

Seven Elements of an Effective Compliance Program

Don't Miss the Train

Paul Nash

Group Publisher, HCPro Inc.

Bruce D. Armon, Esquire

Partner, Life Sciences Group, Saul Ewing LLP



The federal and state governments have the pharmaceutical industry in their enforcement crosshairs. Multihundred million dollar settlements are no longer uncommon. As a result of these high-media-profile activities, large and small pharmaceutical companies are paying closer attention to the activities of their employees and contractors to help ensure compliance with federal and state statutes. The activities of the sales and marketing staff are particularly important because these individuals are on the "front lines" interacting with health-care professionals and potentially exposing the company to significant liability. Proper staff training is perhaps a company's best and most effective deterrent to help prevent individuals from operating outside the law. While ignorance may be bliss in certain circumstances, in today's environment a company must train its staff to act appropriately at all times and understand the potential personal and corporate liabilities for failing to do so.

Effective Training and Education

In May 2003, the OIG published a voluntary guidance specifically intended to help pharmaceutical companies prevent and reduce fraud and abuse in federal healthcare programs. When the Medicare Part D prescription drug benefit takes effect Jan. 1, 2006, it will become even more important for sales and marketing staffs to adhere to their company's compliance program. The OIG identifies seven elements that "have been widely recognized as fundamental to an effective compliance program." Not surprisingly, one of these elements is effective training and education. There are seven training tips that a company can employ for its compliance program to minimize potential legal consequences.

- **Train and Retrain.** The OIG doesn't state how often employees should be trained, but it does suggest that one-time training is not enough. Companies should consider at least annual training or, if there are changes in internal standards or procedures or relevant statutes and regulations, more often as necessary. And they need to make sure all new hires receive training as part of their orientation before they're in a position to act inappropriately.

- **Determine the Training Cycle.** Companies should provide each employee with a minimum number of compliance training hours per year. The company must determine how many hours comprise the "minimum." This decision, which should be documented as part of a company's compliance program, should be based on the compliance risks faced by each segment of employees. Sales reps who are in the field, for example, may face more risks — and require more training hours — than brand managers who are largely based in corporate headquarters and have minimal interaction with external audiences.

- **Customize the Training.** While training programs should include gen-

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eral sessions that apply across the company, the compliance training should be tailored to certain job functions. For example, the sales and marketing staff must understand the federal antikickback statute and its safe harbors. In contrast, a session on drug pricing is less important to these individuals.

- **Document the Training.** Prepare and retain attendance logs, descriptions of training sessions, and copies of the materials presented. This documentation may help demonstrate that the company provided proper instruction to sales and marketing staff regarding lawful product promotion tactics.

- **Make Training Interactive.** For a compliance program to work, the OIG says, "employees must be able to ask questions and report problems." While videotapes, audio conferences, and computer-based training programs are effective ways to reach employees who are separated geographically, they might not lend themselves to question-and-answer discussions. Companies should provide forums that allow employees to ask questions. Prospectively, the company should consider a compliance telephone "hotline" to allow staff members to have questions answered in a timely manner.

- **Don't Forget Contractors.** If a company uses contractors for sales or other functions, it is responsible for their actions. Companies can't assume these individuals have received compliance training, or that their training is the same as their internal training. Companies should train this group the same way it would train their own employees.

- **Train the Trainer.** The best compliance programs have multiple individuals who can provide training. This helps reinforce the company's mission and dedication to acting appropriately.

An Evolving Process

An effective training program should be reviewed and updated regularly. A company should not merely go through the motions, but actually set the stage for good practices. An employee who misses the train will have a difficult time catching up and the repercussions will impact the entire company. ■

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