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Proposed Amendments to the Safe Harbor Regulation Concerning Certain Discounts: Potential Impacts on Manufacturers' Government Program Pricing Metrics

The Proposed Removal of Safe Harbor Protection for Certain Rebates and Creation of New Safe Harbor Protection for Certain Point-of-Sale Price Reductions, Potential Shift in Discount Arrangements, and the Potential Impact on Certain Government Program Pricing Metrics

For:
Clients and Friends of Riparian, LLC

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1.0 Background

1.1 Introduction

In February 2019, the Office of Inspector General ("OIG"), Department of Health and Human Services ("HHS") Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees proposed rule was published in the Federal Register.

The HHS proposes to amend the discount safe harbor to explicitly exclude manufacturer rebates to plan sponsors under Medicare Part D and Managed Medicaid plans, and create new safe harbors for point-of-sale discounts that are designed to benefit patients and certain PBM service fees. The proposed revisions to the discount safe harbor will give rise to a new infrastructure necessary to support the massive shift in contracting that will occur, and will redefine current framework used by Medicare Part D and Managed Medicaid plan sponsors when evaluating the design of prescription drug plans. The proposed rule clearly signals a potential watershed event for the health care ecosystem and the various stakeholders within that ecosystem – including manufacturers, pharmacy benefit managers ("PBMs"), and patients.

However, rather than addressing the broader issues that such a watershed event would implicate, this white paper addresses the anticipated "shift" in manufacturer discounts, how that shift may impact certain government program pricing metrics, and their potential impact on manufacturer discount obligations with respect to those government programs.

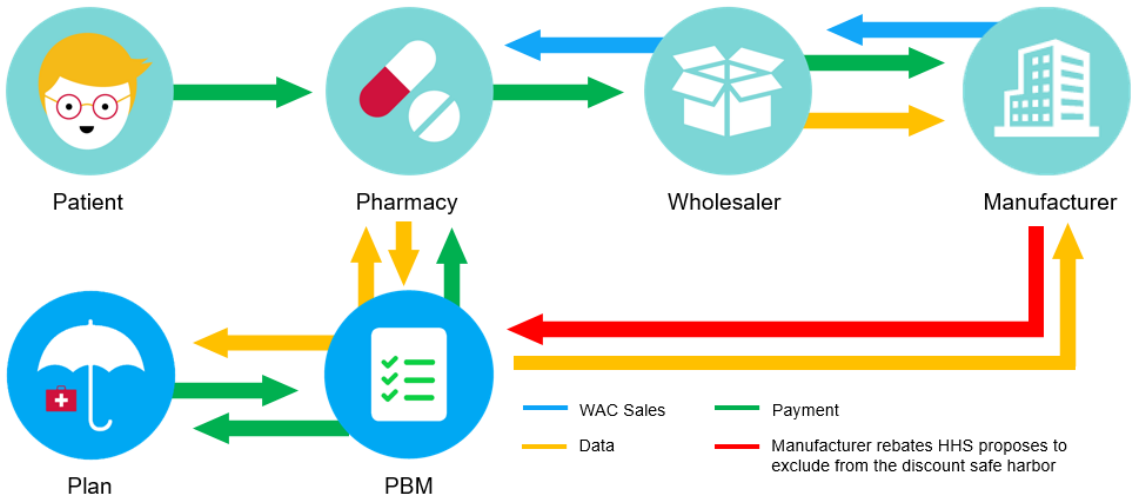
1.2 Overview of the Proposed Amendments and Intent of Proposed Changes

TBD – potentially co-author with J Shakow

1.3 Pharmacy Benefit Managers and the Current State Drug Distribution Model

Pharmacy benefit managers ("PBMs") have an important role within the U.S. prescription drug supply chain. PBMs manage prescription drug programs on behalf of various types of health plans including employer plans, commercial health plans, and Medicare Part D and Managed Medicaid plans. PBMs engage in various negotiations on the behalf of their clients (plans). PBMs negotiate reimbursement rates with contracted pharmacies for drugs dispensed to plan beneficiaries, as well as rebates from manufacturers for inclusion or tier placement on the formularies for each plan.

The following is a simplified drug distribution model that illustrates the direct and indirect flow of certain data and payments between a manufacturer and a PBM.

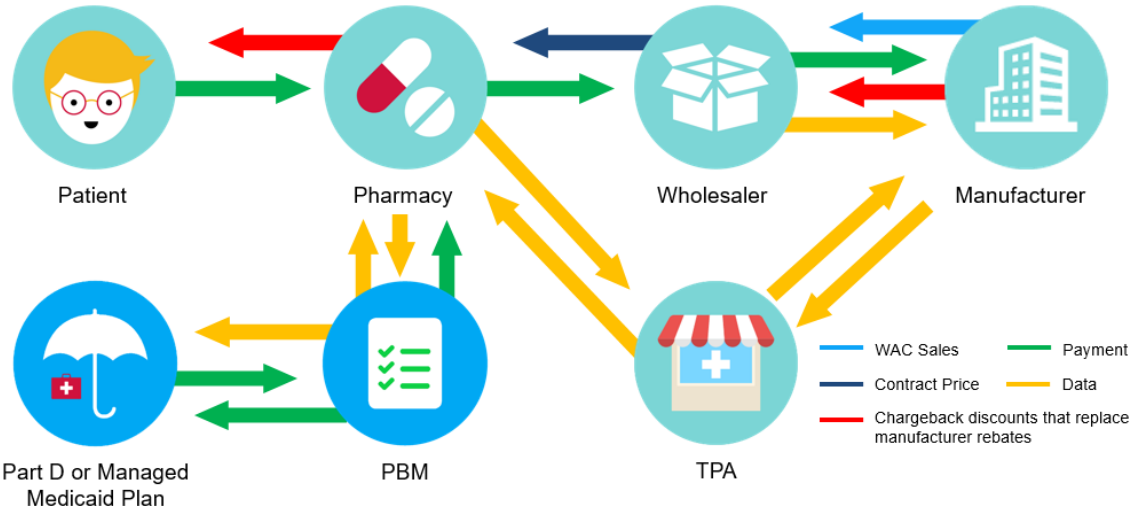


1.4 Potential Future State Drug Distribution Model

It is unclear exactly what the new model will look like in the event the HHS' proposal to amend the discount safe harbor comes to fruition.

One potential model may look similar to the replenishment model that is commonly used by 340B Covered Entities (or its Contract Pharmacies) to manage their participation in the 340B Drug Discount Program. Under a replenishment model, there is no physical separation of 340B and non-340B drugs; rather, non-340B units are purchased initially and dispensed. When non-340B units are dispensed to 340B patients, replacement units are purchased at the 340B ceiling price, and replenish the "regular" non-340B inventory accordingly. A software system or Third Party Administrator ("TPA") determines which of the drugs are eligible to be purchased at 340B pricing and replenished; these determinations may be made at the point of sale or retrospectively.

The following is a potential future state drug distribution model in a world where manufacturer rebates to plan sponsors under Medicare Part D and Managed Medicaid plans are excluded from the discount safe harbor, and are replaced by chargeback discounts passed on to patients through dispensing pharmacies.



2.0 Potential Outcomes

2.1 Current State Government Program Reporting Requirements

The regulations dictating the manner by which manufacturers are required to calculate and report pricing metrics such as the Medicaid Average Manufacturer Price ("AMP"), Best Price ("BP"), and Medicare Part B Average Sales Price ("ASP") were authored and implemented at a time in which manufacturer rebates to plan sponsors under Medicare Part D and Managed Medicaid plans, often a PBM contracted by the Medicare Part D or Managed Medicaid plan, were commonplace.

The following chart summarizes the manner by which manufacturers are required to account for rebates to plan sponsors under Medicare Part D and Managed Medicaid plans when calculating AMP, BP, and ASP.

	AMP	BP	ASP
Medicare Part D	Excluded [Federal Register Vol. 81, No. 20, 5223, §447.504(e)(8)]	Excluded [§447.505(c)(6)]	Excluded [§414.804(a)(4)]
Managed Medicaid[1]	"Traditional" AMP: Excluded [§447.504(c)(18)] 5i AMP: Included [§447.504(d)(4)]	Included [§447.505(b)]	Included [§414.804(a)(2)]

[1] Does not include rebates paid pursuant to section 1927 of the Social Security Act, which are determined on the basis of Medicaid AMP and/or BP.

2.2 Impact on Government Program Pricing Metrics

A successful bid by HHS to amend the discount safe harbor is expected to result in a massive shift in manufacturer discounts away from PBM rebates determined on the basis of formulary negotiations that are adjudicated using monthly or quarterly utilization claims data, toward point-of-sale discounts that are adjudicated upon drugs being dispensed to patients.

The following chart summarizes the potential directional impact to AMP, BP, and ASP, resulting from the anticipated shift in manufacturer discounts.

<table>
<tr><th></th><th>AMP</th><th>BP</th><th>ASP</th></tr>
<tr><td rowspan="2">Medicare Part D</td><td>〓</td><td>〓</td><td>〓</td></tr>
<tr><td colspan="2">Provided that the point-of-sale discounts qualify as “prices charged which are negotiated by a prescription drug plan under Part D of title XVIII, by any MA-PD plan under Part C of such title for covered Part D drugs, or by a Qualified Retiree Prescription Drug Plan for such drugs on behalf of individuals entitled to benefits under Part A or enrolled under Part B of Medicare”.</td><td>See Operational Consideration relating to the use of chargeback data in lieu of rebate utilization data for purposes of identifying ASP-exempt indirect sales.</td></tr>
<tr><td rowspan="3">Managed Medicaid[2]</td><td>“Traditional” AMP 〓
Provided that the point-of-sale discounts may be wholly attributed to patients.</td><td rowspan="2">↑</td><td rowspan="2">↑</td></tr>
<tr><td>5i AMP ↑
A shift from rebates to PBMs for Managed Medicaid plans (included in 5i AMP) to point-of-sale discounts will likely decrease the amount of price concessions that are included in 5i AMP (thereby increasing</td></tr>
<tr><td colspan="2">Provided the BP-setting net price setting BP would have otherwise been established by a rebate to a PBM for a Managed Medicaid plan, and that the point-of-sale discounts in its place may be wholly attributed to patients.</td><td>A shift from rebates to PBMs for Managed Medicaid plans (included in ASP) to point-of-sale discounts will likely decrease the amount of price concessions that are included in ASP (thereby increasing ASP), provided that the point-of-sale discounts may be wholly attributed to patients.</td></tr>
</table>

[2] Does not include rebates paid pursuant to section 1927 of the Social Security Act, which are determined on the basis of Medicaid AMP and/or BP.

	AMP), provided that the point-of-sale discounts may be wholly attributed to patients.		

As a result, a manufacturer's Medicaid rebate obligation may potentially increase (as a result of an increase to AMP), decrease (as a result of an increase to BP), or remain steady (if the AMP increase is offset by the BP increase). The likelihood of such impact may be more predictable for certain products (e.g., it may be more straightforward to predict the impact for a generic 5i covered outpatient drug, where the rebate is established on the basis of AMP only).

There are other impacts as well. The reimbursement limits for a manufacturer's drug may potentially increase, provided those reimbursement limits are tied to AMP or ASP (e.g., the Medicaid FUL or payment allowance limits based on the ASP methodology for Medicare Part B drugs).

2.3 Operational Considerations

As indicated in the above-referenced chart, a shift in manufacturer discounts – from rebates to Medicare Part D and Managed Medicaid plan sponsors to point-of-sale discounts designed to benefit patients – can have varying impacts on the various government pricing metrics that establish manufacturer discount obligations and/or provider reimbursement limits. However, the potential directional impacts described in this white paper rely upon certain assumptions being true/ conditions being met (e.g., that point-of discounts pursuant to Managed Medicaid plans may be wholly attributed to patients, and that no portion of the discount is retained by the dispensing pharmacy).

- Legal Considerations: Manufacturers will need to carefully evaluate the design and contractual language governing their point-of-sale discount arrangements and are encouraged to seek legal guidance as to whether the assumptions that are made in relation to each arrangement are reasonable and consistent with the body of statutory, regulatory, and program guidance that has been issued by the relevant managing agencies.

- Source Data Considerations: Manufacturers will also need to evaluate the source from which data will be used to capture the Medicare Part D sales that are to be deducted from the ASP calculation. One potential avenue is to use adjudicated chargeback claims as the data source in the event the point-of-sale discounts are captured as chargebacks. Another potential avenue is to use utilization data in the event utilization data are used to adjudicate claims for bona fide service fees. Manufacturers will at a minimum need to ascertain the manner by which such data will be captured and the systems in which the data will be maintained to determine the source that is most complete and accurate.
- Calculation Methodology Considerations: Government program pricing calculation methodologies are established on the basis of the business circumstances that are relevant at a given point and time. In light of the potential changes that will be brought about by the shift in manufacturer discounts, manufacturers ought to re-evaluate their calculation methodologies and consider the adjustments that are necessary in light of those changes.

3.0 References

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