?** There will not be a demonstration for the proposed Pharmacy Concession rule even if it is finalized as effective for 2020.

- **When is the application process?** If the demonstration occurs, further guidance will be given regarding the application process at a later date. Applications would probably occur in late summer or early fall.
- **Which plans are allowed to participate in the demonstration?** The demonstration is only for plans that bid, so EGWPs are excluded.
- **What if everyone wants to participate?** The demonstration is set up to accommodate all plans choosing to participate.
- **Does a plan have to opt in all of its contracts and PBPs to participate?** Plans could opt in on a PBP by PBP basis.
- **Will there be enough time for plans to apply?** There will be sufficient time to opt in to the demonstration if and when the Safe Harbor rule becomes effective.
- **Will the demonstration affect the bidding framework?** No, CMS instructions indicate the demonstration will not affect the bidding framework; it only affects reconciliation.
- **What happens if a plan assumes the Safe Harbor rule will not be finalized and does not participate in the demonstration?** The plan's bid stands as is, but the plan would still need to comply with whatever rules were in effect for 2020.
- **Will there be a new formulary submission window?** There will not be a new formulary submission window even if the demonstration occurs. The submission window will still occur around late July or early August.

If the Safe Harbor rule is finalized for 2020 and the risk corridor demonstration occurs, then CMS stated they will release additional guidance, which we assume would address several unanswered questions, including:

- **the demonstration's applicability to PACE, PFFS, and MMP plans,**
- **risk corridor provisions for 2021, and**
- **timing of the opt in application process.**

What Happens in 2020?

If either of the two rules are implemented, what will happen to 2020 financial results? Currently, rebates are shared only between the plan sponsor and CMS. If rebates move to point of sale, they will now also be shared by the beneficiary, and the drug manufacturer (via the drug manufacturer discount program). See Figures 2 and 3 below.

Figure 2: Post-Sale Rebates

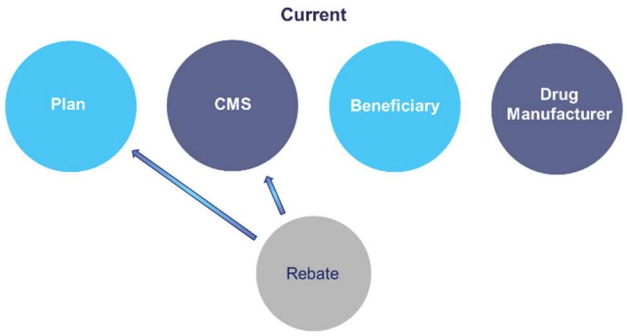
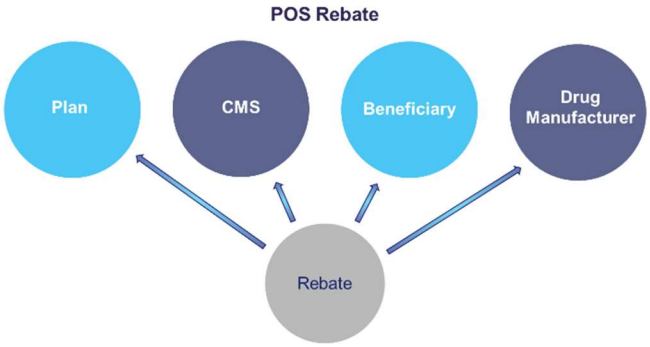


Figure 3: Point-of-Sale Rebates



If rebates must be reflected at point of sale, several components of the Part D program will be affected. For a defined standard plan, due to lower allowed costs at the point of sale, beneficiaries' cost sharing will decrease. Beneficiaries will pay lower prices at the pharmacy, and they will move more slowly through the benefit phases. For example, the deductible phase will last longer, and the catastrophic phase will be reached less often. Due to lower spending in the catastrophic phase, CMS federal reinsurance payments will decrease. Similarly, there will be lower coverage gap discount payments by drug manufacturers in the gap phase.

Since rebates will be shared among more parties, plan liability will increase, and consequently, the basic bid liability for plan sponsors will increase.

If a plan offers an enhanced alternative (aka "supplemental") benefit, the impact on expected supplemental claim liabilities under Safe Harbor or Pharmacy Concessions rule will vary depending on the benefit design. We expect plan designs that use copayments for all formulary tiers except specialty would see lower supplemental costs due to reduced allowed costs and a shift of expenses from the coverage gap phase to the initial coverage limit phase when rebates are 100% shifted to point of sale (if some portion of rebates are shifted to point of sale and the remainder lost to the plan sponsor, then results will be different). Figures 4 and 5 compare gross drug cost PMPM distributions by benefit phase under current rules ("status quo") and POS rebates for a hypothetical general enrollment plan with no deductible and the following cost sharing structure in the initial coverage phase and no additional gap coverage beyond the defined standard benefit:

Tier	Description	Cost Sharing
1	Preferred Generic	$2
2	Generic	$10
3	Preferred Brand	$45
4	Non-Preferred Brand	$90
5	Specialty	33%

Figure 4: Cost Distribution Status Quo vs. POS Rebates

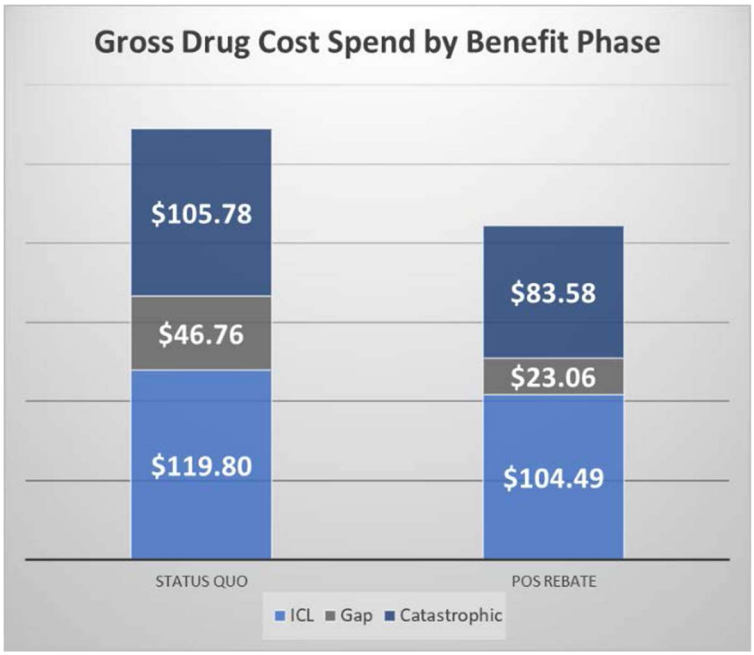
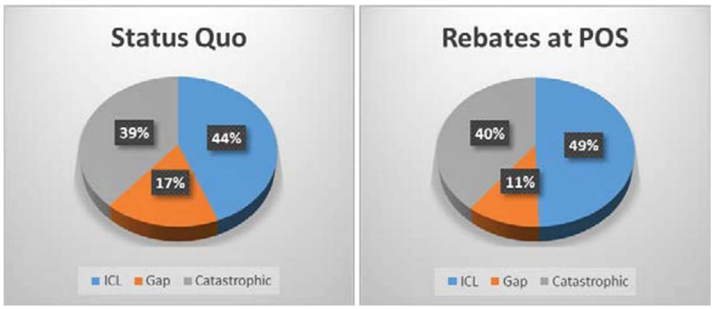


Figure 5: Cost Distribution Status Quo vs. POS Rebates



Given the significant shifting of drug spend under POS rebates, it is important for plan sponsors to project 2020 cash flows that incorporate CMS bidding guidelines and the risk corridor demonstration for revenue and projected costs assuming lower drug costs at point of sale.

Continuing with the hypothetical plan above, we project risk corridor revenue and expenses under three scenarios – 1) no change to rebate treatment, 2) POS rebates and participation in the risk corridor demonstration, and 3) POS rebates without participation in the risk corridor demonstration. Direct Subsidy, basic premium, and supplemental premium revenue for all three scenarios remain constant under current bidding rules.

		POS Rebate	
Cash Flow Component	No POS Rebate	Risk Corr	No Risk Corr
Direct Subsidy	$13.75	$13.75	$13.75
Basic Premium	$32.60	$32.60	$32.60
Risk Corridor	$0.00	$20.37	$15.14
Total Revenue	$46.35	$66.72	$61.49
Basic Claim Expense	$39.37	$62.11	$62.11
Administrative Expense	$5.52	$5.52	$5.52
Basic Profit PMPM	$1.46	($0.91)	($6.14)
Supplemental Premium	$18.60	$18.60	$18.60
Supplemental Claim Expense	$15.76	$9.31	$9.31
Administrative Expense	$2.23	$2.23	$2.23
Supplemental Profit PMPM	$0.61	$7.06	$7.06
Basic + Supplemental Profit PMPM	**$2.07**	**$6.14**	**$0.92**

Again, it is important to note that the risk corridor will only be available if the Safe Harbor rule is implemented for 2020.

Based on the assumptions underlying the hypothetical plan, our analysis shows:

- It is financially advantageous for the plan to participate in the risk corridor.
- The supplemental benefit produces a significantly higher profit under a POS rebate assumption, because the revenue is based on a higher assumed cost than is actually realized.
- The combined profits of basic and supplemental coverage are higher under POS rebates if the plan participates in the risk corridor demonstration.

It is important to note that these results are specific to the cost profile and benefit structure we modeled. Even though this is only one example, it does illustrate the magnitude of potential cash flow changes and the importance of financial modeling.

Below we discuss strategic considerations on a broader level.

What are Some Strategic Considerations?

Given the potentially significant impact to 2020 bids if the proposed rules are finalized and the risk corridor demonstration occurs, plans should be thinking about several strategic considerations.

The impact of POS rebates on Part D costs is complex and depends on the size of rebates as a percentage of allowed costs, the benefit structure, and the allowed costs associated with the population underlying the bid.

The short answer to strategic decision making is for plans to model their specific plans, so the optimal decision can be determined. Although the results of such modeling will vary, there are certain results we believe will apply to all situations:

- The gross cost of drugs will decrease as

rebates are moved to point of sale.

- Since the gross cost of drugs decreases, costs in the initial coverage limit (ICL) benefit phase will decrease, but ICL drug spend as a percentage of total will increase while the percentage in the coverage gap phase will decrease.
- The shifting of expenses between the ICL and gap benefit phases will be more dramatic for plans that primarily use copayments for non-specialty tiers.
- Basic costs (i.e. costs assuming the defined standard benefit) will increase if rebates move to point of sale.

Scenario Testing

Building on the analysis discussed above, we varied certain key assumptions in order to better understand Part D financial results under different benefit, rebate level, and expected allowed costs assumptions.

Some of our findings were:

- Defined Standard, Actuarial Equivalent and Basic Alternative plan designs will be worse off financially under POS rebates even if the plans choose to participate in the risk corridor. This is because the submitted bid will be inadequate as Part D claim expenses increase when rebates are moved to point of sale, and the risk corridor demonstration will not offset 100% of this unfavorable experience.
- The higher the rebates, the more dramatic the changes in expected costs and potential 2020 financial results if rebates are moved to POS.
- Benefit designs that use copayments for all non-specialty tiers will preserve more of the rebates for plan sponsors (versus sharing with beneficiaries and drug manufacturers). Such benefit designs also experience a bigger shift in the percentage of allowed claims classified as ICL versus gap, as compared with coinsurance designs.
- In testing a benefit design that exclusively used coinsurance for all formulary tiers with the same net cost as our hypothetical plan discussed earlier in this report, we found that the plan would be worse off financially under POS rebates even if the plan participated in the risk corridor demonstration.
- Very rich copayment-based benefit designs (e.g. significant coverage in the gap) produce the biggest favorable financial result under POS rebates with participation in the risk corridor. Of course, a large member premium will still be required, so radically improving the enhanced benefit could also imply a very different member premium or medical benefit in an MA-PD plan.

Other Considerations

The issues raised in this report do not represent a comprehensive list of factors for plans to consider when evaluating the impact of the pharmacy price concession and manufacturer rebate rules.

Below we briefly discuss other considerations that plans will want to keep in mind, and possibly quantify:

- Financial risk if plans sponsors price bids and set benefits assuming the Safe

Harbor rule happens and the risk corridor demonstration is available, but they do not occur.

- Impact of the pharmacy concession rule becoming effective for 2020, but published after the June 3, 2019 bid submission deadline.
- Effect of the rules, bidding guidance and potential risk corridor demonstration on the national average bid and average member premium. There will be greater uncertainty in projecting these national averages this year given that plan sponsors will likely evaluate the regulatory and bidding environment differently, even with the published CMS bidding guidance.
- PBM contracts. Plan sponsors should be actively discussing how rebates will be shifted to point of sale. A key question will be whether plans can expect rebates to be translated dollar-for-dollar to the point of sale.
- Ensuring that the plan has at least one plan in each service area or region that satisfies the Basic Part D offering requirements.
- Impact of financial results under POS rebate scenarios on the 85% minimum loss ratio requirement for 2020.
- How global capitation and other risk sharing arrangements that include Part D risk are affected by POS rebates.

Please contact Tim Courtney(timc@wakely.com) or Dagny Grillis (dagny.grillis@wakely.com) with any questions.