Implementation Issues for Mandatory Rebates at POS

As MedPAC noted in its comments on the RFI, "[w]e are concerned that CMS's proposed approach would be complex to implement, administratively burdensome and, for drug classes with few competing therapies, would risk disclosure of confidential rebate information."

There are significant, unaddressed issues that would materially impact the ability of Part D plan sponsors to implement a mandatory POS rebate program. These would have to be addressed before Part D beneficiaries could receive mandatory rebates at POS.

We have divided the issues into two groupings: the first list sets out the issues based on the content of the RFI itself; the second list is a related set of key significant issues not addressed at all in the RFI. All of the issues identified would materially impact Part D plan sponsor IT systems, contracting with manufacturers and pharmacies, bid development, reporting obligations, PDE (claim) submissions, formulary development, beneficiary materials (e.g., notices and appeals), and more.

A. Issues Directly Raised in the RFI

1. **Specified minimum percentage**. CMS would need to specify the minimum percentage of manufacturer rebates that would have to be passed through at POS. CMS also would need to specify how often the percentage should be updated by CMS.

2. **Definitions related to rebated drugs**. CMS would need to provide guidance on the following aspects of rebated drugs:

    - What is the definition of a rebated drug? If a drug is rebated for some portion of the Part D drug benefit (e.g. in the Initial Coverage Limit (ICL)), must it be rebated for ALL portions of the Part D benefit (e.g. in the donut hole as well)?
    - What drug classification system would be used to define drug category or class?
    - How often would the drug classification system be updated (e.g. USP only updates every three years, which is a very long time in the drug development arena)?
    - What would be the time period for weighting by total drug costs for each drug (e.g., monthly, quarterly, yearly)? How would value-based contracts be averaged into the weighting calculation? If a value-based rebate agreement specified that the manufacturer refunds the cost of the drug if it does not work, would the plan get the rebate back from the beneficiary?
    - What would be the time period for plans to recalculate the applicable average rebate?

3. **Definition of Negotiated Price in the Coverage Gap**. As CMS notes, CMS would need to address the issue of whether it has the authority to require sponsors to include pharmacy price concessions in the negotiated price for purposes of determining

manufacturer coverage gap discounts. In either event, CMS would need to explain how this would work.

4. **Pharmacy DIR**. Would CMS adopt the "lowest possible amount" option for pharmacy payment? If so, how would the "lowest possible reimbursement amount" be determined at the drug level, when many pharmacy DIR arrangements are based on aggregate, rather than drug level, metrics? If not, what approach would CMS use to determine pharmacy payment?

B. Other Implementation Issues Not Raised in the RFI

1. **Medicare Plan Finder**. CMS would need to provide direction on how the rebates would be reflected on Medicare Plan Finder (MPF).

    - How often would the prices be expected to be updated?
    - What would be the expectation in terms of accuracy – given that the rebate pass-through amount would be an estimate – and how would this work with the newly proposed MPF price accuracy standard scheduled to take effect January 1, 2019, which makes it impermissible for the NPF to have any errors?

2. **Applicability to copayments**. CMS would need to address how the mandatory POS regime would apply when the cost-share for the branded rebated drug is a set copayment, in contrast to a coinsurance. Would the POS rebate only apply to coinsurance?

3. **Tiering exceptions**. The agency would need to assess how the rebate levels related to the current tiering exceptions rules which allow beneficiaries to appeal to get a drug that is covered in one tier (e.g., non-preferred brand) at the same cost-sharing as applicable in a lower tier (e.g., preferred generic). If a beneficiary would get a rebate for the brand at the original higher tier, could she still get the rebate when the drug were treated as a generic for out-of-pocket payments? What if that meant that the plan was essentially paying the beneficiary and providing the drug for free because the rebate amount exceeded the cost-sharing?

4. **MTM program**. The formula for who must be eligible to be part of MTM programs includes whether the enrollee is likely to incur annual costs that exceed a predetermined level. Assuming the reduced out-of-pocket amounts resulting from the POS rebate would keep some beneficiaries from reaching the level, would beneficiaries who should otherwise be receiving MTM services no longer necessarily qualify for them? How would this change impact the ongoing MTM demonstration projects?

5. **Pharmacy performance-based and preferred network**. There are a number of specific issues related to the impact of the mandatory pharmacy DIR proposal that would have to be addressed as well, including:

- Value based payments. CMS noted that performance-based pharmacy arrangements could continue but does not provide any direction on how that would work. Given that most pharmacy DIR is performance based and provides significant benefits and savings to Part D, we would really like to understand how this could happen. Value-based arrangements should not be discouraged or prohibited; they are widely considered the future of health care reimbursement.

- Preferred network disruption. Likewise, we are very concerned that the RFI would eviscerate the very popular preferred pharmacy networks because there would be severe limits on the flexibility of plans to reduce cost-sharing differentially for network pharmacies. CMS would need to articulate how Part D sponsors could still craft preferred networks.

- Pharmacy cash flow. Since the RFI program would very likely result in decreased reimbursement rates for all pharmacies, if existing overall reimbursement rates held and did not increase, this could result not only in cash flow problems for pharmacies but also in pharmacies that could no longer afford to be in the network, reducing consumer access to broad pharmacy networks. CMS would need to take steps to make sure that pharmacies were aware of, and had plans to deal with, this unintended consequence of the mandatory POS pharmacy DIR rebate.

6. **Use of existing reporting mechanisms**. CMS states that it would try to use existing reporting mechanisms to review plan calculations such as the estimated rebates field at POS in the PDE claim. Has CMS confirmed that this is realistically doable both for the manufacturer and the pharmacy DIR amounts? We note that this field is for "estimated" rebates which actually may not be applicable here, and even if it were, we understand that new NCPDP fields would need to be developed, tested, and implemented to accomplish this. This is usually a lengthy process.

7. **Other reporting requirements**. As CMS is aware, there are significant DIR reporting requirements currently, which are modified every year and which address every aspect of the DIR arrangements. The current version dated June 23, 2017 (applicable to the 2016 DIR filings which were due to be filed in the summer of 2017) is 38 pages. CMS always provides stakeholders an opportunity to comment on the drafts. We assume that there would need to be comparable, detailed reporting requirements (also subject to stakeholder input) along these lines for reports due for the mandatory POS rebates.

8. **Reconciliation process**. How would the current very detailed PDE claims reconciliation process be revised to accommodate the new approach? With claims based on an estimated average rebate or estimated per drug rebate, claims reconciliation would become more complicated. Would Part D plans have to reprice every single claim once the rebates are determined, well after the close of a year? If so, plan administration costs would increase significantly. Would this put plans in danger of missing their MLR requirements?

9. **Bid pricing tool**. The current bid pricing tool does not envision mandatory rebates at POS. We assume this would have to be revised to reflect this program.

10. **Beneficiary financial considerations**. CMS recognizes that it may be hard to establish accurate amounts when rebate agreements are structured with contingencies that are unclear at POS. Thus it is very likely that there would be scenarios where the rebate at POS "paid" to the beneficiary would have been too high and the beneficiary would technically owe funds back to the plan sponsor. How would plans be expected to collect this refund? Would the beneficiary be expected to pay interest on the amount? What would happen if the beneficiary refused to repay the amount? Likewise, if the rebate was too low, and the beneficiary should have been given a bigger rebate, how would this work? Would the plan be expected to send the beneficiary a check, or credit her premium, or otherwise make her whole?

11. **Beneficiary interactions**

    - Communications. How would the mandatory POS at rebates program be explained to beneficiaries? Would they get specific notices? Would the plan Annual Notice of Change (ANOC) have to be revised every year to reflect changes in rebate status? It is a very complicated concept and may be readily misunderstood by beneficiaries who may believe they would be receiving a rebate check in the mail.
    - Appeals. Would beneficiaries be able to appeal the amount of the rebate they received (or did not receive) due to the mandatory POS rebate? How would this process work? If beneficiaries complain about not getting enough of a rebate, even though the plan is properly administering the program, would CMS hold plans harmless from negative star ratings results?

12. **Manufacturer agreement to participate in mandatory rebate program**. For the coverage gap program, CMS has, and updates periodically, an "Agreement for Drug Manufacturer Participation in Coverage Gap Discount Program." If a manufacturer is not on the list of who has accepted these terms, then a Part D plan sponsor cannot contract with them for Part D. Would there be a similar agreement so that CMS could essentially pre-qualify those manufacturers who have agreed to the terms and conditions for the Mandatory POS program so that Part D plan sponsors could rely on the manufacturers to comply with the terms of the program?

13. **Disclosure of confidential rebate information**. Since we are not aware of any proposal for mandatory rebates at POS that would not require plans/PBMs to reveal confidential contract information, we would ask that CMS address how it would handle their exposure should a manufacturer claim that plans/PBMs released confidential information.

14. **Application to EGWPs**. CMS would need to determine if the mandatory POS rebates program applied to EGWPs, and if so, issue guidance on how that would work.

C. Other Considerations on Implementation of Mandatory POS Rebates

1. **Paperwork Reduction Act**. A lot of the guidance referenced above would be in materials that would need to be approved through the PRA process.

2. **Dept. of Justice Memorandum**. Decisions on many of the issues noted above appear to be the type of substantive guidance as to which the recent DOJ memo on limiting the use of agency guidance documents would be applicable.

3. **Recent Enactment of the BBA**. The recently enacted BBA includes provisions whose interactions with the proposed mandatory rebate at POS need to be assessed, such as moving the closing of the donut hole up a year (and increasing manufacturer liability to 70%) and providing that biosimilars are now subject to the required manufacturer discount in the donut hole.

    - **For example, interaction with coverage gap discount**. If POS rebates were payable in the coverage gap as well as up to the ICL and in reinsurance and if the 70% coverage gap discount combined with the POS rebate exceeded 25% of the total cost of the drug, would beneficiary cost-sharing drop below the percentage specified in statute? If not, would the difference be retained by the manufacturer or could the plan put it toward premium reduction?

4. **Compliance**. CMS expects all plan sponsors to certify to the accuracy, completeness and truthfulness of all data. Since rebates are by definition uncertain, without complete and detailed and workable guidance on every facet of this undertaking, plan sponsors would not be able to make these certifications. Thus CMS must provide an alternative compliance scheme here as the standard one would not be viable.