Laws & Regulations in an Evolving Healthcare Marketplace

*Real Life Implications for Biopharmaceutical Industry*

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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

RECORD-CHALLENGING HEAT
THROUGH MONDAY

HOTTEST
PREDICTED
HIGHS

106°
Reno

114°
Fresno

105°
Boise

105°
Salt Lake
City

130°
Death Valley

117°
Las Vegas
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