



Politics 'Trumps' Rational Policy Rule Change on Ending Rebates to PBMs for the Medicare Program

August 2019

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George A. Chressanthis, Ph.D., Principal Scientist, Atria Inc.

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Politicians and diapers have one thing in common – they both should be changed regularly and for the same reason!

Author unknown

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Politics is the art of looking for trouble, finding it, misdiagnosing it, and then misapplying the wrong remedies.

Groucho Marx
American comedian

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1. Trump Administration Blinks on Rule Change to End Drug Rebates to PBMs for the Medicare Program

Alex Azar, Secretary of Health and Human Services (HHS), made a significant game-changing announcement on February 1, 2019 to prescription drug pricing to propose a rule change to eliminate rebates to pharmacy benefit managers (PBMs) in the Medicare and parts of the Medicaid programs by January 1, 2020.¹ Most pharma experts, including a sample of our own Atria principals,² predicted this rule change over time would lower out-of-pocket

spending for patients, improve patient adherence to medicines with concomitant beneficial effects to health and economic outcomes, and increase pricing transparency in a part of the pharma sector that has remained very opaque.¹ The rule change had its predictable proponents and opponents:

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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

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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*

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Former FDA Commissioner Scott Gottlieb was also a big proponent of eliminating the system of rebates as the quote below clearly notes:

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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 on May 3, 2018*

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Lastly, the Trump administration made eliminating rebates a significant part of the *American Patients First* blueprint initiative launched in May 2018 to reduce out-of-pocket prescription drug costs.³

Thus, the announcement on July 11, 2019, that President Trump would not pursue implementation of this PBM rebate rule change came somewhat as a surprise given the fanfare of the blueprint initiative and the importance attached to addressing rebates to PBMs as a critical policy component.⁴

What happened to cause the change of mind? One word – ‘politics’, as exemplified by the title of this paper, illustrated by the opening quotes, and explained how it trumped (pun intended, using the Bridge card game term) a rational approach on this issue. Secretary of HHS Alex Azar favored the policy rule change as someone who came from the pharma industry and probably has the best knowledge on the effect of rebates to PBMs on drug pricing.⁴ However, virtually everyone else among the White House top policy advisers involved in discussions were against him instead favoring eliminating this rule change.⁴ Fears raised were its effect on the Medicare budget estimated at \$180 billion over the next 10 years (questions have been raised how this estimate was calculated), but more importantly, that increases in Medicare premiums on seniors would come right before the 2020 presidential election.⁴ Alternative proposals to reduce drug prices being discussed that we know from prior research work would be highly detrimental to the industry and patients.⁴ One proposal is capping out-of-pocket costs in Medicare drug benefits which would act like a price control.⁴ Another proposal is importing drugs from lower-priced countries like Canada, again, acting like a price control.⁴ This policy approach unfortunately may become a reality. The Trump administration on July 31, 2019 announced steps it was taking to eventually allow the importation of drugs from Canada.⁵ Politics is the major driver of this policy shift as the Trump administration makes reducing drug prices a

top priority ahead of the 2020 presidential election.⁵ While any possible implementation of this policy allowing the importation of drugs from Canada is still 2-3 years away,⁵ we know from previous analyses that such a policy will not bring about the desired change in drug prices for a whole host of reasons.⁶ The concern of this author is that the 2020 presidential election will move President Trump to seek further blunt and populist policy instruments to reduce drug prices that would be harmful to the industry and ultimately to patients.

Reactions to the PBM rule pullback were also predictable as seen in these two quotes:⁴

“Only drug manufacturers have the power to set drug prices. We believe that the key to lowering drug costs is to enact policies that encourage greater competition.”

JC Scott
President and CEO, Pharmaceutical Care Management Association (PCMA)

“Of all the policies proposed in Washington right now, this was the only proposal that would provide immediate savings at the pharmacy counter.”

Holly Campbell
Deputy Vice President of Public Affairs, PhRMA

How did markets respond to the pulling back of this rebate policy? Shares of health insurers and PBM owners added around \$28 billion in market value, while pharmaceutical companies of the S&P 500 were down \$26 billion on Thursday, July 11, 2019 afternoon trading.⁷ Leading health insurers that also have a PBM role saw their stock prices increase on the news, e.g., Cigna (9.24%), UnitedHealth (5.53%), Humana (4.58%), and Anthem (5.54%),⁸ while major pharma company stocks were hit by the news, with investors fearing what the administration may now do to reduce directly drug prices.⁹ This is a clear indication about how efficient markets assessed the ‘winners’ and ‘losers’ from pulling back on this rule change.⁷



2. What Should Pharmaceutical Companies Do?

The failure of President Trump to move forward on the policy rule change to end rebates to PBMs for the Medicare program, while disappointing from the viewpoint of the author, has produced some desirable effects coming from this open debate:

- 1) Attention has been focused on the opaque world of pharma rebates (see the quote below), which up to now, has received little to no attention in the public policy discussion arena, and how they contribute to drug pricing trends.

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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.

Matthew Herper

From “Inside The Secret World Of Drug Company Rebates,” Forbes (2012)¹⁰

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- 2) It is the belief of this author that the use of rebates as currently applied will eventually see their end. There is a desirable movement to seek more clarity and transparency on drug pricing. This means that pharma companies will have to rely more heavily on health economics and outcome research (HEOR) and real-world evidence (RWE) to support payer performance-based contracts than the use of rebates to incentivize plan adoption of drugs.
- 3) This debate once again demonstrates that there is a broken pharma commercial model and pricing system for the industry.

This fundamental structural problem represents a significant threat and opportunity to pharma companies and patients in need of new treatments. This is a defining moment for the pharma industry. 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.¹¹ There would be significant adverse consequences to R&D innovation and diffusion of 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.

This paper ends with comments from the same two principals at Axtria who contributed to our earlier white paper on this topic and the pullback from President Trump on this rebate policy rule change,² and a final quote. Their comments are noted below.

Devesh Verma, Ph.D., Principal, Axtria

- 1) “While the reversal from the administration is unfortunate, I am not surprised. Changing the makeup of healthcare is extremely challenging in our country. There are powerful lobbying groups, and they protect the interests of insurance companies and PBMs.
- 2) Pharma companies need to shell out much higher rebates to Part D plans than commercial plans. At the same time, Part D patients pay much higher average copays compared to equivalent commercial plans. Hence, the elimination of rebates would result in the utter disruption of the payer landscape and potentially higher copays and premiums for the patients. I strongly believe the payers and the pharmaceutical manufacturers need to sit down with the politicians (the 3 Ps of the healthcare landscape!) to solve this problem. The payers need to recommend a common strategy between their commercial and Part D plans. Unless that’s solved, we will continue to have misfires in the system, like the most recent one.
- 3) I still believe better transparency can be provided on rebates that can keep the current structure in the short-term, but the market forces will eventually lead to gravitation towards the mean and bring down the prices.”



Vikram Batra, Principal, Atria

“The administration’s decision to not move forward with the proposed rule related to Medicare part D is obviously unfortunate. Seniors may have benefitted by paying less for the drugs at the pharmacy. With the proposed rule now out of the picture, the administration may still want to pursue other options to reduce costs, and the target now could be the pharma manufacturers. The administration may resort to more drastic measures, such as the indexing of drug pricing that has also been suggested. So, this may not be good news for pharma, but again there is no certainty how all this will play out (as we have seen with this rule as well as the one displaying drug pricing in TV ads). The lobbies are strong on both sides and to fix the system would require both parties to come together to find a solution. But one thing is certain; the topic of prescription drugs is certainly going to stay as a hot topic for the near future as we get closer to the 2020 presidential and Congressional elections.”

Finally, this paper ends with a quote that embodies the skepticism of this author that today’s politicians will be

unable to address rationally the complex world of drug pricing in a responsible way, especially given the poor public reputation of the pharma industry, and the desire of our public officials to seek scapegoats and easy solutions. This should cause concern among pharma executives, meaning they should plan accordingly for worst-case drug pricing scenarios, quantify their effect on company operations, and be ready to take countermeasures if needed.

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Ninety percent of the politicians give the other ten percent a bad reputation.

Henry A. Kissinger

Former U.S. Secretary of State

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George A. Chressanthis, Ph.D.

Principal Scientist, Axtria Inc.
300 Connell Drive, Suite 5000
Berkeley Heights, NJ 07922
E: george.chressanthis@axtria.com

Contact Us

+1-877-9AXTRIA
info@axtria.com

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