



## GUEST ARTICLE

# ANTI-KICKBACK LAWS POSE RISK TO HEALTH CARE DEALS



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“The U.S. Department of Justice has a major ongoing offensive against health care fraud and abuse.”

**H**ealth care industry investors need to be aware that life sciences companies, even those in the early stages of product development, may be subject to the federal anti-kickback and related fraud and abuse statutes.

Well planned due diligence during the investment process and ongoing compliance oversight, both at the board and operating level, is increasingly important for venture capital investors to protect the value and growth of their life sciences companies. As these companies advance products through clinical trials and obtain FDA approvals or clearances, the likelihood increases that Medicare, Medicaid or another federal health program will pay for some portion of clinical trial costs or even hospital capital charges, the latter of which may include medical device costs. That federal payment, prosecutors may assert, will implicate the broad anti-kickback and fraud and abuse statutes. Triggered by federal program billing, these statutes regulate not only sales, marketing and discount practices, but also may apply to common life sciences company arrangements such as scientific advisory board (SAB) engagements.

Numerous pharmaceutical and medical device companies have become subject to governmental health care investigations that resulted in substantial penalties and even criminal liability, including indictments of company executives. The U.S. Department of Justice has a major ongoing offensive against health care fraud and abuse, and carefully scrutinizes compensatory arrangements and the sales, rebate and marketing practices of health care companies. Investors, including the board of directors, must assess the compliance risks of their portfolio companies, which in turn should institute a tailored compliance program that addresses such risks. Company boards should also allocate sufficient resources to implement appropriate policies. Given the complexity of this regulatory area, compliance efforts generally require a team approach, sometimes involving a board member and often utilizing in-house or outside counsel familiar with both health care operations and fraud and abuse laws.

### What to watch out for

Health care “fraud and abuse” regulation is primarily circumscribed by three laws: the federal anti-kickback statute, the Stark law and the False Claims Act. Here’s how they work:

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**Anti-kickback statute.** This federal law generally makes it illegal to knowingly solicit, offer, receive or pay “remuneration” in exchange for patient referrals or to induce a person to arrange for or recommend the purchase, lease or order of any item of service payable in whole or in part by a federal health care program, such as Medicare or Medicaid. “Remuneration” includes anything of value, whether in cash or in kind. Penalties include substantial monetary fines and/or imprisonment, as well as potential exclusion from participation in the Medicare or Medicaid programs.

**The Stark law.** This law prohibits physicians from making a referral to an entity for the furnishing of a certain Medicare covered services if the physician (or immediate family members) has an ownership or other financial interest in the entity. Unlike the anti-kickback statute, the Stark Law only covers referrals by physicians for “designated health services” that federal authorities consider vulnerable to over-utilization. These include, among others, clinical laboratory services, medical equipment and supplies, prescription drugs and inpatient and outpatient hospital services.

**False Claims Act.** This law penalizes the knowing submission of inaccurate, inflated, or fraudulent bills to federal health care programs. Billing Medicare for medically unnecessary services can give rise to false claims prosecution and substantial damages.

**Exceptions.** The Stark law makes exceptions for non-abusive arrangements that generally must be met precisely to

afford protection. The anti-kickback statute provides exceptions termed “safe harbors.” Arrangements that do not fit squarely within a safe harbor are not illegal per se, but must be carefully analyzed to ensure that they do not suggest disguised payments intended to reward the referral or inducement of healthcare business.

## Do your homework

When making an investment in or an acquisition of a life sciences company with relationships involving physicians, an investor should include compliance with fraud and abuse laws as part of his or her due diligence. An analysis of the company’s relationships and arrangements with customers, physicians and other health care providers, clinical trials and related billing procedures, referral policies, data reporting to governmental agencies, and compliance policies can help uncover lurking problems. Unexpected issues that surface can then be addressed prudently before investors or buyers assume any risk of potential liabilities. Once an investment is made, investors should ensure that the company’s board of directors and management are aware of these issues so that they can actively manage the company’s compliance risks to avoid impairing the value of the investment or reducing the company’s flexibility to undertake liquidity events.

Many commonplace practices in early stage life sciences companies potentially implicate the fraud and abuse laws. Such practices include consulting or SAB arrangements, research or educational grants, and even payment of business expenses, entertainment or gifts to physicians. These arrangements should be ana-

lyzed to determine the nature of the relationship between the parties, the manner in which remuneration is determined and paid, the value of the remuneration, the potential for triggering fraud and abuse laws, and possible conflicts of interest created by the remuneration.

## Clinical trials

In 2000, Medicare issued a national coverage decision to permit reimbursement of certain routine costs of qualifying clinical trials that meet CMS criteria, including items and services used to diagnose and treat complications arising from participation in the trial. A clinical trial sponsor may not be aware that the hospital or investigator conducting its trial is billing Medicare for such costs. Inappropriate or double billing of clinical trial costs by the hospital can result in substantial liability under the anti-kickback statute and False Claims Act. To decrease these risks, the sponsor should include appropriate financial disclosure language in the patient’s informed consent and coordinate the billing of such costs with the hospital or research entity. The compensation arrangement between the trial sponsor and the hospital or investigator also should be structured appropriately.

The payment of compensation, whether cash or equity, to consultants, SAB members and other advisors may implicate the anti-kickback and fraud and abuse laws if the compensation is in excess of fair market value and the recipient is in a position to refer patients to the study, or promote the study product. In the anti-kickback context, fair value is generally defined as the value in an arm’s length transaction that would result from

bona fide bargaining between a buyer and seller not otherwise in a position to generate business for the other party. When equity in the company is paired with significant cash payments, the compensation on its face may, in retrospect, appear excessive in light of the services to be provided. The issuance of equity at a discount to consultants who may participate in clinical trials may also trigger FDA scrutiny, if the FDA determines the investigator's financial interest raises an issue about the reliability of the study data.

These arrangements should be reviewed to ensure that they meet or approximate the terms of an applicable safe harbor under the anti-kickback statute. One such safe harbor permits compensation arrangements with referral sources if the arrangement is embodied in a signed writing having a term of at least one year, covers legitimate services that are actually provided, and involves compensation that is fair market value, set in advance, and not determined on the basis of the value or volume of potential referrals of patient business. A corresponding exception under the Stark law is similar, but does not require aggregate compensation to be set in advance.

If the arrangement does not squarely fit into a safe harbor, then rigorous steps should be taken to determine and document the fair market value of the compensation and provide evidence of an appropriate purpose for the arrangement. If equity is issued as part of the arrangement, the company's board should consider undertaking a carefully documented stock valuation, which may include an opinion or valuation by a

third-party expert where appropriate, to determine the fair value of the equity at the time of the initial grant.

Arrangements that provide free or below-market-price goods or services to referral sources create an anti-kickback risk since they confer an economic benefit. Recent enforcement actions in this area have involved referral payments in the form of free rent or equipment, free office personnel, free drugs or other supplies, lucrative consulting contracts and vacation-type travel and entertainment to physicians. These types of arrangements should be avoided unless they involve fair market value exchange for legitimate and necessary services that are actually performed under terms that meet a safe harbor.

Physicians and other health professionals who are considered "thought leaders" have sometimes been offered gifts, entertainment, travel, meals, sponsorships and other business gratuities. When this is done in association with marketing activities—such as attending conferences in a passive capacity, or engaging in promotional or "hyping" activities about the company's products—those arrangements may trigger governmental review. Research and educational grants or other funding to physicians may raise anti-kickback risk when linked to or conditioned on the promotion or purchase of products or where the company has significant control over the speakers or content of such programs. These arrangements should also be vetted for conflicts of interest by requiring that conflict disclosures be made to both the company and the physician's affiliated institution.

## Game plan

In 2003, the Department of Health and Human Services Office of Inspector General (OIG) issued guidance to assist pharmaceutical companies in developing internal controls and procedures for ensuring compliance with fraud and abuse laws. Much of that guidance applies equally to life sciences and medical device companies. Some of the recommendations in the guidance are described below.

**Adopt a compliance policy.** Investors in life sciences companies gearing up for clinical trials or seeking FDA approvals should require them to adopt and distribute written standards and procedures, or refine compliance policies as necessary. Good starting points are the "Code of Interactions with Healthcare Professionals" published by the Pharmaceutical Research and Manufacturers of America (PhRMA code) and the "Code of Ethics for Interactions with Health Care Professionals" published by the Advanced Medical Technology Association (AdvaMed Code), both of which set out compliance benchmarks.

Companies preparing to launch a new product should adopt a compliance program in conjunction with their sales and marketing efforts well in advance of the product rollout. Even early stage companies with limited resources should consider adopting a compliance program at some point. Support from senior management is essential to successfully implement an effective compliance program.

**Comply with safe harbors or document arrangements that do not fit into a safe harbor.** Whenever possible,

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remunerative arrangements should be structured to comply with an applicable safe harbor. Arrangements that do not clearly fit within a safe harbor should be reviewed on a case by case basis with supporting justification and documentation of the expected services, the determination of the fair value of the compensation (which should be commensurate with the advisor's credentials and actual performance of the specified services), the reasonableness of the compensation for the services to be provided, any potential conflicts of interest and then careful tracking of such services. In consulting or advisory arrangements, companies should monitor the attendance, deliverables, record keeping, hours and the like.

**Designate a compliance officer and a compliance committee.** Companies should designate a dedicated compliance

officer who has responsibility for overseeing and communicating the compliance program. A compliance officer with the authority and sufficient resources to coordinate compliance efforts is essential to the success of a program. A designated board member can also provide additional support and decision-making authority in problematic situations.

**Conduct effective training and education.** Companies should develop a regular and relevant education and training program for officers, directors, employees and sales agents and a means for disseminating such information. Training materials should ensure that sales employees also understand the PhRMA and AdvaMed Codes and other applicable industry standards. In addition to education, companies may wish to conduct periodic audits to monitor compliance

with the program and determine if the program is effective.

By conducting targeted due diligence, investors in life sciences companies can identify potential fraud and abuse problems and mitigate the risks at a much earlier stage. An effective compliance program can help identify problems early and thereby minimize financial liability for the company and investors.

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