

Transparency and Aggregate Spend Overview

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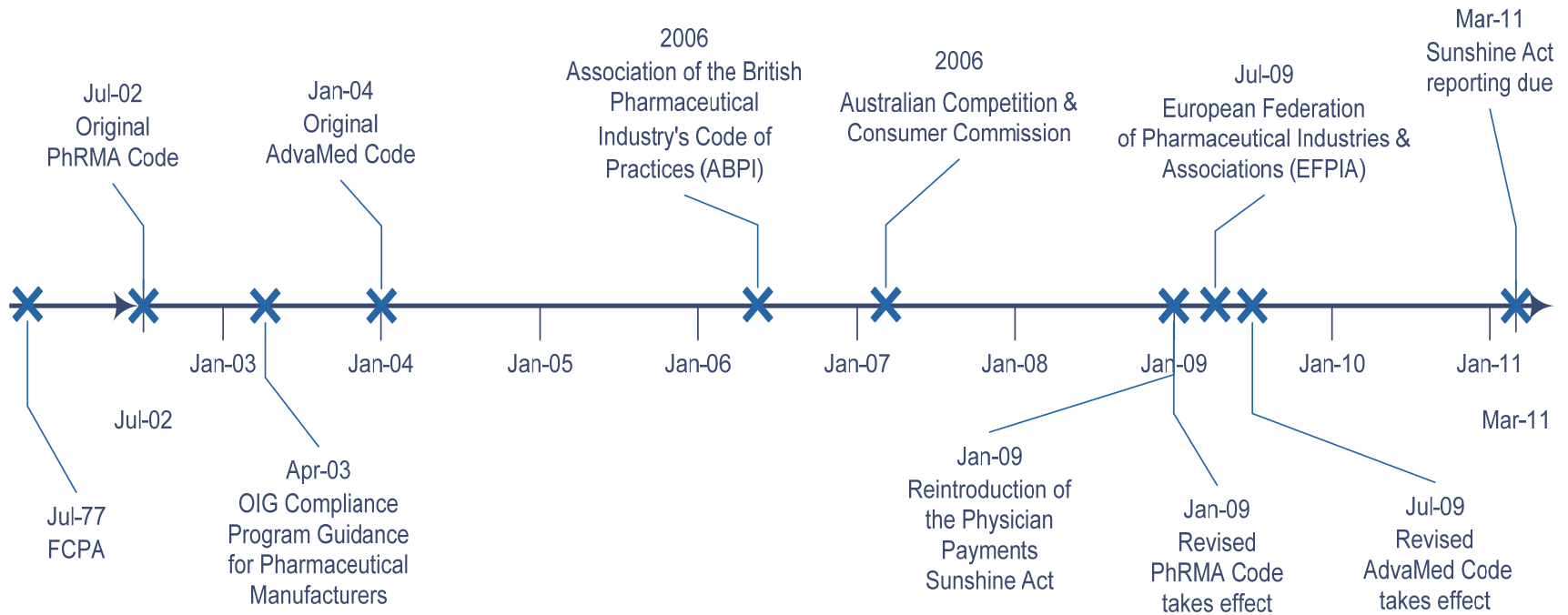
Agenda

- Current State of Disclosure – US & rest of world
- Operational Impacts
- How others are approaching the challenge?
- Q&A

The Global Trend toward Transparency

- We have witnessed significant parallels between the U.S. and rest of world related to the development around, and enforcement of, laws, regulations and industry guidances.
 - ✓ Industry Codes of Conduct (PhRMA Code → IFPMA Code)
 - ✓ Payments to Healthcare Professionals (Federal False Claims Act → FCPA)
 - ✓ Data Privacy (HIPAA → EU Data Protection)
 - ✓ State Laws → Local Country Laws
- The next major trend is toward an industry standard for **Transparency**, specifically as it relates to how, and how much, companies are spending money on health care professionals, organizations and other related entities.
- We are already seeing other countries – such as Australia and the U.K. – develop **Transparency** standards.

Healthcare Compliance Legislation and Regulatory Guidelines Timeline



US State Marketing and Disclosure Laws

States have been pushing for stricter and tougher requirements on the industry to openly share with the public the relationships with and financial investments made to Healthcare Professionals (HCPs) and institutions.

Several states have enacted state marketing and disclosure laws setting limits on industry payments to physicians and / or requiring the disclosure of these payments and associated marketing and advertising costs.

- California
- Minnesota
- West Virginia
- District of Columbia
- Maine
- Nevada
- **Newly passed**—Massachusetts (takes effect 7/1/09 with first disclosure report due 7/1/2010 for time period 7/1/09–12/31/09)
- **Newly revised** – Vermont (takes effect 7/1/09 with reports to be filed by 10/1/2010 covering all payments made 1/10/2010-6/30/2010)

In addition, during 2008, there were 22 states that had legislation pending that would create new state marketing disclosure laws.

US State Marketing and Disclosure Laws

Each state's requirements differ with regards to what information companies must disclose. This disparity between states makes it very difficult for companies to comply.

	DC	ME	MA	MN	VT	WV	S. 301
Applicability							
Pharmaceutical Manufacturers	X	X	X	X	X	X	X
Medical Device Manufacturers			X				X
Disclosure Requirements							
Meals	X	X	X		X	X	X
Gifts	X	X	X		X	X	X
Travel	X	X	X	X	X	X	X
Honoraria	X	X	X	X	X	X	X
Grants	X	X			X	X	X
Research Payments (Clinical Trial/Product Development)			X*	X			X
Product Sample							
Advertising	X	X				X	
Employer/ Contractor Cost	X	X					
Ownership or Investment Interest							X
Reporting Threshold							
Reporting Threshold	\$25	\$25	\$50	\$100	\$25	\$100	\$100
Reporting Timeline							
Reporting Deadline	7/1	7/1	7/1	5/1	12/1	4/1	3/31

* Includes Seeding Trials only

Other Drivers of Disclosure

- **Pending Federal Physician Payments Sunshine Bill (S. 301)** – reintroduced to Senate in 1/09 requiring companies to significantly increase the transparency of their financial relationships with HCPs via aggregate spend reporting; provisions include additional customer types, spend types and customer attributes

- **Corporate Integrity Agreements (CIA)**

The more recent Corporate Integrity Agreements have included “enhanced” provisions including the posting of payments made to Healthcare Professionals on company websites (e.g., Smith & Nephew, Cephalon, Lilly)

- **Industry Voluntary Disclosure** - Several companies have proposed plans to post physician payments publically on their websites, including Pfizer, Lilly, Merck, & GSK

- **Disclosure Requirements of Medical Schools & Institutions** – academic medical institutions and networks requiring their physicians and researchers to disclose their industry relationships and payments received (e.g. Partners Healthcare, Johns Hopkins, Cleveland Clinic, Duke University)

European Developments:

ABPI Code of Practice – 2006

- Companies operating in the UK have to declare which patient groups they are supporting.

Revisions to ABPI Code expected within the next year and likely to include:

- Mandatory transparency for all regions - publish lists of the healthcare organizations and patient groups that are given support and financial grants
- Disclose nature of the support and potentially the \$ amounts involved
- Controls related to “Travel Grants”

European Federation of Pharmaceutical Industries & Associations (EFPIA) - 2009

- Requires similar declarations to ABPI be written into all national codes
- Disclose name of patient groups they are supporting and the nature of the support (not the amount)
- “Encouragements” to also declare payments made for services provided by healthcare professionals and grants made to healthcare organizations.
- Individual educational sponsorship for individuals not included

Asia-Pac Developments:

The Medicines Australia Code of Conduct sets the standard for ethical marketing and promotion of medicines, including bans on gifts, entertainment and lavish hospitality in conjunction with educational meetings

Australian Competition and Consumer Commission (ACCC) - 2007

- Drug companies required to regularly and publicly disclose details of which restaurant they used for their educational events, how much the meals cost, and how many doctors were attending
- Medicines Australia publishes a report with detailed findings every 6 months
- There is no requirements to disclose the names of individual doctors
- Disclosures cover only educational events and does not include other financial interactions

Elements of an Effective Compliance Program

It has become accepted industry standard that there are 7 elements to an “effective” compliance program for how companies should establish internal controls to ensure adherence to applicable statutes, regulations and program requirements. These recent disclosure developments and requirements raise the bar for compliance programs to address an **8th element....**

7 8 Elements for an Effective Compliance Program:

- 1) Written Policies and Procedures
- 2) Compliance Officer and Compliance Committee
- 3) Training and Education
- 4) Reporting and Investigating (Effective Communication)
- 5) Monitoring and Auditing
- 6) Enforcement and Discipline
- 7) Response and Prevention
- 8) ***TRANSPARENCY***

Where is the Industry Today?

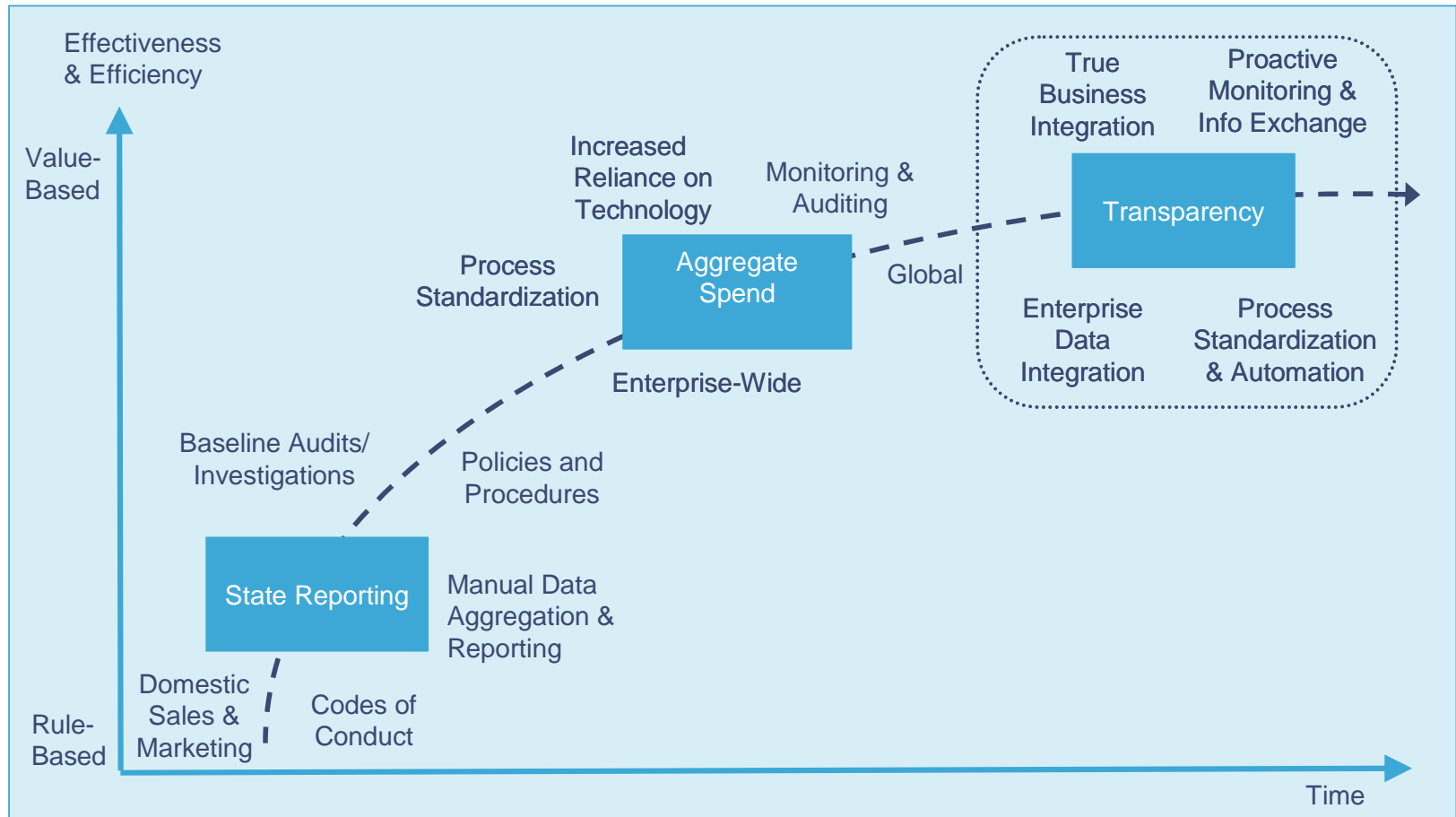
A majority of manufacturers have already taken steps to address the physician reporting requirements enacted in the various states.

- 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

Transparency Continuum

As companies mature along the continuum, the trend is shifting from internally driven efforts to more externally focused with the universe of impacted stakeholders expanding proportionally toward global networks and enterprise-wide span of control.



Operational Challenges - Customer Scope

Existing and emerging disclosure regulations are requiring disclosure of industry relationship and financial investments made to “covered recipients” that expand beyond the scope of healthcare practitioners (HCPs), thus requiring companies to capture profile information for individuals, institutions, as well as organizational hierarchy and affiliation information (HCP to HCP; HCP to HCO; HCO to HCO)

The effort to gather and align the data to individual customers becomes even more difficult as each department/business unit often has a separate profile established to identify the HCP and institution.

- Healthcare Practitioners (HCPs)
- Physician Medical/Group Practices
- Consumer/Patient Groups
- Hospitals, Clinics, Nursing Homes
- Pharmacists/ Pharmacies/ PBMs
- Health Benefit Plan Administrators
- Medical Schools and Institutions
- Medical/Professional Organizations
- Government Officials
- Third-Parties

Operational Challenges - Spend Types

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
- Research payments (seeding trials, clinical trials, product development)
- Product sampling
- Advertising spend in state
- Aggregate employee/contractors costs associated with advertising/promo activities
- Ownership or Investment Interests

Required data attributes reside in separate systems and contracts within:

- Sales (including independent sales forces, contract sales agents, distributors)
- Marketing
- Medical Affairs
- Finance (including expense systems)
- Legal
- HR
- Research and Development
- Third-Party Vendors

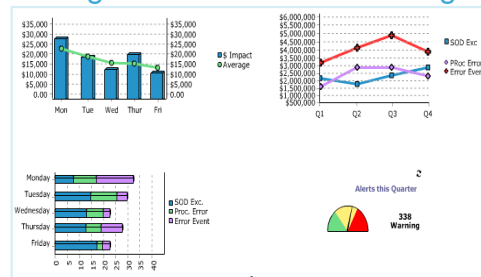
Vision for Transparency

Transparency is enabling access to enterprise-wide information to meet the dynamic needs of internal and external stakeholders.

Benefits

- Proactively detect issues/violations
- Efficient federal/state compliance
- Effective business input into strategies, tactics, resource allocation
- Identify cost reduction opportunities
- Corporate integrity & transparency

Driving value through Insight & Information Exchange



Customer Engagement Types

Sales & Marketing <ul style="list-style-type: none"> • Gifts, Meals, Entertainment • S&M Customer Expenses, Samples • Fee-for-Service Arrangements • Advertising • Patient Education • Conventions 	R&D and Medical Affairs <ul style="list-style-type: none"> • Clinical Trials • Fee-for-service Arrangements • Medical Liaison Customer Expenses • Medical Publications • Medical Information 	Corporate Affairs <ul style="list-style-type: none"> • Charitable Contributions • Advocacy • Corporate Memberships • Grants • Sponsorships • Fellowships 	3rd Party Vendor/Partners <ul style="list-style-type: none"> • Market Research • Vendor-Managed Programs • CME • Clinical Trials
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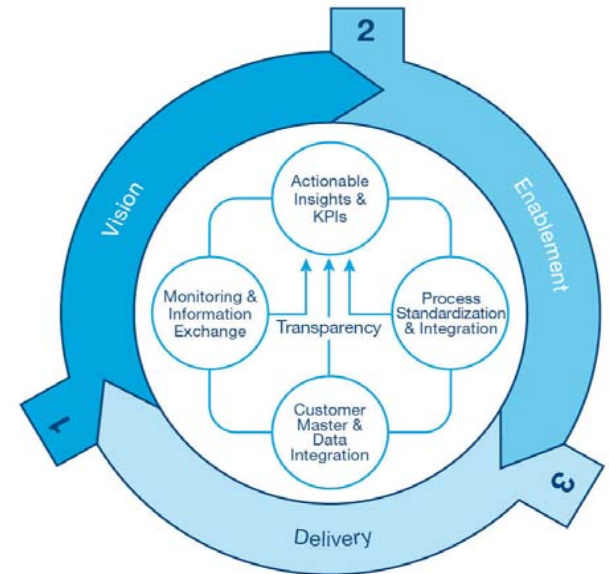
Compliance Program Elements



How Others are Approaching the Challenge

Accurate spend reporting requires an understanding and management of the interrelationships between policies, business processes, and data capture and integration

1. Establish Overall Transparency Vision
2. Current State Assessment
3. Enable Vision – Process Standardization & Automation
4. Enable Vision – Enterprise Data Integration
5. Proactive Monitoring and Information Exchange
6. Drive Business Value



1. Establish Overall Transparency Vision

- Determine scope of Aggregate Spend
 - Current and emerging requirements (spend types, customer types, customer attributes)
 - Prioritize channels for customer engagement and spend
 - Enterprise-wide scope (R&D, Sales, Marketing, Medical Affairs, Finance, Third-Parties)
 - Aggregate View across Divisions, Geographies, Products
 - Global considerations and scalability

- Create an inventory and establish common definitions of customer and spend activity types

- Identify impacted departments/stakeholders and processes
- Support applications and data sources

- Incorporate Agg Spend into Transparency Vision

- Identify key stakeholders (internal & external) & info needs
- Extend voluntary disclosure
- Overall Communication Plan (who, what, why, how?)

- Align Transparency/Aggregate Spend with overall Global Compliance Program and initiatives

The diagram illustrates a classification hierarchy. At the top is 'Report classification', which encompasses 'Customer classification'. 'Customer classification' further encompasses 'Aggregate Spend classification'. The 'Aggregate Spend classification' is detailed in the table below.

Customer activity	Spend type	Definition	Source systems		
			System 1	System 2	System 3
Speaker program	Fee (Honoraria)	The fees and associated costs that are either paid for or reimbursed to an HCP for attending an event that discusses Pharmaceutical Manufacturer's drugs and related medical conditions	•		
	Lodging/Travel		•		
	Meals		•		
Meals	Lunch & Learn	All kinds of meals either within the premises of the HCP's office or outside that are paid for by Pharmaceutical Manufacturer			•
	Dinner				•
Clinical Trials	Fees	Fees and materials (including drugs) provided for purposes of clinical trials either Pharmaceutical Manufacturer or physician/institution sponsored	•		
	Materials			•	
	Drug samples			•	
Medically-relevant items		Medically-relevant gifts are those that the HCP can use to demonstrate medical conditions and/or how certain drugs may function, i.e. For medical purposes			

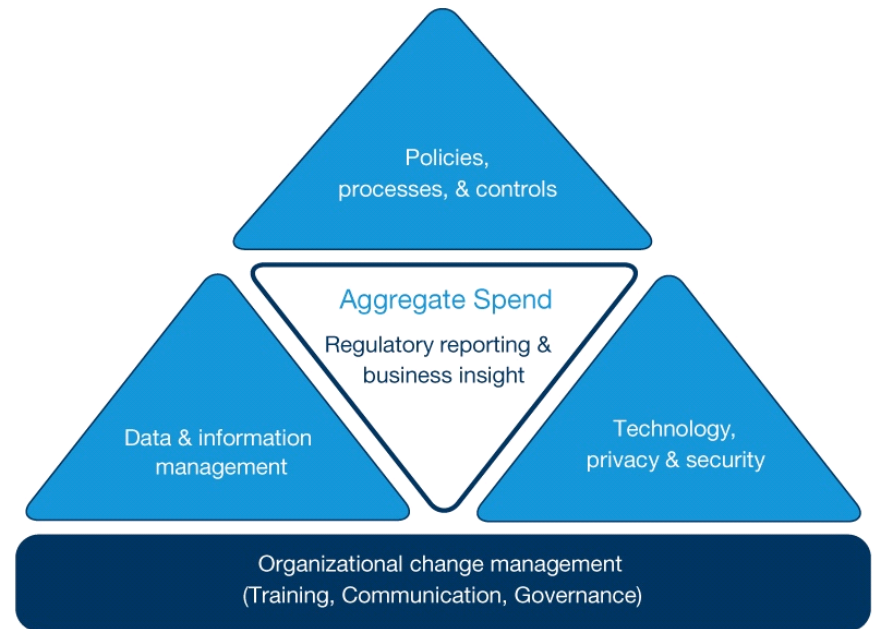
2. Current State Assessment

- Conduct Current State Assessment & Identify issues and improvement opportunities

- Policies and procedures
- Business processes
- Data architecture and integration
- Front-end applications and enabling technology
- People, communication, & training
- Proactive monitoring, reporting and analytics
- Regulatory compliance

- Develop phased Roadmap

- Conduct gap analysis of current/future state
- Prioritize needs & opportunities
- Develop phased roadmap of initiatives
- Identify costs & benefits (business case)



3. Enable Vision – Process Standardization & Automation

- Policy and Process Alignment

- Consistently apply compliance policies across business units to ensure consistent reporting
- Clear understanding of policies and spend limits at the time of customer engagement or spend commitment
- Embed compliance and monitoring controls within business processes

- Business Process Improvement

- Streamline and standardize end-to-end Procure-to-Pay and customer Fee-for-Service processes across business units and geographies
- Enhance or change existing business processes (how recipients are engaged or paid) to consistently capture required data for reporting
- Modify processes & front-end applications to consistently capture the right level of detail at the point of engagement

- Automate processes, workflow, and business rules via Business Process Management (BPM) and Business rule Engine (BRE) solutions

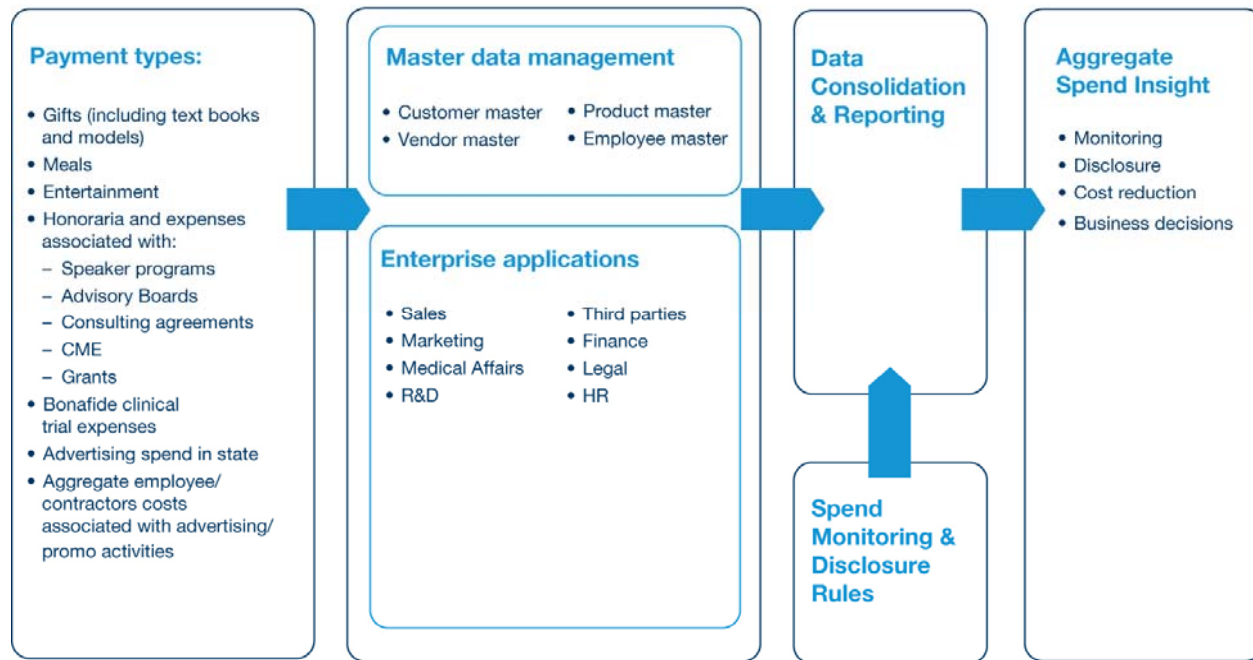
- Eliminate the majority of manual activities and paperwork and establish an audit trail
- Greatly reduce the risk of human error & automate decisions based on rules for increased accuracy
- Mitigate risk through consistent application of policy, ongoing monitoring, and consistent approvals

4. Enable Vision – Enterprise Data Integration

- Establish a clear data strategy (how, when & where data is captured & integrated)
- Enterprise-wide Master Data Management

- Customer Master
- Vendor Master
- Customer Affiliations
- Product Master
- Employee Master

- Enterprise data integration
- Business Intelligence
- Data Governance
- Incorporate privacy & security considerations



5. Proactive Monitoring and Information Exchange

- Enterprise-wide reporting framework

- Standardize metrics (definitions and calculations) and report layouts
- Capture data at atomic level but data models allow for roll-up of information to deliver key information to stakeholders at all levels
- Establish data governance model to centrally manage report/KPI additions or modifications

- Deliver information to key internal & external stakeholders

- Internal reports (Sales, Marketing, Executive Management, Compliance) to analyze/manage spend
- State and Federal Submitted Reports and Voluntary website disclosures
- Preemptive reports to customers and requested information/reports by customers
- Response to inquiries (methodologies, interpretations, errors)

- Proactive monitoring (detective and preventative)

- Migrate to “dashboards” - one place for users to go to view near real-time critical info pertinent to them with alerts and flags
- Leverage technology to proactively detect potential compliance issues and/or violations across the organization before they become material or widespread
- Provides for true end-to-end monitoring – issue identification, trend analysis, incident management, continuous compliance program improvement and business improvement opportunities

6. Drive Business Value

- Aggregate Spend can provides additional insights back to the business to further improve compliance, public perception, and product strategies and tactics
- Compliance Monitoring and avoidance of conflicts of interest
 - Modest meals
 - Minimum attendance
 - Fair market value
 - Promotional \$ caps
 - Outliers
- Cost Containment
 - Speaker payments for cancelled programs
 - Unused minimum guarantees
 - Unapproved pass-through expenses
 - Spending on non-HCPs and non-targets
- Better business decision making
 - Optimize promotional programs
 - Analyze information to determine appropriate resource allocations based on brands, geographies, seasonality, etc.

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