

the **Federal Register** soliciting comments and recommendations on what should be included in this compliance program guidance.² Following our review of comments received in response to the solicitation notice, we published draft compliance guidance in the **Federal Register** in order to solicit further comments and recommendations.³ In addition to considering the comments received in response to that solicitation notice and the draft compliance guidance, in finalizing this guidance we reviewed previous OIG publications, including OIG advisory opinions, safe harbor regulations (including the preambles) relating to the federal anti-kickback statute,⁴ Special Fraud Alerts, as well as reports issued by the OIG's Office of Audit Services and Office of Evaluation and Inspections relevant to the pharmaceutical industry. (These materials are available on the OIG Web page at <http://oig.hhs.gov>.) In addition, we relied on the experience gained from investigations of pharmaceutical manufacturers conducted by OIG's Office of Investigations, the Department of Justice, and the state Medicaid Fraud Control Units. We also held meetings with four groups of industry stakeholders—Pharmaceutical Research and Manufacturers of America (PhRMA) and pharmaceutical manufacturer representatives; health plan and health plan association representatives; representatives of pharmacy benefit managers (PBMs) and representatives of the American Medical Association (AMA) and its member organizations.

A. Benefits of a Compliance Program

The OIG believes a comprehensive compliance program provides a mechanism that addresses the public and private sectors' mutual goals of reducing fraud and abuse; enhancing health care provider operational functions; improving the quality of health care services; and reducing the cost of health care. Attaining these goals provides positive results to the pharmaceutical manufacturer, the government, and individual citizens alike. In addition to fulfilling its legal duty to avoid submitting false or inaccurate pricing or rebate information to any federal health care program or engaging in illegal marketing activities, a pharmaceutical manufacturer may gain important additional benefits by voluntarily implementing a compliance program. The benefits may include:

- A concrete demonstration to employees and the community at large of the company's commitment to honest and responsible corporate conduct;

- An increased likelihood of preventing, or at least identifying, and correcting unlawful and unethical behavior at an early stage;
- A mechanism to encourage employees to report potential problems and allow for appropriate internal inquiry and corrective action; and
- Through early detection and reporting, minimizing any financial loss to the government and any corresponding financial loss to the company.

The OIG recognizes that the implementation of a compliance program may not entirely eliminate improper conduct from the operations of a pharmaceutical manufacturer. However, a good faith effort by the company to comply with applicable statutes and regulations as well as federal health care program requirements, demonstrated by an effective compliance program, significantly reduces the risk of unlawful conduct and any penalties that result from such behavior.

B. Application of Compliance Program Guidance

Given the wide diversity within the pharmaceutical industry, there is no single "best" pharmaceutical manufacturer compliance program. The OIG recognizes the complexities of this industry and the differences among industry members. Some pharmaceutical manufacturers are small and may have limited resources to devote to compliance measures. Conversely, other companies are well-established, large multi-national corporations with a widely dispersed work force. Some companies may have well-developed compliance programs already in place; others only now may be initiating such efforts. The OIG also recognizes that pharmaceutical manufacturers are subject to extensive regulatory requirements in addition to fraud and abuse-related issues and that many pharmaceutical manufacturers have addressed these obligations through compliance programs. Accordingly, the OIG strongly encourages pharmaceutical manufacturers to develop and implement or refine (as necessary) compliance elements that uniquely address the areas of potential problems, common concern, or high risk that apply to their own companies (or, as applicable, to the U.S. operations of their companies).

For example, although they are not exhaustive of all potential risk areas, the OIG has identified three major potential risk areas for pharmaceutical manufacturers: (1) Integrity of data used by state and federal governments to

establish payment; (2) kickbacks and other illegal remuneration; and (3) compliance with laws regulating drug samples. The risk areas are discussed in greater detail in section II.B.2. below. The compliance measures adopted by a pharmaceutical manufacturer should be tailored to fit the unique environment of the company (including its organizational structure, operations and resources, as well as prior enforcement experience). In short, the OIG recommends that each pharmaceutical manufacturer should adapt the objectives and principles underlying the measures outlined in this guidance to its own particular circumstances.⁵

II. Compliance Program Elements

A. The Basic Compliance Elements

The OIG believes that every effective compliance program must begin with a formal commitment by the pharmaceutical manufacturer's board of directors or other governing body. Evidence of that commitment should include the allocation of adequate resources, a timetable for the implementation of the compliance measures, and the identification of an individual to serve as a compliance officer to ensure that each of the recommended and adopted elements is addressed. Once a commitment has been undertaken, a compliance officer should immediately be chosen to oversee the implementation of the compliance program.

The elements listed below provide a comprehensive and firm foundation upon which an effective compliance program may be built. Further, they are likely to foster the development of a corporate culture of compliance. The OIG recognizes that full implementation of all elements may not be immediately feasible for all pharmaceutical manufacturers. However, as a first step, a good faith and meaningful commitment on the part of the company's management will substantially contribute to the program's successful implementation. As the compliance program is implemented, that commitment should filter down through management to every employee and contractor of the pharmaceutical manufacturer, as applicable for the particular individual.

At a minimum, a comprehensive compliance program should include the following elements:

(1) The development and distribution of written standards of conduct, as well as written policies, procedures and protocols that verbalize the company's commitment to compliance (e.g., by including adherence to the compliance