

CME Providers Court Peril by Ignoring New Compliance Guidelines

Accredited medical education content providers who assume that they need not take notice of new compliance guidelines could be in for a rude awakening. A result of the concern over corporate conduct as well as from increasing prescription drug costs, the new wave of guidelines and codes is being earnestly heeded by the pharmaceutical companies. Most now are developing compliance programs affecting all levels of their operations, including their dealings with medical education vendors and CME providers. Many have also started to actively audit their promotional and accredited programs, and experts believe it is just a matter of time until the pharmaceutical companies will request more active participation in auditing CME programs from accredited providers (most notably the academic health centers, or AHCs).

Providers, in fact, carry more than their fair share of the burden in proving adherence to current rules, and no grant—large or small—is exempt from rulings issued by agencies such as OIG, the FDA, PhRMA and ACCME. According to ACCME Commercial Support Policies 1990-A-14, “The accredited provider must maintain and be able to produce as documentation a full accounting of the funds.” In addition, the FDA places responsibility for ensuring that the educational activity comes within the provisions of a safe harbor with the company funding the activity (FDA: The Final Guidance – December 1997).

The “Draft OIG Compliance Program for Pharmaceutical Manufacturers” encourages the use of internal controls, processes, and regular audits to monitor adherence. The seven OIG

guidelines are having an immediate and profound impact on pharma companies who are anxious to head off more direct regulatory controls, as well as any repeat of the recent ethical debacles that have tarnished the accounting industry, financial institutions, and others. AHCs and other accredited providers are responsible for the compliant execution of their CME programs, so they can no longer focus exclusively on developing content and delegate all responsibility for the management of funds and logistics to the meeting planning companies and other third party vendors. The accredited providers will have to translate and apply the seven OIG guidelines (see Box on p. 8) to their accredited CME programs, just as the drug manufacturers have already done.

Audits are a revealing source of all-too-typical compliance issues. One audit uncovered instances of a meeting planning company unable to back up its invoices with receipts, as well as billing the CME program for non-physicians—including personal expenses for members of the company staff. Another case showed marketing and sales personnel committing breaches of compliance protocols including dictating a list of speakers, directing the content of program slides, and traveling on CME funds. A third audit found examples of a meeting planning company diverting CME funds to promotional programs. Another case showed numerous instances of completed programs which lacked required documentation such as grant requests, letters of agreement, speaker contracts, and even a final budget.

These cases are not isolated examples. Still, it's important to keep in mind that all of the abuses cited were uncovered and corrected—just as the new guidelines intend—as a result of audits conducted by the pharmaceutical manufactures. Another reason for optimism is that the

guidelines' focus on internal reforms such as developing company-wide compliance policies and designating compliance officers makes it possible to treat the root causes of the infractions without the necessity of more direct regulatory controls. In other words, these guidelines can work.

Before looking at how the guidelines can be used by AHCs to correct compliance problems, it is instructive to look at how so many compliance infractions have come about in the first place. Systemic flaws in the burgeoning meeting planning industry constitute a great source of these problems. The field that has become a high income industry practically overnight—with revenues of \$2.5B—and has had to contend with rapid growth, high staff turnover, and a relative lack of staff training. With new rules virtually streaming out of regulatory agencies, training on the new and complex compliance issues is even more important than ever. However, meeting planning staff members are rarely trained as well as they should be in this area.

Unfortunately, poor training and staffing concerns on the vendor side are often echoed by problems coming from the manufacturer's side. Product managers who lack time and resources managing compliance issues are less likely to review the execution of programs. Every major agency has come out with new guidelines in the last year and keeping on top of them has become a crucial management concern. Objectivity is also a concern since product managers who have a strong incentive to increase market share might be inclined to interpret some compliance guidelines in their favor.

There have also been instances of misinformation being purposefully generated, resulting in clear breaches of ethical conduct. A ‘don’t ask, don’t tell’ policy results when it is felt that certain questionable practices are tolerable because the chance of getting audited is almost nil; and, even if detected, the consequences of such practices are minimal as long as there is some kind of corrective behavior after the fact.

None of this is good news for the AHCs and other accredited providers who find themselves responsible for policing actions that are beyond their control. They are suddenly accountable in areas that have heretofore been beyond their jurisdiction, since they have historically relied on meeting planning companies to handle all logistical matters (and—it is worth noting—to provide the grants). In fact, their longtime allies in the meeting planning companies are the very group they are now being called upon to audit.

In fact, what might be most vexing for the AHCs and other accredited providers is that they are being required to play “watchdog” to companies upon whom they rely for funding. Some fear this dilemma: Do they turn a blind eye to questionable compliance and financial dealings occurring under their watch and risk regulatory citation and censure? Or, do they do the right thing by forcing compliance on their vendor partners, and then risk vendor censure and the possibility of losing needed grants?

Of course no one seriously thinks that accredited providers will hesitate in meeting whatever obligations the rules place on them—no matter what the funding consequences. The group predominantly consists of academic health centers that have rightfully earned a solid

reputation for honesty and credibility. Just as clearly, however, no one relishes jeopardizing an important source of financial support.

Fortunately there are ways for the AHCs to impose auditing, without unduly risking censure, and at the same time, adding value to their programs in the eyes of the pharmaceutical manufacturers.

At least three broad avenues are open to academic health centers in addressing the latest responsibilities placed on them by compliance regulations. They are: 1) internal steps on the individual AHC-level; 2) a group-wide banding together of AHCs, following the PhRMA model of pharmaceutical manufactures; and 3) a partnership between AHCs and the pharmaceutical manufacturers. Each approach has specific strengths and weaknesses, and none will come without considerable effort, time, and expense by the AHCs. Still, it would be an egregious mistake for AHCs to do nothing at this time. Remaining in a holding pattern exposes AHCs to a variety of dangers, not the least of which are the potential for being caught up in an ethics controversy or having a compliance “solution,” which they have had no say in creating imposed upon them by regulators or the pharmaceutical companies.

The most independent potential AHC response, the internal approach, is exactly in keeping with the guidelines that encourage the use of in-house controls and processes to ensure compliance adherence. Indeed, whatever steps AHCs take beyond active internal policing (be they group-wide or in concert with the manufacturers), it would seem highly risky for an AHC to not have formal in-house processes in place by now. The seven OIG guidelines (see Box on p. 8)

should be highly useful to AHCs in devising their internal AHC response. They center on naming a compliance officer or committee in each group and the creation and implementation of internal policies and procedures. Another helpful step, not described in the OIG guidelines, is the use of internal compliance audits of existing or completed projects. Audits are an excellent way to identify compliance issues, since the same ones tend to come up over and over again within an organization or with a specific vendor. Audits are also a valuable way to spot-check continuing compliance adherence once an internal system is in place.

Another “pro” of an internal approach is that it is relatively easy for an AHC to take, as they need not depend upon others in order to undertake it. There are several “cons” to the internal approach, however. The greatest might be cost, since a go-alone approach means the AHC would have to foot the bill entirely by itself. Another minus is the relative lack of objectivity inherent in any process restricted to insiders, especially since objectivity is so important in a meaningful examination of compliance issues. Also, there is the fact that one AHC alone would have little muscle in pressing compliance concerns with meeting planning companies, or with anybody else, for that matter. This relates to the earlier discussion of content providers often being reliant on the meeting planners for a significant source of their funding. On a whole, it appears that the go-alone approach to compliance—while a necessary basis for any AHC effort—is ultimately too limiting to serve as the complete answer.

The second potential AHC approach, a PhRMA-like ACH group-wide response, would have the major advantage over a go-alone approach in that it would represent the strength of numbers. It stands to reason that vendors and manufactures alike would have to take notice of a

group representing a large segment of the content-providing community. But therein is a great drawback to this approach: How on earth would such an association come together? It would be extremely difficult to bring together a critical mass of AHCs, and some tireless soul would have to take on the near-Herculean burden of making this happen. There would be other “pros” to the group-wide approach, such as the spreading out of costs over many AHCs and the increase in objectivity versus one AHC on its own, but the difficulties in forming such a grouping seem—at this time, at least—to rule it out as a plausible response to the compliance guideline situation.

The other potential approach, AHCs partnering with the pharmaceutical manufactures, is perhaps the best “perfect world” solution to the problem, but it too might be an idea whose time—while clearly coming—is not yet quite here. Under this scenario, AHCs would ask the pharmaceutical company program sponsors to be audited for compliance as a part of the overall agreement. One big plus for AHCs, is that the manufacturers would pick up the tab for these audits. But the manufacturers would be getting value as well, in that they would be actively demonstrating their commitment to full compliance. Whether the third-party vendors involved in the programs would be included in these audits as well is an open question, but it seems logical that they would.

The benefits the partnership approach are not only financial for the AHCs. By its very nature, the partnership would represent an investing in and strengthening of the AHC’s relationship with the pharmaceutical manufacturer. Another plus, relative to the other approaches, is that an outside audit ensures the highest amount possible of objectivity in a compliance review.

If there is a “con” to the partnership approach for the AHC will have to cede any control over the process to the pharmaceutical manufacturer. AHCs agreeing to compliance audits must be prepared for the auditor’s results. It seems most likely, however, that AHCs who are strong in the area of compliance will welcome a process through which their strict adherence is objectively tested and verified. If AHCs take the correct internal steps now, then there is no reason why they should have to have anything to fear from compliance auditing when it comes about.

But when will widespread compliance auditing come about? Indications are that it is on its way, but not yet here. The hurdle of the pharmaceutical companies footing the bill is considerable, but there have already been instances of pharmaceutical companies motivated by concern over compliance issues taking the initiative to audit programs involving AHCs, without any prompting from the AHC. With the regulatory focus on compliance showing no signs of abating, it seems likely that this trend will continue. Even if this were not the case, however, it seems exceedingly clear that AHCs should be taking the first steps towards heading off compliance worries in the future by setting up the internal compliance processes urged by OIG and others now. In all likelihood, those who do that now will better positioned to thrive in the future. Not only will they have taken the steps to avoid both potential embarrassments and even stricter, more direct regulation, but they will also have demonstrated that they are able to face and meet challenges and are among the more forward looking in their field. Clearly there is a brighter future for AHCs who fit that profile than for those who do nothing and hope for this situation to go away of its own accord.

Box:

The OIG has spelled out what the pharma companies must do for corrective measures. This process can and should easily be adapted to AHCs as well.

The OIG proposes:

Implement written policies and procedures

Designate a compliance officer and compliance committee

Conduct effective training and education

Develop effective lines of communication

Conduct audits on CME and promotional programs

Enforce standards

Respond promptly to detected problems and undertake corrective action