

# ADDRESSING CURRENT CHALLENGES OF VALUE-BASED CONTRACTING FOR PRESCRIPTION DRUGS AND MEDICAL DEVICES

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# What is Value-Based Contracting: Examples

- **Pharmaceutical / device models:**
  - Cure
  - Decrease Hospitalization
  - Real World Outcomes
  - Decrease Costs
- *Provider models:*
  - PCP-centered shared savings and population health management
  - Quality benchmarks, such as reduced readmissions or hospital-acquired infections
  - Bundled and capitated payments

# Why Value-Based Contracting?

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**HEALTH**

## Big Pharma's Go-To Defense of Soaring Drug Prices Doesn't Add Up

Just how expensive do prescription drugs need to be to fund innovative research?

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Drugs that cost as much as a house are on the way to treat rare and devastating diseases. The US is scrambling to figure out how to pay for them.

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## It Will Take More Than Transparency To Reduce Drug Prices, Economists Say

**BIOPHARMADIVE** MENU ☰

**BRIEF**

## Medicare to pay hundreds of thousands for CAR-T therapies

# HHS' Position on Value-Based Contracting

- “Value-based transformation of our entire healthcare system as one of the top priorities of our department”
  - greater consumer control over information (interoperability/data access)
  - greater transparency/collaboration between providers and payors
  - greater use of experimental models to drive use case
  - removing government burdens

*Secretary Alex Azar – March 2018 speech to Federation of American Hospitals*

# Challenges: Value-Based Contracting

- What to measure
- How to collect data
- Contracting considerations
- Regulatory challenges/Government Burdens
  - AKS
  - Best Price
  - Data Privacy
  - Off-label
- Proposed Reforms

# Challenge: What to Measure

- Needs to tie to intended use of the product
- Needs to tie to payor's value proposition for the product
- Needs to address multiple indications or uses
- Value can vary based upon co-morbidities

# Challenge: How to Collect the Data

- Variability of EMR
- Variability of coding practices
- Data completeness
- Churn among membership
- Use of cash
- Other coverage (eg, auto insurance)

# How do Wearable Tech and Mobile Apps Fit in?

- Rich data set
- Inconsistency of use
- Changes in apps and devices over time
- Self-selected population of adopters and users



# Confounding Factors

- Persistency and compliance
- Proper use of drug and device
- Changes in dosage
- Social determinants of health
- Changes in lifestyle / dietary habits
- Off label usage

# Challenge: Aligning Incentives of Manufacturers, Payors and Providers?

- Cost savings may only materialize over time
- Payors often do not retain the same membership over long periods

# Challenges that Contracting May Overcome

- Need for clear data collection and measurement standards
- Importance of data audit rights
- Robust interim reporting to head off disputes
- Should manufacturers seek to employ alternate data source than counter-party payor to:
  - Validate payor data
  - Supplement payor data

# Challenge: Regulatory Misfit

- Best price
- AKS
- Off-label
- Data privacy

# Best Price Challenging

- Is it fair to provide CMS “best price”?
  - How to calculate when price is not set up front?
  - Population subject to VBC may differ?
- CMS acknowledges but has not addressed

# Anti-kickback Statute

- Safe Harbor application?
  - How to deal with data analytics or services attendant to the VBC?
  - For devices, what about bundled services?
  - Warranties beyond price of product?
- OIG acknowledges issues – recent call for comment

# Off-Label

- How issue arises?
- Regulatory landscape on off-label communications
- Recent FDA guidances
  - statements consistent with labeling
  - payor communications

# Examples of Permissible Health Economic Communications

- With disclaimers
  - Long term use (beyond studies in product labeling)
  - Economic consequences (missed days of work)
  - Validated surrogate endpoints
  - Product comparisons



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