Capturing & Reporting HCP-Related Meeting Spending
Let the Sun Shine In

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Life science companies—pharmaceutical companies, biotech firms, medical device companies, etc.—are struggling to understand the complex reporting requirements and compliance issues presented by existing and new regulations like the Sunshine Act, provisions of which were included in the Patient Protection and Affordable Care Act of 2009 that was signed into law on March 23, 2010. Starting on January 1, 2012, manufacturers must record all transfers of value, including honoraria and travel expenses, paid to physicians who participate in healthcare provider (HCP)-related meetings.

These laws are putting the public spotlight on meetings and meeting-related expenses. “There’s been a lot of public scrutiny on meetings expenditures,” said Kevin Iwamoto, Vice President, Enterprise Strategy, StarCite. Iwamoto was speaking at a recent webinar titled Capturing HCP-Related Meeting Spend Doesn’t Have to be Difficult, which was hosted by StarCite, which is a meetings management technology company. “There’s been scrutiny due to the PhRMA Code, Sunshine provisions, and new EMEA (European Medicines Agency) global codes,” said Iwamoto. “All of these require life science companies to do strict tracking and monitoring of royalties, honorariums, speaker’s fees, entertainment and travel costs, etc.”

**How Much Does Pharma Spend on Meetings?**

According to a recent study by Carlson Wagonlit Travel Management Institute, the pharmaceutical industry had a per-attendee spend of $1,214 per meeting (see Figure 1, page 2).

“Pharma’s meeting spend—especially the spend per attendee—is much higher than most other industries,” noted Iwamoto. He suggested that it is a significant area of opportunity in terms of cost savings tracking, compliance and risk mitigation.

**Get Ready to Mitigate Your Risk**

If your company can’t answer the following questions regarding the capture and reporting of HCP-related meeting spending, it is time to start planning:

1. What is your company’s total meeting-related HCP spend by product and therapeutic area?
2. Can you break that spend out into all of the categories defined by the Sunshine Act?
3. Do you have an online approval process specific to HCP meetings?
4. Is there a specific sourcing process in place to meet the needs of HCP meetings?
5. How is your HCP meeting spend going to be consolidated with all of the other HCP spend categories?
6. Who will be held accountable for what?

“This really is a global issue,” said Allan Brown, Director, Strategic Accounts at StarCite. “A number of countries in the EU are also rolling out their own legislation, their own controls and reporting initiatives. Some of them are stricter than others but any organization that is trying to do business globally is going to have to address these.” Brown, however, focused in detail about what is happening in the U.S.

**PhRMA’s Code and State Laws**

The origins of transparency with respect to physician payments goes back to PhRMA’s (Pharmaceutical Research and Manufacturers of America’s) Code on Interactions with Healthcare Professionals (PhRMA Code). The goal of these voluntary guidelines was to minimize the perception that there was inappropriate corporate influence over healthcare providers.

“The focus was on driving modest and appropriate expenditures and encouraging companies to define and manage inappropriate expenditures,” said Brown. The PhRMA Code set some hard dollar limits on certain types of educational and promotional materials. Individual states also started to weigh in on regulations and state regulations are “all over the map on this,” said Brown working the pun. California, for example, simply requires companies to adopt the PhRMA Code. That is, California made the Code mandatory by law rather than voluntary. Vermont has gone so far as to say there are no items of value that can be delivered to Vermont physicians in any form. “There is also talk of some states putting the burden on healthcare providers to do the disclosing,” Brown pointed out.

“Consequently,” said Brown, “you have to be aware of the mix of regulations regarding restrictions on spend and you always need to think in terms of where the healthcare provider is licensed and where the event is taking place.” Brown recommended to have your spend capturing and reporting processes designed to address the most demanding regulations so that you can handle whatever you’re obligated to track and manage in any state.

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Figure 1. Meeting and Event Spend per Attendee Break Down by Industry. The meeting duration and average room rate in the pharmaceutical and technology sectors are higher than other vertical industries. Room rate represented approximately 45% of per participant spend by pharma. Source: CWT Travel Management Institute.

Physician Payment Sunshine Act
The Physician Payment Sunshine Act takes what some of the states have been doing to the next level. “The end result will be a national, searchable, reportable database of payments,” said Brown. “A place that anyone can go and see the sum total of what a company has paid to a healthcare provider.”

Reporting companies, which include all U.S. manufacturers of drug, device, biologics, and medical supplies covered under Medicare, Medicaid, or SCHIP, must report payments on an annual basis—starting on March 31, 2013 with data collected starting January 1, 2012—to the department of Health and Human Services, which will post the information on a public website by September 30, 2013. This timeline is being pushed by Senators Grassley and Kohl, the original authors of the bill (see “Senators Grassley and Kohl Ask Government to Move Forward on Physician Payment Sunshine Implementation”; pg 4).

Disclosure of payments—whether cash or in-kind transfers—to all covered recipients (ie, physicians and teaching hospitals) include:

- compensation;
- food, entertainment or gifts;
- travel;
- consulting fees;
- honoraria;
- research funding or grants;
- education or conference funding;
- stocks or stock options;
- ownership or investment interest;
- royalties or licenses;
- charitable contributions;
- any other transfer of value as described by the secretary.

“Some of these payment categories such as food, entertainment, and travel are very closely tied to meeting and event activities,” noted Brown. “They’re the sorts of things that all of us need to be aware of, need to track and need to have good process around gathering.”

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Exemptions include:

- Educational material provided for the benefit of patients
- Rebates and discounts
- Loans of covered devices
- Items provided under warranty
- Dividend or investment interests in a publicly-traded security or mutual fund
- Payments made to a physician who is a patient, or an employee of the reporting company
- Payments less than $10 until the aggregate annual total per company, per covered recipient, reaches $100, at which point all payments (retroactively) must be disclosed
- Prescription drug and device samples

“Although individual payments of less than ten dollars can be exempt, once the aggregate spend reaches $100 per physician, all payments do become reportable events retroactively,” Brown emphasized. “No one has the luxury of assuming that small payments might not count if over time they start to add up to a significant number.”

There are fines for failure to comply with the law and these may influence state decisions regarding a company’s right to operate and an HCP’s right to prescribe. “But the stakes in all of this go beyond fines,” said Brown. “Above and beyond any monetary penalty there is a huge public relations hit that a company can take if it violates the law.”

Millennium: A Case Study
Colleen Kenney, Senior Manager, Corporate Meetings & Conventions, Millennium: The Takeda Oncology Company, said that most pharmaceutical companies are capturing “some HCP spend as far as spend limits when it comes to honorariums and expenses, but the number of companies that can report total HCP spend is probably on the lower end. As far as who really should be the executive sponsor in leading this initiative, at Millennium our compliance operations group is leading it in conjunction with the head of compliance.” Kenney was a guest speaker at the StarCite webinar.

Millennium recently implemented a Strategic Meetings Management Program using StarCite’s meetings management technology (see “StarCite Rolls Out Life Sciences SMMP Solution,” pg 5). “When I started, about a little over a year and a half ago,” said Kenney, “we were recording anywhere from 200 to 250 meetings a year. By the end of this year, thanks to StarCite, we’ll be recording at least double that number.” By recording all of its meetings, Millennium will ensure that data for each individual meeting is consolidated within StarCite for comprehensive reporting.

A snapshot of Millennium’s meeting planning group:

- Meetings team = 6 planners + 2 managers
- Falls under Strategic Sourcing (Procurement) and reports up into the CFO
- 200-250 meetings managed by the meetings team in 2009, with many more expected in 2010 (roughly 50% of total meetings are managed)

Presently, there is no mandated policy that requires all meetings come through the central planning team, but such a policy is currently under review and the plan is to have it implemented in January, 2011.

Program covers meetings globally

In 2010 there was more focus on consolidating meetings management within StarCite technology

Approximately 40% of all Millenium meetings involve healthcare professionals. The company partners with several 3rd parties that help assist it in the planning and execution of meetings.

Trains, Planes, Automobiles

“At Millennium we break down expenditures to the nth degree because that's where compliance is heading,” said Kenney. Food-related expenditures, for example, can be broken down to expenditures during travel to the meeting and while at the meeting. “When someone asks, ‘What's the food and beverage cost when the doctor is attending a meeting?’, we can separate that from the miscellaneous travel expenses that also can include food,” said Kenney. “When it comes to travel, we're even separating planes, trains and automobiles, according to how the doctor actually went to the meeting.”

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StarCite Rolls Out Life Sciences SMMP Solution

Event-management technology company StarCite has released a version of its strategic meetings management solution that is designed to help life sciences companies adhere to regulatory demands that they track and report all expenses that involve healthcare professionals. In the United States, some states have passed laws requiring companies to report payments to HCPs licensed in that state. The Physician Payments Sunshine Provision in the national healthcare reform legislation that became law in March, 2010, also requires drug and medical device manufacturers to publicly report gifts and payments made to physicians. Failure to comply with state and national regulations can result in hefty fines and penalties.

Designed using customer best practices in a process similar to what the company used to develop a tailored SMMP tool for financial services firms, the company’s Life Sciences Solution includes meeting request and approval processes designed to ensure that all the necessary data is collected and all required approvals are secured. It also includes sourcing controls that allow meeting professionals to ensure the sites selected are appropriate for HCP meetings and that budget fields and line items match what is required for HCP meetings. Other features include a new HCP reporting package and the ability to integrate HCP and other meetings data with customer-relationship management and expense-management systems.

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StarcCite is a tool that Millennium plans to use more extensively for this whole reconciliation process. “Right now we capture aggregate spend in an Excel sheet and upload it into the meeting file,” said Kenney.

“Our goal next year is to work with StarcCite closely to be able to actually have that in the database so that if Dr. Smith is attending three meetings for us in a year, we’ll be able to capture all of his spend across all meetings.”

**Preparing for Sunshine Provisions**

“Our goal,” said Kenney, “is to develop relationships with our internal clients to strongly suggest that they use our events team not just for HCP meetings but for all meetings so that we can truly track total meeting spend within the company.” She summarized how Millennium is preparing for the Sunshine Act provisions as follows:

- Cross-functional team led by Compliance
- Six months of assessment and planning to date
- Plan in Place:
  - Mandate usage of Meetings and Events team
  - Leverage CRM system in Sales as central data warehouse
  - StarCite will be the default data repository for all meeting spend
  - Continue to use 3rd parties for HCP meetings
    - Strong focus on education around policies and process
    - Mandate that all meetings must be planned within StarCite
  - Expand consistent usage of HCP IDs to facilitate reporting
  - All HCP IDs to be uploaded into StarCite’s Attendee Management system in Q1 2011 (to support the focus on consistent HCP identification)

With regard to HCP IDs, Kenney noted that “eventually, the federal government is assigning HCP IDs so that no matter what company is hosting a meeting each doctor attending, the identifier will be captured and they will be able to get a total meeting spend per doctor. Right now there is no set date for when the federal government will be issuing that, so Millennium has decided to start our process internally so that when it does happen, it’s like clockwork and we’ve already implemented it and we’re not changing any sort of process.”

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Best Practice Recommendations
Kenney outlined her suggestions for meeting planning best practices as follows:

• Mandate your policy whenever possible
• Define an internal value proposition for compliance
• Partner with the Chief Compliance Officer
• Automate your processes—do your research and find the right solution for your company
• Build in plenty of training for meeting planners and partners
• Create an ongoing audit process—address potential problems before they are problems
• Be conservative—set policies that meet the most stringent requirements where you do business. You will need an exception process.

StarCite’s technology manages the whole cycle from the early request and planning process right through budgeting for the meeting, sourcing the meeting, marketing the meeting to attendees and managing those attendees as they register.

Technology Enables Efficient Tracking
“One of the keys is mapping the budget categories to the regulatory requirements,” noted Brown. “Our technology provides a summary view that makes it easy at any time to understand what has been spent on HCP versus all the other spending that might go on for other events or for non-HCP oriented portions of events,” said Brown.

The key benefits of StarCite’s Life Sciences SMMP Solution include:

• Best practice based roadmap—learn from the experience of others
• Consistent terminology to ensure reporting clarity
• Reports that allow high level and detailed views of overall meeting program metrics as well as specific HCP-related metrics
• Meeting request and approval process that support complete and consistent HCP data collection
• Integration opportunities to create a closed loop for HCP data
• Experienced implementation and account management experts
• A full configuration plan customized for industry requirements
• The ability to be flexible to address company-specific and market-specific needs
• A streamlined implementation process / timeline

Integration with CRM
The real power of these data, noted Brown, comes from aggregating all the meeting spend in StarCite and then feeding that data into a compliance reporting data warehouse at a company level. This reporting data warehouse becomes the master repository and the tool for doing all your compliance reporting. This data can also be fed into the company’s Customer Relation Management (CRM) system so that the company’s sales system also knows the sum total of what has been done on behalf of these individuals. “When the time comes to potentially invite a Doctor to an event,” said Brown, “the CRM and StarCite systems know the sum total of everything that has been spent to date on that HCP and a decision can be made in advance of sending the invitation whether it’s appropriate to invite them to another event or not. And that really becomes the most powerful proactive tool for managing compliance with all of this regulation.”

Pharmaceutical companies need to focus on how to manage HCP-related meeting spend better, smarter, and more carefully to avoid all the costs, financial and otherwise, associated with failing to comply with the regulations.

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To learn more about StarCite’s Life Sciences SMMP Solution, please visit www.starcite.com where you can listen to the webinar and download a whitepaper.