

## *Sills Cummis & Gross P.C. Life Sciences and Health Care Series – Part VII*

# Physician-Vendor Arrangements: Legal Compliance Challenges

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Arrangements between vendors of healthcare products and services, such as pharmaceutical manufacturers, medical device makers and hospitals, and physicians are increasingly becoming the subject of intense scrutiny by the federal government. Recently, federal investigators have targeted these types of vendors for a variety of practices designed to generate illegal referrals for their products and services, including providing physicians with all expense paid trips to Europe and resort destinations and other types of “freebies” and making payments under sham medical director and consulting arrangements and speaking engagements.

Very often, these actions result in settlements of tens and even hundreds of millions of dollars. In light of the potential for heightened government scrutiny and costly litigations and settlements, vendors need to be extremely cautious in their dealings with physicians (or other providers or entities which are in a position to generate referrals

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of items and services that are reimbursed by federal health care programs such as Medicare).

This article provides a brief overview of some of the legal issues that impact vendor-physician arrangements and offers some examples of “do’s” and “don’ts” when structuring an arrangement.

### **Legal Issues**

The recent federal enforcement actions have focused on two main federal laws governing the payment of illegal kickbacks (the Anti-Kickback Statute or “AKS”) and the physician prohibition on making self-referrals (the Stark law). (Note, in addition, each state may have its own version of these laws, the discussion of which is outside the scope of this article).

*The Anti-Kickback Statute.* The AKS makes it a crime for any person to knowingly and willfully solicit, receive, offer or pay remuneration: (i) to induce or reward referrals; or (ii) in return for purchasing, leasing, ordering or arranging for any item or service, which is reimbursable by a federal healthcare program. Violations of the AKS can result in criminal prosecution,

substantial civil penalties and exclusion from participation in federal healthcare programs. Several regulatory “safe harbors” exist under the AKS – if an arrangement meets all of the criteria of a safe harbor it will be considered compliant with the AKS. However, failure to meet a safe harbor does not necessarily make an arrangement illegal; ultimately, liability under the AKS depends on the parties’ intent.

The Office of the Inspector General (“OIG”), which is charged with ensuring compliance with the AKS, has issued some guidance on the types of permissible vendor-physician arrangements. In general, the OIG’s guidance suggests that vendors should consider the following: (i) whether the incentive to the physician may interfere with clinical decision-making; (ii) whether the physician receives accurate, complete and truthful information; (iii) whether there is a potential to increase costs to federal healthcare programs or beneficiaries; (iv) whether the arrangement poses a risk of overutilization or inappropriate utilization; and (v) whether there are any patient safety or quality concerns.

*The Stark Law.* The Stark law prohibits a physician from referring certain types of items and services to an entity in which the physician has a financial relationship if such items and services will be paid for by the Medicare/Medicaid programs. As with the AKS, there are several exceptions to this general prohibition. However, unlike the AKS, the Stark law is a strict liability statute, which means that a financial relationship *must* satisfy all of the requirements of an exception in order to be compliant. A

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financial relationship includes both an ownership and a compensation interest.

### Industry Guidance

In addition to the OIG, several industry organizations have promulgated codes of ethics or codes of conduct which provide valuable guidance on structuring arrangements with physicians. Some of the more comprehensive examples of such guidance include the Advanced Medical Technology Association (AdvaMed) Code of Ethics on Interactions with Health Care Professionals and the Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Healthcare Professionals. Compliance with industry codes is voluntary and does not necessarily mean that an arrangement is legal. However, adherence to industry codes of ethics will likely be viewed as a good faith compliance effort by enforcement authorities. For instance, the OIG's Compliance Guidance for Pharmaceutical Manufacturers expressly recommends that pharmaceutical vendors, at a minimum, comply with the PhRMA Code.

#### *"Do's" and "Don'ts" – Structuring Compliant Arrangements*

Whether a vendor-physician arrangement passes muster under the above described federal laws must be considered on a case-by-case basis. No "magic formula" exists. Set forth below is a list of "do's" and "don'ts" based on guidance from the OIG and the AdvaMed and PhRMA codes of ethics, which may help reduce the risk of an impermissible arrangement:

- Certain types of arrangements should be avoided altogether. For example:

- \* "tying" arrangements (providing cash, gifts or other benefits contingent upon physician referrals of the vendor's products),

- \* "switching" arrangements (offering cash or other benefits for changing a patient's prescription to the manufacturer's product from a competing one), and

- \* "detailing" (compensating for time spent listening to marketing information).

- Gifts of cash or cash equivalents (i.e. gift certificates) are highly suspect and should be avoided.

- Other types of gifts should be of minimal value (e.g., less than \$100) and should primarily benefit the patients or serve an educational function, such as, for example, anatomical models and text books. Promotional products are acceptable if they relate to the physician's practice – pens and notepads are acceptable; golf balls are not.

- If the arrangement is subject to the Stark law, it must comply with one of the

applicable exceptions for gifts – for example, a vendor may provide non-cash gifts with an aggregate annual value of up to \$329 (adjusted annually) if such gifts are not solicited by the physician and do not take into account referrals generated by the physician. Additionally, a hospital may provide certain incidental benefits to all members of its medical staff if such benefits are of nominal value (less than \$28 dollars, adjusted annually), do not take into account referrals generated, and are utilized at the hospital in connection with the provision of medical services.

- Product support services (e.g. basic training on product utilization, reimbursement consultation, and billing assistance) are generally not suspect because such services are not considered to have substantial independent value. However, note that if product support services are accompanied by a service which confers an independent benefit on a referring provider, the arrangement will raise red flags. For example, offering a reimbursement guarantee which eliminates a provider's financial risk in conjunction with reimbursement support services is suspect.

- Vendors may give informational presentations regarding their products if such presentations are "modest," informational and provide scientific and educational value.

- Manufacturers may pay a direct subsidy to a Continuing Medical Education (CME) conference organizer provided that the subsidy is used to reduce conference fees for all attendees. The PhRMA Code prohibits a vendor from directly paying for a physician's travel, lodging, meals, or other personal expenses. By contrast, AdvaMed's Code allows a manufacturer to compensate the physician for reasonable travel and modest lodging – a conservative approach would be to avoid payments for these items altogether.

- Vendors should ensure that they are not using CME programs or other educational/promotional presentations to pay improper remuneration to physicians in a position to generate business. Vendors should not influence or control the content of any educational programs and should follow FDA guidelines with respect to their involvement.

- Research whose only purpose is to generate business or promote a product should be avoided.

- When engaging physicians to provide research services, vendors must ensure that any such program: (i) is not initiated or directed by marketing personnel; (ii) includes genuine scientific oversight; (iii)

avoids unnecessary or duplicative research; and (iv) is not a post-marketing pretense to promote a product.

- All consulting and medical director agreements should attempt to meet the AKS safe harbor for personal services and, if applicable, the Stark law exception for personal services. At a minimum, the parties should ensure that: (i) a signed written agreement is in place; (ii) there is a legitimate need for the physician's services; (iii) the required services are actually provided; and (iv) the compensation is fair market value. These facts should be documented prior to paying the physician, and the arrangement should be monitored on an ongoing basis to ensure that the parties' written agreement reflects their actual practice.

- Generally, fair market value payments to a small number of physicians are unlikely to raise fraud and abuse concerns by the OIG, provided that such payments are for bona fide and reasonable consulting and advisory services. Entering into arrangements with a large number of physicians may raise concerns that some or all of the physicians are not providing legitimate and necessary services and instead are being compensated for referrals.

- Paying physicians for consulting or advisory services where the physicians are expected to attend conferences and meetings in a passive capacity is suspect.

- Entering into consulting arrangements with physicians for marketing services such as "ghost-writing" and speech-making implicates the AKS and other laws. Such arrangements must be carefully structured to ensure that the marketing practices in general and the physician's involvement, in particular, is compliant.

In conclusion, many types of vendor-physician arrangements are common business arrangements in the health care industry that are necessary to promote advancements in medicine, science and technology. In recent years, however, the proliferation of a variety of these arrangements has resulted in increased federal government scrutiny, much of which is often initially triggered by "whistleblower" actions by former employees of vendors. Thus, in light of this enforcement environment, vendors should review their inventory of arrangements and conduct an in-depth legal compliance analysis. The various industry codes of ethics, while not carrying the force of law, can provide meaningful, practical guidance for structuring compliant arrangements and serve as a good educational resource for employee training.