The National Disclosure Summit

The Leading Forum on Disclosure, Transparency and Aggregate Spend for Drug, Device and Biotech Companies

Pre-Conference Questions: Legal/Regulatory & Operational Considerations

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ARNOLD & PORTER LLP

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Legal & Regulatory Considerations

Question #1

Who are the company stakeholders in the disclosure debate?

- Virtually every department and level
  - Board
  - Officers/Management
  - Compliance
  - Legal
  - Medical Affairs
  - Sales and marketing
  - Regulatory/Clinical
  - Government Affairs
  - External Affairs/Communications
  - Etc.

Question #2

How do we prepare company leadership for disclosure?

- *Carefully* examine assumptions regarding the business case for physician payment activities
- Internal training on disclosure developments
  - Focus on benchmarking
- Wargaming disclosure scenarios

Question #3

How do we benchmark our disclosure policies to prepare for future requirements?

- Examine currently available resources and proposals
  - Mechanisms for monitoring developing state requirements
  - Review of settlements and corporate integrity agreements
  - Peer company voluntary transparency initiatives
  - Developing federal legislation

How do we assess the potential impact of disclosure?

- Conduct a targeted review to highlight potential vulnerabilities
  - Adequacy of internal controls and processes
  - Bona fide nature of relationships
  - Fair market value
  - Code compliance
  - Agreement adequacy
  - HCP obligations
  - Profile of thought leaders and related controversies

Question #5

How do we defuse potential controversies resulting from disclosure?

- Consider reforms, initiatives and voluntary disclosures to blunt impact
- Prepare HCPs for the impact of disclosure
- Prepare public responses to questions regarding specific relationships and areas of concern

Operational Considerations

Question #6

How do we determine the solutions that best fit our company?

- Determine Build vs. Buy for technical architecture
- Integrate Customer Master / Master Data Management
- Implement Aggregate Spend solution for reporting needs

Question #7

What are the steps to performing a gap analysis to determine strengths/weaknesses?

- Create an “As-Is” state to determine blueprint of current systems and processes
- Develop “To-be” strategy to map optimized structure
- Build Roadmap to blueprint how to achieve next-generation state

Question #8

How can we map spend types to systems and processes?

- Determine which spend types are stored as data in specific systems
- Create policies and procedures to optimize the spend process

Question #9

How can my company identify all HCP/HCO touchpoints?

- Understand all of the circumstances under which healthcare entities are given payments, educations items, or other economic benefits.
- Determine where the spend is spread across the organization's divisions and its external vendors.

What are the steps to understanding systems and processes?

- Gain an understanding of all systems and processes through which HCPs/ HCOs may receive value
- Capture all data necessary
  - – ERP Systems
  - – CRM / SFA Systems
  - – T&E Applications
  - – Grant Management tools
  - – KOL Tracking
  - – Clinical Activity solutions

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