

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

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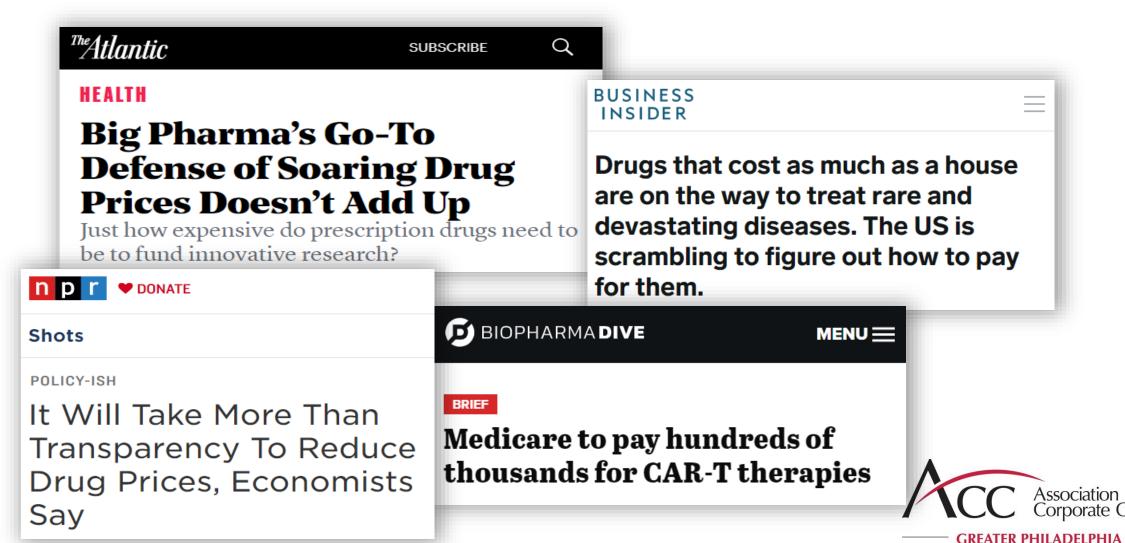
What is Value-Based Contracting: Examples

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 hospitalacquired infections
 - Bundled and capitated payments



Why Value-Based Contracting?



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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