The Draft Guidance serves as an indicator of current OIG enforcement priorities.

OIG Releases Draft Compliance Guidance for Pharmaceutical Manufacturers

On October 3, the HHS-Office of Inspector General (OIG) released its long awaited draft compliance program guidance (Draft Guidance) for pharmaceutical manufacturers. Interested parties have until December 2 to provide comments to the OIG regarding the draft guidance.

The OIG limited the application of the Draft Guidance to pharmaceutical manufacturers, instead of the pharmaceutical industry as a whole (which would include retail pharmacies and pharmacy benefits managers, among others) because of the significant compliance and operational differences between pharmaceutical manufacturers and other segments of the pharmaceutical industry. As such, we anticipate that the OIG will issue separate guidelines for those other segments of the pharmaceutical industry at a later date.

The Draft Guidance identifies the following “high risk” areas for pharmaceutical manufacturers, with a particular focus on compliance vulnerabilities under the Anti-Kickback Statute:

- **Discounts and Other Price Concessions:** Any inducements, pricing or otherwise, offered to customers are potential Anti-Kickback Statute risks, and the OIG recommends compliance with the safe harbor for discounts.

- **Provision of Value Added Services:** Provision of value added services to customers, such as free or reduced rate reimbursement consultation or billing assistance programs, presents Anti-Kickback Statute risk (if requisite intent exists), particularly if made available only to a select group of customers or if offered in combination with other risky activities such as a guarantee of a minimum “spread” between the price and third-party reimbursement.

- **Average Wholesale Price (AWP):** “Active” marketing of the “spread,” when coupled with manipulation of AWP, is sufficient to meet the Anti-Kickback Statute’s unlawful intent requirement, according to the OIG.

- **“Switching or “Conversion” Arrangements:** Any marketing practice that even indirectly rewards “switching,” such as discounts or rebates based on market share, may be problematic under the Anti-Kickback Statute.

- **Payments or Arrangements with Prescribers:** All consulting, advisory, or research agreements between manufacturers and professionals who prescribe or order their products should meet the Anti-Kickback safe harbor for
personal service arrangements. Pharmaceutical manufacturers should, at a minimum, also comply with the recently released Pharmaceutical Research and Manufacturers of America (PhRMA) Code of Ethics.

- **Payments to Sales Agents:** All arrangements are subject to scrutiny and the OIG urges meeting an Anti-Kickback safe harbor.

- **Data Integrity:** Manufacturers may be liable under the False Claims Act for knowingly failing to report or generate their pricing information fully and accurately, if federal health program reimbursement depends, even in part, on such information.

- **Drug Samples:** Pharmaceutical manufacturers should adhere to the Prescription Drug Marketing Act (PDMA) requirements and train their sales forces to inform sample recipients of the limitations on sample use.

**Impact on Health Care Entities**

The Draft Guidance provides valuable insight into the OIG’s view of particular areas of compliance vulnerability as well as its probable enforcement priorities. At a minimum, pharmaceutical manufacturers and combination drug/device manufacturers should review their practices internally and with counsel with respect to the three main risk areas—anti-kickback, data integrity and drug sample risk. In addition, other indirect providers, such as medical device manufacturers and entities involved in other segments of the pharmaceutical industry, should be aware of the Draft Guidance in assessing their own compliance risk. Entities wishing to submit comments to the OIG on the Draft Guidance should also consult counsel.

**Compliance Program Guidelines: Background**

The Draft Guidance, the 11th in the OIG’s series of health industry-specific guidance documents, is still in draft form, but reflects the OIG’s position on a wide range of compliance issues and enforcement priorities, listing specific “risk areas.” As noted above, although these risk areas are specific to pharmaceutical manufacturers, other indirect providers (such as combination product and medical-device manufacturers) would be well advised to keep the OIG’s discussion of risk areas and compliance issues in mind when evaluating their own operations, interactions, and relationships. Indeed, the OIG acknowledged that in drafting this guidance it has taken into account past as well as ongoing OIG and Department of Justice fraud investigations.

**Risk Areas for Pharmaceutical Manufacturers**

In the Draft Guidance, the OIG identifies the following three major potential risk areas for pharmaceutical manufacturers: (1) kickbacks and other illegal remuneration; (2) the integrity of the submission of information to federal and state health programs; and (3) drug samples. The OIG cautions, however, that its discussion only focuses on topics that are “currently of most concern to the enforcement community.” Therefore, the issues raised in the guidance document should not be considered an exhaustive list of potential compliance risks.

**Anti-Kickback Statute Risks**

Until recently, many pharmaceutical manufacturers and other indirect providers believed that the federal fraud and abuse laws did not apply directly to them. However, the TAP settlement and other recent developments have caused pharmaceutical manufacturers and their compliance/legal departments to realize the need to be attentive to the federal fraud and abuse laws, and the Anti-Kickback Statute in particular. Indeed, in this Draft Guidance the OIG warns pharmaceutical manufacturers (including their employees and other agents) to be cognizant of the “constraints” the Anti-Kickback Statute places on marketing and promotion activities. The OIG also reminds manufacturers that, in its view, a violation of the Anti-Kickback Statute may give rise to False Claims Act liability under certain circumstances. Accordingly, the OIG recommends that pharmaceutical manufacturers structure their arrangements within one of the Anti-Kickback Statute’s safe harbors, whenever possible.

In this draft guidance, the OIG identifies three specific categories of Anti-Kickback Statute risk for pharmaceutical manufacturers. The OIG cautions, however, that an entity’s compliance risk is not limited
to these relationships. Specifically, the OIG believes that manufacturers should devote significant compliance attention to their relationships with (1) their purchasers; (2) physicians and other health professionals; and (3) sales agents.

**Relationships With Purchasers**

*Price Concessions and Other Benefits to Purchasers*

The OIG warns manufacturers that any inducements (including pricing) they typically offer customers may implicate the Anti-Kickback Statute, if the related products are reimbursable by a federal health program. As an example, the OIG states that a discount (or other price concession) offered to a wholesaler may be problematic, if the discount or other benefit is offered to induce the wholesaler (1) to purchase the product; and (2) to recommend, or arrange for, the purchase of the product by a person or entity that submits claims for payment to a federal health care program. Moreover, the OIG also asserts that pharmaceutical manufacturers should be aware that there is Anti-Kickback Statute risk even in incentive payments to entities that are not themselves purchasers. Examples of such entities are those that are in a position to influence the purchase of a product, such as group purchasing organizations (GPOs) and PBMs.

The OIG urges manufacturers to familiarize themselves “thoroughly” with the Anti-Kickback Statute’s safe harbor for discounts, and that whenever possible, a price concession should meet the safe harbor’s requirements. The practical benefit of the discount safe harbor in this context is limited, however. As the OIG acknowledges, the exception covers only “actual reductions in the product’s price.” Accordingly, other benefits or concessions, such as signing bonuses or discounts on other products, will not qualify for protection and therefore may pose risks. Moreover, the OIG also explains that because one of the relevant elements of the safe harbor requires a seller to inform the customer of any of the customer’s discount reporting obligations, manufacturers must therefore know the reimbursement methodology pursuant to which its product is billed.

**Value Added Services**

Another Anti-Kickback Statute risk identified by the OIG is a manufacturer’s provision of value added services to customers in connection with the sale of products. Examples of such services include free or reduced rate reimbursement consultation or billing assistance programs. The OIG believes that such activities may implicate the Anti-Kickback Statute if the manufacturer provides the benefit to the customer with the intent to reduce or reward the purchase or ordering of products. There is particular risk if the benefit is made available only to a select group of customers, such as high volume prescribers or if the good or service eliminates an expense the purchaser or referral source would otherwise have incurred. Such benefits become even more problematic, in the OIG’s view, when offered in combination with other risky activities such as a guarantee of a minimum “spread” between the price and third-party reimbursement.

**Manipulation of Average Wholesale Price**

In light of the well-publicized TAP investigation and settlement, the OIG finds significant compliance risks relating to AWP reporting. In particular, the OIG warns manufacturers against manipulating and marketing the “spread.” The spread is the difference between the amount an entity pays to acquire a product from a manufacturer and the amount the entity receives from the ultimate payor. A pharmaceutical manufacturer’s manipulations of AWP to enhance the spread, as well as the manufacturer’s marketing of the spread are fraught with compliance risk. Accordingly, the OIG recommends that manufacturers review their AWP practices and ensure that marketing considerations do not influence their AWP methodology. The OIG asserts that “active” marketing of the spread, when coupled with manipulation of AWP, is sufficient to meet the Anti-Kickback Statute’s unlawful intent requirement. This leaves open the question of the amount of risk involved in a manufacturer marketing the spread in the absence of any AWP manipulation.
**Relationships With Physicians and Other Health Care Professionals**

In the Draft Guidance, the OIG advises that pharmaceutical manufacturers carefully examine any and all remunerative relationships with health professionals who order or prescribe their products. Although many such arrangements are entirely legitimate, the OIG is concerned that in many circumstances remuneration is provided to prescribers in order to induce the referring or ordering of the manufacturer’s product. The OIG believes that “switching” arrangements, consulting or advisory payments, and remuneration inconsistent with the recently released PhRMA Code of Conduct pose the most significant potential risk.

**“Switching” Arrangements**

It should come as no surprise to pharmaceutical manufacturers that the OIG believes that “switching” arrangements are highly suspect under the Anti-Kickback Statute and should be examined thoroughly and carefully. The OIG roughly defines a “switching” arrangement as the practice of offering cash or other benefits to a pharmacy, PBM, or physician or other prescriber for each instance in which the pharmacy, PBM, or prescriber convinces a patient to “switch” to the manufacturer’s product from a competitor’s product. Of concern to many interested parties, the OIG implies in the Draft Guidance that any marketing practice that even indirectly rewards “switching,” such as discounts or rebates based on market share, could be problematic.

**Consulting and Advisory Payments to Prescribers**

Many pharmaceutical manufacturers engage as consultants, advisors or researchers certain of the health professionals who prescribe or order the companies’ products. In this Draft Guidance, the OIG clearly expresses its skepticism of the legitimacy of these arrangements. Although the OIG acknowledges some of these relationships may have legitimate purposes, on the whole the OIG believes that they “pose a substantial risk of fraud and abuse” and therefore should be entered into only with “appropriate safeguards.”

The OIG advises pharmaceutical manufacturers to ensure that consulting and advisory arrangements with prescribers are for legitimate and identifiable services. Further, the OIG recommends that all consulting, advisory, or research agreements between manufacturers and professionals who prescribe or order their products meet the Anti-Kickback Statute’s safe harbor for personal service arrangements.

**Other Remuneration and the PhRMA Code of Conduct**

The OIG also is concerned about a wide variety of other remuneration provided by manufacturers to health professionals, GPOs, PBMs, and hospital systems. The OIG is chiefly concerned about benefits such as entertainment or meals, sponsorship or financing of educational conferences, research or educational grants, and gifts or gratuities. The OIG identifies the PhRMA Code of Conduct that became effective earlier this year as a starting point on such interactions and relationships. The OIG states that remuneration or arrangements that fail to meet the PhRMA Code’s minimum standards will receive increased government attention, thereby making nearly mandatory what was intended to be a voluntary industry code of conduct. Conversely, however, the OIG states that compliance with the PhRMA Code’s standards alone will not protect parties from scrutiny or prosecution. In other words, pharmaceutical manufacturers should not limit their compliance efforts to the PhRMA Code’s standards.

**Relationships With Sales Agents**

Another Anti-Kickback Statute risk highlighted by the OIG relates to manufacturer compensation to their sales forces. Indeed, according to the OIG, any remunerative relationship between a pharmaceutical manufacturer and a sales agent with regard to items or services reimbursable (directly or indirectly) by a federal health care program potentially implicates the Anti-Kickback Statute. The OIG believes that there are risks inherent in relationships with sales agents, regardless of the compensation methodology. For example, the OIG warns manufacturers of the potential for rogue sales agents to create liability for the manufacturer by engaging in improper activities.
In addition, payment methodologies that reward aggressive marketing practices pose significant potential for abuse, according to the OIG. Under the OIG’s logic, commission-based compensation to sales agents would seem to pose a compliance risk for entities. The OIG recommends that a pharmaceutical manufacturer (1) ensure that its sales force compensation arrangements fit within a safe harbor; and (2) train its sales force properly and comprehensively on compliance issues, on a regular basis.

**Integrity of Data Used to Establish Government Reimbursement**

In addition to Anti-Kickback Statute compliance issues, the OIG also cautions pharmaceutical manufacturers regarding the integrity of data submitted to or otherwise used to establish federal health care program reimbursement. Continuing its logic from TAP and other settlements, the OIG asserts in this Draft Guidance that pharmaceutical manufacturers bear responsibility for the accuracy of information submitted to a federal health program regarding the manufacturers’ products, even if the claim or request for payment is submitted by another party. The OIG claims that manufacturers may be liable under the False Claims Act for knowingly failing to report or generate their pricing information fully and accurately, if federal health program reimbursement depends even in part on such information. Any such reported pricing information must take into account all discounts, rebates, or other price concessions or benefits conferred on purchasers.

**Drug Samples**

The final area of compliance risk addressed by the OIG in the Draft Guidance relates to drug samples. Although the OIG acknowledges the benefit to patients inherent in drug sampling, the OIG continues to believe that the provision of drug samples is fraught with compliance risk if not done appropriately and monitored carefully. In this guidance, the OIG reminds pharmaceutical manufacturers of its view that in addition to PDMA liability, the inappropriate provision of drug samples may also lead to False Claims Act or Anti-Kickback Statute liability. The OIG recommends that pharmaceutical manufacturers adhere to the PDMA requirements and train their sales forces to inform sample recipients of the limitations on sample use. The OIG further reminds pharmaceutical manufacturers that recent enforcement activity has focused on both manufacturers and physicians in those instances in which physicians sold or billed for products they received as samples from manufacturers.

**Conclusion**

The OIG draft compliance program guidance for pharmaceutical manufacturers provides guidance that pharmaceutical manufacturers and other indirect providers such as combination product and medical device manufacturers should review carefully. The Draft Guidance serves as an indicator of current OIG enforcement priorities. Entities interested in submitting comments on the Draft Guidance to the OIG should consult counsel.

**Endnotes**

1 67 Fed Reg. 62057 (Oct. 3, 2002). This draft guidance follows the OIG’s June 11, 2001 request for input for developing compliance guidelines for the pharmaceutical industry. 66 Fed. Reg. 31246 (June 11, 2001).

2 The Anti-Kickback Statute establishes criminal and civil penalties for any person who knowingly and willfully offers, pays, solicits, or receives any remuneration in return for (i) referring an individual to another person or entity for the furnishing (or arranging for the furnishing) of any item or service that may be paid in whole or in part by a federal health care program, including Medicare and Medicaid, or (ii) purchasing, ordering, leasing, or arranging for, or recommending purchasing, ordering, leasing, or ordering any goods or services payable under a federal health care program, including Medicare and Medicaid, or (ii) purchasing, ordering, leasing, or arranging for, or recommending purchasing, ordering, leasing, or ordering any goods or services payable under a federal health care program. Illegal payments or solicitations of payments include those in cash or in kind, those made directly or indirectly, and those made overtly or covertly. See 42 U.S.C. § 1320a-7b(b). Violations of the Anti-Kickback Statute are subject to criminal prosecution and fines of up to $25,000 per violation, imprisonment for up to five years, and exclusion from the Medicare and Medicaid programs, as well as other federal programs.

3 In October, 2001, TAP Pharmaceutical Products agreed to pay $875 million to the federal government to settle charges of fraudulent drug pricing and illegal marketing activities.
The False Claims Act allows the government to impose severe penalties on any person who knowingly presents (or causes to be presented) a false or fraudulent claim for payment or approval to the federal government. See 31 U.S.C. § 3729 et seq. Liability involves significant financial liability, including up to $11,000 for each false claim submitted as well as damages of up to three times the amount unlawfully claimed.

The OIG made public its concern with such arrangements as early as 1994 in a Special Fraud Alert on product conversion arrangements (available at http://www.oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html).

If you have any questions about this Client Alert, please contact Stuart S. Kurlander or Jeffrey S. Peters in our Washington, D.C. office, or any of the following attorneys.