

Compliance Now



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Is your company walking the walk?

How effective is your compliance program?

As state and federal compliance regulations continue to expand, companies need not only to refine their written policies and procedures, but also evaluate the effectiveness of their compliance program. By now, the OIG's seven elements should be commonplace in every compliance program. However, merely having the seven elements is not enough to protect companies from possible fines or prosecution. In other words, a "check the box" written policy is no longer good enough.

What must a company do to ensure their program is properly detecting and preventing criminal conduct? Part of the answer is to simply ask different questions. Instead of asking whether the seven elements are present in a program, ask whether the seven elements are effective.

For example, when determining if the OIG element of "education and training" is present, a compliance officer should ask if there are mandatory orientation programs, annual training, *etc.* But in order to establish whether the company is providing *effective* education and training, the compliance officer should also ask whether the staff are tested on the material. Is the education sinking in? Is the staff actually learning what the company is teaching? If the staff were singled out and questioned on HIPAA disclosures, would they get it right?

As you can see, there is a difference between reviewing whether a policy exists and whether the policy is effective.

The former may be called a quantitative review, the latter is referred to as a qualitative review. The government certainly will look at the quantitative aspects of a compliance program, but recent regulations also call for government to look at the *quality* of the program as well. Is your compliance program just words on paper? If so, the government may find your company is talking the talk, but not walking the walk.

This issue of *Compliance Now* is dedicated to helping companies determine if their compliance programs are effective.

Increased enforcement PPACA brings more compliance regulation

PPACA includes new tools for the government to use in enforcing fraud and abuse against the health care system. Here are just a few of the changes that will result under PPACA:

- ◆ No new physician-owned hospitals will be allowed under the Stark law
- ◆ For certain providers, compliance plans will be made mandatory
- ◆ Under the Anti-Kickback statute, the intent standard is clarified
- ◆ 60 day overpayment return
- ◆ Payment suspension where there is a credible allegation of fraud
- ◆ Patient notifications for certain in-office ancillary services
- ◆ National coordination of anti-fraud activities

Q&A

Questions to ask to determine effectiveness of each of the seven OIG elements

Development and distribution of written standards of conduct, policies and procedures

Do employees know where the policies are located? Are the policies accessible to all employees? How often are the policies updated? Are there policies on fraud and abuse? If so, do employees understand reporting requirements?

Designation of a chief compliance officer and other appropriate bodies

Do employees know who the compliance officer is? Do employees understand the role of the compliance officer? Does the compliance officer have direct access to management and/or the board?

Development & implementation of regular, effective education & training programs for all affected employees

Are employees tested on the training material? How often are employees receiving compliance education? Is compliance training also required for management? Do employees know what to do if they suspect a compliance problem?

Maintenance of a process (e.g., hotline), to receive complaints, and the adoption of procedures to protect the anonymity of complainants and to protect whistleblowers from retaliation

If there is a hotline, do employees know the number? Do employees know where to find the number? Do employees feel as though their complaint will be reviewed? Do employees feel as though the company has retaliated against former employees who turned in a complaint? Are there compliance questions on annual performance reviews? Where is the compliance office? When a complaint or lawsuit arises, is there an internal investigation?

Development of a system to respond to allegations of improper activities & the enforcement of appropriate disciplinary action against employees who have violated policies or laws

If an employee is disciplined for wrong-doing, is the discipline consistent? Are there policies on self-disclosure, and if so, how are the policies enforced? When does the company decide to hire an outside expert or order an external review of an issue? When an internal investigation reveals a problem, what is the company's response?

The use of audits and other evaluation techniques to monitor compliance and assist in the reduction of the identified area

Is the company data-mining its own data on a regular basis to determine the presence of any wrong-doing? How is data tracked? How often are audits implemented? Are audits implemented before or after a problem arises? Who are the audits reported to? Are there any conflicts of interest in who is performing the audit? How often are the auditor's credentials/qualifications reviewed?

The investigation and remediation of identified systemic problems and the development of policies addressing the non-employment or retention of sanctioned individuals

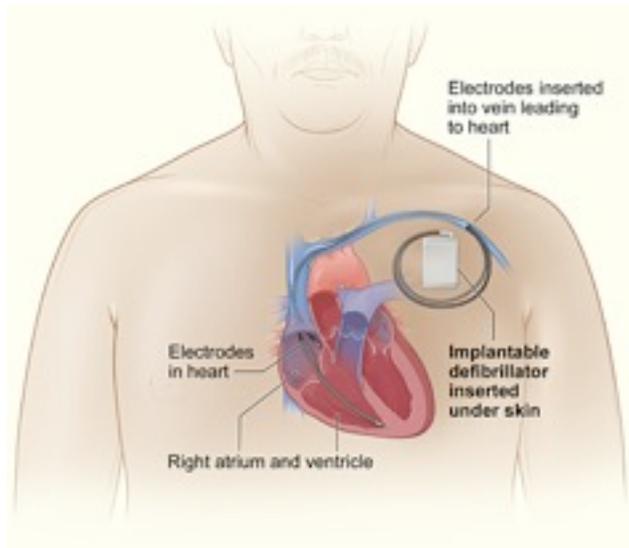
Are there policies to address wrong-doing and how often are they updated? Has an audit been done to review whether discipline is consistent? Do employees understand the possible sanctions of non-compliance when they are hired? Are these policies contained in the employee handbook? Do employees sign a document indicating they understand the sanctions?

ABOUT OUR FIRM

MATTHEWS LAW FIRM, P.A. was founded in 2007 and is located in Bartow, Florida. Our practice areas include health care compliance and criminal defense. Our two attorneys, Scott & Autumn Matthews, have over 15 years combined experience in our practice areas, including experience in drafting compliance policies and assisting with internal investigations. Additionally, our attorneys have tried approximately 100 criminal jury trials.

Experience is important. Preparation is critical. We pride ourselves on providing both. If you would like to contact us, our office is located at 170 North Florida Avenue, Bartow, FL 33830 and you can call us at (863) 533-4400. We can also be reached online at www.MatthewsPA.com.

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WHAT IS AN ICD?

An implantable cardioverter defibrillator (ICD) is a small battery-powered electrical impulse generator which is implanted in patients who are at risk of sudden cardiac death. The device, once surgically implanted, is programmed to detect cardiac arrhythmia and correct it by delivering a jolt of electricity.

If the ICD fails to operate properly when needed, a person can die within minutes.

Case Law Update

Withholding information from the FDA has serious consequences

Guidant LLC, a subsidiary of Boston Scientific Corporation, was sentenced January 13, 2011 by U.S. District Court Judge Donovan Frank for violations of withholding information from the FDA regarding catastrophic failures in some of its defibrillator devices. Guidant was sentenced to pay more than \$296 million in criminal fines and also to serve three years of corporate probation. While on probation, Guidant will be required to make quarterly reports to the U.S. Probation Office and to submit to regular, unannounced inspections of its records. The court also required Guidant to notify its employees and shareholders of its criminal conviction.

The court found that Guidant made decisions at various times to conceal information from the FDA and medical

professionals regarding the implantable cardioverter defibrillator device (ICD) failures. In June 2005, the company finally went public about the problem it had known about for 10 months, only after three deaths had occurred.

The Justice Department's sentencing memorandum explains how Guidant decided to continue to implant hundreds of defective devices, even after the company had decided to stop shipping them from the factory due to the serious health risk they represented. Guidant developed a strategy to mitigate the health risk while not informing the FDA of the defect. This mitigation strategy included the company advising its sales reps to tell physicians that "nothing was broken" with the device, and falsely telling the FDA that changes it proposed to the device in response to the electrical short-circuiting "were not being done to correct device flaws that threaten patient safety" but were rather "to improve process throughout."

"The sentence the court imposed reflects the seriousness of Guidant's conduct", Assistant Attorney General

Tony West said. "Patients are put at risk when health care companies fail to meet their responsibility to provide complete and accurate information to the FDA."



An illustration of one type of ICD produced by Guidant.



Upcoming Calendar Events

April 10-13, 2011
HCCA Compliance Institute
Orlando, FL

May 6, 2011
HCCA Regional Conference
Columbus, OH

June 6-9, 2011
HCCA Basic Compliance Academy
Scottsdale, AZ

Practice Tip

Providing effective education and training

The best training programs teach employees and management what constitutes unethical conduct so they can recognize wrongdoing and make the proper reports. Here are five suggestions as to how your organization can provide more effective employee training:

- Have senior management play an active role in driving ethics training efforts.
- Educate on values – in addition to laws and rules – to inspire principled behavior and avoid workplace harassment.
- Make ethics training interesting, provocative and engaging.
- Make ethics training relevant to actual "real world" scenarios that employees often face.
- Reinforce ethics training and apply learning to on the job experiences.

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