

## Physician Spend Management: How Health and Life Sciences Companies Can Simplify Regulatory Compliance Using Master Data Management

Health and life sciences companies in the U.S. have grappled with marketing disclosure regulations since the early 2000s. But as mandatory state-level regulations have superseded early voluntary measures, such as the PhRMA Code and the OIG Compliance Program, compliance has taken on far greater importance. Today, pharmaceutical companies and medical devices manufacturers must comply with disclosure or spending cap laws in eight states, and they are likely to face a Federal mandate in the near future as the Physician Payments Sunshine Act of 2009 appears likely to gain congressional approval soon. The upshot of this regulatory activity is that health and life sciences firms face a difficult data management challenge. Firms must now track and control all marketing expenditures that benefit healthcare providers, and do so with a high degree of specificity, or face expensive penalties.

### Why is Compliance Such a Difficult Problem?

The scope of the physician spend management challenge is daunting because regulations vary state to state, and the combination of per-provider spending caps and reporting provisions impose steep record-keeping requirements. Device manufacturers and pharma companies must now:

- Track the spend benefiting each healthcare provider by expense type.
- Control the spend on every healthcare provider by expense type based on various state limits.
- Report on spend per healthcare provider.
- Maintain the capability to document that the company is in compliance with each of the state's regulations—at any time.

These challenges are complicated by the reality that most companies store and track physician information across disparate transactional systems. If there were any discrepancies, conflicts or duplicate records in this underlying data, firms would not be able to determine:

- The number of organizations with which a healthcare professional is associated.
- The state(s) in which the healthcare provider practices.
- The relationship between sales reps and prescribers (sales territory alignment).
- The exact total spend at any time on each healthcare provider across several payment systems such as reimbursement, grants, accounts payable, etc.

## Fundamental Problem: Getting the Data Right

In effect, compliance with physician spend management regulations is a master data management (MDM) problem. For companies to gain an accurate understanding of how much money they are spending on any given physician, the company must first be certain they have the correct basic physician identifying information. Take the example in Diagram 1. At the top of the column on the left we have an entry taken from a legacy sales database, with correct address, yet an incorrect honorific (Mr. rather than the more appropriate Dr.) and missing professional specialty information.

The second entry from the CRM system includes the accurate title (Dr.) and specialty information, yet it has an incorrect street address. The third entry from the expense tracking system maintained by the company's sales rep whose territory includes Vermont, gets the doctor's honorific wrong and also misspells his last name.

Based on these three records, the obvious problem is that the traditional approach to physician spend tracking would mistakenly regard this doctor as three different individuals. But consider that this might not be a mistake at all, or that there are in fact multiple Dr. Smythes and a Dr. Smyth practicing in the same area. In addition, in medicine, family practices are not at all unusual. Frequently, fathers and sons or brothers both go into the profession and practice in the same area, or even the same building. Quite often, names and addresses alone are not adequate to make an accurate identification. As compliance demands become more complex, firms will need to gather and maintain more information—and more accurate information in order to meet state and/or national regulations.

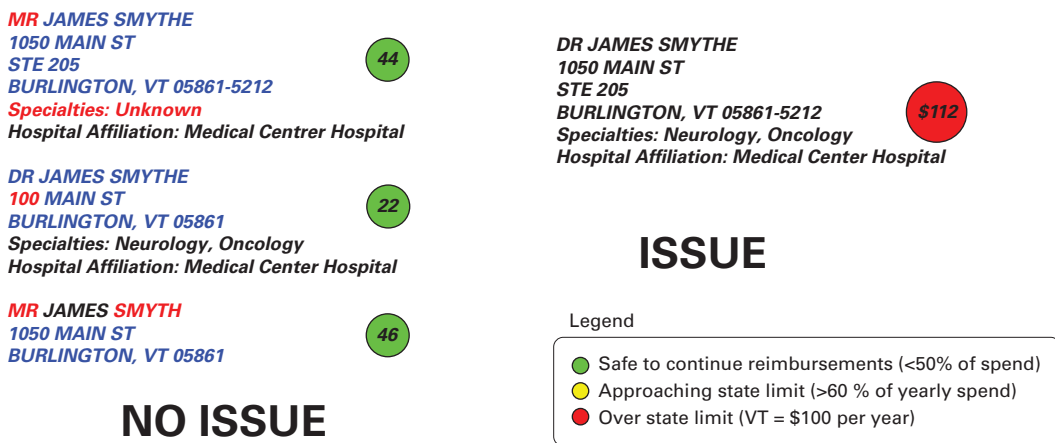


Diagram 1: Discrepancies and duplications in data can lead directly to regulatory breaches.

## Another Problem: Diversity of Payments

Misidentifying physicians because of inaccuracies in basic identifier data would appear to be a problem with a straightforward solution, namely to cleanse and update the underlying data in each system. What remains to be addressed, however, is the transfer of value issue. Device manufacturers and pharmaceutical companies convey gifts and payments to physicians in myriad ways including: free samples, direct payments, gifts, honoraria, speakers' fees, research grants, and consulting fees. Moreover, these payments originate from various departments within the company. Consider a typical scenario. The regional sales manager takes a Vermont hospital's oncology department out for dinner where the tab runs up to \$230. With five physicians in the department, each received \$46 in value, plus a gift bag containing free samples worth \$22. Later, the same company's marketing department sponsors the Chief of Oncology to give a talk about a new drug at a symposium in New York City and provides a speaker's fee of \$44.

Each of these payments or transfers of value are duly recorded in the relevant system. The salesperson enters the value of the dinner, so he gets reimbursed and per-physician amounts are allocated. The

value of the sample bag is noted in the CRM system, and the marketing department notes the speaking fee in its national sales database. However, with inaccurate underlying data, and no mechanism for integrating financial data, the company isn't aware—until it's too late—that total spend on Dr. James Smythe, head of the oncology department at Medical Center Hospital in Burlington, has exceeded the state spending cap of \$100 for the year.

## Toward A Solution: Recognizing the Scope of the Challenge

The unique nature of the health and life sciences business contributes to the difficulty companies face in tracking and documenting physician spend. Drug and device firms work with physicians in developing new offerings, testing them, using them in practice and explaining their benefits to other practitioners. Not only do companies often have multiple points of contact with doctors but they also often interact with doctors in multiple geographic locations. Since virtually all state-level spending cap provisions are based on some kind of annual timetable, companies also need to be aware of scheduling when spend events take place. Is it within a reporting time limit? In developing new drugs and devices, companies need physician participation in clinical trials and tests that may take place over long periods of time. Can a research contract for a two-year trial be spread over reporting periods? Or does it have to count under a single year? Must a California-based doctor participating in a symposium in Boston report her speaking fees to both the California authorities and the Massachusetts authorities? If a device manufacturer loans several new pieces of equipment to a hospital, does the value of using the device accrue to the physician using it? If so, at what price? And what if that physician practices at several hospitals in the area—would that need to be factored into the equation?

### Serving and Working With the Medical Profession

The sheer size and scope of the medical industry itself adds to the challenge. Consider some numbers<sup>1</sup>:

- There are approximately 850,000 physicians in the U.S.
- Virtually all physicians (94 percent) have some type of relationship with the pharmaceutical and medical device industries.
- 83 percent of physicians report receiving food and beverages from pharmaceutical/device companies in their workplace.
- 78 percent receive drug samples from manufacturer representatives.
- 35 percent receive reimbursement for expenses related to professional meetings or continuing medical education.
- 28 percent receive payments for consulting, speaking or enrolling patients in trials.

### Crucial Capabilities: Detection, Prevention, Reporting

Given the complex nature of the relationships between pharma/device companies and physicians, simple off-the-shelf IT solutions are not capable of addressing multiple disclosure requirements and spending limits. As we can see in our business case example above, in order to effectively comply with spending caps, firms need to be able to *anticipate* potential cap violations. Passive tracking and reporting capabilities that provide after-the-fact insight into violations is of little use in a regulatory environment where million-dollar penalties are a possibility. Moreover, reinventing the wheel is out of the question. Most large firms already have in place expense tracking, BI reporting and other IT infrastructure that supports critical compliance tasks. The most sensible approach is one that takes advantage of these investments and maximizes previous technology investments.

1. Campbell EG, Gruen RL, Mountford J, Miller LG, Cleary PD, Blumenthal D. A National survey of physician–industry relationships. *N Engl J Med* 2007; 356:1742-1750.

2. Campbell EG, Gruen RL, Mountford J, Miller LG, Cleary PD, Blumenthal D. A National survey of physician–industry relationships. *N Engl J Med* 2007; 356:1742-1750.

<http://www.premierfacts.com/issues/policy-position-physician-payment-08.pdf>

Given these realities, the only certain course of action is to build a reliable, integrated source of physician data that can easily cross-reference to various accounts payable, expense reporting, ERP, and clinical trial management systems (CTMS). While reporting requirements will continue to morph, putting in place a reliable data foundation will allow pharmaceutical companies and device manufacturers to rapidly respond to these changes as they occur. There are certain ground rules to follow, however. A strong data foundation must plug equally well into existing BI environments, where the bulk of regulatory reporting is likely to occur, as into the operational systems that firms use to alert personnel to spend limits. How to go about creating such a strong data foundation? Several health and life sciences companies have optimized their regulatory compliance capabilities using master data management.

## Master Data Management Simplifies Physician Spend Compliance

Physician spend management efforts built on the master data management (MDM) approach have proven tremendously successful because effective compliance requires that accurate data be available in real time throughout the enterprise, and that's exactly what MDM provides. Effective MDM systems consolidate information across all applications and makes data available for tracking against regulatory initiatives, reporting periods, geographical locations and any number of other attributes. Moreover, by consolidating data across internal applications, MDM creates one single reliable source of truth. This prevents discrepancies and duplicates, eliminating confusion and potential oversights that can lead to spending cap or reporting violations. Implemented correctly, MDM enables pharmaceutical companies and device manufacturers to:

- Authoritatively determine the exact total spend at any time on each healthcare provider across several payment systems such as reimbursement, grants, accounts payable, etc.
- Ascertain all the organizations a healthcare professional is associated with.
- Confirm the state/s in which a healthcare provider practices
- Provide visibility into all physician spend transactions, including payment, reimbursement, related to each healthcare provider.
- Maintain a dynamic view of the relationship between the sales reps and the healthcare provider.
- Anticipate and prevent possible regulatory violations.
- Maintain compliance with any number of Federal and state-level disclosure laws.

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*Diagram 2: Rich, accurate physician descriptions made available to all systems across the enterprise eliminate confusion, and provide the foundation for reliable and effective compliance efforts.*

## Conclusion

The relationship between the medical community and the health and life sciences industry has been extraordinarily beneficial in the development of life-saving drugs, devices and procedures. The Federal Sunshine Act and state-level disclosure laws present industry with an opportunity to demonstrate to the public a new level of openness regarding the drug and device development process. At the core of these regulations is an organization's ability to access current and reliable information related to a company's interactions with physicians. After all, without having access to a central repository of reliable information, companies will find it very difficult, if not impossible, to comply. Worse, predicting how regulations will change in the coming years, or determining what unforeseen event that may trigger new regulations, is a near impossible endeavor. Yet, it is certain that new regulations will demand that companies have a more clear understand of who their customers and business partners are and the nature and terms of their business relationships. Master data management presents the most sensible and effective way to achieve physician spend management and regulatory compliance.

## Master Data Management in Action

### Fortune 50 Pharmaceutical Company Complies with Physician Spend Management Laws Using Siperian MDM

Industry: Pharmaceuticals

Solution: Compliance Master: Physician

#### The Challenge

As the world's largest research-based biomedical and pharmaceutical company, this Fortune 50 Company needed to document exactly which healthcare professionals and medical facilities are on the receiving end of their products. Information about these individuals and their facilities such as names, titles, addresses, communication preferences, state licenses, medical specialties and DEA numbers must be collected and made available to government officials. Specifically, regulations require a regular, consolidated accounting of payments including:

- Contracts with physicians to speak on their behalf
- Meals provided at speaking seminars
- Contracts with physicians to conduct medical research
- Grants to medical institutions to conduct education programs
- Fees for consulting and advisory services
- Practice related gifts
- Targeted marketing and advertising to physicians

Further, since these spending caps vary by state, this company faced challenges in meeting its numerous compliance objectives. Failure to accurately track and report marketing activities could result in fines or critical damage to the reputation of its brands.

#### The Solution

Selecting Siperian MDM Hub™, the firm implemented a Physician Master that laid the foundation for an accurate reporting framework by creating a single source of truth for sales and marketing spend across all hospitals and healthcare professionals with which it works.

#### The Impact

With the successful implementation, the company was able to meet the various state and Federal deadlines for spend compliance reporting within six months. Additionally, they were able to expand the use of Siperian beyond compliance reporting to other areas in the organization.

#### About the Author

Ravi Shankar is the Senior Director of Product Marketing for Siperian. With more than 20 years of experience, Ravi directs product and technical marketing activities for the Siperian MDM Hub. Ravi is a published author and a frequent speaker on master data management (MDM) and data governance. Previously, Ravi has directed product marketing, product management, and business development efforts at Oracle. Ravi holds BS (Honors) and MS in Computer Science and MBA from the Haas School of Business at the University of California, Berkeley.



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