Market Committee at its meeting held on August 13, 2002.[1]

The Federal Open Market Committee seeks monetary and financial conditions that will foster price stability and promote sustainable growth in output. To further its long-run objectives, the Committee in the immediate future seeks conditions in reserve markets consistent with maintaining the federal funds rate at an average of around 1¾ percent.

By order of the Federal Open Market Committee, September 27, 2002.

Vincent R. Reinhart,

Secretary, Federal Open Market Committee.

[FR Doc. 02–25142 Filed 10–02–02; 8:45 am]

BILLING CODE 6210–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

White House Initiative on Asian Americans and Pacific Islanders President's Advisory Commission; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), announcement is made of the following National Advisory body scheduled to conduct a public meeting during the month of October 2002.

Name: President's Advisory Commission on Asian Americans and Pacific Islanders (Commission).

Date and Time: October 11, 2002; 12:30 a.m.–5 p.m. HST.

Location: Hawaii State Capitol, State Capitol Auditorium, 415 S. Beretania Street, Honolulu, HI 96813.

The meeting is open to the public.

The President's Advisory Commission on Asian Americans and Pacific Islanders (AAPIs) will conduct a public meeting on October 11, 2002, from 12:30 p.m. to 5 p.m. HST inclusive.

Agenda items will include, but will not be limited to: testimony from community-based organizations and individuals; testimony from federal, state and local agencies; comments from the public; administrative tasks; deadlines; and upcoming events.

The purpose of the Commission is to advise and make recommendations to the President on ways to increase opportunities for and improve the quality of life of approximately thirteen million AAPIs living in the United States and the U.S.-associated Pacific Island jurisdictions, especially those that are the most underserved.

Requests to address the Commission should be made in writing and should include the name, address, telephone number and business or professional affiliation of the interested party. Individuals or groups addressing similar issues are encouraged to combine comments and make their request to address the Commission through a single representative. The allocation of time for remarks may be adjusted to accommodate the level of expressed interest. Written requests should be faxed to (301) 443–0259.

Anyone who has interest in joining any portion of the meeting or who requires additional information about the Commission should contact: Ms. Betty Lam or Mr. Erik F. Wang, Office of the White House Initiative on AAPIs, Parklawn Building, Room 10–42, 5600 Fishers Lane, Rockville, MD 20857, Telephone (301) 443–2492. Anyone who requires special assistance, such as sign language interpretation or other reasonable accommodations, should contact Mr. Wang no later than October 4, 2002.

Dated: September 27, 2002.

Christopher J. McCabe,

Director, Office of Intergovernmental Affairs.

[FR Doc. 02–25118 Filed 10–2–02; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Meeting of the President's Council on Bioethics

AGENCY: The President's Council on Bioethics, HHS.

ACTION: Notice.

SUMMARY: The President's Council on Bioethics will hold its seventh meeting, at which it will discuss, among other things, technological enhancements of human memory; the use of assisted reproduction and other technologies (including PGD) to choose the sex of children; and a presentation by Ms. Suzi Leather, chair of the Human Fertilisation and Embryology Authority (HFEA) of the United Kingdom on how the UK regulates infertility clinics and embryo research. The Council may also touch on subjects discussed at past meetings, including human cloning, embryonic stem cells, and the patentability of human organisms.

DATES: The meeting will take place Thursday, October 17, 2002, from 9 a.m. to 6 p.m. ET; and Friday, October 18, 2002, from 8:30 a.m. to 12:15 p.m. ET.

ADDRESSES: Hotel Monaco, 700 F Street, NW., Washington, DC 20004.

Public Comments: The meeting agenda will be posted at *http://www.bioethics.gov.* Members of the public may submit written statements for the Council's records. Please submit statements to Ms. Diane Gianelli, Director of Communications (tel. 202/296–4669 or e-mail *info@bioethics.gov*). The public may also express comments during the time set aside for this purpose, beginning at 5:15 p.m. ET, on Thursday, October 17, 2002. Comments will be limited to no more than five minutes per speaker or organization. Please give advance notice of such statements to Ms. Gianelli at the phone number given above, and be sure to include name, affiliation, and a brief description of the topic or nature of the statement.

FOR FURTHER INFORMATION CONTACT: Diane Gianelli, 202/296–4669, or visit *http://www.bioethics.gov.*

Dated: September 26, 2002.

Dean Clancy,

Executive Director, The President's Council on Bioethics.

[FR Doc. 02–25117 Filed 10–2–02; 8:45 am]

BILLING CODE 4150–24–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Draft OIG Compliance Program Guidance for Pharmaceutical Manufacturers

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice and comment period.

SUMMARY: This **Federal Register** notice seeks the comments of interested parties on draft compliance guidance developed by the Office of Inspector General (OIG) for the pharmaceutical industry. Through this notice, the OIG is setting forth its general views on the value and fundamental principles of compliance programs for pharmaceutical manufacturers and the specific elements that pharmaceutical manufacturers should consider when developing and implementing an effective compliance program.

DATES: To assure consideration, comments must be delivered to the address provided below by no later than 5 p.m. on December 2, 2002.

ADDRESSES: Please mail or deliver written comments to the following address: Office of Inspector General, Department of Health and Human Services, Attention: OIG–8–CPG, Room 5246, Cohen Building, 330 Independence Avenue, SW., Washington, DC 20201.

We do not accept comments by facsimile (FAX) transmissions. In commenting, please refer to file code OIGB8–CPG. Comments received timely will be available for public inspection as they are received, generally beginning

[1] Copies of the Minutes of the Federal Open Market Committee meeting on August 13, 2002, which includes the domestic policy directive issued at the meeting, are available upon request to the Board of Governors of the Federal Reserve System, Washington, DC 20551. The minutes are published in the Federal Reserve Bulletin and in the Board's annual report.

approximately 2 weeks after publication of a document, in Room 5541 of the Office of Inspector General at 330 Independence Avenue, SW., Washington, DC 20201 on Monday through Friday of each week from 8 a.m. to 4:30 p.m.

FOR FURTHER INFORMATION CONTACT: Mary E. Riordan or Nicole C. Hall, Office of Counsel to the Inspector General, (202) 619–2078.

SUPPLEMENTARY INFORMATION:

Background

Compliance program guidance is a major initiative of the OIG in its effort to engage the health care community in preventing and reducing fraud and abuse in Federal health care programs. The purpose of the compliance program guidance is to encourage the use of internal controls to efficiently monitor adherence to applicable statutes, regulations and program requirements. In the last several years, the OIG has developed and issued compliance program guidance directed at the following segments of the health care industry: The hospital industry; home health agencies; clinical laboratories; third-party medical billing companies; the durable medical equipment, prosthetics, orthotics and supply industry; Medicare+Choice organizations offering coordinated care plans; hospices; nursing facilities; and individual and small group physician practices. The OIG has also issued draft guidance directed at ambulance suppliers. Copies of these compliance program guidances can be found on the OIG Web site at *http://oig.hhs.gov/fraud/complianceguidance.html.*

Developing Draft Compliance Program Guidance for the Pharmaceutical Industry

On June 11, 2001, the OIG published a solicitation notice seeking information and recommendations for developing compliance program guidance for the pharmaceutical industry (66 FR 31246). In response to that solicitation notice, the OIG received eight comments from various outside sources. In developing this draft guidance for formal public comment, we have considered those comments, as well as previous OIG publications, such as other compliance program guidances and Special Fraud Alerts. In addition, we have taken into account past and ongoing fraud investigations conducted by the OIG's Office of Investigations and the Department of Justice, and have consulted with the Centers for Medicare and Medicaid Services (CMS) (formerly known as the Health Care Financing Administration).

This draft guidance for pharmaceutical manufacturers contains seven elements that have been widely recognized as fundamental to an effective compliance program:

- Implementing written policies and procedures;
- Designating a compliance officer and compliance committee;
- Conducting effective training and education;
- Developing effective lines of communication;
- Conducting internal monitoring and auditing;
- Enforcing standards through well-publicized disciplinary guidelines; and
- Responding promptly to detected problems and undertaking corrective action.

These elements are included in previous guidances issued by the OIG. As with previously-issued guidances, this draft compliance program guidance represents the OIG's suggestions on how pharmaceutical manufacturers can establish internal controls to ensure adherence to applicable rules and program requirements. The contents of this guidance should not be viewed as mandatory or as an exclusive discussion of the advisable elements of a compliance program. The document is intended to present voluntary guidance to the industry and not represent binding standards for pharmaceutical manufacturers.

Although the June 11, 2001, solicitation notice requested information and recommendations for developing a compliance program guidance for the pharmaceutical industry generally, the OIG has since decided to focus this draft compliance program guidance specifically on *pharmaceutical manufacturers* and not to address other segments of the pharmaceutical industry, such as retail pharmacies. This decision was reached, in part, in response to comments from both pharmaceutical manufacturers and retail pharmacy chains, suggesting that the differences between pharmaceutical manufacturers and retail pharmacy chains, both in terms of operational issues and compliance issues, are significant enough to warrant addressing them separately.

Public Input and Comment in Developing Final Guidance

In an effort to ensure that all parties have an opportunity to provide input into the OIG's guidance, we are publishing this guidance in draft form. We welcome any comments from interested parties regarding this document. The OIG will consider all comments that are received within the above-cited time frame, incorporate any specific recommendations as appropriate, and prepare a final version of the guidance thereafter for publication in the **Federal Register**. The final version of the guidance will be available though the OIG Web site at *http://oig.hhs.gov.*

Draft Compliance Program Guidance for Pharmaceutical Manufacturers

I. Introduction

The Office of Inspector General (OIG) of the Department of Health and Human Services is continuing in its efforts to promote voluntary compliance programs for the health care industry. This compliance guidance is intended to assist companies that develop, manufacture, market, and sell pharmaceutical drugs or biological products (pharmaceutical manufacturers) in developing and implementing internal controls and procedures that promote adherence to applicable statutes, regulations, and requirements of the Federal health care programs [1] and in evaluating and, as necessary, refining existing compliance programs.

This guidance provides the OIG s views on the fundamental elements of pharmaceutical manufacturer compliance programs and principles that each pharmaceutical manufacturer should consider when creating and implementing an effective compliance program. This guide is not a compliance program. Rather, it is a set of guidelines that pharmaceutical manufacturers should consider when developing and implementing a compliance program or evaluating an existing one. For those manufacturers with an existing compliance program, this guidance may serve as a benchmark or comparison against which to measure ongoing efforts.

A pharmaceutical manufacturer's implementation of an effective compliance program may require a significant commitment of time and resources by various segments of the organization. In order for a compliance program to be effective, it must have the

[1] The term ''Federal health care programs,'' as defined in 42 U.S.C. 1320.a–7b(f), includes any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States government or any state health plan (*e.g.,* Medicaid or a program receiving funds from block grants for social services or child health services). In this document, the term ''Federal health care program requirements'' refers to the statutes, regulations and other rules governing Medicare, Medicaid, and all other Federal health care programs.

support and commitment of senior management and the company's governing body. In turn, the corporate leadership should strive to foster a culture that promotes the prevention, detection, and resolution of instances of problems. Although an effective compliance program may require a reallocation of existing resources, the long-term benefits of establishing a compliance program significantly outweigh the initial costs.

In a continuing effort to collaborate closely with the pharmaceutical industry, the OIG published a notice in the **Federal Register** soliciting comments and recommendations on what should be included in this compliance program guidance.[2] In addition to considering the comments received in response to that solicitation notice, in drafting this guidance we reviewed previous OIG publications, including OIG advisory opinions, safe harbor regulations (including the preambles) relating to the Federal anti-kickback statute,[3] 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.

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 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.

A. 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 manufactures 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.

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

[2] *See* 66 FR 31246 (June 11, 2001), ''Notice for Solicitation of Information and Recommendations for Developing a Compliance Program Guidance for the Pharmaceutical Industry.''

[3] 42 U.S.C. 1320a–7b(b).

commitment to compliance (*e.g.*, by including adherence to the compliance 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 whistle blowers 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 excluded individuals or entities, 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 non-compliance 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.

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 addresses the following major 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. This section focuses on areas that are currently of most concern to the enforcement community and is not intended to be exhaustive of all potential risk areas for pharmaceutical manufacturers.

a. Integrity of Data Used to Establish Government Reimbursement. Many Federal and state health care programs establish 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 Act,[4] 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, rebates, up-front payments, coupons, goods in kind, free or reduced price services, grants, or other price concessions or similar benefits offered to some or all purchasers. If a discount, price concession, or similar benefit is offered on purchases of multiple products, the discount, price concession, or similar benefit should be fairly apportioned among the products. Underlying assumptions used in connection with reported prices should be reasoned, consistent, and appropriately documented, and pharmaceutical manufacturers should retain all relevant records reflecting reported prices and efforts to comply with Federal health care program requirements.

Given the importance of the Medicaid Rebate Program, as well as other programs that rely on Medicaid Rebate Program benchmarks (such as the 340B

[4] The False Claims Act (31 U.S.C. 3729–33) prohibits knowingly presenting (or causing to be presented) to the Federal government a false or fraudulent claim for payment or approval. Additionally, it prohibits knowingly, making, or using (or causing to be made or used) a false record or statement to get a false or fraudulent claim paid or approved by the Federal government or its agents, like a carrier, other claims processor, or state Medicaid program.

Program [5]), manufacturers should pay particular attention to ensuring that they are calculating Average Manufacturer Price and Best Price accurately and that they are paying appropriate rebate amounts for their drugs.[6]

In sum, pharmaceutical manufacturers are responsible for ensuring the integrity of data they generate that is used for government reimbursement purposes.

b. Kickbacks and Other Illegal Remuneration. Pharmaceutical manufacturers, as well as their employees and agents, should be aware of the Federal anti-kickback statute, and the constraints it places on the marketing and promotion of products reimbursable by the Federal health care programs. The anti-kickback statute is a criminal prohibition against payments (in any form, whether the payments are direct or indirect) made purposefully to induce or reward referrals of Federal health care business. The anti-kickback statute potentially implicates not only the offer or payment of anything of value for patient referrals, but also the offer or payment of anything of value in return for purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or ordering of any item or service reimbursable in whole or part by a Federal health care program. Under certain circumstances, a violation of the anti-kickback statute may give rise to liability under the False Claims Act.

Activities that fit squarely in one of the safe harbors set forth in 42 CFR 1001.952 are deemed immune from sanction under the anti-kickback statute. We recommend that pharmaceutical manufacturers structure their arrangements to fit in a safe harbor whenever possible. Potentially relevant safe harbors include: personal services and management contracts, warranties, discounts, employees, group purchasing organization arrangements, and shared risk arrangements. Even where an arrangement cannot be structured to fit in a safe harbor, the safe harbor regulations (and accompanying **Federal Register** preambles) provide valuable guidance for assessing risk of abuse under the anti-kickback statute. In addition, parties seeking guidance about their particular arrangements may apply for an OIG advisory opinion using the procedures set out at 42 CFR part 1008.

The following discussion addresses key areas of potential risk under the anti-kickback statute arising from pharmaceutical manufacturers relationships with three groups: purchasers; physicians and other health care professionals; and sales agents. This discussion is intended to be illustrative, not exhaustive, of potential risk areas.

(1) *Relationships with Purchasers. (a) Discounts and Other Terms of Sale.* Pharmaceutical manufacturers offer customers a variety of price concessions and similar benefits to induce the purchase of their products. Such inducements potentially implicate the anti-kickback statute if the products are reimbursable to the customers, in whole or in part, directly or indirectly, by any of the Federal health care programs. Moreover, price concessions and similar benefits offered to a wholesaler potentially implicate the statute if the concessions or benefits are offered to induce the wholesaler to purchase the products and to recommend the products to, or arrange for the purchase of the products by, customers that submit claims to the Federal health care programs. Finally, incentive payments to GPOs, PBMs, and other persons or entities in a position to influence the purchase of a manufacturers's products, but that do not themselves purchase the products, also potentially implicate the anti-kickback statute.

Discounts. The anti-kickback statute contains a broad exception for discounts offered to customers that submit claims to the Federal health care programs, if the discounts are properly disclosed and accurately reported. *See* 42 U.S.C. 1320a–7b(b)(3)(A); 42 CFR 1001.952(h). However, to qualify for the exception, the discount must be in the form of *a reduction in the price* of the good or service based on an arms-length transaction. In other words, the exception covers only actual reductions in the product's price. Moreover, the regulations provide that the discount must be given at the time of sale or, in certain cases, set at the time of sale, even if finally determined subsequent to the time of sale (*i.e.*, a rebate). Other kinds of price concessions (including, but not limited to, discounts on other products, other free or reduced price goods or services, ''educational'' or other grants, ''conversion payments,'' signing bonuses, or ''up-front rebates'') do not qualify for the discount exception and should be carefully reviewed.

Manufacturers offering discounts should thoroughly familiarize themselves, and have their sales and marketing personnel familiarize themselves, with the discount safe harbor at 42 CFR 1001.952(h). In particular, manufacturers should pay attention to the safe harbor requirements applicable to ''sellers'' and ''offerors'' of discounts. Under the safe harbor, sellers and offerors have specific obligations that include (i) informing a customer of any discount and of the customer's reporting obligations with respect to that discount and (ii) refraining from any action that would impede a customer's ability to comply with the safe harbor. To fulfill the safe harbor requirements, manufacturers will need to know how their customers submit claims to the Federal health care programs (*e.g.*, whether the customer is a managed care, cost-based, or charge-based biller).

Other terms of sale. Any remuneration provided as part of a sale, other than a price reduction covered by the discount exception, potentially implicates the anti-kickback statute. Non-price terms of sale make it difficult to ensure that the value of the remuneration is appropriately apportioned and accurately reported and that costs are not shifted disproportionately from private payers to the Federal health care programs. Arrangements involving such non-price terms should be evaluated on a case-by-case basis. Arrangements that may increase the risk of overutilization, higher government program costs, inappropriate steering of Federal health care business, or unfair competition are particularly suspect.

Pharmaceutical manufacturers sometimes offer certain services in connection with the sale of their products. Such services include, among other things, product-related billing assistance programs, reimbursement consultation, or other types of programs. Any time a pharmaceutical manufacturer provides free or below market rate goods or services to a purchaser (or other potential referral source, such as a physician who might prescribe a manufacturer s product or a PBM that might put it on a formulary), it should examine whether it is providing a valuable tangible benefit to the recipient with the intent to induce or reward referrals. For example, a manufacturer should examine whether the services are made available to all customers or only to a select group (*e.g.*, high volume prescribers). If the purchaser or referral source is in a position to make or influence referrals, and if the goods or services provided by the manufacturer eliminate an expense that the purchaser or referral source

[5] The 340 B program, contained as part of the Public Health Services Act and codified at 42 U.S.C. 256b, is administered by the Health Resources and Services Administration (HRSA).

[6] 42 U.S.C. 1396r–8. Average Manufacturer Price are defined in the statute at 42 U.S.C. 1396r–8(k)(1) and 1396r–8(c)(1), respectively. CMS has provided further guidance on these terms in the National Drug Rebate Agreement and in Medicaid Program Releases available through its Web site at *http:www.hcfa.gov/medicaid/drugs/drug.mpg.htm.*

would have otherwise incurred, the arrangement is likely to be problematic from a kickback perspective. Similarly, if a manufacturer provides a service having no independent value (such as limited reimbursement support services in connection with its own products) in tandem with another service or program that confers a benefit on a referring provider (such as one that eliminates normal financial risks), the arrangement could raise kickback concerns. For example, the anti-kickback statute would be implicated if a manufacturer were to couple a reimbursement support service with (i) a requirement that a purchaser pay for ordered products only if the purchaser is paid or (ii) a guarantee of a minimum ''spread'' between the purchase price and third party reimbursement levels.

(b) *Average Wholesale Price*. The ''spread'' is the difference between the amount a customer pays for a product and the amount the customer receives upon resale of the product to the patient or other payer. In many situations under the Federal programs, pharmaceutical manufacturers control not only the amount at which they sell a product to their customers, but also the amount those customers who purchase the product for their own accounts and thereafter bill the Federal health care programs will be reimbursed. A subset of the manufacturer's customers, including certain medical specialists, PBMs, HMOs, and institutional providers, are also in a position to influence substantially a physician's or other health care professional's selection of the product. To the extent that a manufacturer controls the ''spread,'' it controls its customer's profit.

Average Wholesale Price (AWP) is the benchmark often used to set reimbursement for prescription drugs under the Medicare Part B program. For covered drugs and biologicals, Medicare Part B generally reimburses at ''95 percent of average wholesale price.'' 42 U.S.C. 1395u(o). Similarly many state Medicaid programs and other payers base reimbursement for drugs and biologicals on AWP. Generally, AWP is reported directly by pharmaceutical manufacturers.

A pharmaceutical manufacturer's purposeful manipulation of the AWP to increase its customers profits by increasing the amount the Federal health care programs reimburse its customers implicates the anti-kickback statute. Unlike *bona fide* discounts, which transfer remuneration from a seller to a buyer, manipulation of the AWP transfers remuneration to a seller's immediate customer from a subsequent purchaser (the Federal or state government). Under the anti-kickback statute, offering remuneration to a purchaser or referral source is improper if one purpose is to induce the purchase or referral of program business.

In the light of this risk, the OIG recommends that manufacturers review their AWP reporting practices and methodology to confirm that marketing considerations do not influence the process. Furthermore, manufacturers should review their marketing practices. Manipulation of the AWP to induce customers to purchase a product, coupled with active marketing of the spread is evidence of the unlawful intent necessary to trigger the anti-kickback statute. Active marketing of the spread includes, for example, sales representatives promoting the spread as a reason to purchase the product or guaranteeing a certain profit or spread in exchange for the purchase of a product.

(2) *Relationships with Physicians and Other Health Care Professionals*. Pharmaceutical manufacturers and their agents may have a variety of remunerative relationships with physicians and other health care professionals who order or prescribe their products. As these relationships may implicate the anti-kickback statute, they should be examined carefully. Relationships with particular parties should be evaluated individually and in the aggregate. The following discussion highlights some of the most significant areas of potential risk.

''Switching'' arrangements. As noted in the 1994 Special Fraud Alert (59 FR 65372; December 19, 1994), product conversion arrangements (also known as ''switching'' arrangements) are suspect under the anti-kickback statute. Switching arrangements involve pharmaceutical manufacturers offering pharmacies, PBMs, physicians or other prescribers cash payments or other benefits each time a patient's prescription is changed to the manufacturer's product from a competing product. This activity implicates the statute, and, while such programs may be permissible in certain managed care arrangements, manufacturers should review any marketing practices utilizing ''switching'' payments in connection with products reimbursable by Federal health care programs very carefully. In addition, arrangements that have the effect of rewarding switching indirectly should also be carefully reviewed. Such arrangements include payments by pharmaceutical manufacturers to pharmacies, PBMs, or others for contacting patients or their physicians to encourage them change a prescription from another product to the company's product, and discounts or rebates based on movement of market share.

Consulting and advisory payments. Pharmaceutical manufacturers frequently engage physicians and other health care professionals to act as ''consultants,'' ''advisors,'' or ''researchers'' in connection with various types of marketing and research activities. For instance, pharmaceutical manufacturers may engage physicians to perform research, data collection, and consulting services, to serve on advisory boards, to participate in focus groups, or to speak at meetings. While there may be legitimate purposes to these arrangements, they pose a substantial risk of fraud and abuse; without appropriate safeguards, they can result in payments for referrals.

Pharmaceutical manufacturers should ensure that they (and their sales agents) compensate health care professionals only for providing actual, reasonable, and necessary services and that the arrangements are not merely token arrangements created to disguise otherwise improper payments. Moreover, payments should be fair market value for the services rendered, and manufacturers should take steps to ensure appropriate documentation of the fair market value determination, as well as the performance of the services. Whenever possible, the OIG recommends that consulting and advisory arrangements be structured to fit in the personal services safe harbor (42 CFR 1001.952(d)).

Other remuneration. Pharmaceutical companies and their employees and agents engage in a number of other arrangements that offer benefits, directly or indirectly, to physicians or others in a position to make or influence referrals. These arrangements potentially implicate the anti-kickback statute. They include:

- Entertainment, recreation, travel, meals, or other benefits in association with information or marketing presentations;
- Sponsorship or other financing related to third-party educational conferences and meetings attended or taught by physicians or others in a position to generate or influence referrals;
- Scholarships and educational funds;
- Grants for research and education; and
- Gifts, gratuities, and other business courtesies.

These practices raise a particular risk where they involve parties in a position to prescribe or order the manufacturer's

products or to influence such prescriptions or orders. These parties include physicians and other health care professionals, as well as PBMs, GPOs, hospital systems, and the like.

With respect to these practices, a good starting point for compliance purposes is the ''PhRMA Code on Interactions with Healthcare Professionals'' (the ''PhRMA Code''), a voluntary code promulgated by the Executive Committee of the Pharmaceutical Research and Manufacturers of America (PhRMA), that became effective July 1, 2002. It is available through PhRMA's Web site at *http://www.phrma.org*. The PhRMA Code provides useful guidance for evaluating relationships with physicians and other health care professionals. The OIG recommends that pharmaceutical manufacturers at a minimum comply with the standards set by the PhRMA Code. Arrangements that fail to meet the minimum standards set out in the PhRMA Code are likely to receive increased scrutiny from government authorities.

While the PhRMA Code provides important and practicable benchmarks for manufacturers and government when evaluating practices involving gifts, gratuities, and other benefits, it must be understood that compliance with the relevant sections of the PhRMA Code will not necessarily protect a manufacturer from prosecution or liability for illegal conduct. Thus, all arrangements should be reviewed with the following issues, among others, in mind:

- Is the gift or other benefit made to a person in a position to generate or influence business for the paying party?
- Does the gift or other benefit take into account, directly or indirectly, the volume or value of business generated (*e.g.*, is the payment or gift only given to persons who have prescribed or agree to prescribe the product)?
- Is the gift or benefit more than nominal in value and/or does it exceed the fair market value of any legitimate service rendered to payer?
- Is the gift or benefit unrelated to any services at all other than the referral of Federal health care business?

(3) *Relationships with Sales Agents.* Sales agents, whether employees or independent contractors, are in the business of recommending or arranging for the purchase of the items or services they offer for sale on behalf of the pharmaceutical manufacturer they represent. Accordingly, any compensation arrangement between a pharmaceutical manufacturer and a sales agent for the purpose of selling health care items or services that are directly or indirectly reimbursable by a Federal health care program potentially implicates the anti-kickback statute, irrespective of the methodology used to compensate the agent. In addition, sales agents may engage in improper marketing and promotional activities that may give rise to manufacturer liability. Of particular concern are situations in which a sales agent's express or implied duties include offering or paying remuneration (in any form) to purchasers or prescribers of the pharmaceutical manufacturer's products or in which a sales agent's compensation methodology creates an undue incentive to engage in aggressive marketing or promotional practices.

As an initial matter, the safe harbors for personal services arrangements and employment, 42 CFR 1001.952(d) and (i), are available to protect many compensation arrangements with sales agents. While compliance with safe harbors is voluntary and failure to comply does not necessarily mean that an arrangement violates the anti-kickback statute, the OIG strongly recommends that manufacturers structure their relationships with their sales force to fit in a safe harbor whenever possible. Compensation arrangements with sales personnel that do not fit in a safe harbor should be reviewed carefully.

It is in a pharmaceutical manufacturer's best interests to: (i) Develop a regular and comprehensive training program for its sales force, including refresher and updated training on a regular basis, either in person or through newsletters, memoranda, or the like; (ii) institute and implement corrective action and disciplinary policies applicable to sales agents who engage in improper marketing; (iii) avail itself of the advisory opinion process if it has questions about particular practices used by its sales force; and (iv) establish an effective system for tracking, compiling, and reviewing information about sales force activities.

c. *Drug Samples.* The provision of drug samples is a widespread industry practice that can benefit patients, but can also be an area of potential risk to a pharmaceutical manufacturer. The Prescription Drug Marketing Act of 1987 (PDMA) governs the distribution of drug samples and forbids their sale. 21 U.S.C. 353(c)(1). A drug sample is defined to be a unit of the drug ''that is not intended to be sold * * * and is intended to promote the sale of the drug''. 21 U.S.C. 353(c)(1). Failure to comply with the requirements of PDMA can result in PDMA sanctions. In some circumstances, if the samples have monetary value to the recipient (*e.g.*, a physician) and are used to treat Federal health care program beneficiaries, the provision of samples may also trigger potential False Claims Acts or kickback liability.

Pharmaceutical manufacturers should closely follow the PDMA requirements (including all documentation requirements). In addition, manufacturers can minimize their risk of liability by (i) training their sales force to inform sample recipients in a meaningful manner that samples may not be sold or billed; (ii) clearly and conspicuously labeling individual samples as units that may not be sold; and (iii) including on packaging and any documentation related to the samples (such as shipping notices or invoices) a clear and conspicuous notice that the samples are subject to PDMA and may not be sold. Recent government enforcement activity has focused on instances in which drug samples were provided to physicians who, in turn, sold them to the patient or billed them to the Federal health care programs on behalf of the patient.

C. Designation of a Compliance Officer and a Compliance Committee

1. Compliance Officer

Every pharmaceutical manufacturer should designate a compliance officer to serve as the focal point for compliance activities. This responsibility may be the individual's sole duty or added to other management responsibilities, depending upon the size and resources of the company and the complexity of the task. If the individual has additional management responsibilities, the pharmaceutical manufacturer should ensure that the individual is able to dedicate adequate and substantive time and attention to the compliance functions. Similarly, if the compliance officer delegates some of the compliance duties, he or she should, nonetheless, remain sufficiently involved to fulfill the compliance oversight function.

Designating a compliance officer with the appropriate authority is critical to the success of the program, necessitating the appointment of a high-level official with direct access to the company's president or CEO, board of directors, all other senior management, and legal counsel. The compliance officer should have sufficient funding, resources, and staff to perform his or her responsibilities fully. The compliance officer should be able to effectuate change within the organization as necessary or appropriate and to exercise independent judgment. Optimal placement of the compliance officer within the organization will vary

according to the particular situation of a manufacturer.[7]

Coordination and communication with other appropriate individuals or business units are the key functions of the compliance officer with regard to planning, implementing or enhancing, and monitoring the compliance program. The compliance officer's primary responsibilities should include:

- Overseeing and monitoring implementation of the compliance program; [8]
- Reporting on a regular basis to the company's board of directors, CEO or president, and compliance committee (if applicable) on compliance matters and assisting these individuals or groups to establish methods to reduce the company's vulnerability to fraud and abuse;
- Periodically revising the compliance program, as appropriate, to respond to changes in the company's needs and applicable Federal health care program requirements, identified weakness in the compliance program, or identified systemic patterns of non-compliance;
- Developing, coordinating, and participating in a multifaceted educational and training program that focuses on the elements of the compliance program, and seeking to ensure that all affected employees and management understand and comply with pertinent Federal and state standards;
- Ensuring that independent contractors and agents, particularly those agents and contractors who are involved in sales and marketing activities, are aware of the requirements of the company's compliance program with respect to sales and marketing activities, among other things;
- Coordinating personnel issues with the company's Human Resources/ Personnel office (or its equivalent) to ensure that the List of Excluded Individuals/Entities [9] 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 non-compliance 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 non-compliance);
- 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.[10]

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.[11] 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.

[7] The OIG believes it is generally not advisable for the compliance function to be subordinate to the pharmaceutical manufacturer's general counsel, or comptroller or similar financial officer. Separation of the compliance function helps to ensure independent and objective legal reviews and financial analysis of the company's compliance efforts and activities. By separating the compliance function from the key management positions of general counsel or chief financial officer (where the size and structure of the pharmaceutical manufacturer make this a feasible option), a system of checks and balances is established to more effectively achieve the goals of the compliance program.

[8] For companies with pharmaceutical manufacturers multiple divisions or regional offices, the OIG encourages coordination with each company location through the use of a compliance officer located in corporate headquarters who is able to communicate with parallel compliance liaisons in each division or regional office, as appropriate.

[9] As part of its commitment to compliance, a pharmaceutical manufacturer should carefully consider whether to hire or do business with individuals or entities that have been sanctioned by the OIG. The List of Excluded Individuals and Entities can be checked electronically and is accessible through the OIG's Web site at: *http://oig.hhs.gov.*

[10] There are many approaches the compliance officer may enlist to maintain the vitality of the compliance program. Periodic on-site visits of regional operations, bulletins with compliance updates and reminders, distribution of audiotapes, videotapes, CD–ROMs, or computer notifications about different risk areas, lectures at management and employee meetings, and circulation of recent articles or publications discussing fraud and abuse are some examples of approaches the compliance officer may employ.

[11] The compliance committee benefits from having the perspectives of individuals with varying responsibilities and areas of knowledge in the organization, such as operations, finance, audit, human resources, legal, and sales and marketing, as well as employees and managers of key operating units. The compliance officer should be an integral member of the committee. All committee members should have the requisite seniority and comprehensive experience within their respective departments to recommend and implement any necessary changes to policies and procedures.

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 the 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. 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.

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.[12]

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 sale 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

[12] In some cases, employees sue their employers under the False Claims Act's *qui tam* provisions after a failure or apparent failure by the company to take action when the employee brought a questionable, fraudulent, or abusive situation to the attention of senior corporate officials. Whistleblowers must be protected against retaliation, a concept embodied in the provisions of the False Claims Act. *See* 31 U.S.C. 3730(h).

information (*e.g.*, by publishing the hotline number or e-mail address on wallet cards) or conspicuously posting the information in common work areas.[13] 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 may 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: (1) The pharmaceutical manufacturer has policies covering the identified risk areas; (2) whether the policies were implemented and communicated; and (3) whether the 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 conduct or policies and procedures. A pharmaceutical manufacturer should consistently undertake appropriate disciplinary action across the company in order for the disciplinary policy to have the required deterrent effect. Intentional and material noncompliance should subject transgressors to significant sanctions. Such sanctions could range from oral warnings to suspension, termination or other sanctions, as appropriate. Disciplinary action also may be appropriate where a responsible employee's failure to detect a violation is attributable to his or her negligence or reckless conduct. Each situation must be considered on a case-by-case basis, taking into account all relevant factors, to determine the appropriate response.

H. Responding to Detected Problems and Developing Corrective Action Initiatives

Violation of a pharmaceutical manufacturer's compliance program, failure to comply with applicable Federal or state law, and other types of misconduct threaten the company's status as a reliable, honest, and trustworthy participant in the health care industry. Detected but uncorrected misconduct can endanger the reputation and legal status of the company. Consequently, upon receipt of reasonable indications of suspected noncompliance, it is important that the compliance officer or other management officials immediately investigate the allegations to determine whether a material violation of applicable law or the requirements of the compliance program has occurred and, if so, take decisive steps to correct the problem.[14] The exact nature and level of thoroughness of the investigation will vary according to the circumstances, but the review should be detailed enough to identify the root cause of the problem. As appropriate, the investigation may include a corrective action plan, a report and repayment to the government, and/or a referral to criminal and/or civil law enforcement authorities.

Reporting

Where the compliance officer, compliance committee, or a member of senior management discovers credible evidence of misconduct from any source and, after a reasonable inquiry, believes that the misconduct may violate criminal, civil, or administrative law, the company should promptly report the existence of misconduct to the appropriate Federal and state authorities[15] within a reasonable period, but not more than 60 days,[16] after determining that there is credible evidence of a violation.[17] Prompt

[13] Pharmaceutical manufacturers should also post in a prominent area the HHS–OIG Hotline telephone number, 1–800–447–8477 (1–800–HHS–TIPS).

[14] Instances of noncompliance must be determined on a case-by-case basis. The existence or amount of a *monetary* loss to a Federal health care program is not solely determinative of whether the conduct should be investigated and reported to governmental authorities. In fact, there may be instances where there is no readily identifiable monetary loss, but corrective actions are still necessary to protect the integrity of the health care program.

[15] Appropriate Federal and state authorities include the OIG, the Criminal and Civil Divisions of the Department of Justice, the U.S. Attorney in relevant districts, the Food and Drug Administration, the Federal Trade Commission, the Drug Enforcement Administration and the Federal Bureau of Investigation, and the other investigative arms for the agencies administering the affected Federal or state health care programs, such as the state Medicaid Fraud Control Unit, the Defense Criminal Investigative Service, the Department of Veterans Affairs, HRSA, and the Office of Personnel Management (which administers the Federal Employee Health Benefits Program).

[16] In contrast, to qualify for the ''not less than double damages'' provision of the False Claims Act, the provider must provide the report to the government within 30 days after the date when the provider first obtained the information. 31 U.S.C. 3729(a).

[17] Some violations may be so serious that they warrant immediate notification to governmental authorities prior to, or simultaneous with, commencing an internal investigation. By way of example, the OIG believes a provider should report misconduct that: (1) Is a clear violation of administrative, civil, or criminal laws; (2) has a significant adverse effect on the quality of care provided to Federal health care program beneficiaries; or (3) indicates evidence of a systemic

voluntary reporting will demonstrate the pharmaceutical manufacturer's good faith and willingness to work with governmental authorities to correct and remedy the problem. In addition, reporting such conduct will be considered a mitigating factor by the OIG in determining administrative sanctions (*e.g.*, penalties, assessments, and exclusion), if the reporting company becomes the subject of an OIG investigation.[18]

When reporting to the government, a pharmaceutical manufacturer should provide all information relevant to the alleged violation of applicable Federal or state law(s) and the potential financial or other impact of the alleged violation. The compliance officer, under advice of counsel and with guidance from the governmental authorities, could be requested to continue to investigate the reported violation. Once the investigation is completed, and especially if the investigation ultimately reveals that criminal, civil or administrative violations have occurred, the compliance officer should notify the appropriate governmental authority of the outcome of the investigation, including a description of the impact of the alleged violation on the operation of the applicable Federal health care programs or their beneficiaries.

III. Conclusion

In today's environment of increased scrutiny of corporate conduct and increasingly large expenditures for prescription drugs, it is imperative for pharmaceutical manufacturers to establish and maintain effective compliance programs. These programs should foster a culture of compliance that begins at the executive level and permeates throughout the organization. This compliance guidance is designed to provide assistance to all pharmaceutical manufacturers as they either implement compliance programs or re-assess existing programs. The essential elements outlined in this compliance guidance can be adapted to the unique environment of each manufacturer. It is the hope and expectation of the OIG that the resulting compliance programs will benefit not only Federal health care programs and their beneficiaries, but also pharmaceutical manufacturers themselves.

Dated: September 26, 2002.

Janet Rehnquist,

Inspector General.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Data Collection; Comment Request; California Health Interview Survey (CHIS) Cancer Control Module (CCM)

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the National Institutes of Health (NIH), National Cancer Institute (NCI) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection

Title: California Health Interview Survey (CHIS) Cancer Control Module (CCM). *Type of Information Collection Request:* New. *Need and Use of Information Collection:* NCI sponsored a Cancer Control Modules to the National Health Interview Survey (NHIS) and to the California Health Interview Survey (CHIS) administered in 2000. While the NHIS data have proven extremely useful in monitoring risk factors and screening related to cancer control, the national sample does not provide adequate numbers of racial-ethnic minorities to analyze particular domains within them, such as age by gender and income or education. The CHIS telephone survey, administered for the first time in 2000–2001, is designed to provide population-based, standardized health-related data for California counties. Initiated by the California Department of Health Services (CDHS) Center for Health Statistics, the Public Health Institute (PHI), and the UCLA Center for Health Policy Research (UCLA), the survey is largely funded by California sources. The 2000 CHIS CCM is similar in content to the 2000 NHIS CCM, and met its target of one sample adult in 55,000 households. California, the most populous state in the nation, is also the most racially and ethnically diverse. Specific populations of interest include Black or African American, Hispanic or Latino, Asian, Native Hawaiian or Other Pacific Islander, and American Indian or Alaska Native. The CHIS data was released in July 2002. NCI is using the CHIS and NHIS data from 2000/2001 to better estimate health-related behaviors and cancer risk factors for smaller racial/ethnic minority populations. Preliminary analyses suggest that the CHIS will provide improved estimates for cancer risk factors and screening among racial/ethnic minority populations. NCI will sponsor questions on cancer screening in the 2003 NHIS and to provide better estimates for smaller racial-ethnic minority populations, anticipates also sponsoring cancer-screening questions on the 2003 CHIS. NCI will also take advantage of the Housing and Environment Module to be included in the 2003 CHIS to ask respondents questions about environmental tobacco smoke and physical activity. *Frequency of response:* One-time. *Affected public:* Individuals. *Types of Respondents:* U.S. adults.

The annual reporting burden is as follows:

TABLE A.12–1.—ANNUALIZED BURDEN ESTIMATES FOR CHIS DATA COLLECTION

Data collection	Estimated number of respondents	Frequency of response	Average time per response	Annual hour burden
Adult Core	55,000	1	.42	23,100
CCM	55,000	1	.08	4,400
Totals	55,000	.....	.....	27,500

failure to comply with applicable laws or an existing corporate integrity agreement, regardless of the financial impact on Federal health care programs.

[18] The OIG has published criteria setting forth those factors that the OIG takes into consideration in determining whether it is appropriate to exclude an individual or entity from program participation pursuant to 42 U.S.C. 1320a–7(b)(7) for violations of various fraud and abuse laws. *See* 62 FR 67392 (December 24, 1997).