Compliance Sales Training

Peter T. Francis
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When a laboratory hires someone (or assigns a current employee) to market its lab services, the lab should undertake one important educational duty within the first few days: review laboratory sales compliance rules, regulations and policies. Nothing should interfere with this, and it must be non-negotiable. Even if the representative has had prior lab sales experience, it remains important for the employer to provide documented annual training, either through in-house resources or from a third party.

Intense Government Focus on Health Care

The reason why this becomes important is because of the intense spotlight the government has directed to uncover healthcare fraud and abuse. The Department of Justice's fiscal budget increases every year for this enforcement effort.

The Laws

There exist key laws salespeople must understand before they engage in conversations with healthcare professionals and their staff. The laws are the False Claims Act, Anti-Kickback Statute, Stark Laws, Civil Monetary Laws (CMP) and applicable state laws. These broad statutes affect such topics as offering reimbursement in exchange for services, persuasion tactics to order unnecessary tests, in-office phlebotomy/processor, client supplies, leasing space in a doctor's office, non-monetary compensation, test fees charged to physicians and custom profiles. This paper is not an exhaustive treatise, but it will examine a few key points with which marketing people should be fully cognizant.

False Claims

The False Claims Act (FCA) 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 the provider did not provide, (2) submits a claim for reimbursement containing false information, or (3) seeks reimbursement for medically unnecessary services. While this may seem to affect the billing department more than sales, the government has been

involved in numerous cases in which marketers have persuaded providers to change ordering patterns that result in unnecessary tests. Such conduct can implicate the False Claims Act.

Anti-Kickback

The Anti-Kickback Statute (AKS) is of paramount importance to employees in marketing positions. This statute specifically states 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, steeply discounted client bill fees below fully loaded cost-of-testing can implicate the Anti-Kickback statute; authorities may assume it is an inducement to receive federal program reimbursement. Offering cash, bio-hazard pick-up, exam gloves, free point-of-care drug testing cups are a few elements that fall under this law. The AKS follows a broad basis, and it applies to individuals and entities on *both* sides of a prohibited transaction.

Stark Law

The Stark Law is often referred to as the "Stark Self-Referral Prohibition," because it states that a physician may not refer a Medicare/Medicaid patient to a clinical lab (or other designated health service) 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 significant points within this law that sales representatives must understand. One of these is the provision of non-monetary compensation to physicians. In each calendar year, the government assigns a certain dollar limit that labs and other designated health services may provide non-monetary compensation (e.g. lunch) to physicians (i.e., those that order laboratory tests for federal beneficiaries). Thus, labs should inform their rep(s) of the specific dollar amount calculated by the government each year, and the lab should keep track of the money spent on each physician to confirm they are meeting the law's requirements. In addition, the following conditions must be met:

- The compensation cannot be determined when considering the volume or value of referrals by the physician.
- The physician or the physician's office staff may not solicit the request.
- 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 remains important due to the ignorance of both the field rep *and* the physician's office staff. A ubiquitous statement from a doctor's office is, "If you bring in lunch, you can meet with the doctor and the staff." 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 in this situation—but not for the client to make the request. Obviously, if the representative calls on a *prospective* account (where there is no referral testing to the marketer's lab), there is no Stark infringement for the client to request lunch.

State Laws

Field marketers must also familiarize themselves with the state laws in which he/she markets lab services. Many states have their own kick-back laws and contain their own unique provisions. An example is billing. Some states have direct-bill laws (i.e., no doctor billing) while others have anti mark-up and truth-in-billing laws. Several states have enacted specific laws that affect only pathology billing. Some states do not permit labs to provide phlebotomists to physicians. Some states make it illegal to rent space from a doctor.

Penalties

The punishment for violating these laws fall under criminal and/or civil. Conviction for a single violation under the Anti-Kickback Statute may result in a fine up to $100,000 (each for civil and criminal wrongdoing) and imprisonment up to ten years. And, depending upon the situation, not only does the laboratory become entangled, but also the client and, possibly, the field rep. Abuse of the False Claims Act results in Civil Monetary Penalties between $10,781 and $21,563 for *each* false claim submitted to a government health care program. In addition to that substantial fine, damages can equal three times the amount wrongfully paid in reimbursement (referred to as "treble damages"). Exclusion from billing the federal programs for both the lab *and* the client can also occur. A frequent situation arises when the government uncovers violations involving multiple laws within one situation (e.g., combining AKS and FCA penalties). Obviously, this results in significant financial consequences.

The federal government is not the only entity that can initiate lawsuits. Private insurance companies can also bring charges under state laws. The takeaway is breaking federal and state laws can lead to astronomical outcomes for labs and healthcare providers (and, possibly, sales reps).

Summary

Due to the direct contact between salespeople 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.

*Peter Francis is president of **Clinical Laboratory Sales Training, LLC**, a unique training and development company dedicated to helping laboratories increase their revenues and reputation through prepared, professional and productive representatives. Visit the company's web site at www.clinlabsales.com for a complete listing of services.*