A world without rebates? How will the Part D market react to the new proposed safe harbor for rebates?

Commissioned by PhRMA

Amy Kwong, FSA, MAAA, MPH
Bruce Pyenson, FSA, MAAA

Milliman

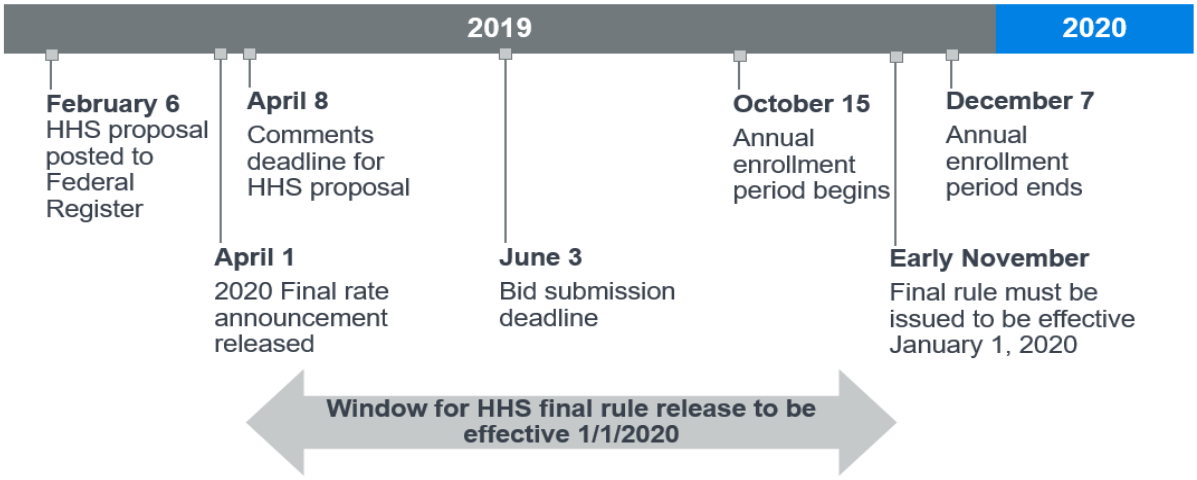
On January 31, 2019, the U.S. Department of Health and Human Services (HHS) Office of the Inspector General (OIG) proposed a rule that would eliminate the long-standing safe harbor protection for prescription drug manufacturer rebates paid to Medicare Part D sponsors and pharmacy benefit managers (PBMs).[1] Under the proposed rule, manufacturer rebates paid to Part D plans would be protected by a new safe harbor only if the amount of the rebate was set in advance and used to reduce the price at the point of sale (POS). The proposed rule would shift the risk dynamics among the beneficiaries, government, and manufacturers and affect how Part D plan sponsors make money, compete, and manage risk. This paper describes at a high level how the proposed rule may affect the Part D market.

Uncertainty—what and when

One of the key documents for the 2020 Part D bids, *Part II of the 2020 Advance Notice and Draft Call Letter*, was released just one day before the proposed rule and does not address the proposed rebate changes. But, if implemented, the proposed rule will significantly impact Part D bid assumptions and change the flow of funds through the Part D program. The updated policies for the 2020 bids will be published on April 1, 2019 (the 2020 Medicare Advantage and Part D Rate Announcement and final Call Letter), which is *before* the April 8 comment period for the proposed rule closes. While the final rule could be released any time after the close of the comment period, there will be, at best, only a few weeks for Part D plans to consider the new rule before they submit bids on June 3.

[1] Maggie Alston, Carol Bazell, David R. Mike. "Changing the Rebate Game: A Primer on the HHS Proposed Rule to Shift Drug Rebates to POS." Milliman, 19 Feb. 2019, www.milliman.com/insight/2019/Changing-the-rebate-game-A-primer-on-HHSs-proposed-rule-to-shift-drug-rebates-to-POS.

Tight timeline for 2020 bids and proposed rule



If the final rule is to be implemented starting January 1, 2020, and if the final rule details are not released prior to the June 3, 2019 bid submission deadline, plans will have to decide whether to reflect the proposed rule in their bids. It may be possible that CMS will allow Part D plans to modify their bids in some way. With the tight timelines and uncertainty, plan sponsors will likely want to model scenarios that include assumptions that rebates may or may not be used to lower POS prices.

The basics of Part D bids add another dimension of uncertainty. Part D plans are funded by both the government (through the direct subsidy, low income subsidies, and reinsurance payments) as well as by member premiums. The direct subsidy is determined by the difference between the national average bid amount (NABA) and the national average member premium (NAMP). But both the NABA and NAMP are, as the names suggest, national averages of amounts in all plan bids. For 2020, the national averages will be based on the bids submitted on June 3. Each year, there is uncertainty about where the national averages will land, but the proposed rule will introduce additional risk.

Additional sources of uncertainty and possible plan sponsor responses include:

- To retain members, many plan sponsors may want to avoid large increases in premiums. Consequently, plans may adjust their formularies or margins to reduce premiums. This is especially true for plans that have substantial low income subsidy (LIS) membership or plans that attract members seeking low premiums. Plans with large LIS membership could lose virtually all their LIS members if they bid above the regional LI benchmark. As a result, some plans may be under pressure to bid low, which may in turn reduce the NABA and NAMP. It appears as though HHS has not contemplated these potential dynamics in their estimates.
- The Part D program has risk corridors, where CMS shares a Part D plan's gains or losses: in particular, losses greater than thresholds are partially subsidized by CMS. This risk sharing will help moderate the risk to plan sponsors but could encourage relatively

low bids during this period of uncertainty, with losses subsidized by CMS, especially for plans trying to maintain or grow market share.

- Risk scores are designed to compensate Part D plans for higher or lower drug spending if their member enrollment has higher or lower than average risk. There are many open questions about how the proposed rule will work with risk scores. For example, risk scores were calibrated assuming benefit costs before POS rebate reductions. The financial impact of using the current risk model in a POS rebate environment is unclear. CMS has not proposed a revised risk score model.
- Actuarial equivalence rules constrain how cost sharing may deviate from the defined standard benefit design (for example, copays instead of coinsurance in the initial coverage phase). However, the actual calculations will be different for prices that are net of rebates, and thus plans may need to revise their benefit structures if the proposed rule is implemented.
- Medicare Advantage-Prescription Drug (MA-PD) plans typically buy down at least a portion of the Part D member premium for their Part D offering using Part C "rebates" (generated from Part C, or medical, bids projecting savings compared to the county/region benchmarks). MA-PD plans do this to compete against the combination of Medicare fee-for-service plus standalone Part D plans. MA-PD plans may also use Part C "rebates" to offer subsidized supplemental medical benefits. If standalone Part D premiums increase, MA-PDs plans could subsidize their associated Part D benefits to make their offering more attractive than standalone Part D plans.

Historical precedents

If history can provide some perspective on how the market may react to the proposed rule, here are some precedents to consider:

- **Introduction of ACA Exchange plans**: During the early years of the ACA Exchanges, many insurers underpriced commercial plans, possibly to gain market share or because they underestimated enrollee costs. As cost for enrollees became clearer in subsequent years, insurers increased their premiums. In the first three years of ACA Exchanges, insurers expected the protection of federal risk corridors and federal reinsurance, which may have encouraged relatively low premium filings.

  Similarly, the proposed rule may encourage insurers to submit low Part D bids in order to preserve or grow their membership, particularly plans with significant enrollment in low-cost or LIS plans. As previously mentioned, the federal Part D risk corridor offers some protection to plans that underbid. Part D's price sensitive market can also encourage some plans to favor low premiums to attract members.

- **Introduction of Medicare Part D**: In the first year of the Part D program, plans overestimated costs and approximately 80% of plan sponsors returned overpayments to Medicare through risk corridors[2].

[2] Goodall S. Risk Corridors (Updated). *Health Affairs.* Feb 19, 2015, www.healthaffairs.org/do/10.1377/hpb20150219.938066/full/.

Similarly, in these uncertain times, some plans will worry about losses if they bid too low and may add margin to their bids.

Will the changes promote competition?

One of the stated goals of the proposed rule is to change the dynamics of drug formulary design, and in the current environment Part D plans tend to favor high-priced drugs that pay high rebates. This preference is because the plan-retained portion of rebates can be higher than the plan liability in both the coverage gap and catastrophic phase. However, the proposed rule would create incentives to favor lower net-priced drugs, regardless of rebate, because the plan would no longer retain a portion of the rebates. This could create new opportunities for biosimilars, less-established brands, and certain generics to obtain favorable formulary placement. On the other hand, some have expressed the concern that manufacturers could try to reduce rebates for brands with limited competition, which could increase net prices.

The pharmaceutical supply chain is complex, and, in addition to PBMs, drug wholesalers, group purchasing organizations, specialty pharmacies, drug stores, and mail order pharmacies all play key roles. The proposed rule would apply only to PBMs and Part D plan sponsors (as well as to Managed Medicaid plans), but these other stakeholders of the supply chain, such as wholesalers and group purchasing organizations, may find opportunities to become more involved in Part D.

Operational impact

The proposed rule would introduce uncertainty to the operations of PBM and plan sponsors. Depending on how the rebate chargeback is structured, PBM cash flow may be impacted if PBMs are required to pay out rebates by reducing POS prices *before* receiving rebates from drug manufacturers. PBMs will still be allowed to retain fixed fees for services provided to prescription drug manufacturers and may try to generate more revenue to compensate for lost rebates by shifting utilization to their mail order or specialty pharmacies[3]. Plan sponsors would need to make sure claim processing and prescription drug event (PDE) submissions reflected prices at the point of sale.

Market impact for drug manufacturers and plan sponsors

The elimination of rebates to PBMs and plan sponsors will reshape the competitive landscape among drug manufacturers. Currently, rebates are shared between Part D plan sponsors and the federal government, and also reduce member premium. However, rebates are not directly shared with the members at the pharmacy counter. The contract terms, which vary by drug, manufacturer, and Part D sponsor, are considered proprietary trade secrets and thus closely guarded. Members do not have visibility to the actual net cost of the drugs they receive. Such

[3] Klaisner, J., Holcomb, K. and Filipek, T. “Potential Changes to the Treatment of Manufacturer Rebates.” 31 Jan. 2019, aspe.hhs.gov/system/files/pdf/260591/MillimanReportImpactPartDRebateReform.pdf.

lack of transparency has been associated with higher drug costs at the POS[4] , although some economists have also argued that transparency can lead to higher prices[5].

Plans may respond to POS rebates by focusing on the value of drugs on the formulary: removing low value drugs while adding high value drugs to the formulary. The impact of these changes on various therapeutic classes will differ. Plans may narrow formularies to save costs, but that could also discourage patients seeking particular drugs from enrolling in plans with narrow formularies. It may be difficult to distinguish cost controls from attempts at selection. If such trends are observed, plan sponsors may face scrutiny from CMS.

Transparency between manufacturers and PBMs may lower barriers to new Part D plans. With rebates no longer a driving issue, other organizations in the supply chain may see opportunities to launch their own Part D plans. For example, group purchasing organizations (GPOs) such as employer group waiver plans (EGWPs), wholesalers, and drug store chains may directly contract with drug manufacturers, using discounts and service arrangements. This could induce new competition in the Part D market.

The proposed rule introduces uncertainty to Part D plan sponsors and PBMs. Plan sponsor responses will vary with their circumstances including their tolerance for risk in underbidding or overbidding. PBMs will need to re-think their business strategy and operations to reflect a new world without rebates. If finalized, the proposed rule will redefine the competitive landscape for Part D plan sponsors and PBMs and reshape the contracting relationships between all key stakeholders from members and manufacturers to the Part D plan and dispensing pharmacy.

This article was commissioned by PhRMA. Bruce Pyenson and Amy Kwong are members of the American Academy of Actuaries and meet its qualifications for this work. The authors do not imply Milliman endorsement of any policy or recommendation. The reader should keep in mind that the authors relied on information in the proposed rule; this paper may lose relevance if the final rule differs from the proposed.

Milliman

Milliman is among the world's largest providers of actuarial and related products and services. The firm has consulting practices in life insurance and financial services, property & casualty insurance, healthcare, and employee benefits. Founded in 1947, Milliman is an independent firm with offices in major cities around the globe.

CONTACT

Bruce Pyenson
bruce.pyenson@milliman.com

milliman.com

[4] "The Gross-to-Net Bubble Topped $150 Billion in 2017." Drug Channels, 24 Apr. 2018, www.drugchannels.net/2018/04/the-gross-to-net-rebate-bubble-topped.html.
[5] Sinaiko, Anna D., and Meredith B. Rosenthal. "Increased price transparency in health care—challenges and potential effects." New England Journal of Medicine 364.10 (2011): 891-894.