

A PROCESS-BASED APPROACH TO AGGREGATE SPEND

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EXECUTIVE SUMMARY

Pharmaceutical and Medical Device Companies have been facing increased pressure and scrutiny concerning their relationships with Health Care Providers and Institutions. Over the past several years, twenty state governments have introduced legislation requiring manufacturers to disclose their financial value exchanges with HCPs and HCIs, and just this year the federal government passed sweeping legislation that requires disclosure on a national scale. Given the sudden and large increase in the scope of this requirement, companies are now looking for both process and technology solutions to ease the burden of compliance. We propose a strategy companies may use to confront this new challenge, involving an up-front process analysis designed to assist organizations in understanding their current needs and environment before making the “Build or Buy” evaluation. A hasty decision to implement an automated solution could incur millions of dollars in professional fees, lead to a breakdown in cross-functional activities, further “siloeing” of the organization and a compliance and business nightmare. The assessment we recommend will result in the detailed understanding of your current environment that is needed to implement an automated solution, as well as identify policy and procedure gaps, control weaknesses, opportunities to implement industry better practices, while also ensuring accurate and complete Federal and State disclosure. Understanding the existing systems, their relationships to one another and operational procedures are crucial steps in reporting Aggregate Spend and designing a technical solution that best fits the organization and leverages existing systems, thereby reducing the solution’s overall cost. Any attempt to implement an automated solution without performing a similar assessment will have difficulty driving accurate results.

INTRODUCTION

Interactions between pharmaceutical, medical device and biologic (collectively “LifeScience”) companies and various healthcare providers (“HCPs”) and institutions (“HCIs”) over the past decade have been under increased scrutiny. The LifeScience industry’s various interactions with HCPs/HCIs have led to:

- ✓ Revisions to the PhRMA and AdvaMed Codes;
- ✓ Internal compliance and legal investigations;
- ✓ OIG and DOJ investigations;
- ✓ Large Civil and Criminal Fines, Penalties and Settlements;
- ✓ Costly Corporate Integrity Agreements;

Furthermore, various State disclosure and aggregate spend reporting requirements; and most recently the enactment of the Physician Payments Sunshine Act on March 23, 2010 in the Patient Protection and Affordable Care Act (“PPACA”) have required the LifeScience industry to understand and interpret regulatory requirements designed to report these interactions with HCPs/HCIs to State and Federal Agencies. This has required the LifeScience industry to develop and implement policies, procedures, systems, and controls to successfully gather and report certain interactions with HCPs/HCIs. In addition, monitoring and auditing processes need to be designed to identify non-compliant activities, as well as maintain data integrity and compliance when internally and externally reporting these activities. This has become challenging for many companies, because the various activities and data are not centrally located or maintained, but rather are housed in separate systems and information silos based on functional area. Addressing this challenge requires a cross-functional effort. In addition, the data required to comply with the Federal and State reporting rules may be inconsistent, incomplete or non-existent within these systems.

Many consulting and software companies have developed so-called “off-the-shelf” software designed to provide the LifeScience industry an automated solution to gather, maintain and report these amounts. The LifeScience industry needs to carefully understand their current IT environment, infrastructure, capabilities and limitations before trying to select and implement externally developed software solutions. Many times simple policy, procedure,

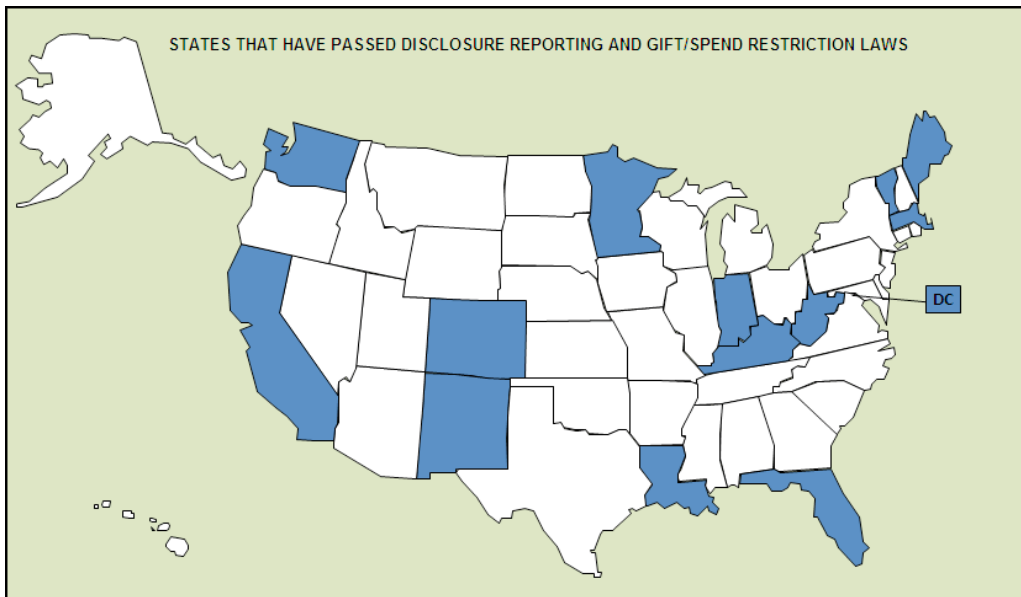
system and control changes to the current environment can reach the same successful conclusion and save the company millions in software, consultant, legal and implementation fees.

The following article outlines an up-front approach designed to assist organizations in understanding their current needs and considerations to be taken when making the “Build or Buy” evaluation. A hasty decision to implement a state-of-the-art automated solution could incur millions of dollars in professional fees, lead to a breakdown in cross-functional activities, further “siloeing” of the organization and a compliance and business nightmare.

DISCLOSURE LAWS – THE CURRENT ENVIRONMENT

The current legislative environment includes 20 states with legislation introduced requiring pharmaceutical and medical device companies to disclose various financial transactions or exchanges of financial value to healthcare providers (HCP) and affiliated healthcare organizations (HCOs). As of this writing, 13 states and Washington D.C. have passed legislation requiring the reporting of activities and value transferred to HCPs. The current state-level reporting requirements are not consistent from state to state and cannot be broadly interpreted regarding the definitions of terms, the reportable entities, or the types of transactions to be reported. The current state reporting requirements include:

- ✓ **Gift Restrictions/Spend Limits** – California, Louisiana and Minnesota and Vermont
- ✓ **Spend Reporting** – District of Columbia, Louisiana, Maine, Minnesota, Vermont and West Virginia
- ✓ **Advertising Cost Disclosures** – District of Columbia, Maine and West Virginia
- ✓ **Clinical Trial Disclosure** – Maine
- ✓ **Sample Theft/Loss Reporting** – Colorado, Florida, Indiana, Louisiana, New Mexico, Vermont and Washington
- ✓ **Legislation Recently Introduced** – Arizona, Connecticut, Iowa, Illinois, Maryland, New York, New Jersey, Oregon and Texas



The list of states enacting disclosure laws is growing, and the federal requirement makes disclosure mandatory across the entire U.S.

As we mentioned above, on March 23, 2010 President Obama signed into law the PPACA, which contains the first-ever national standard reporting requirement. Beginning on March 31, 2013 and annually thereafter the *Reporting Requirement for Payments to Physicians and Teaching Hospitals* (§ 6002) requires US operating pharmaceutical, biological and medical device companies to report payments and other transfers of value made during a prior year to physicians and teaching hospitals. The Department of Health and Human Services (“HHS”) will publish the reportable amounts on the Internet in searchable form no later than September 30, 2013. Although PPACA preempts state laws that require reporting of the same types of information, it does not prevent states from adding their own reporting requirements that go above and beyond the PPACA.

A PROCESS-BASED APPROACH

Whether you decide to build or buy an automated solution, you should consider beginning with a “Process-Based” assessment to understand all your company’s interactions with HCP/HCLs and how those interactions are performed and recorded within your existing systems. This type of assessment will result in a detailed understanding of your current environment that is needed to implement any automated solution, as well as identify policy and procedure gaps, control weaknesses, opportunities to implement industry better practices, while also ensuring accurate and complete Federal and State disclosure.

A Process-Based assessment provides the detailed forensic analysis and monitoring needed to assure compliance results. This approach is essential for the disclosure reporting required and addresses the central visibility of your firm’s current technology systems. Understanding

these existing systems, their relationships to one another and operational procedures are crucial steps in reporting Aggregate Spend. Any attempt to implement an automated solution without performing a similar assessment will have difficulty driving accurate results. The complexity begins with the fact that interactions with HCP/HCLs occur within a multitude of functional areas and departments, are recorded in separate systems or databases and inconsistencies may exist with the way the various data are recorded (or not recorded) and maintained. Our assessment approach provides the necessary understanding into the existing systems before a proper automated solution (both internal and external) can be incorporated.

Companies must realize that there are several data administration and retention systems within an organization that monitor, administer and record the financial transactions for each of the different interactions with HCP/HCLs. In addition, these environments look different both company by company (multi-divisional entities), as well as within each company (i.e. functional area/department by functional area / department). That being said, performing this forensic type of analysis and gap assessment will enable you to do the following:

- ✓ **Identify the HCP Touch Points** – Obtain a clear understanding of the current and proposed interactions with HCPs throughout the organization, for all functional areas within the commercial, clinical, and R&D environments.
- ✓ **Identify HCP Payment Systems and Processes** – Based on the understanding of the HCP Touch Points, identify the interactions that result in value being transferred to an HCP (i.e. meals, publication reprints, contractual arrangements, ad-hoc

advisory services, clinical studies, etc.) across each functional area within the organization – particularly Sales, Marketing, Medical Affairs, Finance, Legal, Compliance, Clinical, Research & Development, etc.

- ✓ **Map the HCP Touch Points to Systems and Processes** – This will provide the “as is” data and process flow environment for recording interactions with HCPs, based on a review of applicable documents and on interviews and walkthroughs with key internal and external stakeholders. It will serve as the starting point for a future-state environment designed to accurately capture and report the required information, as well as meet the compliance and business needs of the organization.
- ✓ **Gap Analysis** – Based on the above walkthroughs, identify gaps within your organization’s policies, procedures, controls, auditing and monitoring, training and system solutions both short term and long term. Any solutions identified should take into consideration your current and future resource restrictions, operations, IT infrastructure and state of the organization.
- ✓ **Master Customer Data** – One of the keys to this process is to identify all repositories of customer information throughout the business and how these databases are maintained and administered. A consideration may be to have a single point of reference for each functional area or department when assigning an HCP/HCI to his or her respective financial transaction resulting from an interaction. This analysis of existing customer data stores can be the first step toward building a centralized Customer Master Database, which is crucial to being able to link different value transfers made to the same HCP/HCI.
- ✓ **Training and Monitoring** – During the entire process you need to identify the control points within the organization, as well as identify additional proposed controls through the gap analysis (see above). The business stakeholders, along with IT, compliance and legal, should develop real-time and retrospective auditing procedures designed to ensure that policies are practiced throughout the organization. The key to this is training. The development and implementation of training delivered to all levels of the organization, taking into consideration the short term and long term solutions to be implemented, is a necessity.

WHERE TO BEGIN

A proven and cost-effective approach to performing this assessment is to create a cross-functional steering

committee. The steering committee members would include key stakeholders in the affected functional areas (i.e. Clinical, Marketing, Medical Affairs, any other functional areas that interact and transfer value to HCPs and HCIs) along with IT, Finance, Legal and Compliance. The steering committee’s mission would be to address the needs outlined above by doing the following:

- ✓ Review the current policies and fill any gaps in addressing the current and future Federal and State reporting requirements. In addition, develop a complete Federal and State specific reporting policy library.
- ✓ Document and assess the current systems and data environment through input from stakeholders representing each functional area that interacts and transfers value to HCPs and HCIs. The documented walkthroughs are designed to provide a detailed understanding of the following:
 - a. **Process** – How is data captured, approved, and overridden or manipulated, as well as the various control points throughout the process?
 - b. **Systems** – In what systems is the data maintained and what are the relevant controls and validation procedures?
 - c. **Data Elements** – What data elements are available to meet the reporting requirements?
 - d. **Data Gathering Procedures** – What processes are necessary to capture accurate and complete relevant data?
- ✓ Identify short and long term system and procedure solutions designed to meet data collection and maintenance challenges. This can include many or all of the following:
 - Identify resources within the organization to perform various data gathering, validation and reporting functions;
 - The assessment will identify the current and recommended controls to ensure that accurate and compliant reporting is performed;
 - Work closely with IT and operations to develop a “build or buy” appraisal taking into consideration the “as is” and future-state data and process flow, budget and resource needs of the entity;
 - If the assessment determines that a software system would be the most efficient solution, the results of the assessment can be used to reduce

the cost of the implementation (i.e. data field layouts are defined, system specification documents are completed, etc.);

- The steering committee should continue to oversee the development and implementation of any automation solution, whether purchased from a vendor or custom-built;
- Once the process is put into place, develop – and obtain steering committee approval for – a training program to roll out the new policies and procedures that were developed and implemented during this process.

BUILD OR BUY? THE TECHNOLOGY CHOICE

The process-based approach we advocate is not a substitute for system automation but rather an important precursor to selecting a technology solution that fits your organization’s needs. Once you have the insights from a thorough process analysis, you will be in a much better position to know how technology can benefit you most. You’ll also know what you *don’t* need. Armed with this knowledge, you can better evaluate your technology options. Companies with a limited volume of reportable transactions may find that they only need to adjust their manual processes and controls based on the knowledge gained from the process and gap analysis. Many will need technology to help them manage the large amounts of data they must collect to comply with the disclosure rules.

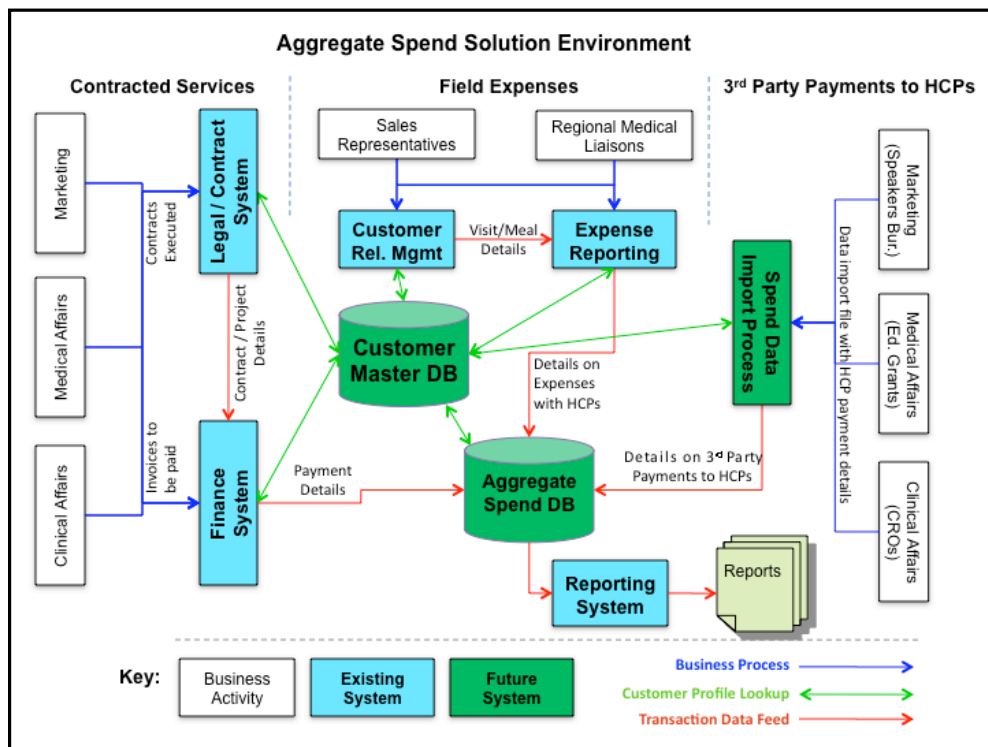
It is important at this stage to involve your IT partners to determine your organization’s standards for certain types of solutions, whether they are developed in-house, purchased from a vendor and implemented internally, or the emerging breed of hosted “Software as a Service” (SaaS) systems. Some solutions may be ruled out based on your company’s standards and preferences. All remaining potential solutions can be evaluated together, against the business requirements developed during the process analysis.

Before you go any further, you should take stock of what required functions may be handled by systems you already own. Companies of any size are likely to

have already installed systems that perform functions related to the aggregate spend processes, such as:

- ✓ **Financial** – systems that send and track payments
- ✓ **Customer Relationship Management** – information about Customers (many of whom are HCPs) and interactions with them by company representatives
- ✓ **Legal / Contracting** – contractual arrangements with HCPs who provide consulting, serve as clinical investigators or advisory board members, etc.
- ✓ **Expense Reporting** – expenses that may arise from non-financial value transfers (such as meals) to HCPs
- ✓ **Reporting / Analytics** – systems that can derive meaningful business information out of large data repositories

As illustrated in the schematic below, a complete aggregate spend solution can leverage these existing systems to pull much of the information needed for disclosure. Regardless of whether you buy or build, these systems need to be connected to your final solution, and may even form the basis for a core system component. For example, your organization’s existing Customer Relationship Management (CRM) system may serve as the starting point for a Customer Master Database.



If your list of potential solutions includes those provided by outside vendors, then the process analysis and the resulting business requirements may be used to develop a complete Request For Proposals to send to candidate vendors. Since this document will provide details on your current systems environment, vendors will have to address the need to integrate the existing systems into the final solution. It can also prompt a discussion of whether their solution duplicates any of the functions your systems already provide. In this way, the process-based approach can help drive down the cost of the ultimate solution by trimming the solution to only the required elements.

CONCLUSION

In some Utopian parallel universe, regulations across different levels of government are harmonized and consistent. As you have undoubtedly noticed, we don't live there! Complex and conflicting requirements are the norm and there is no silver bullet, commercial software package, or online service that solves them out of the box. We believe that you give yourself the best chance of finding a solution that fits your organization's needs and budget if you follow a process-based approach first and define your specific needs, environment and resources before embarking on a quest for technology solutions.

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