

Pharmaceutical
Executive

MEDICAL EDUCATION MEETINGS

SUPPLEMENT TO PHARMACEUTICAL EXECUTIVE SEPTEMBER 2006

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The feds and states pile on layers of new regulations governing medical education. Companies interpret the rules. Know how to manage the risk.



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The feds and states pile on layers of new regulations governing medical education. Companies interpret the rules. Here's how to manage the risk.
By Nooshine Dayani and Andy Bender

FOR A WHILE THERE, it looked like pharma had lost its appetite for big investments in the \$3-billion medical-education market. With new OIG guidelines and corporate integrity agreements limiting their business and increasing compliance-risk exposure, many pharmaceutical companies seemed to be wondering: “Why invest in CME at all?” »

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Now, as the dust settles, many companies have found creative solutions to staying in the CME game while adhering to the ethical spirit of the guidelines. Most companies have gone through a painful and expensive phase of reorganizing their processes, developing policies and procedures, training and educating their staff, and implementing monitoring and auditing procedures.

And then there is the simple fact that guidelines must be interpreted. This can be very tricky. For example, most companies agree with OIG that marketing and sales should not be involved in allocating grants. However, they ask, is there still a role for marketing at all? Or, to what level can marketing be involved in identifying and defining educational objectives? Depending on the appetite for risk, the company might have taken a conservative or a more aggressive approach interpreting these guidelines. Most of the top issues facing companies have several interpretations—and very different degrees of compliance risk.

Keeping Out Grants

Sales and marketing departments traditionally decided on grant allocation. They were able to determine who would get a grant. And of course they knew who the high prescribers of their drugs were. Consequently, there was an inherent risk of providing kickbacks (grants) to high prescribers. What looked like a beneficial relationship with a good customer soon began to look like a kickback, especially under OIG guidelines—not to mention Senator Charles Grassley's scrutiny.

To avoid this kickback risk, companies have been moving grant allocation to parts of the organization that do not report to sales and marketing, and which do not have an incentive to increase revenue by providing grants. Most companies have formed a new grant office and have staffed it with personnel to handle only grant allocation. This new grants office, in most instances, reports to medical affairs.

Since marketing has a clear understanding of what physicians' educational needs are, some companies are

Regulations Old and New

Here is a list of recent guidelines, regulations, and federal government investigations that involve medical education activities:

PhRMA Code on Interactions with Healthcare Professionals, 2002

OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 2003

FDA Guidance on Industry Supported Scientific Education (ISSE), 1997

ACCME Standards of Commercial Support, 1992 (updated in 2004)

Various state marketing laws asking for detailed grant-funding information to be disclosed annually

Senator Grassley and the Senate Finance Committee's two-pronged public investigation into 23 companies' practical application of the above guidelines on medical education activities

allowing the marketing department to define high-level educational objectives and communicate these to the grants office, so that grants can address these needs. These objectives cannot be too specific.

Companies are therefore developing standard operating procedures to instill the right checks and balances in the grant allocating process. This is meant to avoid undue influence from marketing while allowing the department to provide valuable information to the grant review committees.

The grants office cannot rely only on the input from marketing. It needs to be able to define the educational needs for a therapeutic area independently. Therefore, the grants office must have subject matter experts on staff who understand the therapeutic area's educational needs—and can identify grant requests that address those needs. These are experts within the therapeutic area who interface with the grant-requesting organization, communicate with marketing, commission independent studies, and develop their independent view on what the educational objectives are.

Same Goes for Reps and MSLs

Sales representatives and medical science liaisons (MSLs) have been stripped of many tools they used to influence physicians' prescribing behavior. One of the last to go was the ability to give grants. The average grant ranged from \$1,500

to \$2,500, and was used to cover educational activities. Physicians now have to submit proposals for a grant to the grants office, which approves grants independently.

In order to mitigate the pain, some companies have decided to notify sales reps when physicians in their calling areas submit grant applications. In addition, some companies have decided to notify reps when one of their doctors gets a grant approved. Companies that interpret the OIG guidelines strictly will not notify the reps at all. Others will only notify reps during a transition phase of six months to a year, after which rep notification will be eliminated. Many companies only allow reps to distribute a business reply card if they receive an unsolicited request for a grant from the physician. The business card directs the physician to the Web site or telephone number of the grants office.

The companies that have decided to inform their reps use the argument that the reps cannot use grants to influence the physicians' behavior toward the company.

In order to facilitate the change process, companies must educate MSLs and reps to stay out of the grant-submission process. The new roles and job description of MSLs and reps should reflect this new regulatory landscape. Steps must also be taken to manage change. MSLs and reps might ask: What can I do now that the grants

are taken away from me? How do I add value to the organization? Does this mean that my job will be eliminated? To reassure them that they will not suffer from the changes, it is important to provide a clear new job description that points in a defined direction. This will enable reps and MSLS to align themselves with the new way of doing business.

New Relationship with Providers

The ACCME guidelines and other governing bodies have clearly established that CME events must be independent of sponsoring companies. Companies that interpret the OIG guidelines strictly will not contact CME vendors or accredited associations, since they believe that it amounts to solicitation and jeopardizes the independence of the program. They respond only to unsolicited applications.

In some instances the grants office defines the standard operating procedures on relationships with accredited institutions. Some pharmaceutical companies choose a riskier approach and develop a list of preferred accredited institutions. Similar to a strategic sourcing department, the grants office evaluates a list of accredited providers based on the value they bring to the grants office and the pharmaceutical company.

However, developing a relationship with a provider could create mutual expectations—either defined or implicit—that smell like quid pro quo, or kickback. Developing a list of preferred providers can be an efficient way to address educational needs, but the associated process required to guarantee independence and avoid kickbacks can be cumbersome or hard to develop and enforce. This is a high-risk area.

Other pharmaceutical companies take even greater risks and choose to pre-qualify CME vendors, despite that this may increase the risk of influence. The best practice would be to allow all accredited associations to apply for CME grants and then allow the grant committee to review all applications before making a final decision.

To facilitate the change process, companies must educate MSLS and reps to stay out of the grant-submission process. The new roles and job description should reflect this new regulatory landscape.

Following the closure of a CME event, the sponsor should require vendors to reconcile their books (matching actual expenses and receipts with proposed expenses). They should then file a grant-consolidation report on the financial and operational status of the events. The operational reconciliation should include the number of certificates that were awarded and the number of attendees (actual versus estimated participants). This consolidation will enable pharmaceutical companies to better forecast future events.

Grants for Unmet Needs

Occasionally, pharmaceutical companies may have educational needs that are not addressed by the grant requests submitted by providers. In the past, the marketing department addressed these

needs by contacting a CME vendor and suggesting a program addressing a specific need. Today, that knowledge gap is harder to fill. The pharmaceutical companies may act in one of the following three ways:

First approach The companies do not communicate this knowledge gap to vendors. Although this is the safest way out and the most compliant approach, it may not provide the greatest benefit for physicians and patients operating in a specific underserved therapeutic area.

Second approach Many pharmaceutical companies publish a list of their therapeutic areas along with a list of permitted and prohibited grants in the public domain (usually on the Internet), and wait to see whether the needs are addressed by submitted grant requests.

Third approach The riskiest approach is to contact CME providers, communicate the educational needs, and solicit a grant request. This puts both the CME provider and the pharmaceutical company at risk for failing to comply with the ACCME guidelines, as well as FDA ISSE Guidelines.

Focus on Outcomes Research

The terms “outcomes research” is used in many contexts these days. When it comes to CME, outcomes research involves understanding how medical education can increase the effectiveness of CME when focused on physician behavior and patient care.

CME outcomes research concen-

Electronic Expense Tracking

Tracking the expenditures made in thousands of grants every year requires efficient reporting. Most of the larger pharmaceutical companies are automating their CME grant-making processes. Automating the process has additional advantages, including:

- » Documenting a process makes it more consistent and transparent
- » Consistent and complete documentation is submitted with every grant
- » Grants are easier to audit and review; data is easily retrieved
- » Management develops, controls, and manages CME budgets
- » Provides insights and criteria to optimize operational processes
- » Expenses are easily reconciled and benchmarked

trates on whether the medium (teleconference vs. live presentation) is effective, how well the speaker communicated the training materials, and whether needs assessment was successful. In addition, companies and CME providers need to seek feedback from physicians on whether there are additional training gaps or topics that need to be covered in future CME programs.

As we mentioned before, the new grants office is somewhat insulated from direct physician feedback, and therefore must actively solicit and research feedback. In addition to outcomes research, the office might turn to:

- » Market research; using the internal market research department and commissioning research conducted by external entities
- » Interviewing marketing and sales departments to obtain high-level educational needs by therapeutic area.

Although currently in its infancy, outcomes research has always been there. The ACCME requires accredited organizations to evaluate the CME program. Because of the new guidelines, the grants office has to take a more analytical approach to developing educational needs, a process that will enhance the effectiveness of education in the long run. By increasing effectiveness, funding will likely increase over time.

Investigations, CIAs, and Decrees

Some new regulations have arrived in the form of corporate integrity agreements (CIAs) with OIG. Others have come as consent decrees and senate investigations.

In June 2005, 23 pharmaceutical companies received letters from Senator Grassley (R-IA), chairman of the Senate Finance Committee, requesting very specific information related to educational grants. He gave companies one month to reply. In January of this year, the senator followed up with a request for additional information, citing that his earlier investigation had revealed that sales and marketing personnel, rather than medical professionals, con-

For outcomes research, companies and CME providers need to seek feedback from physicians on whether there are additional training gaps or topics that need to be covered in future programs.

tinued to control the process of awarding grants to CME providers. Grassley also found that this education, in turn, is being used to promote products, perhaps for off-label uses. The letter also raised concerns that companies are funding outside organizations known to advocate a company product, or that those organizations have come to expect funding from the pharmaceutical company, thereby jeopardizing the program's independence.

The type of information the senator requested is proof that he is investigating the true educational nature of the programs as well as whether there is a distinct separation of the grant-making function from the sales and marketing departments.

By linking the issue of educational grants to off-label promotion, Grassley further increased industry focus on this issue. In reaction to this, companies have sped up the process of moving grant allocation out of their sales and marketing departments. In order to respond to such requests for quick turnarounds, companies are in the process of automating the grant-making process

so that detailed information can be provided more quickly and efficiently. Automation also facilitates the retention of appropriate documentation like "needs assessment" to ensure that a grant request is made for truly educational purposes.

Recent consent decrees and CIAs have drawn attention to the increased regulatory scrutiny of CME events by both OIG and FDA. The Eli Lilly consent decree, for example, requires disclosure to attendees of Lilly's support and any financial relationship with faculty and speakers. The government stipulates that the program shall have an educational focus and the content shall be independent of Lilly. The consent decree also requires a review of all Lilly's systems, processes, policies, and procedures relating to CME, including those by which requests for support are referred to the Lilly grant office.

In addition, the Serono CIA requires the company to disclose financial support for educational activities, and to disclose financial relationships with faculty, speaker, or organizers.

The CIA emphasizes the importance of educational focus, independence, and non-promotion in the tone and nature of a CME course. It also looks at compliance with FDA statutory and regulatory requirements, in particular the anti-kickback and FDA sponsorship requirements. Finally, it stipulates that all agreements need to be in writing and signed, including record retention of initial request, internal evaluation, and consideration of any support provided by the pharmaceutical company to the sponsor, including the source of the budget.

None of these are new guidelines. What is new is that they are being emphasized and that companies are facing additional scrutiny.

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Both the Serono and Lilly cases involved off-label promotion. With a reported 150 pending cases that involve off-label marketing, CME departments need to be aware that CIA and consent-decree standards are going to determine the industry norm. Senator Grassley's investigations teach us that it is important to take the more conservative rather than aggressive approach when interpreting the CME guidelines.

Marketing-Cost Disclosure Laws

Six states have passed legislation either requiring an annual spending limit on marketing expenses to healthcare providers or healthcare organizations, or an annual disclosure of those expenditures.

While the focus of these laws is on marketing costs and gifts, some of the states have included educational activities as well. At least three states—Maine, Minnesota, and DC—have explicitly requested disclosure of educational expenditures.

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The industry strategy for meeting the uncoordinated and inconsistent state marketing-disclosure laws is to implement complex technology solutions that incorporate multiple types of spend into an aggregate system, which could be used to respond to all types of state marketing laws.

Grant allocation by the pharmaceutical companies serves business as well as patient needs. At the end of the day, if grant making is conducted by ethical standards, both the grant-making organization as well as the patient population will benefit. Nobody will benefit from a

restrictive environment where it would become too costly for pharmaceutical companies to provide grants.

Adjustments to the new grants process have been painful, cumbersome, and expensive. But there has been a bright side as well: Most companies have ended up with a more efficient and more strategic process of allocating grants, even as they address the new guidelines. Compliance has been used to re-engineer the grant-making process. By using the compliance process creatively, many companies have become more efficient and more strategic grant makers. [®]

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