ARNOLD & PORTER UPDATE

HHS OIG Releases Draft Compliance Guide for Pharmaceutical Industry

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On Monday, September 30, 2002, the Office of Inspector General, U.S. Department of Health and Human Services ("HHS OIG" or "OIG") released its "Draft OIG Compliance Program Guidance for Pharmaceutical Manufacturers." The OIG document provides guidance for pharmaceutical manufacturers on compliance program structure as well as on specific "risk areas" that should be the focus of special attention. While the pharmaceutical guidance, like prior OIG guidances, is voluntary, the OIG's suggestions could become "de facto" standards for the industry. Interested parties may submit comments on the draft guidance through early December. The OIG is expected to publish a final version of the guidance in early 2003.

Background

The OIG periodically publishes guidances to encourage companies in the health care industry to establish compliance programs and internal controls to reduce fraud and abuse in Federal health care programs. Other guidances have addressed potential fraud and abuse issues with respect to the hospital industry, Medicare+Choice organizations, small group physician practices, and other groups that affect Federal health care reimbursement. On June 11, 2001, the OIG published in the Federal Register a solicitation for comments seeking information and recommendations for developing a compliance program guidance for the pharmaceutical industry.

Scope and Coverage

After suggesting initially that it would issue guidance that would pertain to pharmaceutical manufacturers and pharmacies, the OIG has limited the draft guidance to pharmaceutical manufacturers: companies that develop, manufacture, market, and sell pharmaceuticals. The draft guidance is intended to assist such companies in the design of internal controls and compliance programs for adhering to the statutes, regulations, and other requirements of Federal health care programs (*e.g.*, Medicare and Medicaid).

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Significantly, the guidance focuses only limited attention on compliance with rules and regulations under the jurisdiction of the U.S. Food and Drug Administration ("FDA"), and on its face, the draft guidance does not appear to apply to medical device manufacturers.

Compliance Program Structure

As in the past, the draft guidance recommends the adoption of compliance programs that address the seven elements of an effective compliance program as outlined in the U.S. Sentencing Commission's organizational guidelines. Among other things, the OIG draft calls for the establishment of a compliance officer, who should be responsible for overseeing implementation of the compliance program, reporting compliance activities to senior management, coordinating education and training, and performing similar functions. The OIG suggests that, while the placement of the compliance officer will vary by company, "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." The draft guidance also recommends establishing a compliance committee to advise the compliance officer and assist in implementation of compliance activities.

A company's board of directors, CEO, president, and other senior managers should participate in the development of "all aspects of the compliance program, especially the code of conduct," according to the OIG.

Compliance Activities

OIG's draft guidance suggests that effective compliance programs will have several elements, including:

> **Education and Training.** The draft guidance emphasizes the importance of education and training. Such programs should include sessions summarizing the company's compliance program, written standards, and applicable Federal health care program requirements. The compliance officer should assure that such training is documented. The guidance also suggests that the format of effective training may vary (*e.g.*, larger companies may wish to use the Internet or video conferences to reach widely dispersed workforces).
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> **Internal Communication (including Hotlines).** The draft guidance emphasizes the importance of open lines of communication between employees and the compliance officer. The OIG encourages the use of hotlines, emails, newsletters, and suggestion boxes for such communication. Reported matters should be investigated promptly, and policies or procedures should be established to protect reporting employees from retaliation.

Monitoring and Auditing. Companies should incorporate monitoring of compliance and provide reports of suspected non-compliance to senior management. Such reviews should also include evaluations of whether the company's policies and procedures adequately address risks identified by the OIG and other Federal and state regulators. For the first time, the OIG also specifically recognizes the value of prospective as well as retrospective or back-end audits.

Enforcement of Internal Standards. Companies should establish clear consequences for violating the law or internal codes of conduct. Intentional and material noncompliance should lead to "significant" disciplinary sanctions.

Responding to Possible Violations. Where the compliance officer and/or senior management believe that investigated misconduct violates criminal, civil, or administrative law, the company should "promptly report" the existence of such misconduct within a reasonable period of time, but not more than 60 days after determining that there is credible evidence of a violation. Prompt voluntary reporting will be considered a mitigating factor if the reporting company becomes the subject of an OIG investigation.

Risk Areas

The draft OIG guidance highlights three compliance risk areas: (i) integrity of data used to establish government reimbursement; (ii) kickbacks and other illegal remuneration; and (iii) drug sampling.

Data Integrity. Price reporting used in the calculation of Federal reimbursement rates should accurately take into account, among other things, coupons, goods in kind, price reductions, rebates, and grants. Underlying assumptions should be "reasoned, consistent, and appropriately documented." A manufacturer may be liable under the False Claims Act, the OIG states, if government reimbursement rates for products "depend[], in whole or in part, on information generated or reported by the manufacturer, directly or indirectly, and the manufacturer has knowingly . . . failed to generate such information completely and accurately." Manufacturers should ensure that they calculate "Average Manufacturer Price" and "Best Price" accurately for purposes of calculating Medicaid rebates.

Kickbacks. The anti-kickback statute is a criminal prohibition against payments made purposefully to induce or reward referrals of Federal health care business. HHS has provided safe harbors, set forth at 42 C.F.R. § 1001.952. Potential safe harbors include personal services contracts, warranties, and group purchasing organization arrangements. Areas that could implicate the anti-kickback statute include:

- Price discounts that are not properly and accurately reported. *See* 42 C.F.R. § 1001.952(h).

- Manipulation of Average Wholesale Price ("AWP") to increase customers' profits. The OIG advises manufacturers to review their AWP reporting practices "to confirm that marketing considerations do not influence the process."

- Switching payments for products reimbursable under Federal health care programs.

- Physician consulting and advisory payments that do not reflect "actual, reasonable, and necessary services and that are not merely token arrangements created to disguise otherwise improper payments."

- The draft guidance states that arrangements such as entertainment, sponsorship of third-party educational conferences, scholarships, and grants raise particular risks. With respect to these practices, however, "a good starting point for compliance purposes" is the PhRMA Code on Interactions with Healthcare Professionals.

- Compensation to sales agents that does not fall within the safe harbors of 42 C.F.R. §§ 1001.952(d) and (i) (the safe harbors for personal services contracts and compensation to employees).

Drug Samples. The draft guidance emphasizes the importance of adhering to the Prescription Drug Marketing Act ("PDMA") with respect to samples. Samples should be clearly marked that they are not to be sold, and sales forces should be trained appropriately.

OIG Views on the PhRMA Code

As noted above, the draft guidance states that the PhRMA Code on Interactions with Healthcare Professionals may serve as a compliance benchmark with respect to such activities. The draft guidance states, "Arrangements that fail to meet the [Code's] minimum standards … are likely to receive increased scrutiny from government authorities." The draft guidance, however, does not create a safe harbor in the PhRMA Code. The OIG states that "compliance with the relevant sections of the PhRMA Code will not necessarily protect a manufacturer from prosecution or liability for illegal conduct." The OIG appears to be implying that the PhRMA Code represents a minimum standard, but companies may want to exceed this standard.

Implications for Pharmaceutical Companies

The draft OIG guidance represents a significant attempt by HHS to address certain pharmaceutical practices that could affect Federal reimbursement rates and rebates, as well as the drugs prescribed to beneficiaries of Federal health care programs such as Medicare and Medicaid. These practices affect, among other things, pharmaceutical pricing, marketing, educational programs, and grants. In some instances, particularly with regard to recognition of the PhRMA guidelines, the OIG has indicated its willingness to clarify what it considers to be appropriate conduct. The draft guidance also describes the structural components of a robust compliance program.

As mentioned above, pharmaceutical companies and others have two months to submit comments on this draft guidance.

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Arnold & Porter's Food, Drug & Medical Device Practice Group provides counsel on a wide-range of issues for pharmaceutical and medical device companies. If you would like more information about the Draft OIG Compliance Program Guidance for Pharmaceutical Manufacturers, or other compliance-related issues, please do not hesitate to contact us.

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