

**THE OIG'S DRAFT COMPLIANCE GUIDANCE FOR PHARMACEUTICAL
MANUFACTURERS:
*One More Compliance 'Script' for the Health Care Industry***

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The United States Department of Health and Human Services (“HHS”) Inspector General Janet Rehnquist announced the issuance of the much anticipated “Draft OIG Compliance Program Guidance for Pharmaceutical Manufacturers” (“Draft Guidance”) on October 1, 2002 at the Health Care Compliance Association and American Health Lawyers Association Fraud & Compliance Forum. The Draft Guidance, published in the Federal Register on Thursday, October 3, 2002, is available on the Internet at: <http://oig.hhs.gov/fraud/docs/complianceguidance/draftcpgppharm09272002.pdf>. Comments to the Draft Guidance were due to the OIG by December 2, 2002. We expect that the Draft Guidance will be published in final form in the Federal Register no earlier than the Spring of 2003.

Through this Draft Guidance, the Office of the Inspector General (“OIG”) of HHS sets forth its general views on the “value and fundamental principles of compliance programs” for pharmaceutical manufacturers. The Draft Guidance also describes some of the specific elements that pharmaceutical manufacturers should consider when developing and implementing an effective compliance program.

This Draft Guidance follows a June 11, 2001 Federal Register preliminary announcement (“Notice”) issued by HHS OIG seeking input, comments and suggestions from interested parties on the development of a model compliance program guidance for the pharmaceutical industry, broadly defined at that time to include all of those entities involved in the “manufacturing, marketing or providing of goods or services to Medicare, Medicaid and other Federal health care program beneficiaries”.² Significantly, the Draft Guidance specifically narrows the initial scope of this OIG initiative by limiting its direct focus to pharmaceutical *manufacturers*, defined as “companies that develop, manufacture, market, and sell pharmaceutical drugs or biological products.” The OIG explained that its decision not to include directly other sectors of the

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² Although the direct focus appears to be manufacturers of drugs and biologics, many aspects of this Draft Guidance would apply to medical device manufacturers.

pharmaceutical industry in the Draft Guidance was, in part, a response to comments submitted in connection with the Notice that discussed the significant operational differences and compliance distinctions between pharmaceutical manufacturers and retail pharmacies. It is likely that the OIG will develop additional compliance guidance(s) targeted to other segments of the pharmaceutical industry in the future such as for retail pharmacies.³

What is an OIG Compliance?

By way of background, HHS OIG has elected to issue voluntary compliance program guidances in order to encourage particular segments of the health care industry to develop effective internal controls that detect, prevent and reduce the potential for fraud and abuse by promoting adherence to applicable laws relevant to the Federal health care programs including Medicare, Medicaid, Department of Defense and CHAMPUS. The OIG accomplishes this goal by issuing *non-binding* direction to the targeted industry as to the processes the organization could adopt to encourage legal compliance and by identifying the “hot button” risk areas that the OIG believes to be ripe for misconduct. As you will see below, although risk areas are identified, these OIG guidances do not address the specifics as to how companies should act to avoid or at least minimize their liability exposure in these identified risk areas.

The OIG guidances are not intended to serve as compliance programs. Rather, these OIG issuances to provide predominately procedural and structural guidance to an industry for designing an effective compliance program. In that regard, the Draft Guidance relies upon the elements set forth in the Federal Sentencing Guidelines for corporations as well as relevant industry investigations and civil settlements.

The voluntary initiative by OIG to issue these compliance guidances stands in contrast to the statutory authority that the OIG has been afforded under the Health Insurance Portability and Accountability Act of 1996¹ to issue educational materials in the form of Safe Harbors, Advisory Opinions, and Special Fraud Alerts. Although the OIG has no specific statutory authority to issue industry compliance guidance, since 1997, the OIG has issued nine final guidances for various areas of the health care industry. Existing OIG guidances are directed to clinical laboratories, hospitals, home health agencies, nursing facilities, durable medical equipment suppliers, third party medical billing companies; hospices, Medicare+Choice organizations offering coordinated care plans and individual and small group physician practices.⁴

Additionally, these OIG compliance guidances should be distinguished from the Food and Drug Administration (FDA) guidance documents. The FDA has statutory authority to issue guidance documents and, in fact, is required to develop, issue and use guidance documents to comply with the Food and Drug Administration Modernization Act of 1997.² In 1997, the FDA

³ Those future guidances are also likely to affect pharmaceutical manufacturers and should be reviewed at this time.

⁴ The OIG guidance for ambulances remains in draft.

even amended its administrative regulations to codify its policies and procedures and specifically address its use of guidance documents.³

What Are the Processes Identified in the Draft Guidance?

Although there was initial speculation that the Draft Guidance would differ materially from the previous OIG compliance guidances because of the differences between a pharmaceutical manufacturer that does not submit claims directly to a federal health care program when compared to an entity, such as a hospital or physician, that directly submits claims to the federal health care programs, the Draft Guidance is not materially different from past OIG Guidances. Rather, the Draft Guidance reiterates the seven basic elements of an effective corporate compliance program derived from the Federal Sentencing Guidelines similar to the OIG compliance guidances for other industries. These seven elements are as follows:

- ***Put it in Writing:*** The OIG recommends that a pharmaceutical manufacturer develop written policies and procedures that address important risk areas and govern the manufacturer's conduct. In this Section of the Draft Guidance, the OIG identifies the "hot-button" risk issues for the industry that are discussed below. By identifying specific risk areas, the OIG is announcing to the public its interpretation of the current state of the law. This does not mean that such an interpretation may not evolve further over time. Also, the OIG does not present all the legal nuances for a pharmaceutical firm to consider in an attempt to avoid or minimize liability exposure in these specific risk areas.

In addition, other risk areas may exist that are not identified specifically in the Draft Guidance that a manufacturer should consider. The Sources for identifying other risk areas include OIG work plans, descriptions of covered conduct in recent settlements, trends in current enforcement activities based upon public information and special fraud alerts.

Moreover, the OIG also recommends that a manufacturer draft and adopt a code of conduct that enumerates the manufacturer's standards for ethical business practice in a manner that may be comprehended by all levels of employees in an organization.

- ***Put Someone in Charge:*** The OIG recommends that an organization designate a compliance officer and establish other appropriate compliance bodies, such as committees and task forces on special topics. This is to ensure that a senior level individual within the corporation oversees all components of the compliance program. The OIG recognizes that the placement of this individual within an organization will vary depending on the particular situation of the entity. However, in selecting this individual, the OIG expresses its concern that a system of "checks and balances" be maintained and that this individual be independent from and in a position to be objective during any legal review or audit. In that regard, the OIG states that it is "not advisable for the compliance function to be subordinate to...the general counsel, or controller or similar financial

officer.” Further, the OIG wants to ensure that the organization devotes sufficient funding and resources in order for the compliance officer (and program) to be effective.

- ***Train Employees:*** The OIG recommends that a manufacturer train and periodically retrain officers, directors, employees, contractors, and agents. General training should address the manufacturer’s compliance program, written standards, and applicable Federal health care program requirements. Additionally, targeted training to certain personnel should include the anti-kickback statute, and calculating and reporting pricing information. The Draft Guidance suggests that participation in such training should be a condition of continued employment, and adherence to the training requirements should be factored in to disciplinary actions and performance reviews. Moreover, training activities need to be documented and archived.
- ***Give Employees a Voice.*** The Draft Guidance aims to ensure that employees may ask questions and report problems. The OIG recommends that confidentiality and non-retaliation policies be developed to assist in this process. In addition to establishing open lines of communication between the compliance officer and employees generally, manufacturers should use specific lines of communication such as hotlines, suggestion boxes, and newsletters to facilitate open communications. Access to the established lines of communication should be readily available to all employees and contractors.
- ***Punish Wrongdoers.*** The OIG recommends that manufacturers have clear and specific disciplinary policies, and consistently undertake appropriate disciplinary action under them, subjecting violators to sanctions. The OIG states that each situation should be considered on a “case-by-case basis, taking into account all relevant factors, to determine the appropriate response.”
- ***Self-Evaluate.*** The OIG recommends that manufacturers utilize internal or external evaluators with relevant experience should perform compliance reviews regularly. Particular attention should be paid to the specific risk areas identified below, as well as to “divisions or departments with substantive involvement with or impact of Federal health care programs (such as the government contracts and sales and marketing divisions).” Such reviews should evaluate whether appropriate policies exist, whether such policies were implemented and communicated, and whether the policies were followed. Audits may be prospective or retrospective.
- ***Find It and Fix It:*** The OIG recommends that a manufacturer develop procedures to respond to detected offenses, initiate prompt corrective action and take action to prevent it from happening again. Such procedures should include a process for disclosures to the appropriate government agency, if warranted. The OIG cautions manufacturers that disclosures may even be appropriate in circumstances where there is no loss to a federal health care program, yet corrective action is taken.

What Are the “Hot Button” Risk Areas to “Put In Writing” and to “Train” about?

The Draft Guidance identifies three major potential risk areas specific for pharmaceutical manufacturers that should be addressed in the manufacturers policies and procedures: (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 OIG’s discussion of these risk areas provides insight into its current interpretation of the law as well as active investigations. The OIG’s insights in this section are relevant and significant not only for pharmaceutical manufacturers, themselves, but also to the customers of the manufacturers, such as payers and providers.

The OIG’s discussion of these risk areas in the Draft Guidance identifies the issue and sets forth the OIG’s position on the issue but does not does elaborate on what would be “appropriate”⁵ under the circumstances. That is one of the greatest challenges in the Draft Guidance. Some of these risk areas are addressed below.

- ***Integrity of Data Used by State and Federal Governments to Establish Payment***

The Guidance directs manufacturers’ attention to potential liability in connection with information “directly or indirectly” supplied by manufacturers to Federal or state programs. Specifically, the OIG states that manufacturers may be at risk under the federal False Claims Act, the federal anti-kickback statute, and various civil monetary penalty laws for such direct or indirect price reporting. Yet, in August 2002 Special Advisory Bulletin, the OIG stated its position that “drug manufacturers” were not generally subject to the federal health care program civil monetary penalty provisions, “unless the drug manufacturers also own or operate, directly or indirectly, pharmacies, pharmacy benefits management companies, or other entities that file claims for payment under the Medicare or Medicaid programs.”

The OIG directs manufacturers to ensure that “where appropriate,” reported prices account for “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”. This list is notably broader than the Medicaid Best Price law which requires manufacturers to include “cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates” in price reporting. 42 U.S.C. § 1396r-8(c). Accounting for all “grants” in price reporting may represent a dramatic change for some manufacturers.

Additionally, the Draft Guidance sets forth the OIG’s expectation that manufacturers be accountable for “price and sales data directly or indirectly furnished by pharmaceutical manufacturers”, and that if a discount, price concession, or similar benefit is offered on purchases of multiple products, it should be fairly apportioned among the products, and that

⁵ Significantly, the term “appropriate” appears thirty-nine times in the Federal Register publication. However, what would be “appropriate” under the particular circumstances is not discussed.

manufacturers should use reasoned, consistent, and appropriately documented assumptions in connection with reported prices. This may assume a transfer of data that does not occur currently.

Further, under the Draft Guidance, the OIG states that manufacturers should ensure that reported Average Manufacturer Price and Best Price calculations used in the Medicaid Drug Rebate Program are accurate. Additionally, the Guidance leaves open the possibility that Average Wholesale Price (“AWP”) reporting may be scrutinized by federal regulators.

- ***Kickbacks and Other Illegal Remuneration***

The Draft Guidance states that manufacturers, 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.” Significantly, the Draft Guidance recommends that manufacturers structure arrangements to fit within the “safe harbors” to the anti-kickback statute whenever possible such as personal services and management contracts, warranties, discounts, employees, group purchasing organization arrangements, and shared risk arrangements. The “key areas of potential risk” identified are: (1) relationships with purchasers, including discounts, other terms of sale, and average wholesale price issues; (2) relationships with physicians and other health care professionals, including ‘switching’ arrangements, consulting and advisory payments, and other remuneration, and (3) relationships with sales agents.

- ***Relationships With Purchasers***

A “variety of price concessions and similar benefits” may implicate the anti-kickback statute if offered to purchasers where the products are reimbursable by any of the federal health care programs, or if offered to a wholesaler to purchase the products and recommend the products to, or arrange for the purchase of the products by customers that submit claims to the federal health care programs. Additionally, the Draft Guidance states that “incentive payments to GPOs, PBMs, and other persons or entities in a position to influence the purchase of a manufacturer’s products, but that do not themselves purchase the products” potentially implicate the anti-kickback statute.

Manufacturers are instructed to pay particular attention to the requirements applicable to “sellers” and “offerors” under the “Discount” safe harbor at 42 C.F.R. § 1001.952(h). The OIG states that the following arrangements are suspect and do not qualify for the discount safe harbor: “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, [and] ‘up-front rebates’” Yet, certain discounts on other products that are reimbursed under the same methodology could satisfy the discount

safe harbor.⁶ Other non-price terms of sale that may increase the risk of overutilization, higher government program costs, inappropriate steering of federal health care business, or unfair competition “are particularly suspect” under the anti-kickback law. The Draft Guidance also cautions against manufacturers subsidizing the business expenses of purchasers or referral sources.

The Draft Guidance sets forth examples of several potentially suspect off-invoice price reductions and other financial arrangements that may run afoul of the anti-kickback law. Many of the examples of improper behavior described in the Draft Guidance regarding relationships with purchasers appear to derive from the *TAP Pharmaceutical Products* case, which resulted in a \$875 million settlement in October 2001. In addition to proscribing the provision of free or below-market rate goods or services to purchasers, the Draft Guidance proscribes a manufacturer’s “purposeful manipulation of the AWP to increase its customers profits by increasing the amount the Federal health care programs reimburse its customers”, also known as “marketing the AWP spread”. Manufacturers are advised to “review their AWP reporting practices and methodology to confirm that marketing considerations do not influence the process.”

- ***Relationships With Physicians and Other Health Care Professionals***

The Draft Guidance reiterates the OIG’s concern with “switch” or “therapeutic interchange” programs, set forth initially in a 1994 Special Fraud Alert, under which payments are made by manufacturers to encourage that prescriptions be switched. 59 Fed. Reg. 65,372 (Dec. 19, 1994). Moreover, the OIG classifies “discounts or rebates based on movement of market share” as a suspect “switching arrangement”, without analyzing the appropriate distinctions between market share rebates/discounts and more traditional “switch” programs. In fact, the OIG states that “certain managed care arrangements” “may be permissible”. Therefore, the OIG’s attempt to classify market share based discounts or rebates as a suspect “switching arrangement” may have a dramatic impact on some pharmaceutical manufacturers and their customers, many of which typically structure rebates based on market share achievements.

Additionally, consulting and advisory payments are discussed in some detail, with the OIG recognizing that there may be legitimate purposes to such arrangements, but cautioning manufacturers that they pose a “substantial risk of fraud and abuse” without “appropriate” safeguards. The OIG recommends that such arrangements be structured to fit within the “personal services” safe harbor, 42 C.F.R. § 1001.952(d), whenever possible. That safe harbor requires a compensation methodology based upon fair market value and set in advance in the aggregate for one year.

The recently promulgated “PhRMA Code on Interactions with Healthcare Professionals” (the “PhRMA Code”) is incorporated by reference into the Guidance, as an indication of how manufacturers should evaluate the various forms of other remuneration that

⁶ The Draft Guidance attempts to add a new requirement to the current discount safe harbor by stating that “manufacturers will need to know how their customers submit claims to the Federal health care program...”

might occur with their relationships with physicians and other health care professionals. In one of the most controversial sections of the Guidance, 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” [emphasis added]. As the PhRMA Code is a “voluntary” ethical code, and the Guidance is a “voluntary” compliance standard, it appears somewhat inconsistent that the OIG has set the PhRMA Code as a *minimum* standard for anti-kickback compliance.

- ***Relationships With Sales Agents***

According to the OIG, “any compensation arrangement between a pharmaceutical manufacturer and a sales agent for the purposes 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.” Sales agents include both employees and independent contractors. Additionally, anti-kickback issues may arise from sales agents engaging in improper marketing and promotional activities. The OIG raises specific concerns with situations in which “a sales agent’s express or implied duties include offering or paying remuneration (in any form) to purchasers or prescribers”, or in which the compensation methodology “creates undue incentive to engage in aggressive marketing or promotional practices.” Among other things, the OIG recommends that manufacturers’ compensation arrangements with their sales force be structured to fit within the personal services safe harbor to the anti-kickback statute. Structuring sales force compensation and incentive arrangements within the personal services safe harbor may be onerous for manufacturers who typically employ their sales force “at will”, because the safe harbor requires, among other things, a written contract setting forth the specifics of the services, term and compensation. Also, co-promotion agreements will need to be reviewed with these compliance suggestions in mind.

- ***Drug Samples***

Although the Draft Guidance does not generally discuss compliance issues under the Federal Food, Drug and Cosmetic Act (the “FDCA”), a brief section requires compliance with the provisions of the Prescription Drug Marketing Act (the “PDMA”) and discusses potential anti-kickback and false claims liability for non-compliance. Specifically, manufacturers are encouraged to comply strictly with PDMA sampling restrictions, prohibiting sales agents from encouraging providers to bill for free samples, and ensuring appropriate labeling, packaging and documentation of such free samples. In this respect, the Draft Guidance again appears to use the conduct alleged in the *TAP Pharmaceutical Products* case as an example, referring to “recent government enforcement activity” without specifically mentioning the case. Of course, there are other FDCA and PDMA topics that manufacturers may wish to include as high risk areas. The mere fact that the Draft Guidance only addresses samples should not suggest that these other areas are not high risk. They just may not have come to the OIG’s attention yet from the investigational activities to date.

Does A Pharmaceutical Manufacturer Have To Comply With the OIG's Draft Guidance Once Finalized?

Although the OIG is the first to say that these guidances are “voluntary”, the mere issuance of such guidances does send a strong signal to the public of what may be expected if a pharmaceutical manufacturer wants to demonstrate that its compliance program is “effective” – the standard. While some may believe that “effectiveness” is important only to government investigators or regulators, a company’s board of directors (as well as senior management) is likely to ask if company policies and procedures including employee training and educational activities and the like are “effective”. Consequently, if a manufacturer elects to deviate from the OIG’s “suggestions” that will be set forth in the final Guidance, it will be prudent for the manufacturer to document and archive why such deviations were adopted to improve the compliance program’s “effectiveness.”

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¹ Social Security Act, 42 U.S.C. § 1128D(a)-(c), Public Law No. 104-191, § 205.

² Pub. Law No. 105-115, § 405 (1997).

³ See Administrative Practices and Procedures, Good Guidance Practices, 65 Fed. Reg. 56,468 (Sept. 19, 2000) (Final rule).