

program as an element in evaluating management and employees) and address specific areas of potential fraud and abuse, such as the reporting of pricing and rebate information to the federal health care programs, and sales and marketing practices;

(2) The designation of a compliance officer and other appropriate bodies (e.g., a corporate compliance committee) charged with the responsibility for developing, operating, and monitoring the compliance program, and with authority to report directly to the board of directors and/or the president or CEO;

(3) The development and implementation of regular, effective education and training programs for all affected employees;

(4) The creation and maintenance of an effective line of communication between the compliance officer and all employees, including a process (such as a hotline or other reporting system) to receive complaints or questions, and the adoption of procedures to protect the anonymity of complainants and to protect whistleblowers from retaliation;

(5) The use of audits and/or other risk evaluation techniques to monitor compliance, identify problem areas, and assist in the reduction of identified problems;

(6) The development of policies and procedures addressing the non-employment or retention of individuals or entities excluded from participation in federal health care programs, and the enforcement of appropriate disciplinary action against employees or contractors who have violated company policies and procedures and/or applicable federal health care program requirements; and

(7) The development of policies and procedures for the investigation of identified instances of noncompliance or misconduct. These should include directions regarding the prompt and proper response to detected offenses, such as the initiation of appropriate corrective action and preventive measures and processes to report the offense to relevant authorities in appropriate circumstances.

B. Written Policies and Procedures

In developing a compliance program, every pharmaceutical manufacturer should develop and distribute written compliance standards, procedures, and practices that guide the company and the conduct of its employees in day-to-day operations. These policies and procedures should be developed under the direction and supervision of the compliance officer, the compliance committee, and operational managers.

At a minimum, the policies and procedures should be provided to all employees who are affected by these policies, and to any agents or contractors who may furnish services that impact federal health care programs (e.g., contractors involved in the co-promotion of a manufacturer's products).

1. Code of Conduct

Although a clear statement of detailed and substantive policies and procedures is at the core of a compliance program, the OIG recommends that pharmaceutical manufacturers also develop a general corporate statement of ethical and compliance principles that will guide the company's operations. One common expression of this statement of principles is the code of conduct. The code should function in the same fashion as a constitution, *i.e.*, as a document that details the fundamental principles, values, and framework for action within an organization. The code of conduct for a pharmaceutical manufacturer should articulate the company's expectations of commitment to compliance by management, employees, and agents, and should summarize the broad ethical and legal principles under which the company must operate. Unlike the more detailed policies and procedures, the code of conduct should be brief, easily readable, and cover general principles applicable to all employees.

As appropriate, the OIG strongly encourages the participation and involvement of the pharmaceutical manufacturer's board of directors, CEO, president, members of senior management, and other personnel from various levels of the organizational structure in the development of all aspects of the compliance program, especially the code of conduct. Management and employee involvement in this process communicates a strong and explicit commitment by management to foster compliance with applicable federal health care program requirements. It also communicates the need for all employees to comply with the organization's code of conduct and policies and procedures.

2. Specific Risk Areas

This section is intended to help prudent pharmaceutical manufacturers identify areas of their operations that present potential risk of liability under several key federal fraud and abuse statutes and regulations.⁶ This section focuses on areas that are currently of concern to the enforcement community and is not intended to address all potential risk areas for pharmaceutical

manufacturers. Importantly, the identification of a particular practice or activity in this section is not intended to imply that the practice or activity is necessarily illegal in all circumstances or that it may not have a valid or lawful purpose underlying it.

This section addresses the following areas of significant concern for pharmaceutical manufacturers: (1) Integrity of data used by state and federal governments to establish payment amounts; (2) kickbacks and other illegal remuneration; and (3) compliance with laws regulating drug samples.

This guidance does not create any new law or legal obligations, and the discussions that follow are not intended to present detailed or comprehensive summaries of lawful and unlawful activity. Rather, these discussions should be used as a starting point for a manufacturer's legal review of its particular practices and for development of policies and procedures to reduce or eliminate potential risk.

a. *Integrity of Data Used To Establish or Determine Government Reimbursement.* Many federal and state health care programs establish or ultimately determine reimbursement rates for pharmaceuticals, either prospectively or retrospectively, using price and sales data directly or indirectly furnished by pharmaceutical manufacturers. The government sets reimbursement with the expectation that the data provided are complete and accurate. The knowing submission of false, fraudulent, or misleading information is actionable. A pharmaceutical manufacturer may be liable under the False Claims Act⁷ if government reimbursement (including, but not limited to, reimbursement by Medicare and Medicaid) for the manufacturer's product depends, in whole or in part, on information generated or reported by the manufacturer, directly or indirectly, and the manufacturer has knowingly (as defined in the False Claims Act) failed to generate or report such information completely and accurately. Manufacturers may also be liable for civil money penalties under various laws, rules and regulations. Moreover, in some circumstances, inaccurate or incomplete reporting may be probative of liability under the federal anti-kickback statute.

Where appropriate, manufacturers' reported prices should accurately take into account price reductions, cash discounts, free goods contingent on a purchase agreement, rebates, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or