The OIG's Draft Compliance Guidance for Pharmaceutical Manufacturers: One More Compliance 'Script' for the Healthcare Industry

by Wendy C. Goldstein and Lynn Shapiro Snyder

The U.S. Department of Health and Human Services (DHHS) Inspector General Janet Rehnquist announced the much anticipated "Draft OIG Compliance Program Guidance for Pharmaceutical Manufacturers" (Draft Guidance) on October 1, 2002.[1] Comments to the Draft Guidance were due to the OIG by December 2, 2002.

Through this Draft Guidance, the Office of the Inspector General (OIG) sets forth its general views on the "value and fundamental principles of compliance programs" for pharmaceutical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 The Draft Guidance also describes some of the specific elements that pharmaceutical manufacturers should consider when developing and implementing an effective compliance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This Draft Guidance follows an OIG Notice in the June 11, 2001 *Federal Register* seeking input, comments, and suggestions from interested parties on the development of a model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or providing of goods or services to Medicare, Medicaid and other Federal healthcare program beneficiaries."[2] The Draft Guidance narrows the initial scope of this OIG initiative by limiting its direct focus to pharmaceutical *manufacturers*, defined as "companies that develop,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The OIG explained that its decision not to include other sectors of the pharmaceutical industry in the Draft Guidance was, in part, a response to submitted comments that discussed the significant operational differences and compliance distinctions between pharmaceutical manufacturers and retail pharmacies. It is likely that the OIG will develop compliance guidance(s) targeted to other segments of the pharmaceutical industry.[3]

What Is an OIG Compliance?

The OIG has elected to issue voluntary compliance program guidances in order to encourage particular segments of the healthcare 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 healthcare programs (e.g., Medicare, Medicaid, the Department of Defense, and CHAMPUS. The OIG accomplishes this goal by issuing *nonbinding* direction to the targeted industry as to the processes that could encourage legal compliance and by identifying the "hot button" risk areas that the OIG believes to be ripe for misconduct. Although risk areas are identified, these OIG guidances do not address specifically how companies should act to avoid, or at least minimize, their liability exposure.

The OIG guidances are not intended to serve as compliance programs; rather, they provide predominantly procedural and structural guidance to an industry for designing an effective compliance program. The Draft Guidance relies upon the Federal Sentencing Guidelines for corporations, as well as relevant industry investigations and civil settlements.

The OIG's initiative to issue these compliance guidances contrasts with the statutory authority afforded the OIG under the Health Insurance Portability and Accountability Act of 1996[4] to issue educational materials in the form of Safe

Ms. Goldstein is a Health Law Partner in the law firm of Epstein Becker & Green, New York, NY. She chairs the Pharmaceutical Health Regulatory Practice Group within the firm's National Health Law Practice.

Ms. Snyder is a Health Law Partner in the law firm of Epstein Becker & Green, Washington, D.C. She chairs the Third Party Payment Practice Group and co-chairs the Health Care Fraud and Abuse Practice Group within the firm's National Health Law Practice.

Harbors, Advisory Opinions, and Special Fraud Alerts. Although it has no specific statutory authority to issue industry compliance guidance, since 1997 the OIG has issued nine final guidances for various areas of the healthcare industry: 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.[5]

These OIG compliance guidances should be distinguished from Food and Drug Administration (FDA) guidance documents. FDA does have statutory authority to issue guidances—in fact, FDA is required to develop, issue, and use guidance documents to comply with the Food and Drug Administration Modernization Act of 1997.[6] FDA also amended its administrative regulations to codify its policies and procedures and to address specifically its use of guidance documents.[7]

The Draft Guidance reiterates the seven basic elements of an effective corporate compliance program.

What Are the Processes Identified in the Draft Guidance?

There was initial speculation that the Draft Guidance would differ from earlier guidances because of the differences between a pharmaceutical manufacturer (which does not submit claims directly to a federal healthcare program) and an entity such as a hospital or physician (who does directly submit claims), to the federal healthcare programs, but the Draft Guidance is not materially different from past OIG Guidances. As derived from the Federal Sentencing Guidelines and as applicable to other industries, the Draft Guidance reiterates the seven basic elements of an effective corporate compliance program

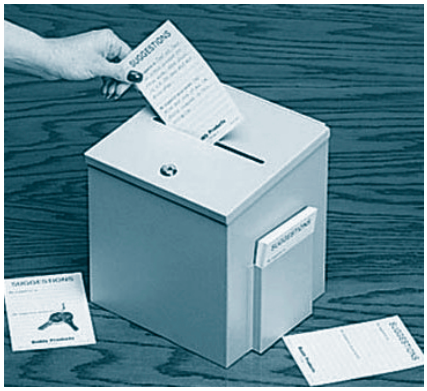
- *Put It in Writing*. The OIG recommends that a pharmaceutical manufacturer develop written policies and procedures that address important risk areas and govern the manufacturer's conduct. The OIG identifies the "hot-button" risk issues for the industry, thus publicly announcing its interpretation of the current state of the law. Other risk areas may exist that are not identified specifically in the Draft Guidance, and sources for identifying these include: OIG work plans, descriptions of covered conduct in recent settlements, trends in current enforcement activities, and special fraud alerts.

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 employees in an organization.

- *Put Someone in Charge*. The OIG recommends that an organization establish appropriate compliance bodies, such as committees and task forces on special topics, and designate a compliance officer to ensure that a senior level individual oversees all components of the corporate compliance program. The OIG recognizes that the placement of this individual will vary depending on the particular situation of the entity, but expresses its concern 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 the organization to devote sufficient funding and resources 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 healthcare program requirements. Targeted training to certain personnel should include the Anti-Kickback Statute, as well as 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 into 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 a problem, and the OIG recommends that confidentiality and nonretaliation 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 facilitate specific lines of communication such as hotlines, suggestion boxes, and newsletters. Access to 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, under which they consistently undertake appropriate disciplinary action and subject violators to sanctions. Each situation, says the OIG, 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 to perform compliance reviews regularly. Particular attention should be paid to the specific risk areas identified, as well as to "divisions or departments with substantive involvement with or impact of Federal healthcare 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, to initiate prompt corrective action, and to take action to prevent them 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 be appropriate even in circumstances where a corrective action takes place but there is no loss to a federal healthcare program.

What Are the "Hot Button" Risk Areas?

The Draft Guidance identifies three major potential risk areas that should be addressed in pharmaceutical 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 insights in this section are relevant not only to pharmaceutical manufacturers, 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"[8] under the circumstances.

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

The Draft 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. However, in a Special Advisory Bulletin in August 2002, the OIG stated that drug manufacturers generally were not subject to the federal healthcare 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."[9]

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.[10] 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"; 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 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.

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. The Draft Guidance leaves open the

possibility that federal regulators may scrutinize average wholesale price (AWP) reporting.

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 healthcare programs." Significantly, the Draft Guidance recommends that manufacturers structure arrangements to fit within the "safe harbors" of the Anti-Kickback Statute whenever possible. These safe harbors include personal services and management contracts, warranties, discounts, employees, group purchasing organization arrangements, and shared risk arrangements. Several relationships and/or situations were identified as "key areas of potential risk," and each is discussed in turn.

- *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 healthcare 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 healthcare 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.[11] 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.[12] Other nonprice terms of sale that may increase the risk of overutilization, higher government program costs, inappropriate steering of federal healthcare business, or unfair competition "are particularly suspect" under the Anti-Kickback Statute. 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 Draft Guidance examples of improper behavior regarding relationships with purchasers appear to derive from the *TAP Pharmaceutical Products* case, which resulted in an $875 million settlement in October 2001.[13] 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 healthcare 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 Healthcare Professionals*. The Draft Guidance reiterates the OIG's concern, set forth initially in a 1994 Special Fraud Alert,[14] with "switch" or "therapeutic interchange" programs, under which payments are made by manufacturers to encourage the switching of prescriptions. 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 "certain managed care arrangements . . . may be permissible." Therefore, the OIG's attempt to classify market share-based discounts or rebates as suspect "switching arrangements" may have a dramatic impact on some pharmaceutical manufacturers and their customers, many of which typically structure rebates based on market share achievements.

Consulting and advisory payments are discussed in some detail. The OIG recognizes that there may be legitimate purposes to such arrangements, but cautions 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[15] whenever possible. That safe harbor requires a compensation methodology that is based upon fair market value and is set in advance in the aggregate for one year.

The recently promulgated "PhRMA Code on Interactions with Healthcare Professionals"[16] is incorporated by reference into the Guidance, as an indication of how manufacturers should evaluate the various forms of other remuneration that might occur in relationships with physicians and other healthcare professionals. In one of the most controversial sections of the Guidance, the OIG recommends, "pharma-

ceutical 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 healthcare items or services that are directly or indirectly reimbursable by a Federal healthcare 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. Restructuring sales force compensation and incentive arrangements 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 (FDCA), a brief section requires compliance with the provisions of the Prescription Drug Marketing Act (PDMA) and discusses potential anti-kickback and false claims liability for noncompliance. 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 free samples. The Draft Guidance again appears to use the conduct alleged in the *TAP Pharmaceutical Products* case as an example; it refers 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 fact that the Draft Guidance addresses only samples should not suggest that other areas are not high risk.

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 as to what may be expected if a pharmaceutical manufacturer wants to demonstrate that its compliance program is "effective." 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, educational activities, and the like—are "effective." If a manufacturer elects to deviate from the OIG's "suggestions" that will be set forth in the final Guidance, it will be prudent to document why such deviations were adopted to demonstrate the compliance program's "effectiveness."

[1] The Draft Guidance was announced at the Health Care Compliance Association's and American Health Lawyers Association Fraud & Compliance Forum. It was published in the *Federal Register* (Oct. 3, 2002), and is available on the Internet at: http://oig.hhs.gov/fraud/-docs/complianceguidance/draftcpgpharm09272002.pdf.

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

[3] Those future guidances also are likely to affect pharmaceutical manufacturers.

[4] Pub. L. No. 104-191, § 205 (codified at 42 U.S.C. § 1128D(a)-(c)).

[5] The OIG guidance for ambulances remains in draft.

[6] Pub. L. No. 105-115, § 405 (1997).

[7] *See* Administrative Practices and Procedures, Good Guidance Practices, 65 Fed. Reg. 56,468 (Sept. 19, 2000) (final rule).

[8] Significantly, the term "appropriate" appears 39 times in the *Federal Register* publication. What would be "appropriate" under the particular circumstances, however, is not discussed.

[9] OIG Special Advisory Bulletin, Offering Gifts and Other Inducements to Beneficiaries, at 5 (Aug. 2002), available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsand inducements.pdf.

[10] 42 U.S.C. § 1396r-8(c).

[11] 42 C.F.R. § 1001.952(h).

[12] The Draft Guidance attempts to add a new requirement to the current discount safe harbor by stating, "manufacturers will need to know how their customers submit claims to the Federal health care program . …"

[13] United States v. TAP Pharmaceutical Products, Inc., No. 01 CR 10354 (D. Mass.) (sentencing Dec. 6, 2002). *See also* Steven M. Kowal, *The TAP Prosecution: Taking Enforcement to a New Level*, FDLI UPDATE, Jan./Feb. 2002, at 30.

[14] 59 Fed. Reg. 65,372 (Dec. 19, 1994).

[15] 42 C.F.R. § 1001.952(d).

[16] PhRMA Code on Interactions with Healthcare Professionals (effective July 1, 2001), available at http://www.phrma.org/publications/policy/2002-04-19.391.pdf.

Update 2003, Issue 1.
With permission from FDLI.