The Perfect Storm: Aggregate Spend

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Over the last few years, compliance officers in the life science industry began to face the challenges of balancing competing priorities, as new pressures arose from government and industry. As firms finalize preparations for 2006, a new item is beginning to percolate to the forefront of the Compliance field – Aggregate Spend.

As with the "Perfect Storm," this topic has gained momentum from three separate motivations combining into a maelstrom. Thus, federal guidance, state regulations, and business concerns have joined forces to leave compliance and operations departments with little choice but to team together to identify resources to tackle aggregate payments to health care professionals and organizations.

1. OIG Concerns

In the September 30 issue of Rx Compliance Report, the OIG revealed its top ten "lessons learned" from existing corporate integrity agreements. Mary Riordan, senior counsel at the OIG, reported that one of those lessons included the need to develop tools to measure aggregate payments.

Specifically, Riordan said, the OIG is interested in the "aggregate amount of money the respective sales force is providing any individual practitioner."

As Riordan points out, the OIG has begun to focus on the multiple ways pharmaceutical firms compensate physicians. An individual health care professional may be paid as a speaker, as a consultant, and as an investigator. While each, taken individually, may be benign, the OIG appears to be concerned if the total compensation to an individual health care professional could result in undue influence, thus implicating federal anti-kickback statutes.

While statements made by the OIG are not "black letter law," state laws provide specifics on what aggregate spend must require.

2. State Laws

Currently there are seven states with laws that require some type of spending reporting or tracking. California requires an annual spend limit on items of value provided to healthcare professionals against which firms should monitor in order to ensure compliance. Vermont, the District of Columbia, and Maine require annual reporting of marketing costs to specific healthcare professionals and organizations. Minnesota requires annual reporting of spending on practitioners for a few defined areas. West Virginia requires annual reporting of advertising costs. Lastly, the Louisiana Lobbying Law requires annual reporting of spending on state officials.

Furthermore, the past two legislative sessions have shown an escalation in the number of states seeking to pass legislation requiring the reporting of marketing costs. In 2005, the number of states with pending legislation reached 27.

In order to prevent having to conduct "firedrills" every time a new state law hits the books, some firms have opted to take a holistic look across all healthcare professionals and organizations. As firms began to assess their spending under the constraints of state laws, many are realizing other uses for the data.

3. Business Rationale

Detailed aggregate spend information will improve the way pharmaceutical manufacturers set and utilize their budgets. Aggregate spend reporting provides greater transparency showing where and how firms spend their money as an organization, rather than confined solely to a specific department or brand view. Currently, most pharmaceutical firms are unable to assess their total spending for a specific healthcare provider, although several have begun to implement aggregate spend solutions. By reporting on aggregate spend, firms should be able to increase efficiency and save the company money.

For instance, as firms went through manual processes to identify the total spending for each individual health care professional in Vermont, many began to ask questions about the data uncovered.

- “Do we really spend that much on Dr. X?”
- “How many times did our reps take Dr. Y to lunch?”
- “Is this the best way to spend our money?”

Methodology

So, how should firms solve this aggregate spend dilemma? Firms should follow five basic steps to implement an aggregate spend solution:

- Step 1: Define categories and healthcare professionals and organizations
- Step 2: Conduct technology and vendor gap assessment
- Step 3: Prioritize IT spending categories and set policies
- Step 4: Update current systems and build new applications
- Step 5: Create comprehensive (or “canned”) and ad-hoc reporting capabilities

Step 1: Define Categories and Healthcare Professionals and Organizations

To calculate aggregate spend, companies must first identify all items of spending on healthcare providers to the most granular level of detail. This includes identifying what type of healthcare professional or organization receives such spend (e.g., physicians, nurse practitioners, pharmacists, formulary committee members, medical students, hospitals, etc.), and segmenting the items and activities of spending into categories.

It is important to remember that spending on healthcare professionals is not limited to sales and marketing activities, but should also include other payments or items provided to healthcare professionals and organizations, such as investigator compensation or meals at clinical subject-recruitment meetings. One way to help organize this approach is to create a matrix of spend recipients and spend categories.

Step 2: Conduct Technology and Vendor Gap Assessment

After defining the items of spend and the types of organizations, firms need to determine if it is possible to track each type of these spend categories to an individual healthcare professional as they occur. This is usually done by tracking spending against an existing unique identifier for the physician - typically, the same ID number used to record and track sales call data.

To accomplish this, firms must look at the recording capabilities and data format of existing systems. Companies will need to examine data available from a variety of systems and sources, including call logs, T&E reports, promotional activities, such as speaker programs and conventions, and contractual arrangements, such as investigator contracts and consultant agreements.

In addition to looking at their own IT systems, firms must also examine spend distributed by third-party suppliers. This could include contract organizations such as CSOs, but also traditional vendors such as meeting planning companies. Firms will want to examine the way that vendor data can be included in the aggregate spend analysis.

A Sample Matrix of Healthcare Professionals/Organizations and Categories:

	MDs	NPs	Medical Students	Hospitals	MCO	PBMs
Speaker Honoraria	✓	✓	X	X	X	X
Speaker Meals	✓	✓	X	X	X	X
Speaker Travel	✓	✓	X	X	X	X
Speaker Lodging	✓	✓	X	X	X	
Attendee Meal	✓	✓	✓			
Attendee Parking	✓	✓				

Step 3: Prioritize IT Spending Categories and Set Policies

Once all systems are evaluated to determine the current state of available data, firms will need to prioritize how to spend their internal IT budgets. As companies look to prioritize these categories, some of their criteria to help prioritize their IT would include:

- Impact on Aggregate Spend
- Cost to update/build
- Length of time and ease of implementation
- Alternative options (e.g., manual reporting)
- Compliance

Therefore, firms will recognize they can concentrate their IT budget on key drivers of aggregate spend as promotional speaking programs. Firms must then develop a long-term IT plan based on how they intend to capture aggregate spend categories over the next few years.

In some instances, rather than specifically allocating cost to an individual health care professional, firms may opt to set policy and audit against a particular category of spend. For instance, systems may not be in place to trace actual gift spending to a specific physician. As a result, companies may develop a corporate policy that limits frequency and types of gifts in lieu of recording and tracking all gifts to all physicians.

Additionally, in this phase, firms will need to develop policies related to spending allocation. For instance, companies should set policy on how they will allocate spending on meals provided to healthcare professionals and non-health care professional office staff. Additionally, firms may need to develop policies on health care professional definitions such as how to assign corporate entities wholly owned by an individual health care professional.

Step 4: Update Current Systems and Build New Applications

After identifying which systems are to be updated, firms should decide whether to build these systems with internal IT department resources or bid out the project to a third-party IT shop. If firms decide to outsource the design and construction of new applications, they should consider competitively bidding the project to ensure that vendors are capable of meeting their IT needs.

As firms develop their IT systems, it is important to remember they will also need to integrate data provided by third-party vendors.

Step 5: Create Canned and Ad-Hoc Reporting Capabilities

Once IT systems are updated to record data on aggregate spend, a reporting system needs to be created to help facilitate state law disclosures and managerial tools. For instance, canned reports should be created for each state that require per health care professionals disclosures. Additionally, operation managers should identify reports that will help them to manage the business based on identified objectives or auditing and monitoring criteria.

In addition to running canned reports, the reporting capabilities must be flexible enough to access "ad-hoc" reports (useful for auditing and monitoring activities) as well as create new canned reports (e.g., for new state laws).

Conclusion

As a result of the confluence of three specific dynamics -- OIG pressure, state laws, and operational efficiency needs -- pharmaceutical firms need to commit IT and human resources to calculating aggregate spend per healthcare professional and organization. In the coming months, firms should first focus on defining the problem and the scope of system improvements. Over the next few months, they will need to prioritize which activities must be completed first. Then, they will need to enhance their IT capabilities and vendor reporting requirements to ensure they can track all spending to a per health care professional level. While the overall process may require several years, given mounting industry pressure, firms that address this compliance concern proactively, will greatly reduce risks of not complying with federal and state regulation.

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