The Hidden Costs of Free Lunches: Fraud and Abuse in Physician-Pharmaceutical Arrangements

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When it comes to physician-pharmaceutical manufacturer relationships, the old adage "there's no such thing as a free lunch" has been given much support lately by federal fraud and abuse enforcement authorities. In light of recent enforcement developments and initiatives, physicians must now, more than ever, develop an understanding of the legal boundaries of regulatory and ethical guidelines and carefully evaluate their relationships with pharmaceutical manufacturers for compliance.

This article reviews existing regulatory and ethical guidance applicable to physician-pharmaceutical industry relationships, applies that guidance to common interactions between physicians and the industry, and offers tips for maintaining compliance.

Key Words: Fraud and abuse; physician-pharmaceutical manufacturer arrangements; anti-kickback statutes; Stark regulations.

Editor's Note: *This very important article delineates the relationship of physicians with pharmaceutical manufacturers. It behooves providers to be familiar with governmental regulations that define appropriate dealings with such firms and their representatives, as well the American Medical Association's ethical guidelines in these matters.*

Recent enforcement actions by federal fraud and abuse authorities have emphasized the need for physicians to make themselves aware of regulatory and ethical guidelines regarding their relationships with pharmaceutical companies.

For example, TAP Pharmaceutical Products Inc. entered into a civil settlement with the federal government in fall 2001 agreeing to pay $875 million to settle charges that it violated the federal Anti-Kickback Act and the False Claims Act by engaging in certain marketing activities related to its drug, Lupron.

Among the issues raised by the Department of Justice (DOJ) against TAP were that it engaged in marketing schemes designed to reward physicians for prescribing Lupron. One scheme involved the provision of free samples of Lupron, together with advice from TAP that physicians bill Medicare for the samples. The DOJ also alleged that TAP paid kickbacks to physicians by inflating the average wholesale price of Lupron to increase the amount Medicare would reimburse for that drug. It then sold Lupron to prescribing physicians at a discount, enabling the physicians to benefit from the profit margin between the discount they paid for the drugs and the amount Medicare would pay.

Other charges against TAP included the payment of kickbacks, in the form of educational grants, travel and

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entertainment expenses, consulting and audit services, and free electronic equipment. A number of the physicians have been indicted.

As a further indication that the heat is on, the Office of Inspector General (OIG) has published model compliance guidance for the pharmaceutical industry. Moreover, its 2002 Work Plan indicates that the OIG will be focusing on how the industry spends an estimated $12 billion per year on physician marketing.

The Food and Drug Administration (FDA) announced in 2001 that through its Division of Drug Marketing, Advertising, and Communications, it would be monitoring marketing activities by the pharmaceutical industry for compliance with FDA regulations.

Finally, the American Medical Association (AMA) has launched an initiative to reinvigorate its ethical "Guidance on Gifts from Industry." Originally published in 1990, these ethical opinions were designed to establish when and under what circumstances physicians may accept gifts from industry. At the same time, the AMA also published an ethical opinion on sponsorship of educational activities.

COMMON PHYSICIAN-PHARMACEUTICAL MANUFACTURER INTERACTIONS

Gifts. The most common interaction physicians have with the pharmaceutical industry is in "detailing" by manufacturer sales representatives, a practice that begins as early as residency. Physician detailers often present an arsenal of gimmicks and freebies to get physicians to notice and hopefully prescribe their products instead of those of their competitors. Gifts commonly range from inexpensive trinkets such as key chains and coffee mugs to free office lunches, expensive dinner meetings, and travel expenses to exotic conference destinations.

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The first authoritative review of these activities was by the OIG in a 1991 study. In 1994, the OIG released a fraud alert identifying certain marketing activities as suspect under the Anti-Kickback Act, including:

- Payments or gifts to a person in a position to generate business for the sponsor.
- Payments or gifts of more than nominal value or that exceed fair market value of any legitimate service rendered to the sponsor.
- Payments or gifts if unrelated to any service other than referral of patients.

Gifts from the pharmaceutical industry may implicate the Anti-Kickback Act, exposing both the entity giving the gift and the physician who receives it to significant civil and criminal liability. That statute applies only to items and services covered by federal- or state-funded health-care programs. Except for chemotherapy drugs, the Medicare program does cover a limited number of prescription drugs, but as the list of covered drugs grows, the potential for these arrangements to implicate the statute also increases.

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In addition, physicians must be wary of drugs covered under other federal programs such as CHAMPUS (Civilian Health and Medical Program of the Uniformed Services) and the Federal Employee Health Benefit Program, as well as Medicaid. The new Medicare drug benefit will only intensify these problems. Courts have said the Anti-Kickback Act is violated where only one purpose of a payment is to induce referrals. So, even where a gift may serve a legitimate purpose other than to induce physicians to order drugs, this benefit will not redeem the gift if it has as an ulterior purpose the intent to induce prescriptions.

In addition, the statute applies to any remuneration "in cash or in kind," so free meals, travel expenses, or any other free or below-market value item or service could implicate the statute. Moreover, it applies to remuneration of any value. That a gift is of only nominal value is irrelevant where the requisite intent to induce referrals exists. Finally, the statute applies to both the giver of remuneration and the recipient, so physicians have just as much exposure as the industry.

The OIG has a position on the value of remuneration offered to referring physicians. Specifically, when the safe-harbor regulations were published in 1991, the OIG confirmed that a free computer, which is to be used only as an integral part of a service provided by the entity giving the computer, would have no independent value apart from the service being provided and would not, therefore, be illegal remuneration. The example offered was a lab providing a free computer to a physician to access and review lab results. The OIG cautioned, however, that where the computer had independent value to the physician—for example, where it could be used as a personal computer for purposes beyond just getting lab results—it could violate the statute. Since adoption of the safe harbors, the OIG has applied the "independent value" analysis to a variety of other free items such as fax machines and consulting services. Physicians must, however, view all free items from pharmaceutical manufacturers with caution in light of the following comments by the OIG in a 1997 guidance letter:

> "Frankly, we are concerned that many of these arrangements are shams. Not only is there often no substantial business need for the equipment,

> but also there is no attempt to police the arrangement to ensure that the 'restrictions' are being followed... we view all such arrangements with skepticism."

A secondary source of guidance for physicians in evaluating gifts from industry, though not carrying the weight of the law, is the AMA's Ethical Opinion. At the heart of the AMA's guidance is the notion that gifts from industry should: primarily entail benefit to patients, be of insubstantial value, and come without strings attached.

In 2001 the AMA published a supplement to its original Ethical Opinion where it gave new examples of conduct that would run afoul of the opinion. Specifically, the AMA cited as problematic donations by a pharmaceutical company to a charity selected by physicians, vouchers offered by manufacturers for uncompensated care physicians provide, and gifts that are the equivalent of cash.

Discounts. The concern with discounts under the Anti-Kickback Act is the same as with free goods and services. The discount may be considered a form of remuneration that is intended to induce potential purchasers to choose one manufacturer's drug over another's. Regulators have recognized that from a public policy standpoint, however, discounts may also save the Medicare program money if providers take discounts they receive into account when submitting charges to Medicare. Consequently, there is a safe harbor under the statute for discounts. For a discount to be protected from liability, the buyer and seller in the transaction must meet certain specific obligations. Sellers must document the discount on the buyer's invoice and must inform the buyer of its obligations to report the discount to Medicare.

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In addition, the seller is prohibited from doing anything to prevent the buyer from meeting its obligations under the safe harbor. When the safe harbor was first published, physicians were required to disclose on their Medicare claims any discounts received on line items. This requirement has now been eliminated, but charges to Medicare must still reflect the discount. In other words, physicians must factor the discounts into their charges, although there is no requirement that the entire discount be passed along to Medicare.

The safe harbor also applies to rebates that are not given at the time of the purchase of the item but at some later time, such as at the end of a year or after some purchase volume threshold has been met. To have safe-harbor protection, the terms of a rebate must be set and made known to the buyer at the time of the sale. Once the rebate amount has been calculated, the seller must provide the buyer with the calculation and must document the specific goods or services to which the discount applies.

Drug purchasing arrangements. In an effort to garner purchasing power, many physicians join or form group purchasing organizations (GPOs) to negotiate special arrangements with manufacturers and suppliers. Since contracting with GPOs creates an opportunity for manufacturers to increase market share, they will very often offer cash payments to the GPOs themselves, in addition to discounts and other favorable purchase terms to the GPO members.

Since these cash payments may be construed to be inducements to the GPO to influence purchases by its members, they could run afoul of the Anti-Kickback Act. Although large, national GPOs have now come under public scrutiny, there is a safe harbor for these payments as well. To obtain safe-harbor protection, payments by a vendor to a GPO as part of an agreement to furnish those goods to the GPO's members must meet certain parameters. The GPO must have a written agreement with its members that provides either that: the vendors from which the members will purchase goods will pay a fee to the GPO of 3 percent or less of the purchase price of the goods provided by the vendor; or if the fee paid to the GPO is not fixed at 3 percent or less, the agreement specifies the amount (or if the amount is not known, the maximum amount) the GPO will be paid by each vendor.

Where the members are health-care providers, the GPO must annually disclose in writing to the members and to the Secretary of the Department of Health and Human Services upon request, the amount paid to the GPO by each vendor with respect to purchases made by or on behalf of the GPO members. Although the safe harbor does not limit the amount vendors may pay to GPOs, the OIG stated: "We agree that it is not necessary, in all circumstances, to specify the exact fees the GPO will receive from its vendors as a result of a particular member's purchases. The legislative history to this exception, however, shows Congress's concern for excessive GPO fees, particularly those exceeding 3 percent." As recently as a 2001 advisory opinion, however, the OIG explicitly permitted administrative fees paid by a vendor to a GPO where the payments by the vendors exceeded 3 percent of the goods sold to the GPO's members.

Drug purchasing arrangements may also have implications for physicians under the federal Stark statute because outpatient prescription drugs are a Stark-designated health service. In the preface to the final Stark regulations released in early 2001, the Centers for Medicare and Medicaid Services (CMS) addressed this issue, stating that generally it would not consider a prescription to be a referral to the manufacturer of the drug. CMS also acknowledged, however, that where the manufacturer is also the entity that dispenses the drug, such as where

the manufacturer operates a retail pharmacy, there could very well be a Stark referral.

There are exceptions under Stark that will permit otherwise prohibited referrals. For example, there is an exception for compensation paid to a physician for personal services that is similar to the anti-kickback safe harbor. There is also an exception for payments to a physician, provided those payments are consistent with fair market value. Depending on the nature of that relationship, Stark exceptions may permit the arrangement, anyway. Although Stark regulations are less a problem than the Anti-Kickback Act, it is critical to take the Stark prohibitions into account.

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Sponsorship of educational activities. Sponsorship may take a variety of forms, such as educational grants to conference organizers to pay for speakers or defray conference costs; reimbursement of travel, lodging, and meal expenses for conference speakers and/or attendees; or compensation to physicians for serving as panelists at conferences. Regardless of the type of sponsorship, the legal concerns under the Anti-Kickback Act are the same as with any other payments to a potential referral source to induce physicians to prescribe the sponsor's drugs.

The AMA has also addressed educational sponsorship from the pharmaceutical industry, stressing that first and foremost, educational activities should primarily promote objective scientific and educational activities. The AMA also advises that organizers of the activities should disclose to attendees financial support and any potential conflicts of interest, and should strive to maintain control over the form and content of the program.

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In addition, the AMA's Ethical Opinion condemns acceptance of travel, lodging, or other personal expense reimbursement. The opinion stipulates that subsidies should be paid to conference organizers and not physician attendees directly, although the opinion permits speakers to accept reasonable honoraria and reimbursement of expenses. It also states that physicians may be paid reasonable compensation for serving as consultants, where they render genuine consulting services.

The FDA has also weighed in on the issue of educational sponsorship. One of the FDA's responsibilities is to oversee marketing of prescription drugs through the provisions of the Food, Drug and Cosmetic Act. Violations of the labeling and advertising provisions of the act are punishable by imprisonment for up to a year and criminal penalties of up to $1,000 per violation. Where violations involve fraud, penalties include imprisonment for up to three years and fines of up to $10,000. In 1997, the FDA published Final Guidance on Industry-supported Scientific and Educational Activities.

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According to the Final Guidance, the FDA will consider the following factors in determining whether a promotional activity is labeling and advertising, and, therefore, subject to the provisions of the act:

- Whether the activity organizer has maintained full control over the content of the program, planning its content, and selection of speakers and moderators
- Whether there was meaningful disclosure to attendees of: sources of funding; and significant relationships between the sponsor and the organizer, presenters, or moderators.
- Whether any unapproved uses of sponsor products were or will be discussed.
- Whether there are promotional activities, such as presentations by sales representatives or promotional exhibits by the sponsor, taking place in the meeting room.

As with the AMA's Ethical Opinions, the FDA Final Guidance will not affect the legality of an arrangement under fraud and abuse laws. Failure to comply with the Final Guidance, however, creates yet another level of exposure, so it is advisable to take this guidance into account along with applicable fraud and abuse provisions when evaluating and structuring sponsored activities.

Personal service arrangements. Recognizing the risks of giving physicians free goods and services, some pharmaceutical manufacturers instead compensate physicians for performing consulting or other administrative services. Generally, the Anti-Kickback Act is unconcerned with fair market value compensation arrangements. Where no real services are performed for that compensation, however, and the arrangement is merely a subterfuge for illegally remunerating a physician for referrals, the statute will be implicated. As an example of such an arrangement, in its 1994 Fraud Alert, the OIG identified as suspect a "research grant program" in which physicians administering the manufacturer's drug were paid for making brief notes about the treatment outcome. The OIG concluded that the notes were of no real scientific value.

There is also a regulatory safe harbor for personal service arrangements. To receive protection, a personal service arrangement must be spelled out in a written, signed agreement with a term of at least a year. The agreement must spell out the specific services to be rendered and the compensation for them. Finally, the compensation must reflect fair market value for the services rendered and may not fluctuate with the volume or value of business generated between the parties.

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Clinical trial sponsorship. To assist physician investigators with the additional administrative costs of participating in clinical trials and to motivate their participation, many manufacturers compensate investigators, typically on a per-patient basis or in a lump sum. Obviously, these arrangements have legal pitfalls, too. As with other personal service arrangements, where this compensation reflects fair market value, it will not present issues under the Anti-Kickback Act. Where, however, that compensation is disproportionate to the services rendered as a means of inducing the investigator's prescription of the sponsoring manufacturer's other, already approved drugs, for example, the Anti-Kickback Act will be implicated.

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For physicians who engage in clinical trials, there are additional concerns under the federal False Claims Act (FCA). The FCA, punishable by potential penalties equal to three times the damages sustained by the government plus civil fines of between $5,000 and $10,000 per false claim submitted, prohibits a provider from presenting, with knowledge, a false or fraudulent claim or a false statement to obtain payment from a health-care program.

The concern under the FCA arises out of the fact that in 2000 Medicare began covering routine costs associated with clinical trials. Now, where physician investigators submit claims for these costs while also receiving funds from trial sponsors that may cover the same costs, the investigator may get paid twice. Medicare is an insurance program that reimburses beneficiaries for costs they incur for covered services. Where those costs are covered by another source, Medicare has no obligation to reimburse the beneficiary (or a physician who accepts assignment of benefits from that beneficiary). Submitting a claim for such services, therefore, may amount to a false claim.

Not all services associated with clinical trials are covered by Medicare, so physician investigators may still legitimately receive sponsorship from manufacturers for services and costs associated with trials that are not covered. The key is understanding what is covered and allocating the sponsorship funds only to those expenses that are not covered. Medicare covers the routine costs of a clinical trial including the following:

- Items or services that are typically provided absent a clinical trial.
- Items or services required solely for the provision of the investigational item or service, the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications.
- Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service—in particular, for the diagnosis or treatment of complications.

Medicare does not cover:

- The investigational item or service itself.
- Items and services provided solely to satisfy data collection and analysis needs of the trial and that are not used in the direct clinical management of the patient.
- Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial.

PRACTICAL TIPS

Given the recent attention to these significant relationships, physicians and others ought to confront explicitly the risk areas we have identified.

Gifts. The threshold issue here is whether the gift amounts to remuneration at all. Gifts that are really nothing more than reminders about a manufacturer's drug, such as refrigerator magnets or Post-it notes, may not rise to the level of "remuneration." The OIG has taken the position that a gift that has no independent value to the receiving physician may be permissible under the Anti-Kickback Act. Policies and procedures should expressly address the circumstances under which gifts may be accepted from the pharmaceutical industry (or any other vendor for that matter), and the types and scope of gifts that may be accepted. Also, personnel should be required to report all proposed and accepted gifts to the compliance officer for evaluation, and, if necessary, return.

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Contracting. Arrangements with pharmaceutical manufacturers for discounts, clinical trials, sponsored educational activities, or personal services should address the following:

- The arrangements should be reduced to formal contracts so they better withstand question.
- Contracts should be drafted with advice of health-care counsel to address key compliance requirements and issues such as the obligation to report discounts and the ability to renegotiate contracts where changes in law render them illegal or suspect.
- Someone in the practice should monitor implementation of contracts to be sure that both parties comply with all applicable laws and payer requirements.
- Sponsorship agreements should identify the scientific or educational purposes of the sponsored activity and contain safeguards against influence by sponsors over program content and form.

Group purchasing organizations. All proposed supplier contracts and offers should be reviewed by legal counsel for fraud and abuse concerns. Where the GPO is a component of a larger, multipurpose entity, such as a physician network, the entity's formation documents and participation agreements should be reviewed to ensure that the entity is authorized by its members to act as a GPO.

Finally, GPOs should establish policies to ensure that administrative fees are used to further the GPO's activities (e.g., to defray operational or educational costs) and not to benefit participants directly. Supplier contracts should be structured so that fees are payable only to the GPO, not individual participants.

Clinical trials. Where physician investigators submit claims for clinical trial reimbursement, sponsorship agreements should identify those costs for which sponsorship funds are to be used so that investigators are reimbursed only once for their costs. Maintaining these boundaries should be addressed in the compliance plan.

CONCLUSION

As physicians continue to experience reimbursement cuts and rising overhead, the temptation to seek alternative sources of reimbursement will increase. The pharmaceutical industry has demonstrated its willingness to be one source of funding; but, as demonstrated by the TAP Pharmaceuticals case, the industry is also willing to be aggressive in finding ways to make its dollars available to potential prescribers.

Physician-pharmaceutical manufacturer relationships can benefit patient care and substantially advance treatment options. There are many legitimate ways to structure them. Physicians need not be dissuaded by recent enforcement developments from exploring these arrangements, but we advise a healthy measure of caution. ■