The Drug Rebate Rule Would Have Fixed Misaligned Incentives and Should Not Have Been Dropped

Early this month, the Trump administration withdrew the proposed Drug Rebate "Safe Harbor" Rule. Under the proposed rule, rebates currently paid by pharmaceutical companies to pharmacy benefit managers (PBMs) and payers would instead be passed directly to consumers. The Congressional Budget Office (CBO) estimated that the rule would cost the federal government $177 billion over 10 years. According to news sources, the administration decided to withdraw the rule due to concerns over cost, as well as potential windfall profits to the pharmaceutical industry.

This outcome is unfortunate, as the current rebate rule is riddled with misaligned and perverse incentives which harm consumers. Under the current system, payers use rebates paid by pharmaceutical companies to enhance their competitive advantage by lowering premiums for all individuals. While this may seem appealing, it effectively creates a system where the sick subsidizes the healthy, by using rebates that the sick generate to lower the premiums of the healthy. This is the opposite of what insurance should be as a vehicle to protect against catastrophic risk. PBMs retain part of the rebate as profit, creating perverse incentives to favor expensive drugs in their formularies. Likewise, pharmaceutical companies sometimes create rebate walls, which make rebates for market leading drugs contingent on favorable formulary position of their less competitive drugs. These rebate walls significantly hinder lower-priced competition from gaining market share.

The proposed rule would disallow pharmaceutical companies from giving rebates to payers, and instead require them to be given to patients who take the medication that generate the rebates. Under the proposed rule, the payers, without the ability to use rebate dollars to lower premiums for all, will be incentivized to negotiate drug prices on a net cost basis. In the absence of the perverse incentive to favor high cost drugs that generate the most rebate dollars, PBMs will focus more on net cost effectiveness. Finally, pharmaceutical companies will no longer have the ability to use rebate walls, which should increase competition in the market. The proposed rule would have simultaneously remedied multiple perverse incentives in the highly dysfunctional pharmaceutical market to benefit all consumers.

On the other hand, the proposed rule certainly has its flaws. First, it is expected to increase insurance premiums for most people, since rebate dollars generated by high medication users will no longer lower premium for all patients. Second, it is unclear whether pharmaceutical companies will pass along the entirety of the current level of rebates to consumers, or retain a certain amount to enhance their profits. The CBO cost estimate of $177 billion reflects this concern, as they assume the pharmaceutical industry will only pass along 85% of existing rebate under the new rule.

However, the CBO analysis contains a significant shortfall, in that it fails to account for likely behavioral changes. According to the report, the $177 billion projected cost is based specifically on "manufacturer' withholding 15 percent of current-law rebates, increases in federal subsidies for premiums, changes in annual thresholds at which beneficiaries' cost sharing requirements and other program rules change, and the costs of implementing the chargeback system." The agency did not consider likely positive behavioral changes by the relevant

stakeholders due to removal of the current perverse incentives. A study commissioned by the Department of Health and Human Services (HHS) and conducted by Millman estimated cost savings in 5 out of 6 behavioral changing scenarios, ranging from $21 to $188 billion. These behavioral changes include increased formulary controls, increased or reduced price concessions, decreased brand unit cost growth, increased utilization leading to improved health outcomes, and increased pharmacy rebates. When payers can no longer receive rebates, they will be incentivized to negotiate the best net drug price to competitively price their premiums. Without retained rebates as a profit source, PBMs will likely move to a fee-based model based on negotiation of net drug price. For drug manufacturers, removal of rebate walls will likely enable greater competition, which should lead to lower net price of drugs. For patients, lower net drug price will likely lead to better medication adherence, which leads to improved health outcomes. While these are hypothetical behavioral changes, they are all highly probable outcomes from removing perverse incentives under the current system, the ripple effects of which has the potential for meaningful systemic cost savings.

The CBO's position is unfortunate but understandable, as the agency bases its analysis on well-established behavior and data. While positive behavioral changes to the rebate rule are highly logical and likely, there is little historical precedent for analysis and the effects are hard to quantify. However, the actions of the private sector provide useful insight. In a speech to the National Business Group on Health, HHS Secretary Alex Azar noted that UnitedHealth, which introduced direct to consumer rebates in 2018, predicted that bringing discounts to patients would increase (medication) adherence so much that it would meaningfully reduce their healthcare costs. One year into the program, UnitedHealth saw a noticeable increase in

medication adherence (4 – 16%), and were "so pleased with the results that they will actually refuse to write new self-insured polices that don't fully pass on rebates at the pharmacy counter." UnitedHealth is one of the largest and often regarded as the best managed care company in the United States. If they are pursuing and expanding this particular strategy, the rest of the market should pay attention.

Ultimately, the CBO's failure to consider the potential positive changes from the rebate rule likely led to the administration's decision to withdraw the proposed rule. Nevertheless, the rhetoric and analysis by policymakers at the HHS indicates that they have a deep understanding of the perverse incentives inherent in the current system. It remains hopeful that the administration will come up with new proposals to lower drug costs.

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