Establishing Responsible Relationships with Drug and Device

How Physician Practices and Hospitals Can Safeguard Against Fraud and Abuse

The Office of the Inspector General (OIG) of the Department of Health and Human Services (HHS), the Department of Justice (DOJ), and various state attorneys general each have singled out certain marketing practices by pharmaceutical companies as potential violations of federal and state fraud and abuse laws. This enforcement activity has raised concern among providers who fear that their interactions with pharmaceutical companies may also come under intense scrutiny from federal authorities.

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Federally subsidized drug costs are a frontline concern of Congress. Drugs command an increasing piece of the health care dollar, and soon even more pharmaceutical products will be eligible for Medicare reimbursement. This climate has led enforcement agencies to more closely examine the promotional activities of drug and device manufacturers and the response of health care professionals to these promotions.

The increased prevalence of formularies and group purchasing organizations and competition among drug companies for formulary placement has spurred an intense examination of how manufacturers' products are chosen. Pharmaceutical contracts and services are growing more complex—evolving from distributing complimentary prescription pads to subsidizing a consultant contract worth thousands of dollars. The government may perceive these contractual agreements as having the potential to unduly influence a physician's prescribing judgment.

The OIG has stated that it will be examining many types of arrangements among sellers, buyers, and prescribers of pharmaceutical products to determine whether they contain overt or disguised incentive payments intended to induce physicians to prescribe a particular manufacturer's product. According to the OIG's 2002 Work Plan, the agency "will evaluate the extent of gifts and payments to providers from pharmaceutical companies. The pharmaceutical industry currently spends about $12 billion a year on marketing to providers, and some of these gifts may present an inherent conflict of interest between the legitimate business goals of manufacturers and the ethical obligations of providers to prescribe drugs in the most rational way."

DOJ representatives have publicly announced their intention to continue to examine both sides of the transaction—manufacturers and physicians—for unlawful actions that leave both sides vulnerable to potential prosecution. In addition, several state attorneys general have filed broad, consumer-based suits that appear poised to name providers as defendants as identities are uncovered during the discovery process.

Caveat Emptor!

Providers are responsible for exercising their professional judgment when providing or ordering medical care. If a provider prescribes drug X instead of drug Y for any reason related to financial gain or need—even if the patient is requesting one product instead of the other—they might incur legal risks. For example, if a physician prescribed drug X because it was cheaper or because the patient had a free-trial or copay-waiver coupon, malpractice allegations could be filed if drug X caused problems or was generally proven to be less effective than drug Y. Providers may not be able to insulate themselves

Manufacturers

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from malpractice liability merely by demonstrating that their patients requested the cheaper drug.

This equation becomes even riskier if the financial incentives flow to the prescriber. Federal and state governments are actively investigating cases where there is a "spread" between what it actually costs to purchase a drug and what the provider is reimbursed by third-party payers, which is typically based on the reported average wholesale price (AWP). If a practice shows a pattern of choosing the drug with the biggest "spread," or changes from one drug to another for reasons related to the profits reaped from high reimbursement (referred to as "return to practice" in the article about TAP Pharmaceutical Products on page 35), the practice may be placed in the difficult position of demonstrating that prescribing decisions were not motivated by personal financial incentives.

Furthermore, although Medicare reimbursement is still tied to AWP, physicians cannot safely assume that Medicaid reimbursement follows the same logic. A significant number of states require physicians to bill Medicaid at their *actual acquisition cost* for the drug product, or at wholesale cost. In such cases, billing Medicaid at the same rate as Medicare could be considered indefensible.

Hospitals, Be Aware

Hospitals generally bear legal responsibility for any acts performed by employees and agents acting on their behalf. If a hospital pharmacy purchasing employee or agent improperly solicits benefits from a manufacturer or otherwise enters into a contract that violates the fraud and abuse laws, the hospital could be held liable for that conduct.

This is not to say that hospitals are prohibited from negotiating discounted prices for pharmaceuticals. There are special "safe harbors" in the federal anti-kickback law that permit drug manufacturers to extend discounts to hospitals and other purchasers. If drug manufacturers comply with all the requirements of a safe harbor, they will not be at risk of prosecution under the anti-kickback law.

Hospitals must meet certain obligations to qualify for a safe harbor. To the extent it is able or required to do so, the hospital must properly disclose the negotiated discount so the government may also take advantage of the savings by adjusting its reimbursement to reflect the actual cost of the service components. A hospital was recently prosecuted for failing to inform the government it had received a discount from a manufacturer of X-ray film. The manufacturer, on the other hand, had properly advised the hospital that the price of the product included a discount and was not found to have violated the anti-kickback law (*U.S. ex rel. Walsh v. Eastman Kodak Company, 47 Fed.R.Serv.3rd 97*).

Hospitals are generally paid a set, diagnosis-determined amount by federal programs, and do not usually have any incentive to choose drugs with a spread, although they do benefit from lower-priced products. Hospitals should not make formulary decisions based solely on financial considerations, and should be careful not to forge buying group affiliations that will force them to limit their access to a full range of drug and device choices. Furthermore, hospitals must carefully question "bundled" arrangements that permit them to obtain free equipment or services in return for paying an undiscounted price for drug products. The discount safe harbor may not cover a sale that involves multiple items or products unless all of the bundled items are reimbursed by the federal payers using the same methodology.

In summary, all providers, including hospitals, reduce risks if they make formulary and purchase decisions that focus on and prove to be in the best interests of their patients.

Establishing A Responsible Relationship with Manufacturers

Providers should avoid establishing risky relationships with the pharmaceutical industry, particularly ones that create a perception of violating the federal anti-kickback law. One such relationship, known as product conversion payments or "push fees," occurs when a pharmaceutical company offers a cash award or another benefit (such as frequent flyer miles) to retail pharmacies or pharmacy benefit management companies that directly or indirectly help persuade providers to chose or switch from one pharmaceutical product to another. The switch is generally between therapeutically equivalent, but not generically equivalent, products, and some patients who are switched may complain of adverse reactions or reduced effectiveness.

Research grant programs also can be viewed as potential violations of the anti-kickback law if the research grant is little more than a "sham." For instance, a pharmaceutical company may pay providers substantial amounts for useless research or *de minimus* record keeping tasks relating to a research project. The amount of funding received by a provider who accepts a grant should be equivalent to the fair market value of the work actually completed, and the grant award or administration should be independent of all product-purchasing decisions. Similarly, pharmaceutical companies should not underwrite (and physicians should not accept) trips to continuing education conferences. An exception may be made if the physician is speaking on behalf of the

How Best to Comply and Reduce Your Risk

Compliance plans should address the pharmaceutical and device issues that are the focus of government attention, as well as:

1 *Ensure that billings are correct.* Moreover, be sure that billings are submitted only for medically necessary and covered procedures, that free samples are not improperly billed to payers, and that the books and records of the practice properly reflect all discounts received on drug and device purchases.

2 *Establish stringent protocols and rules for dealing with sales representatives and manufacturers.* A set "no gifts accepted" policy is the easiest to enforce and the least risky. Staff should be trained not to solicit or accept inappropriate payments or benefits from manufacturers. For example, it is safest if practices do not allow manufacturers to directly or indirectly subsidize those functions that properly fall within the office's overhead (i.e., organizing and stocking medicine shelves, doing billing paperwork for the physician). Also, physicians should not place standing orders for routinely delivered free samples for products, even when they are careful not to bill for them.

3 *Develop policies and procedures regarding receipt of grant money and participation in clinical trials.* Grant money should not be tied to an agreement to purchase or prescribe a particular product. Practices and hospitals should document the time and costs associated with their responsibilities in clinical trials because the government may underestimate the actual burden of participation in the absence of written proof. If the grant involves the administration of a pharmaceutical product, the manufacturer that is subsidizing the research or clinical trial should supply the product, and drug product costs should not be billed to an insurer (*U.S. ex rel. Hamel v. Fresenius, DCMA*, Civ. *99–12455–N.G.* settled 05/03/02)

4 *Include a Code of Conduct that applies to all employees, including independent contractors.* The practice should also develop and enforce protocols to monitor self-referrals, anti-kickbacks, and improper inducements.

5 *Appoint a compliance officer and develop a job description that outlines the responsibilities of the job.* The compliance officer should educate all employees and independent contractors on the practice's Code of Conduct, and be available to answer questions or investigate complaints.

6 *Include policies that reflect state laws and regulations regarding the practice and dispensing of medicine.* Make sure that access to appropriately labeled pharmaceutical samples is subject to procedural controls that prevent theft or diversion. All staff should be educated on the importance of accurate and contemporaneous documentation with regard to drug dispensing and prescribing. For example, if a physician switches a patient from one drug to another for sound medical reasons, ensure that those reasons are documented in the medical record. If samples are given to a patient, that also should be noted.

7 *Take seriously any fraud and abuse concerns raised by employees.* Respond to detected violations and ensure that the compliance officer keeps track of all actions taken to correct known problems. If employees believe their concerns have been downplayed or responded to with meaningless statements, they may be more likely to file a whistleblower lawsuit alleging intentional fraud. Organizations should conduct exit interviews with departing employees to both test the compliance plan and to help detect aberrant practices. If documented, these interviews may help a company defend against allegations of fraud made by the exiting employee.

Of course, obtaining and documenting complaints are not enough. The organization must also respond to and correct any valid concerns. When dealing with potential violations, the organization and the compliance officer should work with an attorney specializing in health care compliance to develop and implement corrective action.

pharmaceutical company's product or otherwise rendering a legitimate and valuable service to the manufacturer.

If the government identifies even one purpose of a benefit as an inappropriate inducement for a provider to choose a product paid in full or in part with federal funds, it may seek to prosecute the provider under the federal anti-kickback law. Physicians should not ask for benefits of any type in return for meeting with a sales representative.

In April 2002, the pharmaceutical industry released new guidelines governing relations with providers. Pharmaceutical companies should use these guidelines as a tool to ensure that they are not using economic incentives to influence providers to prescribe their products—a violation of the anti-kickback law. In the guidelines, the Pharmaceutical Research and Manufacturers of America (PhRMA) advises that, "Nothing should be offered or provided in a manner or conditions that would interfere with the independence of a health care professional's prescribing practices." (Visit:*http://www.phrma.org/publications/documents/backgrounders//2002-04-19.388.phtml*, to learn more about these voluntary guidelines that took effect July 1, 2002.)

Although drug companies may pay for modest meals that accompany discussions of educational or scientific value, or provide doughnuts when educating staff on a

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…ignorance will NOT EXCUSE providers from repaying amounts billed in error…

TAP Turns It Around

TAP Pharmaceutical Products, Inc., has established one of the most comprehensive and innovative ethics and compliance programs in the industry. Led by TAP's ethics and compliance officer, Steve Vincze, who was recently named Chairman of the Health Care Compliance Association's Compliance Program Measurement Task Force, the program is supported by an ethics and compliance committee—comprised of senior management—that assists in compliance efforts and investigations into reported violations.

Since 1999, annual training on ethical and legal business practices is mandatory for *every* TAP employee and contractor, and is part of every employee's annual performance review. TAP's ethics and compliance training uses computer-based interactive modules to educate employees on company and government laws, as well as place employees in different workplace scenarios. An anonymous, internal hotline is available to employees reporting inappropriate activities or requesting guidance on compliance issues.

The program is in response to a six-year federal investigation into the marketing of Lupron, TAP's drug used to treat prostate cancer and infertility, which resulted in the largest health care fraud settlement in history. On Oct. 3, 2001, federal officials announced that TAP had agreed to pay $875 million to resolve criminal and civil charges based on fraudulent drug pricing and marketing conduct.

TAP pleaded guilty to providing free samples of Lupron to providers, who in turn sought Medicare reimbursement for administering the free sample. The free samples and an alleged reimbursement spread—which TAP emphatically denied—were believed to have induced providers to prescribe Lupron over its competitor, Zoladex. (For the first quarter of 2002, TAP reported $209 million in sales of Lupron, a 3.6 percent increase from 2001 first-quarter sales.)

TAP was also accused of giving providers trips to expensive resorts, providing free consulting services and medical equipment, and forgiving practice debts to compensate for unpaid beneficiary copayments. The legal claims included conspiracy to defraud Medicaid by failing to offer this program its best commercial prices, conspiracy to violate the Prescription Drug Marketing Act (by causing free samples to be illegally billed to the Medicare program), and violations of the federal anti-kickback statute.

new product line, they should not pay for entertainment or purely recreational events. The complimentary distribution of cups, pens, notepads, and items that will directly or indirectly benefit patient care is deemed acceptable. Items unrelated to patient care, such as sports tickets, should not be offered or accepted.

Perhaps the biggest change is that the guidelines advise against drug manufacturers' paying for selected individual providers to attend continuing medical education or professional conferences. Instead, the guidelines suggest that manufacturers subsidize the conference itself so the sponsor can use the money to reduce the conference registration fee for all attendees.

The Compliance Plan—How to Protect Against Claims of Fraud and Abuse Violations

Given the increased enforcement of anti-kickback and fraud and abuse laws, providers should stay abreast of changes in the regulatory landscape and establish procedures and protocols that will protect them in their hospital and medical practices.

Since the OIG has stated that compliance planning is recommended for all medical practices as of Jan. 1, 2001, ignorance will not excuse providers from repaying amounts billed in error and/or shield them from severe monetary penalties for overbilling or anti-kickback violations. Private practices and hospitals should carry out regular compliance reviews and self-assessments.

The OIG has designated physician offices as a high priority target for fraud and abuse audits in four areas: billing and coding, medical necessity documentation and compliance with self-referral regulations, anti-kickbacks, and improper inducement regulations. A compliance plan should be focused on controlling risk-oriented behavior in these target areas.

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