Barriers to Value-Based Contracts for Innovative Medicines

PHRMA MEMBER SURVEY RESULTS

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Executive Summary

As the US health care market is becoming more competitive, payers are increasing their demands for new medicines to demonstrate added value. In response, manufacturers have shown growing interest in pursuing a range of novel, "value-based" contract arrangements that tie payment to outcomes or otherwise reduce payer financial risk. A prior survey funded by the Pharmaceutical Research and Manufacturers of America (PhRMA) found payer interest in pursuing such contracts, but concern about potential regulatory and operational barriers.[1] This survey examined the extent to which innovative biopharmaceutical companies share these concerns and found similar concerns that regulatory and operational barriers limit expansion of value-based contracts. While more companies have been able to successfully navigate these challenges in recent years, reducing legal barriers could have significant benefit in expanding the number or scale of value-based contracts, which hold promise in improving access while reducing costs for patients, supporting better quality care and addressing payers' concerns about product value.

Introduction

The market for innovative medicines is becoming more competitive and in recent years has shifted to demand that new medicines demonstrate added value over competing products. In addition, new medicines must prove their benefit in a marketplace where nearly 90 percent of prescriptions are for generic medicines.[2] Highly consolidated payers have a range of tools at their disposal to limit access to medicines and control costs.[3] Physicians and other providers are increasingly accountable for the cost and quality of care provided to their patients and so they are critically evaluating the medicines they prescribe for patient use to ensure that they demonstrate value. Third party groups are conducting value-assessments and using real world data to make determinations about the relative benefits and costs of medicines. Innovative biopharmaceutical companies are responding to these pressures by finding new ways to demonstrate the value of their products.

Contracts that more closely tie payment for a new medicine to the outcomes it delivers, or otherwise reduce the risk borne by insurers, are a visible example of the approaches being taken by companies. A key example is outcomes-based contracts, where the final price is tied to actual performance on outcomes in a payer's population. Risk-sharing contracts include both outcomes-based contracts and other contracts where financial risk is shared but not tied to performance on outcomes. Another example is indication-based pricing, where the price varies based on the indication for which the drug is used in cases where the evidence suggests that the drug is more effective for one indication than another.[4]

The number of novel, value-based contracts between private payers and manufacturers in the United States has increased greatly in recent years – as evidenced by the increase in publicly announced risk-sharing contracts. Only 7 private sector risk-sharing contracts were announced from the late 1990s to 2013.[5] In contrast, 16 risk-sharing contracts were announced publicly from 2015 through early 2017 (See Figure 1).[6,7] Payers are interested in pursuing additional outcomes-based contracts in a range of therapeutic areas.[8] Other models, such as indication-based pricing are also being tested.[9]

The expansion of value-based contracts has a range of potential benefits. Patients can benefit from more affordable access to innovative medicines as these contracts often provide better formulary position, reducing copays or cost-sharing.[10] They may help ensure that a new medicine is provided with formulary access, rather than being blocked by the payer. Payers recognize the potential benefits of these contracts for understanding their patient population and subpopulation while working to improve overall health system affordability.[11] Such contracts can support better real world understanding of product benefits, supporting more effective use of medicines to improve health outcomes.

Despite clear stakeholder interest in pursuing more value-based contracts, a range of factors limit their number and scale. To better understand these factors, PhRMA funded two surveys, one on payers' perspectives and a second on our members' perspectives. The first survey was released in a Health Affairs Blog late last year.[12] It found that concerns about the anti-kickback statute, FDA regulation of manufacturer communications, and government price reporting rules were the greatest barriers limiting proliferation of these contracts. This white paper contains the results of the second survey.

Figure 1: Risk-Sharing Arrangements Reported in the Media from 2015 to Early 2017

Drug	Manufacturer	Payer	Year Announced
Enbrel (etanercept)	Amgen	Harvard Pilgrim	2017
Forteo (teriparatide)	Eli Lilly	Harvard Pilgrim	2017
Januvia (sitagliptin) and Janumet (sitagliptin/metformin)	Merck	Aetna	2016
Trulicity (dulaglutide)	Lilly	Harvard Pilgrim	2016
Entresto (sacubitril/valsartan)	Novartis	Harvard Pilgrim	2016
Entresto	Novartis	Aetna	2016
Entresto	Novartis	Cigna	2016
Repatha (evolocumab)	Amgen	Cigna	2016
Praluent (alirocumab)	Sanofi, Regeneron	Cigna	2016
Iressa (gefitinib)	AstraZeneca	Express Scripts	2016
Repatha	Amgen	Harvard Pilgrim	2015
Repatha	Amgen	CVS Health	2015
Repatha	Amgen	Prime Therapeutics	2015
Harvoni (sofosbuvir/ledipasvir)	Gilead	Cigna	2015
Praluent (alirocumab)	Sanofi, Regeneron	Prime Therapeutics	2015
Viekira Pak (Dasabuvir, ombitasvir, paritaprevir and ritonavir)	Abbvie	Express Scripts	2015

Results

Results are presented for the following three types of value-based contracts:

- **Outcomes-based contracts:** Designed to tie costs or discounts to patient outcomes.
- **Indication-specific pricing contracts:** Payments vary based on efficacy of different indications, as defined by the contracting entities.
- **Expenditure cap contracts:** Limit drug costs to a certain negotiated threshold; this has been implemented as a version of indication-specific pricing for infused cancer drugs.[13]

For all contract types, the treatment goals, outcomes, or other clinical or economic endpoints, were defined as agreed to by the private contracting entities. Some of these contract types may also include support services for data collection, treatment adherence, or contract adjudication. These contracts are not intended to be an exhaustive list of all possible value-based contract types that do, or could, exist in the private market. Our analysis focused on potential barriers that were identified as a high or very high importance by one-third or more of survey respondents, and therefore could be considered an actual barrier to expansion of these contracts.[a] Figure 2 lists the barriers identified.

Based on the survey results, the top legal/regulatory barriers include concerns about how the contract might affect price reporting metrics, concerns about potentially implicating the federal anti-kickback statute, and concerns or uncertainty about Food and Drug Administration (FDA) regulations regarding clinical or economic outcomes claims.

The top operational barriers include those related to measurement and payer incentives – inability of the payer, manufacturer or third party to measure outcomes, lack of payer culture of and capabilities for measuring outcomes, and payer access to both medical and pharmacy data. While operational barriers can be addressed by improvements in the market place – through efforts to improve data collection and deploy better tools for measuring outcome in particular – legal and regulatory barriers should be addressed through government policy change.

[a] For the purposes of this survey, the term "barrier" was defined so that it did not necessarily mean an obstacle so large that it prevents the contract; a barrier could also be a concern that reduces the degree of interest in an arrangement, or an uncertainty about a legal question, requirement, or process associated with the arrangement that can lead the parties to structure the arrangement in a manner that does not maximize its potential benefit.

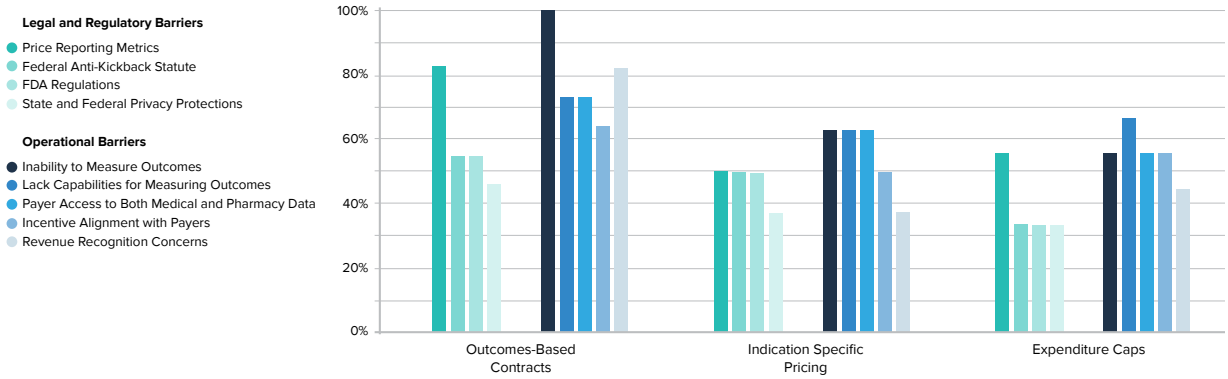
Figure 2: Barriers to Expanded Value-Based Contracts

Description of "Barrier" from Survey Instrument	Number (Percent) of "High" or "Very High" Responses (n=28)*
Legal / Regulatory	
Concern or uncertainty about how the contract might affect **price reporting metrics** (e.g., *Medicaid Best Price, Average Sales Price, Average Manufacturer Price*)	18 (64%)
Concern about potentially implicating the federal **anti-kickback statute** (which generally prohibits providing something of value in return for Medicare or Medicaid business) or uncertainty about how to structure the arrangement to ensure compliance with the anti-kickback statute	13 (46%)
Concern or uncertainty about **FDA regulations** concerning clinical or economic outcomes claims	13 (46%)
Concern about ensuring compliance with state and federal privacy protections (e.g. *HIPAA*)	11 (39%)
Operational	
Inability of payer, manufacturer, or third party to measure outcomes	21 (75%)
Lack of payer culture of and capabilities for tracking and measuring outcomes, especially claims data	19 (68%)
Payer access to both medical and pharmacy data	18 (64%)
Incentive alignment with payers (e.g., *overall spending by payers, payer interest in long-term outcomes benefits, payer willingness to engage*)	16 (57%)
Revenue recognition concerns (e.g., *manufacturer accounting system ability to pay back or delay payment intake for product sold*)	16 (57%)

*This sample size reflects 11 participants responding to questions on *Outcomes-Based Contracts*, 9 responding to questions on Expenditure Caps, and 8 responding to questions on Indication-Specific Pricing Arrangements. This created 28 data points per barrier across the three contract types.

Figure 3 shows the number of companies ranking each barrier as high or very high importance, by contract type.

Figure 3: Share of Companies Ranking Barrier as "High" or "Very High" Importance, By Contract Type



The survey results show that there are greater barriers associated with contracts tied to measuring a drug's actual effect in a payer's patients, when compared with contracts where payment does not vary based on patients' real world experience. The challenges associated with contracting approaches that vary payment according to actual outcomes in a payer's population have also been recognized elsewhere.[14] The significant increase in outcomes-based and risk-sharing contracts highlighted earlier in this paper reflects commitment of individual biopharmaceutical companies to navigate these challenges. However, it is very possible that the level of risk-sharing is still limited by the barriers identified by survey respondents.

Discussion and Recommendations for Major Barriers

Price Reporting Metrics

By law, drug manufacturers must calculate and report to the federal government various drug pricing metrics that affect the drug's payment rate or the manufacturer rebate in certain government programs (e.g., Medicaid Best Price, Average Sales Price, or Average Manufacturer Price). Uncertainty about how the contract might affect price reporting metrics was identified as a top legal/regulatory barrier across contract types. The complex and highly technical government price-reporting rules were established long before the introduction of new approaches to contracting. While price-reporting rules do permit biopharmaceutical companies to make reasonable assumptions, to the extent there is ambiguity about how to capture innovative contracting methods, this can create uncertainty for biopharmaceutical companies. Value-based contracts in the private market necessitate a more modern and flexible approach to price reporting.

Anti-Kickback Statute

Concern about potentially implicating the federal anti-kickback statute or uncertainty about how to structure the arrangement to ensure compliance with the anti-kickback statute was also identified as a substantial barrier across contract types. The anti-kickback statute is broadly written. While it was designed to achieve the important goal of deterring health care fraud, it may also inadvertently thwart beneficial innovative programs that present low risk of fraud and abuse and could lead to better patient outcomes and significant savings for our health care system. Legislative exceptions and regulatory safe harbors were created to protect beneficial arrangements under the anti-kickback statute; however the key safe harbor regulations for manufacturers were developed over twenty years ago, and did not anticipate the market's shift to value-based payment and contracting. Value-based contracts should have clear protection under the anti-kickback statute.

FDA Regulation of Manufacturer Communications

This survey was conducted before the FDA released two new draft guidance documents, including draft guidance on communications with payers and formulary committees.[15] This draft guidance states that FDA "does not regulate the terms of contracts between firms and payors." However, it does not address many of the communications that may take place in the contracting negotiations, does not address pre-approval discussion of new indications of marketed products, and leaves ambiguity about the extent and substance of discussions prior to new product approvals in order to facilitate timely post-approval access for appropriate patients. Thus, although the draft guidance provides some helpful clarification to manufacturers on FDA's current viewpoint on payer communications, the guidance leaves many questions unanswered, so further change is needed.

Operational Barriers

A range of measurement challenges were identified as the primary operational concerns across contract types – from difficulty in measuring the outcome, to payer data limitations and lack of payers' incentive or culture to supports measurement of outcomes. Prioritization of these challenges by survey respondents demonstrated the importance of ongoing efforts to improve measurement of health outcomes, including development of patient-centric and patient-reported outcomes. It also suggests an ongoing need to improve data systems to reduce the burden of outcome measurement. Many organizations are working to address these challenges and build a system that can support expansion of value-based contracting for biopharmaceuticals and broader development of a value-driven healthcare system.

Conclusion

Significant barriers identified by biopharmaceutical manufacturers limit the number and scale of value-based contracts in the private market. At the same time, the recent increase in risk-sharing contracts suggests that companies are willing to engage in these contracts to the degree currently allowed under existing laws and regulations. The survey results indicate that contracting approaches that vary payment based on outcomes within a payer's population are more difficult to implement than other approaches. Public policy changes to address legal barriers could allow a greater diversity of contracting approaches and foster more contracts or a greater degree of risk sharing. Expansion of these contracts can benefit patients by supporting better access to medicines and encouraging continued development of new, high value therapies.

Sources

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