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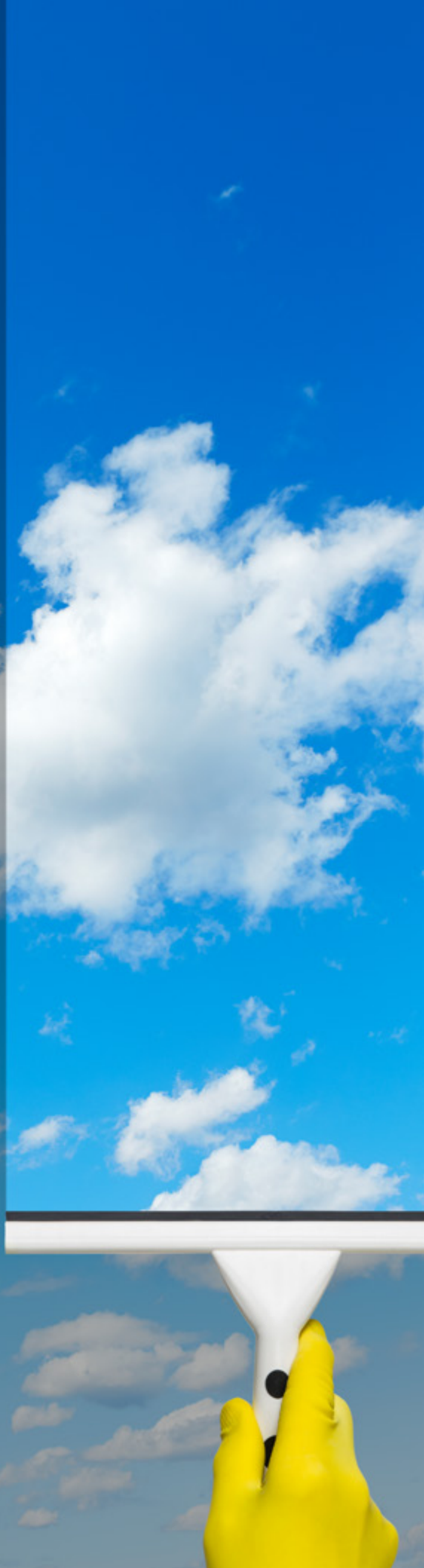
Embracing transparency

How pharma companies can turn pricing reform to their advantage



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Just the beginning

With a lot of discussion around drug pricing in the past few years, Health and Human Services' (HHS) proposal to change *safe harbor* practices around rebates to PBMs may be a harbinger of things to come and is certainly a significant step toward pricing transparency.

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Reactions to the regulation reflect the varying perspectives of stakeholders across the US healthcare ecosystem:

— From the Trump administration's perspective, the aim of policy changes such as this seems to be to break the cycle of offsetting PBMs' growing demands for rebates with significant annual list price increases.[i]

— PBMs may argue that the rebates they receive are mostly passed back to the health insurers and employers they serve, thus reducing premiums for consumers.[ii]

— For patients, when manufacturers increase list prices by, say, 10-20 percent, out-of-pocket payments go up, particularly for those with high deductible plans and co-insurance, or those with no drug coverage at all. Further, the current system puts the highest utilizers of expensive drugs in the position of paying the most out of pocket. This drives them into the *catastrophic phase* of Medicare drug benefits more quickly, thus increasing costs to both the consumer and to the government.

Drug makers contend that they are forced to raise prices in response to rebate demands because PBMs exert tremendous negotiating power in the market. And failure to offer substantial third-party rebates could drive a drug to less preferred or even "uncovered" formulary status (on or off PDL in MMCOs), causing market share and profits to plummet.

In this briefing, we seek to guide pharmaceutical manufacturers through what further pricing reforms could mean for them, as well as the business model shifts they should consider as they seek to stay afloat in an unpredictable regulatory environment.

On the Chopping Block: "Pay to Play" Rebates to PBMs

Proposed HHS rule to amend *safe harbor* regulations under the Federal Anti-Kickback Statute (AKS) as they relate to rebates from manufacturers to PBMs[1]

Critical changes:

1. Exclude from safe-harbor protection PBM rebate payments made to secure formulary placement

What it means: *Rebate payments that don't benefit consumers will be subject to criminal penalties.*

2. Create a new *safe harbor* to protect certain price reductions offered to Part D and Medicaid managed care sponsors (or PBMs working on their behalf)

What it means: *Fixed discount amounts must be established in advance, reflected in drug prices offered to patients at the point of sale, and paid directly or indirectly to the pharmacy.*

Public comment deadline: April 8

In effect: January 1, 2020

1 B. Daniels, K. Faget, J.A. Waltz, H. Sorensen (2019). HHS Proposes New Rules To Eliminate Drug Rebates and Encourage Direct Discounts for Federal Beneficiaries, *Healthcare Law Today*.

Beyond *Safe harbor*

The revised *safe harbor* regulations will likely be the first of many new measures aimed at drug pricing. In addition to putting forward legislative proposals to extend rebate reforms to the commercially insured market, it seems that policymakers intend for these changes to spark a knock-on effect. In other words, the shift in thinking may drive drug manufacturers and PBMs to offer more up-front consumer discounts and reverse the trend toward annual price increases, particularly for costly specialty drugs.

With myriad other regulatory and legislative proposals related to drug pricing under consideration, manufacturers should develop strategies to deal with the possibility of three potential trends:

Prepare for greater pricing transparency

The lack of net pricing transparency could be viewed as one of the major contributors to high drug costs in the US market. Therefore, it is possible that regulators and legislators will introduce new measures compelling drug makers to report the discounts and other pricing deals offered to different types of stakeholders. This would extend beyond the current requirements for manufacturers to report the aggregated rebate and discount results on most drugs for establishing Medicaid rebates[iii] and for hospitals to post prices for both healthcare services and drugs prescribed during in-patient treatment.[iv]

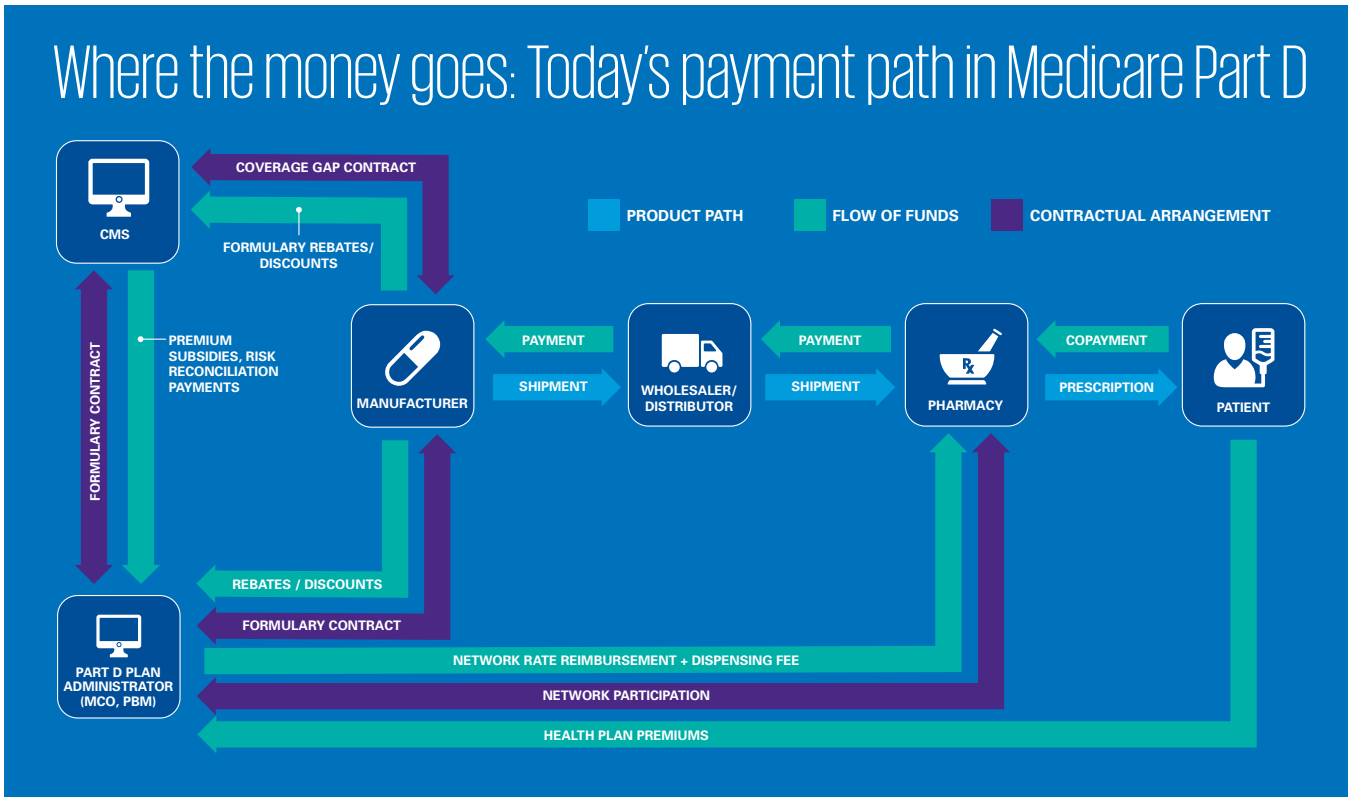
CMS has already proposed that, in 2020, Part D plans will have to start providing pricing transparency in patients' monthly explanations of benefits (EOBs) and offer physicians real-time benefit checks (RTBC) so they can view costs at the point of prescribing.[v] Further, proposed rules requiring drug prices to be disclosed in direct-to-consumer television advertisements and, to an even greater extent, in electronic medical records (EMRs) could become reality. Beyond these measures, it is conceivable that Americans may someday have access to user-friendly, digital applications that report net prices of drugs with as much precision and granularity as we currently see with consumer packaged goods and personal electronics. The thesis here is that better information could help correct misaligned incentives and encourage a more even-keeled approach to pricing.

Adjust for caps on price growth

Recent proposed legislation suggests that the Federal government could institute policies that cap the amount any drug manufacturer can raise list prices in a given year.[vi] In pharmaceutical markets across Europe and Japan, this is a fact of life. These types of policy changes could come in the form of annual price increase limits or overall caps on per-year drug costs within a given class or indication.[vii] Drug makers may still have discretion when it comes to setting initial prices, but would likely have fewer incentives to compensate for rebates with higher prices. This mindset can already be seen in the proposed Medicare Part D rule, which could allow health plans to use price as one of the decision factors in determining coverage for drugs in protected classes.[viii] Finally, there is also some discussion around a proposed rule to align US drug prices more closely with other countries using international reference pricing in Medicare Part B.[ix] Could the days of truly free pricing, post-launch, be numbered?

Expect more effective negotiating power

Although a true single payer system in the US is politically unlikely in the current Congress, it is conceivable that policymakers could extend CMS's ability to negotiate directly with manufacturers on price at launch and throughout a product's lifecycle.[x] While Medicare-covered lives would represent only one, albeit large, segment of this market, direct government pricing negotiations in Medicare would likely spill over to the commercial market, especially if the climate continues to shift toward greater pricing transparency.



Implications for drug makers' business models

While the scope of government intervention into drug pricing has yet to be fully realized, the shift toward transparency will likely continue to build momentum. On the one hand, drug manufacturers would be well advised to take a hard look at some of their pricing practices and interrelationships with other industry players. And yet, there are also some proactive strategies that manufacturers can take to turn pricing reform into competitive advantage. Based on our extensive experience in the pharmaceutical marketplace, following are three approaches manufacturers could take, as well as some longer-term considerations for discussion:

Double down on innovation

Drug developers have long-touted *first in class, best in class* as the recipe for gaining market share at premium prices following launch. However, since no pipeline can consistently yield the first or the best in a class, this strategy has been challenging for most drug makers to sustain, particularly in competitive classes and rare disease spaces: Manufacturers have faced a race to the bottom on pricing and the laws of commodity markets, even in diseases once considered to have exceedingly high unmet medical need. And, since expensive, single-course therapies (e.g., CAR-T, HCV) struggle for reimbursement pathways in Medicare and Medicaid, the question remains whether government is ready to pay for where pharma is going, or if price controls in some form are inevitable.

On the other hand, as the need for specialty drugs continues to grow, some pharma companies can increase their odds of selecting a winner by investing heavily in developing the most robust clinical datasets possible. Leaders taking this approach will need to up their game when it comes to flexible and efficient R&D portfolio management that rewards the most promising drug candidates with clinical investment dollars. At the same time, they should develop backup compounds that could later emerge as shining stars if early drug candidates fizzle. Other players may exit R&D all together, striving to be the highest bidders for innovations with superior clinical outcomes that are likely to convince even the most stringent payers to offer significant price premiums at launch.

A step further: Consumer strategies

Most manufacturers will be comfortable with innovating when it comes to new types of drugs or delivery mechanisms. However, disruption—from both potential new regulations and new entrants to the industry—may force them to consider innovating on how they interact with consumers as well. Therefore, for a longer-term strategy, manufacturers should consider the following questions:

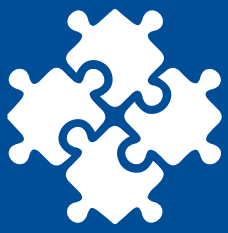
- Are consumers open to receiving drugs and medical management support services directly from manufacturers if it means lower overall out-of-pocket costs?
- How should PBMs' role in the pricing equation evolve?
- Should we consider loyalty or points programs as a means of consumer discounting?
- Should we tier customers according to severity of illness? Adherence to recommended protocols? How would this affect outcome measurement?

Strive for value

Most large pharmaceutical companies have already explored outcomes-based contracting that ties net price to a product's performance in real-world clinical practice. Many of the outcomes-based deals between pharma on the one side and payers and PBMs on the other require manufacturers to pay larger rebates when drugs underperform. However, this practice may be challenged if the new *safe harbor* proposals take effect in 2020 as written. Without the ability to differentiate based on rebates, some pharma companies may be reluctant to offer steep discounts for under-performance in order to secure favorable formulary positioning or exclusive preferred status within a class.

Instead, manufacturers should explore newer forms of outcomes-based contracting, which will require them to garner longitudinal real-world evidence showing that products improve patients' quality of life and/or lessen the burden of illness. While, in the past, payers may have preferred rebates to the complexity of managed drug costs, they too may be open to a critical mass of outcomes-based deals that policymakers could plausibly put back under *safe harbor* status.

A jump further: Integrated services



Patients have a broad array of needs *beyond the pill*, including determining related medical interventions, receiving care in the right setting, and understanding self-care protocols. Over time, convergence will be needed between the value derived through clinical care and the value derived through drug treatment. Getting to an integrated service approach will require manufacturers to explore the following questions:

- What role can pharma play in helping health systems address inefficiencies and fragmentation?
- What type of data would be required to conduct complex pricing analyses comprising diagnoses, hospitalizations, out-patient care and drug protocols?
- What technology tools would be required to track issues like patient adherence and outcomes once patients are out of the care setting?

Counter with scale

If US government payers start to negotiate prices directly for individual drugs – or even hold competitive tendering processes within certain drug classes – some pharma players should consider scaling up in certain areas to ensure access to more of the best innovation.

However, given that today's innovation is often tomorrow's old news, these players must also be nimble enough to know when and how to exit businesses before pricing pressures take hold. These types of biopharma leaders will be naturally acquisitive, looking for consolidation plays across disease areas and mechanisms of action that they can truly own until the assets run their course.

A leap further: Vertical deals

Although vertical integration has certainly taken hold in healthcare – with the CVS/Aetna deal being a particularly prominent example, this path to value realization has yet to extend to the pharmaceutical industry. However, given the complexity of pricing, collecting real-world evidence and measuring value, vertical integration between manufacturers and either payers or PBMs might be a more viable model in the future. As manufacturers consider this longer-term strategy, following are some questions they should ask themselves:

- Would integrating with a payer give me greater access to the advanced data and analytics capabilities needed to analyze longitudinal patient outcomes?
- If we integrated with a payer, would we be able to move closer to combination pricing, i.e., bundled costs for multi-drug and other therapeutic intervention protocols with outcomes measured and value ascribed to each of the components?
- How would integrating with a PBM or payer impact formulary placement?

In conclusion

Our hope is that this paper will help drug manufacturers get out ahead of pricing reform and use the changes they make as sources of differentiation and leadership in the market. While there will likely be challenges with compliance – and with the renegotiation of roles across the ecosystem – the reality is that thoughtful attention to the issue of pricing could open up opportunities for meaningful transformation. From increasing focus on innovation, value-based contracting and scale – to having a longer term vision encompassing direct-to-consumer strategies, integrated services and vertical deals – forward-reaching manufacturers have significant opportunities to achieve competitive advantage.

How KPMG can help

KPMG helps pharmaceutical companies weigh market access strategies in terms of feasibility and priority, integrate payer perspectives into R&D and commercial processes, anticipate and react to developments by commercial and government payers, and ensure that their products are well-positioned and supported by robust evidence of meaningful outcomes for cost. We work with companies on transforming the way they approach market access, new product development and portfolio management through our Nine Levers of Value methodology connecting business model design (strategy) and business model implementation (execution). With senior practitioners dedicated to R&D and commercial strategy in the life sciences sector, regulatory affairs, risk consulting, and M&A advisory, our one firm approach to client engagements results in an enterprise-wide view from strategy through results.

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vi S. Pearson, L. Nichols, A. Chandra (2018). Policy Strategies for Aligning Price and Value for Brand-Name Pharmaceuticals, Health Affairs.

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viii V. Colliver (2019). Medicare Part D Rule Aims to Lower Drug Costs, Politico.

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x H.R. 275: Medicare Prescription Drug Price Negotiation Act of 2019, govtrack.us.

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