



Compliance: What Every Reference Lab Representative Should Know

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Following the hiring of a sales representative, one of the first duties of any clinical or anatomical pathology lab is to expose the new employee to the lab's compliance obligations. Regardless of whether the person has been selling within the lab industry or not, it remains essential to review compliance as it relates to sales.

It needs to be clearly stated that the discussion provided in this document equates to a broad overview for general informational purposes only. Any legal questions or advice should be addressed to an attorney, especially one well-versed in laboratory-related compliance.

Compliance Overview

There exist a number of constituents within a sales compliance program. Among them are those relating to fraud and abuse authorities (e.g., false claims, anti-kickback statute and Stark Laws), pricing issues, in-office phlebotomy, client entertainment and donations of electronic medical records software.

The False Claims Act

The conduct of sales people can trigger cases under the False Claims Act as they can be based upon alleged violations of other laws, such as the Anti-Kickback Statute. In addition, to the extent that the conduct of sales representatives gives rise to changes in test-ordering patterns, allegations can be made under the False Claims Act that medically unnecessary services have been performed. A lab faces severe financial penalties for violating the False Claims Act (up to \$11,000) for each claim for reimbursement submitted to a federal government health care program (e.g., Medicare or Medicaid) plus three times the amount "wrongfully" paid in reimbursement).

The Anti-Kickback Statute

This area demands full cognizance of sales representatives. The Federal Anti-Kickback statute specifically states that a person may not knowingly or willfully offer, pay, solicit, or receive remuneration to induce, or to recommend or arrange for, referrals of

Medicare/Medicaid patients or items of services provided to such patients. Penalties include criminal fines and imprisonment, significant civil money penalties and/or exclusion from the Federal Programs, including Medicare and Medicaid.

The Stark Self-Referral Prohibition

The Stark Laws dictate that a healthcare provider may not refer a Medicare or Medicaid patient to a clinical lab with which the physician (or an immediate family member) has a financial relationship. Sanctions include denial of reimbursement, exclusion from Medicare and/or Medicaid and substantial civil money penalties.

Under the Stark II Laws, Designated Health Services (DHS) for Medicare and Medicaid patients may not be referred by a physician to a DHS provider if he or an immediate family member has a financial relationship with that provider. Clinical labs, radiology, radiation therapy, physical and occupational therapy and home health services are examples of businesses that fall within the DHS definition.

The Stark II Laws apply to *non-monetary compensation*. Under the non-monetary compensation rules, in 2010, a representative may not offer clients items or services that are valued at more than \$355/year. One might think that if there were four physicians in a group practice, a rep could offer a one-time/year non-monetary compensation gift of \$1,400. This is *not* the case, however. Also, any form of entertainment or non-cash item(s) cannot take into account the client's testing volume. In addition—a point rarely understood by lab sales reps—a physician or *any member* of the doctor's office may not solicit non-monetary compensation (e.g. lunch) *if* the representative's lab currently receives Medicare/Medicaid testing referrals from that physician. In addition, bringing lunch to a prospective client who sees Medicare or Medicaid patients can be seen as implicating the the Anti-Kickback Statute.

Regrettably, many office personnel (and physicians) have not been educated about the DHS rules. Therefore, if the lab sales rep hears from a *current client*, "If you want to speak to the doctor, you'll have to bring in lunch..." a conversation should ensue that explains how labs fall under the DHS rules under the Stark II Laws. While it remains lawful under Stark II for the lab rep to offer to bring in food to the client, neither the doctor nor any member of the office staff may make the request.

In-Office Phlebotomists (IOP)

According to the HHS Office of Inspector General, the provision of an IOP by a laboratory at no cost remains acceptable so long as certain safeguards are observed. The IOP may only provide duties associated with specimen collection and preparation. He/she may not offer (or be asked) to help with traditional office duties or assist with testing the office routinely performs. The doctor's office, of course, may not charge for phlebotomy services performed by the lab's IOP. It should also be noted that some state laws prohibit IOPs.

Leasing Space in a Doctor's Office

Sometimes sales reps become involved with a client who wants to lease space to the lab as a full-access patient service center ("PSC"). As a general matter, this stands as permissible, but certain "rules of the road" should be followed. For example, the agreement must be in writing, the space must be used solely by the lab, the monthly lease must be fair market value, the term must be for a minimum of twelve months and the rental charges must be a set fee and not based upon specimen volume. In addition, the PSC should serve patients in addition to those of the lessor-physician.

Supplies

Representatives may not offer free items such as biopsy needles, gloves, or fax machines to test-ordering physicians. Nor should they supply a volume of free specimen transport items to test ordering physicians that exceed the volume of specimens referred to the lab that employs the sales rep. If the lab furnishes any type of hardware to a physician to be used for test ordering, specimen preparation, or result reporting, the physician should sign a written equipment loan agreement with the lab. The agreement should prohibit use of the equipment for anything other than the client's testing to be sent to the lab, and the equipment should be retrieved if the physician ceases to be a client.

Electronic Medical Record (EMR) Donation

This exception to the Stark Law and the Anti-Kickback Statute allows labs to provide EMR software and related training to a physician's office practice so long as certain rules are followed. Hardware is not permitted, however. The software must be interoperable, meaning that it must be able to interface with any lab or any other provider.

Labs may donate up to 85% of the cost of the EMR software (two entities may contribute to the 85% limit). This EMR donation cannot be tied to the volume of referrals. If the client stops the referrals, the lab may not request a refund or discontinue the monthly payments. The client must pay the additional 15% of the software cost. Many labs prefer paying the software company directly as opposed to making payments to the client. Bottom line, the lab sits "on-the-hook" for the donation even if the client decides to take his business elsewhere at a future point in time.

There remain several gray areas regarding EMR donations. The best policy prevails to check with legal counsel before engaging in a donation program.

To meet the requirements of the exception, the transfer of the items and/or services that comprise the EMR donation must occur before December 31, 2013 as the exception will end on that date.

Insurance Write-offs

If a laboratory does not have a contract with an insurance company (or a particular product of the insurance company), it must decide as a business matter whether to accept samples of patients who are covered by that plan. If, however, a lab decides not to bill anyone for the service, a compliance issue may be created. Such compliance risks may be heightened if the test ordering physician benefits from the lab's decision not to bill.

Typically, private health insurance companies offer two types of coverage—in-network ("par") and out-of-network. The former involves using only those providers (doctors, labs, imaging, etc) who have contracts with the insurance company and who appear in the insurance company's directory. This contract generally requires that the par providers accept an agreed-upon rate for services and collect co-payments from patients. In return for agreeing to these conditions, providers receive direct payment from the insurance company and, they hope, a higher volume of patients.

In the out-of-network scenario, the provider (physician, lab, etc) does not have a contractual relationship with the insurer. There may be strict limitations on this type of coverage. Generally, the insurance company will pay benefits only after the patient satisfies a deductible. Even after the deductible has been met, the patient may be responsible for co-insurance (a percentage of the allowable charge).

If a lab holds an out-of-network position, its business opportunities may be more problematic. Labs may bill 100% of their charge to an insurance company but, in order to remain competitive with in-network participating labs, they may consider writing-off any patient balance (accepting as payment-in-full the amount from the insurance company). However, a lab may be liable for waiver of co-insurance, deductibles or balance obligations. This type of activity can raise issues under various fraud and abuse laws. As a simple example, a lab bills a test for \$100 to an insurance company with the expectation that it will receive \$80. In normal circumstances, the lab expects the patient to pay \$20 co-insurance. If it waives the \$20 patient co-payment, some regulators and/or prosecutors argue that the lab's usual and customary charge actually becomes \$80, not \$100. Consequently, they assert that the insurer's obligation should be \$64, not \$80, and they contend that billing \$100 with the expectation of receiving a total of \$80, rather than the billed \$100, raises compliance issues. To avert this situation, some laboratories bill patients for the co-insurance amounts but do not aggressively pursue payment with multiple bills.

Pricing

If a particular state or insurance plan permits "doctor billing" of lab tests, sales representatives may want to offer discounts to test ordering physicians wishing to purchase testing services. If a lab grants discounts, it should strive to match the prices at which it sells its testing to the tests' fair market value. The Office of the Inspector General may take exception to below fair market prices that are offered in

return for referrals of testing that will be reimbursed by the Federal programs. As noted previously, the anti-kickback statute makes it a criminal offense to knowingly and willfully offer, pay, solicit or receive remuneration to induce service referrals reimbursable by Federal health care programs. When a laboratory offers testing at a price that is less than fair market value, the OIG may infer - depending on the facts - that the below fair market value price was offered in exchange for higher paying Federal health care program business. The question, therefore, is whether the discounted price represents a fair market value rate.

As a side note, sales people must realize that the anti-kickback statute ascribes liability to *all* parties of an impermissible kickback transaction (i.e., the lab, sales rep *and* the physician are equally involved).

Custom Profiles

Sometimes, a physician may request a custom profile of tests that facilitates his test ordering. Compliance safeguards for custom profiles include annually securing the physician's signature on a custom profile form that: (i) identifies the tests that the physician wants included in the profile, (ii) recommends that the physician order the profile for his Medicare and Medicaid patients only when all of the tests that are included in it are medically necessary for the patient for whom the profile is being ordered, and (iii) discloses the Medicare reimbursement amount for each component of the profile. The lab must also inform the physician(s) that using a custom profile may result in the ordering of tests which are not covered, reasonable or medically necessary. The doctor should sign and date the notice and return it to the laboratory

Summary

Due to the direct contact between sales people and their clients/prospects, they are at risk for tripping into the laws that regulate conduct between those who refer and those who receive referrals. Compliance programs exist to reduce the likelihood of inadvertent violation of the fraud and abuse laws.

The penalties for violation of the fraud and abuse laws can be extremely severe. It behooves every laboratory to develop its own compliance plan and ensure that those individuals who interface with clients and prospective customers fully understand the legal "rules of the road."

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