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End Game for Pharmaceutical Kickbacks

By Kenneth J. Nolan, for HealthLeaders News, Sept. 3, 2003

SUMMARY (full story below)

Taking inducements to prescribe certain drugs is more than ethically questionable. It's against the law, says HealthLeaders member Kenneth Nolan, and healthcare leaders had better know what the penalties are and how to avoid any trouble in the first place.

FULL STORY

The pharmaceutical industry in recent years has spent more than $10 billion annually on "marketing." Some would argue that a relatively significant portion of this may have been used to provide unlawful inducements in exchange for prescriptions. True or not, now is the time for healthcare leaders to understand that every healthcare organization that violates the federal Anti-kickback Statute by accepting benefits from a pharmaceutical company is risking civil and criminal liability, and that the only way to protect themselves in the future is to build a firewall between themselves and the pharmaceutical industry.

The federal Anti-kickback Statute, 42 U.S.C. § 1320a-7b(b), prohibits any person or entity from making or accepting payment to induce or reward any person for referring, recommending or arranging for federally-funded medical

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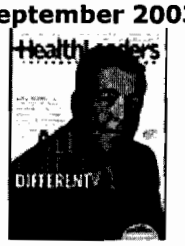

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services, including services provided under the Medicare, Medicaid and TRICARE programs. It arose out of congressional concern that payoffs to those who can influence healthcare decisions will result in goods and services being provided that are medically unnecessary, of poor quality, or even harmful to a vulnerable patient population.

To protect the integrity of the program from these difficult-to-detect harms, Congress enacted a per se prohibition against the payment of kickbacks in any form, regardless of whether the particular kickback gave rise to over-utilization or poor quality of care.

Protection from Investigation

Healthcare leaders must take steps to ensure that their company's relationships with pharmaceutical companies withstand the strict scrutiny that is emerging. Healthcare organizations, not just physicians, must re-examine how they are interacting with pharmaceutical companies, and take steps to avoid the receipt of anything of value. Compliance oversight must be directed not just to physicians, but also to pharmacy directors, purchasing agents, department directors, materials management professionals, and anyone else who is in a position to receive cash, services, or items of value from pharmaceutical companies.

Since 1990, when the American Medical Association's Council on Ethical and Judicial Affairs first created guidelines on gifts to physicians from the pharmaceutical industry, they have largely been ignored. What's worse, they were filled with loopholes and gray areas, opening the door to the next wave of fraud and abuse. For example, they allowed for gifts to doctors from pharmaceutical companies, but stipulated that they should be of benefit to patients and of minimal value. They permitted industry subsidies for conferences and meetings, but prohibited them from being given directly to doctors. Camels could get in through the eye of these needles--and they did.

Reality check: Since 1999, there has been a groundswell of government investigations, civil lawsuits and criminal prosecutions, all concerning the sales, marketing and pricing practices of pharmaceutical companies. Indeed, major drug companies, including Bristol-Myers Squibb, Biovail Corp., and Schering-Plough Corp., just to name a few, face government probes of sales and marketing practices. TAP Pharmaceutical Products Inc., Pfizer Inc., AstraZeneca Pharmaceutical, L.P., Bayer Corp. and GlaxoSmithKline, for example, have relatively recently resolved cases in which their marketing and/or pricing practices were at issue.

Even legislators have joined the hunt. In June, the House Energy and Commerce Committee sent letters to over two dozen pharmaceutical companies as part of its investigation into pharmaceutical reimbursements and rebates under the Medicaid program.

Voluntary Compliance

In the wake of these investigations, as well as increasing government and whistleblower scrutiny concerning sales and marketing practices, the pharmaceutical industry banded together through the Pharmaceutical Research and Manufacturers of America ("PhRMA") to adopt a voluntary code on interactions with physicians. The text of the "PhRMA code" can be found online here . Adopted on April 18, 2002, the new code went into effect for PhRMA's members on July 1,

2002. While the effectiveness of a voluntary code may be questionable to some, it marked a first step in the recognition that compliance with the federal Anti-kickback Statute had increasing importance.

Risk areas for healthcare organizations and pharmaceutical companies include:

1. Price concessions and similar benefits (kickbacks) made to induce the purchase of prescription drug products, which in turn would violate the federal Anti-kickback Statute.
2. Switching arrangements, where pharmacies, PBMs, or other controllers of the market are offered cash payments or other benefits each time a patient's prescription is changed to the manufacturer's product from a competing product.
3. Consulting and advisory payments, created to disguise kickbacks, and not made on the basis of a legitimate arrangement with a physician to perform research, data collection, etc.
4. Other remuneration, including entertainment, recreation, travel, meals, sponsorship or other financing relating to third party educational conferences, including grants and scholarships, gifts and gratuities.
5. The practice of providing drug samples (usually injectable or cancer drugs which are directly billable by healthcare providers) provided to physicians who, in turn, bill them to the federal healthcare programs.
6. The purposeful manipulation of the AWP (a benchmark for Medicare and Medicaid reimbursement) to increase physician or institutional profits - known as "marketing the spread"-a practice that could alter a physician's judgment.

In April, 2003, the Department of Health and Human Services, Office of Inspector General ("OIG") released its final "Compliance Program Guidance For Pharmaceutical Manufacturers."

"This Guidance explains the value of compliance programs and details specific elements that pharmaceutical manufacturers should consider when developing and implementing an effective compliance program," Former Inspector General Janet Rehnquist said at the time of its release. "It is designed to help companies prevent healthcare fraud and abuse by promoting a high level of ethical and lawful corporate conduct." The Guidance is available online here .

Like it or not, healthcare organizations now have no choice but to adopt a policy of zero tolerance regarding accepting pharmaceutical marketing inducements. Those who claim that pharmaceutical companies have a right to advertise and educate healthcare professionals about their products are purposely trying to muddy the issue. Legitimate education and advertising is in no way, shape, or form to be confused with giving remuneration or items of value as inducements to prescribe their drugs -- and deep down, everyone knows the difference between the two.

The best way for healthcare organizations to protect themselves is to accept nothing, not even the slightest trinket,

from a pharmaceutical company. Without a firewall between themselves and pharmaceutical companies, healthcare organizations are opening the door for the next round of qui tam whistleblowers and government enforcement to be directed at them - not just at the pharmaceutical companies. Times have changed. Pharmaceutical companies have begun the process - healthcare organizations must change with them -or hold themselves responsible for the negative consequences of their own making.

Kenneth J. Nolan is the president of Kenneth J. Nolan, P.A., a law firm dedicated to the representation of qui tam relators, a unique mechanism in the law that allows persons and entities with evidence of fraud against federal programs or contracts to sue the wrongdoer on behalf of the government. Contact Kenneth J. Nolan at 800-372-8304 or mailto:%20info@health-care-fraud.comThis article is intended for informational purposes only, and should not be construed as legal advice.

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