



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"

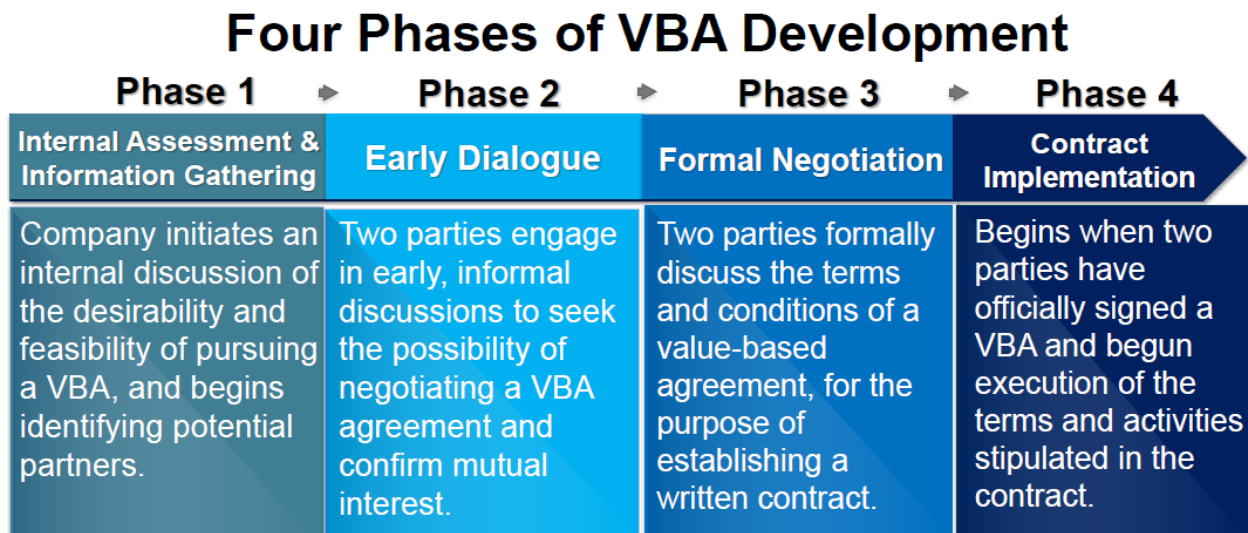
Now we're going to ask you about your company's experiences with negotiating and implementing value-based agreements (VBAs). We describe what we mean by VBAs below and provide some additional background information that may help you answer the next set of questions.

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)

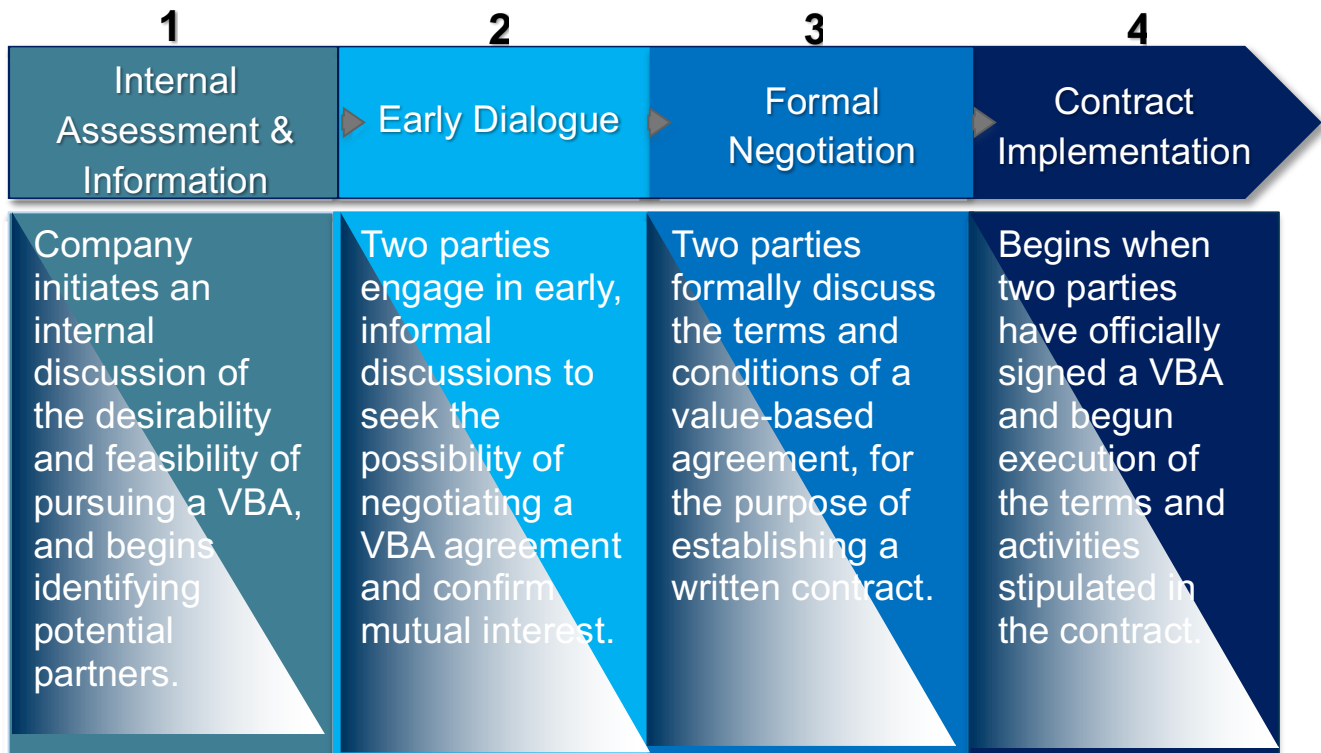
Q30. Has your organization developed any tools, systems, or processes that have helped facilitate the successful negotiation and implementation of VBAs? (If yes, please describe them)

- No
- Yes, these tools: _____.

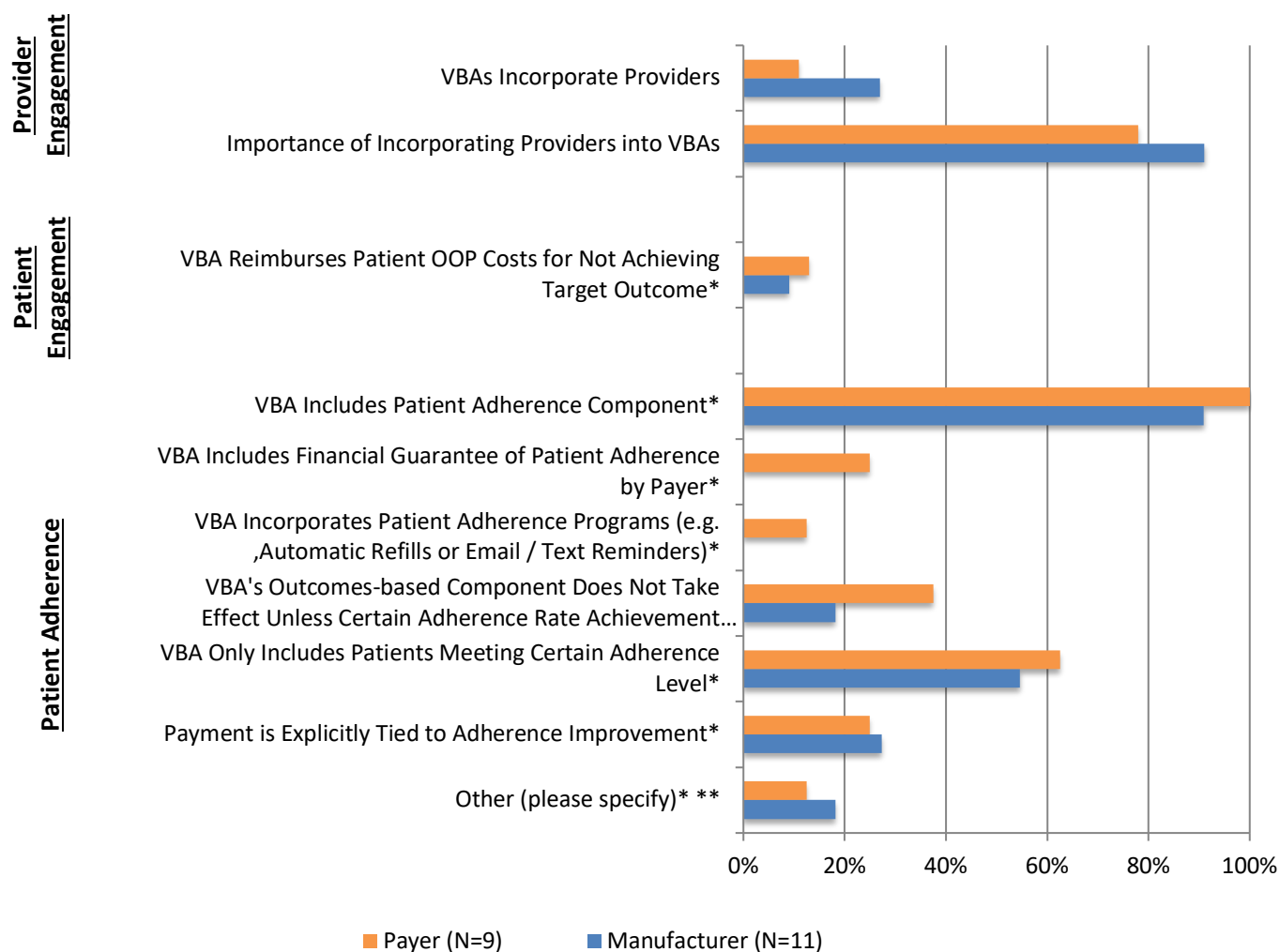
Thank you for participating in this survey!

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.