NEW REQUIREMENTS for ADVISORY MEETINGS Provide New Opportunities

This past decade has brought increased focus and attention to pharmaceutical company interactions with healthcare providers regarding marketed products. Further to the 1992 AMA Guidelines on Gifts to Physicians from Industry, pharma marketers must now take into consideration the PhRMA Code on Interactions with Healthcare Professionals and the OIG Compliance Program Guidance for Pharmaceutical Manufacturers. In July of this year, PhRMA made its revised code available online (phrma.org).

"In addition to this continuing regulatory scrutiny, the lay media and medical journals also have added accusatory voices about how physicians are being remunerated for their involvement as investigators, consultants, and advisors to pharmaceutical companies," says Joan Bradley, Pharm.D., president of The JB Ashtin Group. "As a result, the number of advisory meetings that were undertaken by pharmaceutical companies has predictably fallen, as those in the professional education departments scramble to come up with creative ways to assess their educational messages without the benefit of direct professional feedback."

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CHANGING WITH THE TIMES

Before 2002, there were only very basic guidelines from the AMA to regulate industry "gifts" to physicians and these did not specifically address advisory board and consultant meetings, those meetings where subject matter experts are gathered together to provide advice to pharmaceutical companies.

According to Dr. Bradley, such meetings were considered an essential component of any marketing plan; one-on-one, personal feedback from a medical professional who regularly sees patients can provide clearer, more relevant, and valuable insights than dozens of anonymous focus groups.

"Historically, the major limiting factor to conducting any number of these key advisory meetings was the available A&P budget," she says. "Today, the cost of the meetings has become of lesser importance and presently is actually among the least-limiting factors. Under the new PhRMA revisions, education departments and brand teams must review why each specific attendee is being invited, what content will be shown, what feedback will be obtained, how that feedback will be used, and what methods will be used to evaluate how that feedback is used. Accurately reviewing and documenting the answers to these questions requires significant additional resources and, in many cases, additional full-time staff and the accompanying budget to support that staff. The actual cost of the meeting itself becomes a minor concern."

Now that the PhRMA Code has been updated, the ambiguous language of the old code has been replaced with concise language and examples that make it impossible to misinterpret what falls within code and what does not, she says.

Dr. Bradley provides several examples. The code published in 2002 stated that "…the venue and circumstances of any meeting with consultants are conducive to the consulting services and activities related to the services are the primary focus of the meeting, and any social or entertainment events are clearly subordinate in terms of time and emphasis."

The new code clarifies that holding advisory or consultant meetings in resort locations is prohibited. Even the simple act of providing a pen for advisor use during a meeting may be viewed as a violation of the code in that the new code states "providing items for healthcare professionals' use that do not advance disease or treatment education — even if they are practice-related items of minimal value (such as pens, note pads, mugs and similar 'reminder' items with company or product logos) — may foster misperceptions that company interactions with healthcare professionals are not based on informing them about medical and scientific issues."


Dr. Joan Bradley

In the years to come, the industry can certainly be confident that these regulations will not be relaxed or be minimized.

There is no benefit to sitting back and hoping this will pass; diligent companies that find their way through the labyrinth will enjoy a substantial advantage over those that do not.

INCREASED SCRUTINY CHANGES SOPS

Combined with the revised PhRMA Code, which speaks directly to the consulting arrangement, the 2003 U.S. Department of

FOUR AREAS OF FOCUS

IN GENERAL, THERE ARE FOUR MAIN CATEGORIES THAT PHARMACEUTICAL EXECUTIVES MUST FOCUS ON TO COPE WITH THE NEW REGULATORY REQUIREMENTS:

1 **Documentation.** Premeeting documentation is as critical as postmeeting documentation. Steps must be taken to ensure that there is thorough documentation to secure internal meeting approval and to guarantee that postmeeting activities demonstrate justification. Educational and marketing departments need to make certain that documentation and procedures meet the needs of all team members involved in the justification process, such as compliance, legal, marketing, medical, and education.

2 **Strategic planning.** Gone are the days when meetings routinely could be planned in a month. A realistic timeline is essential to adhering with compliance policies.

3 **Communication.** Talking and planning with the compliance department in advance of proceeding with the meeting is crucial to the timely success of your meeting.

4 **Strategic partners.** Using an experienced third-party vendor or medical communications firm can help significantly with the above categories and eliminate time-wasting guesswork and indecision.

Health and Human Services Office of Inspector General (OIG) Compliance Program Guidance for Pharmaceutical Manufacturers, Dr. Bradley says, gives direction to pharmaceutical companies regarding their use of healthcare providers as advisors.

"In other words, the OIG addresses any situation in which the pharmaceutical company is providing a fee for service for a prescriber," she says. "This includes how much a company is paying the physician, why it is inviting that physician, what the company is paying him or her for, and how much it is paying the physician throughout the course of the year."

The impact of this combination on a company's standard operating procedures (SOPs) is substantial, impeding the implementation of traditional marketing activities.

"In many cases, companies have been forced to create new SOPs to address the compliance program as mandated by the OIG and the PhRMA code, which in turn requires additional staff to manage the SOPs and new internal review processes to be put into place," Dr. Bradley says. "Because getting a meeting approved through these various channels can be very difficult and overwhelming, the marketing team often becomes frustrated and simply moves marketing dollars into other initiatives. This leads to the loss of the valuable insights that have traditionally played a key role in guiding and developing brands."

Dr. Bradley says it has been five years since the OIG guidance was put in place, and the industry is still learning the optimal method of documenting compliance.

Even the state attorneys general are getting involved, and there are now many states that require pharmaceutical companies to disclose what they are paying physicians by way of fees, meals, lodging, and materials.

"In Minnesota, for example, a physician cannot accept anything from a pharmaceutical company — not even a pen," she says. "Pharmaceutical companies are required to report on an annual basis every single one of their contributions to prescribers, even if it is simply a package of Post-it notes."

COMPLIANCE OVERHAUL

Savvy pharmaceutical executives have been aggressively working on updating their compliance programs, rapidly dissecting the new regulations, and constructing a response formula that will ensure that the guidance provided by their clinical advisors and subject matter experts (aka, key opinion leaders) is not interrupted.

"For most companies, however, these new regulations have presented yet another barrier in their regulatory obstacle course," she says. "Whereas it may be difficult to see past the additional drain on time and resources, the new PhRMA Code presents the opportunity for adaptable companies to respond effectively before January 2009, when the new code takes effect, and maintain the critical stream of feedback from their subject matter experts. By doing so, these companies would enjoy a significant advantage over those unable to react quickly and effectively." ✦

PharmaVOICE welcomes comments about this article. E-mail us at feedback@pharmavoice.com.