



LEGAL AND REGULATORY CHALLENGES REGARDING RISK- SHARING ARRANGEMENTS

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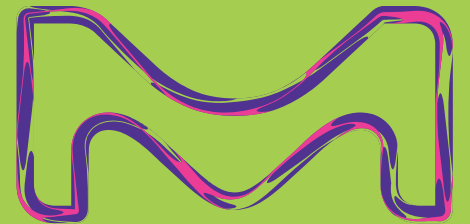
Agenda

1. Overview of Risk-Sharing Arrangements
2. Outcomes-Based Contracts in the US
3. Legal and Other Considerations
4. Questions / Discussion



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OVERVIEW OF RISK-SHARING ARRANGEMENTS



What is Outcomes-based Contracting?



Neumann et al defines an outcomes-based contract as:¹

A contract between a payer and a manufacturer in which the reimbursement for a drug is tied to the health outcomes achieved with “real-world” use

Other examples may include:

Supplemental rebates

Discounts

Other contract components



Outcomes-based Contracts Reflect a Shift to Real-World Demonstration of Effectiveness



Focus on high-cost diseases



40% for chronic diseases



52% for oncology products



8% for devices & diagnostics



What are some other Risk-Sharing (Value-Based) arrangements?

- Free trial – first cycle or first dose of therapy is free
- Price caps – payor does not pay for more than a certain amount per patient
- Indication specific pricing – price differs depending on, for example, tumor type being treated



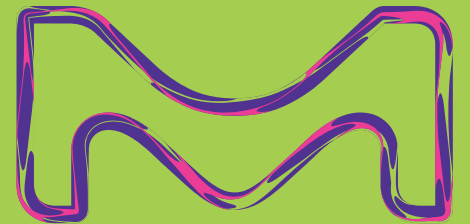
What are the advantages of Risk-Sharing arrangements?

- For Payors:
 - Reduces the risk of paying for a product with unpredictable benefits
 - Provides budget predictability
 - Reduces costs
- For Manufacturers:
 - Encourages adoption of product with unpredictable benefits
 - Highlights what is good about the product
 - Puts your “money where your mouth is”















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OUTCOMES-BASED CONTRACTING AGREEMENTS IN THE US



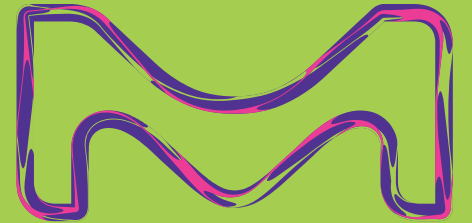
Outcomes-Based Contracts in the US

					
Partner					
Disease		Relapsing Multiple sclerosis (MS)	Type 2 diabetes	Osteoporosis	Breast Cancer
Payer					
Outcome Measure		Relapses requiring hospitalizations ¹	Mean HbA1c (across all type 2 diabetes patients) ²	Number of non-spinal fractures; adherence ²	Number of women receiving chemotherapy ²
Year Initiated		2011	2009	2009	2007



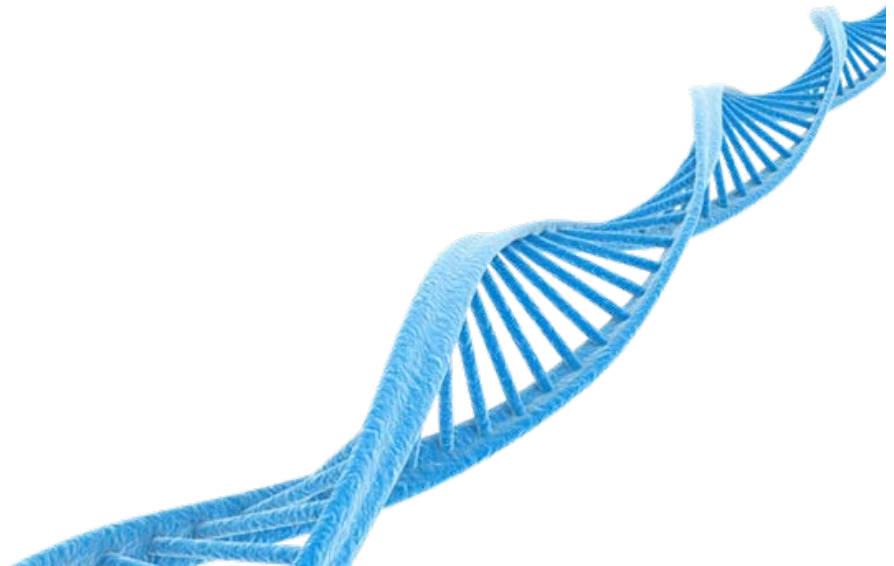
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LEGAL AND OTHER CONSIDERATIONS



Legal and Other Considerations

- Anti-kickback statute
- Government price reporting challenges
- “Off-label” promotion considerations
- Data collection and data privacy
- Key operational considerations



Anti-Kickback Statute

- AKS prohibits any person from:
 - Knowingly and willfully
 - Offering, paying, soliciting or receiving
 - “Remuneration”
 - Directly or indirectly
 - With the intent to induce or reward business reimbursable under federal healthcare programs
- Arrangement does not violate the AKS if it falls within a statutory exception or regulatory safe harbor
- No guidance from OIG on extent to which discount safe harbor may apply to risk-sharing or value-based arrangements
- What do you do?



Government Price Reporting

- Manufacturers must report to the government data on commercial drug sales as a condition of government reimbursement
 - Reported metrics calculated on per unit basis
- Medicaid Best Price is the lowest price paid in any one quarter by a commercial customer on a per unit basis
- No exception for risk-sharing or value-based arrangements
- A low Medicaid Best Price means that:
 - Higher rebates paid by manufacturer on Medicaid utilization
 - Lower Medicaid reimbursement rates on physician administered drugs
 - Lower 340B prices



Government Price Reporting (con't)

- Depending on the type of risk-sharing value-based arrangement you have, it could result in a very low unit Medicaid Best Price
 - Capped price
 - Per course of therapy price
 - Pricing that varies by indication
- What do you do?
 - Focus on arrangements where the outcome measure impacts the rebate percentage for the quarter (instead of giving a specific patient free or significantly discounted product)
 - Be prepared to allocate if rebate percentages will vary over time (bundles over time – satisfying a contingency in one quarter affects discounts in another quarter)
 - Best price protection contract provisions (claw-back)



“Off-label” Promotion and Data Issues

- “Off-label” Promotion
 - Is the outcome being measured on-label for the product?
 - If there is significant off-label use of product, consider whether such off-label use will skew outcome results
- Data Collection and Data Privacy
 - Who will collect the necessary data to measure the relevant outcome in such risk-sharing value based arrangements?
 - Does the manufacturer pay the customer for this (is it a bona fide service)?
 - Unless de-identified, detailed outcomes data would likely be PHI (limited disclosure to manufacturer)



Key Operational Considerations



Selection of the appropriate product / therapeutic area

- Most contracts are for therapies in high-spend, high-impact disease states¹
- Potential benefits > implementation and transaction costs²



Collaboration between the manufacturer and the payer on the outcomes measured

- “Objective, clearly defined, reproducible, and difficult to manipulate”³
- Appropriate measurement period (1–2 years)³



Access to adequate data and personnel

- Complexity of outcomes dictates the needs and level of IT³
- Payment and reimbursement mechanisms are clearly established²



Engagement of payer and manufacturer resources is critical to support tactics leading to desired patient outcomes





QUESTIONS/DISCUSSION

