

National disclosure audio conference: Analysis of the revised Physician Payments Sunshine Act and state drug marketing laws February 10, 2009

“Where we are today on state and federal disclosure, transparency and aggregate spend?”

Presented by Jennifer Colapietro

Current state of disclosure

Consistent with the theme of **transparency** embraced by the new Obama administration, there is a push for stricter and tougher requirements on the industry to openly share with the public the financial investments they are making in Healthcare Professionals (HCPs).

- California
- District of Columbia
- Maine
- Minnesota
- Nevada
- Vermont
- West Virginia
- **Newly passed**—Massachusetts (first disclosure report is due 7/1/2010 for time period 7/1/09–12/31/09)
- **Pending**—Physician Payments Sunshine Act

Where are manufacturers today?

A majority of manufacturers have already taken steps to address the physician reporting requirements enacted in the various states.

- Incorporated state disclosure requirements and thresholds within existing policies and procedures
- Interpreted state requirements to understand data attributes necessary to report and mapped to source systems for data retrieval
- Formalized processes and responsibilities for data collection, consolidation, validation, and reporting
- Developed short-term, semi-automated solutions

Primarily still a manually-intensive, cumbersome process to gather, consolidate, validate and report total physician spend

Data is captured in disparate systems

The majority of the data that is required to be reported is either manually captured, is duplicated in multiple systems and needs to be reconciled, and/or is resident in siloed applications or data repositories across the organization.

Payment types:

- Gifts (including text books and models)
- Meals
- Entertainment
- Honoraria and expenses associated with:
 - Speaker programs
 - Advisory Boards
 - Consulting agreements
 - CME
- Grants
- Bona fide clinical trial expenses
- Advertising spend in state
- Aggregate employee/contractors costs associated with advertising/promo activities

Required data attributes reside in separate systems and contracts within:

- Sales
- Marketing
- Medical affairs
- Finance (including expense systems)
- Legal
- HR
- Research and Development
- Third-Party Vendors

Unique customer identification is necessary for aggregate reporting

The effort to gather and align the data to individual health care professionals becomes even more difficult as each department/business unit often has a separate profile established to identify the physician.

- Most companies have established a Sales and Marketing Customer Master for matching/merging, unique identification, and profiling
- But few companies have achieved the ideal state of an enterprise-wide Customer Master to match all profiles and establish a unique HCP ID across Sales, Marketing, Medical Affairs, R&D, and Finance
- More stringent reporting requirements require an understanding of organizational hierarchy and affiliations

Current Infrastructure is not sustainable if Federal Physician Payments Sunshine Act is passed

There are certain "must-dos" for companies to prepare for and comply with respect to the new Federal Physician Payments Sunshine regulations.

Highlights of pending federal legislation:

- Applicable to all manufacturers of a covered drug, device, biologics or medical supply, including GPO ownership disclosure
- Report payments to all physicians, physician medical practice, and physician group practice in US
- Additional payment disclosures
- New payment exceptions
- Additional reporting attributes required
- Stronger penalties
- Public availability

Current state assessment:

- Assess the impact to current interpretation, processes, organizational impact, data integration, supporting applications, reporting, communication and training

Data access, integration and reporting:

- Define the best strategy for extracting and aligning the new data to report total aggregate health care provider spend

Customer master enhancements:

- Determine a future strategy to establish a single consistent view of the customer across the company

Physician Payments Sunshine Act presents a new opportunity

- Physician payment reporting is generally reactive and typically viewed by the industry as an administrative burden required to meet regulations
- Manufacturers have a unique opportunity to do more than just put in the basic systems, processes and controls to ensure compliance. They have an opportunity to:
 - Raise the bar for corporate compliance efforts
 - Improve industry perception and relationships with its consumers, the regulators and other key stakeholders
 - Better link compliance and business operations and drive additional value to the business beyond just compliance

Compliance as a competitive advantage

If companies truly want to drive value to the business with this investment, they should strongly consider using this as an opportunity to establish an **integrated, transparent** system and obtain the associated benefits:

- Risk mitigation
- Cost reduction
- Efficiency
- Effectiveness
- Corporate integrity
- Positive public perception
- Actionable insight for better business decision making, resource allocation, and avoidance of conflict of interests

What you should do now?

To accomplish this improved state of **transparency**, companies should consider establishing the following:

- **Corporate vision for transparency**—Establish a global strategy and vision for what transparency can mean to your organization and how it can provide a competitive advantage both from an internal and external stakeholder perspective
- **Streamline and standardize**—Consider aggregate spend in light of your other performance improvement initiatives focused on finance effectiveness, healthcare compliance, FCPA, Sales and Marketing cost reduction, R&D efficiency, corporate reporting and analytics, or IT/data management initiatives
- **Proactive monitoring and actionable analytics**—Establish and operationalize an enterprise wide framework for transparent monitoring, reporting, and analysis with Key Performance Indicators (“KPIs”) and dashboards used to detect and prevent issues

Thank you!

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