EXECUTIVE INSIGHTS

Value-Based Contracting and Pharmacy Benefit: Challenges and Sources of Incremental Improvement

Across the healthcare industry, providers and payers alike are shifting their business models away from fee for service (FFS) and instead adopting value-based contracting (VBC) or risk-sharing models. This transition to VBC is visible across the care delivery continuum, with providers being reimbursed based on improvements in care quality and reductions in the total cost of care (TCOC) rather than on volume of services delivered. Medicare Advantage (MA) and risk-bearing primary care providers (e.g., Chen Med, Oak Street, Iora, Cano) are examples of particularly successful VBC arrangements, having found ways to manage patient populations in a capitated reimbursement environment without compromising on patient satisfaction or outcomes.

Meanwhile, by continuing to focus on volume-based revenue models and showing sluggish uptake of risk-sharing or outcomes-based reimbursement models, pharmacies are increasingly becoming the odd one out. Although this lag does have cost and outcomes implications, the barriers to adoption of VBC in the pharmacy category are not insurmountable. An increase in the use of value-based contracting models would potentially reduce overall cost of care and thus reaffirm a patient-centric approach to administration of the drug benefit.

By investigating the challenges facing the industry today and discussing potential sources of incremental improvement, this L.E.K. Consulting *Executive Insights* highlights how administration of the pharmacy benefit can evolve — and why it must do so now.

The industry is shifting to VBC and risk-sharing reimbursement models

Forty-six U.S. states and two territories now employ one or more value-based reimbursement models for the medical benefit in their local markets, up from just six in 2013. Among participating states and territories, over half have implemented value-based contracting programs with more than one payer.[1] At the federal level too, the Centers for Medicare & Medicaid Services (CMS) has been actively pushing VBC. In 2020, ~41% of total U.S. healthcare payments flowed through VBC and alternative payment models (APMs), with ~58% of MA and ~43% of traditional Medicare utilizing VBC.[2] CMS also promotes the Comprehensive Primary Care Plus (CPC+) model, which strengthens value-based care by incentivizing care delivery transformation and instituting multi-payer reimbursement reform; ~2,600 primary care practices across eighteen states have enrolled in the program.[3]

At both the state and federal levels, multiple programs have also been implemented to apply VBC principles to specific patient populations such as orthopedics (Comprehensive Care for Joint Replacement) and home care (Independence at Home Demonstration).[4] In addition, VBC programs with incentives targeting professional services costs rather than pharmaceutical spending have been initiated in disease states such as oncology (Oncology Care Model) and end-stage renal disease (Comprehensive Kidney Care Model), where a significant portion of total cost is represented by pharmacotherapy. Taken together, these efforts are making providers more familiar with, and receptive to, a variety of VBC models across the care continuum.

Key barrier: Lack of APMs is causing negative patient outcomes and high system costs

In 2020, U.S. spend on prescription drugs reached ~$540B, up from ~$427B in 2015 — an increase of ~5% annually (significantly higher than the ~1.5% average annual year-over-year inflation over the same period).[5] Excessive focus on volume negatively impacts not only patient outcomes but also system-level spending. Over 15% of U.S. adults are on six or more concurrent prescription medications, a figure that increases to ~42% for adults over age 65. Extreme polypharmacy is associated with a range of adverse events (AE); in 2018, an estimated 10 million Americans ages 65 and older experienced a drug-related AE, leading to more than 250,000 hospitalizations.[6]

In addition to missing opportunities for improved patient outcomes and lower system costs, stakeholders in the pharmacy ecosystem face direct risks from delayed adoption of a VBC model. As the rest of the healthcare industry moves toward more efficient and cost-effective APMs, pharmacy benefit holdouts for FFS are unlikely to receive positive attention from the public. In addition, should the industry experience significant regulatory change, navigating

new territory is likely to be more onerous than if the pharmaceutical space had gotten on the bandwagon of its own accord. Initiating incremental change now could lead to less industry disruption and a more hospitable regulatory environment in the future.

Additional barriers: Pharmacy is being 'left at the station'

While U.S. healthcare makes overall progress in moving toward alternative payment models, the pharmacy benefit has lagged behind and now risks missing the VBC train. Few value-based contracting arrangements are currently in place between either payers and manufacturers or payers and providers. Indeed, the barriers to VBC adoption are numerous and represent a complex web of interdependency, not only between the core stakeholders of the pharmacy benefit, but in the wider healthcare system. These barriers can broadly be grouped into the following categories.

Administrative burden

The first barrier to designing and implementing VBC arrangements is also the most intuitive: They require more work to execute. Designing a VBC contract often entails new institutional learning on the front end. Furthermore, day-to-day VBC management is resource intensive due to a need for more frequent communication and coordination; instead of simply tracking scripts written and reimbursement dispensed, value-based contracting necessitates collecting and processing multiple metrics to update reimbursement levels in near-real time. Under the current system, that effort is often not transferable to subsequent VBC initiatives, as each project can rely on custom data collection/analysis systems that are specific to the drug in question.

> **"Most of the work I've seen is being done at the drug level. In any individual value-based contract, there is some similarity with another, but really each of them is unique, and we have never seen a scalable out-of-the-box product. For that reason, there is no economy of scale. You have a ton of work to get every one of these off the ground, and that work really does continue over time relative to a traditional contract."**
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> — Director of pharmaceutical trade relations, large PBM

Connectivity and data sharing

To appropriately stratify the risk of the patient panel in question, payers require as much information as possible, including claims data (both medical and pharmacy), encounter data and patient demographics. Capturing all this data efficiently (and thus preventing the rise of an additional barrier) requires the development of secure, effective linkages across IT systems. Yet several friction points — including pharmacists' poor data-collection and -sharing capabilities,

integration of social determinants of health (SDoH) data into claims data, and compatibility of sharing stakeholders' back-end systems — tend to limit progress in that direction. The inability to integrate multiple data streams (and to share them among payers, manufacturers and potentially providers) means that parties involved in a VBC arrangement rarely have access to the same data, which limits their ability to negotiate and operate in good faith.

> **"The real trick to ramping up VBC is getting data to feed back and forth between the parties. Pharmacy claims have a standardized format, but you need the medical data to interface with that, plus any other data that might be useful — and right now there is no software system that can cut across it all. It would [take] a huge investment to make all that integration happen in the current environment."**
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> — Director of pharmaceutical trade relations, large PBM

Difficulty in defining and tracking endpoints

To establish VBC arrangements, providers and drug manufacturers must reach agreement with payers on both the reasonable metrics for each party's impact and the types of change in said metrics that should determine reimbursement levels. Clinical outcomes are an unreliable option because many factors, including differences in provider care delivery, contribute to a patient's response to pharmacotherapy. Claims-based outcomes (e.g., ER/ED utilization, medication adherence) introduce even more intervening variables between the performance of a medication and the observed metric. Finally, although a TCOC measurement scheme may be the easiest for a payer to track, it is also the least specific to the impact of pharmacotherapy. The metrics conversation is further complicated by the relatively short, often unpredictable tenure of patients on a given health insurance plan.

> **"We looked into trying VBC with a clinical outcomes component for higher-priced diabetes medications and found that only 10% or so of diabetes patients get their A1C levels tested when they should. So you have nice and neat outcomes expectations from the clinical trials that you cannot benchmark against in the real world because the data isn't being generated."**
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> — Director of pharmaceutical relations, large PBM

> **"We had an instance where we looked at a VBC arrangement for [rheumatoid arthritis] that would be based on the testing that was done in the drug's clinical trials, but every provider we went to was doing something different — which goes to show that even if you have a metric from the Phase III, the variability in how those measures are used in practice is substantial."**
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> — Senior medical director, large PBM

Attribution of risk and outcomes among diverse stakeholders

In addition to the challenges around designing contracts, defining metrics and communicating data, further complexity is introduced as VBC agreements seek to distribute risk and attribute positive outcomes among stakeholders in the pharmacy landscape. For a patient receiving multidisciplinary care in addition to pharmacotherapy, attributing improvement to a single party for a certain lab metric, improved adherence or reduced ER utilization, or lower TCOC is extremely challenging. For example, the results of effective pharmacotherapy, paid for under the pharmacy benefit, are often realized in the form of reduced care utilization, which shows up as savings in the medical benefit. If the pharmacy and medical benefits are owned by separate entities, however — or even by the same entity with poor internal communication — the party holding the pharmacy costs may find it difficult to bear an appropriate combination of risk for negative outcomes and attribution for improvements.

> **"VBC is hard in such a fractured environment. You have a payer, a PBM and a provider who could all be independent of each other, so who gets the credit for reduced costs from better pharmacotherapy?"**
>
> — Director of pharmaceutical trade relations, large PBM

Lack of incentives to change

Finally, a lack of incentives hinders stakeholders in the pharmacy ecosystem from making meaningful investments in VBC, which also represents a barrier to adoption. From the perspective of pharmacy benefit managers (PBMs), no regulatory pressures or generally accepted view of competitive advantage could increase the funds moving through VBC enough to eclipse guaranteed rebate-based contracts. Drug manufacturers are concerned about the "best price" implications of VBC contracting on their wider book of business, especially with CMS so slow to update best-price regulations. Meanwhile, as the likely candidate to bear the administrative and data burden for VBC models, payers see little competitive advantage to be gained as first movers in an expensive, largely untried business

model. Lastly, across the pharmacy benefit ecosystem, stakeholder incentives still heavily favor volume over outcomes. "Improvement" in whole-patient management is typically considered to mean a reduction in polypharmacy and the replacement of pharmacotherapy with non-drug interventions.

> **"A health plan owns a covered life and the direct costs associated with that patient, while the PBMs own just the pharmaceutical spend. If better pharmacotherapy results in reduced costs, that's really only appealing to the health plan. There's no carrot there for the PBM, or the drug manufacturer for that matter, to get them on board with a VBC model if it means patients are reducing their drug volume."**
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> — Former VBC lead, large pharmaceutical manufacturer

Proposed solutions: How to 'build a better mousetrap'

The good news is, these challenges may not be insurmountable, as none of them represent an immutable aspect of U.S. healthcare regulation or a foundational disagreement with good medical practice. The following is intended as a non-exhaustive, thought-provoking list of strategic options for promoting VBC in pharmacy at scale — incremental changes or industry forces that could help increase the adoption of value-based contracting across the pharmaceutical ecosystem.

Start with large, integrated payers

Introduction of an integrated payer/provider or PBM/payer, with access to several key data feeds within an existing IT system, could be key to driving initial VBC uptake. More important, this solution offers a feasible strategy for medical savings to offset the pharmaceutical costs in the same organization, thus preventing many of the outcomes attribution and TCOC challenges that occur when different stakeholder entities cover different capabilities.

> **"An integrated entity like UHC and Optum has a potential advantage in implementing VBC because they see both sides of the coin and can thus make a holistic financial decision. They might give up rebate value on drug spend by going to VBC, but what the PBM gives up, the health plan could make up in medical savings."**
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> — Director of pharmaceutical trade relations, large PBM

> **"A fully integrated entity like Kaiser, where the payer, PBM and providers are all together, could solve a lot of the issues around data connectivity and having consistent access to the population."**
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> — Senior medical director, large PBM

Embrace baby steps

Absent significant regulatory change at the federal level, success in incorporating VBC into the pharmacy ecosystem will require a long view. That long-term perspective could lower the threshold for what constitutes meaningful action today, help motivate risk-averse stakeholders to gradually phase in VBC, and allow stakeholders to develop institutional knowledge and VBC best practices while the financial risk remains low. Eventually, a virtuous cycle of small improvements by one market leader, which then cascade out to its competitors, could also trigger greater involvement by policymakers in promoting VBC models.

> **"As much as I thought a top-down government approach was the way to go, the lobbying from all sides is so strong that it's impossible to get anything through these days. I now think change will be slow and gradual, with a few players helping to lead the way."**
>
> — Former VBC lead, large pharmaceutical manufacturer

Target pre-launch programs

Initiating VBC arrangements from drug launch could provide several practical advantages to all stakeholders, but to drug manufacturers in particular. By building VBC into the go-to-market strategy, a manufacturer's product leaders can ensure that VBC assumptions are already baked into financial projections and contracting expectations. This would prevent brand leaders' uncertainty around revenue targets for an existing market product with internally agreed-upon financial projections. Pre-launch initiation of VBC also maximizes the time that the drug manufacturer has to negotiate with payers and to develop the right internal systems and expertise so it can support the drug from day one. Practicing VBC processes while the drug's volume is still low can prevent hiccups at peak revenue moments and thus further mitigate risk to the manufacturer.

> **"No brand leader wants to take the chance of reducing product revenue or having to discount their forecast, which is a risk that VBC introduces if you try and negotiate a VBC once the product is on-market. We only**

> ever looked at VBC for pre-launch so that both payers and manufacturers could plan around it."
>
> — Former VBC lead, large pharmaceutical manufacturer

Target the right drug candidates

Certain types of drug candidates are better aligned with VBC than others, based on both the underlying disease state and the attributes of the product itself. Therapeutics for disease states with large patient populations (e.g., COPD, diabetes, arthritis) or high per-patient costs (e.g., MS, sickle cell) account for enough payer spending to generate internal support for value-based contracting projects. Another indicator of a potential VBC candidate is drug therapy in a disease state with clear nonclinical markers of therapeutic response, such as conditions where poor patient response requires a script for rescue medication, acute disease exacerbations that require hospitalization, or conditions that cause missed work when poorly managed. Chronic disease therapies are also more amenable to VBC because patients are more likely to be on therapy for long periods of time, which increases the ability of payers and manufacturers to generate patient-level, longitudinal data sets.

> "We looked at a VBC arrangement for hereditary angioedema, which has a chronic use drug and an acute use drug; the theory was that if the chronic use drug was working, then you would use less of the acute use drug. So we tracked claims for the acute use drug as a metric on the success of the chronic use drug. That allowed us to avoid direct clinical metrics."
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> — Director of pharmaceutical trade relations, large PBM

Find ways to standardize

For VBC to scale up in today's healthcare landscape, creating shared standards for metrics, data collection and data dissemination is critical. Rather than build a custom model for every drug launch, payers and drug manufacturers need a way to recognize some economies of scale on the internal investments made to build out VBC governance overall. Although the sheer number of stakeholders may seem daunting, trade associations can begin the dialogue between pharmaceutical manufacturers and payers around standardizing, so that VBC models and systems are seen as an efficient path forward. America's Health Insurance Plans (AHIP) and Pharmaceutical Research and Manufacturers of America (PhRMA) could solicit input from a diverse group of stakeholders and engage in negotiations in a more practical, centralized fashion.

> **"Approaching the standards issue on a company-by-company basis is just not reasonable, but there are governing bodies for both pharmaceutical manufacturers and payers. If you could start from PhRMA and AHIP, that could be the way to push a set of standards out to the hundreds of companies in the space, and that standardization is critical to making VBC scalable."**
>
> — Former VBC leader, large pharmaceutical manufacturer

Be willing to experiment

Nobody has found the winning model or built the better mousetrap just yet, so the development of scalable and durable VBC models for various players in the healthcare market is anybody's game. Some options mentioned by market participants include:

- Using outcomes-based models where a patient's response to therapy dictates reimbursement over time (e.g., two patients could see a significant difference in reimbursement for the same drug based on their response to treatment, which would better reflect the treatment's value to the system)
- Linking reimbursement of pharmaceutical manufacturers partially to the performance of the high-priced specialty therapeutics (thus guaranteeing a minimum revenue level but allowing for upside potential based on the therapy's performance)
- Using an evidence-based model agreed upon by both payers and the drug manufacturer (e.g., a pre-launch HEOR assessment) that reimburses the drug at a consistent launch price, based on the strength of clinical evidence for the drug and on its clinical value to society
- Instituting outcomes-based pricing for curative specialty therapies, with reimbursement spread over time and contingent on clinical milestones (so drug manufacturers and payers are incentivized to achieve a patient's long-term success)
- Placing pharmacy under capitated primary care, with PCPs determining a fee or an outcomes-based revenue model for pharmacy underneath their global cap for patients

View VBC investment as future-proofing

Payers do not see significant spend in the pharmacy benefit moving through VBC models today, and indeed these capabilities will take years to build and refine. Without the initial infrastructure and the lessons from longtime experience, they will be caught flat-footed when a shift occurs in the market. Even where VBC arrangements may be little more than showpieces in the current market dynamic, they still constitute an investment against future

disruption in the space. While agreement is tough to find on what kinds of changes are on the horizon, there is universal agreement on one thing: The status quo is unsustainable. Minor investments today to hedge against this uncertainty are therefore both feasible and prudent.

> **"Right now, most payers are really only doing VBC to show some market differentiation and say that they are sophisticated enough to do it. But if VBC does become more common due to market demand or regulation, the payers that did the proof-of-concept work now will have the foundation to quickly scale up since they already made the upfront investment."**
>
> — Director of pharmaceutical trade relations, large PBM

Conclusion

The sluggish adoption of alternative payment models in the pharmacy space can be ascribed to the inertia of a large system that has failed to outweigh a body of challenges to the status quo. Yet upon closer examination, the obstacles in VBC's path are revealed as discrete stumbling blocks, with each offering an approach to address the difficulty in detail. If the pharmaceutical ecosystem decides that moving in tandem with the rest of the healthcare industry is a sound investment, then the multifactorial process of change can start with small efforts that address the individual challenges to VBC adoption. To be clear, there is no silver bullet solution, and the process will require dedicated spending and risk taking. Still, the results would realign pharmacy with the broader healthcare industry and would bring a welcome cascade of positive effects on both innovation and cost of care in the pharmacy benefit.

For more information, please contact strategy@lek.com.

Endnotes

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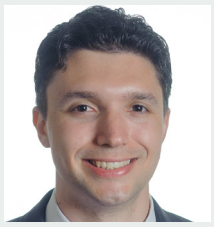

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