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How to Ask a Question

Type your question here in the “Questions” area.

Today’s Presenters

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Today's Agenda

- AMCP Partnership Forums: Overview and Accomplishments
- Value-Based Contracting (VBC) Forum
- Results from our Membership VBC Survey
- Forum Findings and Recommendations
- Next Steps and Action Items
- Time for Q&A
What are AMCP Partnership Forums?

Forum brings together a diverse group of health care stakeholders to discuss key issues facing managed care pharmacy and collaboratively help shape the changing health care landscape.

Conclusions and recommendations:

- Shared via webinars
- Proceedings published in the Journal of Managed Care and Specialty Pharmacy
- Drive AMCP strategic initiatives

Previous Forum Results/Accomplishments

- Advanced preapproval and post-approval communications policies (Preapproval Information Exchange and FDAMA Section 114)
- Addiction Treatment Advisory Group
- MTM Advisory Group
- Biologics and Biosimilars Collective Intelligence Consortium (BBCIC)
2017 AMCP Partnership Forums

Advancing Value-Based Contracting
June 20 - 21, Arlington, VA

Patient Reported Outcomes – The Missing Link in Defining Value
October 19, Dallas, TX

Driving Value and Outcomes in Oncology
November 14 - 15, Arlington, VA

Managing Care in the Wave of Precision Medicine
December 7 - 8, Arlington, VA
VBC Goals and Objectives

Define Value-Based Contracting
Explore Value-Based Contracting Opportunities and Hurdles
Create an Action Plan

VBC Forum Participants

30+ participants from health plans, integrated delivery systems, pharmacy benefit managers, employers, data and analytics experts, and biopharmaceutical companies

Aetna
Amgen
Blue Cross Blue Shield Association
Bristol-Myers Squibb
CareFirst BlueCross BlueShield
Deloitte Consulting
DLA Piper
Eli Lilly and Company
Essentia Health
Evolent Health
Harvard Pilgrim Health Care
Healthagen Outcomes, Division of Aetna
Healthcare Consulting
Heritage Provider Network
Kaiser Foundation Hospitals
Magellan Rx Management
Massachusetts General Hospital
Merck & Co.
Milliman
National Health Council
National Pharmaceutical Council
Network for Excellence in Health Innovation (NEHI)
Novo Nordisk
Pharmaceutical Research and Manufacturers of America
Predictive Health
Premier Inc.
Prime Therapeutics
PriorityHealth
Rampy Northrup LLC
RxAnite
Takeda
University of Utah College
Xcenda
Thank You to Our Forum Sponsors!
AMCP Membership Survey

Survey: Objective and Method

To better understand payer and manufacturer experiences, perceptions, and readiness to implement outcomes-based contracts (OBCs).

Participants (n=65) completed a brief online survey between May 12 and June 4, 2017

- 35 Payers
- 30 Manufacturers

- Current and planned experience with OBCs
- Measures included in OBCs
- Availability of OBC-applicable resources (payers only)
- Barriers/limitations to OBC implementation
- Importance of specific elements to successful OBC implementation

A variety of factors were rated on their (a) impact, (b) ease of implementation, and (c) level of urgency.
Payer Insights: Presence of OBCs

While only one-fifth of payers currently have an OBC in place, most are interested in instituting them in the future or have one pending.

- Yes, outcomes based-contract in place: 20%
- No, but interested: 60%
- No, but pending: 11%
- No, not interested: 6%
- Not sure/I don’t know: 3%

Q1. Does your organization currently have an outcomes-based contract for one or more products in place with a manufacturer?

Manufacturer Insights: Presence of OBCs

One-third of manufacturers have an OBC in place and almost an additional two-thirds have one pending or are interested in instituting one in the future.

- Yes, outcomes based-contract in place: 33%
- No, but interested: 50%
- No, but pending: 13%
- No, not interested: 0%
- Not sure/I don’t know: 3%

Q8. Does your organization currently have an outcomes-based contract for one or more products in place with a payer?
Payer Insights: Elements of Successful OBCs

Successful OBCs include measurable outcomes, risk sharing with manufacturers, sufficient patient population, contract flexibility and reasonable time-frames.

- Simple/easily measurable outcomes: 71% extremely important, 20% somewhat important, 9% not at all important
- Risk sharing between manufacturer/payer customer: 57% extremely important, 31% somewhat important, 6% not at all important
- Sufficient sized patient population: 34% extremely important, 43% somewhat important, 17% not at all important
- Flexibility in the type of contract: 26% extremely important, 54% somewhat important, 17% not at all important
- Reasonable time-frame of contract: 17% extremely important, 51% somewhat important, 26% not at all important
- Pharma support of case management and adherence/compliance initiatives: 34% extremely important, 29% somewhat important, 14% not at all important
- Manufacturer support with data mining/infrastructure: 37% extremely important, 29% somewhat important, 17% not at all important
- Potential of including a mediator to analyze the risk before OBC discussions are initiated: 23% extremely important, 34% somewhat important, 29% not at all important

Q.7 On a scale from 1 to 5, please rate the importance of the following elements in establishing successful outcomes-based contracting?

1 (not at all important) to 5 (extremely important)

Manufacturer Insights: Elements of Successful OBCs

Successful OBCs include measured outcomes, risk sharing with payer, sufficient patient population, and reasonable time-frames.

- Simple/easily measured outcomes: 80% extremely important, 20% somewhat important
- Risk sharing between the manufacturer/payer customer: 50% extremely important, 37% somewhat important, 10% not at all important
- Reasonable time-frame of contract: 50% extremely important, 33% somewhat important, 13% not at all important
- Flexibility in the type of contract: 37% extremely important, 33% somewhat important, 27% not at all important
- Sufficient sized patient population: 37% extremely important, 53% somewhat important, 10% not at all important
- Potential of including a mediator to analyze the risk before OBC discussions are initiated: 10% extremely important, 17% somewhat important, 47% not at all important

Q13. On a scale from 1 to 5, please rate the importance of the following elements in establishing successful outcomes-based contracting:
Potential Impact on OBCs: High Impact (Rated 4, 5)

Clarification of off-label communication/FDA regulations and anti-kickback statute may have highest impact among payers and manufacturers

HCEI – healthcare economic information.
Base: Total payers (35) * total manufacturers (30).* Caution: Small base.
Q14. Please rate each item listed below on its potential impact level by typing in the appropriate number using the rating scales indicated.

Survey Summary

- Per survey results, implementation is low but interest is high, reinforcing the need for a path forward
- There is a tremendous amount of activity going on in this space, but stakeholders may believe there is little happening
- Different needs should be addressed depending on the stakeholder, but commonalities exist
- Multi-stakeholder collaboration will be essential for progress

Poster presented at AMCP Nexus Conference
Survey published in JMCP late October/early November
Forum Findings and Recommendations

Participants assembled into 4 working groups representing a variety of stakeholder perspectives.

Each group presented their findings to the entire group for additional input. Forum consensus was reflected in final proceedings.
Participants needed to develop a value-based contract (VBC) definition for the purpose of facilitating discussion with key policy-makers and regulators.

The definition and debate was thorough!

Value-Based Contract vs Outcomes-Based Contract?
What is an outcome?
VBC vs OBC?
Participant Consensus Definition

“A value-based contract is a written contractual agreement in which the payment terms for medication(s) or other health care technologies are tied to agreed-upon clinical circumstances, patient outcomes, or measures.”

Guiding Principle Considerations

• Definition should be flexible to allow for innovative value-based contracting approaches that have yet to be developed
• Must be shared accountability for outcomes and costs
• Outcomes should be designed to engage patients and improve their health outcomes
• Definition should evolve to align and engage all relevant parties to achieve optimal outcome
• Definition does not include contracts that are based on volume or share
• Terms and outcomes included in the contract are pre-determined
Participants looked at a variety of key considerations that further defined VBC while helping to align with provider incentives and measure outcomes.

**Contract Types**

- **Risk Sharing**: Charge less for suboptimal outcomes
- **Coverage with Evidence**: Liability or upside based on real evidence outcomes
- **Shared Accountability**: Incorporates services to optimize and support outcomes (registries, active surveillance, claims)
- **Bundled Services**: Additional services offered to patient on the product(s)
Work Group Insights

Which patient populations should be included in a VBC?

- Population Factors (e.g., covered in clinical trials and labeling)
- Real World Factors (e.g., eligibility consideration, duration of treatment, enrollment)
- Human Factors (e.g., adherence)

Patients to Include

Work Group Insights

What considerations need to be made regarding the capacity to collect and analyze data?

- Data sources: How it will be collected, validated, analyzed
- How to define patient populations that are included in the data analysis
- How to ensure that a patient’s diagnosis and treatment is aligned with the data needed for the contract
- Process for aggregating and analyzing the data in a HIPAA-compliant manner
- Infrastructure development
What should the contract duration and timeline be?

Most patients enrolled with payers on an annual basis, but...

- Many VBCs have outcomes that take longer than 6-12 months to emerge
- Some expensive single-use medications have long-lasting benefits

Surrogate and escalating endpoints could be used to align outcomes with allotted time period

- Surrogate endpoints are short-term markers that are a valid proxy for a clinical endpoint
- Escalating endpoints build upon each other over multiple time periods

Explore VBC alignment with alternative care and payment models

Do we need to demonstrate a reduction in the total cost of care?

VBC is not for circumstances where the goal is to reduce the cost of the drug regardless of any impact on outcomes. That's what volume and share contracts do.

VBC is focused on value, which adds a new dimension (did the drug work or not) to the three payments:

- Payment for MD diagnosis and write Rx
- Payment to the PBM for processing the claim
- Payment to the pharmacy for product/service
CREATE AN ACTION PLAN

Participants assessed the regulatory and legal environment and identified an action plan to mitigate barriers.

Work Group Insights

Regulatory and Legislative Environment

FDA-specific federal rules and regulations need to be revised to enable payers and manufacturers to engage more broadly in VBCs.

Specifically:

- Anti-Kickback Statute
- Medicaid Best Price
- 21st Century Cures Act
## Work Group Insights

### Anti-Kickback Statute
Long term changes to federal fraud, waste, and abuse laws and regulations are necessary – near term, a new safe harbor for VBCs or clarification on existing federal rules is needed.

### Medicaid Drug Rebate Program - Best Price Requirement
Exemption for VBCs that include 100% price discount from Medicaid Best Price Rule.

### 21st Century Cures Act
Payers and manufacturers allowed to have limited but necessary pre-approval communication via The Pharmaceutical Information Exchange (PIE) Act of 2017 (H.R. 2026).

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Next Steps and Action Items

Help the marketplace understand how to implement and work with VBCs

- Policy and advocacy efforts to reduce VBC barriers
- Communications strategy to urge VBC definition adoption
- Webinars and informational sessions at AMCP live meetings
- Comprehensive training tools for VBC fundamental and advanced learning
- Research and pilot programs to promote VBC adoption
- Value and innovations network to promote VBC discussions

JMCP Publication

- Forum Proceedings
- OBC Survey

Nexus Poster

- OBC Survey
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Next Steps and Action Items

Time for Q&A

Refresher: How to Ask a Question

Type your question here in the "Questions" area.
Thank you