



# Advancing Patient Interests Through Value-Based Arrangements for Prescription Drugs

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# Introduction

With rapid improvements in pharmaceutical therapy development, patients stand to benefit immensely as previously incurable diseases become treatable and chronic diseases become increasingly manageable. However, patients may not fully benefit if they cannot access nor afford innovative treatments. Affordability issues have, in part, contributed to the advent of high-deductible health plans (HDHPs). In HDHPs, patients pay lower premiums and face high out-of-pocket (OOP) responsibility. As such, patients are exposed to the full price of a therapy during the deductible phase. While HDHPs reflect a system that is seeking to align value with spending, plan designs with high patient OOP have been shown to decrease medication adherence and discourage treatment initiation.<sup>1</sup> Poor adherence to a drug regimen may increase patients' overall cost of care due to avoidable complications. This all-too-common dynamic reflects a healthcare system that—while moving toward value—still misaligns incentives between manufacturers, plans, and providers to the detriment of patients. Social determinants of health (SDoH)<sup>2,3</sup> may also prevent patients from fully realizing the benefits of new drug therapies. For instance, a patient who can easily afford medication for a chronic condition but lacks the ability to get to the pharmacy<sup>4</sup> or to obtain the food for a product's supplementary nutritional strategy will not fully recognize that treatment's value.<sup>5</sup> Though data on the real-world uses of innovative therapies could enhance treatment for many patients through improved clinical decision making, data sharing of real-world evidence remains limited. To effectively prioritize patient needs, care delivery must encompass accessibility to both therapies and laboratory testing, patient affordability, disease management, prescriber education, and the improvement of overall quality of life.

Fortunately, there is significant opportunity to address these concerns through the development of value-based arrangements (VBAs) for prescription drugs and biologics. Value-based payment for medical services has proliferated in recent years as VBAs have been recognized as tools to improve outcomes and control costs. Such models, like bundled payments for knee replacements or total-cost-of-care arrangements for primary care, often do not incorporate prescription drugs. Though payers are also increasingly adopting drug-focused VBAs,<sup>6,7,8</sup> these arrangements only indirectly address affordability and other elements of access critical to patients. Future VBAs for prescription drugs could further benefit patients by improving affordability and focusing on patient-focused metrics like extended lifespan, reduced side effects, or lessened caregiver burden. VBAs that embrace this approach could enable greater access to innovative drugs and improve the patient experience; however, policymakers must address significant barriers for patients to fully realize those benefits.

**Lilly believes moving from volume to value is one of the most important changes, long term, we can make as an industry. We partnered with Prime Therapeutics to explore what the next generation of VBAs could look like, and how they can put patients front and center. We look forward to future collaboration to bring these ideas to life.”**

**Erin Huntington,**  
Senior Director, PRA Strategy & Marketing, Lilly

**Prime's leadership in value-based contracting has advanced our clients, their members, and the health care system. However, policy barriers continue to limit our ability to deliver direct value to patients through innovative contracts. Prime is honored to collaborate with Lilly to identify solutions so we and others can more fully and broadly use value-based contracting.”**

**Kelly Pokuta,**  
Vice President, Prime Therapeutics



# Overview of VBAs for Prescription Drugs

VBAs are innovative contracting arrangements between payers (or others) and manufacturers that tie a drug’s net payments (list price minus discounts) to measures of value. Through these arrangements, patients may benefit from streamlined access to a therapy, improved quality of care, and lower insurance premiums.<sup>9</sup>

Under VBAs, prior authorizations may be streamlined or lifted entirely because access to the product is incentivized through VBA drug performance value metric terms.<sup>10</sup> The structure of VBAs creates a feedback loop for payers to consider outcomes metrics in formulary decision making, such as basing prior authorization criteria on data points correlated with patient success in the VBA. Improvements in diagnostic technology, coupled with learnings from VBAs, could potentially limit the use of access restrictions in the long term.

In addition to improving and/or simplifying prior authorization or other similar processes, VBAs have the potential to improve patient outcomes.

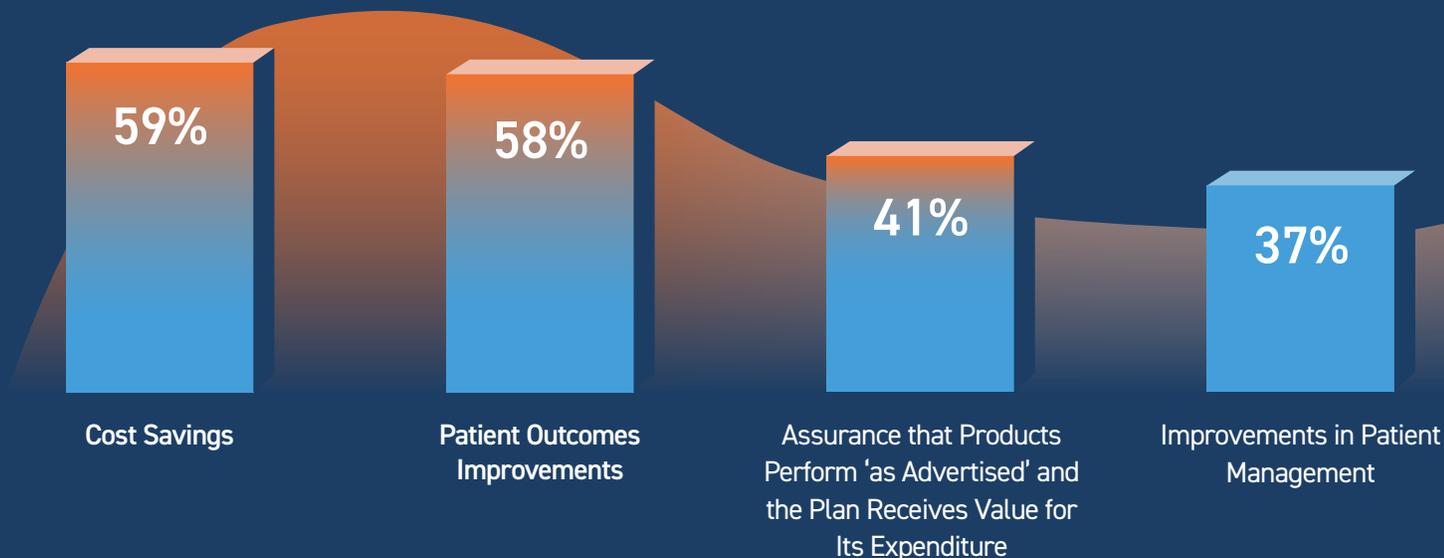


### Patient Outcomes

A study from Avalere Health showed that 58% of payers operating outcomes-based contracts reported improvements in patient outcomes.<sup>11</sup>

Patient affordability may also be improved via lower formulary tier placement or lowered premiums. As plans save money from the value gained through these arrangements, they pass the savings on to patients or provide more services, as required by law.<sup>12</sup>

## Experienced Advantages to Date with VBAs



Source: Avalere. "More Than Half of Health Plans Use Outcomes-Based Contracts." 1 October 2019.

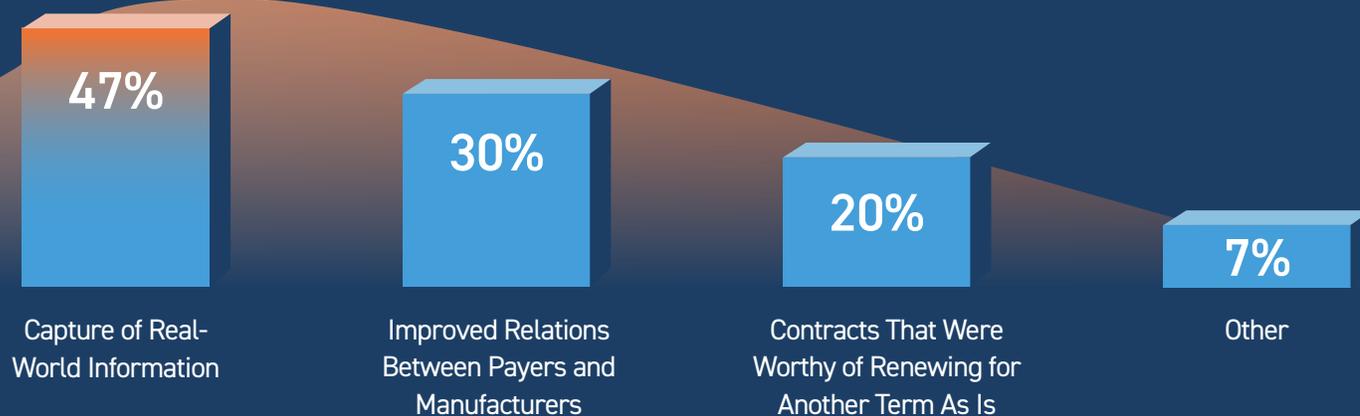
Typically, VBAs are structured using retrospective rebates, where discounts are provided after the point of sale based on a predetermined metric or outcome. If a patient under treatment does not meet the targeted metric, the manufacturer provides price relief to the payer. Currently, VBAs tend to be based on a relatively limited set of measures (e.g., adherence, total cost of care). VBAs are in some ways like a warranty for a consumer good: if an appliance fails to function as advertised, the appliance manufacturer provides the consumer with a refund or replaces the product with a fully functioning item. Similarly, VBAs can act as a guarantee to patients and plans that if a drug does not work as expected, the manufacturer will refund some or all the drug's cost to the plan, as the plan pays the vast majority of the drug cost.

1. Incorporate value metrics that more explicitly reflect value to patients, including patient-reported outcome measures relevant to functional capacity and quality of life, clinical outcomes, and long-term efficacy
2. Reduce patient OOP costs through value-based insurance design (VBID), rebate pass through, or other innovative affordability solutions
3. Incorporate care management and support services related to SDoH to increase medication accessibility and adherence
4. Facilitate clinical improvement through VBA-enabled data sharing to allow for more accurate prescribing

More detail on each of these points is outlined on the following pages.

## How Next-Generation VBAs Can Put Patients Front and Center

Though some patients are already benefiting from VBAs, patients could see even greater value from next-generation VBAs that:



# 1 | Patient-Focused Value Metrics

Patients could benefit from the increased use of robust, patient-centered value metrics in VBAs. While current models of adherence- or cost-based VBAs increase access for some drugs, VBAs that include advanced metrics could further increase access for drugs that improve quality of life or reduce functional decline. These advanced metrics could include detailed clinical outcomes data, patient- and caregiver-reported outcomes, and metrics tied to the long-term impact of a treatment.



## Clinical Outcomes Metrics

Would include targeted variables reflecting the impact on patient health—e.g., blood glucose levels—rather than relying on process measures like adherence data or total-cost-of-care measures. Use of clinical measures would incent improvements in clinical care and focus the definition of value on the patient's health.



## Patient-Reported Outcomes and Measurements

Could capture patients' enhancements to health and well-being. For example, a VBA that includes a self-reported measure tied to level of physical functionality for a patient with multiple sclerosis (MS) codifies these direct patient benefits as measures of success.<sup>13</sup> VBAs could also encompass caregiver-reported outcomes. Caregivers play a vital role in patients' lives and may be best suited to report on metrics for many patients.



## Metrics Tied to Treatments' Long-Term Impact

Could benefit patients by going beyond immediate outcomes and extending the warranty concept of a VBA further into the future. For products expected to extend a patient's life or remain effective over a span of time, a VBA could incorporate payment to the payer (i.e., patient and plan) to ensure the durability and longitudinal effectiveness of a therapy. Further, VBAs could be structured to include specific patient interventions to help promote long-term effectiveness. This type of VBA could also account for unexpected side effects that may emerge years into a therapy or the need for additional therapy as a treatment's effectiveness declines. Focusing on and tracking the long-term patient experience could help structure the outcomes metrics for VBAs to make them as beneficial and meaningful as possible for patients.

# 2 | Affordability

A next-generation VBA could improve affordability for patients by linking outcomes to decreased OOP costs via real-time cost-sharing adjustments, retrospective OOP adjustments, or VBIDs.

For example, a patient could receive a discount on their OOP cost under a VBA for a diabetes product that ties a point-of-sale rebate (i.e., a rebate received at the pharmacy counter) to a patient's recent outcomes.

## — Real- Time OOP Adjustments

To make real-time OOP adjustments possible, stakeholders across the healthcare system would need to collaborate to share patient metrics and details of VBAs.

Digital health technologies could contribute to this effort. To take one example, patients could use a smartphone application or use a wearable technology that monitors blood glucose levels, weight, and other key data points. Those data would be transmitted to the payer, PBM, and pharmacy in real time to determine the patient's OOP cost for the next fill. A VBA could also reduce patient cost sharing through longer-term retrospective OOP adjustments, whereby the payer would receive a repayment if treatment did not result in a targeted outcome. This type of longer-term arrangement could tie payment amounts to the patient's future expenditures (e.g., OOP, lost productivity, caregiver expenditures) related to the therapy's failure to deliver on the defined value or unanticipated side effects of the treatment. Any of these types of arrangements would require substantial technological and data transfer/tracking capabilities.



## — Patient Affordability

Patient affordability could also be improved through differentiated benefit designs tied to VBAs.

These benefit designs could offer reduced cost sharing via placement on a lower formulary tier for specific patient populations for whom a product is expected to be effective. Payers could enhance this structure by developing benefit designs that improve tier placement for products with VBAs that incorporate therapeutic value and cost effectiveness. For example, certain sodium-glucose cotransporter-2 (SGLT-2) inhibitors have substantially more value among patients with coronary artery disease than among those without; simplifying access and lowering OOP for the relevant patient population through targeted VBAs would greatly benefit patients. Organizations that advocate for patients or independent entities that evaluate the cost effectiveness of a drug (e.g., Institute for Clinical and Economic Review (ICER), NICE, IQWiG<sup>14</sup>) could provide valuable input on measures that patients would find meaningful while also considering affordability. By incorporating recommendations from these entities, payers could develop benefit designs with reduced cost sharing tied to products with proven therapeutic efficacy and cost effectiveness as enabled through a VBA; however, lack of consensus over the definition of value makes widespread adoption of these recommendations difficult. Further, new VBAs could serve as a mechanism for determining patient-centric clinical and economic value measures that reflect patient outcomes and real-world evidence, creating a virtuous cycle of data generation and value assessment.



# 3 | Supportive Services Addressing Social Determinants of Health

Addressing SDoH is increasingly recognized as key to improving patient outcomes and quality of life.<sup>15,16</sup> SDoH supports incorporated into VBAs could ease access challenges (administrative, logistical, and geographical) for patients and improve medication adherence, leading to enhanced clinical benefits, lower healthcare costs, and improved quality of life.<sup>17,18</sup> Some patients commonly need assistance with transportation, in-home support, and nutrition.<sup>19,20</sup> A VBA that incorporates coverage of transportation services to and from chemotherapy, for example, could ensure that a patient completes treatment, as well as reduce the amount of time a caregiver has to take off work to drive to and from appointments.



## Stability & Support

This type of support for SDoH would provide stability to both the patient and the patient's support system.<sup>21</sup>

Other research has shown connections between health outcomes and nutrition<sup>22</sup> and in-home care (i.e., primary care and case management services provided in the patient's home) for older populations.<sup>23</sup> A VBA for a cardiovascular disease therapy focused on senior populations could, for example, incorporate a heart healthy meal delivery service and/or proactive home care check-ins and heart monitoring to improve outcomes.



# 4 | Improvements in Clinical Knowledge and Prescribing

VBA's have the potential to inform and improve broader public health discussions and policies in addition to increasing affordability and access for specific patients. Confirming the safety and efficacy of drugs is one of the foremost priorities of manufacturers and regulatory bodies. The FDA has expressed a growing interest in the use of real-world evidence (RWE) to inform the approval of new indications for products.



## Accessible Database

The creation of a widely accessible database that allows clinicians, plans, patients, and manufacturers to observe the effects and real-world use of therapies in a HIPAA and PHI compliant manner, could enable RWE data sharing and could inform clinical decision making.

Facilitated through next-generation VBAs that collect and collate data on specific patient outcomes, plans, patients, prescribers, manufacturers, and health and data technology organizations can share real-world and real-time evidence on the clinical endpoints of new therapies, enabling a community-wide focus on improving value for patients through innovative therapies.

# Policy, Regulatory & Operational Challenges to Advancing Next-Generation VBAs

For patients to realize the potential benefits of next-generation VBAs, legal and regulatory barriers, misaligned incentives, and operational and technological obstacles must be addressed. Lilly has written previously<sup>24,25</sup> on the many policy-related challenges hindering the adoption of VBAs. While some of these concerns have been addressed by regulators,<sup>26</sup> many persist.

In particular, the Best Price requirement in the Medicaid Drug Rebate Program<sup>27</sup> disincentivizes manufacturers from participating in VBAs that could include large rebates. Best Price is the pricing benchmark Medicaid uses to ensure state Medicaid programs never pay more than the lowest price offered in other markets for a therapy. Under current regulations, payments from manufacturers to health plans under a VBA would likely be included in Best Price calculations, which could potentially result in a drastically lower Best Price for the therapy. The threat of impacting revenue in Medicaid and the 340B program inhibits manufacturers from entering VBAs where they might be exposed to this risk.

Other policy barriers include the federal Anti-Kickback Statute (AKS), Medicare regulatory requirements, FDA regulations on the use of RWE, and laws that limit data sharing.

Plan incentives, often dictated by policy constructs, may also limit the extent to which VBAs can benefit patients. For instance, under the Medicare program, standalone Part D Prescription Drug Plans (PDPs) are responsible only for outpatient drug costs and do not benefit from savings on medical services. PDPs, therefore, have limited incentives to engage in arrangements that may reduce a patient's total cost of care but increase the cost specific to that patient's drug benefit. Further, PDPs are not responsible for physician-administered drugs, which are covered under Part B. For specific therapeutic areas, such as oncology, which utilize concurrent regimens of oral and IV-administered drugs, structuring VBAs would require sharing total-cost-of-care responsibility across Medicare benefits.

VBA that involve payment over time face additional complications. For example, a VBA for a curative gene therapy that allows a payer to pay for the therapy over several

years, with future years' payments dependent on durability of cure, would need to account for the potential for the patient to switch insurance plans during that time. In public programs, statutory definitions of payment processes and timelines do not allow for transfer of payment between types of coverage or even payment of a single treatment over multiple years. For instance, Best Price reporting requirements may lead most VBA outcomes to be limited to a 3-year time horizon. This may not be long enough to fully assess the value of many therapies. CMS' June 2020 proposed rule<sup>29</sup> would extend drug price reporting timelines for VBPs, allowing manufacturers to account for rebates paid more than 3 years' beyond the use of a drug. Though this would alleviate some barriers to longer-term VBAs, other stated complications could still hinder the use of pay-over-time agreements.

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## Anti-Kickback Statute

The AKS prohibits remuneration for referrals for healthcare services or products that are paid for by federal programs. While there are safe harbors for post-sale rebating, the AKS does not clearly allow for more flexible arrangements.<sup>30</sup> VBAs that transfer rebates, data fees, or other administrative fees (directly or indirectly) to consumers or that incorporate SDoH support services, for example, may not be permitted. A recent proposed rule from the HHS OIG revisits and revises portions of the AKS relevant to VBAs,<sup>31</sup> such as the local transportation requirements,<sup>32</sup> but pharmaceutical manufacturers have largely been excluded from the proposed changes that would facilitate VBAs.

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## Medicare Part D Regulations

Medicare Part D regulations requiring uniformity of benefits prevent plans from varying benefits between enrollees.

## Medicare Part D Regulations (cont.)

The Medicare Advantage (MA) Value-Based Insurance Design (VBID) has expanded flexibilities to vary cost sharing for Part D drugs for certain patient populations, a positive development. However, these flexibilities are not available for

the majority of Part D Plans,<sup>33</sup> which must offer identical benefits to all enrollees, regardless of treatment regimen or additional health needs.<sup>34</sup>

## FDA Regulations Regarding the Communication of Off-Label Use

FDA regulations regarding the communication of off-label use of drugs often do not keep pace with real-world utilization of new therapies. These regulations pose challenges for efforts related to RWE data sharing, including RWE used as part of VBAs, since VBAs cannot be based on outcomes related to off-label use. Under current FDA guidance, manufacturers interpret marketing beyond label to include creating VBAs for therapies without an approved indication. Manufacturers also avoid developing VBAs with outcomes measures not in the label for products with an approved indication (or at least with published clinical trials demonstrating statistically significant improvement). However, a drug may offer significant value

in clinical scenarios beyond those sanctioned under its label. FDA has stated that it does not intend to regulate the terms of contracts between drug manufacturers and payers, such as those within the confines of VBA negotiations, but enforcement uncertainty remains, potentially limiting valuable uses of products.<sup>35</sup> Many payers, including Medicare, reference compendia for the purposes of coverage or access decision-making. These compendia often reference off-label uses of products,<sup>36</sup> reinforcing the need for payers and manufacturers to have the ability to discuss and contract on clinically acceptable uses of products to ensure patient access.

## Data-Sharing Policies, Such as HIPAA or Informed Consent Requirements

Data-sharing policies, such as HIPAA or informed consent requirements, can make it more difficult to establish large-scale RWE data-sharing efforts (e.g., aggregation of RWE across VBAs) and the data transfers needed to operationalize patient cost-sharing reductions tied to VBAs. While provider data sharing has improved in recent years and recent policy changes will likely bring further enhancements, significant interoperability challenges remain throughout the healthcare system.<sup>37,38</sup> Beyond the policy considerations, the use of clinical outcomes data faces other challenges. While many providers have adopted electronic health record (EHR) systems, gaps still exist. According to the US Office of the National Coordinator for Health Information Technology (part of HHS), 97% of hospitals have adopted a certified EHR, but only 80% of physicians have such systems.<sup>39</sup> Adoption remains particularly low in children's and psychiatric facilities. Without these systems, rapid data sharing is exceedingly difficult. In addition, even where there is an EHR, certain data may not be collected at all or in a similar manner across programs. The lack of a universally adopted data dictionary and system

architecture further negatively impacts information sharing and interoperability. These interoperability issues can make it difficult or impossible to collect and query clinical data to determine if VBA outcomes were met. A recent final rule from CMS regarding interoperability (CMS "Interoperability and Patient Access") will help to solve many of these challenges by standardizing API data requirements across many payers (Medicare, Medicaid, exchanges).<sup>40</sup> This could provide a significant advantage to VBA development and outcomes measurement. However, the operationalization and connectivity of patient records to payer systems and between payers and third parties will require substantial industry collaboration and innovation. Coordination may be driven by payers as the rule is primarily directed at payers and claims data aggregators rather than providers and EHR solutions. Additionally, patient consent will remain a challenge, as the federal agencies are largely deferring to industry for the development and operationalization of consent capture and tracking (e.g., Fast Healthcare Interoperability Resource (FHIR) standards for consent management).

# Recommendations

Incorporating patient-centric value into next-generation VBAs can be accomplished by redefining value from the patient perspective, improving operational and technological capabilities, and advancing policies that support this evolution. Lilly and Prime Therapeutics recommend that policymakers at the state and federal levels consider and adopt policy changes outlined in previous white papers<sup>41,42</sup> and on the following table.

Critically, Lilly and Prime Therapeutics recommend the creation of a process where VBAs could be excluded from calculations of Best Price, where it is obvious that Medicaid would still be able to obtain a significant discount, but where inclusion in Best Price otherwise impedes the use of a VBA. CMS recognizes the importance of this flexibility in its June 2020 proposed rule on VBPs, which outlines flexibilities for VBPs to be included in bundled sales or to be structured with separate VBP Best Prices that would not apply to utilization outside of VBPs. It is encouraging that CMS has acknowledged the importance of VBAs and proposed these changes, especially changes to Best Price. However, the flexibilities outlined in the rule need to be clarified to ensure that payers and manufacturers understand what is required of them and how these flexibilities would be operationalized, and CMS should engage stakeholders in developing and implementing guidance or a process for CMS review. The rule creates questions related to the operationalization of bundled sales vs. multiple Best Prices; even if that is clarified, reporting multiple Best Prices could lead to additional challenges and complexities. Additionally, the preamble to

the proposed regulatory text explicitly notes that it is focused on creating flexibilities for gene-based therapies and other outcomes driven therapies, but VBA flexibilities should apply more broadly to create the greatest potential benefit to patients. Finally, the rule's flexibilities would be limited to VBAs that meet CMS's definition of VBP, which could limit the creativity and scope of VBAs.

This flexibility was proposed in the draft Patient Affordability, Value and Efficiency (PAVE) Act,<sup>43</sup> which would provide a statutory exemption for VBAs from AKS liability and would exempt VBA concessions from having to be reported in Best Price. Clarity regarding the AKS safe harbors would further enable the use of support services in VBAs to help ensure that the treatments underlying the VBAs can be more effective and that patients have a better experience. By adding this exclusion, it would provide the necessary clarity to ensure that parties are not at risk by entering into such arrangements, and provide clarity such that rebate pass through to patients can be a protected feature in the financial structures of VBAs.

In order to increase PDP willingness to participate in VBAs, Congress should provide incentives for PDPs to be accountable for a patient's total cost of care. In the absence of Congressional action, a Center for Medicare and Medicaid Innovation (CMMI) demonstration could enable similar changes. Giving PDPs responsibility over medical costs would enable VBAs with PDPs that value medical outcomes, rather than purely patients' drug costs.

Finally, there are many federal and state laws that inhibit data access and release that can be improved in order to facilitate the data sharing and transparency needed for next generation VBAs. In addition to standardizing data formats, participants in VBAs involving multi-party collection of data will need to come to agreement regarding data sharing. Most existing VBAs are highly proprietary in nature and industry practices limit the sharing of certain types of data. Participants in VBAs, including manufacturers, third-party vendors, payers, employers, and patients, will need to align on what data will be collected and with whom it will be shared. In addition, it will be important for third parties who are accessing this data to receive consent first from the patient and to fully disclose how the information could be used. Failure to be transparent and receive informed consent for data sharing could potentially lead to enforcement actions and penalties from the Federal Trade Commission (FTC).<sup>43</sup> In general, data sharing policies related to VBAs are likely to be highly contingent on disease state and patient population. These contracts will also likely include audit rights that, when activated, add to the VBA administrative costs, as well as exposure risk for private health information.

Development of aligned standards, led by stakeholders and government entities (e.g., the ONC), could allow next-generation VBAs to be based on more real-time and patient-focused metrics. This access to actual claims and encounter data may enable new patient affordability solutions (e.g.,

OOP reduction at the point of sale), especially for pharmacy transactions. In particular, the recent interoperability rule from CMS requires that plans provide patients standardized health claims data for at least the previous five (5) years, which could help to solve data complications related to patient churn that complicate VBAs when patients move from plan to plan. Per the CMS rule, patients will be able to access those five (5) years of claims data regardless of payer. This access may allow for a longer look-back period for a multi-year VBA and ensure that outcomes can be captured and assessed even after changing plans. This could allow VBAs to follow the patient. Further, standardized data requirements would enable developers to more easily merge information and create applications that could make it easier for patients to access their data. However, the mandates in the rule do not come into effect for nearly two (2) years, and payers will need to complete substantial technological infrastructure build-outs to ensure they can access this information before these potential gains can be realized.<sup>44</sup>

A summary of potential challenges and proposed policy solutions, in order of importance, is encapsulated on the following page.

## Problem

## Potential Solution

<p>1</p>	<p>Medicaid Best Price disincentivizes manufacturers from offering significant price relief</p>	<p>Clarify Best Price flexibilities outlined in CMS VBP proposed rule<sup>46</sup> and/or allow for a broader exemption of VBAs from Best Price</p> <p>The flexibilities outlined in the VBP proposed rule could alleviate some concern around the impact of VBAs on Best Price; however, the rule's impact would be limited as described above. Legislation exempting VBAs from impacting Best Price for all pharmaceuticals, not limited to gene therapies, (e.g., the draft Patient Affordability, Value and Efficiency (PAVE) Act<sup>47</sup>) would create more significant flexibility for VBAs</p>
<p>2</p>	<p>Lack of clarity around AKS hinders development of VBAs and use of supportive services (e.g., transportation, nutritional assistance) as part of VBAs</p>	<p>Explicitly include manufacturers, PBMs, and plans in workable safe harbors, and provide clarity regarding AKS and VBAs</p>
<p>3</p>	<p>Plans cannot reduce cost sharing on a drug just for those enrollees who are most likely to succeed on the product</p>	<p>Allow for VBID in Part D so that VBAs could be tied to lower cost sharing for higher-value patient sub-populations</p>
<p>4</p>	<p>Sharing EHR and claims data between stakeholders remains a challenge</p>	<p>Build on recent CMS and ONC interoperability rules to encourage development of shared platforms that will enable improved data transferability and ensure that patient consent and data use agreements have a clear path forward</p>
<p>5</p>	<p>Regulation regarding off-label use of products does not keep pace with front-line usage</p>	<p>Align FDA oversight enforcement discretion with practice of medicine, such as that described in widely recognized compendia and guidelines, or through use of pilot studies or robust data collection efforts (e.g., registries)</p>
<p>6</p>	<p>Data sharing laws and regulations that prevent information sharing</p>	<p>Require data collection and standardization so information can be shared in real-time among patients, manufacturers, payers, and providers and exempt "data" and "data analysis" from the definition of "remuneration" for purposes of AKS compliance</p>

# Conclusion

Policy changes are necessary, but not sufficient, to enable VBAs to provide the maximum benefit to patients. Payers, manufacturers, employers, and patients will need to become more comfortable and willing to share data generated from VBAs, including real-world usage of innovative therapies, anonymized patient-reported outcomes data, and other real-world data. In some instances, payers or other parties may need to provide support to providers and patients to facilitate the collection of granular data that may not be easily collected in existing systems. Collaboration is more than just sharing data; it will require a paradigm shift from considering patient, clinical, and cost data as trade secrets and private assets to data that can be used to facilitate individual VBAs and also increase the base of medical knowledge, leading to improved outcomes for patients.



## Focus on Value to Patients

Finally, these improvements to VBAs require first and foremost that the “value” in VBAs represents value to patients, reflecting improvements in specific, meaningful clinical outcomes and quality of life metrics.

Lilly and Prime Therapeutics are excited to be on the front lines of designing the next generation of patient-centric VBAs and look forward to partnering with the medical community in that effort.

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## Establish

a process to exclude VBAs from Best Price requirements

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## Provide

VBAs safe harbor in the AKS statute

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## Allow

value-based insurance design (VBID) in Part D

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# About Eli Lilly and Company

Lilly is a global health care leader that unites caring with discovery to create medicines that make life better for people around the world. We were founded more than a century ago by a man committed to creating high-quality medicines that meet real needs, and today we remain true to that mission in all our work. Across the globe, Lilly employees work to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease, and give back to communities through philanthropy and volunteerism. To learn more about Lilly, please visit us at [lilly.com](http://lilly.com) and [lilly.com/newsroom](http://lilly.com/newsroom).

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# About Prime Therapeutics

Prime Therapeutics LLC (Prime) makes health care work better by helping people get the medicine they need to feel better and live well. Prime provides total drug management solutions for health plans, employers, and government programs including Medicare and Medicaid. The company processes claims and offers clinical services for people with complex medical conditions. Prime serves more than 30 million people. It is collectively owned by 18 Blue Cross and Blue Shield Plans, subsidiaries or affiliates of those plans. As a pioneer in value-based contracting since 2010, Prime's manufacturer contracts analyze the value of a selected medicine when taken appropriately, with the goal of improving outcomes and lowering total cost of care. Prime is transforming its value-based contracts, which are an integral part of its value and health outcomes strategy, by leveraging integrated pharmacy and medical data, showing members' total health picture and providing actionable information to design high-touch interventions.

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