

## **VALUE, ACCESS, AND INCENTIVES FOR INNOVATION: POLICY PERSPECTIVES ON ALTERNATIVE MODELS FOR PHARMACEUTICAL REBATES**

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**Amanda Cole, PhD**

Principal Economist

Office of Health Economics

**Adrian Towse, MPhil**

Emeritus Director and Senior Research Fellow

Office of Health Economics

**Celia S. Segel, MPP**

Director of CER Policy Development

Institute for Clinical and Economic Review

**Chris Henshall, PhD**

Independent Consultant and Visiting Fellow

Office of Health Economics

**Steven D. Pearson, MD, MSc**

President

Institute for Clinical and Economic Review

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## **Executive Summary**

The combination of rising drug costs at the health system level and increasing financial stress for individual patients has triggered intense national concern. One target has come under particular scrutiny: rebates.

Drug makers in the US face no federal process whereby prices are evaluated in comparison to evidence of clinical benefit, but they must negotiate with a myriad of payers (including both insurers and pharmacy benefit managers [PBMs]). Discounts to the list price of drugs (rendered post-sale as rebates) are negotiated in exchange for preferential formulary placement, which increases sales. Rebate agreements are often quite complex, with the possibility of “stacked” rebates paid to PBMs: combined payments related to formulary placement, variously named administrative fees, price increase protection guarantees, and other programs.

Rebates are a key negotiating tool for payers and help produce lower *net* prices for drugs that can help reduce the overall costs of drug spending. But for many years the PBM business model has included a revenue stream gained by retaining a percent of the absolute rebate amount they return to plan sponsors. Drug makers argue that this “rebate economy” forces them to increase list prices in order to offer ever larger rebates to PBMs to gain preferred formulary status. The effect of rebates in lowering net prices may reduce plan sponsor costs and therefore help moderate the cost of insurance premiums for all plan members. However, some plan sponsors have suggested that the profitability of the rebate model provides an incentive for PBMs to prioritize high-rebate drugs that might not have the lowest net cost for the plan sponsor. All would agree that higher list prices hurt many patients who need ongoing drug treatment, since the increase in the use of co-insurance and of high-deductible plans has meant that rising numbers of patients are required to pay their out-of-pocket share for drug coverage in relation to the list price, not the negotiated rebate price.

Rebates have therefore become an extremely contentious topic, praised by many as the best tool available to provide competitive leverage for payers seeking lower net prices, but reviled by others who view it as the chief sin in a system that punishes sick patients with higher out-of-pocket costs and absorbs billions of dollars that could otherwise either reward innovative treatments or keep costs down, or both. Recently, both payers and drug makers have introduced new approaches that experiment with alternative approaches to rebates; and in January 2019, the Trump administration issued a draft rule that would expressly exclude from safe harbor protection under federal Anti-Kickback Statute any rebates paid by manufacturers to contracted PBMs or payers in Part D plans and Medicaid managed care organizations.<sup>1,2</sup>

The Health and Human Services (HHS) proposal would create a new safe harbor for prescription drug discounts offered directly to patients, as well as fixed-fee service arrangements between drug manufacturers and PBMs. The administration is openly “soliciting comments on whether the proposed effective date gives affected entities a sufficient transition period for any necessary restructuring of arrangements,” with an ambitious target implementation date as early as 2020.<sup>2</sup>

But amidst both this federal effort and several private-market initiatives intending to address some of the concerns about rebates, there remain many questions about how the rebate system interacts with other elements of drug pricing, coverage and delivery. Similarly, the potential benefits and possible negative consequences of realistic possible alternatives for different stakeholders have received little analysis. This White Paper, benefitting from interviews with numerous participants in the rebate process – from plan sponsors, to insurers, to PBMs, to drug makers – addresses these questions and lays out a framework for evaluating proposed alternatives to a rebate model that has served as the cornerstone of drug pricing and coverage negotiation for decades. The focus will primarily be on examining options for rebate models within Medicare Part D and the prescription drug benefits offered in the commercial market by plan sponsors.

### ***What are the major alternative options for rebate models?***

There are three major alternative options to the current rebate model. The first two options represent rebate “reform” and may be implemented separately or, as many have argued, combined; but it is important for policy makers to consider the potential advantages and disadvantages of each element separately. The third option would involve eliminating rebates and moving exclusively to a system of upfront discounts.

#### ***OPTION 1: 100% Pass-through (All rebates flow to plan sponsors)***

The first option is to require that PBMs pass 100% of rebates and associated manufacturer fees based on list price through to plan sponsors in order to eliminate the incentive for PBMs to develop formularies that drive utilization to highly rebated drugs despite higher net costs for payers. PBMs would be paid instead solely through fees from plan sponsors. It is important to note that in addition to rebates, PBMs can receive “fees” from manufacturers that may still lead to an incentive for preferential formulary placement of drugs with a higher net cost to the plan sponsor. Therefore, a 100% pass-through model will be most effective if all rebates and manufacturer payments are included. Although arrangements between PBMs and health plans which specify 100% pass-through of rebates are already becoming more common, a more universal requirement could be linked to a move to flat fees for distributors and pharmacies, helping to wean the entire drug delivery chain off its reliance on rebates and percentage fees.

A 100% pass-through model could be combined with a requirement for some proportion of rebates to be shared with patients at the Point of Sale (POS). This combination and its differentiation from a model of upfront discounts will be addressed in the Discussion section below.

Potential advantages: With less incentive for PBMs to develop rebate-driven formularies, a 100% pass-through model would diminish financial incentives for high list prices. This would benefit individual patients financially if their cost-sharing is linked to list price (which could lead to better adherence and outcomes). Net prices could remain confidential, and rebates could, in principle, continue to be linked to formulary placement and utilization at the population level. Proponents also believe that passing all rebates – and any other form of manufacturer fee or payment – back to plan sponsors would allow payers to compare PBM offerings more transparently and improve the negotiating power of payers. This alternative rebate model could also improve transparency for the individual payer so that they understand why certain decisions are being made by a PBM with regards to formulary design.

The law already requires that payers who participate in Medicare Part D pass back to the government all negotiated rebates, pharmacies' fees, and other forms of price concessions. The Medicare program defines these payments as direct and indirect remuneration (DIR). But policy analysts have noted that Medicare is not receiving all DIR that it is entitled to receive.<sup>3</sup> Prescription drug plans (PDPs) and PBMs can classify certain items to exclude them from DIR. Furthermore, if PDPs and PBMs underestimate the amount of DIR in their initial bids, they can retain a proportion of the DIR they receive beyond the initial estimation due to how Part D risk corridors are designed.<sup>3-5</sup>

These features encourage PDPs and PBMs to favor drugs with high DIR, which are typically drugs with high list prices. A complete pass-through of DIR to Medicare, including all fees that are “DIR in disguise,” could therefore have a potentially significant impact on Medicare Part D much in the way it would in the private market. By cutting the link between PDP and PBM profit and DIR, incentives would shift toward more efficient formulary management decisions.

Lastly, compared to a complete replacement of rebates by upfront discounts, the implementation of a pass-through model would involve relatively little disruption to the existing agreements between manufacturers and wholesalers, some of which are passed on to pharmacies and other dispensers. It would, however, still entail the challenges of a piecemeal transition over months to years from existing contracts between PBMs and plan sponsors that are not based on a 100% pass-through.

Potential disadvantages: This alternative model might achieve little if PBMs continue to retain revenue obtained from manufacturers as “fees” instead of “rebates.” It would also do little for patients in the short term if the increased rebates flowing back to plan sponsors are not reflected in lower co-pays (i.e. if this reform were not implemented alongside requirements around applying rebates to the point of sale – see option 2). The potential impact on the gross-to-net gap and overall spending is also unclear because many plans now expect, and some may prefer, to have large and guaranteed rebates.

In addition, the primary potential advantage of a pass-through model may also represent one of its greatest potential disadvantages for both payers and patients. If PBMs are paid a fixed fee independent of negotiated rebates, they could have less incentive to put great effort into fighting for the lowest net price unless plan sponsors help create a truly different competitive landscape in which PBMs compete on the basis of patient outcomes and lowest net cost instead of just lowest fees.

Further, it is important to consider whether requiring PBMs to pass along all rebates to plan sponsors might limit PBMs efforts to benefit from economies of scale to achieve greater savings beyond what a single plan could on its own. If PBMs are prohibited from aggregating rebates across multiple Part D plans, it might lead to a reduction in negotiating leverage, and therefore higher overall net costs for payers and plan members.

#### ***OPTION 2: Point of Sale (POS) rebates for patients***

POS rebates involves passing all or a proportion of rebate savings directly to patients. This option appears to most directly address the problem of high out-of-pocket costs, and some private health plans have recently begun offering benefit designs with POS rebates that seek to share the financial benefits of rebates with patients without undermining competitive leverage by allowing direct back-calculation of net prices.

Potential advantages: Action taken to require POS rebates with any rebate at the payer level could have several important advantages. First, and most importantly, patients who require extended use of expensive medications for chronic conditions could have their financial burden lessened. Whilst the evidence is limited, there is also some indication that POS rebates could improve adherence and consequently clinical outcomes. Second, aligning patient cost-sharing with net price can facilitate the effectiveness of value-based formularies if patient co-pays are lowest, as a consequence of the POS rebates, for the most cost-effective treatment.

Potential disadvantages: POS rebates give to individual patients some of the money that would otherwise flow back to the plan sponsor. The payer no longer has the option to apply those funds in ways that reduce overall health insurance premiums, which some stakeholders view as the priority for any change to the current rebate system. For Medicare Part D, some fear that POS rebates would lead plans to increase premiums enough to have an important negative impact on the affordability of plans for financially vulnerable patients.

POS rebates by themselves are not a cure for the financial burdens faced by many patients who need high-cost medicines but only have access to health insurance benefit designs with high deductibles and/or co-insurance. Many patients who need expensive, chronic treatment may still reach their annual out-of-pocket maximum. Furthermore, while applying POS rebates will reduce out-of-pocket cost for specific patients, they will not impact the most economically vulnerable patients on Medicaid, whose copayments are kept low already. For these patients, as well as others who have reached their out-of-pocket maximums in their respective plans, the rebate savings will continue to flow directly to the payer.

The impact of POS rebates on overall spending is unclear. Some commentators worry that POS rebates would include information for patients that inadvertently discloses the rebate level and undermines the leverage held by payers through confidential negotiations. POS rebates would also not neutralize the incentives for PBMs and others in the drug delivery chain that may lead them to seek higher list prices and larger rebates. Another potential risk is that unless POS rebates are carefully calibrated, they could reduce the out-of-pocket cost of a branded drug to the extent that these are chosen by members in place of generics that cost less to the plan.

### ***OPTION 3: Eliminate rebates and move to upfront discounts***

Although most stakeholders believe that eliminating rebates in favor of upfront discounts would prove the most disruptive possible alternative model to the current rebate system, some commentators believe that moving to upfront discounts is both feasible and the best way to accomplish the chief aims of many stakeholders. In their draft rule, the Trump Administration took a strong stand in favor of this approach.<sup>2</sup>

Potential advantages: The main argument for upfront discounts in place of rebates is that it removes the PBM incentive to generate revenue from rebates that many feel can lead to higher list prices and a less transparent flow of money between manufacturers, PBMs, and payers. Upfront discounts could also be the alternative model that most facilitates the application of cost-effectiveness findings to the development of formularies. Since the effective price is known at the outset, cost-effectiveness can be determined and compared. Discounts could be allowed to vary depending on clear criteria such as cost-effectiveness or expected volume. If discounts were transparent, clinicians could more readily become involved in choosing the most cost-effective treatment for their patients.

Potential disadvantages: Many have argued that upfront discounts would impact payer leverage, and drug pricing behavior by drug manufacturers. For one, payers may not have the same level of leverage in negotiating uniform discounts as they do in negotiating rebates that are linked to utilization/market share. The implicit transparency in upfront discounts is also viewed as problematic, potentially leading manufacturers to set single discount levels for all payers that would increase overall costs. Some have argued that publishing discounts would increase the risk of tacit collusion on price discounting among competing manufacturers. It could be possible to implement upfront discounts that are confidential so preserving bargaining power, but this puts at risk some of the benefits of increasing transparency.

Another consequence of shifting to upfront discounts and eliminating retro-active rebates would be a risk of undermining progress toward meaningful outcomes-based contracts and indication-specific pricing arrangements, both of which require some kind of back-end reconciliation process. Moreover, it should not be forgotten that in the legal settlement 22 years ago that led to the abandonment of discounts in favor of rebates, drug manufacturers agreed they would not offer upfront volume discounts, and instead agreed to offer similar pricing contracts to all purchasers that demonstrated they could move market share. The legal context has not changed, so it is not clear whether manufacturers could legally offer upfront any differentiation of discounts without violating antitrust law.

In addition, from a practical perspective, a move to a fixed-price discount approach is viewed by all stakeholders as requiring a major, complicated restructuring of both Medicare Part D and commercial contracts. Wholesalers and pharmacies could end up dealing with dozens of different (discounted) prices for each drug (varying by plan) and it is not clear how such a system would move such differently priced drugs through the supply chain. It also may have significant implications for “best price” rule payments by manufacturers to State Medicaid plans.

## ***Discussion***

There is no perfect solution that eliminates all the challenges created by rebates while leaving payers with a similar level of negotiating leverage to help moderate costs. It is possible that all options could increase overall net costs, and none of them addresses drug maker launch prices or price inflation. Forcing an abrupt transition away from rebates would therefore raise significant questions about the impact on total costs of care and on patient access and outcomes. Even small increases in health care insurance premiums might have significant effects on individuals who already struggle to afford health insurance for drugs through their employer, health insurance exchange, or Medicare.

Other potential unintended consequences might occur due to a shift in the competitive landscape and its impact on investment choices by drug makers. For example, health plans can negotiate a rebate in return for placement of a new drug as one-of-two first line therapies in tiered formulary structure. This structure rewards innovation at the expense of me-too products; but it also reduces near-term opportunities to realize cost savings associated with having 3 or 4 similar molecules in the market. All three options to the current rebate model could disrupt this dynamic, potentially incentivizing manufacturers to shift investment to me-too products, while reducing incentives to be first to market with truly innovative products. Any effort at rebate reform should therefore realize the broad effects of any change and the potential for unintended consequences.

It is conceptually attractive to consider combining a POS rebate for patients with a model that also passes 100% of rebates through to plan sponsors. This combination would function in many ways like a system of upfront discounts, and, conceptually, would be able to match many of the same goals. There are three main points of differentiation. First, a combination of 100% pass-through and POS would not by itself re-orient the rest of the drug delivery system, i.e. wholesalers and pharmacies, away from rebate incentives that favor higher list prices. Transitioning to flat fees for wholesalers and pharmacies could only be accomplished as a separate step requiring manufacturers to take the initiative to re-contract with all elements of the delivery chain, and it is unclear if market forces would compel that effort.

The second distinguishing factor between upfront discounts and a combination of 100% pass-through and POS rebate system is one that favors the latter approach: it would still accommodate retrospective payments needed to support outcomes-based contracts, utilization-linked rebates, or the reconciliation needed for indication-specific pricing agreements. The ability to accommodate these initiatives would be viewed as a benefit by many stakeholders, and the inability of upfront discounts to readily support them is considered an important limitation.

However, the third distinguishing element between the two approaches heavily favors upfront discounts. Transparency around pricing and revenue flows is a central short-term goal held by many plan sponsors. Transparency also figures among the higher aspirations of all stakeholders who view it as a necessary driver of desired changes to the entire chain of drug pricing and delivery. Upfront discounts with transparency also are more likely to support a rapid transition to flat fees for wholesalers and pharmacies along the delivery chain. Although full price transparency is viewed with alarm by some stakeholders who fear it will undermine the negotiating power of payers, it does represent the best way of assuring plan sponsors that the entire system of formulary development is not being perversely determined by the influence of rebates and obscure fees. Indeed, it maybe that some would be willing to accept higher net prices as a price worth paying, at least in the short run, for greater transparency. We also note however, that upfront discounts could be confidential. There is a general assumption that the upfront discount model will have transparent net prices, but this may not be the case. If discounts were confidential, then bargaining power would be maintained but the benefits of transparency would be lost.

Taking stock of the options for alternative rebate models, each with its own potential advantages and disadvantages, most stakeholders in the health care system realize that some form of change to the current paradigm of rebates is both needed and inevitable. The market has already shifted toward providing more plan sponsors with 100% rebate pass-through agreements. The Trump administration proposal ensuring a POS element that fully returns rebates to patients mirrors early efforts in the private market at establishing a POS rebate model, although it is too early to evaluate the outcomes. And while there are still many unknowns regarding the ultimate financial consequences, an aspirational target of moving fully toward a system in which upfront discounts are part of a broader transformation in drug negotiation and delivery is shared by a surprising number of stakeholders. But the way forward is fraught with risk and uncertainty, with deep trade-offs between short-term feasibility and long-term goals evident at every step. We hope this white paper will chasten policymakers who might have seen eliminating rebates or any of the other options as an easy, clean procedure. We equally hope that it will hearten and inform those who wish to take a thoughtful, careful approach to near-term reform while laying the groundwork for a greater transformation to come.

## 1. Introduction

### 1.1. Context

As pharmaceutical spending has risen in the US, health plan sponsors, insurers, and Pharmacy Benefit Managers (PBMs) have faced increasing challenges to maintain affordability. Among the mechanisms that have been implemented to try to control overall costs, health insurance benefit designs based on high initial deductibles and co-insurance within a tiered drug formulary have been effective, but have placed ever greater financial burdens on patients, especially those who require expensive on-going treatment for chronic conditions. The combination of rising drug costs at the system level and increasing financial stress for individual patients has triggered intense national concern.<sup>6,7</sup> Policy makers across the political spectrum are eager to find root causes, highlight unfair market practices, and find solutions that can control drug costs and improve patient access and affordability.

As policy solutions have been sought, one target has come under increasing scrutiny: rebates. Rebates are a staple of negotiations between pharmaceutical companies and payer organizations (which we define as including health insurers and PBMs) and represent a *quid pro quo*: discounts to the list price of drugs (rendered post-sale as rebates) are offered in exchange for preferential formulary placement. Concern about drug prices initially brought negative attention to the role played by drug makers in setting and raising prices, but soon the focus was expanded to include the role that “middlemen” such as PBMs played in rebate negotiations.<sup>8,9</sup> The claim against PBMs is that a substantial part of their revenue has traditionally come from keeping a percent of the absolute rebate amount they can negotiate, thereby creating a pernicious incentive to favor higher list prices from which a larger rebate can be obtained. This in turn is felt by some to lead to PBM-developed formularies to be composed of a mix of higher priced and even higher net-priced drugs. And even if the net price to insurers and plan sponsors does not change if increases in list prices are matched by correspondingly larger rebates, patients often face the full impact of higher list prices since it is to these prices that benefit designs usually link out-of-pocket requirements. Rebates have therefore rapidly become an extremely contentious topic, still praised by many as the best tool available to provide competitive leverage for payers seeking lower net prices, but reviled by others who view it as the chief sin in a system that punishes sick patients with higher out-of-pocket costs and absorbs billions of dollars that could otherwise either reward innovation or keep costs down, or both.<sup>10</sup>

Some stakeholders have also noted that rebates can warp the competitive landscape for new drugs trying to compete with existing drugs that have broader indications and significant market share, allowing their manufacturers to offer far more substantial rebates to PBMs and payers.<sup>11-13</sup> For example, in crowded drug classes such as autoimmune therapies, some drug makers have contended that new drugs with only a single indication, including some biosimilars, cannot get preferable formulary placement over existing leading drugs, even when new drugs are shown to offer better outcomes at a lower price, because the older drugs have multiple indications and billions of dollars of sales, generating rebates that are so substantial that payers would lose money by switching to more cost-effective options for a single indication.

Given these concerns, calls for reform of the rebate system have multiplied. In early 2019, after months of speculation, the Trump administration issued a draft rule for a sixty-day public comment period to eliminate rebates in public programs by amending an existing safe-harbor regulation that exempts rebates from the Federal anti-kickback statute.<sup>1</sup> The proposed rule was widely anticipated and would eliminate rebates in Medicare Part D, Medicaid Managed Care, and any PBMs in contractual relationships with these public entities, potentially disrupting any use of rebates across the market. In place of rebates, the administration expressed support for transparent discounts directly passed on to patients.<sup>2,14</sup>

Private companies have also responded to the rapidly evolving policy debate targeting rebates. After almost years of fierce competition among brand drugs for the treatment of chronic Hepatitis C, Gilead announced in September 2018 that it would launch authorized generics of its two best selling drugs in this category – Epclusa® and Harvoni® – with steep discounts of 68% and 62% off of their list prices for a course of treatment.<sup>15</sup> Payers will now be able to choose between the discounted authorized generic and the full-price rebated drug. In October 2018, Amgen announced they would lower the list price of their cholesterol drug, Repatha, by 60% in lieu of seeking a similar net price through steep rebates.<sup>16</sup> To capitalize on these moves by drug makers, and to lay the groundwork for further private market action to reduce the role of rebates, Express Scripts announced that it would offer a new “Flex” formulary option in 2019 to allow plan sponsors to select options with lower list prices and no rebates over options of the same drugs paid at a higher list price and corresponding rebate. Express Scripts said its explicit goal was to offer formulary designs that can ‘reduce reliance on rebated brand products.’<sup>17</sup>

With action within the federal government and the private market, the US thus appears poised for dramatic changes to a fundamental part of the drug pricing and coverage landscape. But what is known about how the rebate system interacts with other elements of drug pricing, coverage and delivery? And, for different stakeholders, what are the potential benefits and possible negative consequences of realistic possible alternatives? This White Paper, benefitting from interviews with numerous participants in the rebate process – from plan sponsors, to insurers, to PBMs, to drug makers – seeks to address these questions and to lay out a framework for evaluating proposed alternatives to a rebate model that has served as the cornerstone of drug pricing and coverage negotiation for decades.

## 1.2. Our Approach

This White Paper is structured to provide first an overview of the development of the current rebate system (section 1); describe how rebates flow between manufacturers, payers, and patients (section 2); explore what impact rebates have on key stakeholders in the health care system (section 3); outline two key aspects for consideration of reform (section 4); and analyze the potential consequences of alternatives that might replace the current rebate model (section 5). We conclude with a discussion of key issues (section 6).

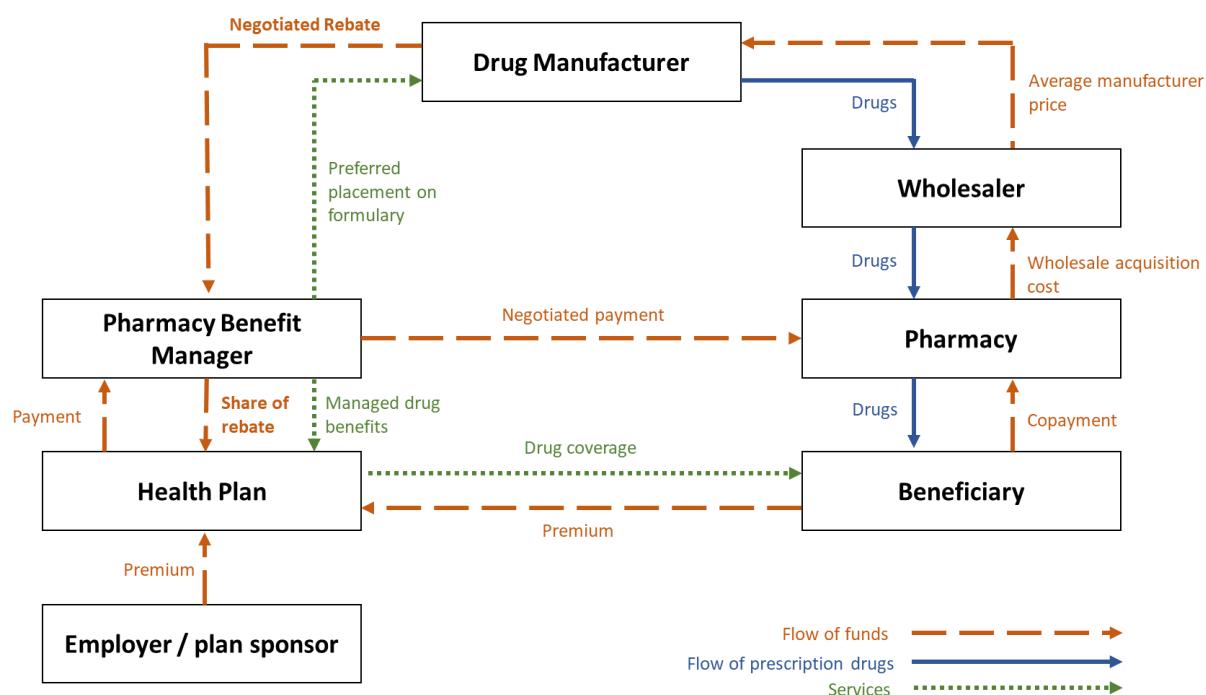
In preparing the paper we undertook a focused literature review and evaluated the written responses to the HHS Blueprint on drug pricing from key stakeholders, including all participants in the ICER membership program. We also conducted ten interviews covering PBMs, public and private payers, manufacturers, academics, benefit consultants, and trade associations. An earlier version of this paper was sent out as a pre-read for the ICER Policy Summit. This version of the paper takes account of the discussion at that meeting and comments from ICER members.

Throughout this paper we describe how all alternatives to the current rebate system offer potential risks or disadvantages as well as potential benefits, and that the implementation of any major reform may pose daunting practical challenges given the multitude of ways that rebates affect various parties within the drug delivery chain. We outline the evidence presented to date, and the key questions that still need to be answered.

### 1.3. How do rebates work?

The supply chain for pharmaceuticals in the US is complex, involving many different stakeholders with competing interests. Sood et al.<sup>18</sup> calculate that 41% of prescription drug expenditure accrues toward intermediaries in the pharmaceutical distribution system. The following figure illustrates the flow of services, products, and payments (including rebates).

**Figure 1.1. Simplified illustration of the flow of products, payments and services in the pharmaceutical supply chain**



**Source:** Illustration based on Congressional Budget Office<sup>19</sup>

Rebates are negotiated between drug makers and payers (insurers or PBMs) when drugs first enter the market and can be renegotiated on a regular or ad hoc basis. As mentioned earlier, rebates can be based on a mixture of payments from drug manufacturers to PBMs, but their primary function is to serve as an element of negotiating favorable placement within a drug formulary. For example, a company desiring its drug to be placed in the best tier of a formulary, in which the drug can be considered a “preferred” drug for clinicians, with more limited drug management and low out-of-pocket payments required from patients, may offer a larger rebate off the announced list price.

Rebates are thus more common and usually larger in drug areas in which there is significant competition among branded drugs, especially when competition is among drugs with similar mechanisms of action and only incremental, if any, differences in clinical risks or benefits. Drug areas with substantial rebates include drugs for diabetes and autoimmune agents used for conditions such as rheumatoid arthritis and psoriasis.

Although rebate levels are negotiated “upfront” before the drugs are prescribed, they are not implemented as discounts on the price paid by the patient or even by the payer at the time of the original transaction. Instead, rebates are paid retroactively, and may include a sliding scale based on other factors such as market share or the aggregate amount of other fees wrapped into the overall rebate agreement. PBMs share all or some portion of rebates and other fees derived from agreements with manufacturers with the health insurer or the plan sponsor based on their contractual agreement.

Manufacturers say that they can offer larger rebates if they increase their list prices. However, as discussed in Section 1.5, the relationship between list price trends and trends in rebates is not straightforward.

#### **1.4. History of the Transition from Discounts to Rebates**

Historically, PBMs competed by negotiating terms with pharmacy networks, managing the delivery of specialized pharmaceutical products, and processing prescription transactions (claims) on behalf of health plans. The role of PBMs has expanded from claims processing, to the development of formulary management, which has coincided with their exercising of market power to negotiate with drug manufacturers to encourage competition on prices in drug categories where there are multi-source products or several on-patent products competing in a therapeutic area.

Prior to 1996, manufacturers offered discounts to health plans for their drugs, while charging an undiscounted list price to wholesalers and pharmacies. Wholesalers would then bill the manufacturer for the difference between the amount they purchased the drug for from the drug manufacturer, and the amount they were reimbursed for the drug, as determined by the discounted rate negotiated by the health plan. This was known as a *chargeback*. Pharmacies, however, had no direct relationship with drug manufacturers and could not negotiate similar discounts, or chargebacks. As a result, pharmacies paid the wholesale price for the drug to the wholesaler, while all other parties achieved discounts by directly negotiating with drug manufacturers. Chain pharmacies attempted to negotiate directly, and as part of a collective, but were denied discounts by all drug manufacturers.

In 1996, a class action lawsuit was brought by retail pharmacies against major drug manufacturers alleging that they had violated the Sherman Antitrust Act.<sup>20,21</sup> Pharmacies argued that manufacturers conspired to keep prices “artificially high” for the retail sector, denying any attempt by pharmacies to negotiate discounts, while offering discounts to all other parties in the supply chain, including HMOs, wholesalers, hospitals, and other buyers.<sup>22</sup> This lawsuit resulted in manufacturers entering into a court-approved settlement in which they agreed that they would (1) not refuse to discount goods based solely on the status of the buyer entity and (2) offer the same types of discounts previously reserved for plans to pharmacies and retail buying groups that could demonstrate an ability to affect market share in the same manner.<sup>20</sup> As a result, manufacturers restructured their contracts with payers based on retroactive rebates tied to prescription volume and market share rather than upfront discounts. Pharmacies would be paid by payers for the drug at the price at which it was obtained from the wholesaler plus any supply chain markups. And payers would then receive any retroactive rebate direct from the drug manufacturer.

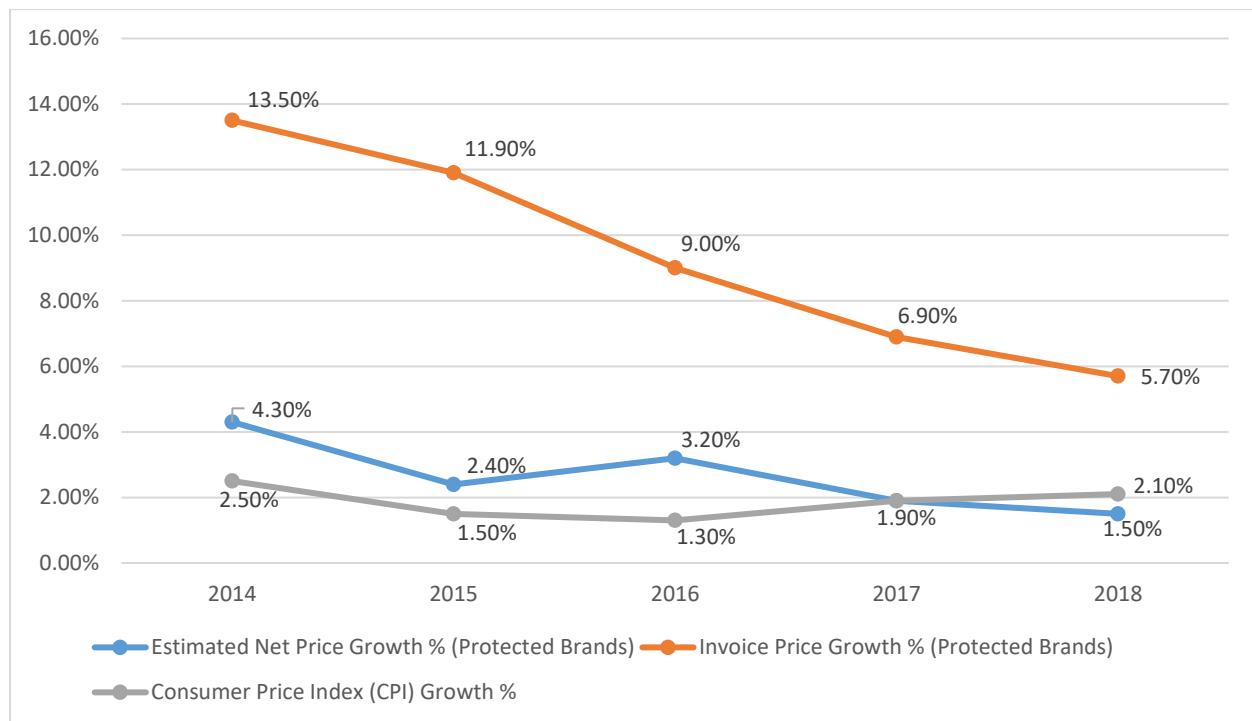
In reaction to this evolving landscape toward rebates and away from upfront discounts, the Office of the Inspector General at HHS issued a “safe harbor” protection in the late 1990s to shield drug companies’ rebate contracts from the implications of the Anti-Kickback Statute (AKS). The AKS prohibits remuneration for referrals or services that are payable by a federal program (i.e. Medicare) - in effect paying someone to recommend your product under a federal health care program.<sup>23</sup> In place since 1971, this safe harbor provision is now what may be amended by HHS. Its revocation by the federal government could serve as a powerful tool to reshape the discount/rebate structure in federal health programs with knock-on implications for private sector health insurance markets.

### 1.5. Perspectives on the “Gross-to-Net” Price Gap

Opinions on the magnitude of the difference between list prices and net prices following rebates, and the role that rebates play in driving overall drug expenditures, are highly contentious across different stakeholders and commentators. Manufacturers say that they can offer larger rebates if they increase their list prices, which is supported by some analyses linking increased overall spending on rebates with increasing list price trends.<sup>24</sup> Some drug companies have released aggregate net price results suggesting that net costs to the payer have declined when rebates are factored in. However, studies commissioned by the Pharmaceutical Care Management Association (PCMA) and the America’s Health Insurance Plans (AHIP) demonstrate no positive relationship between list price levels and the amount obtained in rebates for specific drugs and drug classes.<sup>24,25</sup>

There is general agreement that the gap between list price and net price is widening as a cumulative sum: over the five years between 2012 and 2016 the total value of pharmaceutical manufacturers’ off-invoice rebates and other price concessions more than doubled from \$59 billion to \$127 billion.<sup>26,27</sup> IQVIA has shown that invoice price growth (i.e. gross price) has continually out-paced net price growth (which accounts for rebates). Both are, however, declining, with net price growth coming closer in line with general inflation. This is shown in Figure 1.2.

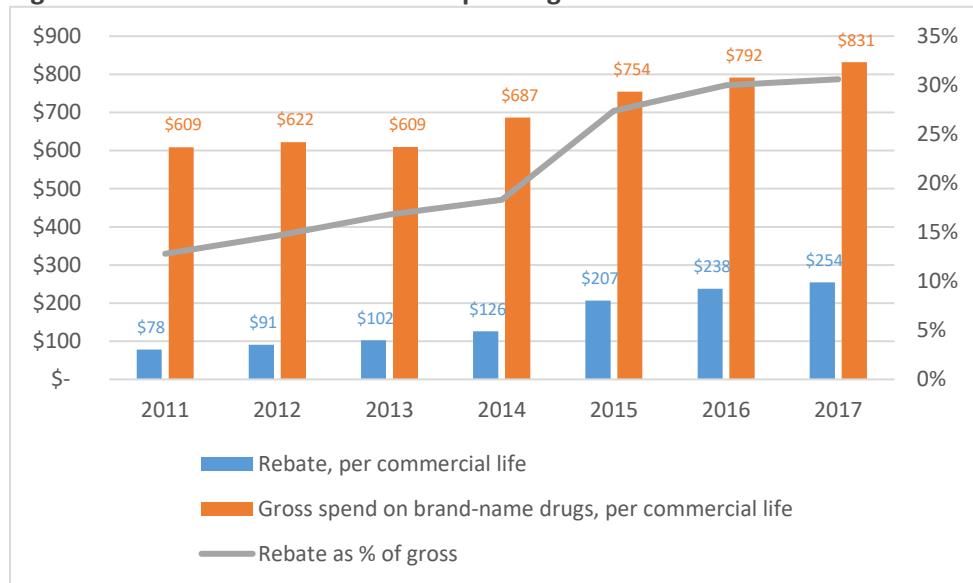
**Figure 1.2. IQVIA: US Price Growth Comparing Brands\* Invoice Price and Net Price Growth 2014-2018**



**Source:** Data from IQVIA.<sup>28</sup> \*Protected Brands are products that have been on the market two years or more and have yet to reach patent expiry.

Data from the Office of the Inspector General (OIG) and CVS corroborate this growing gap between list price and net price.<sup>29,30</sup> In a 2018 report, the OIG demonstrates that while reimbursement for Medicare Part D increased 62% from 2011 to 2015 (\$49 billion to \$80 billion), rebates more than doubled (\$9 billion to \$23 billion) over the same timeframe.<sup>29</sup> CVS data also demonstrate that whilst gross expenditure on brand-name drugs has increased, the corresponding level of rebate has increased faster, leading to a higher proportion of gross expenditures being rebated from 13% in 2011 to 31% in 2017; this is represented in Figure 1.3.

**Figure 1.3. CVS Health: Brand-name spending and rebates 2011-2017**



**Source:** Data from CVS Health<sup>30</sup>

For patients, the gap between list and net price can substantially affect out-of-pocket spending at the pharmacy counter. In the past decade, employers and individuals have shifted toward benefit designs with high out-of-pocket cost structures, including deductibles, co-insurance, and tiered formulary design. Patients' out-of-pocket expenditure has been linked to list prices instead of net prices since net prices are considered proprietary and are only determined retroactively. A large gap between list and net price therefore matters to patients, who, in some cases, might pay more out-of-pocket for the drug than its actual true (net) cost to the plan.<sup>31</sup> And rebate payments are made to payers even when patients are in the deductible phase of their insurance benefit and paying the full price of treatment. Examples of patients paying high out-of-pocket costs, without benefiting from the rebates negotiated for a therapy, have become commonplace in mainstream news throughout the past several years, including high profile stories about insulin and the EpiPen.<sup>32,33</sup>

## 2. Rebates in Different Insurance Markets

The size of rebates on branded drugs varies between drugs administered through the medical benefit and those obtained through outpatient prescription drug coverage. Rebates also differ by drug types; a study of Medicare Part D rebates found that rebates were highest for drugs with brand competition (average 39% of gross cost), while protected class drugs<sup>a</sup> had lower average rebates: 14%.<sup>34</sup>

Werble et al. estimated that negotiated rebates are, on average, approximately 30% of the list (wholesale acquisition cost or WAC) price.<sup>35</sup> Roehrig estimated that Medicare Part D plans achieve higher average rebates (31%) than private plans (16%), and Medicaid, where state governments have the additional leverage of the “best price” rule, receives the highest average rebates on branded drugs (61%).<sup>36</sup> These figures have been challenged, however, both because average Medicaid rebates at that level lack face validity, and because other sources have found that rebates for brand drugs are lower for Medicare than for the private sector.<sup>34</sup>

### 2.1. Medicaid

Because of the Medicaid Best Price rule, introduced in the Omnibus Budget Reconciliation Act of 1990, Medicaid programs across the country obtain either (a) a minimum rebate of 23.1% off the average manufacturer price (AMP) for branded drugs or (b) the “best price” offered to any other public or private purchaser (whichever is the higher discount). The intent of this rule is to enable the public sector to get the benefits of private sector bargaining power and ensure the Medicaid program is not paying more than the private sector for its drugs.<sup>37</sup> In turn, Medicaid programs must cover all prescription drugs (with some exceptions).

State based Medicaid programs can negotiate deeper, “supplemental” rebates themselves or through a PBM. These negotiations are on a state-by-state basis, or sometimes achieved through cooperatives of states collectively bargaining on drug prices. State negotiated supplemental rebates can be applied to drugs purchased by all Medicaid managed care organizations contracted through the state. The impact of rebates on out-of-pocket costs for patients is not an issue in Medicaid, as beneficiaries have very low cost-sharing, which is often fixed and not related to drug cost. However, in order to incentivize negotiations for supplemental rebates, states can put therapies on a preferred drug list to streamline access for their members without drug management requirements.

Depending on the state Medicaid program, an important feature may be that rebates can be used to cross-subsidize other state spending. Given that Medicaid programs obtain substantial rebates, some PBMs believe that this revenue stream is so important to states that it reduces their interest in eliminating rebates.

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<sup>a</sup> There are six protected classes (anticonvulsants, antidepressants, antineoplastics (including many oral chemotherapy drugs), antipsychotics, antiretrovirals, and immunosuppressants. Part D plans to cover “all or substantially all drugs” within each of the classes.

There are several factors that contribute to the high rebate rates that are achieved under the Medicaid program. One is that manufacturers who refuse to participate in Medicaid are excluded by law from Medicare (which represents a much larger market share for prescription drugs). In addition, the government requires that Medicaid receive a minimum of 13% of AMP rebate on generic drugs.<sup>36</sup> Between 2006 and 2009, the Office of the Inspector General (OIG) found that Medicaid recouped through rebates between 29% and 38% of its prescription drug expenditures each year, resulting in an average annual savings of about \$8 billion. These arise both from the best price rule and an additional rebate based on an inflationary component if the increase in a drug's AMP exceeds the increase in the Consumer Price Index.

Private payers argue that the Best Price Rule sets an artificial floor for their negotiations, limiting their ability to negotiate rebates deeper than 23%. Soon after the creation of the Medicaid Drug Rebate Program (along with its 'best price' principle), payers viewed increased prices in the commercial sector as an effort by manufacturers to offset losses in the Medicaid program or to avoid "resetting" their best price. Both Congress and HHS have tried to address this effect by excluding certain prices, discounts, and rebates from the definition of AMP and best price.<sup>38</sup>

## 2.2. Medicare

Under Medicare Part D, private insurers negotiate rebates with manufacturers independently with no government involvement, but all savings must be reported and paid to the government.<sup>b</sup> Medicare Part D drugs obtain high rebates compared with those covered by private insurance. This is believed due to “the wider use of utilization management and multi-tiered and exclusionary formularies in Medicare Part D than in commercial plans [which] creates a greater risk/reward for the exclusion or inclusion of a manufacturer’s brand and encourages greater concessions through competitive forces.”<sup>39</sup> In addition, Medicare Part D beneficiaries are more sensitive to premium levels since many are on fixed incomes, and are therefore more likely to accept a restrictive formulary, enhancing the bargaining power of Part D plans.<sup>36</sup>

While higher rebates in Part D compared to the commercial market may help moderate premium growth, cost-sharing for Part D patients is linked, as it is for commercially insured patients, to the list price. However, Medicare Part D has reinsurance for high cost patients who have paid over \$5,000 in true out-of-pocket costs (TrOOP costs). After this “catastrophic” threshold is met, the government picks up 80% of the bill, Part D plan liability is just 15%, with the remaining 5% paid by patients.<sup>40,41</sup> A number of commentators have highlighted that this shift in financial responsibility at the catastrophic threshold gives PBMs and Part D plans an incentive to favor high-cost high-rebate drugs as high list prices push beneficiaries into the catastrophic phase more quickly, and the compulsory discount manufacturers are required to give patients included in the patient cost calculation when determining whether the “catastrophic” threshold is reached.

The end effect has been that the share of the overall cost that Part D plans pay is decreasing as high-price, high-rebate arrangements increase. And this effect is magnified by the increase in the number of new, high-priced specialty pharmaceuticals coming into use over recent years. According to Antos and Capretta,<sup>40</sup> the government spent \$37 billion in 2017 covering expenses for beneficiaries above the catastrophic threshold, which was \$9 billion (about 25%) higher than in 2008. In line with this cost growth, the Medicare reinsurance subsidy (on a per member-per year basis) grew at an annual rate of nearly 17% between 2010 and 2015.<sup>41</sup> CMS policy makers have concluded that “Under current rules, Part D sponsors may have weak incentives, and, in some cases even, no incentive, to lower prices at the point of sale or to choose lower net cost alternatives to high cost-highly rebated drugs when available.”<sup>42</sup>

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<sup>b</sup> As noted in the footnote to Table 2.1 there is an exception for the risk corridor.

## 2.3. Commercial Markets

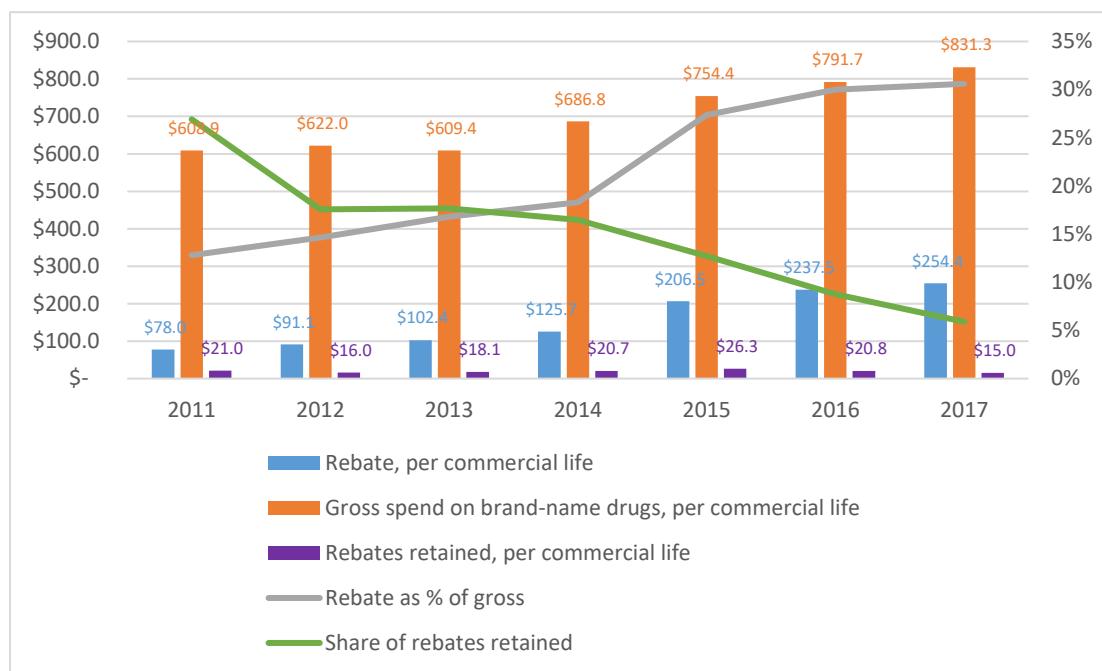
### *Flow of rebates from PBMs to payers*

The contractual relationships between PBMs and payers take many different forms. As part of these contracts, PBMs often retain a percentage of rebates, although a growing number of payers are now seeking contracts in which all rebates are returned to the payer, often called a rebate “pass-through.”<sup>43</sup> As described earlier, there are many different forms in which payments can flow back from manufacturers to PBMs, and which may – or may not – be included in any particular rebate pass-through agreement. These payments can include administrative service fees, which are often between 4-5% of WAC and therefore can represent large amounts of money; “price protection” guarantees, which are additional penalties in the event that the list/net price increase for a drug exceeds a certain threshold; and other forms of lagged discounts, such as payments contingent on market share or patient/population outcomes. In some cases, PBMs offer a contract with a guaranteed level of rebate to the payer, an arrangement which subjects the PBM to more risk but offers the payer a predictable cash flow.<sup>30</sup> While PBMs and plan sponsors differ on which of the two groups is most responsible for driving interest in guaranteed rebate agreements, all agree that the end effect is to perpetuate the incentive for PBMs to prioritize high-rebate drugs.

The percent and absolute amount of rebates retained by PBMs has been evaluated by different groups but results remain controversial, arguably due to the existence of a permeable membrane between what are called rebates and what are called fees. A survey report from the Pharmacy Benefit Management Institute (PBMI) reported that just under half of employer respondents said they received 100% of rebates (either with a minimum rebate guarantee [27%] or without [22%]), a significantly higher percentage than similar estimates from 2014.<sup>44</sup> A recent study by Visante on behalf of PCMA states that, on average, around 90% of rebates are passed through to payers.<sup>25</sup> Cumulatively, Roehrig finds that in 2016, \$89 billion in rebates were paid to health insurers, reducing total retail drug spending by 21%.<sup>36</sup> This same study estimates total PBM profits to be \$11 billion and suggests that the notion that PBMs divert a large share of rebates to excess profits is not supported by the data.

Two large PBMs – CVS and Express Scripts – have made statements claiming that rebate retention is no longer a significant part of their business model. Data that CVS has published shows a downward trend in rebate retention over time.<sup>30</sup> Figure 2.1 illustrates the amounts in rebates obtained and retained by CVS from 2011 to 2017.

**Figure 2.1. CVS Health: Brand-name spending, rebates and rebate retention 2011-2017**



Source: Data from CVS Health<sup>30</sup>

It can be observed from the Figure above that whilst rebates over time have increased substantially (from 13% of gross spend in 2011 to 31% in 2017), the share of those rebates retained by CVS has declined, from 27% in 2011 to just 6% in 2017. According to their data, in the first half of 2018, CVS Caremark retained just 2% of rebates.<sup>30</sup> Similarly, Express Scripts states that they pass on 95% of rebates, and that nearly half of their clients opt for 100% pass-through of rebates.<sup>45</sup> The implication is that PBMs are shifting to charge for more of their services in other ways than taking a share of rebates. Plan sponsors are generally skeptical of claims that the contracts offered by PBMs with “100% pass-through of rebates” have solved the problem of PBMs receiving revenue from manufacturers linked to high list prices. Some plan sponsors believe that a lack of standardization of fee terminology has allowed PBMs to adopt 100% pass-through agreements while shifting some manufacturer payments into forms of fees that plan sponsors may not be fully aware of and that are excluded from the pass-through requirement.

#### ***Flow of rebates from PBMs and payers to patients***

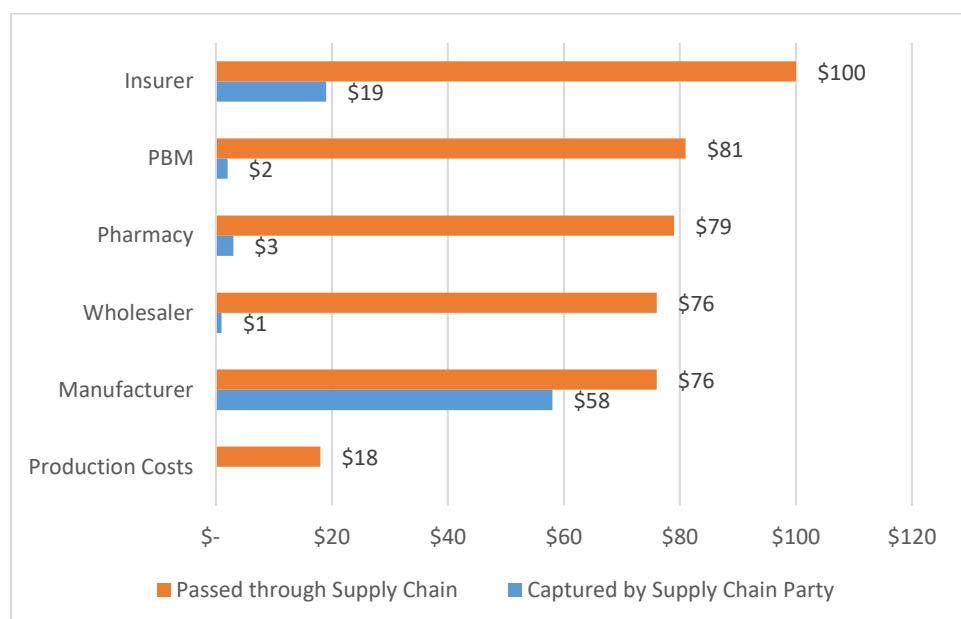
A 2017 PBMI report asked plan sponsors how rebates are used: 68% indicated that rebates are used to reduce plan spend on drug costs, whereas only 4% of plan sponsors were using rebates to reduce member out-of-pocket costs at the point of sale (POS). PhRMA and others critical of the lack of a POS rebate system for patients refer to this as “reverse insurance” in which those who need medications are required to pay more out of pocket to reduce premiums for other plan members.<sup>46,13</sup> It should be noted that some insurers, including major national carriers UnitedHealth Group and Aetna, have recently announced the introduction of POS rebate benefit designs.<sup>47</sup> These benefit designs are being offered at a higher monthly premium than standard designs, and it is too early to determine whether enrollment in these options will be robust or limited.

### 3. How do rebates impact different stakeholders?

#### 3.1. Flow of expenditures through the drug delivery system

Based on gross and net margin estimates derived from SEC filings, Sood et al. developed an analysis to illustrate the average flows of funds to different participants in the drug delivery chain.<sup>18</sup> As shown in the figure below, taken from their paper, for a hypothetical \$100 expenditure on branded drugs, composed of both out-of-pocket expenditure and payer payment, \$76 accrues to the manufacturer, of which more than two-thirds is net profit. Approximately \$19 accrues to insurers, while PBMs retain \$2. Based on their analysis, Sood et al. conclude that PBMs make approximately 4 times more net profit on generic drugs than on branded drugs in which rebates play a role.

**Figure 3.1. Flow of hypothetical \$100 expenditure on branded drugs through the US retail distribution system (Sood, et al.)<sup>18</sup>**



Source: Data from Sood et al<sup>18</sup>

### **3.2. Empirical studies on the impact of rebates on list prices**

There are a small number of empirical studies that consider the relationship between list price and rebate levels. None have been peer-reviewed, and most were commissioned by groups that have direct financial interests in drug pricing and delivery. Their conclusions remain controversial among different stakeholders, and we have not attempted to evaluate the validity of the data or the conclusions of these reports. Those most often noted include the following:

- A report by Milliman prepared for America's Health Insurance Plans (AHIP). This provides an analysis of historical Medicare Part D drug prices and manufacturer rebates. The report finds that brand drugs with rebates have higher trends in historical list price growth than brand drugs without rebates.<sup>24</sup> In addition, the highest cost branded drugs have, on average, the lowest manufacturer rebates. The analysis does not analyze or hypothesize any causation for these relationships.
- CVS Health offers a response to what it describes as the “myth” about a positive relationship between rebate size and list price.<sup>30</sup> Its report, published in August 2018, argues that if this were the case, there would be a strong correlation between rebates and list prices. On the contrary, the report compares list price increases (2015 to 2018) with average rebates for six specific drug categories, showing that list price increases are higher for drug classes with smaller rebates. According to the analysis, list prices for anticonvulsants and multiple sclerosis drugs rose over the time period by 46% and 27% respectively, while annual rebates were only 6% and 7%.<sup>30</sup> However, the authors do not explain how the six drug categories were selected, nor do they evaluate the relationship of rebates and list prices among the drugs within a single drug category. Finally, they do not explore how list price increases might relate to changes to rebates over time.
- A report by Visante on behalf of PCMA similarly argues that there is no correlation between rebate levels and price increases by manufacturers.<sup>25</sup> The authors' analysis suggests that among the top 200 brand drugs, there is no correlation between average rebate levels negotiated with PBMs and increasing prices set by manufacturers. Furthermore, they suggest that manufacturers raise prices even when rebates are low. This is consistent with the hypothesis that there are two different types of market: those where manufacturers have strong market power and those where there is a lot of competition.
- A 2016 Bloomberg analysis illustrates examples of the increasing divergence between list and net prices at the product level.<sup>49</sup> In a study of 39 products with global sales above \$1 billion per year, looking at the six-year period Q4 2009 to Q4 2015, they found that net prices after rebates increased at nearly the same rate as CPI inflation for 12 products (31%); for the other 27 products (69%), net prices rose well above inflation. For 31 of the products (79%), the percentage gap between list price and net price rose over the period. For the remaining eight (21%) it fell.

### 3.3. Public Comments on Rebate System Alternatives from Different Stakeholders

The viewpoints of various stakeholders on the relative benefits and negative consequences of the current rebate system are understandably different. We reviewed the public comments submitted to HHS in response to its request for input. Table 3.1 summarizes the views of organizations participating in the ICER membership program, along with statements from major trade associations who responded directly to the HHS Blueprint. Our summary of the viewpoints is supplemented by information gained from interviews undertaken with key stakeholders.

**Table 3.1. ICER Membership summary of comments to the HHS Blueprint**

<b>21/29 ICER Members submitted comments to HHS blueprint;</b>
Also included are comments submitted by PhRMA, BIO, PCMA, and the Campaign for Affordable Rx Pricing
<b>Payers (Anthem, HCSC, Aetna, AHIP, Cambia Health Services, United, Kaiser) were most likely to:</b>
<ul style="list-style-type: none"><li>○ Oppose prohibiting rebates (86%);</li><li>○ Support reforming Medicaid best price rule because of its impact on negotiating rebates (86%);</li><li>○ Oppose requiring point of sale rebates (86%).</li></ul>
<b>PBMs (CVS, Express Scripts, and PCMA) were most likely to:</b>
<ul style="list-style-type: none"><li>○ Oppose prohibiting rebates (100%);</li><li>○ Oppose fixed price discounts (100%);</li><li>○ Support reforming Medicaid best price rule because of its impact on negotiating rebates (66%);</li><li>○ Support confidentiality (66%).</li></ul>
<b>Pharmaceutical Companies (Biogen, NPC, Genentech, GSK, Mallinckrodt, Merck Inc, Novartis, Regeneron, Sanofi, Alnylam, Astra Zeneca, Johnson and Johnson, PhRMA, BIO) were most likely to:</b>
<ul style="list-style-type: none"><li>○ Support Point of Sale rebates (71% Agree);</li><li>○ Were split on prohibiting rebates (36% yes; 21% no; 7% on the fence; 36% did not state);</li><li>○ Support confidentiality (14%).</li></ul>

## 4. Key aspects for consideration of reform

Before outlining the major policy alternatives to the current rebate system, in this section we highlight two important elements that should be carefully considered in weighing the pros and cons of any potential future model. These are: 1) the impact on transparency; and 2) the impact on the ability to administer outcome-based contracts. We introduce these topics in this section and elaborate where relevant within the discussion of the specific policy options in the next section. Both themes also appear in the major “criteria” that we propose for assessing policy options.

### 4.1. Transparency of Rebate Amounts

The desirability of transparency is contested by many stakeholders, both in responses to the HHS Blueprint and in other statements. Transparency of rebate amounts at the individual drug level is viewed by many as a direct outcome of eliminating rebates and moving to an upfront discount model. With other approaches in which rebates are retained in some fashion, transparency is more often viewed as optional, something that can be accommodated or avoided.

Full price transparency throughout the drug delivery chain is seen by some as the only way for plan sponsors and insurers to fully understand the outcomes of their contractual relationship with PBMs and to ensure that rebates are flowing back to payers as intended. Similarly, it is argued that transparency of rebates and all other fees from manufacturers would limit the incentives of PBMs to include certain drugs in the formulary that generate more revenue for the PBM, but which are not the most cost-effective for the payer. Transparency of rebates for the patient at the point of sale is held out as one way to increase pressure on payers and PBMs to share those rebates with patients.

In contrast, others have argued that too much transparency could lead to higher net prices for two reasons. The first is that it could degrade the ability of manufacturers to offer larger rebates to certain payers. If all payers and PBMs know what the “best” rebate is in the marketplace, all would be able to seek it. As a response, manufacturers would be likely to calculate the most profitable *uniform* level of discount across all payers, which might result in higher net prices overall.

Second, some commentators worry that transparency could even lead to tacit collusion by competing manufacturers. The PCMA highlights in its response to the HHS Blueprint that the Federal Trade Commission (FTC) itself has stated that, “[i]f pharmaceutical manufacturers learn the exact amount of rebates offered by their competitors ... then tacit collusion among manufacturers is more feasible ... Whenever competitors know the actual prices charged by other firms, tacit collusion — and thus higher prices — may be more likely.”<sup>50</sup> CVS supports this point of view, reiterating that the Congressional Budget Office (CBO), FTC, and CMS have all expressed concerns regarding the competitive effects of disclosing drug-specific rebate data. The CBO has stated that the disclosure of rebates could impact Medicare spending for a number of medical conditions where there are only a few drugs available and thus the “disclosure of drug-by-drug rebate data in those cases would facilitate tacit collusion among those manufacturers, which would tend to raise drug prices.”<sup>51</sup> It should be noted that despite the arguments warning about the risk of “too much” transparency, some plan sponsors remain concerned that without full transparency the risk of manipulation of rebates and fees by PBMs remains high.

## **4.2. Maintaining the possibility of implementing outcome-based contracts and indication-specific pricing agreements**

Outcomes-based contracts, sometimes called “value-based contracts,” have become more common over the past decade. These contracts between drug manufacturers and payers feature increased rebates to payers if pre-specified clinical or economic outcomes are not achieved with treatment. For example, Harvard Pilgrim Health Care has announced outcomes-based based contracts with Amgen in which expenditures on Amgen’s PCSK9 cholesterol drug are paid back to the insurer when the protective effect of the drug fails to prevent a heart attack or stroke.<sup>52</sup> Whilst some commentators argue that the evidence that outcomes-based contracts make an impact on cost or quality of care is not convincing,<sup>53</sup> manufacturers, payers and policymakers (including the Trump administration) have identified outcomes-based contracts as one important mechanism for linking the overall payment for drugs to the value of the clinical outcomes they achieve.

In order to work, outcomes-based contracts need some kind of mechanism through which payments from the manufacturer can flow back to the PBM or plan sponsor months or years after the drug is first paid for. Similar requirements are often necessary to support indication-specific pricing agreements between payers and manufacturers.<sup>54</sup> In these agreements the price for a drug is linked to its clinical effectiveness across different clinical indications. For example, if a drug is more effective in treating psoriasis than it is for treating rheumatoid arthritis, its price for the former could be set higher than for the latter condition. This kind of indication-specific pricing is usually accomplished not by administering two different prices but by creating a “blended” single price based on an estimate of the relative proportion of prescriptions that will be written for each indication. Following this approach then requires some form of reconciliation later in time, at which payment from the manufacturer back to the payer may be required if actual use of the drug proved to be higher in the low-price indication than previously estimated. Thus, as with outcomes-based contracts, indication-specific pricing agreements usually need to have an option for some kind of “true-up” payment that, if not called a rebate, would function in a similar manner.

It is important to note that neither outcome-based contracting nor indication-specific pricing can be viewed as a “solution” to the problems arising from rebates. Both approaches are likely to be limited to a relatively small number of drugs, and neither approach addresses concerns about highly price drugs at market entry. But given the general desire to facilitate further experimentation with these kinds of market-based efforts to better align drug costs with clinical value, consideration should be given to designing options to the current rebate model that will protect and, if possible, promote these efforts.

It is in this context that many stakeholders were surprised that the recent HHS proposal to eliminate the current rebate safe harbor appears to provide no exception for any agreement involving a retrospective remuneration from a manufacturer to a PBM/insurer. Stakeholders appear aligned in preferring that future rebate models provide a broad safe harbor for outcomes-based contracts and indication-specific pricing agreements to allow for experimentation that can lead to the establishment of best practices.

## 5. What are the alternative options for rebate models?

Many different alternatives have been put forward by critics of the current rebate system. The major options, however, can be separated into two categories: 1) those that retain retroactive rebates but have some requirements to channel rebates back to payers and/or patients in prescribed ways; and 2) an alternative model that eliminates retroactive rebates entirely, replacing the current structure with upfront discounts. For shorthand, the first set of alternatives can be labeled as ways to “reform rebates” while the second moves formally to a system that “replaces rebates.” It is important to note that the two options to reform rebates could be implemented as stand-alone options, but many commentators suggest that they should be combined. In addition, all of the alternative rebate models can be implemented with varying degrees of transparency regarding the rebate/discount amount, but upfront discounts would most likely force transparency at the individual drug level, given that any linkage of patient payment to the discounted price would allow other stakeholders to gain knowledge of the discount.

The alternative options are portrayed below in Figure 5.1 and consist of:

- **Option 1:** Retain rebates with a requirement that PBMs pass on 100% of manufacturer rebates and fees to the plan sponsor.
- **Option 2:** Retain rebates with a requirement for point-of-sale (POS) rebates to patients.
- **Option 3:** Eliminate rebates in favor of a return to upfront discounts.

**Table 5.1. Alternatives to the current rebate system**

Reform Rebates	Replace Rebates
<p>1. <b>100% pass-through</b> of rebates and relevant fees <i>and/or</i> 2. <b>Point of Sale (POS) rebates</b> applied to patient out-of-pocket cost sharing</p>	<p>1. Eliminate rebates and move to <b>upfront discounts</b>*</p>

\* This option has been proposed by the Trump administration to apply to Medicare Part D, Medicaid Managed Care, and any contracting PBMs for these Federal programs.<sup>2</sup>

In the sections below, we describe each of these alternative options in greater detail. We also analyze their respective advantages and disadvantages, including practical considerations in their implementation. As noted earlier, 100% pass-through and POS reform options could be combined or could be implemented separately, so we address them separately in the section below.

We begin by setting out possible criteria by which the different options should be judged and then, after discussing the options, we summarize the advantages and disadvantages in Table 5.3.

## **5.1. Major Considerations for Alternative Rebate Models**

We have focused on the following criteria by which the various alternatives can be evaluated:

- Impact on patients' affordability, access to care, and clinical outcomes (via improved adherence)
- Impact on overall cost of pharmaceuticals and medical spending
- Impact on competitive outlook for innovative new medicines
- Ability to support outcomes-based contracting and indication-specific pricing agreements
- Impact on efforts to design formularies based on cost-effectiveness of pharmaceuticals
- Feasibility of implementation
- Ability to improve transparency of costs to support public dialogue on value and affordability

## **5.2. OPTION 1: 100% Pass-through (All rebates and associated fees flow to plan sponsors)**

Arrangements between PBMs and health plans which specify 100% pass-through of rebates are becoming more common; we have already described the data demonstrating that PBMs are decreasingly dependent on retaining rebates as revenue, passing more through to the payer. These data do not extinguish concern among plan sponsors that manufacturer payments could be re-labeled as a variety of types of fees that could still be tied to list price and drive formularies with a mix of drugs that are not the most cost-effective choices from the plan sponsor's perspective. Therefore, a more universal move requiring 100% pass-through arrangements of rebates and all manufacturer fees may still represent an important change. If that model can be linked to a move to require manufacturers to pay flat fees to distributors and pharmacies, the entire drug delivery chain could be weaned off of reliance on rebates and percentage fees. Payers argue that flexibility in the amount of pass-through is helpful, given that plan sponsors have different priorities, but many believe that the overall system is moving rapidly toward a near-universal 100% pass-through even without federal action of some kind.

### **Potential advantages**

The most obvious and important potential advantage of this model is that it would eliminate any incentive for PBMs to favor higher list prices just to recoup greater revenue through higher rebates. With less incentive for PBMs to develop rebate-optimizing formularies, individual patients would benefit financially when their cost-sharing is linked to a lower list price (which could lead to better adherence and outcomes). Net prices could remain confidential, and rebates could, in principle, continue to be linked to formulary placement and utilization at the population level. Proponents also believe that passing all rebates – and any other form of manufacturer fee or payment – back to plan sponsors would allow payers to compare PBM offerings more transparently and improve the negotiating power of payers. This alternative rebate model could also improve transparency for the individual payer so that they understand why certain decisions are being made by a PBM with regards to formulary design.

The law already requires that payers who participate in Medicare Part D pass back to the government all negotiated rebates, pharmacies' fees, and other forms of price concessions. The Medicare program defines these payments as direct and indirect remuneration (DIR). But policy analysts have noted that Medicare is not receiving all DIR that it is entitled to receive.<sup>3</sup> This is because both prescription drug plans (PDPs) and PBMs can classify certain items to exclude them from DIR. In addition, if PDPs and PBMs underestimate the amount of DIR in their initial bids, they can retain a proportion of the DIR they receive beyond the initial estimation due to how Part D risk corridors are designed.<sup>3-5</sup> PDPs and PBMs keep all DIR above initial estimates that is within 0–5 percent of the estimated plan cost and a proportion of the DIR above initial estimates that is above 5 percent of the estimated plan cost.<sup>3-5</sup>

These features encourage PDPs and PBMs to favor drugs with high DIR, which are typically drugs with high list prices. A complete pass-through of DIR to Medicare, including all fees that are “DIR in disguise”, could therefore have a potentially significant impact on Medicare Part D much in the way it would in the private market. By cutting the link between PDP and PBM profit and DIR, incentives would shift toward more efficient formulary management decisions.

Another potentially beneficial effect of moving to a universal pass-through model is that PBMs might then need to compete more directly on patient management and the value for money of the drugs utilized. Without an incentive to focus on rebates, PBMs might put more emphasis on distinguishing themselves in the marketplace by achieving superior patient outcomes, for example through methods such as provider education and helping ensure patients receive and take their medications.

Lastly, compared to a complete replacement of rebates by upfront discounts, the implementation of a pass-through model would involve relatively little disruption to the existing agreements between manufacturers and wholesalers, some of which are passed on to pharmacies and other dispensers. It would, however, still entail the challenges of a piecemeal transition over months to years from existing contracts between PBMs and plan sponsors that are not based on a 100% pass-through.

### Potential disadvantages

This alternative model would achieve little for patients if the increased rebates flowing back to plan sponsors are not reflected in lower co-pays (i.e. if this reform were not implemented alongside requirements around applying rebates to the POS as in Option 2). The potential impact on the gross-to-net gap and overall spending is also unclear because many plans now expect, and some may prefer, to have large and guaranteed rebates. Current PBM contracting typically includes minimum rebate guarantees; so even with 100% pass-through there is still potential for PBMs to seek drug options with higher list prices and corresponding rebates so they can compare favorably to other PBMs in the bidding process.

In addition, the primary potential advantage of a pass-through model may also represent one of its greatest potential disadvantages for both payers and patients. It might be possible that if PBMs are paid a fixed fee independent of negotiated rebates, they might have less incentive to put great effort into fighting for the lowest net price. However, as long as plan sponsors select PBMs based on clear metrics related to lowest costs and not guaranteed rebates, this should not be a concern.

Further, it is important to consider whether requiring PBMs to pass along all rebates to plan sponsors might limit PBMs efforts to benefit from the ability to aggregate purchasing power across plans when negotiating lower prices. The PCMA's response to the HHS Blueprint highlighted this issue in relation to Medicare Part D, in particular asking whether imposing a requirement that PBMs act solely in the interest of the Part D plan sponsor might prohibit the practice of PBMs aggregating rebates across multiple plans. Under current practice, PBMs achieve savings through the aggregation of scale purchasing power, negotiating with manufacturers across multiple Part D plans so as to achieve greater savings than a single plan could on its own. If PBMs are prohibited from aggregating rebates across multiple Part D plans, it might lead to a reduction in negotiating leverage, and therefore higher overall net costs for payers.

For health plans that contract for PBM services there are also implications of 100% pass-through on the calculation of the plans' Medical Loss Ratio (MLR). Money retained from rebates by PBMs is counted as a medical cost for the health plan, which may help them reach the legally required MLR. If PBMs shift all rebates to health plans and receive the same overall amount by being paid fees instead, this would count as an increase in administrative cost for the health plan and indirectly put pressure on their ability to meet the necessary MLR. This could require reductions in some plan premiums.

Finally, a 100% pass-through model would be viable for Medicaid but paying contracted PBMs fees for their work in lieu of retained rebates could raise problems in some states bound by cost-based regulatory guardrails that put restrictions on how a Medicaid program can pay an additional profit margin to a third party.

## **Discussion**

Given that 100% pass-through is already in place for many PBMs and plans, this represents the least radical option. However, there are two important caveats. First, the question remains how comprehensive current 100% pass-through agreements are today, and whether they reflect a shifting of manufacturer payment to PBMs from rebates to fees that retain the power to distort drug pricing and formulary selection. Mandating 100% pass-through of rebates would require careful definition of what constitutes a full rebate dollar, and delineation of all the fees associated with rebates. It may be that this option appears least radical but actually implementing it comprehensively and universally would still represent a major change.

Second, whilst it may seem a relatively simple solution to implement, to mandate 100% pass-through would only achieve its goals if it can be combined with a reform to the contracting process between plan sponsors and PBMs. Some contest that the issue is not ensuring 100% pass-through but creating better transparency in contracts outlining what exactly is being passed-through and what is being retained by PBMs. There are also many who question whether a 100% pass-through approach would really tackle the gross-to-net gap issue, as PBMs would still aim to achieve high rebates for their customers (the plans), if they still focused on the size of the rebate guarantee because they have limited awareness of how that affects formulary decisions made at the PBM level.

### **5.3. OPTION 2: Point of Sale (POS) rebates for patients**

The impact of rising list prices on patient cost sharing has been one of the prime motivating forces behind the search for alternative rebate models. Many patients with either Medicare or private insurance have their out of pocket payment for prescription drugs tied to the list price, not the net price after rebates. Some commentators have worried that providing POS rebates would require providing information for patients that inadvertently discloses the gross to net price gap, thereby eliminating confidentiality of the rebate level and undermining the negotiating power held by payers through their ability to get confidential rebates. Lastly, POS rebates by their very nature, give to individual patients some of the money that would otherwise flow back to the payer. The payer no longer has the option to apply those funds in ways that reduce overall health insurance premiums.

Despite these challenges, measures to retain some degree of confidentiality in net pricing are possible, and POS rebates are now offered by many PBMs and a few health plans as well, although most report limited uptake due to higher premiums for this offering:

- According to a CVS report in August 2018, of the total rebates returned to CVS Health by CVS Caremark, \$6.3 million were used at the POS to lower out-of-pocket costs, which improved adherence by between 4 and 6%.<sup>30</sup>
- In March 2018, UnitedHealthcare (UHC) announced that it would provide POS rebates to 7 million enrollees.<sup>55</sup>

UHC has rolled out a POS plan option for its fully insured business, but not for Medicaid, Medicare, or individual plans. In order to prevent simple back-calculation of rebate amounts from individual patient payment details, the rebate passed through to the patient at the POS does not reflect 100% of the true rebate. Varying the amount of the POS rebate is also necessary to maintain good alignment of patient out-of-pocket requirements with the lowest cost alternatives in the formulary. If POS rebates are not carefully calibrated, they could reduce the out-of-pocket cost of a branded drug to the extent that these are chosen by members in place of generics that cost less to the plan.

There are several approaches to designing a POS rebate so that confidentiality of net pricing is retained:

1. “Peanut butter spreading,” a design that spreads the passed through rebates at an equal dollar threshold based on class/category;
2. For Medicare, a threshold for the pass through to patients at the POS set according to therapeutic category or based on chronic vs. acute conditions;
3. Fixing POS rebate levels based on historical or recent year average co-pay levels.

In all of these approaches, the magnitude of POS rebate could be influenced by the benefit design, for example applied more generously in the deductible phase, and in benefit designs that utilize coinsurance as compared to fixed co-payments.

Although these POS rebate models lack perfect transparency around net prices for each individual drug, they meet the goal of helping patients reap some of the benefit from negotiated rebates. The trade-off between transparency and the perceived benefits of confidentiality to support payer negotiating leverage is viewed differently by different stakeholders. Early efforts in the private market have emphasized retaining confidentiality because of payers' view of the benefits for negotiating power, and also because it appears easier to administer a scheme that does not apply a specific rebate percentage to each drug.

An illustration of the possible impact of a POS rebate program for health plan members at the pharmacy is set out in Table 5.2 below, courtesy of UnitedHealthcare.

We can see that the impact on patients varies depending both on which plan design they have and on which phase of their deductible they are in. Payers have noted that this makes estimating the impact on plan finances of the introduction of POS discounts difficult.

**Table 5.2: Illustration of Possible Impact of a POS Discount on Member Payments**

Prescription Cost (List Price)	Drug Cost Discount (Rebates)	
\$400	\$250	
Plan Phase of the Patient	Member pay <i>without</i> POS Discount	Member pay <i>with</i> POS Discount
Deductible	\$400	\$250
20% Coinsurance	\$80 (\$400*20%)	\$50 (\$250*20%)
\$35 Copay	\$35	\$35

Adapted with permission from an illustration by UnitedHealthcare

### Potential advantages

Action taken to require POS rebates at the payer level could have several important advantages. First, patients who require extended use of expensive medications for chronic conditions could have their financial burden lessened. For example, patients in high-deductible health plans who pay the list price each month for insulin (until their deductible is reached) may be paying hundreds—or even thousands—of dollars more annually than their insurer is paying for the drugs. By reducing this financial toxicity, it is likely that adherence with prescriptions will improve, increasing patients' health and potentially sparing downstream health costs attributable to ineffectively treated conditions.<sup>56</sup> An IHS Markit report specifically models the potential impact of POS rebates on: spending by patients; medication adherence; and subsequent healthcare resource savings, through reduced hospitalizations and diabetes-related complications.<sup>57</sup> The authors find that passing through 80% of rebates for diabetes medicines to the patient at the POS could generate 10-year medical savings of \$20 billion.

Another potential advantage of a POS rebate for patients is that could be used to better align patient cost-sharing with the net price in a way that would facilitate the adoption of value-based formularies. POS rebates would reinforce the benefits to patients of a formulary in which the most cost-effective treatment options for the payer are provided with a corresponding financial benefit for the patient.

## Potential disadvantages

POS rebates by themselves are not a cure for the financial burdens faced by many patients who need high-cost medicines but only have access to health insurance benefit designs with high deductibles and/or co-insurance. For many patients with the highest annual out of pocket expenditures, a POS rebate would not save them enough money to likely keep them from spending up to their annual deductible each year. POS rebates on their own would also not neutralize any incentives for PBMs and others in the drug delivery chain to seek higher list prices and larger rebates. They would not lower the aggregate cost of prescription drugs overall, nor help reduce health insurance premiums, which some stakeholders view as the priority for any change to the current rebate system. As noted earlier in the discussion of the UHC introduction of POS plans, another potential risk is that unless POS rebates are carefully calibrated, they could reduce the out-of-pocket cost of a branded drug to the extent that these are chosen by members in place of generics that cost less to the plan.

In private insurance plans, applying rebates at POS will reduce out-of-pocket cost for specific individuals who are on high cost medications. For Medicaid, however, there would be little if any impact because copayments are kept low already. For Medicaid patients, as well as others who have reached their out-of-pocket maximums in their respective plans, the rebate savings will continue to flow to the payer.

Multiple potential disadvantages have been noted if POS rebates were implemented for patients in Medicare Part D. Some fear that POS rebates would unfairly benefit manufacturers, as reduced out-of-pocket costs would lead to fewer patients reaching the coverage gap phase (where manufacturers must provide a discount of 70%). It has been estimated that brand drug manufacturers would pay out nearly \$10 billion to \$29 billion *less* in price discounts in the Part D coverage gap over ten years because fewer patients reach the coverage gap.<sup>58</sup> In addition, this approach would have little benefit for Low Income Subsidy (LIS) or dual eligible patients in Medicare Part D, as their cost-sharing is fixed at a relatively low level.

Importantly, it is also possible that POS rebates would lead plans to increase premiums enough to have an important negative impact on the affordability of Medicare Part D plans for financially vulnerable patients. A Milliman report prepared for PhRMA concluded that POS rebates would be likely to have minimal impact on insurance premiums, but many other commentators have expressed the opposite opinion.<sup>59</sup> CSRxP noted that HHS actuaries have estimated that the policy could cost taxpayers between \$27 billion to \$82 billion over ten years, depending on the minimum rebate amount, as increasing premiums would require more federal subsidy for enrollees.<sup>60</sup> But notwithstanding increasing subsidies, they and others believe that there could be increases to Medicare Part D premiums that lead financially vulnerable elderly patients to forego signing up for Medicare Part D entirely. The Medicare Payment Advisory Commission (MedPAC) was one of several groups expressing this concern and, consequently, it “strongly encourage[d]” CMS to find a less complex policy to lower out-of-pocket spending for Part D enrollees.<sup>61</sup>

## **Discussion**

The debate around rebate reform has been driven by commentary on the affordability of drugs in the US system, particularly for patients. Mandated POS rebates would most directly target this issue, and therefore may be the most politically viable and attractive option. However, some argue that POS rebates would simply shift costs around for patients and enrollees, who may perceive reduced cost-sharing at the expense of higher premiums to be unattractive; for those patients with chronic conditions who would still meet their out-of-pocket limits, there would be little gain. Whilst the evidence is limited, there is some indication, which seems intuitively plausible, that POS rebates could improve adherence and consequently clinical outcomes.

As well as the impact on patients, plans need to understand the impact of POS rebates on premiums. Insurers are likely to favor strategic use of POS rebates at a plan level, to be adapted to meet employer or payer type; therefore, a law mandating 100% pass-through of rebates to the POS is unlikely to be well received. There are multiple ways in which POS rebates could be designed. Following the approach being used by UHC (and potentially others), a *proportion* of the rebate could be applied at the POS, and/or POS rebates might be only applied to certain specialty drugs for specific patient populations. These design elements are key. They also raise important questions about whether payers have the technology solutions needed to implement an effective POS system. Clearly, some major health plans and PBMs do have these capabilities, but it is unclear whether the entire health system has this capacity. To guide future private market offerings and federal policy making it would be helpful to gain a better understanding of how technology can facilitate various POS models. More information is also needed on how POS rebates impact patient spending and plan premiums, but this is likely to vary a great deal depending on benefit structure and specific patient characteristics.

### **5.4. OPTION 3: Eliminate rebates and move to upfront discounts**

Some commentators believe that moving to upfront discounts is a viable alternative that would accomplish the chief aims of many stakeholders. The Trump Administration has moved forward with this idea by issuing a draft rule that would eliminate the use of rebates and require that Medicare Part D, Medicaid Managed Care Organizations, and any PBMs contracting with these Federal payers, move to upfront discounts.<sup>2</sup> Fein has set out the most detailed description of how a discount model could work, including suggestions for product movements, financial flows and contract relationships.<sup>62</sup> He sets out how this would address the current incentive problem, but also explores some of the implementation challenges, including (a) that this level of transparency could reduce the discounts manufacturers are willing to offer and (b) that it could cause conflict with outcome/value-based agreements.

One important ramification of eliminating rebates entirely is that it would necessitate a change to the payment structures for wholesalers and pharmacies. Although uncertain in terms of technological investment required, a “chargeback” model may be a viable alternative to the existing flow of funds in the current rebate model. In a chargeback model the manufacturers and wholesalers could coordinate reimbursement to pharmacies based on the compiled reporting of prescription claim records. Chargeback transactions as they generally exist between manufacturers and wholesalers are viewed as an efficient payment model, since there is far less complexity than required in rebate adjudication and the transac-

tion cycle typically requires less than two weeks for completion from the date of service to closure. Support and administration of this type of chargeback model might provide an avenue for wholesalers to mitigate the loss of revenue in an environment in which drug list price increases are either moderating or declining outright. Independent pharmacies would likely be impacted the most in an upfront discount model, as they may not have the existing infrastructure or resources to quickly adapt.

### **Potential advantages**

The main argument for upfront discounts in place of rebates is that it removes the PBM incentive to generate revenue from the gross-to-net gap that many feel can lead to higher list prices and a less transparent flow of money between manufacturers, PBMs, and payers. Only upfront discounts provide the kind of structural transparency that may truly eliminate the linkage between list price and revenue for PBMs and other parts of the drug delivery chain. Further, manufacturers may more carefully consider pricing approaches that favor lower list prices without rebates, as opposed to investing in the back-of-office infrastructure required to forecast, adjudicate, process and report the substantial sums involved in the “rebate economy.” The cost of the current rebate system to manufacturers is substantial: they employ large numbers of people to navigate the rebate provisions and obligations associated with the multitude of paying customers in the US. Moving to upfront discounts might help consolidate the procurement process and lead to reduced costs, which, ideally, could be passed on to customers.

Upfront discounts could also be the alternative model that most facilitates the application of cost-effectiveness findings to the development of formularies. Since the effective price is known at the outset, cost-effectiveness can be determined and compared. Discounts could be allowed to vary depending on clear criteria such as cost-effectiveness or expected volume. Clinicians can more readily become involved in choosing the most cost-effective treatment for their patients. Rebate pass-through models would also help facilitate value-based formulary design but are more complicated because the final rebate level, and therefore net price, would not be known until some later time point (assuming it varies by utilization), and therefore the ultimate cost-effectiveness of any drug cannot be known at the time it is prescribed.

### **Potential disadvantages**

None of the alternative models to the current rebate system has received as much criticism from payer (and some manufacturer) interest groups as has a shift to upfront discounts. Crucially, many have argued that upfront discounts would not provide the same level of negotiating power as confidential rebates linked to formulary placement. If true this would lead to an increase in overall drug costs. The implicit transparency in upfront discounts is viewed by some as problematic, potentially leading manufacturers to set single discount levels for all payers at levels that maximize manufacturer profits but increase costs for payers. As mentioned previously, some, including the FTC, have argued that transparent discounts also increase the risk of tacit collusion on pricing among competing manufacturers. Knowing a competitor’s price makes it easier to avoid offering discounts that would benefit the payer, but are not necessary to win the business.

Another consequence of shifting to upfront discounts and eliminating retro-active rebates would be a risk of undermining progress toward meaningful outcomes-based contracts and indication-specific pricing arrangements, both of which require some kind of back-end reconciliation process. Moreover, it should not be forgotten that in the 22 year old legal settlement that led to the abandonment of discounts in favor of rebates, drug manufacturers agreed they would not offer upfront volume discounts, and instead agreed to offer similar pricing contracts to all purchasers that demonstrated they could move market share. The legal context has not changed, so it is not clear whether manufacturers could legally offer upfront any differentiation of discounts without violating antitrust law. Ultimately, to facilitate the provision of fixed-priced discounts between manufacturers and payers/PBMs, Congress may need to undertake legislative action to amend the Sherman and Robinson-Patman Acts.

From a practical perspective, a move to a fixed-price discount approach is viewed by all stakeholders as requiring a major, complicated restructuring of both Medicare Part D and commercial contracts. Wholesalers and pharmacies could end up dealing with dozens of different (discounted) prices for each drug (varying by plan) and it is not clear how such a system would move such differently priced drugs through the supply chain. Some stakeholders even believe that, if implemented too precipitously, the elimination of rebates and a shift to upfront discounts would fail, leading to increased net prices and higher premiums, and thereby speeding Congressional consideration of government price negotiation and price setting. Whether that represents an optimistic or a pessimistic scenario remains in the eye of the beholder.

## **Discussion**

As described, a major argument against eliminating rebates is that negotiations could no longer be based on realized utilization/market share, meaning negotiating power for payers could be reduced. But this raises a key question: in today's market, are rebates usually linked with utilization? Multiple payers and manufacturers at the ICER Policy Summit said that the use of utilization-based rebates has nearly vanished from the marketplace, and even use of market-share based rebates has declined, as PBMs and payers have shifted to guaranteed rebate levels that provide greater certainty that helps with overall budgeting. The PBMs and payers in turn seek guaranteed rebates from manufacturers. If this is the case across the health system then a critical argument against the elimination of rebates disappears, and a move to upfront discounts in turn becomes more feasible.

What is indisputable is that eliminating rebates and moving to upfront discounts would have the potential to move the entire drug purchasing, negotiating, coverage, and delivery towards greater transparency and a firmer foundation on true value. Transparency in the price negotiation and formulary development process would not solve the issue of whether there is adequate transparency in how manufacturers derive their pricing bids, but it would still represent a major advance. The need to shield the exact amount of price discounts so that competing manufacturers would not be able to see each other's' bids remains, however, a critical pre-condition for upfront discounts to be effective in driving down prices. And changing the system to eliminate rebates and implement upfront discounts would require the biggest change to the status quo; the implementation challenges are numerous, and therefore the legal and political barriers to this reform are likely to be high. Finally, it is very important to consider the impact of moving away from rebates for Medicaid programs, which currently achieve notably higher rebate levels and are proportionately dependent upon them to meet budgets.

We might expect options that eliminate rebates entirely to reduce the level of resources currently being spent on the complex “rebate economy”, where there are often multiple permutations of a rebate, with various complicated administration fees and price protections, leading to costly and labor-intensive calculations by all parties. In a system based on upfront discounts, plan sponsors and payers could shift their selection of PBMs away from looking predominately at rebate levels, and toward overall quality and value. However, both parties will still seek to calculate the impact of an upfront discount on their costs. It is still possible, however, that notwithstanding the initial implementation issues around a system of upfront discounts, once achieved it could offer a system that would be easiest and best for patients while also aligning the business models of the entire drug delivery chain in a beneficial manner.

### **5.5. A Summary of the Three Alternative Options Against Relevant Criteria**

Our summary table (Table 5.3) is provided on the following page.

**Table 5.3. Evaluating Alternative Rebate Models**

	<b>Option 1: 100% pass through of rebates to plan sponsors</b>	<b>Option 2: POS rebates for patients</b>	<b>Option 3: Eliminate rebates and move to upfront discounts</b>
Impact on <b>patients'</b> affordability, access to care, and clinical outcomes (via improved adherence)	With less incentive for higher rebates, list prices and gross-net gap may decline, benefiting individual patients financially if their cost-sharing is linked to list price (which could lead to better adherence and outcomes).	Individual patients will see lower costs at the pharmacy counter, which could improve adherence and therefore clinical outcomes. However, the broader enrolled population may eventually face higher premiums.	Patients will have lower cost-sharing based on a discounted list price. Premiums may rise, however, if bargaining power is reduced.
Impact on <b>overall cost of pharmaceuticals and medical spending</b>	If implemented comprehensively along with manufacturer fees, would increase money returned to plan sponsors and create more incentives to use low net-cost drugs. Some risk of reducing incentive for PBMs to seek lowest net price. Paying flat fees would impact the Medical Loss Ratio (MLR) calculation which could require reductions in some plan premiums. Would not address the high computational effort and cost associated with the rebate economy.	Transparency of rebates at POS might decrease payer negotiating leverage (but depending on design, confidentiality could be maintained). Increase in plan drug costs because money returned to patients which could lead to premium increases. Overall health costs unlikely to change unless improved adherence drives down non-drug costs. Would not address the high computational effort and cost associated with the rebate economy.	Price concessions may not be as large if transparent across all payers. However, overall drug mix in formulary design likely to change in ways that could reduce overall cost of spending.  Upfront discounts could avoid the costly operational burden of rebate calculation. However, both parties will want to estimate the impact of an upfront discount on their costs.
Impact on <b>competitive outlook</b> for innovative new medicines	No improvement. If plan sponsors receive all rebates, they would have more incentive to favor existing drugs with substantial rebates over new entrant drugs with a single indication. PBMs could offer formularies favoring cost-effective new entrants and allow payers to choose lower list prices or higher list prices with larger rebates.	No direct effect.	New entrants could have improved competitive chances against existing drugs since discounts would not be linked to market share.
Impact on efforts to design formularies based on <b>cost-effectiveness</b> of pharmaceuticals	If 100% pass-through aligns PBM and plan sponsor incentives it could facilitate adoption of value-based formularies based on cost-effectiveness. But post hoc rebates based on utilization make determination of cost-effectiveness within a formulary difficult to assign at product launch. Requires plan sponsors to shift from focus on rebates to value-for-money.	Aligning patient cost-sharing with net price can facilitate the effectiveness of value-based formularies.	Prices are known for formulary design, so provides the easiest platform to construct a value-based formulary based on cost-effectiveness.
Feasibility of <b>implementation</b>	Many PBMs are already offering pass-through options. Transition over time to mandatory model for all PBM-plan sponsor contracts not significantly disruptive.	Although some PBMs are already offering this option, implementation will involve changes in contractual arrangements and information flows.	Potential issues for reconciling the many differently negotiated discounted rates for thousands of drugs along the full supply chain. There is also legal uncertainty about the feasibility of this option.
Ability to <b>improve transparency</b> of costs to support public dialogue on value and affordability	Whilst transparency for payers could be improved if accompanied by clearer dialogue and understanding of rebates, public appreciation of value and affordability unlikely to be affected.	Allowing patients taking a drug to benefit directly from the rebates applied to it is likely to support public dialogue and understanding of value, but likely implementation routes are unlikely to achieve full transparency.	Transparency would be increased, which would support public dialogue on value and affordability. However, it would be possible to implement upfront confidential discounts which would maintain payer bargaining power but not increase transparency of net prices.

## 6. Discussion

### *Many uncertainties and trade-offs*

Through our presentation of the three key options, and their assessment against several major considerations, it is apparent that there is no one ideal solution, and that their favorability turns on how one interprets the evidence as well as what can be hypothesized about future scenarios. On top of this, choosing the best policy option will rest on which goals are given the most weight. It is inevitable that stakeholders will differ as to what they most wish to see accomplished.

For those most concerned about the financial burden on patients, none of the rebate alternatives directly addresses the impact of high deductible benefit designs or formularies that apply high co-insurance rates to expensive medications for chronic conditions. For those stakeholders whose primary concern is the impact of any new rebate system on the innovative landscape for the US health care system, the uncertainty inherent in any major change presents important challenges and potential unintended consequences. One such aspect is the impact of reform on the competitive outlook for innovative new medicines. In the current rebate system, manufacturers of new medicines with limited indications (and therefore market size) are constrained in the absolute level of rebates they can offer, and therefore can be disadvantaged in formulary placement. None of the proposed rebate alternatives would be able to solve this problem.

Lastly, for those focused on drug spending at the system level, rebate model restructuring is unlikely to solve the issue of increasing drug prices and costs. Many of the most expensive pharmaceuticals lack competition and thus do not come to market with any rebates. And some of the more promising efforts to use outcomes-based contracting to share risk and gain some measure of control over the effective drug price would be undercut by a move to upfront discounts. As noted above many times, there is no perfect solution that eliminates all the challenges created by rebates while leaving payers with a similar level of negotiating leverage to help moderate costs. It is even possible that all options could increase overall net costs. None of them addresses price inflation net of rebate that are unsupported by clinical data. Forcing an abrupt transition away from rebates would therefore raise significant questions about the impact on total costs of care and on patient access and outcomes. Even small increases in health care insurance premiums might have significant effects on individuals who already struggle to afford health insurance for drugs through their employer, health insurance exchange, or Medicare.

Other potential unintended consequences might occur due to a shift in the competitive landscape and its impact on investment choices by drug makers. For example, many health plans are willing, in principle, to negotiate a rebate in return for placement of a new drug as one-of-two first line therapies. This would reward innovation at the expense of me-too products but also reduce near-term opportunities to realize cost savings associated with having 3 or 4 similar molecules in the market. All three options to replace the current rebate model could disrupt this dynamic, potentially incentivizing manufacturers to shift investment to me-too products, while reducing incentives to be first to market with truly innovative products. Any effort at rebate reform should therefore realize the broad effects of any change and the potential for unintended consequences.

### ***Combining options: Transparency versus simplicity and negotiating leverage***

It is conceptually attractive to consider combining a POS rebate for patients with a model that also passes 100% of rebates through to plan sponsors. This combination would function in many ways like a system of upfront discounts, and, conceptually, would be able to match many of the same goals. There are three main points of differentiation. First, a combination of 100% pass-through and POS would not by itself re-orient the rest of the drug delivery system, i.e., wholesalers and pharmacies, away from rebate incentives that favor higher list prices. Transitioning to flat fees for wholesalers and pharmacies could only be accomplished as a separate step requiring manufacturers to take the initiative to re-contract with all elements of the delivery chain, and it is unclear if market forces would compel that effort.

The second distinguishing factor between upfront discounts and a combination of 100% pass-through and POS rebate system is one that favors the latter approach: it would still accommodate retrospective payments needed to support outcomes-based contracts, utilization-linked rebates, or the reconciliation needed for indication-specific pricing agreements. The ability to accommodate these initiatives would be viewed as a benefit by many stakeholders, and the inability of upfront discounts to readily support them is considered an important limitation.

However, the third distinguishing element between the two approaches heavily favors upfront discounts. Transparency around pricing and revenue flows is a central short-term goal held by many plan sponsors. Transparency also figures among the higher aspirations of all stakeholders who view it as a necessary driver of desired changes to the entire chain of drug pricing and delivery. Upfront discounts with transparency also are more likely to support a rapid transition to flat fees for wholesalers and pharmacies along the delivery chain. Although full price transparency is viewed with alarm by some stakeholders who fear it will undermine the negotiating power of payers and increase the potential for supplier tacit collusion, it does represent the best way of assuring plan sponsors that the entire system of formulary development is not being perversely determined by the influence of rebates and obscure fees. Indeed, it maybe that some would be willing to accept higher net prices as a price worth paying, at least in the short run, for greater transparency. We also note however, that upfront discounts could be confidential. There is a general assumption that the upfront discount model will have transparent net prices, but this may not be the case. If discounts were confidential, then bargaining power would be maintained but the benefits of transparency would be lost.

Taking stock of the options for alternative rebate models, each with its own potential advantages and disadvantages, most stakeholders in the health care system realize that some form of change to the current paradigm of rebates is both needed and inevitable. The market has already shifted toward providing more plan sponsors with 100% rebate pass-through agreements. The Trump administration proposal ensuring a POS element that fully returns rebates to patients mirrors early efforts in the private market at establishing a POS rebate model, although it is too early to evaluate the outcomes. And while there are still many unknowns regarding the ultimate financial consequences, an aspirational target of moving fully toward a system in which upfront discounts are part of a broader transformation in drug negotiation and delivery is shared by a surprising number of stakeholders. But the way forward is fraught with risk and uncertainty, with deep trade-offs between short-term feasibility and long-term goals evident at every step.

## **6.1. What else do we need to know?**

There are various research questions that arise from our discussion of the various options. As well as understanding what the potential implications would be of a change to the rebate system, there are also several questions about today's arrangements which – if better understood – could help to offer clarity on the attractiveness of the alternatives. One such key question is:

- To what extent are rebates in the current system linked with utilization?

If they are not, then this eliminates one of the arguments against upfront discounts, which would not allow for discount to be linked with (realized) utilization. Other key questions arising are:

Reforming rebates:

- Would enforcing 100% pass-through of rebates to payers have a meaningful impact, given the trend toward this in today's market already?
- Would POS rebates involve a discount to patients that is significant enough to impact adherence?
- Data and evidence are required on the financial implications of POS rebates for plans; this may need to be mapped out on an individual patient basis, complicating planning efforts.

Replacing rebates:

- What would the Sherman Anti-trust Act mean today for a move away from rebates?
- Are there technical solutions that would allow upfront discounts to be known to the payer but not in the public domain, i.e. can we achieve price transparency for the payer without risking plan and PBM bargaining power?

In addition, for each option there needs to be careful consideration of the differential impact of reform for different payer types. For example, for POS rebates, would the impact on premiums be large enough to impact Medicare Part D coverage? If we eliminated rebates, what would be impact be for those that are most dependent on rebates in the current system (e.g., Medicaid)? How much of the Medicaid rebate is wrapped up in best price versus the inflation protection?

## 6.2. Conclusion

In this paper we have sought to bring clarity to the reason for the development of the current rebate system, and why it has become so deeply entwined throughout the drug pricing, coverage, and delivery systems. As noted in the introduction, there are few who do not identify serious shortcomings of the current system. Among these shortcomings, however, one stands out: that patients who require expensive medications are facing rapidly increasing financial burdens as list prices climb at high rates, even if increases in net prices after rebates are more modest. Rebates on a percent of list price skew the incentives of every single part of the drug delivery chain away from what is best for individual patients and for plan sponsors seeking the most cost-effective approach to providing good health coverage. And innovative life science companies can find that new drugs with superior effectiveness and lower prices still cannot get competitive traction when facing the scale of rebates that the makers of large market-share drugs have at their disposal.

And yet, rebates in their current form have played one essential role: they have given payers some element of negotiating leverage with manufacturers, especially in drug classes with multiple drugs of similar effectiveness. Forcing an abrupt transition away from rebates would raise significant questions about the impact on total costs of care and on patient access and outcomes. Even small effects that would increase health care insurance premiums might have significant effects on individuals who already struggle to afford health insurance for drugs through their employer, health insurance exchange, or Medicare. Any effort at reform should therefore realize the broad effects of any switch to an alternative rebate model. The potential for unintended consequences should be fully realized by policymakers.

Nearly all stakeholders in the health care system realize that some form of change in the traditional paradigm of rebates is needed, and plan sponsors have already achieved some progress toward 100% rebate pass-through agreements, although debates continue to rage over whether various fees remain to undermine this effort toward transparency. Early efforts at establishing a POS rebate model to help patients reap the benefits of negotiated prices are also now in play, although it is too early to evaluate the outcomes. Nonetheless, an aspirational target of moving fully toward a system in which upfront discounts could be part of a broader transformation in drug negotiation and delivery is shared by a surprising number of stakeholders. A future health care system whose incentives are fully aligned toward rewarding value while improving access and outcomes for patients will require more radical change than simply giving patients part of the rebate at the POS. We hope this White Paper will chasten policymakers who might have seen eliminating rebates or any of the other options as an easy, clean procedure. We equally hope that it will hearten and inform those who wish to take a thoughtful, careful approach to near-term reform while laying the groundwork for a greater transformation to come.

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