POLICY/REGULATORY
HANDCUFFS: BARRIERS TO DRUG VALUE-BASED ARRANGEMENTS

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QUESTIONS ARE THE SAME
The Department of Health and Human Services plans to link 80 percent of Medicare payments to value.

In 2012, U.S. expenditures related to poor care coordination, administrative burdens, and fraud and abuse topped $1 trillion dollars.

$213 billion in U.S. health care costs could be saved with proper medication adherence for chronic diseases.
CHALLENGES OF VALUE BASED ARRANGEMENTS

- Structural Impediments
- Anti-kickback Laws
- Government Pricing
- Operational Challenges
- Administrative Burdens
- Drug Pricing Proposals
Government Price Reporting

• Average Sales Price
  – Downward pressure on ASP from inclusion of rebates from value-based contracts to commercial insurers
  – Reduced provider reimbursement

• Best Price
  – Medicaid benchmarks based on “single lowest price available” could include value-based contracts
  – Increased 340B liability for manufacturers
Anti-Kickback Laws

- The Anti-Kickback Statue prohibits offering or receiving remuneration to reward referrals
- Office of Management and Budget (OMB) is reviewing HHS Inspector General proposal to both remove current safe harbor protections for drug rebates and create new ones
- “We have got to make sure that there are no regulations or policies in place that deter a pay-over-time arrangement or a value-based arrangement that allows for a refund if it’s not as durable as it was understood.” Joe Grogan - Lead Health Staffer at OMB
External Noise

• Department of Health and Human Services (HHS)
  – Emphasis on lowering list price
  – More competition in Part B space

• Congress
  – Congressional Committees need more education
  – Scoring challenges (Congressional Budget Office)
OPERATIONAL CHALLENGES

• Data and Reporting Requirements
  – Quality metric reporting
  – Clinical data submission
  – Cost reporting

• Emerging Technology
  – Block Chain
  – bioinformatics
  – Artificial intelligence (AI)
OPERATIONAL CHALLENGES

• Alignment among stakeholders
  – Manufacturers, Payers, Providers
  – Agreement on outcomes data, patient safeguards, liability issues, etc.

• Changing Cancer Landscape
  – Shift in site of care
  – Declining reimbursements
QUESTIONS

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