

Value-Based Arrangements May Be More Prevalent Than Assumed

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The US health system faces increasing pressure to improve patient access to highly effective, yet costly, therapies. In line with the broader policy shift toward alternative payment models for healthcare delivery, there is ongoing interest among payers and manufacturers in exploring value-based payment arrangements (VBAs) for pharmaceuticals and medical devices. VBAs, also referred to as “outcomes-based contracts,” “performance-based contracts,” or “risk-sharing agreements,” link coverage, reimbursement, or payment for a product to a prespecified clinical or financial/utilization outcome or set of outcomes. VBAs can include contractual arrangements among manufacturers, payers, and providers to achieve these aims. For example, such arrangements could entail a rebate provided by the manufacturer to the payer when a drug or device does not perform as expected.¹ VBAs have been discussed in the media and in the academic literature for drugs that treat hyperlipidemia, chronic heart failure, rheumatoid arthritis, and osteoporosis, among others.²⁻⁴

Despite growing interest in and discussion of VBAs, there is relatively limited information currently available on the extent to which these arrangements are being pursued. A lack of public knowledge of these arrangements could (1) underestimate their use in the market and (2) limit what could potentially be learned from current experience that would advance the design and implementation of successful VBAs in the future. Recent research based on publicly available information suggests that a relatively small number of VBAs have been implemented in the United States (approximately 26), pointing to a range of contractual, procedural, and regulatory barriers that could impede their pursuit and implementation.^{3,4} Another study found that among 35 payers and 30 manufacturers, the average numbers of total pending/executed VBAs were 5.1 and 3.5, respectively, between 2012 and 2017.⁵ This study aimed to better understand VBAs in the United States, including both public and nonpublic arrangements, with a particular focus on gaining insights into their negotiation, operationalization, and impeding or success factors from the perspectives of manufacturers and payers.

ABSTRACT

OBJECTIVES: To better understand the prevalence of US value-based payment arrangements (VBAs), their characteristics, and the factors that facilitate their success or act as barriers to their implementation.

STUDY DESIGN: Surveys were administered to a convenience sample of subject matter experts who were senior representatives from payer organizations and biopharmaceutical manufacturers. These data were supplemented with qualitative interviews in a subsample of survey respondents.

METHODS: Descriptive statistics, including percentages for categorical values and mean (SD) and median (interquartile range) for continuous variables, were assessed for quantitative questions. Trained reviewers collated responses to free-text survey questions and the qualitative interviews to identify themes.

RESULTS: Of the 25 respondents, 1 manufacturer and 4 payers reported not having explored or negotiated any VBAs. Subsequently, questionnaire results from 11 biopharmaceutical manufacturers and 9 payers who had experience with VBAs were analyzed. More than 70% of VBAs implemented between 2014 and 2017 were not publicly disclosed. Furthermore, although consideration of VBAs as a coverage and payment tool is increasing, VBA implementation is relatively low, with manufacturers and payers reporting that approximately 33% and 60% of early dialogues translate into signed VBA contracts, respectively. Respondents' reasoning for VBA negotiation process breakdowns generally differed by sector and reflected each sector's respective priorities.

CONCLUSIONS: This study reveals that the majority of VBAs are not publicly disclosed, which could underestimate their true prevalence and impact. Given the effort required to implement a VBA, future arrangements would likely benefit from a framework or other evaluative tool to help assess VBA pursuit desirability and guide the negotiation and implementation process.

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METHODS

Study Participants

This study used 2 data sources: an online survey and in-depth qualitative interviews. Target survey participants were subject matter experts from a cross-section of payer and biopharmaceutical companies and were identified through a snowball sampling technique based on existing working relationships, recommendations from others within the field, and internet searches. Senior representatives from 38 payer organizations and 37 biopharmaceutical manufacturers were invited to participate between September 2017 and January 2018. Of those invited to participate, 26 representatives (13 each from biopharmaceutical and payer organizations) agreed to participate in the survey (response rate, 35%). Respondents were contacted for clarification when necessary to ensure validity of responses. Subsequently, 1 biopharmaceutical company's responses were excluded due to a lack of response consistency, resulting in 25 analyzed respondents. Qualitative interviews, conducted with a subsample of survey participants, included 3 payers and 5 manufacturers. Study participants were not compensated for their participation.

Data Collection

First, we conducted an online survey using Qualtrics ([eAppendix A](#) [eAppendices available at [ajmc.com](#)]). This survey, informed by a literature review and expert opinion, was designed to assess the key characteristics and proportion of public and nonpublic VBAs pursued between 2014 and 2017, as well as the factors that led to successful or, alternatively, challenged arrangement implementation. To guide exploration of VBA pursuit, we developed a process map describing 4 phases whereby manufacturers and payers (or providers) negotiate the terms of the arrangement, including (1) internal assessment and information gathering, (2) early dialogue, (3) formal negotiation, and (4) contract implementation ([eAppendix B](#)). The process map and the survey were piloted and refined based on feedback from 5 experts representing both payer and biopharmaceutical organizations. Second, we conducted in-depth qualitative interviews with a subsample of survey respondents to expound upon key survey findings and address any gaps in information collected in the first phase of the study.

Data Analysis

Descriptive statistics were assessed for each survey question by sector, including percentages for categorical values and mean (SD) and median (interquartile range) for continuous variables. A trained senior researcher (E.R.) collated responses to free-text survey questions and the qualitative interviews to identify key themes and substantiate main findings from the quantitative analysis, which were then vetted by the research team.

TAKEAWAY POINTS

Little information is publicly available about the number and characteristics of value-based payment arrangements (VBAs) between biopharmaceutical manufacturers and payers, as well as the underlying reasons organizations do or do not enter these arrangements.

- ▶ Previous estimates of VBAs, using only publicly available data, likely underestimate how many VBAs are currently being implemented.
- ▶ Given the effort required to implement a VBA, future arrangements would likely benefit from a framework or other evaluative tool to help assess VBA pursuit desirability and guide the negotiation and implementation process.

RESULTS

Respondent Characteristics

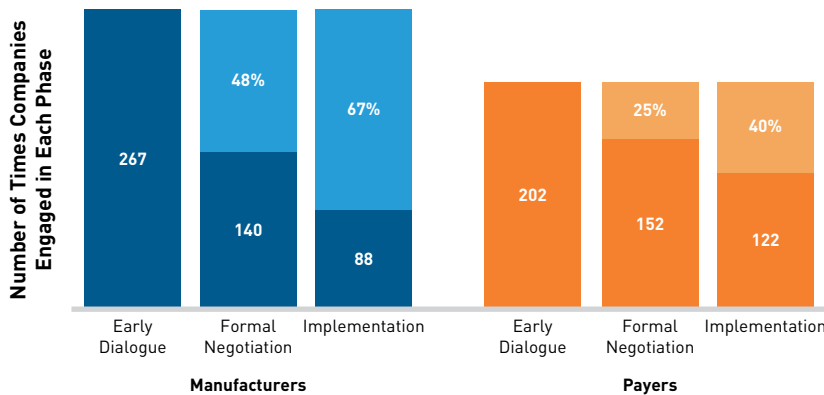
Of the 25 respondents, 1 manufacturer and 4 payers reported not having explored or negotiated any VBAs. Subsequently, questionnaire results from 11 biopharmaceutical manufacturers and 9 payers who had experience with VBAs were analyzed. Manufacturer respondents included 9 large firms ($\geq 10,000$ employees and annual revenues higher than \$15 billion) and 2 medium-sized firms (5000-10,000 employees and revenues between \$2 billion and \$10 billion). Payer respondents included 1 single-state payer, 2 regional payers, and 4 national payers covering approximately 76 million lives. Of these payers, 6 offered both commercial and Medicare Advantage plans, and 1 was a public insurance contractor. There were also 2 pharmacy benefit managers covering an estimated 103 million lives.

Existing VBA Landscape

Manufacturer and payer respondents reported implementing (phase 4) a total of 88 and 122 VBAs since 2014, respectively. However, there was considerable within-group variation in terms of the number of VBAs per firm, with manufacturers ranging from 1 to 15 implemented contracts (median of 9 contracts) and payers ranging from 1 to 40 implemented VBAs (median of 11 contracts) ([Figure 1](#)). Manufacturers and payers also reported that a majority of their company's VBAs are not publicly disclosed (74% among manufacturers and 71% among payers). Additionally, 5 manufacturer and 2 payer respondents reported that none of their company's VBAs are publicly disclosed ([Figure 2](#)). Respondents reported that laboratory value, medical encounter (eg, hospitalization rate/duration), financial, and drug utilization measures are the most common outcomes used in VBAs, whereas the most common payment mechanisms involved the manufacturer paying some portion of supportive product costs or providing a larger rebate or full refund to the payer if target outcomes were not achieved ([Table](#)).

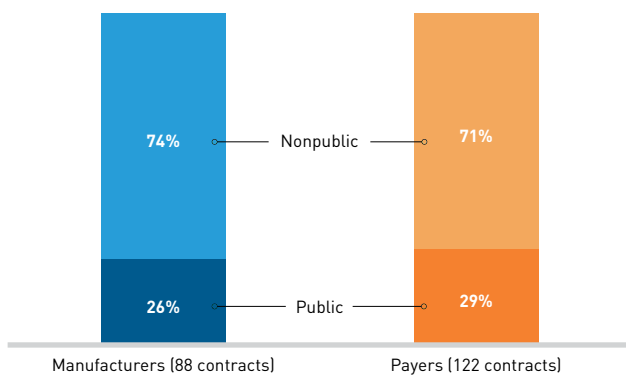
Both payer and manufacturer respondents also highlighted that there were no preferred therapeutic areas for VBAs, but rather that several factors make certain therapeutic areas (eg, asthma, cardiovascular disease, multiple sclerosis, hepatitis C, and diabetes) prime for VBAs, including validated and easily measured outcomes, uncertain value for high-cost products, limited competition, and availability of a diagnostic tool (eg, genetic testing) (results not displayed).

FIGURE 1. Reported Experience With VBA Contracting Since 2014, by Sector



VBA indicates value-based payment arrangement.

FIGURE 2. Proportion of Public and Nonpublic VBAs, as Reported by Payers and Manufacturers, 2014-2017



VBA indicates value-based payment arrangement.

Direct provider engagement in VBAs is limited to date; only 3 manufacturers and 1 payer reported having engaged providers directly (eAppendix B). However, 91% of manufacturers and 78% of payers believe that incorporating providers is important for the future success of VBAs. Only 1 payer and 1 manufacturer reported that they have implemented a VBA in which a patient is reimbursed out-of-pocket costs for outcome failure. In contrast, patient adherence was a VBA component used by all payers and all but 1 manufacturer. Patient adherence was most commonly incorporated into VBAs by manufacturers and payers through patient selection (VBA only includes patients who have met a certain level of adherence) (55% and 63%, respectively), outcome terms (payment is explicitly tied to improvements in adherence [eg, proportion of days covered, medication possession ratio, and discontinuation]) (27% and 25%, respectively), and payment trigger (outcomes-based component does not take effect unless a certain adherence rate is achieved in the patient population) (18% and 38%, respectively).

Characterizing the VBA Negotiation and Implementation Process

The number of VBAs by sector in each stage of the negotiation and implementation process is detailed in the Table. The attrition rate across stages was high for both sectors. Manufacturers reported that only about one-third of the early dialogues conducted (ie, where 2 parties come together to informally discuss a potential arrangement) ultimately resulted in contract implementation. Payers reported that about 60% of the early dialogues with manufacturers resulted in VBA implementation.

Understanding VBA Negotiation Breakdown and Success

Respondents' reasoning for VBA negotiation process breakdowns generally differed by sector and reflected each sector's respective priorities (Figure 3). For example, manufacturers cited challenges related to data collection and evidence development (73%), the availability of appropriate outcome measures (64%), and implementation costs (64%) as major reasons for negotiation failure, whereas payers cited disagreement over incentive mechanisms tying payment to outcome (56%) and financial terms associated with the arrangement (67%). Both groups (64% of manufacturers and 78% of payers) cited Medicaid Best Price (generally, that a manufacturer must offer Medicaid programs the lowest or "best price" based on what is available to other purchasers) as a major reason for negotiation failure.⁶ In their top 5 negotiation success factors, both manufacturers and payers identified (1) the availability of measurable outcomes clearly tied to product use (82% and 100%, respectively), (2) a target patient population that is easily identified in claims (73% and 63%, respectively), and (3) a reasonable administrative burden (45% and 38%, respectively) (Figure 4). Manufacturers also prioritized having partners with the necessary data collection and analysis capabilities (91%), whereas payers emphasized the potential for high budget impact (75%) and having a reasonable data collection and analysis time frame (63%).

DISCUSSION

This study aimed to gain a better understanding of the prevalence and characteristics of public and nonpublic VBAs and to assess where in the negotiation and/or implementation process these arrangements fail and why. Importantly, we found that VBAs are far more prevalent in the United States than previously estimated, based on our sample of respondents. Manufacturer and payer respondents in our convenience sample reported having implemented (phase 4) a total of 88 and 122 VBAs, respectively, between 2014 and 2017. Significant variation in the number of contracts reported by each company was observed, suggesting that some companies may have more success than others in navigating the

complexities of these arrangements. Both payer and manufacturer respondents reported that a majority of these contracts are not publicly known. This demonstrates that a substantial proportion of the activity related to tying payment to outcome measures is happening behind the scenes, which should be considered when evaluating the uptake and success of the broader movement to tie payment to value. However, when contemplating policy decisions associated with value-based payment, it is also important to contextualize the magnitude and potential of VBAs compared with more traditional payer–manufacturer contracts such as rebates (eg, success of VBAs in addressing health spending if they represent only a small proportion of overall contracts).

Follow-up interviews with payers and manufacturers suggested that publicizing VBAs can be beneficial, allowing a company to signal to customers and the public at large that value is an important issue for them, that they are at the forefront of the drug pricing debate, and that they have credibility and enough experience to advance value-based payment discussion and policies. However, the high proportion of nonpublic agreements indicates that many companies believe that the risks associated with publicly announcing a VBA, such as exposure to public scrutiny or yielding competitive advantage, outweigh the benefits. Additionally, contracts between manufacturers and payers are not typically publicly announced, and companies may be unwilling to challenge this norm.

Based on our analysis, successful VBAs—in which initial discussions between interested parties resulted in implementation of an arrangement—possess a range of similar characteristics, namely the availability and measurability of outcomes, uncertain value for high-cost products, and clear patient identification (eg, diagnostic tools), which have been corroborated in previous studies.^{3,7,8} The considerable discrepancy in the reported proportion of early dialogues that ultimately led to contract implementation between the 2 sectors was surprising, and it is unclear why payers report a higher rate of negotiation success. This could be due to certain limitations of our study, detailed later, or differences in interpreting negotiation success, but it could also reflect the relative importance of payer buy-in to achieve VBA implementation.

Although many contracts have indeed been implemented to date, this study underscores the significant effort required to successfully progress through all 4 VBA process phases. Manufacturers and

TABLE. Outcome Measures and Payment Mechanisms Used in VBAs, by Sector, 2014-2017

	Manufacturer		Payer	
	Total VBAs (n = 88)	Company (n = 11)	Total VBAs (n = 122)	Company (n = 8 ^a)
Outcome measure				
Laboratory measures	25	5	19	6
Imaging measures	0	0	1	1
Other biomarker measures (eg, cytogenetic testing)	0	0	1	1
Survival	8	3	8	2
Disease progression	9	3	6	2
Symptom improvement	1	1	0	0
Other nonbiomarker clinical measures (proprietary)	0	0	10	1
Medical encounter process measures	8	3	15	5
Financial measures	13	3	28	4
Drug utilization measures	34	8	42	7
Other ^b	5	2	11	2
VBA incentive mechanisms				
Larger rebate to payer	70	10	85	6
Full refund to payer	13	3	6	2
Full or partial coverage of corrective services by manufacturer	0	0	2	2
Manufacturer receives bonus payment from payer	6	3	1	1
Manufacturer pays some portion of supportive product costs (eg, data analytics, follow-up testing)	6	1	18	1
Other ^c	0	0	19	2

VBA indicates value-based payment arrangement.

^aOne payer who responded to previous questions did not answer this question.

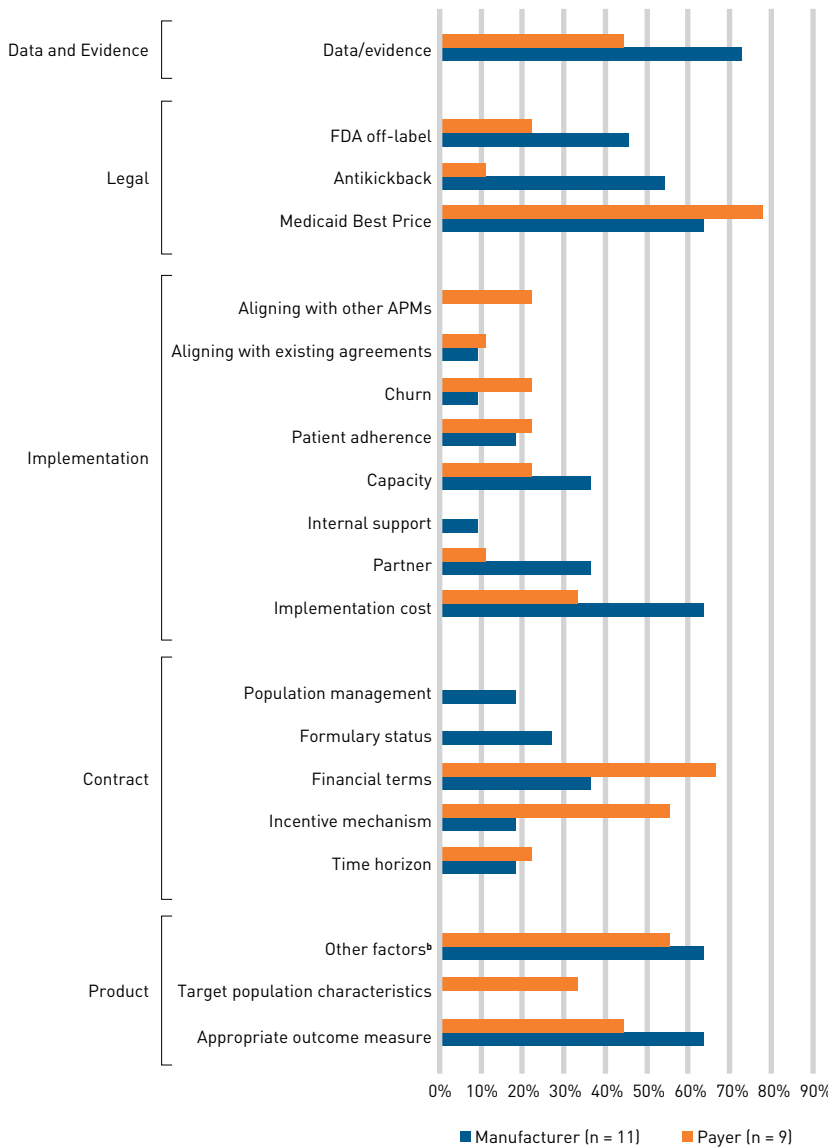
^bOther types of outcome measures reported included persistency, relapse-free rate, total cost of care, polypharmacy reduction, medical cost savings, and channel management.

^cOther types of incentive mechanisms reported included an early discontinuation credit and “superior care model.”

payers reported that approximately 67% and 40% of early dialogues, respectively, do not reach implementation. Next, we discuss a number of major barriers that were highlighted that impede successful negotiation and implementation of VBAs, supporting previous findings.³⁻¹⁴

First, both payers and manufacturers mentioned the need for clarification, and potential reform, of certain legislation and regulation, most notably the Medicaid Drug Rebate Program’s Best Price calculation requirement.⁶ Second, both payers and manufacturers indicated that data collection and analysis issues pose a significant challenge to VBA implementation due to a lack of data infrastructure, which could be addressed through common data standard principles to allow for not only interoperability across platforms for data of the same type (eg, electronic health record

FIGURE 3. Major Reasons for Failure of VBA Negotiation, by Sector, 2014–2017^a



APM indicates alternative payment model; VBA, value-based payment arrangement.

^aOther challenges reported by manufacturers included lack of payer buy-in/risk-bearing. Other challenges reported by payers included return on investment and manufacturer risk-bearing.

^bOther product-related reasons listed by manufacturers included low market share, reliability issues resulting from small population size and effect size, and that the best outcome for measurement was not in label. Other product-related reasons listed by payers included low potential savings and information availability.

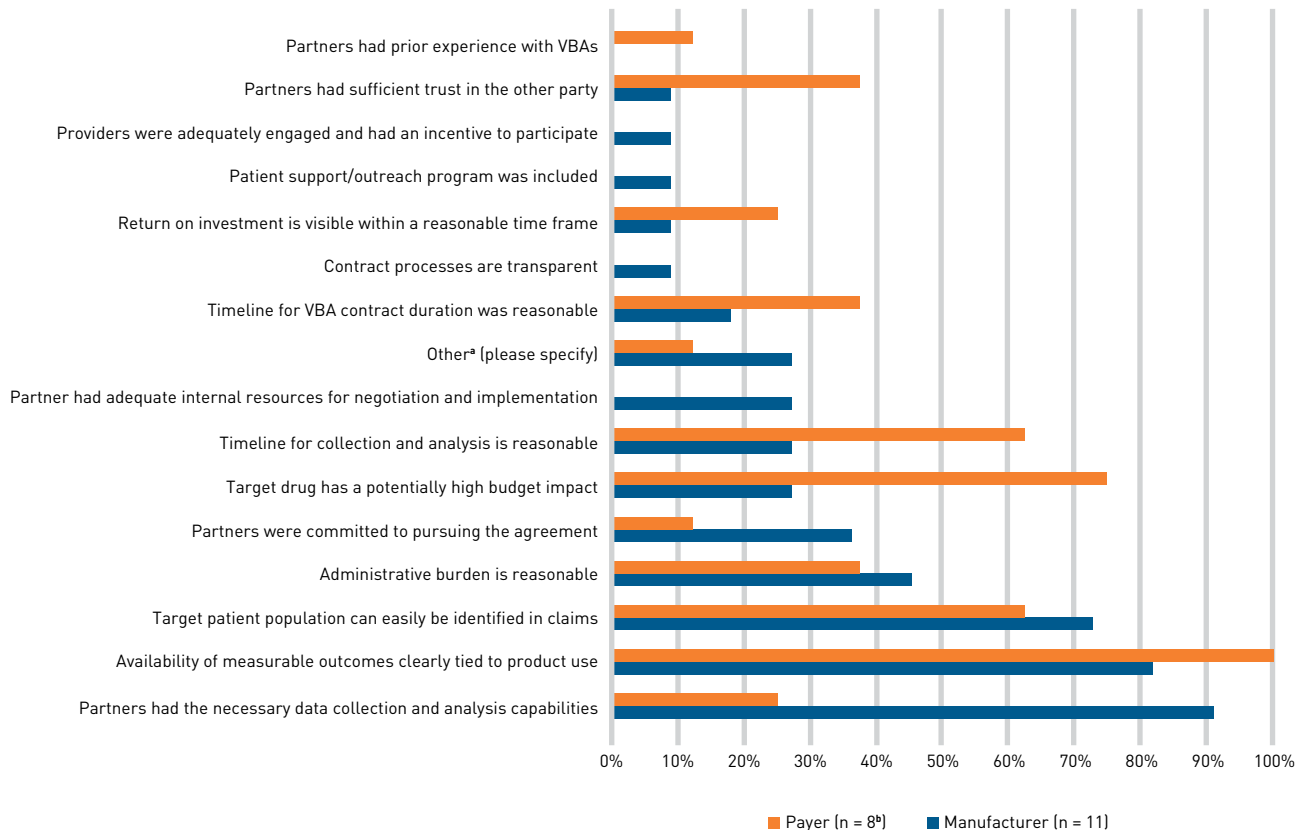
[EHR] data) for aggregation, but also linking across data types (eg, EHR, laboratory, and claims data).^{3-5,10-13,15} Notably, in the follow-up interviews, all respondents predicted that enhanced data sharing/analytic capabilities would result in not only more VBAs, but also more sophisticated arrangements. In the interim, and perhaps even as more advanced evidence-generation capabilities exist, respondents emphasized that contracts should be designed as simply as

possible, including the data collected, outcomes measured, time horizon, and contract terms (eg, payment structure). Third, aligning with prior studies, follow-up interviews revealed that a lack of trust and understanding between payers and manufacturers can impede the negotiation process, particularly disagreement resolution.^{7,9} As a result, stakeholders often partner with organizations with which they have a history of positive, successful relationships to mitigate this risk. In new partnerships, it is essential to establish mutual trust by being transparent with regard to respective goals, notably in the early negotiation stage, which may be facilitated by using frequent communications.¹² Additionally, to enhance trust, partners may consider either working with a third party to research, design, implement, and validate the VBA, or involving a greater range of stakeholders.^{7,8,12} For example, we found that most VBAs are between a payer and a manufacturer, with limited provider and patient partnerships. Increased provider engagement may enhance shared accountability and data measurement, but it could also introduce conflicts between new and existing provider-risk agreements, including alternative payment models, as well as add complexities to the contract negotiation process due to lack of medical benefit/pharmacy benefit integration.

Although patient adherence was frequently used as a VBA component (eg, for patient selection), follow-up interviews suggest that there is uncertainty about whether VBAs improve patient outcomes or benefit patients more broadly, at least in terms of how they are currently designed and executed. For instance, existing VBAs appear to rarely integrate patient-reported outcomes and/or incorporate avenues for patients to share in any savings associated with the arrangement. Greater patient involvement could perhaps address this concern and align with broader efforts to mitigate high patient out-of-pocket costs. As an example, United Healthcare/OptumRx, CVS Caremark, and Express Scripts publicly announced recently

that rebates would be directly shared with certain beneficiaries at the point of sale.¹⁶⁻¹⁹

Overall, this study suggests that the VBA process is complex, requiring different points of alignment to successfully progress throughout all 4 of the suggested phases. As investment in these contracts by payers and manufacturers continues to increase, further research is needed to understand the scope, processes,

FIGURE 4. Key Factors for Successful Negotiation and Implementation of VBAs, by Sector, 2014-2017

VBA indicates value-based payment arrangement.

*Other success factors reported by manufacturer respondents included clinically differentiated products, the ability to demonstrate value, and flexibility/responsiveness. Other success factors reported by payer respondents included that the target population or therapeutic category has the potential to significantly impact overall healthcare costs if treated appropriately.

^bOne payer who responded to previous questions did not answer this question.

and impact of VBAs. The study also highlights additional areas for future research, including the development and collection of VBA outcome measures, incentive mechanisms for participation, and the potential feasibility and impact of provider and patient incorporation into VBAs. However, focusing solely on publicly known VBAs greatly underestimates their prevalence and potential impact in the market, highlighting the need for research on all VBAs in a manner such that organizations can be transparent without disclosing confidential information. More transparent information exchange may also enhance trust among involved stakeholders and broaden participation in VBAs to providers and patients, where warranted. Additionally, more open discourse could help navigate the potential for overlapping contracts to enhance potential collaboration and efficiency of value-based payments.

Considering the various barriers along the path to implementation, it may also be beneficial to develop a tool or guidance document that can help manufacturers and payers assess the desirability of pursuing a VBA and optimize the difficult negotiation process. In

particular, such a planning or evaluation tool could outline key components of a VBA (eg, technology characteristics, data collection and outcome measurement plan, level of risk) to consider at different phases of the process, with a view to highlight those features known to facilitate success. Furthermore, given the current diversity in VBAs, including how they are defined and conceptualized, a guidance document or the like could support greater consistency and quality across arrangements, reduce administrative burden, and increase adoption of VBAs throughout the healthcare system. As more information on VBAs becomes publicly available, such a tool or guidance can be refined and/or expanded to accommodate different types of VBAs.

Strengths and Limitations

Although there are several strengths to this study—including that it is the first study, to our knowledge, that focuses on understanding the extent to which these arrangements are being fully disclosed to the public and made transparent—there are limitations. Generalizability

of these results may be limited because the questionnaire was administered to a small convenience sample with a low response rate, and the follow-up interviews were conducted on a selection of this sample. Next, although we provided a definition of VBAs and a framework for the negotiation and implementation process, there may be heterogeneity in respondents' interpretations. Additionally, the questionnaire collected information only on newer VBAs administered from 2014 to 2017 to provide a feasible and realistic range for respondent recall. However, given that we collected information only from 2014 to 2017, we likely have not captured the full trajectory of previous or impending VBAs. Finally, the extent to which there was overlap between the contracts reported by manufacturers and the contracts reported by payers is unknown. To address this limitation, we surveyed a sample of both payers and manufacturers independently to cross-check validity and corroborate responses.

CONCLUSIONS

As VBAs are still broadly in the experimental stage, their ability to deliver on their promise (ie, increased value and/or improved patient outcomes) is yet to be determined. However, it is important to recognize the progress made in transitioning from volume- to value-based payment. This study reveals that the majority of VBAs are not publicly disclosed. Focusing solely on publicly known VBAs greatly underestimates the prevalence and potential impact of these arrangements in the market, highlighting the need for research on the proportion of VBAs among more traditional rebate contracts in a manner such that organizations can be transparent without disclosing confidential information. Although many negotiations never lead to a signed agreement, pursuit of these arrangements increasingly occurs between payers and manufacturers, highlighting that value considerations are being incorporated into stakeholder decision making. Our study identified several opportunities to address outstanding barriers to VBAs and further accelerate the transition toward value-based payment for biopharmaceuticals. Given the amount of work required, future negotiations would likely benefit from a framework or other evaluative tool that can help manufacturers and payers to assess the desirability and feasibility of pursuing a VBA for a product. ■

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Survey on Value-Based
Agreements for Medical Products

September 2017

Survey Objective

Over the last decade, there has been increased interest among biopharmaceutical manufacturers and health insurers in implementing value-based, performance-based, and/or outcomes-based agreements, all of which link payment for a biomedical product to achieving measurable performance or clinical outcomes. Prior research on publicly known agreements has revealed a number of technological, methodological, regulatory, and operational challenges to their successful implementation. However, additional insights may be gained from agreements that are not public or those which were considered but not ultimately executed.

This project aims to learn from those experiences. More specifically, the purpose of this survey is to gain a better understanding of the structures and processes of both public and non-public value-based payment agreements, the factors related to success of some, and the reasons others did not reach implementation. Learning from these experiences can help researchers, policy experts, and health care decision-makers better design and engage in efforts to achieve higher value care and better outcomes for patients through payment arrangements. Findings from this research project will be published in a peer-reviewed journal, and will also inform the ongoing work at the Duke-Margolis Center for Health Policy around value-based payment for medical products.

Note: This survey is not intended to gather commercially sensitive information, and individual responses will be kept confidential. You should feel free to pause and consult with your colleagues if you are unable to answer all questions on your own. If you need to close the survey and come back to it, you may return to where you left off by clicking on the same link we sent to you. After you reach the end of the survey and submit your responses, you will be unable to come back and edit them. Questions that must be answered before you can move forward in the survey are indicated with an asterisk (*). We would be grateful if you provide as much information as you can for all questions. We estimate that it will take 20-30 minutes for you to complete the survey (if you already have all the needed information at hand).

Q1*. Which segment of the healthcare industry does your organization belong to?

- Biopharmaceutical company
- Payer

Now we’re going to ask you about your company’s experiences with negotiating and implementing value-based agreements.

What we mean when we say “value-based agreements”

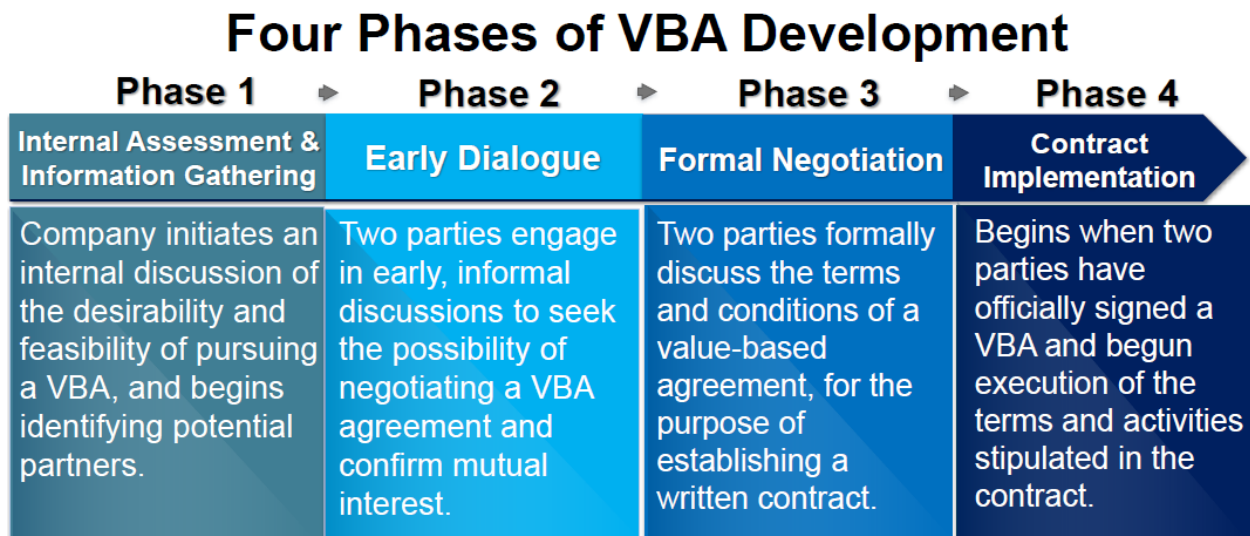
Now we’re going to ask you about your company’s experiences with negotiating and implementing value-based agreements (VBAs). We describe what we mean by VBAs below and provide some additional background information that may help you answer the next set of questions.

VBAs may be referred to by a variety of alternative names, including outcomes-based, performance-based, and/or risk-sharing contracts or agreements. For the purposes of this survey, we mean the following:

“A contractual agreement between a payer and a biopharmaceutical manufacturer that links coverage, reimbursement, or payment for a biopharmaceutical product to a pre-specified clinical or financial/utilization outcome or set of outcomes.”

Four Phases of Establishing Value-based Agreements

In the following survey questions, we distinguish between four phases of establishing value-based agreements. These four phases are defined in the chart below. We understand that these phases may overlap or run in parallel - this chart is only intended to conceptualize the progression of VBA development.



Now we are going to ask you about your company's experiences with negotiating and implementing value-based agreements (VBAs) over the last three years. Please only consider your company's experiences with VBAs from the beginning of 2014 through today.

Q2* Based on the definitions above, has your company engaged in **internal assessment** and **information-gathering** about VBA (Phase 1)?

- No
- Yes

Q2a* If yes, how many times has your company internally assessed the desirability of pursuing a VBA proposal since 2014? (Approximate if necessary)

Q2b* How many of those **internal assessments** (phase 1) moved past this phase into **early dialogue** (phase 2)? (Approximate if necessary)

Q3* Based on the definitions above, has your company engaged in **early dialogue** with potential partners in the US market about establishing a VBA? (Phase 2)

- No
- Yes

Q3a* If yes, how many times has your company engaged in **early dialogue** about the desirability of pursuing a VBA proposal since 2014? (Approximate if necessary)

Q3b* How many of those **early dialogues** (phase 2) moved past this phase into **formal negotiation** (phase 3)? (Approximate if necessary)

Q4* Based on the definitions above, has your company engaged in **formal negotiation** of a VBA with a potential partner in the US market? (Phase 3)

- No
- Yes

Q4a* If yes, how many times has your company engaged in **formal negotiation** of a VBA since 2014? (Approximate if necessary)

Q4b* How many of those **formal negotiations** (phase 3) moved into **implementation** (phase 4)? (Approximate if necessary)

Q5* Based on the definitions above, has your company **implemented** a VBA with a partner in the US market? (Phase 4)

- No
- Yes

Q5a* How many times has your company **implemented** a VBA since 2014? (Approximate if necessary)

Q5b* How many of those **implemented** VBAs are not publicly known? (Approximate if necessary)

Q6*: Approximately what percentage of all the VBAs your company has discussed, negotiated, or implemented have focused on:

- Drugs dispensed in the outpatient setting (covered under the pharmacy benefit)
- Physician-administered drugs (covered under the medical benefit)

Q7*: Which category of drugs do you think is more amenable to a VBA? (Please explain in Q8)

- Drugs dispensed in the outpatient setting (covered under the pharmacy benefit)
- Physician-administered drugs (covered under the medical benefit)
- Both categories are equally amenable

Q8* Why did you choose that answer in Q7?

_____.

Q9* From your perspective, what therapeutic area(s) are most suitable for implementing the VBA model, and why?

_____.

Q10* Providers are increasingly taking on more risk under innovative payment arrangements (ACOs, bundled payments, shared savings, etc). Do you think that incorporating providers is important for the future success of VBAs?

- No
- Yes

Q11* Does your company currently participate in any VBAs that incorporate providers within the contract?

- No
- Yes

Q12. What do you think your company might perceive to be the major benefits of incorporating providers into VBAs?

_____.

Q13. What do you think your company might perceive to be the major barriers to incorporating providers into VBAs?

_____.

Q14*. In your experience, at what stage in the development process described above are VBAs most likely to break down? Please rank from **1 (most likely)** to **3 (least likely)**

- Internal assessment & information gathering (phase 1)
- Early dialogue (phase 2)
- Formal negotiation (phase 3)

Q15. Thinking back to the potential VBAs that your company has discussed or negotiated (phases 2 & 3), but which did **not** reach implementation (phase 4):

* Were any of the following **product-related challenges** major or minor reasons that those agreements were not fully implemented?

	Major Reason	Minor Reason	Not a Reason
Difficulty in identifying appropriate outcome measure(s) for the target drug			
The drug of interest was not a good candidate for a VBA due to target population characteristics			
The drug of interest was not a good candidate for a VBA due to other factors (if this was a major reason, please describe those factors below)			

Q16* Were any of the following **contract-related challenges** major or minor reasons that those agreements were not fully implemented?

	Major Reason	Minor Reason	Not a Reason
Disagreement on the time horizon for measuring outcomes			
Disagreement on the incentive mechanism tying payment to outcome (e.g., additional rebates, favorable formulary placement, payment for additional patient medical costs, etc.)			
Disagreement on the financial terms of the VBA (e.g., the base price of the target product, the amount of discounts/rebates offered, etc.)			
Disagreement on the formulary status of the product			
Disagreement on the population management approach			

Q17* Were any of the following **implementation challenges** major or minor reasons that those agreements were not fully implemented?

	Major Reason	Minor Reason	Not a Reason
Concern over costs of implementation			
Could not identify a good potential partner			
Lack of internal agreement or support within the organization			
Lack of capacity (e.g., human resources, internal expertise) to pursue or manage VBA			
Concern over ensuring patient adherence			
Concern over patients changing insurers			
Difficulty in aligning or reconciling with other existing agreements (i.e., separate agreements already in place with other payers)			
Difficulty in aligning with other alternative payment models underway (e.g., ACOs, bundled payments, MACRA, etc.)			

Q18* Were any of the following **legal and regulatory challenges** major or minor reasons that those agreements were not fully implemented?

	Major Reason	Minor Reason	Not a Reason
Concern over Medicaid Best Price implications			
Concern over Anti-Kickback Statute implications			
Concern over FDA off-label regulations			

Q19* Were **data and evidence challenges** major or minor reasons that those agreements were not fully implemented?

	Major Reason	Minor Reason	Not a Reason
Data and evidence challenges (e.g. issues related to data collection, analysis, sharing, privacy, etc.)			

Q20. Please describe any reasons not previously specified that have prevented your company from successfully negotiating or implementing a VBA:

_____.

Q21* Overall, what do you think is the *biggest* barrier preventing companies from successfully completing formal negotiation of VBAs?

_____.

In the next set of questions, we ask about your company’s active or completed VBAs. (“Active VBAs” means VBA contracts that are currently being implemented; “Completed VBAs” means VBA contracts that have been completed based on the terms of the contract.)

Q22* How many of your company’s **active or completed** VBAs since 2014 use or have used the following outcomes to measure product value? (Enter a number in each box - approximate if necessary)

Measure	Number
Laboratory measures (e.g. HbA1c, LDL cholesterol)	
Imaging measures (e.g. CT, MRI, PET scanning)	
Other biomarker measures (please specify)	
Survival (e.g. overall survival; progression-free survival, disease-free survival)	
Disease progression (e.g. response duration, time to progression, time to recurrence)	
Symptom improvement (e.g. pain reduction)	
Other non-biomarker clinical measures (please specify)	
Medical encounter process measures (e.g. hospitalization rate/duration; readmissions rate)	
Financial measures (e.g. total cost-saving, % increase in total budget, cost effectiveness)	
Drug utilization measures (e.g. adherence, switching or adding therapies)	
Others (any type - please specify)	
Total	

Q23* How many of your company's **active or completed** VBAs since 2014 use or have used the following incentive mechanisms? (Enter a number in each box - approximate if necessary)

Mechanism	Number
Manufacturer provides a larger rebate to payer if target outcome(s) not achieved	
Manufacturer provides a full refund for the product if target outcome(s) not achieved	
Manufacturer fully or partially covers the cost of corrective services or treatment needed if targeted clinical outcome is not achieved (e.g., coverage of surgical costs for patients who experience a fracture while taking an osteoporosis drug)	
Manufacturer receives a bonus payment from payer if population outcome(s) exceed a pre-negotiated threshold	
Manufacturer pays some portion of costs for supportive products or services (e.g., data analytics, follow-up testing, patient adherence tools or services)	
Total	

Q24 Has your company used any other types of incentive mechanisms in its VBAs that weren't described in the previous questions? (If yes, please describe them)

- No
- Yes, these mechanisms: _____.

Q25* Has your company ever implemented a VBA that reimburses some portion of patient out-of-pocket costs if target outcomes are not achieved? (If yes, please enter how many)

- No
- Yes, this many: _____.

Q26* If you answered yes to **Q24**, please approximate how many VBAs used the alternative incentive mechanisms you described.

- How many? (Approximate number) _____.
- My company has not used any alternative types of incentive mechanisms.

Q27* Thinking about your company's active or completed VBAs since 2014, how many incorporate a patient adherence component?

- How many? (Approximate number) _____.

Q27a. In what ways have those VBAs incorporated patient adherence? Select all that apply.

- Payment is explicitly tied to improvements in adherence (e.g., as compared to a baseline).
- The VBA only includes patients who have met a certain level of adherence.
- The VBA's outcomes-based component does not take effect unless a certain adherence rate for a patient population is achieved.
- The VBA incorporates patient adherence programs like automatic refills or email or text reminders.
- The VBA includes a financial guarantee of patient adherence by the payer.
- Other (please specify) _____.
- My company has not incorporated patient adherence into its VBAs over the last 3 years.

Q27b. Please explain the measures used to capture patient adherence under your company's VBA(s): _____.

Next, we ask about the factors that are the most important in successfully negotiating and implementing a VBA.

Q28* Based on your experience, please consider the importance of the following factors in successfully negotiating and implementing a VBA.

Please select the **five** factors you consider to be the most important:

- Availability of measurable outcomes clearly tied to product use
- Target patient population can easily be identified in claims
- Target drug has a potentially high budget impact
- Timeline for VBA contract duration was reasonable
- Contract processes are transparent
- Timeline for collection and analysis is reasonable
- Return on investment is visible within a reasonable timeframe
- Administrative burden is reasonable
- Patient support/outreach program was included
- Providers were adequately engaged and had an incentive to participate
- Partners were committed to pursuing the agreement
- Partner had adequate internal resources for negotiation and implementation
- Partners had prior experience with VBAs
- Partners had the necessary data collection and analysis capabilities
- Partners had sufficient trust in the other party
- Other (please specify) _____.

Q29* Please rank the factors you chose from 1 to 5, with 1 being the most important.

Drag and drop the items to rearrange the list.

- _____ Availability of measurable outcomes clearly tied to product use
- _____ Target patient population can easily be identified in claims
- _____ Target drug has a potentially high budget impact
- _____ Timeline for VBA contract duration was reasonable
- _____ Contract processes are transparent
- _____ Timeline for collection and analysis is reasonable
- _____ Return on investment is visible within a reasonable timeframe
- _____ Administrative burden is reasonable
- _____ Patient support/outreach program was included
- _____ Providers were adequately engaged and had an incentive to participate
- _____ Partners were committed to pursuing the agreement
- _____ Partner had adequate internal resources for negotiation and implementation
- _____ Partners had prior experience with VBAs
- _____ Partners had the necessary data collection and analysis capabilities
- _____ Partners had sufficient trust in the other party
- _____ Other (please specify)

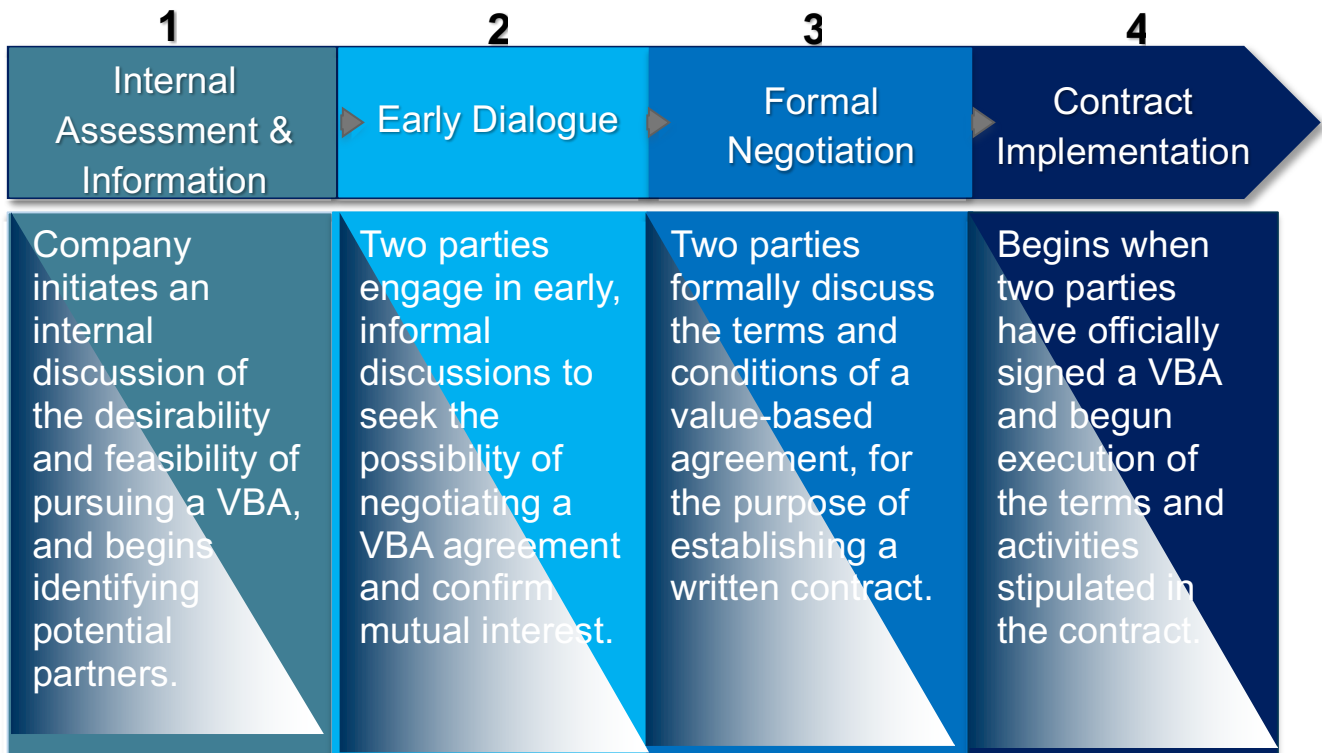
Q30. Has your organization developed any tools, systems, or processes that have helped facilitate the successful negotiation and implementation of VBAs? (If yes, please describe them)

- No
- Yes, these tools: _____.

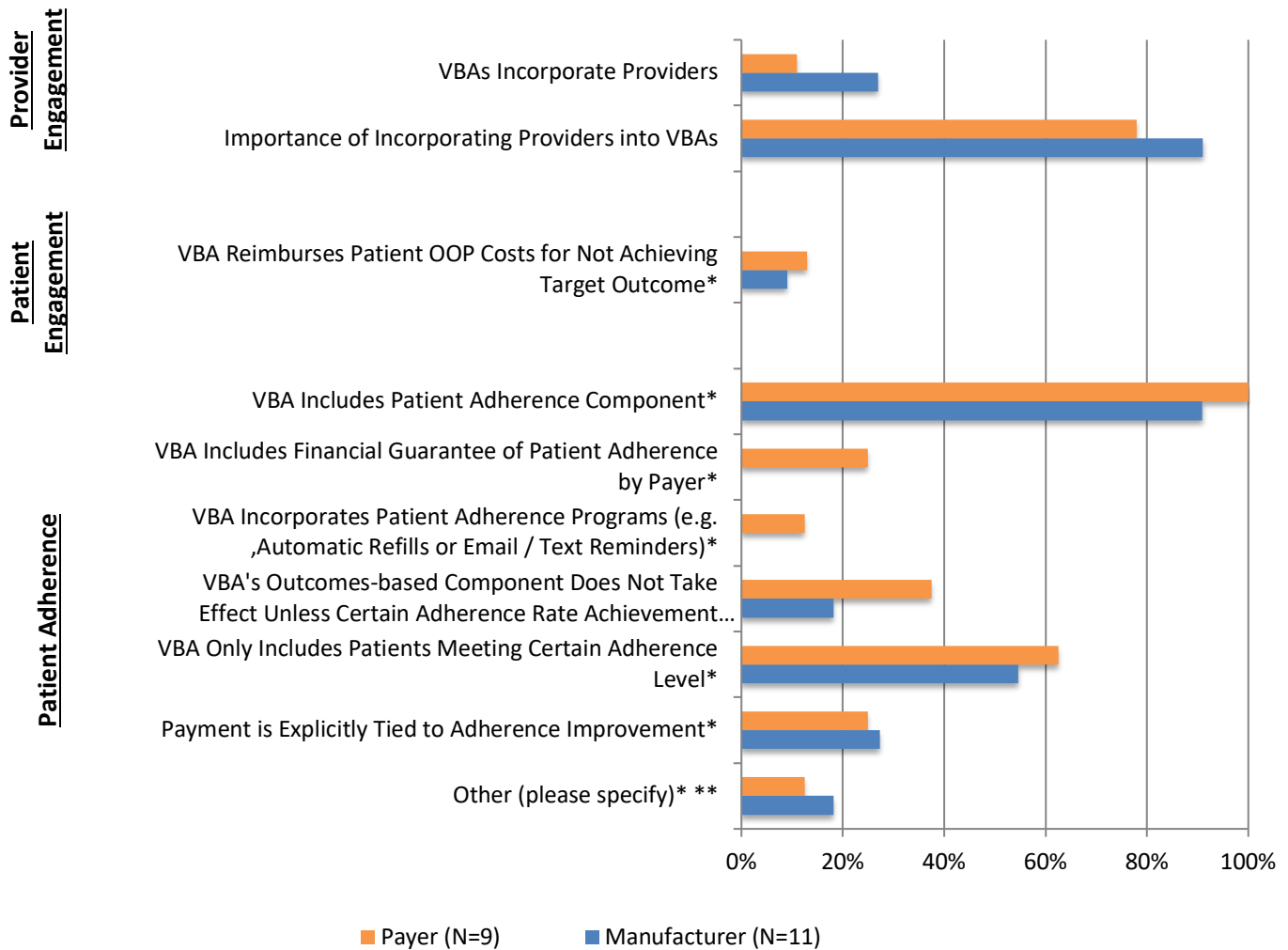
Thank you for participating in this survey!

If you have any additional thoughts or observations about VBAs that you would like to share, please use the space below:

eAppendix B. Stages of VBA Development



eAppendix C. Provider and Patient Engagement in VBAs, By Sector, 2014-2017



OOP: Out-of-pocket

*1 payer who responded to previous questions did not answer this question (N=8)

**Manufacturer: Switching to another product within certain time frame and plan gets reimbursed for PBM for nonadherent patient. Payer: Discontinuation guarantees.