

Health Policy Brief

Getting to value: What policies are on the table to manage drug prices?

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Executive summary

Health care stakeholders agree that the United States needs to improve the value of health care spending; recently, many have focused on how to get to better value for prescription drugs. Drug therapies are important contributors to managing chronic conditions and improving outcomes. What policies are on the table to create incentives for taking full advantage of drugs' therapeutic benefits while meeting society's goal of better value for the health care dollar?

This health policy brief examines some options that health care industry stakeholders and policymakers have proposed for getting better value from prescription drugs, including those related to drug prices. It describes the major policy proposals and outlines the key elements of each—the mechanisms, goals, unanswered questions, and potential unanticipated consequences. This brief is intended to help readers understand the policy landscape and possible implications around emerging value-based strategies to manage drug price and spend. Policies discussed include:

- Clarifying or removing potential regulatory barriers to value-based contracts between private health plans and pharmaceutical companies
- Medicare Part B pilot of a new payment formula for reimbursing drugs under the medical benefit
- Medicare price negotiation for Part D drugs and how value may play a role

The market landscape points to increasingly complex negotiations between biopharma¹ companies and payers including government, health plans, and pharmacy benefit managers (PBMs), with new pricing mechanisms such as risk-sharing and outcomes-based agreements. As a result:

- Biopharma companies may consider a development strategy centered on generating evidence that both supports product approval and informs value-based pricing negotiations.
- Health plans may focus on improving drug therapy-associated outcomes by advancing collaborations with providers and patients, and offering benefit design strategies that engage consumers.
- PBMs may aim to strengthen their role in understanding and monitoring each patient's response to therapies and gaps in care, and encourage the use of cost-effective and generic medications.
- Providers might consider engaging in alternative payment models that capture drug costs; and leveraging value-assessment frameworks as a tool to inform shared decision-making with patients.
- The health care ecosystem as a whole should work toward alignment on how to define value for drug treatment.

Why focus on drug prices?

The debate around prescription drug prices is once again at the forefront. Although a relatively small share of total health care spend, prescription drug spending increased 12.2 percent to \$297.7 billion in 2014, faster than the 2.4 percent growth in 2013.² Several factors are driving this increase, including more patients gaining access to health care, an aging population, and the introduction of innovative but costly new products.

Policymakers and stakeholders are beginning to publicly propose a number of potential approaches to reduce spending—and prices in particular—on prescription drugs.

National Health Expenditure Accounts (NHEA) data sets 2015 US prescription drug spending at about \$457 billion or 16.7 percent of overall personal health care services: \$328 billion, or 71.9 percent, for retail drugs, and \$128 billion, or 28.1 percent for non-retail drugs (drugs that are purchased by providers such as hospitals, physician offices, nursing homes, and home health agencies).³

Specialty drugs, which are often biologics that require special handling and monitoring and are used to treat chronic, serious, or life-threatening diseases, are increasingly contributing to total drug expenditures.⁴

Costs may total thousands of dollars a month and in some cases, may exceed \$100,000 annually. Many of these drugs are for rare conditions or cancer subtypes targeting a specific genetic mutation, so they may not target a large population. In these cases, there are sometimes few, if any, lower-cost options, resulting in little competition.

The US spends less on prescription drugs as a percentage of total health care spending relative to other developed nations.⁵ However, Americans also pay higher prices for drugs compared to other countries' populations.⁶ In countries with a single payer system, the government exerts its purchasing power to drive down costs. The United Kingdom's National Health Service, for example, purchases the country's drug supply. In the US, private and public health plans, employers, PBMs, and hospitals are all purchasers. Many groups negotiate the price they pay directly with the drug manufacturers, resulting in a variety of prices and pricing models (*see sidebar on the following page, The complexities of drug pricing*).⁷

Prices across drug classes often reflect the high cost of research and development, not just to bring a drug to market, but to bring future therapies to market as well. The Tufts Center for the Study of Drug Development reports that bringing a drug to market takes, on average, more than 10 years and \$2.6 billion dollars.⁸ For every successful drug, numerous drugs never make it to market.

Prescription drugs can lower the total cost of health spend by preventing expensive complications and hospitalizations, and many Americans rely on these therapies to improve their health and enhance their quality of life. However, stakeholders pushing to reign in health care spending are exploring a number of policy options to manage drug prices. Some critics fear that increased government intervention on drug prices may deter biopharma industry investments in further innovation, and reduce the number of new therapies that are brought to market.

Policymakers and stakeholders are beginning to publicly propose a number of potential approaches to reduce spending—and prices in particular—on prescription drugs.

The complexities of drug pricing

What is the price of a drug? This is a complicated question, because the term drug price is not always straightforward. The drug pricing debate often centers on the initial US launch price (considered the list price), but actual paid prices vary within different payers and distribution channels across the US health care system and over time.

A drug's list price is often a starting point for negotiations between biopharma companies and private payers: PBMs (which implement prescription drug benefits for more than 260 million Americans who have health insurance through their employer or union) and health plans.⁹ Biopharma companies negotiate prices with each private insurance company and PBM, and government purchasers usually set payment rates through preset formulas referencing prices set in the commercial market. Often the price the government pays is lower than the price the commercial market and other institutional channels may pay because of existing regulation.

Over time, as branded competition enters the market, the price paid for a drug is likely to change. For example, when a new drug is introduced into the market with no therapeutically equivalent options,

there is no competition for the drug during the time it is under patent protection. But, when drugs that act in similar ways enter the market, even while all are covered under patent protection, competition typically results in greater price discounts for health plans and PBMs in exchange for coverage or favorable formulary positioning.

Of note, when drugs lose patent protection, companies introduce generic drugs into the market that are usually 80-85 percent less expensive.¹⁰ Generic manufacturers can sell their products for lower prices because they are not required to meet the same extensive research and development requirements as innovative products, including costly clinical trials. Generics also create competition in the market which can result in lower prices.¹¹ Biosimilars, which are intended to be lower cost alternatives to biologics, are expected to be priced 20-30 percent lower.¹²

Government involvement in price negotiation, a policy discussed in this brief, aims to impact some of these factors that go into the list price. Other policies that would regulate market competition, such as changing the exclusivity period for patented products or regulating the rate of return on innovation, are beyond the scope of this brief.

What value-based policy options are on the table?

Policymakers, consumer groups, health care organizations, and researchers are exploring different types of policies aimed at managing drug prices (see Figure 1). This policy brief discusses the value-centered

proposals that are gaining a lot of attention. Policies that would directly regulate competition or make drugs more affordable to consumers, by limiting cost sharing, are beyond the scope of this brief.

Figure 1. Stakeholders are discussing several policy proposals publicly

Policies focused directly on price or value	Policies focused on competition and transparency
Direct negotiation: Permit Medicare to negotiate with the biopharma companies for better prices.	Exclusivity: Reduce exclusivity for biologics (currently companies have exclusivity for 12 years).
Part B drug initiatives: Encourage more value-based pricing for drugs reimbursed under the Physician Fee Schedule through changing the payment formula as well as exploring reference pricing, indications-based pricing, and risk-sharing agreements.	Rate-of-return regulation: Promote greater transparency into drugmakers' research & development spending.
Comparative effectiveness: Lift the prohibition on government agencies to use comparative effectiveness research to determine the relative value of therapies to help inform coverage decisions and pricing negotiations.	Net price transparency: Encourage companies to be transparent on the net pricing after discounts/rebates/chargebacks that they give across various payers.
Best price: Modify Medicaid best price regulation to allow more value-based contracts between health plans and drug companies.	Re-importation: Allow individuals, pharmacists, and wholesalers to import prescription drugs from licensed Canadian pharmacies.
340B: Determine whether/how forthcoming guidance could limit the availability of discounts under the 340B program.	March-in-rights: Recover federal investments from successful drug developers, using existing authority in the Bayh-Dole Act.

Source: Deloitte analysis of policy proposal categories.

Working to quantify drug value—what price is right?

Researchers and regulators around the world are developing frameworks to assess the value of drug treatments.

Outside of the US, several countries have created government-funded institutions to assess the value of new treatments, a process known as health technology assessment. For example, the UK's National Institute for Health and Care Excellence (NICE) evaluates drugs it expects to have a large budget impact, and quantifies each drug's benefits to generate a cost-quality ratio. NICE uses the Quality-Adjusted Life Year (QALY), which is based on the number of years a treatment would add to a patient's life. Acceptable cost/QALY ratios for the British National Health Service (NHS) ranges from £20,000 to £50,000, meaning that is the price NHS is willing to pay for an added year of life.¹³ Australia conducts a similar cost-benefit analysis. Other countries, including Germany's Institute for Quality and Efficiency in Health Care and France's Haute Autorité de Santé, use comparative effectiveness research (CER) to assess relative clinical benefit, rather than focus on price. Instead, these agencies provide information that other groups use to inform reimbursement decisions.¹⁴

In the US, the Affordable Care Act (ACA) established the Patient-Centered Outcomes Research Institute (PCORI) in 2010 to focus on CER, but the ACA prohibited the partially government-funded research institution from considering the relative value of drugs and from using QALYs as a cost-effectiveness measure.¹⁵ Rather, like models in Germany and France, the goal of PCORI-sponsored CER research is to enable decision makers to include CER data into utilization decisions for innovative treatments.

Other nongovernment groups are developing their own frameworks to determine the value of new drugs in response to a void of cost-effectiveness information in the public marketplace. The Institute for Clinical and Economic Review (ICER) has established a model to help health plans assess the financial impact that some potentially high-value, high-cost drugs and devices may have.¹⁶ The American Society of Clinical Oncology (ASCO) published a conceptual framework to compare the relative clinical benefit, toxicity, and cost of various cancer treatments.¹⁷

Each group has its own methodology and incorporates different dimensions of value; at a minimum, clinical benefit and toxicity. Some include dimensions of value such as novelty, disease burden, or affordability. One example, developed by the American Heart Association (AHA), uses cost/QALY as an output. Using these frameworks, each organization determines a benchmark price for evaluated drugs. Some critics of these approaches have pointed to some of the challenges in assessing value in this way, such as determining what the dimensions of value should be, and how they should be weighted relative to each other. The approaches also often exclude patient characteristics and preferences. Further, many biopharma companies have pointed out that the data used to inform these analyses do not always reflect the best information available.

Private payers are starting to incorporate the results of these analyses in drug price negotiations. For example, Express Scripts has recently launched indication-based pricing using Memorial Sloan Kettering's Drug Abacus to inform the relative value of a drug across the indications it treats.¹⁸ The frameworks, while still experimental, represent the beginning of a broader shift to link the price of drugs to their value.

Value-based contracts between private health plans and biopharma companies

Policy overview

Biopharmaceutical companies are exploring value-based contracts with private health plans. These contracts tie financial incentives to a drug's ability to achieve outcomes within a patient population covered by a health plan. Examples are outcomes-based contracts, financial risk guarantees, and indication-based pricing. Private market examples include Amgen Inc. and Harvard Pilgrim's outcomes-based agreement on PCSK9 inhibitor Repatha® (evolocumab), and Express Scripts' indication-based pricing model for some cancer therapies.¹⁹

Three policy changes might stimulate additional activity around value-based contracts including:

1. Clarifying the Food and Drug Administration (FDA) rules around communicating evidence:

The FDA has regulations regarding off-label marketing, including limiting drug companies' ability to proactively communicate some economic evidence. Part of the FDA Modernization Act of 1997, FDAMA 114 states that health care economic information provided to a formulary committee, or other similar entity, should be based on competent and reliable scientific evidence and would not be considered false or misleading if it directly relates to an FDA-approved indication.²⁰ For example, biopharma companies may have to exclude indirect outcome measures such as reduced readmissions not studied in randomized clinical trials. If organizations must get approval from the FDA before communicating economic evidence, they cannot communicate it with health plans and providers with much advanced notice prior to a product launch. As a result, biopharma companies have been hesitant to proactively share economic information with health plans and providers in a way that would support value-based contracts.²¹

2. Modifying the Medicaid best price policy:

Medicaid reimbursement is tied to the best price any other purchasers receive.²² Manufacturers must also offer the best price to health care providers participating in the federal 340B drug discount program. This legislation limits pharmaceutical companies from tying price to outcomes. For example, if a contract involves a full rebate for a drug's cost in a population where the outcome is not achieved, Medicaid and 340B program participants would have to be offered the drug at the same "price" regardless of whether or not the outcome was achieved in those populations, making it unprofitable. PBMs have suggested solutions to account for these types of repayments, such as using a blended price across populations.²³ Recognizing the importance of this issue, the Centers for Medicare and Medicaid Services (CMS) recently approached manufacturers to understand how Medicaid best price regulations might restrict companies' abilities to offer value-based purchasing agreements.²⁴

In its final rule on Medicaid outpatient drugs released in early 2016, CMS said it hopes to provide more specific guidance on value-based pricing, including the effect on best price and, more broadly, how these types of drug purchasing models could work in Medicaid.²⁵

3. Clarifying safe harbors allowed under anti-kickback rules:

The federal Anti-Kickback Statute (AKS) might limit value-based contracting.²⁶ The law prohibits entities from offering, soliciting, or accepting any type of gifts or remuneration in exchange for referring, ordering, or otherwise making arrangements for the provision of health care services payable by Medicare or Medicaid. Value-based agreements that include services offered by manufacturers, including those around data collection and analysis required to track outcomes, or incentives for providers to increase drug utilization, such as adherence programs, might be considered inducements under this law.²⁷

Questions and potential unintended consequences

Even with clarity on the boundaries of FDAMA 114, what types of evidence would be considered validated and appropriate for biopharma companies to communicate to stakeholders?

Value-based care increases the need for health plans, patients, and the public at large to assess all available evidence on drug treatments, including evidence that falls outside the scope of traditional randomized-controlled trials. Biopharma companies are generating this type of real-world evidence (RWE) as they evaluate their products' clinical and economic value. Stakeholders would need to develop standards regarding appropriate generation, assessment, and application of this type of RWE within the regulated environment. Such standards would help them decipher what types of evidence to consider when assessing a treatment's value.²⁸

Will Medicaid be able to change its best price formula to ensure that the Medicaid patient population benefits from pricing innovation happening elsewhere?

Such innovation is already occurring in the private market, and some wonder if the best price formula can stay current.²⁹ For example, some biopharma companies are exploring the idea of offering mortgage-like payments for very expensive, curative treatments. Other companies are exploring work-arounds to the barriers of existing best price regulation. Express Scripts entered into indication-based pricing arrangements with biopharma companies that apply a blended-rate for all cancer patients expected to take a cancer drug, based on the value defined for each indication.³⁰ Will different formulas be defined for different types of treatments and the scale of outcomes they can achieve in the Medicaid population? Will the formulas be made indication-specific?

What are the appropriate boundaries for partnerships between biopharma companies and providers or health plans?

Biopharma companies are looking for clarity from the federal government around safe harbor under the AKS. For example, will regulators allow adherence solutions that do not influence decision-making? Also, how will stakeholders measure impact to clinical decisions, to prove that prescribing behavior changes are not taking place? Determining what types of partnerships do

not lead to inappropriate inducements, versus those that are a violation of the original intent of the law, is a delicate balance. While it is clear that stakeholders will likely need to work together to make progress toward value-based care goals, it is also important that these partnerships do not lead to inappropriate inducements or unlawful business practices.

Considerations for implementing value-based contracting

Biopharma companies and health plans that have begun implementing value-based contracts in the private sector commonly cite several challenges to successfully executing such arrangements. These considerations would also apply if public payers adopt value-based contracting:

- **Determining the appropriate measures of value to link payment to.** Parties entering into a value-based contract should agree upon a definition of value that can be attributed to the use of drug therapy. This could include a demonstrated endpoint from clinical trials, an outcome that provider organizations are actively measuring under quality initiatives, or some other definition of value.
- **Capturing, integrating, and analyzing data.** Health plans and providers that enter into value-based contracts will likely need robust databases to track individual patients, their drug treatments, and outcomes. Collecting outcomes data may be easier in settings where it is already part of ongoing processes (e.g. quality initiatives), or where providers are more active in population management efforts such as patient-centered medical homes. Health plans would likely need to integrate and track this data through claims. Data validation and analysis would require collaboration and trust between the biopharma company and the health plan, and the companies should agree on methodology early in the process.³¹
- **Controlling for non-drug factors that can influence outcomes.** Other variables that could impact the outcomes of drug therapy include adherence, co-morbidities, and the use of utilization management tools by PBMs, such as step therapy or cost sharing. Utilization management tools could complicate value-based contracts by creating barriers to access, potentially limiting adherence of patients who might otherwise benefit from treatment. Biopharma companies may be reluctant to enter into value-based contracts if the entities do not implement mechanisms to evaluate or reduce the risks of these other variables. Value-based contracts may not be as appropriate for disease areas where patients are often prescribed multiple parallel treatment interventions, and may suffer from complicating comorbidities, such as diabetes.³²

New payment formula pilot for Medicare

Part B drugs

Policy overview

CMS released a proposed rule in March 2016 to pilot a new Medicare Part B payment formula to see if it changes physician prescribing and treatment patterns.³³ The goal is to reward positive patient outcomes and encourage prescribing of the most cost effective drugs. Medicare Part B covers prescription drugs administered in a physician's office or hospital outpatient department, such as cancer medications, injectables like antibiotics, or eye care treatments. Medicare Part B generally pays physicians and hospital outpatient departments the average sales price of a drug, plus a six percent add-on. The proposed model would test whether changing the add-on payment to 2.5 percent plus a flat fee payment of \$16.80 per drug per day changes prescribing behavior and leads to improved quality and value.

CMS plans to pilot the program described in the proposed rule for five years. The new payment formula—like the existing one—has two parts: a base amount per drug and a percentage amount tied to the drug's price. The pilot is a response to concerns that tying a large share of physician reimbursement to the price of the drug might encourage providers to prescribe more expensive drugs. The new formula would pay more in the base amount and less on price.

In the proposed rule, CMS also expressed interest in rolling out a second phase of the pilot that would test value-based payment arrangements, including indications-based pricing, reference pricing, and risk-sharing agreements based on outcomes. CMS is interested in exploring contracts that take into account improvement in outcomes over a previous standard of care, or that recognize that certain individuals may experience better results on a drug than on others (similar to the models described above that the private sector is currently exploring).³⁴ The indications-based pricing proposal test would vary payment for a

drug based on its clinical effectiveness for different indications. For example, a medication might be used to treat one condition with high success rates but an unrelated condition with less effectiveness, or require a longer treatment duration. The reference pricing model would test the practice of setting a standard payment rate—a benchmark—for a group of therapeutically similar drugs, while the risk-sharing agreements would allow CMS to enter into voluntary agreements with biopharma companies, to link patient outcomes with price adjustments.

Questions and potential unintended consequences

Could the change in payment formula result in some health care providers ceasing to furnish Part B specialty drugs, shifting patients to higher-cost sites of care to maintain revenue?

Initially, only certain parts of the country will be required to participate in the proposed pilot, allowing CMS to maintain a control group. Some critics of the proposed rule suggest that multi-practice providers might direct patients away from locations included in the program to those that are excluded. Some providers might shift patients into the hospital setting, especially hospitals that participate in the federal 340B drug discount program, to increase margins on administered drugs. Physician groups without these options might lose significant revenue, spurring them to consider consolidation or new business models.³⁵

For the longer-term parts of the pilot, there are many implementation questions. For example:

How would CMS determine the reference price, or indication-based prices of drugs? CMS describes reference pricing in the proposed policy as paying an average price for a group of drugs deemed to be therapeutically equivalent. Determining therapeutic equivalence would require thorough evaluation of clinical benefit and toxicity information as it would apply to the Medicare population.

How would CMS incorporate other factors, such as patient response and preferences? The government would likely need to thoroughly evaluate the evidence of the indication-based pricing models to determine price per indication based on outcomes achieved in each studied population. Several third party organizations, such as ICER, are developing approaches to determine the benchmark price of drugs (see sidebar on page 5, *Working to quantify drug value—what price is right?*). CMS referenced third parties such as ICER in its proposal, and it is likely that CMS would turn to these third parties to inform benchmarks, or indication-based prices.

Will the change in the payment formula encourage prescribing based on outcomes rather than cost? Some critics, including many patient groups, have expressed concerns that the update to the payment formula in Phase 1 would not change prescribing behavior, but instead negatively impact beneficiaries' access to treatment.³⁶ CMS notes that reimbursing based on a formula with less variable cost removes reimbursement uncertainty, enabling providers to make therapeutic choices based on outcomes. Critics argue that the new formula may incentivize providers to choose therapeutics based on lowest cost, rather than outcome, to maximize reimbursement revenue.

Who takes on the risk of value-based purchasing agreements under Part B—providers, biopharma companies, drug suppliers, CMS, or a combination of all parties?

Value-based contracts for drugs covered under the Part B would involve the provider, who would purchase the drug from a supplier and bill Medicare. Value-based purchasing under Part B might require sharing risk among the biopharma company, the provider, CMS, and even the drug supplier (usually a group purchasing organization).

Would CMS consider moving more costly drugs covered under Part D³⁷ over to Part B in order to more broadly implement value-based purchasing agreements?

Or, will value-based purchasing agreements spread into Part D? Payment changes to the Part B program might affect demand for drugs under Part D. Many complex disease areas are treated by a variety of drug options available through Part B and Part D. Private payers interested in taking advantage of the new payment model might lead the charge to increase adoption of value-based purchasing agreements more broadly.

Medicare price negotiation for Part D drugs

Policy overview

A growing number of policymakers and stakeholders, including the American College of Physicians, are proposing to allow Medicare to negotiate Part D drug prices.³⁸ Federal law prohibits the government from negotiating with the pharmaceutical industry on drug prices; instead, Part D plans (PBMs or Medicare Advantage plans) negotiate with pharmaceutical manufacturers over rebates and other discounts.

Implementation issues include deciding for which drugs negotiation would apply, and whether the negotiations would apply to both the drugs' price and formulary placement. One option is to only allow negotiations for drugs that cost more than a given price threshold. The Department of Health and Human Services (HHS) would also have to decide whether individual Part D plans could negotiate further with manufacturers or whether the Medicare-negotiated price would hold for all of them.³⁹

Questions and potential unintended consequences

How would CMS decide whether drug prices are deemed too high?

Some European countries sponsor cost-effectiveness research to aid in making this determination. ICER and other independent organizations in the US are developing value assessment frameworks, connecting measures such as clinical benefit, toxicity, and burden of disease to price (see sidebar on page 5, *Working to quantify drug value—what price is right?*). The methodology for these types of assessments varies by organization, and stakeholders still consider them experimental. Would Medicare invest in resources to conduct or improve these types of analyses?

What negotiating leverage could HHS exert with biopharma companies?

The Congressional Budget Office has said that the Secretary of HHS would not be able to negotiate lower prices than already exist without restricting access to medicines for beneficiaries through closed formularies.⁴⁰ Consumers would likely oppose any move that may reduce access to some medications.

Would Medicare's large patient population create more purchasing power than individual Part D plans have?

These plans combine their Medicare enrollees with other enrollees (including those with employer-sponsored coverage) in their negotiations. Which strategy would exert the greatest leverage on drug prices? Additionally, if biopharma companies have to offer significant discounts to Medicare, would they offset that loss of revenues by increasing prices for private health plans or PBMs? If they did, those entities might pass the higher prices on to consumers or limit access.

Implications for health care stakeholders

The health care system's transformation toward value-based care continues to gain momentum. The market landscape points to increasingly complex negotiations between biopharma companies and payers including government, health plans, and PBMs through new pricing mechanisms such as risk-sharing and outcomes-based agreements. The proposed policies described in this brief for getting better value in health care all have unanswered questions—finding consensus on how to determine value, figuring out the appropriate boundaries of partnerships between biopharma companies and providers or health plans, access challenges for patients—to name a few. In this evolving environment, what should the different health care stakeholders be most mindful of as they look to the future of drug pricing?

Biopharma Companies

- **Support conversations to advance data availability, transparency, and integration.**⁴¹ At its 2016 annual meeting, Pharmaceutical Research and Manufacturers of America (PhRMA) leaders touted a holistic approach for controlling health care costs, including a mix of reforms that would enable more information sharing with payers and providers. To effectively promote value-based health care, PhRMA urged regulators to allow manufacturers to share appropriate, scientifically sound information on products still in the pipeline to reduce payer uncertainty. Additionally, the group is advocating for the ability to share accurate and straightforward information on clinical and economic outcomes with payers and providers, such as when a drug has been shown to reduce hospital readmissions.⁴²

- **Engage health plans and providers in conversations to define appropriate structures for value-based contracting.** There is evident interest from biopharma companies, health plans, and the federal government to experiment and advance value-based contracting. The effectiveness of these arrangements for biopharma companies involves a clear payment or reimbursement mechanism, well-defined outcome measures, and transparent outcome reporting among physicians, health plans, and biopharma companies.⁴³

- **Reference real-world success factors when engaging in value-based contracting models.** Research on some real-world examples of risk-sharing arrangements show that success factors for biopharma companies typically include: having clear indicators (e.g. biomarkers) in place and being able to measure outcomes in a reasonable time frame; contracting on products that have clinical advantage over lower-cost competitors; and partnering with health plans and providers to ensure that the information technology infrastructure is in place to track and audit data and manage patient registries.⁴⁴

Health Plans and PBMs

- **Continue the focus on population health and patient-centered care.** Accountable care organizations and use of emerging payment models are helping health plans and providers align financial incentives to result in higher quality care. Health plans are also finding that increased use of medical homes and team-based medicine is an important way to engage patients and approach health care more holistically. In evaluating new models of care, health plans should likely take the total cost of care into consideration.
- **Identify effective strategies for communicating with providers so they can quickly adopt leading practices and achieve overall goals of accountable and high-quality care.** Health plans should aim for more proactive and collaborative processes with providers when making appropriate formulary decisions to make certain that clinicians are engaged and understand all pharmacy and therapeutics (P&T) committee⁴⁵ decisions.^{46, 47}
- **Offer benefit design strategies that engage consumers.** Health plans should continue using tools to educate their members about formulary tiers, use of generics, and questions they should ask their physician to encourage shared decision-making. In addition, to address affordability, health plans could further experiment with value-based benefit design, offering financial incentives for patients to choose

and maintain therapy with less costly, effective treatments. Other strategies include health plan programs that focus on prevention, wellness, and chronic care management.

- **Use PBM tools to encourage cost effective and generic medications.** PBMs should consider aiming to strengthen their role in understanding and monitoring each consumer's response to and therapies and gaps in care, and work to enable the most appropriate treatment for the right person at the right time.

Providers

- **Participate in shared decision making with patients.** Most physicians believe that out-of-pocket medication costs are an important factor when prescribing medications, and patients may ask advice from physicians on how to lower medication costs.⁴⁸ Further, cost is an important barrier to medication adherence.⁴⁹ Physicians can work with patients to determine the most appropriate treatment.
- **Consider cost in conjunction with outcomes in evidence-based clinical guidelines.** As discussions around drug pricing and affordability continue, physicians can leverage available information from independent groups such as AHA, ICER, ASCO, and others to inform decisions on which treatments to use in clinical practice.
- **Consider engaging in alternative payment models that capture drug costs.** As providers become more integrated and increase their role in bearing risk through regulations such as the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), value-based pricing agreements could align with provider goals.⁵⁰ Some payment models include the cost of drugs as part of a pre-defined reimbursement target for an episode of care, and new payment models also could incorporate the cost of drugs into their performance and quality scores. Engaging in these types of models will likely align financial incentives between health plans and providers and could help to achieve the goal of reducing cost while maintaining quality.

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