The Increasing Importance of Legal Counsel, Compliance, and Their Interaction with Healthcare Boards

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IN FISCAL YEAR 2015, THE DEPARTMENT OF JUSTICE (DOJ) obtained $1.9 billion in healthcare fraud settlements and judgments from False Claims Act (FCA) cases. The DOJ's winning streak against hospitals and health systems continued in the first quarter of 2016. This underscores both the federal government's continuing commitment to pursuing healthcare fraud and abuse cases and the increasingly important roles played by compliance officers and legal counsel at hospitals and healthcare systems.

There are many factors currently at work that require greater emphasis on strengthening compliance programs within the hospital setting, including:

- **HHS OIG 2016 Work Plan**: The U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) Work Plan for fiscal year 2016 details the OIG's annual goals for preventing and prosecuting healthcare fraud and abuse.[1] This includes many key enforcement areas warranting the vigilance of compliance officers and legal counsel at hospitals and health systems.
- **The Yates Memo**: In 2015, a memorandum issued by U.S. Deputy Attorney General Sally Quillian Yates highlighted a new policy implemented by the DOJ and incorporated into the United States Attorneys' Manual. The memo relates to corporate prosecutions and incorporates new policies focused on individual accountability for wrongdoing.
- **The rising number of whistleblower cases filed under the FCA's *qui tam* provisions**: There has been a steady increase in the number of new fraud matters opened by the DOJ's Civil Division based on newly received referrals, investigations, and *qui tam* actions. The rapidly growing role of whistleblowers in initiating and pursuing FCA cases means that hospitals must a) be aware of the *qui tam* process and b) take steps to reduce exposure to potential whistleblower actions.

The Differing Roles of Compliance and Legal Counsel

Hospitals and health systems must increasingly rely on legal counsel to manage and mitigate risk associated with regulatory compliance. Additionally, it is vitally important for healthcare organizations to foster environments in which legal counsel are positioned to work effectively with the chief compliance officer and the governing board. It is critical for legal

counsel and compliance officers to fully understand and appreciate their distinct roles within an organization. In April 2015, OIG issued *Practical Guidance for Health Care Governing Boards on Compliance Oversight* in which the roles and relationships of the compliance and legal functions were concisely defined:[2]

- Compliance: "The compliance function promotes the prevention, detection, and resolution of actions that do not conform to legal, policy, or business standards."
- Legal: "The legal function advises the organization on the legal and regulatory risks of its business strategies, providing advice and counsel to management and the board about relevant laws and regulations that govern, relate to, or impact the organization."

It is the compliance officer's role to operate and monitor the compliance program and investigate compliance issues, while legal counsel is charged with directing the organization's response to actual or potential violations. Beyond the interpretation of the law, attorneys working with hospitals and health systems provide advice on ethical issues and how to promote a culture of compliance. "Collaboration, not cohabitation," is viewed as the most effective relationship between compliance and in-house

1 *Work Plan Fiscal Year 2016,* U.S. Department of Health and Human Services, Office of Inspector General, November 2015.

2 *Practical Guidance for Health Care Governing Boards on Compliance Oversight,* Office of the Inspector General, U.S. Department of Health and Human Services, Association of Healthcare Internal Auditors, American Health Lawyers Association, Health Care Compliance Association, April 2015.

counsel, and while the two roles are related and complementary, it is optimal "to keep the roles separate and with an equal footing."[3]

In addition to stressing the importance of separating the compliance and legal functions, OIG recommends that the board should receive regular reports regarding the organization's risk mitigation and compliance efforts. For boards, ensuring open lines of communication from throughout the organization is vital. OIG notes that a board can "raise its level of substantive expertise with respect to regulatory and compliance matters by adding to the board, or periodically consulting with, an experienced regulatory, compliance, or legal professional."[4]

The Eight Fundamental Elements of an Effective Compliance Program

In 2010, the United States Sentencing Commission modified the Federal Sentencing Guidelines for organizations, including the provisions that set forth the attributes of effective compliance and ethics programs. Under the Federal Sentencing Guidelines, a convicted organization may be eligible for a reduced sentence if it has established an effective compliance and ethics program. The guidelines describe the key attributes that a compliance and ethics program must exhibit for the organization to be eligible to receive benefits such as reduced fines, reduced sentence, or deferred prosecution. The fundamental elements are:

1. **Implement written policies, procedures, and standards of conduct**. The compliance officer, legal counsel, and the board must work in concert to develop, implement, monitor, and enforce an effective compliance program. Clear policies and procedures should be established regarding regulated actions, such as handling protected health information and combatting fraud, waste, and abuse.
2. **Designate a compliance officer and compliance committee**. Organizations should designate a compliance officer who is chiefly responsible for the compliance program and, if your organization's size and operations allow for it, there should be a compliance committee to oversee the program and advise the compliance officer. In choosing the officer and committee, the organization should consider the independence of the compliance officer and committee as a key component of an effective compliance program.
3. **Conduct effective training and education**. The board must exercise reasonable oversight with respect to implementation and effectiveness of the compliance program. While the board may delegate oversight of the compliance program, it remains accountable for reviewing its status. Training and education on the compliance program is required, and the board should have a means to prove active engagement in the oversight of the program.
4. **Develop effective lines of communication**. Communication between the board/upper management and compliance officer should take place regularly to ensure that the board and senior leadership are briefed on compliance issues and program effectiveness. Regular contact between the board and compliance officer also promotes a culture of compliance because the issues will be discussed routinely and clearly.
5. **Conduct internal monitoring and auditing**. An effective compliance plan will include a method for conducting regular internal audits of the organization to identify and address potential compliance issues. As part of the internal auditing process, an organization should create an audit plan and update the plan regularly to reflect changes in the organization as well as to applicable statutes and regulations.
6. **Enforce standards through well-publicized disciplinary guidelines**. Disciplinary guidelines should strike the right balance between consistency and flexibility. This will ensure that employees understand there will be consequences for non-compliance, but will also enable your organization to adapt disciplinary proceedings according to the situation. As part of this step toward compliance, an organization should have clear consequences for violations of disciplinary procedures.
7. **Respond promptly to detected offenses and undertaking corrective action.** Responding promptly to detected offenses and taking corrective action demonstrates a commitment by the organization to compliance and in some cases, can reduce the potential liability and damage resulting from non-compliance.

In addition, we include an eighth fundamental element:

8. **Evaluate and measure the program's effectiveness regularly**. An ineffective compliance program can lead to unnecessary violations and enforcement actions, which could have been prevented through ensuring maintenance of a program that encourages and aids in complying with all applicable legal and ethical standards.

3 "Should Compliance Report to the General Counsel?," Society of Corporate Compliance and Ethics and the Health Care Compliance Association, March 2013.

4 *Practical Guidance for Health Care Governing Boards on Compliance Oversight,* April 2015.

Introduction

For hospitals and health systems, the roles of legal counsel and compliance officers are now more critical than ever. Scrutiny from government enforcement agencies continues to escalate, and financial recoveries from healthcare providers in the form of penalties and settlements remain at historic levels.

IN FISCAL YEAR 2015, THE DEPARTMENT OF JUSTICE (DOJ) obtained $1.9 billion in healthcare fraud settlements and judgments from False Claims Act (FCA) cases for a total of $16.5 billion recovered in healthcare cases since January 2009.[5] Hospitals and health systems accounted for nearly $330 million of recoveries in 2015.[6]

The DOJ's winning streak against hospitals and health systems continued in the first quarter of fiscal year 2016. South Carolina-based Tuomey Healthcare System paid $72.4 million to resolve a $237 million judgment for illegally billing the Medicare program for services referred by physicians with whom the hospital had improper financial relationships.[7] Weeks later, North Broward Hospital District agreed to pay $69.5 million to settle FCA liability for Stark law violations related to compensation paid to nine employed physicians that exceeded the fair market value of their services.[8] Next, Adventist Health System agreed to pay $115 million to settle FCA allegations based on Stark law violations related to improper bonuses paid to employed physicians.[9] Additionally, 457 hospitals in more than 40 states settled False Claims Act allegations in October 2015 related to the implantation of cardiac devices for more than $250 million.[10]

These settlements underscore both the federal government's continuing commitment to pursuing healthcare fraud and abuse cases and the increasingly important roles played by compliance officers and legal counsel at hospitals and healthcare systems.

5 "Justice Department Recovers over $3.5 Billion from False Claims Act Cases in Fiscal Year 2015," Department of Justice, Office of Public Affairs, December 3, 2015.
6 *Ibid.*
7 "United States Resolves $237 Million False Claims Act Judgment Against South Carolina Hospital That Made Illegal Payments to Referring Physicians," Department of Justice, Office of Public Affairs, October 16, 2015.
8 "Florida Hospital District Agrees to Pay United States $69.5 Million to Settle False Claims Act Allegations," Department of Justice, Office of Public Affairs, September 15, 2015.
9 "Adventist Health System Agrees to Pay $115 Million to Settle False Claims Act Allegations," Department of Justice, Office of Public Affairs, September 21, 2015.
10 "Nearly 500 Hospitals Pay United States More Than $250 Million to Resolve False Claims Act Allegations Related to Implantation of Cardiac Devices," Department of Justice, Office of Public Affairs, October 30, 2015.

HHS OIG 2016 Work Plan and Key Areas of Enforcement Focus

The U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) Work Plan for fiscal year 2016 details the OIG's annual goals for preventing and prosecuting healthcare fraud and abuse.[11] Among the enforcement initiatives focused on hospitals and health systems in the 2016 Work Plan is an emphasis on provider-based status for facilities owned and operated by hospitals, which are permitted to bill as hospital outpatient departments.[12] The OIG is responding to concerns expressed by the Medicare Payment Advisory Commission about financial incentives associated with provider-based status and seeks to determine compliance with applicable standards by such facilities.[13] The 2016 Work Plan also introduced a new initiative focused on the validation of inpatient quality reporting data submitted by hospitals and health systems.[14] The OIG highlighted the importance of quality reporting data with respect to the Hospital Value-Based Purchasing Program and the Hospital-Acquired Condition Reduction Program.

Other key enforcement areas warranting the vigilance of compliance officers and legal counsel at hospitals and health systems include the following.

Physician Compensation and the Intersection of the False Claims Act and the Stark Law and Anti-Kickback Statute

As noted above, several of the recent high-profile False Claims Act settlements involving hospitals and health systems focused on physician compensation arrangements. In June 2015, the OIG issued a fraud alert that bluntly stated that while many compensation arrangements such as medical directorships are legitimate, the arrangement may violate the anti-kickback statute "if even one purpose of the arrangement is to compensate a physician for his or her past or future referrals of federal healthcare program business."[15]

11 *Work Plan Fiscal Year 2016,* U.S. Department of Health and Human Services, Office of Inspector General, November 2015.
12 *Ibid.*
13 *Ibid.*
14 *Ibid.*
15 "Fraud Alert: Physician Compensation Arrangements May Result in Significant Liability," Department of Health and Human Services, Office of Inspector General, June 9, 2015.

As hospitals employ greater numbers of physicians, the likelihood of violations of the complex requirements of the Stark law increase.[16] Since the passage of the Fraud Enforcement and Recovery Act in 2009 and the enactment of the Affordable Care Act in 2010, changes to the False Claims Act have greatly expanded the reach of the law. As a result, non-compliance with the Stark law and the anti-kickback statute renders claims submitted pursuant to the improper relationship "false" and can result in large damage awards.

Among the notable enforcement actions of the past several years that began with a relator, the *Tuomey* case is the most instructive for hospitals with respect to Stark law violations and the False Claims Act. This case began with a *qui tam* action alleging Stark law violations, which were found to affect more than 21,000 claims. While an initial trial ended in Tuomey's favor, the trial judge threw out the verdict and ordered a second trial, which concluded with a $237 million verdict against Tuomey. Tuomey appealed this verdict with the argument that testimony from Kevin McAnaney, a former government attorney subsequently in private practice, should not have been admitted because of his role in drafting a "substantial portion" of the regulations implementing the Stark law. McAnaney had provided Tuomey with an opinion that the compensation provisions of its physician contracts raised potential "red flags" with regard to Stark compliance. The Fourth Circuit rejected these arguments, finding that McAnaney's advice went to the heart of Tuomey's knowledge, a required element of the government's False Claims Act case. The Fourth Circuit held that McAnaney's opinion became fair game once Tuomey asserted the advice of counsel defense, even if Tuomey ultimately chose to rely on the advice of other counsel who did not see the same "red flags" with the contracts at issue.

Patient Status and Short-Stay Cases

For the past several years, both the DOJ and OIG have focused investigation and enforcement resources on inpatient stays of Medicare and Medicaid beneficiaries, specifically "short stays" or inpatient stays of two days or less. CMS noted that high rates of error for hospital services rendered in a medically unnecessary setting (i.e., inpatient rather than outpatient) have been identified through the Recovery Audit Program.[17] In October 2015, quality improvement organizations (QIOs) working under the direction of CMS assumed responsibility for conducting initial patient status reviews to assess the appropriateness of short-stay inpatient hospital claims.[18] In January 2016, recovery auditors began conducting patient status reviews at healthcare providers referred by a QIO if persistent non-compliance with Medicare payment policies is identified. Such non-compliance would include high denial rates and consistent failure to adhere to the two-midnight rule (including the repeated submission of inappropriate inpatient claims for stays not spanning one midnight), or failure to improve performance after QIO educational intervention.[19]

Cardiac Procedures

Since 2010, the DOJ has been investigating cardiac stenting and the use of implantable cardioverter defibrillators (ICDs) in the hospital setting that fail to comply with evidence-based eligibility guidelines. The DOJ's position is that coronary arteries require a 70 percent or greater blockage in order to justify the placement of a cardiac stent. With respect to ICDs, Medicare coverage rules require that implementation take place more than 40 days after a patient suffers acute myocardial infarction or more than 90 days after having a coronary artery bypass graft.[20]

This white paper describes the many factors at work that require greater emphasis on strengthening compliance programs within the hospital setting, including best practices for developing and maintaining a robust compliance program and the related role and relationship of the legal counsel, compliance officer, and board.

The Yates Memo, Individual Liability, and Criminal Prosecution

In 2015, a memorandum issued by U.S. Deputy Attorney General Sally Quillian Yates highlighted a new policy implemented by the DOJ and incorporated into the United States Attorneys' Manual—a set of policies that guide and regulate Justice Department lawyers in civil and criminal enforcement actions.[21] The memo relates to corporate prosecutions and incorporates new policies focused on individual accountability for wrongdoing. Specifically, the revised U.S. Attorneys' Manual:

- Emphasizes "the primacy in any corporate case of holding individual wrongdoers accountable and list a variety of steps that prosecutors are expected to take to maximize the opportunity to achieve that goal."
- Discusses corporate cooperation making clear that, contrary to past practice, "if a company wants credit for cooperating—any credit at all—it must provide all non-privileged information about individual wrongdoing" to the government.

16 Lisa Schencker, "Whistleblower Worries: Hospitals Likely to See More False Claims Suits Tied to Doctor Compensation," *Modern Healthcare,* November 21, 2005.

17 "Fact Sheet: Two-Midnight Rule," Centers for Medicare & Medicaid Services, July 1, 2015.

18 "Inpatient Hospital Reviews," Centers for Medicare & Medicaid Services, October 26, 2015.

19 *Ibid.*

20 "National Coverage Determination (NCD) for Implantable Automatic Defibrillators (20.4)," Centers for Medicare & Medicaid Services.

21 "Individual Accountability for Corporate Wrongdoing," U.S. Department of Justice, Office of the Deputy Attorney General, September 9, 2015.

- Requires companies seeking cooperation credit to conduct investigations that are "timely, appropriately thorough, and independent, and report to the government all relevant facts about individuals involved no matter where they fall in the corporate hierarchy."
- Separates into two categories of credit a corporation's voluntary disclosure and its willingness to cooperate, noting each of these is independently important in evaluating a corporation's response to misconduct.
- Adds a new section relating to civil enforcement of claims against individuals, which stresses that, like in criminal investigations, civil enforcement actions should focus on individual wrongdoing at the outset. The new section applies the same rules to civil cooperation credit requiring full disclosure of individual involvement. This section also emphasizes that in certain civil cases it is appropriate to sue culpable individuals, even where those individuals are judgment-proof in order to ensure that they do not escape accountability for their conduct.
- Modifies the long-standing policy on parallel proceedings by laying out specific steps that criminal and civil attorneys handling corporate investigations should take with respect to communication and referral of matters from "one side of the house to the other" in order to ensure "the fullest and most appropriate use of all the tools in [the Justice Department's] toolbox" when seeking to hold individuals responsible.

The Yates Memo and the revised U.S. Attorneys' Manual underscore the importance of the compliance role in seeking to prevent corporate misconduct before it occurs. In subsequent remarks, Deputy Attorney General Yates called compliance "a crucial partner in the fight against white-collar crime" and stressed the need for "strong compliance programs."[22]

While many of these pronouncements do not fundamentally change the DOJ's focus or approach when bringing criminal and civil actions against corporations, in some areas the changes are substantial and wide-ranging. One example of this is the change relating to when a corporation receives cooperation credit. The new policy codifies a requirement that, in order to earn such credit, the corporation must provide facts relating to individual participation in any misconduct. Failure to do so will mean that a corporation's efforts towards cooperating will not be creditable. Another example is the new requirement that civil enforcement actions include a focus on culpable individuals. This is likely to mean that in addition to healthcare companies being defendants in False Claims Act cases, it is more likely than ever that individuals, including corporate executives and board members, may be made parties in these cases.

With this guidance, DOJ attorneys are likely to first resolve cases against individuals before resolving cases against the hospital or corporate entity. For that reason, board members' and officers' personal liability risks have increased greatly. Individuals who are directly involved in the problematic conduct or are negligent in their oversight responsibilities can no longer expect to avoid personal liability by relying on settlements between the government and the organization or healthcare facility. This shift is significant and greatly impacts the role of legal counsel and compliance officers.

The paragraphs below detail other regulatory concerns directly affecting hospitals and health systems.

With the new requirement that civil enforcement actions include a focus on culpable individuals, it is more likely than ever that in addition to healthcare companies being defendants in False Claims Act cases, individuals, including corporate executives and board members, may be made parties in these cases.

The Role of Billing and Utilization Data in False Claims Act Investigations

Increasingly, the DOJ and OIG are turning to billing and utilization data in False Claims Act cases to identify healthcare fraud and abuse. Data analysis, predictive analytics, trend evaluation, and modeling are among the approaches employed to examine Medicare claims for known fraud patterns, identify suspected fraud trends, and calculate ratios of allowed services as compared to national averages.[23] In addition, data analysis is also being used increasingly by whistleblowers developing False Claims Act actions under the Act's *qui tam* provisions.

Enforcement agencies expect an organization to know its own data. It is important to have software capable of analyzing large volumes of electronic billing information remotely. Agencies can have access to all of an organization's data and are getting more and more experienced at evaluation, so it is important for management to be familiar with this data and capable of readily accessing it.

While intuitive software is important to the accessing of data, it is critical to be wary of evolving payment systems. As these systems continue to evolve, they can sometimes still carry a fair amount of risk to an organization. While the CMS Innovation Center is supportive of various solutions to payment tracking, there are still regulatory issues that remain to be addressed with the systems being provided. We recommend that hospitals and health systems remain cautious of any risky or unwise arrangements by asking if the software being evaluated improves quality or maintains quality at a lower cost. If quality is not improved, it's likely not a valuable resource to the organization.

22 "Deputy Attorney General Sally Quillian Yates Delivers Remarks at American Banking Association and American Bar Association Money Laundering Enforcement Conference," U.S. Department of Justice, November 16, 2015.

23 "The Health Care Fraud and Abuse Control Program Protects Consumers and Taxpayers by Combating Health Care Fraud," Centers for Medicare & Medicaid Services, March 19, 2015.

Rising Number of Whistleblower Cases Filed under the False Claims Act's *Qui Tam* Provisions

Since the late 1980s, there has been a steady increase in the number of new fraud matters opened by the DOJ's Civil Division based on newly received referrals, investigations, and *qui tam* actions.[24] *Qui tam* actions involve a whistleblower, also known as a relator, who reveals misconduct by his or her employer or another business or entity. Most false claims actions are filed under the whistleblower, or *qui tam,* provisions of the False Claims Act.[25] A whistleblower who exposes fraud can bring a *qui tam* lawsuit on behalf of the government, and can receive a share of the recovery as his or her reward. In actions in which the government prevails, the whistleblower is eligible to receive up to 30 percent of the amount recovered in the form of fines, penalties, and/or settlements.[26]

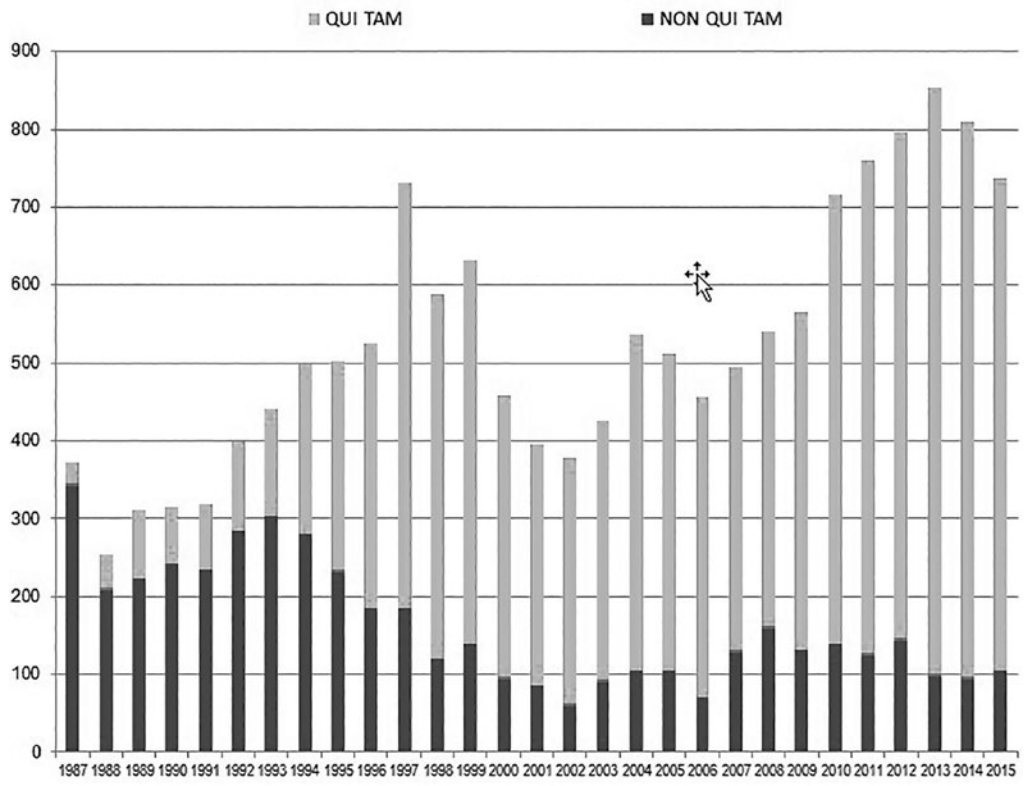
In the past five years, the Department of Justice has opened nearly 3,400 new *qui tam* matters.[27] In total, these matters have more than doubled from 373 in 1987 to nearly 850 in 2013 (see **Exhibit 1**).[28] Healthcare-related matters have increased over the same period from 15 in 1987 to 522 in 2013.[29] Even more dramatic is the shift of new matters based on *qui tam* actions. Until 1992, the majority of new healthcare-related matters opened each year were classified as non-*qui tam* matters by the DOJ.[30] Since 1992, however, the percentage of *qui tam* actions has skyrocketed. In 2013, 500 new healthcare matters were classified as *qui tam* actions compared to a mere 15 non-*qui tam* matters.[31]

Settlement of litigation involving declined False Claims Act cases has also grown increasingly costly. In August 2014, Omnicare paid $124 million to settle a case brought by a whistleblower,[32] and in May 2015, DaVita Kidney Care paid a $450 million settlement to whistleblowers in a declined False Claims Act case.[33]

The Role of the Relator in *Qui Tam* Actions

A *qui tam* action may be filed by a private citizen whistleblower on behalf of the government. The relator must have inside

Exhibit 1. Increasing Number of *Qui Tam* Actions



24 "Fraud Statistics Overview," Civil Division, U.S. Department of Justice, December 23, 2013.
25 "Justice Department Recovers over $3.5 Billion from False Claims Act Cases in Fiscal Year 2015," Department of Justice, Office of Public Affairs, December 3, 2015.
26 *Ibid.*
27 "Fraud Statistics Overview," Civil Division, U.S. Department of Justice, November 23, 2015.
28 *Ibid.*
29 *Ibid.*
30 *Ibid.*
31 *Ibid.*
32 *Ibid.*
33 Lisa Schencker, "DaVita Whistleblower Case Delivers $450 Million Settlement without Feds' Support," *Modern Healthcare,* May 6, 2015.

information regarding a potential False Claims Act violation; allegations cannot be based on publicly disclosed information unless the relator was the original source of the information. If the relator reports conduct that he or she reasonably believes constitutes illegal activity, the belief must be reasonable from a subjective and objective standpoint. The belief does not have to be *correct,* as long as it is *reasonable*.

Relators are often disgruntled or recently terminated employees, and they may even include auditing, legal, or compliance personnel. Relators can also be third parties, such as a vendor responsible for handling compliance complaints. It's important to note that the relator can actually be the individual responsible for the false claims, for instance an employee in the billing department who falsified records or a supervising physician who falsified sign-in logs showing she/he was present in the facility to supervise tests. Despite this seeming contradiction, the relator is still entitled to file a *qui tam* suit and share in recovery, although the court has the discretion in these circumstances to reduce the relator's share.

Additionally, attorneys' fees for the relator are automatically awarded. In 2015, relators filed 638 *qui tam* suits resulting in $2.8 billion in recoveries. The relators' shares of these recoveries came to nearly $600 million.[34] In light of the potential monetary returns associated with successful *qui tam* suits, the growth in *qui tam* actions is hardly surprising.

Equally troubling for hospitals and associated providers is the growing number of cases being pursued by relators despite the DOJ declining to intervene in the False Claims Act action. For many years after the 1986 amendment of the False Claims Act, the number of declined cases litigated by whistleblowers was negligible, but in the past five years, buoyed by aggressive plaintiff attorneys, the percentage of declined cases has risen steadily.[35] In 2015, the federal government recovered $1.76 billion in *qui tam* action where the government intervened or pursued the action.[36] In cases where the government *did not* choose to intervene, however, a staggering $1.14 billion was recovered, a monumental increase from the $80 million recovered in such cases in 2014.[37] The rapidly growing role of relators in initiating and pursuing False Claims Act cases—either with or without government involvement—means that hospitals must a) be aware of the *qui tam* process and b) take steps to reduce exposure to potential whistleblower actions.

34 Schencker, May 6, 2015.
35 Jeff Overley, "Six Tips for FCA Plaintiffs Snubbed By DOJ," Law 360, August 18, 2014.
36 "Fraud Statistics Overview," November 23, 2015.
37 *Ibid.*

Best Practices for Hospitals to Protect Against Whistleblower Lawsuits

In an increasingly aggressive environment for *qui tam* actions, there are a number of best practices that hospitals can follow to help protect against whistleblower lawsuits:

1. Screen new hires carefully and incorporate adherence to the hospital's code of conduct into the expectations for every position.
2. The use of internal reporting procedures should be clearly defined and incorporated into employee evaluations. Supervisors and managers should be trained on how complaints and issues identified through those internal reporting procedures are to be addressed.
3. Supervisors and managers should respond promptly to troubled working relationships before employees become *disgruntled* employees and potential whistleblowers.
4. Employees should be reminded regularly of their duty to report illegal conduct, and annual performance evaluations should include certification that each employee has disclosed any illegal activity of which he or she is aware.
5. Departing employees should confirm that they have disclosed any misconduct during their exit interviews.

In the event that a current or departing employee has reported potentially illegal conduct, the disclosure should be taken seriously and investigated formally. When employees see their concerns being addressed in an active and responsible manner by management, they are often less likely to become whistleblowers. Conversely, employees who feel their complaints have fallen on deaf ears are more likely to pursue a *qui tam* action if they feel it is the only way to get management's attention. Hospitals and health systems should consider involving legal counsel in the investigations and remain mindful of attorney–client privilege issues.

In the event that an employee or other individual opts to pursue a *qui tam* action, the relator must file the case under seal and provide the government with a statement of material evidence. The government then has 60 days to investigate the relator's allegations and decide whether to intervene in the matter. This timeline, however, is frequently extended. During this period, the hospital may have no knowledge of a pending lawsuit, although the government's investigation may involve OIG subpoenas, civil investigative demands, or even search warrants. The hospital's most important goal at this stage is to convince the government not to intervene in the matter. If the government decides to intervene it will take over the case although the relator could still participate. If the government declines, the relator may pursue the case as noted above. Any monetary recovery, however, will ultimately go to the government. Once the intervention decision is made, the case is unsealed and served on the defendant.

The Differing Roles of Compliance and Legal Counsel

In light of the challenges described above and others, hospitals and health systems must increasingly rely on legal counsel to manage and mitigate risk associated with regulatory compliance. Additionally, it is vitally important for healthcare organizations to foster environments in which legal counsel—both in-house counsel and outside counsel—are positioned to work effectively with the chief compliance officer and the governing board.

IT IS CRITICAL FOR LEGAL COUNSEL AND COMPLIANCE OFFICERS to fully understand and appreciate their distinct roles within an organization.[38] In April 2015, OIG issued *Practical Guidance for Health Care Governing Boards on Compliance Oversight* in which the roles and relationships of the compliance and legal functions were concisely defined:[39]

- Compliance: "The compliance function promotes the prevention, detection, and resolution of actions that do not conform to legal, policy, or business standards."
- Legal: "The legal function advises the organization on the legal and regulatory risks of its business strategies, providing advice and counsel to management and the board about relevant laws and regulations that govern, relate to, or impact the organization."

It is the compliance officer's role to operate and monitor the compliance program and investigate compliance issues, while legal counsel is charged with "directing the organization's response to actual or potential violations."[40] Beyond the interpretation of the law, attorneys working with hospitals and health systems provide advice on ethical issues and how to promote a culture of compliance.[41] "Collaboration, not cohabitation," is viewed as the most effective relationship between compliance and in-house counsel, and while the two roles are related and complementary, it is optimal "to keep the roles separate and with an equal footing."[42] Nearly nine out of 10 respondents in a recent survey of compliance professionals voiced opposition to corporate counsel also serving as the compliance officer. The rejection of the idea "was particularly high among respondents from healthcare and the not-for-profit sector."[43] This is a long-held view by OIG, which noted in 1998 that "an organization's compliance officer should neither be counsel for the provider, nor be subordinate in function or position to counsel or the legal department, in any manner."[44]

While the two roles are related and complementary, it is optimal to keep the compliance officer and legal counsel roles separate, but with equal footing.

Despite its strong recommendations for separate compliance and legal functions, OIG recognizes that the specifics of an organization's compliance program may depend largely on the size of the organization and the resources it has at its disposal.[45] These organizations must, however, "demonstrate the same degree of commitment to ethical conduct and compliance as larger organizations."[46] While these programs may be less

38 J. Reginald Hill, Jennifer C. Peters, Sheila W. Sawyer, "The Relationship between the Compliance Officer, In-House Counsel and Outside Counsel: An Essential Partnership for Managing and Mitigating Regulatory Risk," AHLA Fraud and Compliance Forum, October 2014.

39 *Practical Guidance for Health Care Governing Boards on Compliance Oversight,* Office of the Inspector General, U.S. Department of Health and Human Services, Association of Healthcare Internal Auditors, American Health Lawyers Association, Health Care Compliance Association, April 2015.

40 Hill, Peters, and Sawyer, October 2014.

41 Michael W. Peregrine and Joshua T. Buchman, "Managing the General Counsel/Compliance Officer Relationship," *AHLA Connections,* October 2011.

42 "Should Compliance Report to the General Counsel?," Society of Corporate Compliance and Ethics and the Health Care Compliance Association, March 2013.

43 *Ibid.*

44 *Practical Guidance for Health Care Governing Boards on Compliance Oversight,* April 2015.

45 *Ibid.*

46 *Ibid.*

formal or may use available personnel instead of separate staff, OIG stresses that "boards of smaller organizations may need to become more involved in the organization's compliance and ethics efforts than their larger counterparts."[47]

In situations where, due to the size of an organization or the available resources, a single individual is responsible for both the legal and compliance functions, it is of paramount importance that well-defined compliance policies and procedures are in place, "particularly with respect to the reporting of misconduct."[48] This will protect the compliance officer/legal counsel from the appearance of impropriety if an established protocol is followed precisely with step-by-step documentation of the procedures followed by the individual.[49]

Provide Communication and Access to the Board

In addition to stressing the importance of separating the compliance and legal functions, OIG recommends that the board "should receive regular reports regarding the organization's risk mitigation and compliance efforts—separately and independently."[50] A 2014 survey of compliance and ethics professionals found that, in the healthcare industry, nearly two-thirds of compliance officers' reports to their respective boards were not pre-screened or edited by the general counsel or others.[51] Encouragingly, in the same survey, more than three-quarters of respondents reported that the chief compliance and ethics officer is responsible for escalating very serious allegations and/or investigations of non-compliance to the board, indicating that even where compliance reports to others, "in serious cases the board is contacted directly."[52]

For boards, ensuring open lines of communication from throughout the organization is vital. OIG notes that a board can "raise its level of substantive expertise with respect to regulatory and compliance matters by adding to the board, or periodically consulting with, an experienced regulatory, compliance, or legal professional. The presence of a professional with healthcare compliance expertise on the board sends a strong message about the organization's commitment to compliance, provides a valuable resource to other board members, and helps the board better fulfill its oversight obligations."[53] OIG also recommends that a board should receive compliance and risk-related information in a format that satisfies the interests or concerns of its members and matches their ability to understand the information being presented.[54]

47 *Practical Guidance for Health Care Governing Boards on Compliance Oversight,* April 2015.
48 Hill, Peters, and Sawyer, October 2014.
49 *Ibid.*
50 *Practical Guidance for Health Care Governing Boards on Compliance Oversight,* April 2015.
51 *The Relationship between the Board of Directors and the Compliance and Ethics Officer*, Society of Corporate Compliance and Ethics and the Health Care Compliance Association, January 2014.
52 *Ibid.*
53 *Practical Guidance for Health Care Governing Boards on Compliance Oversight,* April 2015.
54 *Ibid.*

Best Practices for Legal Counsel and Compliance Reporting to the Board

- The compliance officer and legal counsel should supply regular, but separate and independent, reports to the board regarding the organization's risk mitigation and compliance efforts. The format of these reports should satisfy the interests/concerns of the board and also match board members' ability to understand the information.
- In cases of very serious allegations and/or investigations of non-compliance, the compliance officer should be compelled to report directly to the board, whether or not he or she has a direct reporting relationship with the board.
- The board should periodically consult with an outside experienced regulatory, compliance, or legal professional.
- The board should consider recruiting a director with healthcare compliance expertise.

The Board's Role in Quality of Care

Payment policies that align payment with quality care have placed increasing pressure to conform to recommended quality guidelines and improve quality outcomes. In response to growing concerns about healthcare quality and patient safety, the government has launched numerous initiatives to increase quality and accountability in the healthcare system. In this new era, the government has charged boards of healthcare organizations with the overall responsibility for the quality of care delivered at their organizations. Boards are increasingly being held accountable for quality failures, which sometimes translates into legal liability.

The basic fiduciary duty of care, which requires a director to act in good faith with the care an ordinarily prudent person would exercise under similar circumstances, is being tested in the current climate. Embedded within the duty of care is the concept of reasonable inquiry, under which directors are expected to make inquiries to management to obtain the information necessary to satisfy their duty of care.

Board involvement is crucial to creating an organizational culture that supports patient safety and quality thus mitigating the potential application of the False Claims Act to quality of care issues. The board should be actively involved in designing a strategic imperative for the organization that focuses on healthcare quality and patient safety and regularly monitors progress toward goals. These comprehensive quality improvement programs will not only serve to avoid costly FCA litigation, but will improve the overall quality and patient safety in healthcare settings.

The OIG created a "Toolkit for Healthcare Boards" to use as a guideline for their responsibility as it relates to quality of care. The OIG's recommendations include:

- Create a comprehensive policy and objectives to define your quality improvement and patient safety program.

- Ensure your stakeholders share a common vision of quality. To give your program real impact, incorporate its objectives into employee performance evaluations and incentive compensation.
- Establish a board quality committee and make quality of care a standing board agenda item.
- Ensure you have sufficient clinical expertise on the board. To address potential conflicts, some hospital boards recruit physicians who are not medical staff members or who are retired.
- Understand how management assesses the credentials of the medical staff and stay current on best practices.
- Implement conflict-of-interest policies to identify and manage financial interests that may affect clinical judgment.
- Use dashboards and benchmarks to measure the success of your organization as it improves outcomes and patient satisfaction. You should track how your organization compares to its peers on these quality indicators. After all, "what gets measured is what gets done."

Be Prepared for Government Inquiry

It is critical to the success of a compliance program to establish credibility early to ensure employees know the risks associated with not following the policies, procedures, and standards of conduct. There should be an unequivocal requirement that contact with enforcement agencies be communicated immediately.

Reduce the burden of responding to the document request by verifying retention and destruction policies. Be in a position to quickly provide the items the government will want at the outset.

Show cooperation by presenting the government with details of the organization's operations and information storage by offering tangible evidence of systemic success. This can be accomplished by readily providing the government with specific examples that show the program is not only well established but operational. Be able to provide them with specific instances where the organization has elevated compliance over profits.

When to Consult Outside Counsel

Even if the board is well equipped and the hospital or health system has an effective compliance program and plan overseen by strong internal counsel and a compliance officer, there are still instances when it is necessary to involve outside counsel. Such instances include:

- Any contact, subpoena, or inquiry from a governmental entity such as the DOJ or the OIG
- Credible allegations of criminal conduct
- Senior management or board members directly involved in a complaint or investigation
- A nuanced analysis when the hospital or health system needs an outside written opinion
- An overtaxed or understaffed compliance department, which is unable to conduct a thorough documented investigation
- A matter when maintaining legal privilege is particularly important and where third parties may need to be hired for investigation or review purposes
- A potential settlement with a governmental agency or relator is being negotiated
- The legal department or counsel for a third-party vendor contacts the health department or health system about a compliance issue
- External validation of the compliance department's effectiveness is needed
- The hospital or health system is without a compliance officer or is developing an entirely new compliance program

The Eight Fundamental Elements of an Effective Compliance Program

In 2010, the United States Sentencing Commission modified the Federal Sentencing Guidelines for organizations, including the provisions that set forth the attributes of effective compliance and ethics programs. Under the Federal Sentencing Guidelines, a convicted organization may be eligible for a reduced sentence if it has established an effective compliance and ethics program.

THE GUIDELINES DESCRIBE THE KEY ATTRIBUTES THAT A compliance and ethics program must exhibit for the organization to be eligible to receive benefits such as reduced fines, reduced sentence, or deferred prosecution. The fundamental elements are:

1. Implement written policies, procedures, and standards of conduct.
2. Designate a compliance officer and compliance committee.
3. Conduct effective training and education.
4. Develop effective lines of communication.
5. Conduct internal monitoring and auditing.
6. Enforce standards through well-publicized disciplinary guidelines.
7. Respond promptly to detected offenses and undertaking corrective action.

In addition, we include an eighth fundamental element:

8. Evaluate and measure the program's effectiveness regularly.

Each of these elements are described in more detail below.

1. Implement Written Policies, Procedures, and Standards of Conduct

The compliance officer, legal counsel, and the board must work in concert to develop, implement, monitor, and enforce an effective compliance program. First, clear policies and procedures should be established regarding regulated actions, such as handling protected health information and combatting fraud, waste, and abuse. The OIG Web site contains a range of guidance on what policies, procedures, and standards of conduct should be included in the compliance program. CMS has also issued new guidelines on mandatory Medicare Advantage and Prescription Drug Plans compliance programs that can aid organizations in developing and revising their compliance program to meet requirements.

The policies, procedures, and standards should articulate the organization's commitment to comply with all applicable federal and state regulations and standards, and compliance expectations should be described as embodied in the standards of conduct. Guidance should be provided to employees and others on how to address and respond to suspected, detected, or reported compliance issues. Members of the organization should also be instructed on how to communicate compliance issues to appropriate compliance personnel. Provide a detailed description of how suspected, detected, or reported compliance issues will be investigated and resolved by the organization. A policy of non-intimidation and non-retaliation for good faith participation in the compliance program should also be memorialized, including, but not limited to, reporting potential issues, investigating issues, conducting self-evaluations, audits and remedial actions, and reporting to appropriate officials.

Other elements of the compliance program may include training requirements for combatting fraud, waste, and abuse; the reporting structure for compliance-related issues; information on other reporting mechanisms, such as a telephone hotline; and the methods that will be employed for investigation and addressing compliance issues. The compliance program should also include a description of the means and schedule for regular updates.

Standards or a code of conduct should detail the principles and values of the organization; the expectation that all employees will act in an ethical manner; and a description of the reporting mechanism for fraud, waste, and abuse and how issues will be handled. The standards of conduct need to be approved by the organization's full governing body and include a commitment to compliance and lawful conduct by every member of the organization. Compliance documents should be reviewed and updated regularly to reflect changes in laws and regulations. The compliance program is distributed to employees within 90 days of initial hiring, whenever there are updates, and on an annual basis.

2. Designate a Compliance Officer and Compliance Committee

Organizations should designate a compliance officer who is chiefly responsible for the compliance program and for compliance issues that may arise. In addition, if your organization's size and operations allow for it, there should be a compliance committee to oversee the program and advise the compliance officer. This is typically a committee that operates at the board level but includes members of management and others throughout the organization. The compliance committee usually includes

some combination of the following representatives: compliance officer, general counsel, internal audit, risk management, human resources, privacy officer, a board member, CEO, COO, CFO, nursing, a physician, and information technology. The compliance officer and committee will be responsible for overseeing and enforcing the organization's compliance program. In choosing the officer and committee, the organization should consider the independence of the compliance officer and committee as a key component of an effective compliance program that will demonstrate commitment to fostering compliance within the organization.

OIG guidelines recommend that the compliance officer be a member of senior management with direct access to the governing body and C-suite to ensure that compliance reports will directly reach the CEO. The compliance officer should have the authority to provide in-person reports to senior leaders and the board. It is also a best practice to require board approval before terminating a compliance officer.

With respect to the compliance committee, OIG guidelines recommend that the committee is positioned to advise the compliance officer and provide oversight of the compliance program. The committee should have decision-making authority over compliance-related issues. The committee should also have responsibility for developing strategies to promote compliance and detection, reviewing and approving compliance training, and providing regular reports to senior executives and the board.

As mentioned previously, if the organization has the resources, the compliance officer should be separate from legal counsel. OIG guidelines pose the question: "Does the compliance officer have independent authority to retain legal counsel?" This question suggests that in-house counsel may not be well suited to serve the advising needs of the organization's compliance officer, and that having the option to seek outside counsel on compliance issues may better preserve the officer's independence. Additionally, new CMS guidelines for Medicare Advantage organizations and Prescription Drug Plans state that the compliance officer "should not serve in both compliance and operational areas" because it creates a conflict of interest. Additionally, a recent deferred prosecution agreement between the DOJ and HSBC required the separation of the compliance officer from counsel and elevated the compliance officer's position in the organization's hierarchy. Organizations with existing compliance programs in place that do not require the separation of the legal and compliance functions should consider updating their program documents to separate the two roles.

3. Conduct Effective Training and Education

The board and senior management have a responsibility to oversee compliance programs and can be held accountable for violations when there is substandard oversight or there is a culture of non-compliance within the organization. In considering the liability of the board, the Supreme Court found that "the Act does not, as we observed in *Dotterweich,* make criminal liability turn on 'awareness of some wrongdoing' or 'conscious fraud.'" In addition the court observed, "it is equally clear that the

government establishes a *prima facie* case when it introduces evidence sufficient to warrant a finding by the trier of the facts that the defendant had, by reason of his position in the corporation, responsibility and authority either to prevent in the first instance, or promptly to correct, the violation complained of, and that he failed to do so." Thus, a board member or member of senior management does not have to have participated in fraud or have actual knowledge of wrongdoing to be held liable for an organization's wrongful acts. A board member or member of senior management may be held liable for violations for failing to act if he or she was in a position of responsible compliance authority.

The OIG is focused on holding responsible corporate officials accountable for healthcare fraud and the responsible corporate officer doctrine is applied extensively in criminal cases. The OIG excluded from the Medicare program a chairman of a large nursing home for his responsibility in alleged substandard care of residents and also excluded the CEO, general counsel, and chief medical officer of Purdue Frederick for 12 years due to their misdemeanor convictions for misbranding OxyContin.

The board must exercise reasonable oversight with respect to implementation and effectiveness of the compliance program. While the board may delegate oversight of the compliance program, it remains accountable for reviewing its status. Training and education on the compliance program is required, and the board should have a means to prove active engagement in the oversight of the program.

Senior management must be engaged in oversight of the program and must ensure that the compliance officer has the credibility, authority, and resources needed to monitor and enforce the compliance program. Senior management must receive regular reports on the compliance program and must be aware of all governmental compliance enforcement activity.

All compliance programs should also include a training program and educational resources for personnel at all levels of the

organization. Without proper training, personnel will not be able to understand their obligations, to identify potential compliance issues, or to report issues to the appropriate authority in a timely manner.

All employees must receive compliance-related training—including the CEO, senior executives and management, the governing body, and any independent physicians with staff privileges. Initial training is conducted at the time of hiring. When new requirements emerge, the training must be updated and employees should receive the updated version of the compliance program. Training should be conducted company-wide annually thereafter. Record and retain any documentation of employee training as evidence of compliance.

Additionally, the compliance officer and compliance committee should receive regular training, and make efforts to stay informed of new compliance requirements through various channels, such as conferences, Webinars, industry publications, and the OIG Web site.

When organizations operate in a transparent way and promote a culture of compliance, their compliance programs are generally more effective at preventing, detecting, and addressing issues when they arise. To promote transparency and a culture of compliance, organizations should:

- Create a code of conduct that demonstrates commitment to compliance.
- Identify conflicts of interest early and address them immediately.
- Ensure regular and effective training.
- Conduct internal audits to ensure compliance with applicable contractual and legal obligations.
- Maintain clear records of compliance issues and their resolution.
- Report potential violations to the appropriate authority without undue delay.

4. Develop Effective Lines of Communication

In addition to implementing the steps above to promote transparency and compliance, an organization should develop and maintain effective lines of communication. Communication between personnel and the compliance officer helps with prevention, since open lines encourage employees to seek advice and clarification and enables a quick response to compliance-related issues.

Communication between the board/upper management and compliance officer should take place regularly to ensure that the board and senior leadership are briefed on compliance issues and program effectiveness. Regular contact between the board and compliance officer also promotes a culture of compliance because the issues will be discussed routinely and clearly.

A clear policy should be established for reporting compliance issues and concerns without fear of retaliation. Utilizing multiple methods of communication will aid in ensuring open and effective lines of communication. Methods may include:

- Newsletters
- Email
- Flyers/posters with contact information
- Telephone hotlines
- Regular meetings
- Intranet postings
- Training materials with clear contacts

5. Conduct Internal Monitoring and Auditing

An effective compliance plan will also include a method for conducting regular internal audits of the organization to identify and address potential compliance issues. Regular internal audits may minimize the effects of non-compliance since the audits can detect compliance issues in their early stages. In some cases, an internal audit may even prevent a compliance violation from ever arising by enabling an organization to pinpoint and correct weaknesses that can lead to non-compliance. As part of the internal auditing process, an organization should create an audit plan and update the plan regularly to reflect changes in the organization as well as to applicable statutes and regulations. Compliance processes, policies, and actions should be reviewed proactively, not reactively, and do so on a regular basis. In addition, include reviews of all areas covered by the compliance program, such as coding, contracts, and quality of care. The cause of any compliance issues identified during the internal audit should be evaluated, and corrective action plans need to be established to address each issue and implement those plans immediately. Results from the audit should be reported to senior management. For guidance on effective auditing procedures, consult the OIG's self-disclosure protocol and current corporate integrity agreements (see www.oig.hhs.gov/compliance/self-disclosure-info/protocol.asp and http://oig.hhs.gov/compliance/corporate-integrity-agreements/index.asp).

6. Enforce Standards through Well-Publicized Disciplinary Guidelines

In order for compliance programs to be effective, employees must have an incentive to adhere to the program. This is where establishing and enforcing clear disciplinary guidelines becomes important. Disciplinary guidelines should strike the right balance between consistency and flexibility. This will ensure that employees understand there will be consequences for non-compliance, but will also enable your organization to adapt disciplinary proceedings according to the situation. As part of this step toward compliance, an organization should have clear consequences for violations of disciplinary procedures, for example:

1. Verbal warning
2. Written warning
3. Retraining
4. Termination
5. Reporting for criminal sanctions

Disseminate disciplinary guidelines and ensure employees are aware of them. Disciplinary guidelines should be applied uniformly across the organization and at all levels of the organization. The CMS guidelines offer more specific advice as to the contents of disciplinary guidelines. At a minimum, the disciplinary procedures should articulate expectations for reporting compliance issues and assisting in their resolution; identify non-compliance or unethical behavior; and provide for timely, consistent, and effective enforcement of standards.

7. Respond Promptly to Detected Offenses and Undertaking Corrective Action

Responding promptly to detected offenses and taking corrective action demonstrates a commitment by the organization to compliance and in some cases, can reduce the potential liability and damage resulting from non-compliance. Establish a system to respond to any issues promptly. Conduct a reasonable inquiry into any potential non-compliance and complete the inquiry as quickly as possible. Use the system to track the issues and their resolution. The board and/or senior management must take appropriate corrective action to correct the current problem and deter future violations. Corrective actions may include:

- Retraining
- Taking appropriate disciplinary actions
- Revising policies and procedures
- Returning overpayments timely
- Reporting to the government
- Notifying law enforcement

8. Evaluate and Measure Program Effectiveness Regularly

Once a hospital or health system has implemented a compliance program, the program should be evaluated and measured for effectiveness on a regular basis. An ineffective compliance program can lead to unnecessary violations and enforcement actions, which could have been prevented through ensuring maintenance of a program that encourages and aids in complying with all applicable legal and ethical standards. After implementation, an organization can take the following steps to help maintain an effective compliance program:

- Set benchmarks and measurable goals.
- Measure attainment of goals regularly.
- Investigate failure to meet goals.
- Report results to board.
- Assess where the problems are and suggest solutions.
- Provide adequate funding.
- Ensure sufficient support throughout the entity, including upper management.

Conclusion

In the post-reform healthcare marketplace, regulatory compliance has become more complicated than ever before and healthcare fraud enforcement is perhaps the only issue with true bipartisan support in Washington, D.C.

THE MONETARY PENALTIES ASSOCIATED WITH FALSE CLAIMS and other compliance violations add even more pressure for hospitals, healthcare systems, and other healthcare companies already faced with growing financial challenges. These factors mean that regulatory compliance must be a priority for every healthcare organization. Boards must not only be knowledgeable about healthcare regulatory issues, but they need to establish an organizational culture of compliance and provide oversight and assistance to compliance officers and in-house legal counsel in dealing with operational and hospital management issues. Boards should take advantage of the wide range of available compliance resources. Additionally, outside legal counsel can serve as an effective bridge between the board, executive leadership, the chief compliance officer, and the in-house legal department. Organizations that fail to capitalize the strengths of both their internal and external resources could find themselves in precarious positions.

Organizations that establish an effective compliance program using the eight fundamental elements described in this white paper will position themselves for success in all areas, from reducing the organization's risk for legal liability, to increased transparency, more effective reporting to the board leading to a better informed board and more effective decision making, and ultimately, creating an organizational culture that supports patient safety and quality of care.