

The OIG recognizes that the format of the training program will vary depending upon the size and resources of the pharmaceutical manufacturer. For example, a company with limited resources or whose sales force is widely dispersed may want to create a videotape or computer-based program for each type of training session so new employees and employees outside of central locations can receive training in a timely manner. If videos or computer-based programs are used for compliance training, the OIG suggests that the company make a qualified individual available to field questions from trainees. Also, large pharmaceutical manufacturers may find training via the Internet or video conference capabilities to be a cost-effective means of reaching a large number of employees. Alternatively, large companies may include training sessions as part of regularly scheduled regional meetings.

The OIG recommends that participation in training programs be made a condition of continued employment and that failure to comply with training requirements should result in disciplinary action. Adherence to the training requirements as well as other provisions of the compliance program should be a factor in the annual evaluation of each employee.

#### *E. Developing Effective Lines of Communication*

##### **1. Access to Supervisors and/or the Compliance Officer**

In order for a compliance program to work, employees must be able to ask questions and report problems. Supervisors play a key role in responding to employee concerns and it is appropriate that they serve as a first line of communications. Pharmaceutical manufacturers should consider the adoption of open-door policies in order to foster dialogue between management and employees. In order to encourage communications, confidentiality and non-retaliation policies should also be developed and distributed to all employees.<sup>18</sup>

Open lines of communication between the compliance officer and employees are equally important to the successful implementation of a compliance program and the reduction of any potential for fraud and abuse. In addition to serving as a contact point for reporting problems and initiating appropriate responsive action, the compliance officer should be viewed as someone to whom personnel can go to get clarification on the company's policies. Questions and responses should be documented and dated and,

if appropriate, shared with other staff so that compliance standards or policies can be updated and improved to reflect any necessary changes or clarifications. Pharmaceutical manufacturers may also consider rewarding employees for appropriate use of established reporting systems as a way to encourage the use of such systems.

##### **2. Hotlines and Other Forms of Communication**

The OIG encourages the use of hotlines, e-mails, newsletters, suggestion boxes, and other forms of information exchange to maintain open lines of communication. In addition, an effective employee exit interview program could be designed to solicit information from departing employees regarding potential misconduct and suspected violations of company policy and procedures. Pharmaceutical manufacturers may also identify areas of risk or concern through periodic surveys or communications with sales representatives about the current marketing environment. This could provide management with insight about and an opportunity to address conduct occurring in the field, either by the company's own sales representatives or those of other companies.

If a pharmaceutical manufacturer establishes a hotline or other reporting mechanism, information regarding how to access the reporting mechanism should be made readily available to all employees and independent contractors by including that information in the code of conduct or by circulating the information (e.g., by publishing the hotline number or e-mail address on wallet cards) or conspicuously posting the information in common work areas. Employees should be permitted to report matters on an anonymous basis.

Reported matters that suggest substantial violations of compliance policies or applicable Federal health care program requirements should be documented and investigated promptly to determine their veracity and the scope and cause of any underlying problem. The compliance officer should maintain a detailed log that records such reports, including the nature of any investigation, its results, and any remedial or disciplinary action taken. Such information, redacted of individual identifiers, should be summarized and included in reports to the board of directors, the president or CEO, and compliance committee. Although the pharmaceutical manufacturer should always strive to maintain the confidentiality of an employee's identity, it should also make clear that there might be a point where

the individual's identity may become known or need to be revealed in certain instances. The OIG recognizes that protecting anonymity may be infeasible for small companies. However, the OIG believes all employees, when seeking answers to questions or reporting potential instances of fraud and abuse, should know to whom to turn for a meaningful response and should be able to do so without fear of retribution.

#### *F. Auditing and Monitoring*

An effective compliance program should incorporate thorough monitoring of its implementation and an ongoing evaluation process. The compliance officer should document this ongoing monitoring, including reports of suspected noncompliance, and provide these assessments to company's senior management and the compliance committee. The extent and frequency of the compliance audits may vary depending on variables such as the pharmaceutical manufacturer's available resources, prior history of noncompliance, and the risk factors particular to the company. The nature of the reviews may also vary and could include a prospective systemic review of the manufacturer's processes, protocols, and practices or a retrospective review of actual practices in a particular area.

Although many assessment techniques are available, it is often effective to have internal or external evaluators who have relevant expertise perform regular compliance reviews. The reviews should focus on those divisions or departments of the pharmaceutical manufacturer that have substantive involvement with or impact on federal health care programs (such as the government contracts and sales and marketing divisions) and on the risk areas identified in this guidance. The reviews should also evaluate the company's policies and procedures regarding other areas of concern identified by the OIG (e.g., through Special Fraud Alerts) and federal and state law enforcement agencies. Specifically, the reviews should evaluate whether the: (1) Pharmaceutical manufacturer has policies covering the identified risk areas; (2) policies were implemented and communicated; and (3) policies were followed.

#### *G. Enforcing Standards Through Well-Publicized Disciplinary Guidelines*

An effective compliance program should include clear and specific disciplinary policies that set out the consequences of violating the law or the pharmaceutical manufacturer's code of