ARNOLD & PORTER UPDATE

HHS OIG Guidance Raises Concerns About Pharmaceutical Sales and Marketing Practices

Government Also Cautions Medical Device Companies on Such Practices

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On April 28, 2003, the Office of Inspector General, Department of Health and Human Services ("HHS OIG") released the final version of its Compliance Program Guidance for the Pharmaceutical Industry ("Pharmaceutical Guidance" or "Guidance") [1]. The guidance reflects the government's continuing concern about sales and marketing practices by pharmaceutical manufacturers, including manufacturer relationships with physicians, pharmacy benefit managers (PBMs), and others in a position to prescribe or recommend their products. Federal and state health care enforcement agencies have brought a number of high-profile criminal and civil actions against pharmaceutical manufacturers. The release of Guidance signals that investigations of pharmaceutical sales and marketing practices will continue to be a top enforcement priority for the HHS OIG and other health care fraud enforcement agencies.

Background on HHS OIG Compliance Guides

The HHS OIG has now released eleven "Compliance Program Guides" for various sectors of the health care industry. The Pharmaceutical Guidance, like past guidances from the HHS OIG, is based generally on the seven elements of an effective compliance program in the U.S. Sentencing Commission Organizational Guidelines. While voluntary, compliance with the HHS OIG guidance is a factor that may be considered by health care fraud agencies when deciding whether to prosecute or settle a particular case.

Scope of the Pharmaceutical Industry Guidance

The Pharmaceutical Guidance is designed to assist pharmaceutical manufacturers "in developing and implementing internal controls and procedures that promote adherence to

[1] The Guidance is available on the HHS OIG website: http://oig.hhs.gov/fraud/docs/complianceguidance/042803pharmacymfgnonfr.pdf

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applicable statutes, regulations, and requirements of federal health care programs [e.g., Medicare and Medicaid]." While focused largely on sales and marketing activities, the Guidance also addresses educational and research funding activities of pharmaceutical companies.

Application to Medical Device Companies

While the Guidance is addressed primarily to pharmaceutical manufacturers, the Guidance states that it "may also have applications to manufacturers of other products that may be reimbursed by federal health care programs, such as medical devices and infant nutritional products."

Risk Areas: Sales and Marketing Practices Likely to Draw Scrutiny

The Pharmaceutical Guidance describes sales and marketing activities "that present potential risk of liability under several key fraud and abuse statutes and regulations." The Guidance focuses on "areas that are currently of concern to the enforcement community," but is not a comprehensive listing of all potential risk areas for pharmaceutical manufacturers. While the Guidance makes clear that the identification of a risk area does not mean that the activity is "necessarily illegal in all circumstances," manufacturers should review such activities carefully to avoid running afoul of federal health care program rules. Moreover, the Guidance encourages companies to develop specific policies and procedures around such activities to reduce the risk that they violate applicable laws.

The guidance groups risk areas into three major categories – integrity of data used to establish or determine government reimbursement, kickbacks and other illegal remuneration, and drug samples – with the bulk of the discussion devoted to anti-kickback issues. Some of the risk areas discussed in the guidance and the OIG's recommendations are outlined briefly below.

(1) Integrity of Data Used to Establish or Determine Government Reimbursement

- The guidance asserts that a manufacturer may be liable under the False Claims Act if: (1) government reimbursement (including Medicare or Medicaid reimbursement) for a product depends partly on pricing information it reported "directly or indirectly"; and (2) the manufacturer knowingly (including recklessly) failed to report such information "completely and accurately."
- "Where appropriate," manufacturers' reported prices should take into account discounts, rebates, "free goods contingent on a purchase agreement . . . up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits" offered to purchasers.
- The guidance makes clear that accurate net prices must be calculated in bundled sales, stating that "any discount…offered on purchases of multiple products should be fairly apportioned among the products."
- The guidance urges manufacturers to "pay particular attention to . . . calculating Average Manufacturer Price and Best Price accurately," but does not provide instructions on Medicaid rebate calculations specifically.

(2) Kickbacks and Other Illegal Remuneration

Discounts and Other Price Concessions

- Manufacturers should carefully review discounts and other price concessions offered to customers. If possible, discounts should be structured so as to fall within the discount safe harbor. Manufacturers also should carefully review "prebates," "upfront payments," and "conversion" payments to customers.
- In the pharmaceutical context, discounts "deserve careful scrutiny particularly because of their potential to implicate the Best Price requirements of the Medicaid Rebate Program," and the OIG fears that manufacturers have "a strong financial incentive to hide *de facto* pricing concessions" that could otherwise affect their Best Price calculations and trigger increased Medicaid rebates.

Educational and Research Funding

- To reduce their risks, manufacturers should divorce educational and research grants and contracts from their sales and marketing functions.
- Educational and research funding should not be linked in any way to the funding recipient's purchases or capacity to generate business for the manufacturer.
- Manufacturers should have no control over the content of funded educational activities. It is not clear why this is an anti-kickback issue but, in any event, the OIG has embraced FDA's CME guidance, and also identified "codes of conduct promulgated by the CME industry" as "a useful starting point for manufacturers." This makes the proposed changes to the ACCME standards more critical, since the ACCME standards are apparently viewed by the OIG as pertinent to anti-kickback compliance.
- Post-marketing research and research not reviewed by a manufacturer's science component deserve heightened scrutiny.

Formularies and Formulary Support Activities

- In several cases, the OIG's pronouncements on formularies involve practices under the control of the PBM — not the manufacturer.
- Formularies are unlikely to raise significant anti-kickback issues as long as "the determination of clinical efficacy and appropriateness of formulary drugs by the formulary committee precedes, and is paramount to, the consideration of costs."
- Manufacturers should "review their contacts with sponsors of formularies to ensure that price negotiations do not influence decisions on clinical safety and efficacy." Any remuneration from a manufacturer to a person capable of influencing formulary decisions is "suspect" and warrants careful scrutiny.

- Manufacturer rebates to PBMs (and other payments to PBMs based on sales to the PBM's clients) can be protected under the GPO safe harbor, essentially by requiring the PBM to make the same disclosures about vendor payments to its clients that a GPO makes to its members. This is likely to fuel the growing trend toward transparency in the PBM industry.

- Manufacturers should still avoid ("carefully scrutinize") "lump sum" payments to PBMs for formulary inclusion or placement. Payments to fund PBM formulary support activities – "especially communications with physicians and patients" – also have a semi-suspect status.

AWP

- The guidance states that "it is illegal for a manufacturer knowingly to establish or maintain a particular AWP if one purpose is to manipulate the 'spread' to induce customers to purchase its product," and manufacturers should thus "review their AWP reporting practices and methodology to confirm that marketing considerations do not influence the process."
- The guidance states that pharmaceutical manufacturers generally report either AWP "or pricing information used by commercial price reporting services to determine AWP," but does not specifically mention WAC or specify whether its recommendation regarding AWP reporting applies to WAC.

Payments to Physicians for Consulting, Advisory, Speaking and Preceptorship Services

- At least generally, fair market value payments to "small numbers" of physicians for bona fide consulting and advisory services are unlikely to raise significant concerns.
- Manufacturers should structure these arrangements to fit within the personal services safe harbor whenever possible, and, at a minimum, should ensure that:
  - The consulting or advisory arrangement is in writing;
  - There is a legitimate need for the services;
  - The services are in fact provided;
  - Compensation is fair market value; and
  - All of the preceding criteria have been documented prior to payment.
- Certain types of service arrangements with physicians create heightened concerns, i.e.:
  - Services connected to a manufacturer's marketing activities, "such as speaking, certain research, or preceptor or 'shadowing' services" and "ghost-written articles"; and
  - "Consulting" arrangements where the physician attends meetings or conferences "primarily in a passive capacity."

Payments for Detailing

- Paying physicians for their time spent listening to marketing presentations is "highly susceptible to fraud and abuse, and should be discouraged."
- The same is true for variations on pay-for-detail arrangements (paying "consulting" fees for a physician to complete "minimal paperwork," or paying physicians for the time spent "accessing websites to view or listen to marketing information or perform 'research'").

Relationships with Sales Agents

- Payments to sales agents should be "carefully reviewed" if they do not fit within a safe harbor (i.e., the employee safe harbor or, for contracted sales agents, the personal services safe harbor).
- Even if compensation payments to sales agents fit within a safe harbor, they "can still be evidence of a manufacturer's improper intent when evaluating the manufacturer's relationships with [potential referral sources]" – for example, providing sales agents with "extraordinary incentive bonuses and expense accounts" might support an inference that the manufacturer "intentionally motivated the sales force to induce sales through lavish entertainment or other remuneration."

(3) Drug Samples

- The basic message in the OIG's discussion of drug samples is that pharmaceutical manufacturers should adhere strictly to the Prescription Drug Marketing Act (PDMA), which forbids the sale of samples.
- The guidance does not address "sample" programs not covered by the PDMA, such as "virtual" sample programs or sample programs involving products other than drugs. However, the guidance recognizes that when physicians cannot sell or bill for samples this "vitiat[es] any monetary value of the sample," thus suggesting that measures to prevent the sale or billing of samples should reduce the anti-kickback risks associated with any type of sample program.

The PhRMA Code

The final Guidance describes the PhRMA Code on Interactions with Healthcare Professionals (the "PhRMA Code")[2] as "useful and practical advice for reviewing and structuring relationships" with physicians and others in a position to prescribe or influence the purchase of a company's products. While compliance with the PhRMA Code is not a legal safe harbor, the HHS OIG states that compliance " will substantially reduce the risk of fraud and abuse and help

[2] The PhRMA Code is available on the website of the Pharmaceutical Research and Manufacturers of America, www.phrma.org.

demonstrate a good faith effort to comply with the applicable federal health care program requirements." Because the PhRMA Code offers far more explicit guidance on many (but not all) of the risk areas in the Guidance, companies are well advised to incorporate the PhRMA Code in their compliance policies and program.

Elements of An Effective Compliance Program

As noted above, the HHS OIG recommends that all pharmaceutical manufacturers develop a compliance program that, at a minimum, contains several essential elements. According to the HHS OIG, the major elements are:

(1) *Written policies and procedures, including specific policies and procedures for identified risk areas.* Company policies should include a high-level Code of Conduct, along with detailed policies and procedures addressing identified risk areas and other aspects of the compliance program.

(2) *A compliance officer and compliance committee.* The Guidance calls on every manufacturer to designate a compliance officer "to serve as the focal point for compliance activities." The compliance officer should have direct access to the company's Board and senior management, and sufficient authority to effectuate change with regard to compliance issues. The Guidance discourages companies from making the Compliance Officer subordinate to the General Counsel or other officer below the level of CEO. The Guidance suggests that companies establish a compliance committee to support the Compliance Officer and designate compliance officers or liaisons in companies with more than one division or business unit.

(3) *Education and training programs*. The Guidance recommends that manufacturers establish compliance education and training programs for all employees and independent contractors, with specialized training for employees responsible for activities in identified risk areas.

(4) *Internal lines of reporting and communication (e.g., compliance hotlines).* The HHS OIG suggests that companies establish internal mechanisms to allow employees or others to ask questions about compliance issues or to report, without fear of retribution, potential violations of law or company policy. The OIG identifies internal "hotlines" as one potential mechanism.

(5) *Auditing and monitoring programs*. Manufacturers should develop procedures to monitor and audit the effectiveness of the compliance program.

(6) *Consistent enforcement of disciplinary standards.* Compliance programs should provide for sanctions for violations of law and company policy, up to and including termination. Moreover, the procedures should ensure that disciplinary standards are fairly and consistently enforced. The HHS OIG also suggests that manufacturers screen employees and independent contractors against the OIG's List of Excluded Persons.

(7) *Procedures for responding to potential violations of law or company policy.* The HHS OIG calls on companies to ensure that they respond appropriately to reports of compliance violations, ensure that future violations do not occur and (where appropriate), self-report violations to governmental authorities.

Conclusion

The Pharmaceutical Guidance is an important milestone in the evolution of compliance activities in the pharmaceutical industry. The final Guidance provides benchmarks against which a pharmaceutical manufacturer can assess the structural elements of a compliance program. It also identifies a wide range of risk areas of concern to the government, many of which are also relevant to other sectors of the health care industry. Manufacturers would be well advised to review their current activities in these risk areas and to develop written policies, procedures and internal controls to help assure that their activities comply with federal health care program rules. The risks of non-compliance – including civil and criminal prosecution of individuals and entities, exclusion from federal health care programs, and related private litigation – are substantial.

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Arnold & Porter's Pharmaceutical and Medical Device Team has counseled numerous drug and device companies on compliance with the entire range of Federal health care program rules and regulations, including the anti-kickback statute, Medicaid Rebate Act, and other fraud, abuse, and compliance laws. Within the recent past, our team has:

- Performed comprehensive assessments of sales and marketing practices for several major pharmaceutical and device companies,
- Conducted internal investigations relating to compliance with company policies and Federal health care rules,
- Drafted policies and procedures for a variety of sales and marketing practices,
- Developed and delivered compliance training programs,
- Benchmarked company compliance programs against HHS OIG and Sentencing Commission guidelines, and
- Assisted companies in implementing compliance hotlines, compliance-related disciplinary procedures, and codes of business conduct.

If you would like more information about Arnold & Porter's capabilities in these areas, please do not hesitate to contact one of the following:

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