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The complex science of regulatory compliance in the laboratory

By Rina Wolf and David Gee

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The degree to which a clinical laboratory understands the complexities of regulatory compliance can mean the difference between its financial solvency and growth and survival. The current regulatory landscape brings increased legislation and agency intervention for seeking out potential fraud and waste in health care, including: the Patient Protection and Affordable Care Act (PPACA), the Fraud Enforcement and Recovery Act (FERA), the Healthcare Fraud Prevention and Enforcement Action Team (HEAT), Medically Unlikely Edits (MUEs), Recovery Audit Contractors (RAC), Comprehensive Error Rate Test (CERT), and a host of others.

As much as $20 billion has been recovered by the government through its health care fraud enforcement activities since 1996, with several significant settlements involving bundled laboratory tests billed as free-standing tests, resulting in a multi-fold increase in charges. The Office of Inspector General (OIG) of the US Department of Health & Human Services (DHHS) reports that the government recovers $6.80 for every dollar it spends on enforcement.[1] Consequently, the government has a powerful financial incentive to expand its fraud prevention budget and activity.

Regulatory compliance challenges

In conjunction with its step-up in other fraud and abuse enforcement activities, the Centers for Medicare and Medicaid Services (CMS) recently announced new screening procedures applicable to providers and suppliers enrolled in Medicare, Medicaid, and the Children's Health Insurance Program (CHIP). Different levels of screening will be applied to providers and suppliers according to the level of perceived risk they pose to potentially commit fraud, waste, and abuse in federal health care programs. The three levels of screening and associated risk are limited, moderate, and high, and are based on CMS's experience in identifying and investigating fraudulent billing practices. Each risk category assigned to a provider or supplier imposes a unique level of screening measure by CMS. Clinical laboratories are considered a moderate risk due to the industry's high volume of submitted claims.

The government has also shifted its focus from "pay and chase" enforcement to front-end detection when it comes to unearthing fraud, abuse, and waste, in the hope that identifying specific trends and billing circumstances will more readily identify aberrational and fraudulent activities.

In addition, CMS's new fraud and abuse measures allow them to suspend reimbursement based

on "credible allegations of fraud," a shift from the higher "reliable evidence of fraud" standard. As a result, CMS is authorized to suspend payments where overpayments are identified, or where there is a credible allegation of fraud.

Although CMS must consult with the OIG in determining whether the allegation of fraud is credible, the government's shift from "reliable evidence of fraud" to a "credible allegation of fraud" as the threshold for suspending payments may force laboratory settlements, regardless of the strength of evidence of fraudulent or abusive activity, or the laboratory's proof to the contrary. Once revenues and principle funding sources are shut off through Medicare and Medicaid programs, laboratories are compelled to settle rather than shut down.

Many other familiar laws have become tighter, such as the False Claims Act (FCA), amended in 2009 through FERA. The FCA has long been the government's biggest anti-fraud enforcement weapon, and forms the basis for *qui tam* lawsuits whereby private or non-governmental individuals assist in prosecuting a claim of fraud against the government in exchange for a portion of monetary penalties or settlement proceed—up to 25% of the recovery. In fact, over 80% of health care fraud settlements arise from *qui tam* cases. In 2010 alone, the government paid *qui tam* relators over $300 million for their participation in qui tam lawsuits.[2] Note that violations of the federal Stark law and Anti-kickback Statute now serve as the basis for a false claims action.

With the government's increased enforcement efforts and arsenal, the need for a comprehensive and highly effective compliance plan has never been greater.

Components of a living compliance plan

OIG spearheads the nation's efforts to fight waste, fraud, and abuse in Medicare, Medicaid, and more than 300 other DHHS programs.

With the passage of PPACA in March 2010, a compliance program is now a legal requirement for providers participating in Medicare or Medicaid programs. It is also essential for clinical laboratories to survive and succeed, as well as for lab owners who plan to exit the industry through a merger or acquisition. In the recent past, investors have walked away from substantial transactions because of compliance problems, and some labs have been unable to sell for the same reasons.

The OIG's recommended requirements for a clinical laboratory compliance program[3] were published in the late 1990s and include the following key components, taken from the Federal Sentencing Guidelines:

- A compliance officer and compliance committee
- A written standard of conduct as well as written policies and procedures pertaining to specific areas of operation
- Education and training programs for affected employees
- A process for receiving complaints
- A system to respond to allegations of improper conduct and impose appropriate discipline
- An auditing/monitoring mechanism
- A plan for responding to detected offenses and implementing corrective action

Let's take a closer look at the major compliance program requirements.

Staffing and organization

One of the most important investments that clinical laboratories can make for their compliance program is to hire and authorize the right compliance officer (CO). To be effective, the CO should be a member of the laboratory management team. The CO must have sufficient management-level authority and independence to carry out the responsibilities of the role.

It is essential that the CO be an active and informed participant and advisor in the management and operation of the lab. However,

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laboratories should ensure that if the CO is also assigned management or operations duties outside the compliance officer role, as may happen in a smaller lab organization, the nature and time requirements of those other responsibilities do not interfere with the duties of the compliance officer. The CO should not have an active role in sales, marketing, billing, or finance.

The OIG guidelines emphasize that an effective compliance plan requires that the CO report directly to the board of directors or a board Compliance Committee that has corporate and legal oversight responsibility for the company. This structure enables the CO to alert the board to regulatory and legal compliance problems and update the board about new compliance requirements that may affect the company. Ideally, the CO's role should be formalized by written board resolution to demonstrate the board's commitment to an effective compliance program. This will also have the effect of emphasizing to other management that the CO has the authority and mandate to direct the company's compliance efforts as a full partner with management in making compliance part of the company's mission.

The importance of this OIG guidance is underscored by the 2010 amendment to the Federal Sentencing Guidelines and related commentary, that one of the key indicators of the effectiveness of a compliance program is that the plan facilitates direct reporting by the CO the to board of directors or board committee, grants the CO express authority to communicate to the board regarding potential criminal conduct, and requires an annual report by the CO to the board regarding the effectiveness of the compliance program.

Compliance Committee

The OIG guidelines recommend that laboratories form and maintain a Compliance Committee composed of management that meets regularly to assist the CO and the company to implement, support, and oversee the company's compliance program. The Compliance Committee helps to carry out essential compliance initiatives and actions, such as review of billing/claims reviews, requisition design, training (compliance and otherwise), compliance auditing and monitoring procedures, compliance communications protocols, and other related responsibilities. The most effective Compliance Committee is composed of the company's key managers to help align, integrate, and coordinate the company's compliance initiatives and activities with the business and technical operations of the organization. Including the leaders of corporate departments also helps to dispel the misperception by employees, or the managers themselves, that compliance is solely the responsibility of the CO.

Systems, procedures, and policies

Billing is the highest compliance risk area for clinical laboratories. As noted above, CMS has determined that clinical laboratories pose a moderate risk of fraud, waste, and abuse due to the "sheer volume of services and associated billing by these entities." Likewise, the majority of past government enforcement activity against laboratories has involved laboratory billing, coding, and reimbursement practices. Not surprisingly, therefore, the OIG's model compliance guidance for laboratories focuses extensively on laboratory billing.

Billing compliance requires clear and current billing policies and procedures, as well as highly trained billing personnel. Equally important is detecting billing irregularities as they occur and, if possible, before claims are posted. In addition to constant and careful monitoring, it is imperative that laboratories utilize an appropriate billing system to manage this effort. A good billing and revenue cycle management system will automatically trigger alerts if any requested actions regarding a claim are questionable or non-compliant.

A system accessible via a Software as a Service (SaaS) model is especially valuable for helping ensure compliance, because the software is automatically updated on an ongoing basis to incorporate ever-changing regulatory and payer rules. The

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billing system should also provide clear documentation and reports to provide the necessary information and analytics required for audits, potential merger and acquisition, or investment due diligence.

Disciplinary actions
Clinical laboratories must have complete knowledge of any employee or client that has been sanctioned by the OIG, because they cannot participate in any Medicare, Medicaid, or other governmental billing activities. Some billing systems can also perform automatic checks to ensure employees have OIG clearance.

Requisition design
Requisition design is another keystone of an effective laboratory compliance plan. The test requisition must be designed to gather all of the information from the ordering physician that is necessary for submittal of a clean claim. The requisition must be designed to meet CMS regulations and guidance, and to ensure that laboratory clients can make informed and appropriate choices when they order testing. Sales and customer service personnel should be well-versed in these requirements, so they are able to educate and assist customers with proper ordering practices.

Fraud alerts and Advisory Opinions
OIG periodically issues Special Fraud Alerts that provide insight and guidance regarding national trends in health care fraud and address potential violations of the Medicare and state health care programs' anti-kickback statute. In 1994, the OIG issued a Special Fraud Alert[4] addressing the relationships between clinical laboratories and ordering practitioners. That Special Fraud Alert stated, among other things, that a phlebotomist may be placed in a doctor's office where state laws permit, noting that several states do not permit this practice; it also provided guidance that laboratories may not provide customers with free supplies and equipment unless they are used solely for the collection, ordering, or reporting of lab tests. A 2000 Special Fraud Alert provides specific guidelines regarding leases with ordering providers.[5]

Likewise, OIG and CMS periodically issue Advisory Opinions, some of which pertain to laboratory practices, such as discounting, free supplies, and phlebotomy services. Laboratories must include these alerts in their compliance program to avoid severe consequences.

Training and education

A well-executed and effective training and education program is integral to a successful compliance plan. Training should be mandatory for all employees, from the chief executive officer to the newest hire. The education program must be comprehensive and emphasize and explain the laws and regulations that govern the lab to ensure that employees are familiar with current standards, policies, and procedures.

Employees in high compliance risk areas such as billing, sales and marketing, and other potential areas of greater concern should have additional, more specialized training. Optimally, the plan should require training to occur within 30 days of hire, and then on an annual basis for the entire company. It is advisable to include expert and reputable consultants in preparing and updating compliance training materials, and in some cases, in presenting the training, to keep the training up to date on important compliance issues. A post-training quiz is recommended to ensure and document that every employee understands the information provided during educational sessions.

Auditing, monitoring, and record retention

If compliance activities are not documented, it is as if they do not exist. A living compliance plan will show documentation of all forms, training activities, and all other compliance actions including investigations, reporting, and corrective actions taken in regards to compliance procedures or incidents. It is advisable to do a baseline audit when the compliance program is initiated to reveal any potential problems, to enable the lab to correct those deficiencies, and to

serve as a reference point to measure progress in future audits.

Regardless of whether an outside government agency makes a routine or surprise compliance audit, the lab should have clear evidence that it has a fully implemented and "living" compliance plan that is integrated and followed by each employee.

Record retention is also critical, and there are various rules as to how long labs must keep records. For example, records that pertain to Medicare advantage plans must be kept for ten years, but other records have a retention statute of only six years.

Every employee must understand that it is their individual responsibility to report any activity that may appear to be suspect, regardless of the source. The compliance program can help facilitate this process by providing a specialized e-mail address, voice mailbox, or electronic hotline. The laboratory may wish to make some or all of these channels accessible to external parties as well for reporting concerns. The more that employees are encouraged and enabled to share their compliance questions and concerns with the company and its compliance team, the less likely that employees will turn to outside entities to help them address their concerns, as whistleblowers or otherwise.

Corrective action

When laboratories discover a problem, they must also have definitive protocols in the compliance plan to immediately correct the violation and fix any structural or organizational failure that may have caused the problem and to prevent recurrence. In some cases, remedial actions may involve reporting the mistake to the government or other affected parties.

Under PPACA and FERA, labs cannot retain a claims overpayment, and PPACA requires that any overpayment received by the lab from a federal program must be repaid within 60 days of discovery. Although the regulations are somewhat vague as to what constitutes discovery triggering the 60-day deadline, laboratories err on the side of caution by immediately refunding the overpayment to the affected program. Note that overpayments include any payments received from the government as the result of activities prohibited by the federal Anti-kickback Statute and Stark laws.

OIG has a self-disclosure protocol for health care providers who voluntarily chose to disclose conduct that they believe to violate federal criminal, civil, or administrative laws, such as the Anti-kickback Statute and False Claims laws. As directed by PPACA, CMS has implemented a self-disclosure protocol for Stark violations. Although both protocols authorize the government to exercise discretion to reduce penalties for the conduct in question, each protocol also involves a careful and thorough review of the facts and circumstances in each case, including such key factors as the nature and extent of the conduct, the timeliness of the lab's self-disclosure, the level of the lab's cooperation, the likelihood of success of litigating the matter, and the financial resources of the disclosing provider. The government will also take into account whether a provider has a complete and effective compliance program.

Conclusion

Compliance plans are now legally mandated for any lab that participates in the Medicare, Medicaid, and CHIP programs. Beyond meeting that new legal requirement, laboratories must develop and maintain "living" compliance programs—a "paper" plan that has not been fully integrated within the lab organization is likely to be more incriminating than helpful.

In light of the intensified legal and enforcement environment facing laboratories and other health care providers, failure to devote sufficient resources to a strong compliance program puts the laboratory and its investors, management, and employees at heightened risk. To protect the interest of each of those stakeholders, laboratories must invest in an effective compliance plan that:

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- is led by a qualified and committed compliance officer appointed by and reporting directly to the board of directors, and a management level Compliance Committee;
- maintains and educates its workforce about essential compliance policies and procedures;
- designs and implements compliant and effective billing systems and controls; and
- detects and promptly responds to violations identified by auditing and by employees who are encouraged and charged to make the program a success.

Ultimately, investment in a robust compliance program contributes to the laboratory's growth, profitability, and survival in a health care industry fraught with regulatory oversight and pitfalls. ■

1. New Tools for Curbing Waste and Fraud in Medicare and Medicaid, Testimony of Daniel R. Levinson Inspector General U.S. Department of Health and Human Services before the U.S. Senate (March 9, 2011), page 4. Available at http://oig.hhs.gov/newsroom/testimony-and-speeches/index.asp
2. The Department of Health and Human Services and The Department of Justice Health Care Fraud and Abuse Control Program Annual Report for Fiscal Year 2010 (January 2010), page 6. Available at http://oig.hhs.gov/reports-and-publications/hcfac/index.asp
3. Compliance Program Guidance for Clinical Laboratories. Federal Register, vol. 63, no. 163, August 1998. Available at http://oig.hhs.gov/authorities/docs/cpglab.pdf
4. HHS-OIG Special Fraud Alert: Arrangements for the Provision of Clinical Lab Services (Issued October 1994). Available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html
5. HHS-OIG Special Fraud Alert: Rental of Space in Physician Offices by Persons or Entities To Which Physicians Refer (February 2000). Available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/office%20space.htm