SAP White Paper
Life Science and Healthcare

ENGAGING THE HEALTHCARE PRACTITIONER

ENABLING TRANSPARENCY AND COMPLIANCE ACROSS THE HEALTHCARE AND LIFE SCIENCE VALUE CHAIN

CONTENT

THE LIFE SCIENCES INDUSTRY
A LOOK BACK AND AHEAD

The life sciences industry, consisting of pharmaceutical, biotechnology, and medical device companies, spends billions of dollars every year to inform, educate, train, and interact with healthcare practitioners. A healthcare practitioner (HCP) as defined by the FDA is an individual, whether a physician or other healthcare provider, who has been licensed under state law to prescribe drugs or medical devices. The industry views HCP interactions as a critical link in the development and adoption of innovative and life-changing therapies that can dramatically improve therapeutic outcomes and the quality of a patient's life. HCPs benefit from an association with pharmaceutical and medical device organizations, insofar as they receive the latest information on clinical trials, product benefits, patient safety issues, and research, which may assist them in their care and diagnosis of patients.

Unfortunately, as the number of interactions has increased over the years – along with resulting HCP marketing spend – so has the incidence of fines and prosecutions for inappropriate and illegal behavior. In the United States, the federal and state governments have aggressively prosecuted cases across the industry, levying fines from hundreds of millions to billions of dollars against pharmaceutical and medical device companies, in an attempt to preserve the integrity of the physician-patient relationship.

More recently, legislation has been proposed to reinforce the integrity and increase the transparency of the relationship between life science manufacturers and the HCP. In 2008, 22 states had legislation in process that would create new marketing disclosure laws. In states like Massachusetts and Vermont, these laws went into effect July 1, 2009. At the federal level, Senators Chuck Grassley of Iowa and Herb Kohl of Wisconsin reintroduced the Physician Payments Sunshine Act (Sunshine Act) to provide federal guidance on monitoring and reporting physician spend activity. The bill is further evidence of the importance of focusing on transparency in the healthcare process and its subsequent impact on healthcare reform.

The Challenge

Legislators believe that the only way to ensure the integrity of the relationship between the medical device manufacturer and the HCP is to make it completely transparent. Transparency requires visibility, but HCP spend transactions are generated across a variety of disconnected systems, while the HCP master data is inconsistent and, in some instances, inaccurate. A multibillion-dollar life sciences organization could have HCP spend transactions originating from as many as 20 different source systems. The transactions could easily cover such diverse areas as clinical research, time and

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expense reporting, honoraria, thought leadership programs, continuing medical education, sales force automation, and grants.

In addition to the challenge of achieving transparency, current legislation mandates life sciences manufacturers to:

- Track and report spend activity for amounts as low as:
  - US$25 at the state level, depending on the statute and state
  - $100 at the federal level in compliance with the Sunshine Act
- Designate spend types, which may include but are not limited to gifts, consulting, entertainment, travel, honoraria, and research
- Observe state-specific spending thresholds and definitions of HCPs now that state legislation has preempted the federal mandate
- Make qualitative assessments based on legal interpretations of both state and federal regulations, a requirement that directly affects the cost, complexity, and timing of HCP reporting

The Opportunity

With a complex array of state reporting requirements to fulfill and federal legislation likely to be enacted in 2010, many life science organizations have taken a tactical approach to meeting reporting mandates. Clearly, complying with reporting deadlines is a priority. However, leading organizations are designing solutions that meet short-term compliance mandates while leveraging a foundational infrastructure that will deliver longer-term business value at a reduced cost. A primary area of process improvement focuses on creating a global HCP master record, the objective being to gain enterprise-wide visibility of HCP spend processes, a global view of the HCP ecosystem, and an improved knowledge base of global HCPs. In capturing data describing HCP affiliations, relationships, and locations of activity, the master-data record can bring dramatic benefits to life sciences companies. Specifically, organizations can leverage the HCP information to help decrease time to market for new drugs and products, reduce delays in clinical trials through improved visibility of investigator recruitment, and improve patient safety and therapeutic outcomes.

An effective process to cleanse HCP spend would aggregate spend data; harmonize HCP demographic information like name, address, and state license number; and create a "golden" HCP record that captures the complex data of the affiliations, relationships, and locations of activity that describe the HCP role. Life sciences companies can reap a variety of benefits by leveraging the data resulting from the cleanse process to:

- Meet U.S. federal, state, and pending global mandates for HCP spend reporting
- Design governance strategies based on HCP master records to enable preventive transactions, which could, for example, identify HCPs before a spend transaction is executed in order to signal when approvals or workflows are required for that transaction
- Provide global visibility into the HCP universe, which can reduce cycle times and generate business value
- Create a global repository of HCPs that provides a global view of physician activities, including marketing, clinical, and sales activities

PHYSICIAN SPEND
AGGREGATING DATA TO ACHIEVE TRANSPARENCY

The premise of the Sunshine Act legislation and state-level mandates is simple: eliminate spending irregularities by making the relationship between life sciences manufacturers and the HCPs completely transparent. The seemingly simple goal quickly becomes complicated when one examines the deep-seated relationships and tight collaboration that have evolved over decades between the two parties. The *New England Journal of Medicine* states that almost all physicians (94%) have some type of relationship with the life sciences industry. Eighty-three percent report receiving food and beverages in their workplace, 78% receive drug samples from manufacturer representatives, 35% receive reimbursement for expenses related to professional meetings or continuing medical education, and 28% receive payments for consulting, speaking, or enrolling patients in trials[1]. This broad base of interactions reflects the prevalence of the collaboration between HCPs and manufacturers as together they strive to manufacture, distribute, and administer to patients products of the highest quality and greatest efficacy.

To make this intricate relationship transparent, life sciences manufacturers must aggregate their physician spend data, which is not a straightforward job. Manufacturers use a wide variety of software applications to interact with physicians. The HCP spend information generated by the disparate applications does not reside in a single repository.

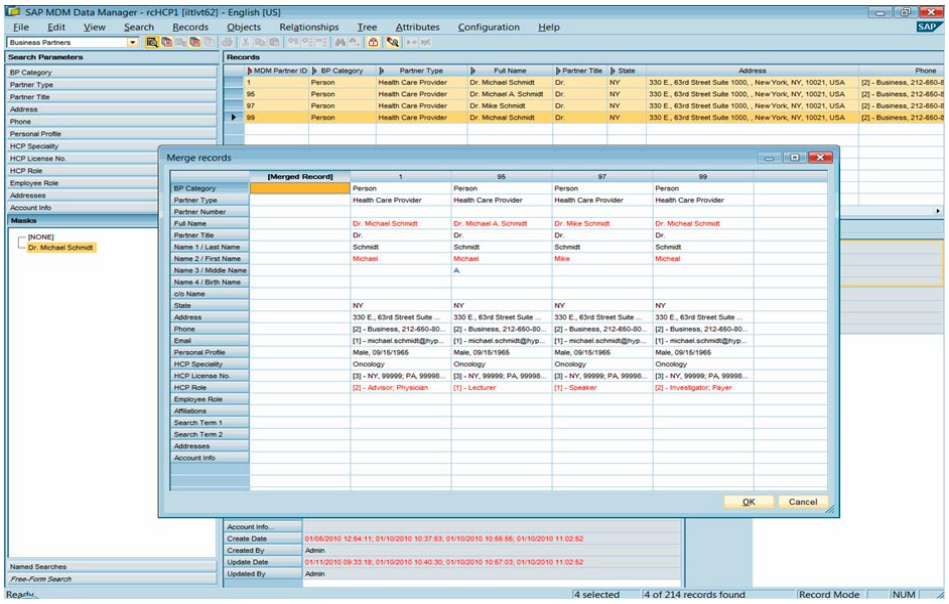

Figure 1: Discrepancy in Data References to One Individual Physician

The information across those repositories is inconsistent, may not be current, and is not monitored by any strict governance process to impose integrity. In fact, the data typically lacks sufficient detail to support such a process. Yet the reports manufacturers must submit in order to comply with regulations must be based on HCP spend data that has been harmonized, aggregated, and analyzed across the organization. The message is clear: life sciences manufacturers must cleanse their data if they are to comply with binding legal requirements.

Aggregating spend information to accurately reflect an individual HCP is an objective of major importance in the process of cleansing HCP data. Yet to accomplish this, organizations need to understand how to cleanse and aggregate the data. Figure 1 highlights a common scenario in which there are numerous references to a single physician across disparate transactional systems that vary but nevertheless refer to the same physician. In cleansing and harmonizing these references, a manufacturer avoids duplications and inaccuracies while improving the overall accuracy of the spend information.

1. Campbell, E. G., R. L. Gruen, J. Mountford, L. G. Miller, P. D. Cleary, and D. Blumenthal, "A National Survey of Physician-Industry Relationships," *New England Journal of Medicine* 2007; 356:1742–1750.

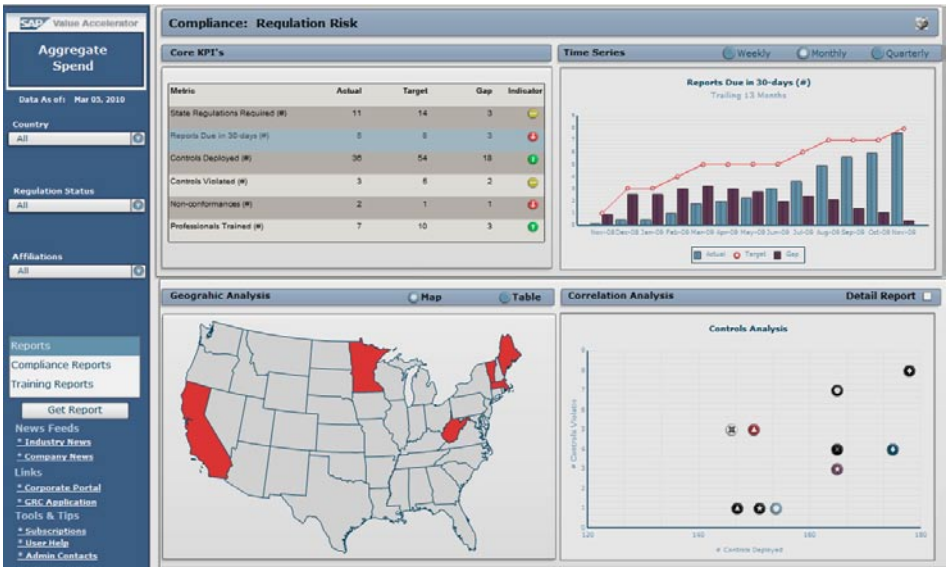

Figure 2: Role-Based Dashboard View of Large Volumes of Data

Support for Robust Master-Data Governance

The data cleansing process should not be viewed simply as a data aggregation issue. Although life sciences companies require a process that aggregates HCP spend data effectively, what's more important is basing that process on structures and rules that can support a robust master-data governance policy. These structures and rules must be rooted in quantitative measurements, or key performance indicators (KPIs), that link business processes with process owners in order to achieve global visibility. For example, aligning KPIs around the process that tracks spend dollars and percentages by spend type, HCP, region, state, and therapy would help achieve global visibility. It would also enable a strong governance process for identifying trends and issues that could be addressed before they become problems.

Monitoring, measuring, analyzing, and controlling are standard components of any quality assurance process, and the area of HCP spend should be no exception. Yet for business, compliance, and quality personnel to enforce the process, they must be able to review large volumes of data efficiently and act on them effectively. Figure 2 highlights how a role-based dashboard can turn large volumes of data into actionable information by displaying the data within a single view. The KPIs thus displayed drive global visibility and heighten awareness of process areas in ways that can prevent issues or problems from occurring, thus enforcing governance policies.

For example, many companies have imposed spending limits for any HCP licensed in a particular state. Focusing on the reporting aspect of the problem will not help them comply with the spend level. Instead, they must be able to track spend data in real time or near-real time. Further, by tracking KPIs related to HCP spend levels by geographic region, therapeutic category, sales personnel, and spend type, compliance personnel will be able to detect any trends in performance levels that require intervention. Thus alerted, they can block undesired transactions by notifying the appropriate personnel or restricting marketing spend on the HCP in question. The broader concept of preventive measures becomes increasingly important as the number, region, and spend types associated with this scenario expand.

HCP MASTER DATA

ENABLING WORKFLOWS, APPROVALS, AND ROBUST GOVERNANCE

Central to the long-term sustainability of a process that aggregates physician spend is enabling business processes that support workflows, approvals, and a robust governance process through HCP master data. But an HCP master-data record is more complex than a traditional master-data element. For example, the most common master-data record describes a product and includes a description, units of measure, and a bill of materials or recipes. In many instances, relationships to features, characteristics, and options are one-dimensional, and they may include additional singular connections to other products.

By contrast, HCP master records are three-dimensional, with a complexity that reflects the intricate relationships that span the life sciences industry. First, the definition of an HCP varies from company to company and may comprise subcategories of physician, nurse, and practitioner, all of whom administer the company's products or drugs in a hospital, clinic, or home care environment. Second, HCPs have a variety of affiliations with hospitals and clinics that need to be tracked in order to better understand their institutional relationships, the impact they have on the demand generated for the company's product at the institution, and an understanding of the hospital or clinic HCP policies and procedures. Third, HCPs maintain relationships with other HCPs that are important to incorporate into the broader context

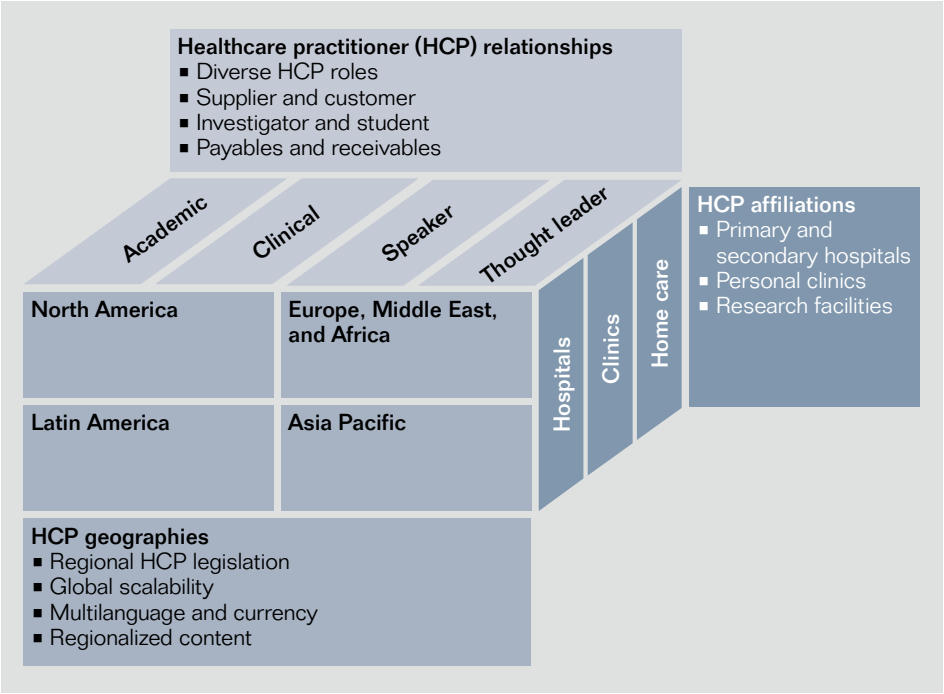

Figure 3: Complexity of the Healthcare Practitioner Master Record

so life sciences organizations understand, for example, which physicians are affiliated with specific hospitals, which nurses and practitioners practice at those hospitals, and which, if any, work closely or directly with the physicians. Last of all, the information must be captured in a global context so that the regulatory and operational aspects meet the requirements of the major North American, European, Asia Pacific, or Latin American regions while simultaneously scaling to support the global volumes and transaction levels associated with multinational life sciences organizations. Figure 3 illustrates the complexity inherent in the HCP master record.

Additionally, the data needs to be accessible in the context of the broader sales and marketing business processes. Incorporation of the master-data element into the business process will increase business value through its integration with financial, sales, and clinical operational areas across the various HCP spend types.

HCP MASTER-DATA GOVERNANCE

EXPLOITING AUTOMATION TO STANDARDIZE HCP PAYMENTS

Once a solid master-data governance process is established within the enterprise framework, organizations will begin to see business benefits in a variety of ways. HCP master data can be leveraged to standardize the process of HCP payments through the use of portal or Web-based access points. These applications may require individuals to complete an HCP spend request before any HCP spend activity is executed. Drop-down menus display validated HCP information that the user selects from. Field-level validations are performed for spend types, hospitals, and dollar amounts. For larger dollar requests that typically require up-front approvals – such as consulting, research, or clinical spend types – specific business processes can be enabled to ensure compliance. This automation is critical if more complex "broker" scenarios are to be supported. A broker scenario is one in which the life sciences manufacturer pays an intermediary, who then pays multiple HCPs for services rendered. In order to comply with current HCP spend legislation, life sciences companies need to track payment to each HCP, not just to the broker.

A clear illustration of the broker scenario is when a life sciences manufacturer uses the services of a clinical research organization (CRO). CROs provide clinical services that primarily involve conducting clinical trials for which they may employ a number of physicians as investigators. In the past, milestone payments were made by the life sciences manufacturer to the CRO based on completed activities, and the CRO paid the HCPs. That is no longer an accepted practice. As mentioned above, current legislation decrees payment for a clinical investigation as a spend type that must be tracked and reported per HCP. Accordingly, the CRO must now provide the names of the physicians participating in a clinical trial and the exact amount each will be paid. Clearly, process changes at the CRO are required, but many life sciences companies expect to leverage Web-based sites to process these types of transactions. HCP information will be included as part of the invoicing process for the CRO and will be required before payment is issued. A simple CRO portal prototype is shown in Figure 4 and highlights how validated data can be incorporated to check the accuracy and completeness of an HCP spend transaction.

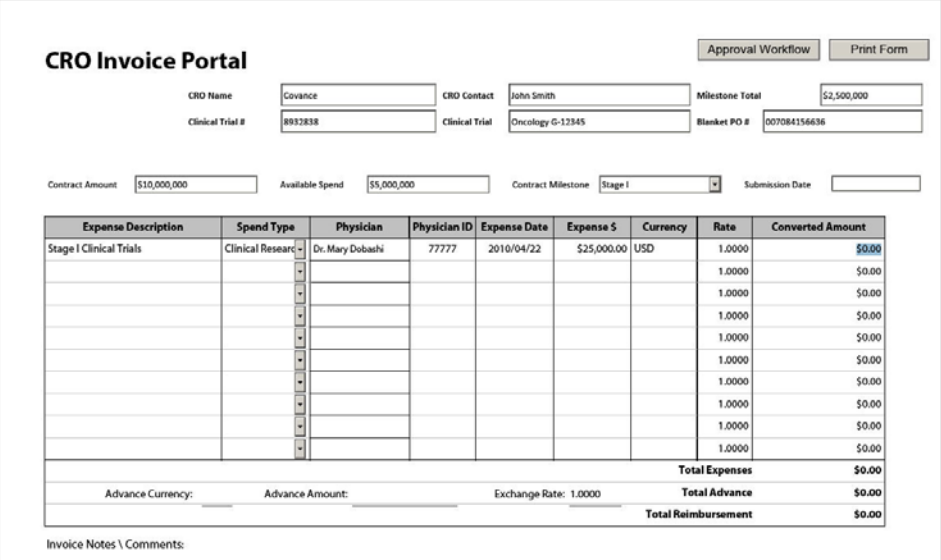

Figure 4: Invoice Portal for Clinical Research Organization

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The form shown in Figure 4 can be broken down into the following functions:

- Header information includes vendor and contract information to validate specific payable information as well as state and regional data.
- Expense-level detail supports field-level validation and requires certain information before any process can be initiated, including:
  - Expense description
  - Spend type, with a drop-down list providing valid choices
  - Physician name and ID, with a search field that finds only approved HCPs
  - Expense date
  - Amount of expense and currency
  - Approval workflow
- Data consolidation across multiple HCP spend transactional systems is performed in order to process the transaction. This is necessary due to the fact that the company most likely uses disparate spend systems.

The form illustrated in this example is less important than the information it contains and the business process it enables. The "golden record," or HCP master data, provides the field-level validation to ensure the integrity of the data, while the resulting business process provides the oversight and governance to ensure compliance with the regulations. The performance loop is closed when the form launches notifications to the dashboards mentioned earlier, thereby ensuring transparency.

RISK-BASED CONTROLS

COMPLYING WITH MULTIPLE REGULATORY MANDATES

Data aggregation issues, process complexities, and global regulatory mandates are a diverse set of challenges that IT, sales, and finance organizations must overcome in order to satisfy the regulatory requirements of HCP spend legislation. Aware of the severe repercussions associated with violating HCP regulations, leading organizations have asked their enterprise audit groups to assist by instituting operational controls to increase visibility and mitigate risk in this area.

For decades, life sciences organizations have leveraged automated processes based on risk-based assessments across a validated environment to ensure compliance with operational regulations. To a lesser extent, this concept should be applied in this area. An organization assesses the risk inherent in its business processes, identifies the areas of greatest impact of the HCP mandates, and ensures that controls, processes, and measurements are in place to validate appropriate governance and performance. These key risk indicators (KRIs) and KPIs provide the basis for role-based dashboards that alert the appropriate personnel when performance variances occur. Unlike operational controls that govern an entire process to ensure regulatory compliance with mandates such as the Good Manufacturing Practice regulations advanced by the FDA, automated controls are more specific. They focus on the most critical or highest risk element of a process. Risk-based controls define specific events that, when they occur, launch business processes that create global visibility into the risk processes and ensure that operational performance aligns with regulatory compliance.

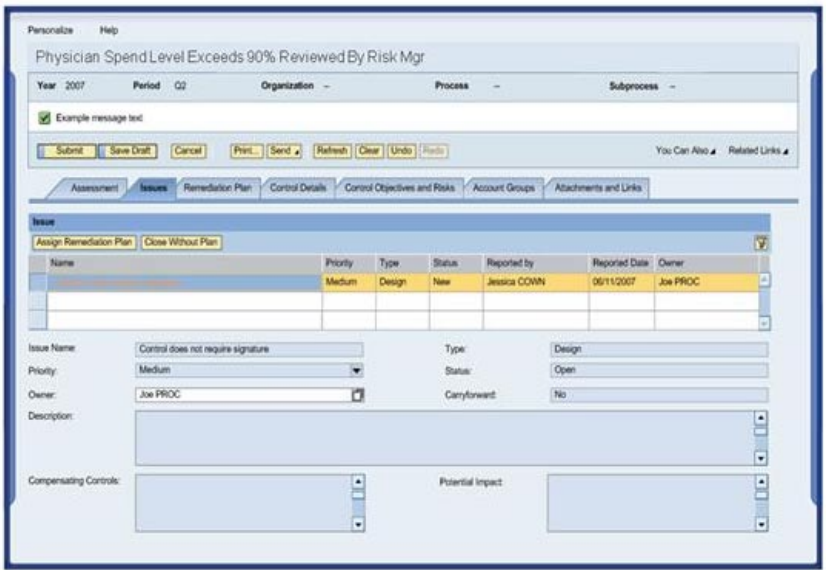

Figure 5: Automatic, Risk-Based Control for Healthcare Practitioner Spending

For example, many organizations set spend levels for specific HCP personnel. Rather than report HCP spend activities from data aggregation after the fact, organizations institute a risk-based control process for HCPs whose spend limit exceeds, for example, 90% of the threshold set, as shown in their latest HCP spend summary. The control tracks the threshold against an HCP-spend KRI. When the threshold is exceeded, the control triggers notifications that are sent to the sales management that owns the hospital where the HCP is affiliated. Simultaneously, notifications are sent to the finance department to put that HCP on a watch list to restrict payments to the HCP in compliance with company-mandated policy and regulatory mandates. The process may be automated, documented, and validated on a regional or global basis, again in conformance with governance for HCP payments.

An example of an automated, risk-based control for the HCP scenario is shown in Figure 5.

Holistic and Automated Approach to HCP Spend Compliance

Governments believe transparency is the critical element in imposing any significant governance process on the healthcare industry and keeping it objective and cost-effective. However, the governance policies that organizations establish in response must be equipped to fulfill legislative mandates not only now but in the future. And those mandates – as well as the corresponding processes – will be evolving globally over the next decades. To be able to do this, organizations must take a holistic, strategic approach toward their HCP spend as well as toward their broader sales and marketing spend.

An integrated HCP master data management program – combined with a "golden" HCP master record that captures complex affiliations, relationships, and global locations for multinational life sciences organizations – will be critical in establishing the integrity of the information. It is just as essential for introducing the processes globally. Standardized on a global basis, this platform for managing HCP spend creates business value across a wide range of areas.

The data cleansing process should not be viewed simply as a data aggregation issue. Although life sciences companies require a process that aggregates HCP spend data effectively, what's more important is basing that process on structures and rules that can support a robust master-data governance policy. These structures and rules must be rooted in quantitative measurements, or KPIs, that link business processes with process owners in order to achieve global visibility.

A CASE STUDY
AGGREGATING HCP SPEND

The Challenge

A multibillion-dollar global manufacturer of medical devices who deals with over 1,000,000 physicians was required to meet state and federal mandates for its HCP spend. Individual HCPs had a number of complex relationships with the device manufacturer. Many were practitioners using or implanting the manufacturer's devices in patients. Others participated in clinical trials for the company's new products. Some provided guidance to other physicians who had not used the manufacturer's products before. Some HCPs performed services to help, consult, or educate a variety of personnel. The device manufacturer's spend activities covered all spend types specified in the federal Sunshine Act as well as in the state-specific versions that were emerging. It was critical that it put a solution in place, because legislation had already been passed in Massachusetts and Vermont requiring reporting in 2010.

The device manufacturer had additional business, process, and IT challenges:

- Business challenges:
  - Complex business arrangement with HCPs
  - An ongoing acquisition strategy that created new HCP records based on acquired therapeutic categories
  - Operational silos with limited or no ownership across those silos
- Process challenges:
  - Data entered casually from many sources
  - Multiple points of data integration
  - No HCP duplicate check
- IT challenges:
  - Variety of source systems with highly fragmented data
  - No single HCP master-data source
  - Lack of data standardization and consistency

The Objective

The device manufacturer had the following key project objectives:

- Enable federal- and state-level reporting to meet HCP aggregate spend legislation
- Provide a centralized HCP master-data repository
- Enable expense tracking using unique identifiers
- Enable aggregation of all HCP spend transactions
- Store HCP affiliations and relationships in HCP master data
- Establish a master-data governance process that enforced duplicate checks for any new HCP request

In short, the goal was to create a single HCP record with a unique ID that referenced each source HCP-spend transactional system. The record would result from a cleansing process that checked the accuracy of the record and validated it for global use.

The Solution

The global device manufacturer adopted a comprehensive solution that supported compliance with state and federal HCP spend mandates while contributing significant business value by establishing a "single version of the truth" for its HCP activities. The solution covered diverse areas, summarized below:

- **Formulated a data governance model** – a key element in gaining control of existing data by establishing an ongoing process to keep data accurate and reliable – which was comprised of the following elements:
  - Governance committee, whose supervisory role included overseeing the processes to maintain the accuracy and integrity of the HCP master data and establishing the additional elements of the governance model, listed next
  - HCP-customer master-data council
  - Standards working group
  - HCP-customer master-data stewards and administrators, responsible for maintaining the HCP master data to keep it accurate and reliable
- **Established processes** to support the new governance policies, specifically:
  - New processes to create HCP master-data records with embedded approval and validation steps to avoid duplication
  - Existing processes that were enhanced to ensure ongoing maintenance of existing HCP and customers
  - New processes to support globalization of the HCP master data
- **Introduced technologies** required to meet new mandates and enable compliance with HCP spend legislation, with support for aggregation, harmonization, and syndication of HCP data and, when necessary, support for data cleansing, matching, merging, and enrichment
- **Leveraged data standards** as an extension of the enabling technology to facilitate the harmonization process and establish data consistency, which included data cleansing, quality metrics, and data controls where appropriate

SUMMARY

RESPONDING WELL TO DRAMATIC CHANGES IN LEGISLATION

The HCP spend legislation has changed and will dramatically change the way that the life sciences industry interacts with HCPs across the United States. Indications are that this type of legislation will be adopted across other regions of the world as well. No longer will organizations spend money on physicians or practitioners without extensive tracking and reporting of the expenses. Visibility into the process and transparency across the relationships will require life sciences manufacturers to competently monitor, track, report, and audit their interactions with HCPs in order to be able to meet applicable state and federal reporting mandates.

Central to the long-term sustainability of a process that aggregates physician spend is enabling business processes that support workflows, approvals, and a robust governance process through HCP master data.

Further, leading life sciences companies, recognizing the risks and costs of noncompliance, will begin to introduce controls to increase visibility of and mitigate risk in their operational processes and to automate the governance process. Best practices from other regulated processes will supply organizations with measurements for monitoring standard operating procedures. This alignment of strategy with execution can be accomplished through the use of role-based dashboards and alerts that notify appropriate individuals when a variance has occurred, prior to any violation of the HCP aggregate spend legislation. Preventive processes will block spending until compliance reviews and approvals have been completed. This limits the number of reporting line items and simplifies the review process.

Ultimately, we believe there is value to a more holistic approach in complying with HCP spend legislation through the use of a cleansed, or "golden," HCP master record. This provides an organization with global visibility into its most strategic business partner, the HCP. Maintaining a deeper understanding of interactions, financial or otherwise, is highly strategic as organizations leverage that information to reduce cycle times and improve responsiveness in operational areas, such as clinical trials, thought leadership programs, and research grants. Achieving these benefits will not be easy, but the reward is well worth it: greater understanding, improved visibility into the HCP universe, and more effective use of the HCP community, which ultimately results in improved therapeutic results and patient outcomes.

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