Proposed Rule to End Rebates to PBMs for Medicare and Medicaid Programs: What Does this Mean for Pharma Companies?

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Proposed Rule to End Rebates to PBMs for Medicare and Medicaid Programs: What Does this Mean for Pharma Companies?

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> We applaud the Administration for taking steps to reform the rebate system to lower patients' out-of-pocket costs. Our current health care system results in patients often paying cost-sharing based on the list price, regardless of the discount their insurer receives. We need to ensure that the $150 billion in negotiated rebates and discounts are used to lower costs for patients at the pharmacy. This proposal would also help to fix the misaligned incentives in the system that currently result in insurers and pharmacy benefit managers (PBMs) favoring medicines with high list prices.
>
> ***Stephen J. Ubl, President and CEO,***
> *Pharmaceutical Research and Manufacturers Association (PhRMA) - Remarks made on January 31, 2019*

> While we are reviewing the proposed rule, we stand ready to work with the Administration to achieve our shared goal to reduce high drug costs. Pharmacy benefit managers (PBMs) are part of the solution to high cost prescription drugs. Drugmakers alone set and raise prices. We have been encouraged by recent proposals aimed at using more PBM tools to increase competition, reduce overall costs, and improve patients' access to needed medications. We are concerned, however, that eliminating the long-standing safe harbor protection for drug manufacturer rebates to PBMs would increase drug costs and force Medicare beneficiaries to pay higher premiums and out-of-pocket expenses, unless there is a viable alternative for PBMs to negotiate on behalf of beneficiaries.
>
> ***JC Scott, President and CEO,***
> *Pharmaceutical Care Management Association (PCMA) - Remarks made on January 31, 2019*

> We should also require drug companies, insurance companies, and hospitals to disclose real prices to foster competition and bring costs way down.
>
> ***President Donald J. Trump***
> *Remarks given during the State of the Union Address on February 5, 2019*

1. New Rule to End Drug Rebates to PBMs for Medicare and Medicaid Programs

1.1 Introduction to the Rebate Rule Change

Alex Azar, Secretary of Health and Human Services (HHS), made a significant game-changing announcement to prescription drug pricing during the federal government shutdown that received little attention in the popular press.[1] In short, the proposed rule would eliminate rebates to pharmacy benefit managers (PBMs) in the Medicare and Medicaid programs by January 1, 2020. A short description of the change and its predicted result over time is quoted here from the *Forbes* article (a more detailed analysis of potential effects and implications are provided in sections 2 and 3):

> As a result, any discounts that PBMs negotiate with drug manufacturers would have to apply to the "list price" that patients using those drugs pay instead of being transmitted in the form of rebates that reduce everyone's premiums. The likely result, over time, should be that list prices in the future look more like the net prices of today, as rebates get converted into direct price discounts. That should mean lower out-of-pocket spending and better patient adherence to medications, especially for seniors enrolled in Medicare Part D prescription drug plans.[1]

1.2 Was this Rebate Rule Change Anticipated?

This change from the Trump administration was not unanticipated. The drug policy positions of Donald Trump the Republican primary candidate, Republican nominee, President-elect, and then President have been made very clear, followed by, and predicted through articles published in the *Axtria Research Hub*.[2-4] In a nutshell, our series of articles has argued President Trump is a change-agent, taking advantage of an undercurrent of widespread dissatisfaction with the high cost of prescription drugs.[5] President Trump and his administration spent much of 2018 making various policy announcements to tackle drug prices as a lead-up to the midterm elections because of challenges by the Democrats on making healthcare a primary topic with the voters.[6] This approach by Democrats in hindsight was arguably effective given their taking control of the House from Republicans through significant gains in key suburbs around the country and especially in California.[6]

Addressing rebates was a significant part of the *American Patients First* initiative launched in May 2018 as a way to reduce out-of-pocket prescription drug costs.[7] This initiative lists four key strategies for reform to address four challenges identified in the report affecting the U.S. drug market: (1) improved competition, (2) better negotiation, (3) incentives for lower list prices, and (4) lowering out-of-pocket costs.[7] A key theme in this proposed is the "appropriate use of premiums."[7] The proposal also has ending "gag clauses" that prevented pharmacists from telling patients that they can save money by paying cash for their prescription than a higher cost through their insurance plan.[7] An executive order was later signed enacting this provision. The implementation of prohibiting gag clauses has analytical implications: (1) this would mean that no insurance claim is generated/adjudicated, and thus the payer will have no idea on the prescription fill/patient compliance, (2) given that a significant rate of payments for generics are already by cash and not captured in claims data, this rule would increase the cash-rate payment, leaving internal and external analytics groups with even less data to work with for studying, (3) ending gag clauses at the patient level will over time (as information disseminates) diminishes the role and power of PBMs. The proposal also contains other changes under "lower list prices" that can affect pharma companies in the areas of changes to 340b (tighter eligibility criteria for institutions), changes to co-pay discounts, and changes in coding so provider-administered medications (as in Medicare Part B) are unbundled.[7] Finally, the proposal also opens to public comment a proposed fiduciary role for PBMs.[7]

Further policy actions by this administration to tackle drug prices were announced throughout the second half of 2018, including the controversial 5-year experiment to import foreign drug price controls from other selected countries for governmental reimbursement under the Medicare Part B plan.[8] In summary, the Trump administration has focused its attention on instituting policies to control drug prices given the topic's populist appeal, with growing emphasis on the issue of rebates and how they contribute to higher patient out-of-pocket costs.[9]

2019 began with continued attention to these issues and calls for action to address the issue of rebates. Respected moderate Republican Senator Susan Collins of Maine, and head of the Senate Special Committee on Aging, asked the Department of HHS to move forward on policy actions outlined in the Trump administration blueprint to reduce out-of-pocket prescription drug costs and fix the opaque system

of pharma rebates and discounts.[10] She also promoted the idea of legislation if needed to fix the system. Senator Collins noted in an interview the following ominous warning, "I'm not prepared to say rebates should be abolished and I don't like the idea of interfering with the marketplace, but the marketplace is failing here."[10] Her call for action and Secretary Azar's announcement of the rebate rule change are not coincidental. Finally, President Trump provided more focus on the issue of prescription drug costs in his 2019 State of the Union (SOTU) address to a joint session of Congress. The comment noted in the opening quote by President Trump shows just how much the pharmaceutical industry is still very much in the cross-hairs of the President and Congress. We anticipate more actions beyond this rebate rule change. While administrative rule changes could be done to undo rebates for governmental programs like Medicare and Medicaid, changes to the structure of rebates for private third-party commercial plans will require Congressional action. In addition, since states have their own health insurance rules, changes in safe harbor protections allowing rebates to PBMs (i.e., anti-kickback provisions) will have to align with federal rules if they want to end rebates to PBMs.[1] Stay tuned to this white paper series for updates and further actions by the administration and Congress. One potential concern is the broader application of a blunt policy approach to reducing drug prices through direct price controls as instituted under the experiment for Medicare Part B pricing and reimbursement. Independent research has concluded such an approach would stifle incentives for future drug R&D and lower patient health outcomes (see a previous *Axtria Research Hub* white paper that reviewed the literature on this topic).[11]

2. How Do Rebates to PBMs Relate to Drug Prices?

> The free market is alive and well when it comes to drug prices – if you're an insurance company or a government program. But not if you're a consumer.[12]
>
> ***Matthew Herper***
> *From "Inside The Secret World Of Drug Company Rebates," Forbes (2012)*

> To take one example, one of the dynamics I've talked about before that's driving higher and higher list prices, is the system of rebates between payers and manufacturers.
>
> ***Scott Gottlieb, M.D., FDA Commissioner***
> *Comments from his keynote address at the 2018 Food and Drug Law Institute Annual Conference, Washington, DC (May 3, 2018)*

2.1 How are Rebates Supposed to Work Versus What Actually Happens?

How are rebates supposed to work? Drug companies supply discounts in the form of rebates to PBMs that negotiate on behalf of health insurance companies for the cost of drugs to plan covered members. The PBMs then pass on most of those rebates to health insurers, keeping some amount as a fee for their service in negotiating these contracts. Health insurers in turn pass along those discounts to covered members in the form of lower insurance premiums. That's the theory. What happens in actual practice?

As explained in the first referenced *Forbes* article,[1] the pharma company "net price" equals the "list price" minus any discounts (rebates) and the cost of co-pay assistance cards to help patients gain access to latest medicines developed through R&D. However, the patient cost is a function of the "list price" minus any deductible benefit, not the discounted price negotiated between pharma companies and PBMs. Greater cost-shifting to patients is occurring by health plans with increases in the advent of new novel but expensive specialty medicines to treat various unmet medical needs (especially in cancer). Rather than being charged a fixed dollar co-pay per prescription, patients are being charged to cover a percentage of the difference between an increasing list price and their drug deductible. This is a significant reason why we see greater use of co-pay cards and increasing their coverage length from 30 to 90 days as a way to increase drug adherence by pharma companies to allow for greater access of these medicines given this increasing cost to patients.[13] However, these pharma company incentives encourage

greater utilization of more expensive medicines which reduces the margins of PBMs, which in return request more rebates, further driving up "list prices," thereby increasing the cost to patients to cover these added costs. This cycle has been repeating itself to the point where rebates for the largest pharma companies represent the single biggest line-item in the budget and threatening their future financial stability unless something changes.[9] Price concessions can significantly vary by individual company depending on the portfolio mix and individual therapy class competition facing each drug. However, rebate and discount amounts are growing over time, significantly affecting biopharma company margins. The total 2018 US pharma industry from rebates, discounts, and other price concessions equaled $135 billion, using $479 billion of total invoice spending and $344 billion on a net basis, for a reduction of gross to net spending by 28%.[13]

Thus, the current drug rebate-pricing system not only encourages increasing list prices but also raises questions as to whether consumers indeed benefit in the form of lower out-of-pocket costs from rebates and discounts paid to PBMs by drug companies. The suspicion is that consumers are not benefitting from these higher levels of rebates and discounts.[14] Evidence supporting this suspicion is the lack of transparency on the distribution effects of rebates and discounts and higher drug cost shifting by payers happening to patients.[13] Additional factors are concerns of greater economic burdens for drug spending placed on people and the healthcare system,[5, 13, 15-16] and especially on the elderly (where higher medical bills are a key factor driving more elderly into bankruptcy)[17] to pay for prescription drugs. The dilemma for pharma companies is just as the science of medicine is unlocking the secrets on how to combat the most difficult diseases, the industry is reaching limits on what society is willing and able to pay for the development and diffusion of this drug innovation.

3. Reactions to the Drug Rebate Rule Change by Axtria Principals

This section will provide some thoughts from two very experienced Axtria Principals who have inside pharmaceutical company experience and years of consulting work across a wide variety of clients as trusted strategic advisors, Devesh Verma, Ph.D. (DV) and Vikram Batra (VB). Below are their reactions (not always the same) to questions posed by the lead author of this white paper.

a. *What are the expected price and utilization effects for branded/generic drugs and biologics/biosimilars if the proposed rule is enacted?* (DV) I expect a flat rebating structure would reduce the difference between "list" and "net price." The difference will be a function of the total rebate offered to a payer. This is already a requirement for Medicare Part B medical drug coverage for "buy and bill" products. Medicare only reimburse net price (which is the list price – GPO rebates + a small markup (somewhere in the 5-10% range) to an office. So, increasing the rebate doesn't impact the amount of spread an office can make. (VB) The list prices will be expected to decline and start to mimic the current net price. This should even the playing field for cheaper generics/biosimilars and the more expensive treatments. Currently, the playing field is not fair since the rebates are incentivizing the PBMs to encourage the use of more expensive drugs. Reduction in rebates should lead to higher utilization of low-cost drugs.

b. *What kind of response(s) can we expect from PBMs?* (DV) A huge backlash! Essentially, the role of a PBM would be significantly diminished in the proposed environment. They won't have any negotiating authority remaining with them. They will become administrators of contracts. (VB) PBMs will not be happy with this change. This will cut into their revenues significantly. Expect a significant backlash from the PBM community, portraying the effectiveness of PBMs in reducing healthcare cost through their price negotiations with the manufacturers.

c. *What spillover effects, if any, will this proposed rule have on rebates applied to PBMs for third-party private commercial plans?* (DV) I expect the PBM rebates also to go down. (VB) Rebates may go up in third-party commercial plans to make up for the lost demand in the Medicare and Medicaid plans. Manufacturers may shift rebate dollars to commercial plans to influence utilization rates of expensive drugs.

d. *What will happen to out-of-pocket cost of prescription drugs for patients, and any resulting effects, such as on drug adherence, and health/economic outcomes?* (DV) In the first year, I don't expect a major change. However, one to two years, the average out-of-pocket (OOP) costs will come down. Secondarily, insurance premiums will also come down over time. (VB) The net effect should be lower OOP costs for patients and consequently lower insurance premiums. Patient adherence has been an issue, especially for patients on expensive treatments due to the higher OOP cost. The change should have an impact on improving treatment adherence rate and health outcomes.

e. *How should pharma companies respond if this rule is enacted?* (DV) It will be a good thing for pharma. Also, they will avoid any negative backlash based on high list prices. Pharma can (potentially) index their list price change relative to inflation. Currently, it's a wild game! (VB) Given the push for the rule change, this will make proving health outcomes for pharma even more crucial to compete with the cheaper drug options. Currently, pharma companies are able to avoid competing on the basis of demonstrating health outcomes by paying high rebates, but that option may not be available for them in the near future. This rule change will also increase pressure on pharma to expedite their R&D efforts and focus on truly innovative therapies that will allow them to stay free of competition from cheaper generics/ biosimilars.

f. *What will happen to pharma company contracting groups as a result of this rule change? For example, will this increase the existence of value-oriented performance-based contracts? What about the changing role of analytics to support such contracts? Etc.* (DV) This rule change may significantly reduce the importance of a managed markets group in a pharma company, at least in their current form. But I agree, they will need to make sure the drug still gets covered. So, the contracts or discussions will be more outcomes driven. I believe the managed market structure will start looking similar to the contracting team structure in EU markets. (VB) Yes, the change should lead to a greater need for value-based contracts and outcomes research. Pricing will need to become a lot more aligned with competition than it is currently, and that would involve making sound a judgment on actual delivered value and perceived value for the patient.

g. *What kinds of analyses should clients be involved in if this proposed rule is enacted (or in anticipation of this rule change)?* (DV) What should be the new list price (assuming all the changes go through)? Frankly, nobody would be able to answer this question in a pharma company right now. (VB) HEOR studies, co-pay program redesign, value-based contracting framework, and gross to net-based targeting/sales force planning.

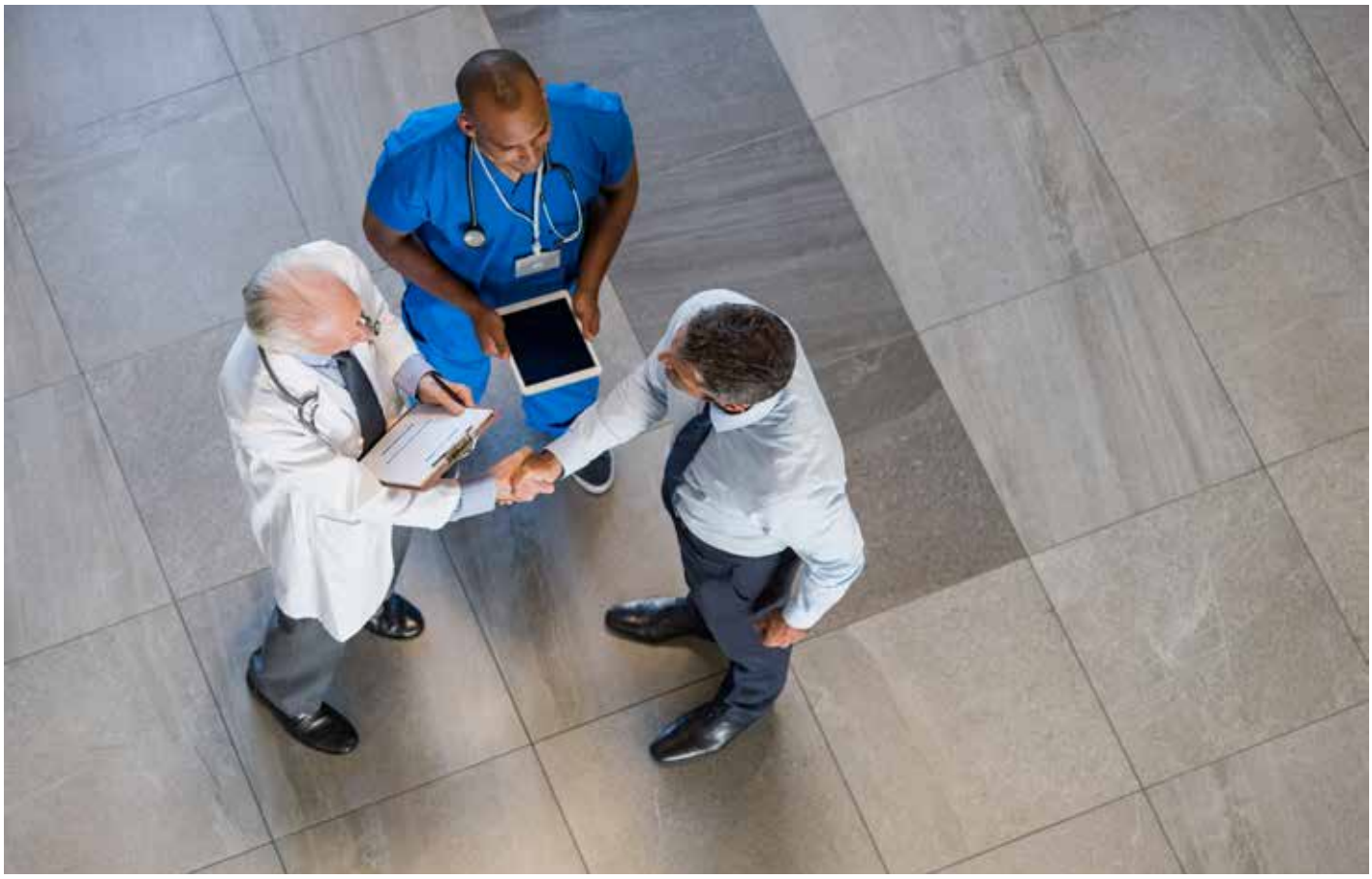
h. *Are there any other important effects that could happen as a result of this rule change and what further actions can a pharma company take?* (DV & VB) Every managed markets group in the industry needs to engage an expert in the pharma space like Axtria. Axtria can start educating pharma clients on this new legislation and what this means for the development of commercial strategy and operations, the applications of new analytics to support strategy and operations, and the creation of new data needs and infrastructure to feed new analytics.

4. What are the Commercial Strategy Implications of the Drug Rebate Rule Change?

There are now tremendous opportunities for the industry beginning to leverage innovative scientific breakthroughs in gene therapies and using the body's own defense mechanisms for immuno-drugs, as seen in oncology. However, the commercialization of these novel therapies is very difficult, with the cost of these new treatments well beyond the ability-to-pay for most individuals, health insurers, and government reimbursement programs. Using

continued price increases, with rebates being at the center of this opaque structure, as the model to raise revenue is not economically sustainable. While there have been different suggestions of pricing schemes, issues with affordability and access to these new treatments will remain unless there are more fundamental changes. If this issue is not solved, or simply ignored by the industry, this unresolved problem will translate into insufficient returns for companies to develop future novel therapies, with ultimate detrimental effects to patients.

There is a broken pharma commercial model and pricing system for the industry. This fundamental structural problem represents a significant threat to pharma companies and patients in need of new treatments. This is a defining moment. The failure for pharma companies to find a viable solution soon will increase the risks of seeing the broad implementation of direct price controls as we now already see in the experimental importation of international price controls for Medicare Part B drugs.[8] There would be significant adverse consequences to R&D innovation for novel medicines, with ultimately negative effects on patient outcomes if a price control public policy approach was more broadly adopted. This response from policy decision-makers must be avoided. The solution for pharma companies is that it is in their longer-term interests (both financially and for the patients they serve) to move more aggressively to a value-based commercial model design (CMD). The current model of rebates and using prices as the primary vehicle to sustain revenue and profitability is not economically sustainable in the longer run. There is a calling and opportunity for pharma companies to create a sustainable CMD that is scalable and operational (along with all the data and analytical support) that can both meet the expectations of pharma company shareholders while addressing the needs of patients, physicians, and other healthcare system stakeholders.



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