

# Laws & Regulations in an Evolving Healthcare Marketplace

*Real Life Implications for Biopharmaceutical Industry*

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# Shifting from Volume to Value

## Obama Signs Health Care Overhaul Bill, With a Flourish

By SHERYL GAY STOLBERG and ROBERT PEAR MARCH 23, 2010



### Accountable Care Organizations, Explained

Updated April 1, 2011 - 2:05 PM ET  
Published January 18, 2011 - 8:21 AM ET

JENNY GOLD

Accountable care organizations take up only seven pages of the massive new health law yet have become one of the most talked about provisions.

FOR IMMEDIATE RELEASE  
January 26, 2015

Contact: HHS Press Office  
202-690-6340  
latest model for delivering services offers doctors and hospitals financial incentives to provide good quality care to Medicare beneficiaries while keeping down costs. A cottage industry of consultants has sprung up to help even ordinary hospitals

**Better, Smarter, Healthier: In historic announcement, HHS sets clear goals and timeline for shifting Medicare reimbursements from volume to value**

In a meeting with nearly two dozen leaders representing consumers, insurers, providers, and business leaders, Health and Human Services Secretary Sylvia M. Burwell today announced measurable goals and a timeline to move the Medicare program, and the health care system at large, toward paying providers based on the quality, rather than the quantity of care they give patients.

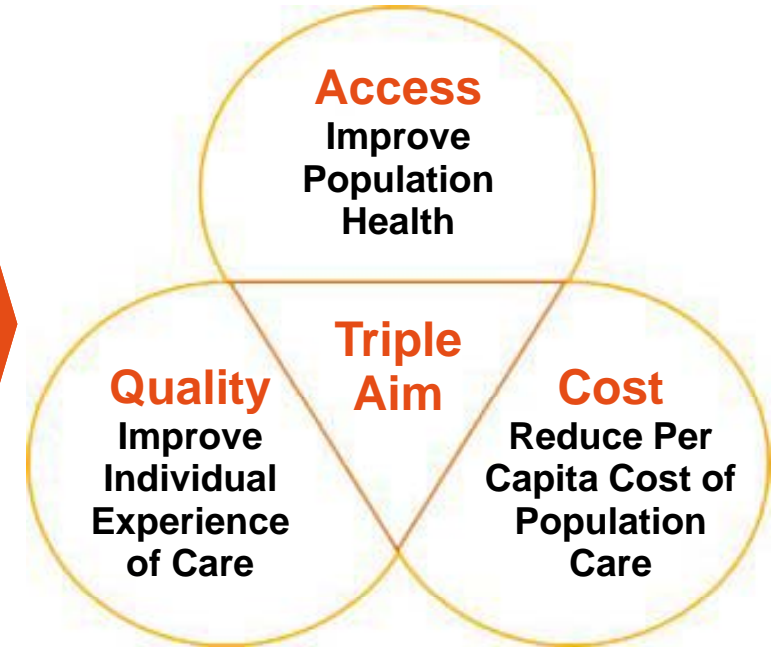
### HealthAffairsBlog

HOME TOPICS ARCHIVE SUBMIT

FOLLOWING THE ACA  
ASSOCIATED TOPICS: COSTS AND SPENDING, MEDICARE, PUBLIC HEALTH, QUALITY

### Berwick Brings The 'Triple Aim' To CMS

Chris Fleming  
September 14, 2010



The healthcare industry is embracing change, but can only advance so far with the current infrastructure

# Laws impacting shift to value-based healthcare

1

**Stark Law &  
Anti-kickback  
Statutes**



2

**Patient  
Privacy  
Rules**



3

**Limiting  
FDA  
Regulations**



# Stakeholders want to create new patient solutions



# Thinking outside the box



# Anti-kickback statutes don't always take into account current healthcare payment and delivery models

1

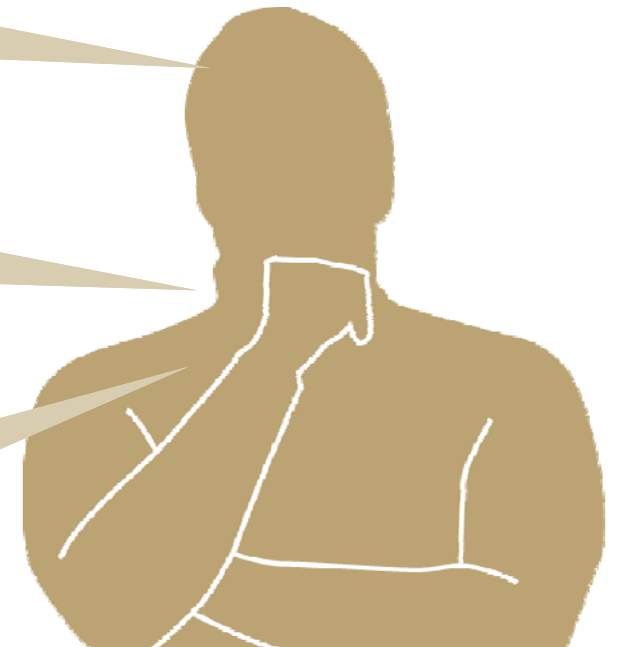
How can we all think and work more creatively for the benefit of improved healthcare outcomes?

2

How do we step out of our silos and work across the system?

3

How can pharma manufacturers work more directly with ACOs or other integrated care entities?



## NDHI Recommendation

**Greater flexibility and new anti-kickback statute safe harbors to achieve increased quality and lower costs**

## We need greater flexibility to **SHARE** scientific and health economic data

- Sharing scientific and healthcare economic information with stakeholders **BEFORE** FDA approval can help improve payers' ability to plan for future healthcare costs



- Establishing metrics for outcomes-based contracts is currently limited to product label primary endpoints which may not align with payers' preferences







# Thank You



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Healthcare Innovation

