LAW WATCH
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OIG ISSUES FINAL COMPLIANCE PROGRAM GUIDANCE FOR PHARMACEUTICAL MANUFACTURERS

On April 28, 2003, the Office of Inspector General of the Department of Health and Human Services ("OIG") released its final Compliance Program Guidance for Pharmaceutical Manufacturers ("CPG"). (The CPG was also published in the May 5, 2003 *Federal Register*.) This is the first OIG compliance program guidance specifically directed at the pharmaceutical industry. As the OIG explained in the draft CPG released in October 2002, this guidance is limited to pharmaceutical manufacturers and does not address retail pharmacy chains and other similar pharmaceutical operations. (See *Law Watch* 02-36, "OIG Issues Draft Compliance Program Guidance for Pharmaceutical Manufacturers," October 10, 2002.)

While the final CPG retains the same structure as the draft CPG, it provides broader insight into those key areas identified by the OIG as presenting significant concern for pharmaceutical manufacturers. The OIG also makes clear that the final CPG is not a mandatory compliance program, but rather a set of guidelines that pharmaceutical manufacturers should consider when developing and implementing a compliance program or evaluating an existing one.

Executive Summary

***Action**: The OIG has issued a final Compliance Program Guidance for Pharmaceutical Manufacturers. A copy of the final CPG can be obtained at http://oig.hhs.gov/fraud/complianceguidance.html.*

***Impact:** The final CPG provides important guidance to pharmaceutical manufacturers on the development of an effective compliance program and the specific elements that manufacturers should consider when implementing a compliance program. In particular, the final guidance details actions that pharmaceutical manufacturers can take to guard against violating federal fraud and abuse laws in their marketing and sales activities.*

***Effective Date:** Immediately.*

Background

In the process of finalizing the CPG, the OIG considered comments received in response to the draft CPG, prior OIG compliance program publications, and ongoing OIG and Department of Justice fraud investigations involving the pharmaceutical industry. The OIG also held meetings with four groups of industry stakeholders – the Pharmaceutical Research and Manufacturers of America ("PhRMA") and pharmaceutical manufacturer representatives, health plan and health plan association representatives, representatives of pharmacy benefits managers, and representatives of the American Medical Association and its member organizations.

The OIG acknowledges that there is wide diversity amongst pharmaceutical manufacturers and that manufacturers are already subject to extensive regulatory requirements. Therefore, the CPG is not intended to be a compliance guidance of universal applicability. Rather, the OIG strongly encourages pharmaceutical manufacturers to use the CPG as a benchmark to develop and implement, or simply refine (as necessary) compliance elements that address the potential problems that apply to pharmaceutical manufacturers' unique business practices.

Consistent with earlier compliance guidance issued for other sectors of the health care industry, the CPG is modeled on basic elements identified by the OIG as fundamental to an effective compliance program. The elements include: (1) developing compliance policies and procedures; (2) designating a compliance officer; (3) developing and conducting appropriate training and education; (4) developing open lines of communication (*e.g.*, through a hotline or other mechanism); (5) conducting audits to monitor compliance; (6) developing policies and procedures to address the non-employment of excluded individuals and entities; and (7) development of policies and procedures for identifying non-compliance or misconduct.

The final CPG places particular emphasis on the development and distribution of written compliance standards, procedures, and practices that

guide a pharmaceutical company. Moreover, the OIG recommends that due to pharmaceutical manufacturers' unique business practices, a company's compliance program should be shared not only with every employee, but also with agents and contractors whose services could impact federal health care programs.

Specific Risk Areas

As in the draft CPG, the OIG identifies three principal potential risk areas for pharmaceutical manufacturers: (1) integrity of data used by state and federal governments to establish payment amounts; (2) kickbacks and other illegal remuneration; and (3) compliance with laws regulating drug samples. According to the OIG, the enforcement community is currently focused on these three risk areas; however, manufacturers should not interpret these risks as the only areas of possible government intervention. The OIG also acknowledges that the final CPG does not create or impose any new law or legal obligations upon pharmaceutical manufacturers (reinforcing that the CPG is voluntary) and that the identification of practices as having the potential for risk does not imply that the OIG believes the practice to be illegal in all circumstances.

Integrity of Data Used to Establish or Determine Government Reimbursement

Following the draft CPG, the final CPG focuses on the data submitted by pharmaceutical manufacturers in connection with government health care programs. In particular, the OIG is concerned with determination of the Average Wholesale Price ("AWP") under the Medicare program and rebates under the Medicaid Rebate Program, both of which depend on price and sales data that are either directly or indirectly furnished by pharmaceutical manufacturers. The government expects that data provided by pharmaceutical manufacturers will be complete and accurate. The OIG emphasizes that the knowing submission of false, fraudulent or misleading information may expose pharmaceutical manufacturers to liability under the federal False Claims Act and/or the federal anti-kickback statute.

The final CPG, like the draft, offers recommendations that may aid pharmaceutical manufacturers in avoiding liability in this area, such as accurately taking into account price reductions, discounts for cash, rebates, goods in kind, free or reduced-priced services, grants or other price concessions, or similar benefits. The final CPG makes clear that pharmaceutical manufacturers are responsible for ensuring the integrity of the data they generate that is used for government reimbursement purposes.

Kickbacks and Other Illegal Remuneration

The final CPG contains some general considerations that pharmaceutical manufacturers should be aware of when evaluating risk under the federal anti-kickback statute. These considerations, which were not included in the draft CPG, advise pharmaceutical manufacturers that the anti-kickback statute prohibits certain sales techniques when used to solicit federal health care program business, even though such techniques may be common or permissible in other industries. The OIG's statements leave little doubt that pharmaceutical manufacturers cannot rely on the acceptability of certain common, widespread practices in order to justify their marketing and sales activities under the anti-kickback statute.

The CPG calls on manufacturers to identify any remunerative relationship that is capable of generating federal health care business, and to determine whether any purpose of the remuneration is to induce or reward the referral of business. Although ultimate liability under the anti-kickback statute will turn on the party's intent, the OIG suggests that identifying such arrangements will aid manufacturers in assessing their risk. The CPG also cautions manufacturers that a lawful purpose will not legitimize a payment that has an unlawful purpose.

To help identify arrangements that pose the greatest risk of prosecution, the final CPG suggests manufacturers ask the following questions, among others, when they identify potentially problematic relationships:

> Does the arrangement or practice have a potential to interfere, skew or influence clinical decision-making, or to undermine the clinical integrity of a formulary process?
>
> Does the arrangement have the potential to increase costs to the federal health programs, beneficiaries or enrollees?
>
> Does the arrangement have the potential to lead to increased or inappropriate utilization?
>
> Does the arrangement raise patient safety or quality of care concerns?

In what appears to be a recognition that not all "suspect" practices or activities are necessarily illegal or unlawful, the final CPG advises that the propriety of any particular arrangement must be based on a careful evaluation of the facts and circumstances. While the OIG emphasizes that the risk areas identified in the CPG must be given close scrutiny, it also indicates that a particular practice or activity may be permissible or, alternatively, may be structured to fit in one of the safe harbors under the anti-kickback statute.

The draft CPG had identified several known areas of potential risk under the federal anti-kickback statute that arise from pharmaceutical manufacturers' relationships with three separate groups – purchasers, health care professionals, and sales agents. The final CPG reiterates the potential risks, and further explains the OIG's concerns with each of these relationships.

- **Relationships with Purchasers and their Agents**

The final CPG addresses a variety of discount arrangements prevalent in the pharmaceutical industry. The OIG makes clear that discount arrangements will garner careful scrutiny because they have the potential to implicate both the anti-kickback statute and the "Best Price" requirements of the Medicaid Rebate Program.

Product support services, such as billing assistance for purchased products, reimbursement consultation, and other programs tied to support of a purchased product, may raise anti-kickback concerns where the service confers a benefit on the referring provider. For example, support programs that are coupled with a promise that the purchaser must pay only if the product is reimbursed by a federal health care program would likely violate the anti-kickback statute.

The final CPG addresses risks associated with educational grants and research funding. The OIG advises pharmaceutical manufacturers to separate their educational grant making functions from their sales and marketing functions and to devoid themselves of any influence over the substance of an educational program or presenter that they may be sponsoring. Otherwise, manufacturers risk a finding that they used a grant program improperly to induce or reward product purchases. The final CPG also indicates that payment for research services should be consistent with fair market value for legitimate, reasonable and necessary services, not simply used as a pretext to generate prescriptions. Although the OIG recognizes that there may be a legitimate purpose behind funding a purchaser's own research, such funding creates a risk that the funds could be misused.

In another change from the draft, the final CPG recognizes the importance of formularies and formulary support activities. The OIG acknowledges that so as long as considerations related to the clinical efficacy and appropriateness of formulary drugs is paramount to cost considerations, the development of a formulary should not raise anti-kickback concerns. However, the final CPG advises that any remuneration from a manufacturer or its agents, directly or indirectly, to persons in a position to influence formulary decisions, as well as rebates or payments to pharmacy benefits managers ("PBM"), should be carefully scrutinized. Any dollars provided by manufacturers (in the forms of grants or funding) that replace dollars that would otherwise be spent by the PBM on formulary support services also present a potential risk.

The final CPG also discusses one of the government's biggest concerns, which is the reporting of AWPs and the reimbursement "spread" that may be created. This area has been and continues to be the focus of many government fraud investigations involving the pharmaceutical industry. The OIG warns pharmaceutical manufacturers that purposeful manipulation of the AWP to increase customers' profits may implicate the anti-kickback statute. Moreover, the CPG puts manufacturers' sales representatives on notice that marketing the AWP "spread" is strong evidence of unlawful intent necessary to trigger the anti-kickback statute. The CPG recommends that manufacturers review their AWP reporting practices and methodology to ensure that marketing considerations do not influence the process.

- **Relationships with Physicians and other Persons in a Position to Influence Referrals**

Although relationships with physicians and others are not necessarily suspect, the final CPG advises manufacturers to examine any gifts of value given to persons in a position to prescribe the manufacturer's products to determine whether the intent is to induce or reward referrals. The CPG reiterates the OIG's warning that a legitimate purpose for a gift may still give rise to anti-kickback liability if there is also an illegal purpose, *e.g.*, the purposeful inducement of business.

To avoid liability, the CPG suggests that manufacturers structure physician relationships to fit into one of the anti-kickback statute's safe harbors. Where a relationship does not qualify for safe harbor protection, manufacturers should consider several factors, including the physician's degree of influence, whether the remuneration is conditioned in whole or in part on patient referrals, whether the remuneration is more than trivial in value, and whether the acceptance of the remuneration has the potential to diminish the objectivity of professional judgment. These considerations reflect the PhRMA Code on Interactions with Healthcare Professionals adopted in April 2002, which the OIG believes provides useful and practical advice.

The CPG also addresses several other marketing practices that the OIG finds problematic. One of the potentially troublesome practices addressed in the draft CPG involved "switching" arrangements in which a physician is paid to switch patients to a different medication. The draft CPG took a broad view of such arrangements by suggesting that even arrangements which have the effect of rewarding switching indirectly should be carefully reviewed. The final CPG reflects a more limited view of such arrangements, indicating that only arrangements which involve pharmaceutical manufacturers offering physicians or others cash payments or other benefits each time a patient's prescription is switched to a competing product would "clearly" implicate the anti-kickback statute. The CPG also identifies a relatively new practice where physicians are compensated for time spent listening to sales representatives market pharmaceutical products or physicians are paid for time spent accessing web sites to view or listen to marketing information. According to the CPG, all such activities are "highly" suspect and should be "strongly discouraged."

- **Relationships with Sales Representatives**

The final CPG strongly suggests that compensation arrangements involving extraordinary incentive bonuses and expense accounts can send the wrong message to pharmaceutical representatives, in that they may be encouraged to induce sales through lavish remuneration. Pharmaceutical manufacturers are also encouraged to develop regular training programs for sales representatives, institute disciplinary policies for improper marketing practices, use the OIG advisory opinion process to determine the propriety of sales tactics, and to establish an effective system for tracking, compiling, and reviewing information concerning sales force activities.

Drug Samples

The final CPG provides little context to explain the compliance issues associated with drug samples. It appears that the OIG's concerns stem from recent government investigations involving physicians who billed federal

health care programs for drug samples that they obtained at no cost. The final CPG advises pharmaceutical manufacturers to closely adhere to the guidelines set forth in the Prescription Drug Marketing Act of 1987, to train their sales representatives accordingly, and to pay close attention to the documentation requirements.

Conclusion

The final CPG contains important information for pharmaceutical manufacturers and their business partners. The CPG explains in detail the OIG's concerns with a variety of sales and marketing activities that pharmaceutical manufacturers engage in and steps that manufacturers can take to protect themselves from liability under federal fraud and abuse laws. There is little doubt that the OIG and other government enforcement agencies intend to continue their close scrutiny of pharmaceutical manufacturers and their business practices. For those pharmaceutical manufacturers that already have an established compliance program, they should use the CPG to evaluate the effectiveness of their existing program. Any pharmaceutical manufacturer that has not already established a compliance program should give strong consideration to implementing a program as soon as possible, using the final CPG as a guide.

If you would like more information regarding the final Compliance Program Guidance for Pharmaceutical Manufacturers or about compliance issues related to pharmaceutical manufacturers generally, please contact **Jeff Micklos** or **Lena Robins** in our Washington, D.C. office, **Fred Entin** in our Chicago office, **Charles Oppenheim** or **Diane Ung** in our Los Angeles office, **Maria Gonzalez Knavel** in our Milwaukee office, **Rick Johns** in our Orlando office, **Mike Scarano** in our San Diego North office, **Judith Waltz** in our San Francisco office, or the member of the firm who normally handles your legal matters.

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