MEDICARE AND MEDICAID

A ROLLBACK OF REBATES

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In January 2019, the Department of Health and Human Services (HHS) put forth a proposed rule to repeal the safe harbor status for Medicare and Medicaid drug rebates under the Anti-Kickback statute.[1] This idea was first conveyed in the American Patients First initiative, which the Trump administration put forth in May 2018.[2] Intended to address many of the systemic issues facing the pharmaceutical industry, its primary focus was on drug pricing. Now, with this potential ruling, HHS attempts to operationalize some of these concepts as part of the administration's promise to "lower list prices and reduce out-of-pocket spending on prescription drugs".[3]

If implemented, the rule would go into effect as of January 1, 2020. While its passage is not certain, understanding the components of this initiative and staying apprised of related developments is critical for industry stakeholders to successfully anticipate and prepare for changes to their business.

BACKGROUND

Anti-Kickback Statue and Rebates

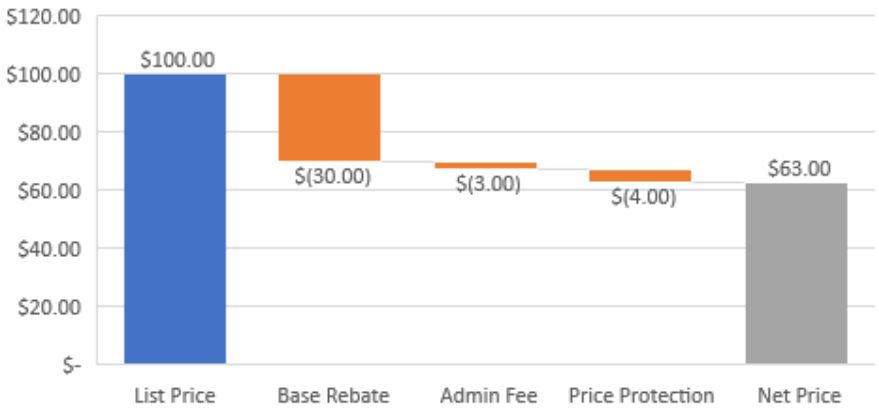
Passed in 1972, the Anti-Kickback Statute imposed restrictions that prevented pharmaceutical and medical device companies from offering financial incentives to persuade patients to use their drugs.[4] However, stakeholders voiced opposition about the fact that the statute's broad guidelines made it difficult to introduce competitive elements into their business that would ultimately help to benefit the patient. As a result, Congress revised the regulation to allow for "safe harbors" in specific scenarios, protecting covered arrangements from being categorized as kickbacks.

One such protected scenario concerned Pharmacy Benefit Managers (PBMs), who manage the drug formularies affiliated with health insurance plans, administer contracted arrangements, and negotiate payments from manufacturers. As rebates collected by PBMs are not directly granted to the insured individual or realized at the point of sale, this provided a rationale for their safe harbor inclusion. While the terms of these rebates are quite varied across the industry, the process of administration is largely standardized.

PBMs gather prescription data from pharmacies and consolidate it into a "utilization file" that is provided to manufacturers, along with an invoice. Manufacturers then perform their own calculation of what's owed based on this data and the relevant contract terms. Over time, the deal structures for these rebates have become increasingly more complex, incorporating performance terms, administrative fees, and price protection clauses. Generally, the reimbursement mechanisms are tied to the list price of a drug, in an effort to manage net costs for providers and ensure that manufacturers aren't paying more in rebates than what the medication is priced for at wholesale.

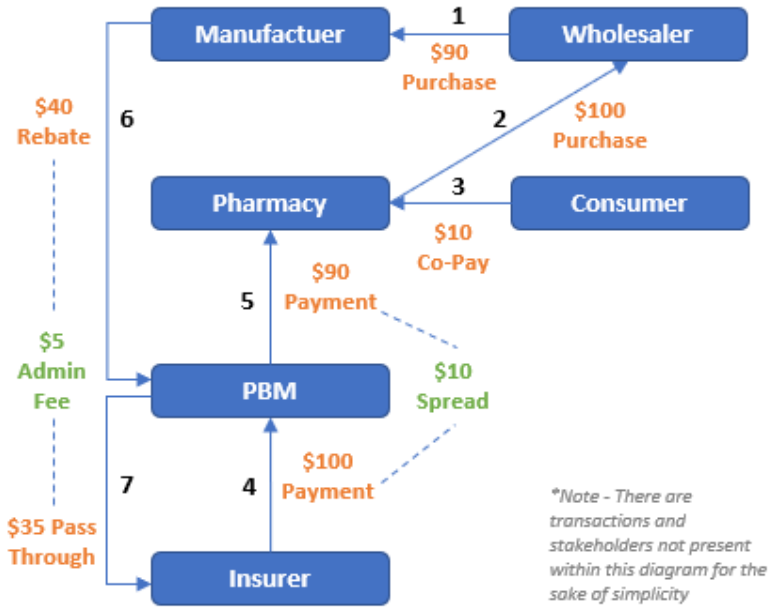
ANTI-KICKBACK STATUE AND REBATES

Figure 1 - The chart below shows an example of how manufacturer rebates paid to PBMs are calculated from, and driven by, the list price of a drug



Once rebates are received, PBMs can either remit all funds to insurance companies, in a "pass through" model, keeping only an administrative fee, or they can retain a portion of the total rebate not passed on to the insurer, in what's known as a "spread" pricing model. Even when PBMs keep a portion of the rebates, the majority typically goes to the insurance plan or plan sponsor, which, in theory, can help to lower premiums. However, this reimbursement model is somewhat opaque, and PBMs can employ a mixture of spread and pass through pricing.[5] This method of cost control and compensation has come under increasingly heavier scrutiny in recent years, as rebate payments grow ever higher, while drug costs and premiums continue to rise.[6] Regardless of their effectiveness in suppressing drug prices, the potential repeal of safe harbor provisions for Medicare and Medicaid rebates will have significant implications for the industry.

*Figure 2 - The image below shows an example of how funds are exchanged between stakeholders in the sale and reimbursement of prescription medication**



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DEVELOPMENTS AND REACTION

Industry Feedback

When the administration first announced their American Patients First Initiative, the announcement surprised industry stakeholders, who immediately began to analyze the potential effects of the suggested changes.[7] [8] While many praised the administration's effort to address a complex matter like drug pricing, there were those who felt that the proposal was not sufficiently specific or prescriptive, requiring additional investigation or legislation to enact.[9] Though the resulting media coverage did successfully coerce several manufacturers into delaying price hikes, many noted that such concessions were voluntary, and therefore likely temporary.[10] [11] In fact, some manufacturers stated explicitly that these pricing freezes would only stay in place until the end of the year if the components of the administration's plan weren't implemented.[12] Furthermore, some believed that even if the proposed changes were realized, they will not have the effect intended by the administration.[13] [14] Others pointed out that, given the complexity of the healthcare market, even the proposals achieving their intended effect will likely have unintended consequences.[15] [16]

The guiding logic behind the safe harbor repeal initially proposed in the American Patients First Initiative and reasserted in this proposed rule is that drug prices will continue to rise to account for the various discounts and price concessions offered to PBMs and insurance companies by manufacturers. It's argued by the administration and others that this creates a backward incentive for manufacturers to keep prices inflated and to keep raising them over time.[3] [4] Therefore, without any legislation or tangible policy in place, it is unlikely that manufacturers will lower their prices, as this will result in lower rebates for other stakeholders, making them paradoxically less appealing than other higher priced options.[17]

However, since a decreased financial burden on manufacturers does not guarantee a reduction in prices, opponents argue that manufacturers will simply keep them static or continue to increase them unless compelled otherwise.[10] To this point, the OIG report indicated that drug price increases are not necessarily motivated by payer rebates, pointing to Medicare Part B drugs, where costs remain high despite the lack of rebates or PBM involvement.[18] Other analyses within the private sector have confirmed this lack of causation as well.[19] Additionally, if rebates are eliminated, the resulting cost burden to insurance companies may mean less protection for patients, incurring higher premiums or higher out-of-pocket costs.[18] Some PBMs have echoed this sentiment, stating that rebates are a method of cost control that can pass on savings directly to insurance companies and plan sponsors, and indirectly to consumers.[20] [21]

Concurrently, CVS Health and Express Scripts, two of the nation's largest PBMs, disclosed that 98 and 95 percent of their rebates, respectively, are passed on to insurance plans and plan sponsors.[22] These rebates are also rarely applied evenly across all drugs, varying by competitiveness and therapeutic class, meaning that consumers could feel any effects disproportionately based on their respective conditions.[23] Furthermore, if manufacturers do choose to voluntarily lower their costs in light of an Anti-Kickback statute rollback, nothing prevents these changes from being rolled back going forward. Absent any legislative mandate or inflation penalty, manufacturers may simply begin raising their prices again over time.[24]

PBMs have generally expressed the belief that HHS is not authorized to roll back safe harbor provisions on rebates, and that any amendment to the provision would require an act of Congress, giving manufacturers some time to analyze the effect to their business.[18] However, the HHS secretary has stated that, since the safe harbor provision for PBMs was originally granted by HHS through regulation, it could be repealed under their authority as well.[25] [26] As healthcare spending continues to grow exponentially, it seems increasingly more likely that the government will take corrective action.

Figure 3 - The charts below, adapted from the administration's proposal, show how prescription spending has risen, while an increasingly wider divide develops between gross and net retail prices for drugs[3]

NEW PROPOSED RULE

Several months after the Safe Harbor repeal was first mentioned in the American Patients First initiative, HHS put forth a proposed rule to convey how it would be implemented. There are a few main provisions in the ruling:

- Rebates for plans, plan sponsors, and PBMs under Managed Medicaid and Medicare Part D will be disallowed. The new rule states that "price reductions on prescription pharmaceutical products from manufacturers to plan sponsors under Medicare Part D, and Medicaid MCOs would not be protected under the safe harbor".[1]
- Commercial insurance rebates will not be affected by this ruling, as HHS has stated that the "rule exercises HHS' regulatory authority to address the rebate system as it relates to federal healthcare programs. Congress has more power to prohibit rebates in commercial insurance."[1]
- Administrative fees and service fees paid to PBMs would be protected under the ruling. However, these fees cannot be tied to the Wholesale Acquisition Cost (WAC) of the drug, as HHS contends that they "could function as a disguised kickback."[1] Instead, these payments must be levied at fixed, flat fees established at "fair market value", and cannot be predicated on volume, value, or performance.[1]
- A new safe harbor would be created to cover point-of-sale discounts provided at the pharmacy to beneficiaries.
- Medicaid rebates paid to states would not be affected. In the text, it states that the rule will "not alter obligations under the statutory provisions for Medicaid prescription drug rebates under Section 1927 of the Social Security Act."[1]

Overall, the focus on government rebates represents a small, but significant change from the administration's first proposal under the American Patients First Initiative, where all rebates, both commercial and government, were being considered for safe harbor repeal.

NEXT STEPS

Considerations

While many questions from the American Patients First Initiative were answered in the new proposed rule from HHS, there are still some areas of ambiguity. Observers have noted that there still is not a direct mandate to lower drug prices if these rebate arrangements are removed. While the administration's plan calls attention to the incentivization of rebates for manufacturers to raise prices, there isn't a compensatory mechanism suggested to ensure that prices either stay flat or rise within an accepted schedule once rebates are eliminated. The viability of such a control mechanism is perhaps made more difficult as the proposal only addresses rebates to government programs.

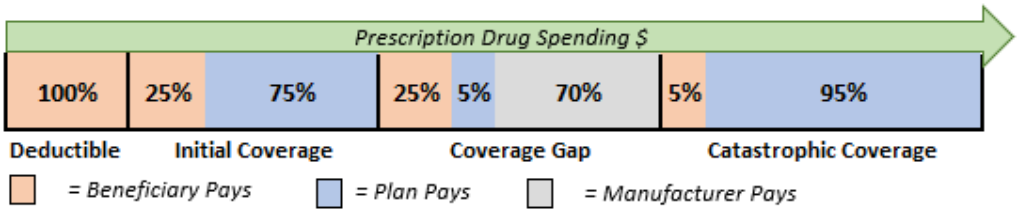
There are temporal aspects to rebates that aren't directly addressed within this proposal either. Since discounts to PBMs and plans are not provided at the point of sale, they're always based on prescription data from a prior period, usually a month or quarter. Additionally, since claims are not always processed immediately, it's a common practice to allow for older scripts to be submitted for a rebate well past the date of dispense. Contracts typically have resubmission or "back bill" windows that extend back several months, a year, or more. Any modifications to the rebate system would have to be "affective dated" to take these considerations into account.

The element of the plan that is perhaps most unclear is how rebates will be provided to beneficiaries at the point of sale. While the proposed ruling establishes a safe harbor for these discounts, it does not make explicit the mechanism by which they will be afforded. While some pharmaceutical companies already offer coupons and co-pay cards, neither of these methods are indicated in the ruling, so it's uncertain whether another means of compensation would be required.

Recommendations

Manufacturers would be well advised to examine their customers, products, and pricing portfolio and determine the relative importance of rebates within their strategic operations. Companies with a product line that is generally dispensed through a retail-based, prescription model will likely be affected by this development more than others. It will be especially impactful for organizations that specialize in competitive, chronic, or specialty conditions like diabetes, cancer, or multiple sclerosis, where discounts tend to be particularly large. This is even more relevant for companies with products that disproportionately serve elderly and indigent populations, who are more likely to be covered under Medicare and Medicaid, respectively. This will also have a corresponding effect on drugs entering the Medicare Part D Coverage Gap as well. If patient net costs are lowered through point of sale rebates, then fewer individuals will enter the Coverage Gap. This would further reduce manufacturer liability, who would otherwise have to pay the majority of costs in the gap.

Figure 4 - The chart below depicts the annual prescription drug payment thresholds for Medicare Part D beneficiaries, plans and pharmaceutical manufacturers



While commercial rebates are excluded from this ruling, a renewed focus on these agreements may be warranted as well, as these changes may exhibit an indirect influence on market forces in that space. Since PBMs administer contract negotiations for commercial and government insurance plans, it's likely that an impact to one of their lines of business would affect complementary ones as well. Also, while Democratic leaders have initially expressed disapproval of the policy, it would be reasonable to assume that commercial rebates could be targeted if the rule is passed, particularly given Congress's recent inquiries into drug pricing.[27]

As part of this effort, manufacturers will also want to consult with their legal counsel and government pricing teams to determine which of their existing discounts or price concessions can be considered rebates, especially since HHS has expanded its definition to more broadly include "price reductions". In lieu of more specific definitions or guidance from the administration, reasonable assumptions will have to be made until more information is available. Staffing may also be a consideration, as companies generally have an assortment of resources fully allocated to the task of loading, processing and calculating rebates. If the proposed safe harbor repeal becomes reality, these employees would likely have to be dedicated towards other functions, perhaps assisting in commercial rebate processing.

Certainly, if rebates do not factor into governmental pharmaceutical contracting in the future, a different contracting strategy will likely grow to fill the void. To ensure readiness from an operational standpoint, organizations will want to assess the flexibility of their applications to handle different deal structures. Most pharmaceutical manufacturers use a Revenue Management System (RMS) designed to operate within a relatively rigid transactional framework. Such drug makers will need to determine if and how their software can be updated to incorporate novel contract terms. Additionally, while the precise mechanics of providing point-of-sale discounts are unclear, it is likely these arrangements would have to be supported as well. If such remunerations needed to be handled in real-time, this would further increase the capabilities required from a company's claim handling software.[28]

Further downstream, manufacturers will want to review their forecasting models, accrual workbooks, price reporting, and gross-to-net calculations to determine the effect of eliminating rebate liabilities from government programs.

More broadly, drug makers should assess their contract and pricing strategies as they pertain to Medicare and Medicaid rebates, and how their profitability will be impacted. While the immediate effect may be an increase in topline revenue, long term effects may not be as consistently favorable. If rebates are used as a critical negotiating tool for access to drug formulary tiers, their displacement would mean that alternative mechanisms would have to be developed to provide competitive advantages in the marketplace.

Most importantly, companies should remain informed of any developments from the administration around this proposed rule and other proposals originally put forth in the American Patients First Initiative to ensure they can remain compliant and can successfully adapt their systems and processes. There is a 60 day comment period for the proposed rule, in which more perspectives, issues and concerns can be raised. It will likely become clearer in the coming weeks if this proposed rule is likely to be implemented and, if so, if it will come into effect as of the intended date of January 1, 2020.

Conclusion

The rebate system serves as a microcosm for the financial complexities of the healthcare market as a whole. Reimbursement systems are multilayered, pricing data is opaque, and the operating logic is esoteric. Similarly, each stakeholder often cites the practices of others in the supply chain for rising costs, while the reality is often much more nuanced. Most importantly, any changes to one aspect of the ecosystem will affect the surrounding areas, and often in unforeseen ways. When such a change is proposed, everyone is best served by thoroughly considering its implications and determining the long-term impact to their business. In an industry where change is a constant, due to both market forces and government regulation, an agile and flexible business model is critical.

About the Author

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Mr. Blank's expertise lies in contracts, pricing, and reimbursement strategies and operations in the life sciences industry. He leverages his expertise to develop and execute revenue management and business process improvement plans for his clients.

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