



Business Strategy: Aggregate Spend Compliance — The Next Frontier of Pharmaceutical Sales and Marketing

IDC Health Insights: Life Science Business Systems Strategy

BUSINESS STRATEGY

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IN THIS EXCERPT

The content for this excerpt was taken directly from the IDC Health Insights Business Strategy, "Business Strategy: Aggregate Spend Compliance — The Next Frontier of Pharmaceutical Sales and Marketing" by Eric Newmark (Doc#HI226907). All or parts of the following sections are included in this excerpt: IDC Health Insights Opinion, In this Study, Situation Overview, The Approach, Future Outlook and Essential Guidance. Also included is Figure 1.

IDC HEALTH INSIGHTS OPINION

Aggregate spend compliance is the most disruptive force affecting pharmaceutical sales and marketing today. While state-by-state mandates have added significant complexity to sales operations by implementing strict promotional spending limits and banning several types of promotional activity, their impact on pharmaceutical manufacturers continues to increase as more states pass aggregate spend laws and a looming set of national regulations will soon take effect. Reporting aggregate spend on promotional activity directed toward healthcare providers (HCPs) and clinicians is much more complicated than it seems. This report provides a snapshot of the industry's current state of readiness for aggregate spend compliance, illustrates various approaches that companies are employing, identifies IT strategies being utilized, and discusses best practices and lessons learned by companies that are furthest along this journey toward compliance. Highlights are:

- The pharmaceutical industry, which is already notorious for siloed data, must now undergo significant effort to identify all touch points with HCPs across divisions, ensure proper data stores exist, correctly identify all spend recipients, ensure all interactions are thoroughly documented, aggregate all data in a consistent and repeatable manner, and regularly report spend in a transparent fashion to multiple regulatory bodies.

- At the same time, cultural roadblocks exist, as significant business process transformation will be required and certain internal resources will have new responsibilities forced upon them.
- The impending national sunshine laws will add a new minimum reporting standard to an existing mix of state-level requirements, but many states will continue to build on top of this groundwork, resulting in a growing body of regulation that will become increasingly difficult to track, interpret, and obey.

IN THIS STUDY

Methodology

IDC Health Insights conducted interviews with 27 pharmaceutical manufacturers to collect both quantitative and qualitative information surrounding current aggregate spend compliance efforts in the United States. Companies were asked about their current state of readiness, challenges encountered, technology preferences, best practices, and lessons learned. Interviews were also conducted with 13 software and service vendors that currently serve the aggregate spend market to gain further commentary on recent trends they have encountered.

The purpose of this study is to provide a snapshot of the industry's current state of readiness for aggregate spend compliance, illustrate various approaches that companies are employing, identify IT strategies being utilized, and uncover best practices and lessons learned by companies that are furthest along this journey toward compliance.

SITUATION OVERVIEW

Aggregate spend compliance is the most disruptive force affecting pharmaceutical sales and marketing today. While state-by-state mandates have added significant complexity to sales operations by implementing strict promotional spending limits and banning several types of promotional activity, their impact on pharmaceutical manufacturers continues to increase as more states pass aggregate spend laws and a looming set of national regulations will soon take effect.

Reporting aggregate spend on promotional activity directed toward healthcare providers and clinicians is much more complicated than it seems. The pharmaceutical industry, which is already notorious for siloed data, must now undergo significant effort to identify all touch points with HCPs across divisions, ensure proper data stores exist, correctly identify all spend recipients, ensure all interactions are thoroughly documented, aggregate all data in a consistent and repeatable manner, and regularly report spend in a transparent fashion to multiple regulatory bodies. At the same time, cultural roadblocks exist, as significant business process transformation will be required and certain internal resources will have new responsibilities forced upon them. For example, R&D departments will need to report certain spend on consulting and sponsored research (spending they have never been asked to track before).

The impending national sunshine laws will add a new minimum reporting standard to an existing mix of state-level requirements, but many states will continue to build on top of this groundwork, resulting in a growing body of regulation that will become increasingly difficult to track, interpret, and obey. While the end result (gaining a thorough and complete single view of the customer) will provide pharmas with a valuable new opportunity for sales and marketing optimization, the effort to become and remain compliant with aggregate spend regulations will undoubtedly be a major contributor to the increased blood pressure among finance and compliance officers in the pharmaceutical industry for the next few years.

THE APPROACH

The 2013 deadline for aggregate spend compliance is quickly approaching. There is little time for procrastination, as becoming compliant will require a tremendous amount of effort by pharmaceutical manufacturers, including new IT systems, major integration efforts, numerous business process changes, and significant training to solidify long-lasting cultural change. While several companies have already made significant progress toward this goal, most companies are still early on in their efforts, and some have not even begun.

If you examine the long list of changes that must take place to become compliant, there is a fairly straightforward four-step process that companies must traverse to attain this goal, though accomplishing them is easier said than done. However, it is important that companies look at this effort as more than simply yet another compliance initiative, and instead utilize it as an opportunity to optimize sales and marketing intelligence and gain a strategic advantage. In the spirit of this, the process outlined below includes an additional fifth step that is important for companies to consider once they do attain compliance.

The recommended five-step process includes:

- **Step 1: Plan.** Identify and map all information to be aggregated, design how it will be done, and detail who will do it
- **Step 2: Integrate.** Unify data across the enterprise to create spending transparency
- **Step 3: Program.** Implement required IT and build rules logic to appropriately track, aggregate, align, and report spend
- **Step 4: Prevent.** Implement proactive measures to prevent noncompliant behavior
- **Step 5: Optimize.** Refine business processes based on newfound visibility and analyze how to best spend promotional dollars for maximum ROI going forward

On average, most companies today are still in step 2 and are diligently working toward step 3, though some companies exist at nearly every stage of the process. Interestingly, during the interview process, there were several instances of anecdotal evidence that suggested companies located on the East Coast were roughly 8 to 12 months further into this process than those residing on the West Coast, though not enough evidence was available to definitively reach this conclusion. Based on the 27 interviews conducted, the step-by-step breakout of pharmaceutical company readiness today is shown in Figure 1.

FIGURE 1

Aggregate Spend Compliance: Industry State of Readiness



Note: Respondents are pharmaceutical companies.

Source: IDC Health Insights, 2010

Although the largest portion of companies reside in step 2, it is noteworthy that there is a tremendous level of detail and effort that goes into each step of the process. Thus, a company that is in the early stages of step 2 could be as much as a year behind another company that is nearing step 2 completion.

Case Study 2: Buy

A top 20 pharmaceutical manufacturer had originally built a homegrown solution that was bolted onto its ERP system to address the first few states with aggregate spend laws. As more states passed similar laws and the impending national sunshine regulations became a reality, the company decided it needed a more robust, scalable longer-term solution. After evaluating several vendor solutions from both large and small vendors, it decided to implement a solution from Health Market Science (HMS). HMS' strong customer references and competitive pricing, combined with its customer master offering, were strong points that ultimately won it the deal. To integrate all spend information across the business and implement the HMS solution took roughly six months. Thinking ahead, the company also chose to reverse integrate spend information back to its SFA system so that sales reps can easily see in each HCP profile what the spending threshold is and how much has been spent against it. This has dramatically improved business process and sales strategy and increased compliant behavior since reps now have knowledge of things such as whether they can bring in food for meetings.

To further solidify compliance, the company is considering the implementation of front-end logic that would completely prevent sales reps from even having the ability to enter transactions into the system that would break an allowable threshold. The company has completed step 4 and now considers itself to have most of what it needs already in place to comply with forthcoming sunshine laws. It has not yet broken ground on step 5 (optimize) but has already begun discussions on how to approach it and plans to dive into sales and marketing optimization within 2011.

FUTURE OUTLOOK

Companies are eagerly working to implement software solutions that will help them manage aggregate spend compliance. Noncompliant pharmas will face fines of several thousand dollars per infraction, making it critical that pharmas get compliant in a timely fashion. This is driving increased spending around data integration work and

business intelligence applications, to help companies gain visibility to all the financial touch points with HCPs across the organization. However, this is just the first step. Once the proper reporting and dashboards are put in place for organizations to monitor spend and be "reactive," pharmas will need to continue investing and working to become "proactive," as described previously in step 5 (optimize). Beyond gaining visibility to where money is being spent, pharmas must create the ability to strategically decide where funds should be directed to get the most bang for their buck. This will enable important decisions to be made, such as deciding which brand team should use the allowable promotional funds within state limits for each particular physician. Should all brand teams split funds equally? Should all funds be spent by one brand? These will be important questions to analyze and answer. The opportunity for business intelligence and analytics applications to add value is substantial, and aggregate spend compliance will continue to drive these investments through 2013.

Potential Impact on Sales and Marketing Operations

Pharmaceutical sales reps have historically leaned heavily on soft-dollar promotional budgets to help create influence and capture the attention of physicians with items like free pens and notepads. More importantly, as physician availability has continually grown more scarce over the years, sales reps have relied a great deal on taking physicians out to lunches, dinners, and offsite meetings to help create an environment where the sales reps can capture the physicians' undivided attention. However, due to the cumulative effect of state-level aggregate spend regulations, gift bans laws, the updated PhRMA code, and the Physician Payment Sunshine Act, most soft-dollar sales tactics are now becoming obsolete. Even those tactics still deemed as acceptable practices have been significantly curtailed by strict spending thresholds. Consequently, opportunities for meaningful in-person physician interactions are becoming even scarcer, and this will continue to diminish as 32 million new insured patients phase into the U.S. healthcare system due to reform legislation.

These developments have placed newfound pressure on pharmaceutical companies to alter the way they approach and interact with physicians, as efforts grow to shift physicians toward increased online touch points. In response, forward-thinking pharmaceutical companies are adopting IT solutions that help automate, simplify, and enhance sales and marketing tasks, including CRM, SFA, CLM, edetailing and, of course, analytics. Social media advertising is another frontier the industry is eager to utilize more broadly, but those investments remain on hold until the FDA releases further guidance on associated rules and liabilities.

ESSENTIAL GUIDANCE

Those companies beginning to travel, or currently in the process of traveling, down the road toward aggregate spend compliance can improve their approach by benefiting from the lessons already learned by other pharmaceutical companies further along in this process. The essential guidance described in the sections that follow combines IDC Health Insights' strategic advice with best practices established by leading pharmaceutical companies interviewed for this study.

Actions to Consider

Plan

- Aggregate spend compliance initiatives have political implications. Sales and marketing resources are concerned of the implications and can be suspicious of the required business process changes. IT personnel are concerned about the tremendous workload being created around the integration and standardization of data and systems. Compliance department employees are stressed about looming deadlines and implementing proper policy. It should be no surprise that executive sponsorship, with intimate executive involvement, is a necessity for these top-down initiatives to succeed long term.
- Many companies (especially SMBs) have aspects of spending that are not automatically captured electronically. It is important during step 1 (plan) that proper discovery is conducted to identify these scenarios and implement automated systems, or well-defined manual protocols, so that these transactions are always captured and tracked in a timely fashion.
- Disputes with sales and marketing over who owns the "customer master" can be avoided by using the term "recipient master" when referring to the aggregate spend HCP master file. A simple, yet effective solution.
- Investment in becoming aggregate spend compliant is important, but it should be weighted appropriately. Relatively speaking, industry fines for off-label marketing will continue to eclipse fines for aggregate spend noncompliance by a large multiple for years to come. Thus, despite the hype and urgency surrounding aggregate spend regulations, companies need to carefully weigh how much they spend on a solution versus other fronts of corporate risk that need addressing.

System Selection

- Regulatory details will continue to evolve and it is hard to predict in what direction. This creates a strong business case for buying rather than building an aggregate spend solution, with the possible

exception of very small companies with a single product. Using a hosted or SaaS solution has advantages because it enables companies to get compliant without tremendous infrastructure investment, it forces the onus on the vendor to keep the solution current with changing regulations, and it enables pharma to remain agile and responsive. Three companies interviewed in our study that chose to build their own solution all commented that in hindsight they should have purchased a COTS solution, and instead are all now struggling to keep their expensive, highly customized solutions up to date with current laws.

- Using a third-party vendor to maintain and update your HCP recipient master not only frees up your resources to focus on more strategic tasks but is often equal or even less expensive. It can also be more accurate since third-party vendors specializing in HCP master file data update their list more regularly, especially concerning newly licensed doctors just coming on the grid.
- Pharmaceutical companies will be required to let HCPs know what spend is reported against them, allow HCPs to review this information, and ultimately provide HCPs the ability to appeal any reported spend that looks incorrect. Many companies will start out using email notifications for this purpose, but that approach is not sustainable over the long term. Eventually, online portals will become mainstream, giving HCPs access to log-in and review reported spend attributed to them. Most pharma are not ready for that level of data scrutiny, but it is important for portal development to be considered when selecting and designing a new aggregate spending solution. The first companies to offer online portals for this purpose may also gain mindshare with HCPs, as its availability will be appreciated.
- If you are using a third-party aggregate spending solution via SaaS, be aware of any existing lag time in data feed synchronization. If your vendor only takes your data on a monthly, quarterly, or biannual basis, understand that if a spending threshold is broken, your company may not realize the infraction occurred until several months after the fact, depending on the architecture of your system and whether some early-stage protection and alerts have been constructed.
- If a spend transaction can't be matched to the master file and is kicked out for manual review, some aggregate spend solutions with better intelligence built in will remember the process you used for matching (address, specialty, etc.) and the HCP chosen so that in the future the number of kickbacks drastically reduces as it learns your preferences.

Prevent

- Reverse integration of aggregate spend information back to CRM and SFA systems is essential for preventing noncompliant sales force behavior. Email alerts of threshold warnings and infractions are not a suitable long-term solution. For example, if an HCP located in Chicago speaks at conferences as a KOL, has a sales rep that regularly visits, and is close friends with a senior executive at the same life science company through a national congress they're both members of and they go out to a few dinners together, using email alerts to create cross-department visibility to avoid spending threshold infractions is not a reliable solution.

Program

- It is important to have a well-defined manual intervention process for HCP spend transactions. No matter how great your master file is, there will always be transactions that do not immediately match up. For example, a third-party vendor may submit transactions to you that simply include a name and a city. Automated matching will likely not succeed, and further manual research will be required for proper recording. Further, in companies that maintain their own HCP master file, if an employee can't find an HCP that matches a transaction within a few minutes, the employee may simply create a new HCP record that could open the door to duplicate and inaccurate records in the master file. A well-defined, tightly controlled, manual intervention process is important to keep compliance policies from breaking down over time.
- Not all transactions are clear cut and easy to match up with an HCP master file. Recognizing the existence of complex scenarios and proactively putting processes in place will make handling them much simpler when they occur. Two examples are:
 - If a physician is brought over from the European Union for a speaking engagement in the United States, how should this be handled when the physician is not in the HCP master file?
 - If a practitioner gets married and hyphenates her last name, then later gets divorced, drops the hyphen, and goes back to her maiden name, how do you ensure situations like this do not become three separate HCP records?

Optimize

- Pursuing step 5 (optimization) will be a touchy subject in some companies, as some compliance departments will want aggregate spend data to be firewalled away from the rest of the company. This will create challenges for sales and marketing departments to utilize this information for strategic analysis and operational optimization. Sales and marketing leadership needs to be diligent

in creating access for themselves to this data in a secure, role-based fashion that allows them to analyze information in a manner through which compliance officers are comfortable.

General Guidance

- Becoming aggregate spend compliant is often looked at as an IT exercise, but significant business process change is required as well. Ongoing employee training is critical to long-term sustainability of the initiative to ensure employees do not revert to their old ways and reinstitute behaviors that will affect compliance.
- A sales lunch may include an HCP and three of the HCP's nonlicensed employees. Recipient master files that include nonlicensed employees allow pharmaceutical companies to break out expenses further, rather than rolling up all spend to a single HCP. There is a growing desire for more nonlicensed employees to be included in recipient master file information for this purpose.
- Regulatory bodies at both the state and the national level will likely experience the same difficulties that companies do in matching up HCPs with spend (due to similar data challenges and a lack of man power), making it challenging to identify instances of noncompliance. Companies should realize they are not going to be alone in this challenge and that strict enforcement of these regulations will likely take time.

Vendor Profiles

Health Market Science

Health Market Science has been serving the pharmaceutical industry for the past 11 years, and its headquarters are located in King of Prussia, Pennsylvania. The company, whose revenue falls in the \$10 million–50 million range, obtains 60% of its revenue from the pharmaceutical industry, with most of its business coming from companies with over \$1 billion in revenue. HMS has roughly 100 employees focused exclusively on the life sciences. 56% of HMS' aggregate spend–related revenue is achieved through its software sales, 5% comes from IT implementation services, 9% comes from strategic consulting, and the remaining 30% comes from data and hosting services. HMS' CompleteSpend product is an end-to-end hosted solution that provides aggregation, validation, interpretation, tracking, alerts, and reporting functionality. The company also offers its HMS Provider MasterFile solution, which is supported by its Provider Data Consortium. HMS currently has 10 pharmaceutical companies using its solution for aggregate spend compliance.

Synopsis

This IDC Health Insights report provides a snapshot of the industry's current state of readiness for aggregate spend compliance, illustrates various approaches that companies are employing, identifies IT strategies being utilized, and discusses best practices and lessons learned by companies that are furthest along this journey toward compliance. The impending national sunshine laws will add a new minimum reporting standard to an existing mix of state-level requirements, but many states will continue to build on top of this groundwork, resulting in a growing body of regulation that will become increasingly difficult to track, interpret, and obey.

Eric Newmark, research manager for IDC Health Insights' Commercial Life Science practice, comments: "Aggregate spend compliance is the most disruptive force affecting pharmaceutical sales and marketing today. While state-by-state mandates have added significant complexity to sales operations by implementing strict promotional spending limits and banning several types of promotional activity, their impact on pharmaceutical manufacturers continues to increase as more states pass aggregate spend laws and a looming set of national regulations will soon take effect. The pharmaceutical industry, which is already challenged by siloed data, must now undergo significant effort to identify all touch points with HCPs across divisions, ensure proper data stores exist, correctly identify all spend recipients, ensure all interactions are thoroughly documented, aggregate all data in a consistent and repeatable manner, and regularly report spend in a transparent fashion to multiple regulatory bodies."

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