



JONES DAY  
**COMMENTARY**

## INCREASED SCRUTINY OF INTERACTIONS BETWEEN HEALTH CARE PROVIDERS AND PHARMACEUTICAL AND DEVICE COMPANIES

Legitimate, useful relationships between health care providers and pharmaceutical, medical device, and diagnostics companies transcend the purchase and sale of drugs and devices. Collaboration between providers and pharma/device companies serves the beneficial purposes of advancing medical technology and drug development, promoting the safe and effective use of products, and developing research, education, and treatment skills. Providers and pharma/device companies must be aware, however, that federal regulators, including the Department of Health and Human Services Office of Inspector General (“OIG”) and the Department of Justice (“DoJ”), are examining these collaborations closely to determine if they violate the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b).

The Anti-Kickback Statute prohibits the payment, offer to pay, solicitation, or acceptance of remuneration to induce patient referrals or the purchase of goods

or services for which payment is made under a federal health care program. This includes payments to induce the purchase of drugs or devices. Ordinary interactions between providers and companies, such as providers’ payments for goods and services and companies’ direct or indirect payments to physicians, researchers, and hospitals, can trigger scrutiny under the statute. The latter category of direct and indirect payments can include rebates, clinical research funding, donations, product royalties, consulting fees, honoraria, reimbursement for continuing medical education, speaking engagements, advisory board participation, travel, sample products, and free equipment. While such exchanges can be completely legitimate and appropriate, if they are motivated by illicit purposes (such as to induce the purchase of goods outside of a safe harbor), they can implicate the federal Anti-Kickback Statute, as well as the False Claims Act, 31 U.S.C. §§ 3729, *et seq.*, and similar state laws.

An anti-kickback investigation focuses on whether a pharmaceutical or device company made a payment, in cash or in kind, to a provider to induce the purchase of the company's goods. Recent well-publicized investigations of pharmaceutical companies, enteral/parenteral companies, orthopedic device companies, and cardiovascular device companies illustrate the types and circumstances of payments targeted by regulators.

## DRUG STUDIES AND CLINICAL TRIALS

DoJ and OIG have investigated industry support for drug studies and clinical trials, including research grants and clinical study payments to doctors and institutions for research of alleged dubious value. Although funding of research and clinical trials can be entirely appropriate, the expenditures must be commensurate with the size and nature of the study, and the funding must be in compliance with the provider's internal review board process and any applicable disclosure and conflict-of-interest requirements. Otherwise, regulators may conclude that the study payments are a pretext for incentives to buy product or, in other words, a kickback.

## PHYSICIAN SERVICES

Recent investigations of orthopedic device manufacturers have questioned the nature of physician services to the companies. The investigations focused on alleged (a) consulting and royalty payments to physicians that either exceeded fair market value or were made without *bona fide* service, (b) training payments for the implantation of certain devices without actual training, and (c) lavish expense reimbursement. Although consulting and training payments are not *per se* problematic, they should be *bona fide*, at fair market value, documented in writing, disclosed to the provider's institution, and in compliance with the institution's conflict-of-interest policies. Payments should not be tied to the utilization of a device or drug.

## GIFTS AND ENTERTAINMENT

Sports tickets, fishing and hunting trips, golf outings, and gift certificates are often viewed by regulators as problematic

under the Anti-Kickback Statute. In considering these types of payments, the codes promulgated by the Advanced Medical Technology Association and the Pharmaceutical Research and Manufacturers of America (the AdvaMed and PhRMA Codes) provide useful guidance on when payment of travel, meal, and hospitality expenses are appropriate. Before making or accepting this type of payment, it is wise to confirm that there is a legitimate purpose to the meeting or conference, that the hospitality is subordinate to the purpose of the conference, and that the expenditures are within reason.

The key to maintaining productive collaborations is to ensure that both providers and pharma/device companies understand the risks in this area and comply with federal and state regulations. All parties benefit by documenting, through contemporaneous evidence, that payments are *bona fide* with a legitimate purpose, commensurate with the activity at issue, and completely disconnected from purchasing decisions. Providers can further mitigate their risks by keeping purchasing decisions within supply chain and quality committees, ensuring that pharmaceutical and device representatives are apprised of institutional conflict-of-interest and compliance policies, and insisting that vendors follow AdvaMed and PhRMA Codes. Moreover, providers should educate and, if possible, obtain from physician researchers regular certification of compliance with procedures governing such relationships and potential conflicts of interest.

## LAWYER CONTACT

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