PHARMACEUTICAL SUMMIT ON BUSINESS & COMPLIANCE ISSUES IN MANAGED MARKETS

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Measuring Up: Compliance and Legal Considerations in Managed Markets

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Important consideration

- The opinions expressed in this presentation are those of the speakers and do not necessarily represent those of their employers.

- None of the information or analyses presented is intended to be legal advice, and should not be relied upon as legal advice.

Agenda

- Panel Introductions
- What is “Managed Markets”?
- True or False: There are no federal legal/compliance risks involving Managed Markets because it involves only dealings with private payors?
  - Key policy issues
  - Potential legal issues
- Discussion of particular Managed Markets topics
- How companies address compliance risks with Managed Markets
- Lessons and Take-aways

Panel Introductions

- Jonathan Connell – Bristol-Myers Squibb
- BJ D'Avella – Huron Consulting
- Jennifer McGee – Otsuka Pharmaceutical

What is Managed Markets?

- How do different companies define this concept?
- How does the government define this concept?
- What are the legal/compliance factors for defining Managed Markets?

True or False?

- There are no federal legal/compliance risks involving Managed Markets because it involves only dealings with private payors.
  - Key policy reasons why Managed Markets arrangements may raise risks:
    - Effect on prescribing decisions
    - Effect on federal health care program payments
  - What laws are potentially implicated?
    - Federal Anti-Kickback Statute
    - Federal Civil Money Penalty Statute
      - Beneficiary inducement provisions
    - HIPAA
    - State Laws

Key Managed Markets Risk Areas

- Issues that may raise legal/compliance risk:
  - Patient Assistance Programs
  - Reimbursement Support/Co-Pay Cards and Coupons
  - Contracting Arrangements/Service Requirements
  - Pricing Issues
    - Rebates
    - Value-Based Pricing

How Do Companies Address Managed Markets Compliance Risks?

- What are the internal definitions of Managed Markets and specific risk areas?
- What internal resources focus on Managed Markets?
- What external resources are regularly used, if any?


Lessons
Learned

Lessons/Considerations

- Today's Compliance Departments must expand their purview and focus
  - Look beyond HCPs and federal health care programs
  - Monitor more than just policies and transactions
    - Must seek insights into what is really going on (*i.e.*, intent)
- Monitor All Trends and Developments
  - Focus on case law, including from the pharma and provider industries
  - Lookout for new DOJ and OIG guidance
  - Take note of all new CIA terms and developments
- Use outside resources for evaluation and benchmarking

Questions?