

Personnel office (or its equivalent) to ensure that the List of Excluded Individuals/Entities¹⁵ has been checked with respect to all employees and independent contractors;

- Assisting the company's internal auditors in coordinating internal compliance review and monitoring activities;

- Reviewing and, where appropriate, acting in response to reports of noncompliance received through the hotline (or other established reporting mechanism) or otherwise brought to his or her attention (e.g., as a result of an internal audit or by corporate counsel who may have been notified of a potential instance of noncompliance);

- Independently investigating and acting on matters related to compliance. To that end, the compliance officer should have the flexibility to design and coordinate internal investigations (e.g., responding to reports of problems or suspected violations) and any resulting corrective action (e.g., making necessary improvements to policies and practices, and taking appropriate disciplinary action) with various company divisions or departments;

- Participating with the company's counsel in the appropriate reporting of any self-discovered violations of federal health care program requirements; and

- Continuing the momentum and, as appropriate, revision or expansion of the compliance program after the initial years of implementation.¹⁶

The compliance officer must have the authority to review all documents and other information relevant to compliance activities. This review authority should enable the compliance officer to examine interactions with government programs to determine whether the company is in compliance with federal health care program reporting and rebate requirements and to examine interactions with health care professionals that could violate kickback prohibitions or other federal health care programs requirements. Where appropriate, the compliance officer should seek the advice of competent legal counsel about these matters.

2. Compliance Committee

The OIG recommends that a compliance committee be established to advise the compliance officer and assist in the implementation of the compliance program.¹⁷ When developing an appropriate team of people to serve as the pharmaceutical manufacturer's compliance committee, the company should consider a variety of skills and personality traits that are expected from the team members. The

company should expect its compliance committee members and compliance officer to demonstrate high integrity, good judgment, assertiveness, and an approachable demeanor, while eliciting the respect and trust of company employees. These interpersonal skills are as important as the professional experience of the compliance officer and each member of the compliance committee.

Once a pharmaceutical manufacturer chooses the people who will accept the responsibilities vested in members of the compliance committee, the company needs to train these individuals on the policies and procedures of the compliance program, as well as how to discharge their duties. The OIG recognizes that some pharmaceutical manufacturers (e.g., small companies or those with limited budgets) may not have the resources or the need to establish a compliance committee. However, when potential problems are identified at such companies, the OIG recommends the creation of a "task force" to address the particular issues. The members of the task force may vary depending upon the area of concern. For example, if the compliance officer identifies issues relating to improper inducements to the company's purchasers or prescribers, the OIG recommends that a task force be organized to review the arrangements and interactions with those purchasers or prescribers. In essence, the compliance committee is an extension of the compliance officer and provides the organization with increased oversight.

D. Conducting Effective Training and Education

The proper education and training of officers, directors, employees, contractors, and agents, and periodic retraining of personnel at all levels are critical elements of an effective compliance program. A pharmaceutical manufacturer must take steps to communicate effectively its standards and procedures to all affected personnel by requiring participation in appropriate training programs and by other means, such as disseminating publications that explain specific requirements in a practical manner. These training programs should include general sessions summarizing the manufacturer's compliance program, written standards, and applicable federal health care program requirements. All employees and, where feasible and appropriate, contractors should receive the general training. More specific training on issues, such as (i) the anti-kickback statute and how it

applies to pharmaceutical sales and marketing practices and (ii) the calculation and reporting of pricing information and payment of rebates in connection with federal health care programs, should be targeted at those employees and contractors whose job requirements make the information relevant. The specific training should be tailored to make it as meaningful as possible for each group of participants.

Managers and employees of specific divisions can assist in identifying specialized areas that require training and in carrying out such training. Additional areas for training may also be identified through internal audits and monitoring and from a review of any past compliance problems of the pharmaceutical manufacturer or similarly situated companies. A pharmaceutical manufacturer should regularly review its training and, where appropriate, update the training to reflect issues identified through audits or monitoring and any relevant changes in federal health care program requirements. Training instructors may come from outside or inside the organization, but must be qualified to present the subject matter involved and sufficiently experienced in the issues presented to adequately field questions and coordinate discussions among those being trained. Ideally, training instructors should be available for follow-up questions after the formal training session has been conducted.

The pharmaceutical manufacturer should train new employees soon after they have started working. Training programs and materials should be designed to take into account the skills, experience, and knowledge of the individual trainees. The compliance officer should document any formal training undertaken by the company as part of the compliance program. The company should retain adequate records of its training of employees, including attendance logs, descriptions of the training sessions, and copies of the material distributed at training sessions.

The OIG suggests that all relevant personnel (*i.e.*, employees as well as agents of the pharmaceutical manufacturer) participate in the various educational and training programs of the company. For example, for sales representatives who are responsible for the sale and marketing of the company's products, periodic training in the anti-kickback statute and its safe harbors should be required. Employees should be required to have a minimum number of educational hours per year, as appropriate, as part of their employment responsibilities.