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Drug Manufacturer Education Grants To Purchasers May Be Kickback, IG Says

05/05/2003

THE-PINK-SHEET, May 5, 2003, Page 3

Education and research grants to purchasers from pharmaceutical manufacturers may violate the anti-kickback statute, the HHS Inspector General's compliance guide contends.

"While educational funding can provide valuable information to the medical and health care industry, manufacturer grants to purchasers, [group purchasing organizations], [pharmacy benefit managers] and similar entities raise concerns under the anti-kickback statute," the IG guide states.

"Manufacturers should establish objective criteria for making grants that do not take into account the volume or value of purchases made by, or anticipated from, the grant recipient and that serve to ensure that the funded activities are bona fide."

IG published the voluntary "Compliance Guidance for Pharmaceutical Manufacturers" on its website April 28. The guide will be published in the Federal Register the week of May 5. The draft compliance guide was issued last fall ("The Pink Sheet" Oct. 7, 2002, p. 11).

In addition to basic compliance recommendations, the guide includes a discussion of three "major potential risk areas" for manufacturers: "integrity of data used by state and federal governments to establish payment;" "compliance with laws regulating drug samples;" and "kickbacks and other illegal remuneration."

The IG guidance warns that contracts with purchasers for research services may be "suspect," particularly if they are offered in connection with sales contracts.

"As with educational grants, if linked directly or indirectly to the purchase of product, research grants can be misused to induce the purchase of business without triggering Medicaid Best Price obligations," the guidance notes.

"Postmarketing research activities should be especially scrutinized to ensure that they are legitimate and not simply a pretext to generate prescriptions of a drug," the guidance states.
Education and research programs for physicians must also be scrutinized, IG said.

"Research contracts that originate through the sales or marketing functions - or that are offered to physicians in connection with sales contacts - are particularly suspect," IG noted.
Manufacturers must take steps to ensure that educational programs for physicians are not

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being used "to channel improper remuneration to physicians or others in a position to generate business for the manufacturer or to influence or control the content of the program," the IG added.

Some companies have been shifting their promotional practices to continuing medical education to come into compliance with the Pharmaceutical Research & Manufacturers of America's marketing code ("The Pink Sheet" Nov. 4, 2002, p. 11). PhRMA adopted the voluntary marketing code April 18; it became effective July 1 ("The Pink Sheet" April 22, 2002, p. 3).

The guidance also warns manufacturers against compensating physicians for listening to sales reps detail products.
"In some cases, these payments are characterized as 'consulting' fees and may require physicians to complete minimal paperwork. Other companies pay physicians for time spent accessing web sites to view or listen to marketing information or perform 'research,'" the IG guidance states.

"All of these activities are highly suspect under the anti-kickback statute, are highly susceptible to fraud and abuse, and should be strongly discouraged."

The guidance dovetails with PhRMA's marketing code by providing "useful and practical advice" for structuring relationships with physicians, IG said.

Sen. Chuck Schumer (D-N.Y.) introduced a bill April 29 on industry gifts to physicians. The "Drug Company Gift Disclosure Act" (S 948) would require manufacturers to report to FDA "any gift, fee, payment, subsidy or other economic benefit with a value of $50 or more."

S 948 is similar to legislation proposed in 2002 to codify the PhRMA marketing guidelines ("The Pink Sheet" Aug. 12, 2002, p. 18).
The draft IG compliance guide viewed the PhRMA code as a "minimum standard." Industry had wanted IG to treat the PhRMA code as a safe harbor ("The Pink Sheet" Feb. 17, p. 19).

"Although compliance with the PhRMA code will not protect a manufacturer as a matter of law under the anti-kickback statute, it will substantially reduce the risk of fraud and abuse and help demonstrate a good faith effort to comply with the applicable federal health care program requirements," the final guidance notes.
The guidance recommends that safe harbors can be used to reduce the risk of an anti-kickback violation. "We recommend that pharmaceutical manufacturers structure arrangements to fit in a safe harbor whenever possible."

Manufacturer arrangements with PBMs may receive increased scrutiny due to rising federal program expenditures for coverage of outpatient pharmaceuticals, IG noted.

"Any rebates or other payments by drug manufacturers to PBMs that are based on, or otherwise related to, the PBM's customers' purchases potentially implicate the anti-kickback statute."
"In addition, some manufacturers provide funding for purchasers' or PBMs' formulary support activities, especially communications with physicians and patients. While the communications may not indirectly benefit the manufacturer, the primary economic beneficiary is typically the formulary sponsor."

During an April 29 analyst call, Caremark CEO Mac Crawford said the IG compliance guidelines will not affect its business practices.
"We're very comfortable with what our business practices are and where we sit today. We don't see that what's come out of these guidelines will have any material impact at all on any way that we do business," he said.

The draft guide discussed manufacturer payments to PBMs, but did not address the activities of PBMs.

The final guide says that safe harbor regulations for group purchasing organizations may be used by PBMs for payments from pharmaceutical manufacturers.

"That safe harbor requires, among other things, that the payments be authorized in advance by the PBM's customer and that all amounts actually paid to the PBM on account of the customer's purchases be disclosed in writing at least annually to the customer."
The guidance also states that safe harbors are available to pharmaceutical companies that have risk-sharing arrangements with PBMs. "Depending on the circumstances, protection for such arrangements may be available under the managed care safe harbors."

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U.S. warns drug makers on illegal sales practices

Robert Pear, New York Times

WASHINGTON, D.C. -- The Bush administration told drug companies Sunday that many of the techniques they use to sell their drugs run a high risk of violating federal fraud and abuse laws.

The warning came as the government issued a compliance guide for the drug industry, telling manufacturers they must not offer any financial incentives to doctors, hospitals, insurers or pharmacists to encourage or reward the prescribing of particular drugs.

Such payments have "a high potential for fraud and abuse," said the guide, issued by Janet Rehnquist, inspector general of the Department of Health and Human Services.

Federal law prohibits payments intended to generate business under Medicare or Medicaid, the federal health programs for 80 million older, disabled or poor people.

The law, known as the "antikickback statute," forbids some practices that are common in other industries, Rehnquist said. She said she was particularly concerned about marketing practices that drive up federal costs, interfere with clinical decisionmaking and lead to overuse or inappropriate use of drugs.

Medicaid and Medicare spend more than $30 billion a year on prescription drugs. The amount would soar if President Bush and Congress agreed on a plan to provide comprehensive outpatient drug benefits to older people.

Drug companies objected to many provisions of the compliance guide when the government invited public comment on its ideas in October. The final version of the document clarifies the government's interpretation of the law and explains why federal officials oppose some drug company practices, including offering doctors gifts, payments and entertainment.

"Any time a pharmaceutical manufacturer provides anything of value to a physician who might prescribe the manufacturer's product, the manufacturer should examine whether it is providing a valuable tangible benefit to the physician with the intent to induce or reward referrals," the compliance guide says.

"A lawful purpose will not legitimize a payment that also has an unlawful purpose," it states.

It also states that drug companies risk prosecution when they encourage the use of their products by making payments to health plans and to the companies that

manage drug benefits for millions of Americans. Such companies, known as pharmacy benefit managers, often receive money from the manufacturer of a drug if sales of that drug reach a certain level -- for example, 40 percent of all the prescriptions for, say, drugs that lower cholesterol.

The inspector general said such payments could violate the law.

Rehnquist also warned drug companies that their research and education grants must be divorced from their marketing, or they risk violating the law.

She also condemned a new arrangement under which drug companies pay doctors for listening to sales pitches.

These payments "are highly suspect under the antikickback statute, are highly susceptible to fraud and abuse and should be strongly discouraged," the guide states.

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VOLUNTARY COMPLIANCE GUIDANCE ISSUED FOR PHARMACEUTICAL MANUFACTURERS

The HHS Office of Inspector General (OIG) today issued final voluntary guidance for pharmaceutical manufacturers that outlines actions they can take to promote compliance with the rules and regulations of doing business with the Medicare, Medicaid and other federal health care programs.

"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," Inspector General Janet Rehnquist said. "It is designed to help companies prevent health care fraud and abuse by promoting a high level of ethical and lawful corporate conduct."

The voluntary guidance identifies potential risk areas for the drug industry and recommends various measures to guard against violating federal fraud and abuse laws, including implementing compliance programs, structuring business arrangements to fit in safe harbors, and utilizing OIG fraud alerts, bulletins and advisory opinions. While specific to pharmaceutical manufacturers, the guidance is also expected to be useful to hospitals, physicians and other health care providers that do business with pharmaceutical manufacturers, as well as health care providers that engage in similar financial arrangements.

The 56-page document, entitled *OIG Compliance Program Guidance for Pharmaceutical Manufacturers*, is available on the OIG Web site, and is to be published as a notice in the *Federal Register* the week of May 5. It is more expansive and detailed in its discussion of risk areas and compliance strategies than the draft version which was published in the *Federal Register* last October for public review and comment. That solicitation resulted in more than 140 responses, many of which are addressed in the final guidance.

The guidance identifies three major potential fraud and abuse risk areas for pharmaceutical manufacturers:

- integrity of data furnished by manufacturers;

- kickbacks and other illegal remuneration; and
- compliance with laws regulating drug samples.

The guidance emphasizes that drug companies are responsible for providing complete and accurate data to the government. Data reported by manufacturers are often used by the government to determine reimbursement under Medicare and Medicaid.

Drug companies are further cautioned about physician marketing activities, including making excessive payments for physician's consulting and research services, and offering inappropriate entertainment, recreation, travel, meals, gifts, gratuities, and other business courtesies to physicians and other health care providers who influence the prescribing of drugs. Payments by drug companies to physicians and pharmacists to switch patients to their drugs from a competitor's are cited as problematic, as are payments to a physician to listen to a drug representative's sales presentation.

The guidance notes that the Pharmaceutical Research and Manufacturers of America Code on Interactions with Healthcare Professionals, adopted on April 18, 2002, provides useful and practical advice for reviewing and structuring relationships with physicians and that adherence to the Code will substantially reduce the risk of fraud and abuse and help demonstrate a good faith effort to comply with the applicable federal health care program requirements.

Also addressed in the guidance are manufacturer arrangements with pharmacy benefit managers (PBMs). The guidance acknowledges the potential benefits of PBM arrangements in controlling drug costs, but cautions that arrangements with PBMs should be properly structured. It further notes that the safe harbor for group purchasing organizations may be available to PBMs.

Another area of concern to the OIG is the improper sale of drug samples. These sales have emerged as a major risk because of violations revealed by recent enforcement activities and the widespread industry practice of providing free samples to physicians. While noting that the public derives significant benefit from the distribution of free drug samples, the guidance warns that both the anti-kickback statute and the False Claims Act may be implicated when the federal health care programs are billed for the samples in violation of the Prescription Drug Marketing Act of 1987. Companies are urged to educate their sales forces and customers about the strictures that govern the distribution of free drug samples and forbids their sale.

This is the eleventh set of voluntary guidelines to be developed by the OIG. Earlier guidance was issued for clinical laboratories, hospitals, home health agencies, third-party billing companies, the durable medical equipment, prosthetics, orthotics and supply industry, Medicare+Choice organizations offering coordinated care plans, hospices, nursing facilities, individual and small group physician practices, and ambulance suppliers. All of the guidances are available on the OIG Web site at http://oig.hhs.gov/fraud/complianceguidance.html#1.

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