Compliance Sales Training

Peter T. Francis

When a laboratory hires or assigns someone to market its lab services, the lab should undertake at least one important educational duty within the first few days of the new employee's start on the job: review laboratory sales compliance rules, regulations and policies. Nothing should interfere with this initial instruction. Even if the representative has come from another lab where compliance had been a part of orientation, it remains important for the new employer to provide its own up-to-date training, either through in-house resources or from outside of the company.

Intense Government Focus on Health Care

The reason why this becomes so important is because of the spotlight the government has directed to uncover healthcare fraud and abuse. The Department of Justice's fiscal year budget increases every year by millions of dollars for health care fraud enforcement efforts.

The Laws

There exist key laws that salespeople must understand before engaging in conversations with healthcare professionals and their respective staff. The laws are the False Claims Act, Anti-Kickback Statute, Stark Laws, and applicable state laws. These broad statutes affect such topics as in-office phlebotomy, client supplies, leasing space in a doctor's office, non-monetary compensation, fees charged to physicians and custom profiles. While this paper is not an exhaustive compliance overview, it will examine a few key points with which marketing people should be fully cognizant.

False Claims

The False Claims Act remains the government's most powerful civil enforcement tool. It can result in liability, for example, when a provider (1) bills a government health insurance program for services that were not provided, (2) submits a claim for reimbursement to a government health insurance program that contains false information, or (3) seeks reimbursement from a government health insurance program for medically unnecessary services. While this may seem to affect the billing department more than the sales function, it is important to understand the government has seen numerous cases in which marketers have sought to persuade providers to

change ordering patterns, or to request unnecessary services. Such conduct can implicate the False Claims Act.

Anti-Kickback

The Anti-Kickback Statute is of paramount importance to employees in marketing positions. This 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. As an example, fees that are discounted below fully loaded cost-of-testing can implicate the Anti-Kickback statute; authorities may assume it is an inducement to receive more lucrative Federal program reimbursement. The Anti-Kickback statute is broad and it applies to individuals and entities on *both* sides of a prohibited transaction.

Stark

The Stark Law addresses issues that are similar to those that underlie the Anti-Kickback Statute. It is often referred to as the "Stark Self-Referral Prohibition" because it says that a physician may not refer a Medicare patient to a clinical lab with which the physician (or an immediate family member) has a financial relationship. A financial relationship is either an ownership interest or a compensation arrangement.

There are several important points within this law that sales representatives must understand. One of these points is the provision of non-monetary compensation to physicians. In each calendar year, the government assigns a certain dollar limit labs may provide non-monetary compensation (e.g. lunches, note pads, pens, mugs) to physicians (who order laboratory tests for Medicare beneficiaries). For example, in 2015, the limit equates to $392 per physician. Thus, laboratories should keep track of the amount of money spent on each physician for lunches and other give away items to confirm they are meeting the law's requirements. In addition, all of the following conditions must be met:

- The compensation cannot be determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician.
- The compensation may not be solicited by the physician or the physician's practice (i.e. employees and staff members).
- The compensation arrangement does not violate the Anti-Kickback Statute or any Federal or State law or regulation governing billing or claims submission.
- The representative cannot circumvent the limit by paying out-of-pocket.

The second bullet above is breached for one main reason: ignorance by both the field rep *and* the physician's office staff. A ubiquitous statement emanating from a doctor's office is, "If you bring in lunch, you can see the doctor." But this statement creates Stark Law issues if (1) it is a *current* client and (2) the office refers Medicare/Medicaid patients to the rep's lab. It is legal, however, for the field person to *offer* to bring in lunch—but not for the client to make the request.

State Laws

Field marketers must also be familiar with state laws to which they are subject. State laws can supersede Federal laws. Some states have direct-bill laws (i.e., no doctor billing) while others have anti mark-up and truth-in-billing laws. Consequently, representatives must be trained on the rules and regulations that apply to the states in which they are marketing.

Penalties

The punishment for violation of these laws can be criminal, civil and administrative. Conviction for a single violation under the Anti-Kickback Statute may result in a fine up to $25,000 and imprisonment for up to five (5) years. And—a point not always understood by salespeople—depending upon the situation, not only does the laboratory become entangled, but also the *client* and, possibly, the field rep. A violation of the False Claims Act can result in up to $10,000 in penalties for *each* false claim for reimbursement submitted to a government health care program. In addition to that penalty, damages can equal *three times* the amount wrongfully paid in reimbursement (referred to as "treble damages"). Exclusion from the Federal programs for both the lab *and* the client can also occur. Depending on circumstances, cases can be brought under multiple laws simultaneously, resulting in serious financial consequences.

The Federal government is not the only entity that can initiate law suits against labs. Private insurance companies can also bring suit. The bottom line is this: breaking Federal and state laws can lead to detrimental consequences for labs.

Summary

Due to the direct contact between sales people and their clients/prospects, field reps need to be sensitive to the laws regulating conduct between those who refer and those who receive referrals. Every commercial and hospital outreach laboratory should conduct yearly training to ensure their employees who interface with clients and prospective customers fully understand the "rules-of-the-road" and the potential consequences of violation.

The author wishes to thank Hope Foster from Mintz, Levin in Washington, DC for review of this manuscript. *Peter Francis, president of **Clinical Laboratory Sales Training, LLC**, provides sales training and coaching for the reference laboratory industry. He has authored over thirty articles focused on selling within the laboratory industry. For more information, visit www.clinlabsales.com.*