THE GROWING GAP
Between List and Net Prices of Drugs

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The gap between list and net prices of drugs has been growing at a rate that many pundits have long speculated is unsustainable. Specifically, the steady increase in unit costs of branded medications and the presence of ever-increasing available rebates has created a significant gap between the list price and the "true" cost of the drug. While such increases in unit cost are theoretically countered by rebates, the beneficiary of such rebates is not always clear. This article will seek to further explain this dynamic, explain regulatory initiatives and provide plan sponsor considerations.

How We Reached This Point

Consumer Concerns

While many PBMs report flat or negative trend, the American public's yearly spending on prescription drugs continues to increase. This type of increased prescription pricing was most clearly seen in Mylan's EpiPen pricing increases. In 2009, pharmacies paid $103.50 for each two-pack of EpiPen Autoinjectors. By 2016, the price had risen to $608.61 for the same two-pack, a 505.11% increase. Many readers are familiar with this example, but while this drug is a commonly used example surrounding drug price inflation, it is also important to remember that this drug likely had a significant rebate, as a percentage of the list price, attached to it. Following wide reporting by the media and outrage over the price, Mylan launched an authorized generic of EpiPen with a list price of around $300. Hence, it can be assumed that the average rebate on the original EpiPen was more than 40% of the list price. As the consumer almost certainly did not directly benefit from any rebate associated with this drug, the ever-increasing list price was felt immediately. Thus, this highlights the reason rebates are top of mind for many regulators.

The List-to-Net Gap

As identified above, the list-to-net gap is the difference between manufacturers' list prices and the net prices paid to the manufacturers after rebates and discounts are considered. The difference between list price and net price has continued to widen over the past decade. There are a variety of contributors to this trend, including PBM market consolidation and increased adoption of exclusionary formularies, all stakeholders in the supply chain benefit when list price increases, advent of price protection rebates and, candidly, the growing appetite for rebates by entities that benefit therefrom, including purchasers.

However, there are three synergistic dynamics that suggest that this bubble could be nearing its expiration date. First, the public outcry and resulting political attention on the high list prices of drugs, made possible by rebates, has somewhat tempered list price increases. Second, the lack of price increases and the associated price protection rebates, many PBMs are over guaranteed and likely have much more of an appetite to explore alternative models or revenue streams. Third, while PBMs still retain a portion of manufacturer revenue, an ever-increasing number of contracts with their clients require a full or nearly full pass-through of these funds, particularly for carved-out plan sponsors. Thus, while thelist-to-net gap impacts all plan sponsors, its impact can vary greatly depending on a plan sponsor's contracted discounts and rebates. Ineffective contract definitions and reconciliation methodologies allow a plan's cost to rise compared to its prudently contracting peers.

Regulatory Efforts

Trump Administration's Blueprint

In the administration's blueprint, it put forth four concepts to achieve a reduction in prescription drug pricing for Medicare Part D.

The first concept sought to increase competition by preventing brand drug manufacturers and generic drug manufacturers from using the regulatory processes to extend their products' exclusivity in the market. **The administration's second concept** was to improve negotiation with pharma by changing Part D plan formulary standards and allow Part D plans to make mid-year substitutions from brand drugs to new-to-market generic drugs. **The final two concepts** most relevant to this article and introduced in the administration's blueprint was creating incentives to lower list prices and the reduction of patient out-of-pocket spending. While a specific methodology was not mandated, the administration presented general concepts that would result in lower prescription drug prices including the idea of applying a substantial portion of rebates at the point of sale.

While this blueprint did not provide a suggested regulatory scheme, its impact is certainly visible in the Health and Human Services ("HHS"), proposed rule.

Proposed Rule and Legislation

Health and Human Services ("HHS") introduced its proposed rule titled Fraud and Abuse; 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 (the "Proposed Rule") in February 2019. The proposed rule seeks to modify the anti-kickback protection discount safe harbor by removing the ability to provide certain reductions in price or other remunerations (rebates) from a manufacturer to a Part D plan sponsor, a PBM in contract with a Part D plan sponsor, or Medicaid. The anti-kickback statute makes it a crime to exchange anything of value in an effort to induce the referral of health care program business unless such effort is covered by a safe harbor. By removing this safe harbor, drug manufacturers would no longer be able to provide rebate payments to plan sponsors or PBMs in exchange for the manufacturers' drugs being purchased by the associated prescription drug plan.

To compensate for the loss of rebates to PBMs and plan sponsors, the proposed rule looks to create two new safe harbors.

1 A safe harbor to allow for point-of-sale reductions in price on prescription pharmaceutical products (point-of-sale rebates). The idea behind this safe harbor would be to provide the consumer with the direct benefits of the negotiated rebate, thus reducing the out-of-pocket cost of the drug.

2 The second proposed safe harbor would allow the payment of service fees by a manufacturer to PBMs that provide certain legitimate services to the manufacturer. This safe harbor would allow the PBMs to continue to be compensated for certain administrative services, such as reporting, performed by the PBM. By requiring legitimate services to be provided, the proposed rule seeks to preclude PBMs from retaining any additional portion of the available manufacturer rebate, thus reducing the overall cost of drugs.

Plan Sponsor Questions

+ What is the cost to finance rebates at the point-of-sale?
+ If necessary, how and when will the rebates be reconciled?
+ How are rebates used today?
+ Must premium contributions be adjusted?
+ How will this impact current plan design?

To be clear, HHS's proposed rule, if made effective, would only regulate Medicare Part D plans, Medicaid Managed Care Organizations' and PBMs' contracts with Part D plan sponsors and not commercial drug plans. However, there is a growing sentiment in the Senate that substantially the same, if not exactly the same, regulations should be applied to the commercial market. In March 2019, Senator Mike Braun introduced legislation into the Senate to do just that.

Plan Sponsor Impact and Considerations

Regardless of if a change is market-driven or a regulatory requirement, plan sponsors must educate themselves about the considerations and financial impact of such an approach. Likely, the biggest question is how the financial operation of the plan will be impacted in the absence of the plan sponsor's receipt of rebates. Most plan sponsors use these rebates to offset the overall cost of their prescription programs and then derive premium contributions for participants based on the net program cost. Alternatively, some plan sponsors use these dollars to fund alternative benefits-related initiatives or programs. Prudent plan sponsors should begin evaluating the possible impact on plan costs and premium contributions should some or all of the rebate be applied at the point-of-sale.

It is also important to remember that, just as plan sponsors will seek to keep their financials constant, all parties in the supply chain will be attempting to do the same. As such, baring a significant change in the pricing model, any change will likely be a repackaging of the existing supply chain and associated processes. For example, the PBM does not receive a rebate at the point-of-sale from the manufacturer today. Rebates are paid retrospectively (60 and 270 days after the quarter in which the claim was processed) by manufacturers to PBMs after utilization data have been aggregated, validated and evaluated against contractual terms, such as market share targets, formulary positioning or price protection guarantees. This results in the PBM identifying an estimated collection and engaging in actual collections at a later point in time. The proposed rule does not impact this mechanism and it will likely continue to exist. This dynamic begs the question; what will be passed through at the point-of-sale? Will it be specific to that drug or a per channel guarantee? Assuming it must be some type of estimate, what is the time value of money to make these funds available prior to collections and how will this be reconciled?

These questions and many others are important to make the best decision for your plan. Also, understanding existing market dynamics and how a plan sponsor's PBM contract currently addresses rebates is helpful. As mentioned above, effective contract definitions, strong reconciliation methodology and effective market checks are all current steps that provide a counterbalance to rising list prices and will continue to benefit plan sponsors. While components may be repackaged, the combination of price and utilization driving total pharmacy costs still holds true.

to Consider

+ Must deductible and max-out-of-pocket levels be adjusted?
+ What is actually being applied at the point-of-sale?
+ Will rebates be applied before or after participant cost share?
+ Will this actually result in lower drug prices over time and more affordable options for plan sponsors and their participants?