



# COMPLIANCE SALES TRAINING

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04-12

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 of laboratory sales compliance rules, regulations and policies. Nothing should interfere with this initial education. Even if the representative has come from another lab where compliance had been part of the instructional component, it nonetheless remains important for the new employer to provide this 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, in part, because of the spotlight the government has directed to uncover healthcare fraud and abuse. In 2011, there were a record number of criminal and civil cases filed and record-breaking financial settlements reported: \$2.4 *billion* in health-care-related settlements and judgments under the False Claims Act alone. In addition, all signs point to *more* enforcement activity. The Department of Justice's (DOJ) FY 2013 budget request includes an additional \$71.7 million over FY 2012 for health care fraud enforcement efforts.

There exist key laws that people 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, electronic medical record donations, non-monetary compensation, 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. Proper training should be more expansive than the content of this document.

### **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 that the government has seen numerous cases in which marketers have sought to persuade providers to change ordering patterns, or to request unnecessary services, and 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. The 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. For calendar year 2012, labs may provide non-monetary compensation (e.g. lunches, note pads, pens, mugs) to physicians (who order laboratory tests for Medicare beneficiaries) worth up to \$373 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 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. The field person may *offer* to bring in lunch, but not the other way around.

### **Anti-Kickback and Stark**

Another area covered by the both the Anti-Kickback Statute and the Stark Law and subject to certain exceptions from the prohibitions established by these laws is assistance with the purchase of qualifying forms of electronic health record (EHR) software. Congress directed that Health and Human Services (HHS) develop these exceptions to encourage EHR proliferation.

As a result of these HHS-created exceptions, labs may donate up to 85% of the cost of the EHR software, but the office must pay the remaining 15%. Sales reps (and donating labs) must understand this requirement: the donation *cannot* be contingent upon referrals. In other words, there is no *quid pro quo*. If the lab donates toward the EHR software, it "sits-on-the-hook" for the gift. The physician's office may decide not to ever refer testing to the donating lab or to change laboratory vendors and to refer to a different lab, and the donating lab may not ask for a refund or discontinue making payments.

In addition to the 15% payment rule for physicians, there are several other requirements that must be met for the exceptions to apply. For example, the EHR software must be certified as interoperable (i.e. connect with others); there needs to be a written and signed contract; and the physician cannot already have equivalent items or services. If an EHR contract has already been signed, it is best to talk to legal counsel if the client requests a donation after the fact. Also, a lab should seek legal advice if it has been approached after a new EHR has been installed and the client suddenly requests a donation. There are many grey areas surrounding this issue of EHR donations. Another one relates to the question of whether a lab may pay for annual EHR maintenance fees. Again, seeking appropriate counsel equals the best policy. As it stands now, the law for EHR donation terminates on Dec. 31, 2013. However, the law enacted in August 2006, and several things have occurred since then (e.g., meaningful use incentives, slow EHR adoption, recommendations to make the safe harbor donation permanent, etc.). Stay tuned.

### **State Laws**

Field marketers must also be familiar with state laws to which they are subject. State laws can supersede Federal laws. For example, New York State has banned EHR donations. 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 in the states in which they are marketing and selling.

## **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 \$11,000 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. Exclusion from the Federal programs for both the lab *and* the client can also occur. Depending on circumstances, cases can be brought under both the False Claims Act *and* the Anti-Kickback Statute.

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 - offering kickbacks and submitting false claims can lead to detrimental consequences for labs.

## **Summary**

Due to the direct contact between sales people and their clients/prospects, field reps should always be sensitive to the laws regulating conduct between those who refer (physicians) and those who receive referrals (e.g., labs) and labs should implement compliance programs to reduce the likelihood of violation of the fraud and abuse laws. The penalties for violation of these laws can be extremely severe. As a result, every laboratory should conduct yearly training to ensure that those individuals who interface with clients and prospective customers fully understand these laws and the consequences that can come from violating them.

*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](http://www.clinlabsales.com).*