

Suits and Scrubs Avoiding Orange Jumpsuits



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Reducing C-Suite Vulnerabilities

Allan P. DeKaye / Gregory J. Naclerio

...Lipstick on your collar
Told a tale on you
Lipstick on your collar
Said you were untrue...¹

While this refrain confirms the obvious evidence of unfaithfulness and deceit, it serves as a reminder that wrongdoing — whether done willfully, surreptitiously, or unknowingly — will leave tell-tale signs, which health care fraud investigators are closely watching and hunting for. When setting aside the fraud and abuse attributable to organized crime and individuals who perpetrate schemes that divert millions of dollars in federal Medicare and Medicaid away from its intended recipients, we are left with a puzzling question: why are providers of care often lumped into these two categories of criminals, when they are expected to be fulfilling the mission and vision of providing for the community good?

To answer this question, the authors have selected and examined several situations and cases to illustrate that bad behavior was avoidable, and the ensuing penalties preventable. Arguably, "...I should have known better..."² is a likely refrain that defense lawyers hear from their clients after having been giving their Miranda warnings following an arrest, or upon implementation of a corporate integrity agreement. In other instances, the payment of penalties for procedural wrongdoing, or simple failure to follow the rules, presupposes that these payments would have been better spent on the mission.

Although many will argue that tort reform is needed to stem the tide of medical malpractice settlements, the system for identifying, prosecuting, and adjudicating clinical mistakes works despite the complaints. However, unraveling the often hidden trail associated with complex provider arrangements and delivery mechanisms

allows these situations to remain uncovered for potentially longer periods, unlike the more obvious and deleterious effects of a botched surgery, until investigators and prosecutors uncover “the smoking gun.”

Prosecutors have been quick to note that, given the high compensation levels of many hospital and other health care chief executive officers (CEOs) and physicians or clinical leaders, personal and corporate greed is very much a motive that clouds decision-making judgment, or promotes outright criminal behavior. In his 2009 article, in addition to outright fraudulent activities or other criminal enterprises, DeKaye identified ego, misguided altruism, and loophole exploitation as among the contributing underlying causes and rationales for poor executive judgment and relates these symptoms to various cases.³ Naclerio provides a behind-the-scenes examination of judgmental errors on the parts of selected defendants and how they could have been remedied by proper review and oversight. When taken together, these two perspectives are intended to keep the “suits” and “scrubs” out of orange jumpsuits.

THE LAW

The U.S. Department of Justice is not only vigorously prosecuting white collar crime, including health care fraud; it is also ratcheting up its enforcement efforts to seek criminal conviction of corporate executives who either engage in criminal conduct or conspire with others to violate the law. The belief is that by going up the chain of command and securing convictions of C-suite occupants, there will be a strong deterrent effect on other executives who in the past may have turned a blind eye in favor of increasing their institution's bottom line. No longer will criminal liability rest solely on the shoulders of a so-called “rogue employee” who violated the law. Government will seek to turn such an employee to go as high in the organization as it can to “cut off the head” of those responsible for criminal conduct.

Federal felonies such as health care fraud,⁴ mail fraud,⁵ and conspiracy⁶ are all charges prosecutors will consider. Also of great exposure for the C-suite is the federal anti-kick-back statute⁷ with its potential criminal, civil, and exclusion from Medicare provisions. If this landscape was not troublesome enough, the ever-expanding cottage industry of “whistleblowing” presents another potential exposure. Under the federal False Claims Act⁸ a defendant can be exposed to three times the amount of the claim plus a \$5,500 to \$11,000 penalty for *each* false claim filed.

The case against the chief operating officer, medical director, and general counsel of Purdue Frederick Co., the pharmaceutical company that developed and marketed Oxycontin, is illustrative. Purdue was convicted of marketing and promoting Oxycontin with intent to misbrand by marketing Oxycontin as less addictive, less subject to abuse, and less likely to cause tolerance and withdrawal than other pain medications. Not satisfied with merely convicting the company, federal prosecutors resorted to a rarely used section of the Food Drug & Cosmetic Act (FDCA), which allows criminal charges to be brought against “responsible corporate officers.”

The thrust of the government's case was that these C-suite occupants, even though they did not participate nor had knowledge of or intended to misbrand Oxycontin, were in a position to prevent or correct the company's fraud but took no action. Each officer pleaded guilty to a federal misdemeanor, agreed to a total “disgorgement” of \$34.5 million, and was excluded from Medicare for a period of 12 years, thus, in effect, ending their careers in health care.

Aside from criminal convictions and exclusions as a result of the FDCA's unique provisions regarding “responsible corporate officers,” the Office of Inspector General (OIG) is seeking to use its “Permissive Exclusion Authority” (42 U.S.C. §1320a-7) to exclude individuals who control a “sanctioned entity” that has been convicted of a crime related to (i) the delivery of an item or service paid for by Medicare/Medicaid, (ii) pa-

tient abuse, or (iii) a felony conviction related to health care fraud or which has been excluded from Medicare or Medicaid.⁹

The mere fact that an individual is an “officer or managing employee” (defined as “an individual including a general manager, business manager, administrator, director, who exercises operational or managerial control over the entity, or who directly or indirectly conducts the day-to-day operations of the entity”)¹⁰ of a sanctioned entity can result in that individual being excluded from the Medicare/Medicaid program for at least the same period of time that the sanctioned entity is excluded. Here, like the responsible “corporate officer” statute, the OIG need not prove the individual had any criminal intent to violate the law. His or her “status” in the organization is all that counts.

So, what does it mean for a person to be “excluded” from the Medicare/Medicaid program? In short, no Medicare/Medicaid payment will be made for anything that an excluded person furnishes, orders, or prescribes. Moreover, the payment prohibition applies to not only the excluded person but to anyone who:

...employs or contracts with the excluded person, any hospital or other provider where the excluded person provides services, and anyone else. The exclusion applies regardless of who submits the claims and applies to all administrative and management services furnished by the excluded person.¹¹

Hence, it is safe to say that any person so excluded will no longer be employable in the health care industry for a minimum of five years (some exclusions have been ordered for up to 20 years), and depending on a variety of factors, this penalty application could constitute a “professional” death penalty.

In October 2010, the OIG issued “guidance” for implementing this permissive sanctioned entity exclusion (hereinafter, “B-15” exclusion).¹² While the OIG B-15

guidance states it has the authority to “exclude any officer and managing employee of a sanctioned entity,” it is “not intended to exclude all officers or management employees, when there is evidence that an officer or managing employee ‘knew or should have known’ of the illegal conduct; however, the OIG will operate with a ‘presumption in favor of exclusion.’”

The factors the OIG will consider with respect to a permissive exclusion include:

- Circumstances of the misconduct and seriousness of the offense:
 - The nature and scope of the misconduct;
 - The level of the entity in which the misconduct occurred (*i.e.*, violation by one field employee versus headquarters involvement);
 - The sanctions (criminal, civil, exclusion) against the entity;
 - Whether the misconduct resulted in actual or potential harm to beneficiaries or resulted in financial harm to a federal health care program.
- The individual role in the sanctioned entity:
 - The position held in the entity particularly at the time of the misconduct;
 - The degree of managerial control;
 - Did the misconduct occur within his or her chain of command?
- The individual’s response to the misconduct:
 - Did he or she take steps to stop or mitigate the ill effects of the misconduct?
 - Did these actions take place before or after the individual became aware of the OIG investigation?
 - Was the misconduct disclosed to the government, and did the individual cooperate with prosecutors?
- Background on the entity:
 - Has the entity previously been convicted of a crime or found liable civilly or administratively?
 - The size of the entity, including number of employees, product lines, divisions;
 - What is the corporate structure regarding subsidiaries and the chain of command between subsidiaries?

Moreover, on March 2, 2011, Lewis Morris, chief counsel to the U.S. Department of Health and Human Services (HHS) Inspector General Daniel Levinson, testified before the House Ways and Means Committee and further staked out the government's position regarding action to be taken against corporate officers. In this context, Mr. Morris opined that some providers of health care fraud consider fines and penalties a "cost of doing business." To address this issue, Mr. Morris testified:

One way to address this problem is to attempt to alter the cost-benefit calculus of the corporate executives who run these companies. By excluding the individuals who are responsible for the fraud, either directly or because of their positions of responsibility in the company that engaged in fraud, we can influence corporate behavior without putting patient access to care at risk.¹³

The OIG's message to managers of health care entities is clear that HHS intends to get tough with senior management of companies who engage in fraudulent conduct.

IF IT SOUNDS TOO GOOD TO BE TRUE...

To avoid possible prosecution and exclusion for your health care entity and yourself, the old maxim, "If it sounds too good to be true, it probably is too good to be true," may be relevant to some of the deals presented to senior management. In the current economy, many businesses, including health care institutions, are suffering losses to the bottom line and experiencing cash flow problems. While consumers may be hesitant to make discretionary purchases, health care is not discretionary. Health care is, in economic terms, "inelastic" (*i.e.*, people will purchase goods and services no matter the price). For example, take gas prices; we complain about the price but still purchase it at \$4 a gallon because we need it. The same may be said for need-

ing a magnetic resonance imaging (MRI) or computed tomography (CT) scan.

Moreover, when most health care costs are paid by commercial insurers or the Medicaid/Medicare program, consumers are becoming less concerned and do not seem to worry about paying the full bill; however, this isn't always the case when the patient is uninsured. Thus, health care institutions, ranging from hospitals and nursing homes to large physician practices, are seeking ways to attract new business by expanding current product lines or establishing new programs. Some aggressive individuals see the "need" of these institutions and prey upon them for their own economic benefit. Some of these "deals," while sounding very good for the bottom line, sometimes place the institution and its senior managers in peril. Let's learn by the misfortune of others by reviewing some real cases.

Case One: Misguided Altruism Gone Badly

A company which billed itself as a "national provider of contractual administrative health care management services to acute care hospitals from coast to coast" targeted several New York State hospitals that were "distressed" and losing money. The company offered an "inpatient medical stabilization" program to treat patients with "drug, alcohol and other health related issues." The company would handle the administration of the program for a flat monthly fee while the hospitals would provide the medical care. The hospitals would bill third-party payers (mostly Medicaid) directly. The hospitals believed the program would bring in "millions of dollars" to the bottom line, thereby helping to turn their red ink to black.

The program sounded "too good," and that observation was confirmed in January 2009 when seven New York State hospitals were sued in a whistleblower civil False Claims Act suit (later joined in by both the United States and the State of New York). The lawsuit charged the hospitals with operating a discrete "Detox Unit" without obtaining a license

from the Office of Alcoholism and Substance Abuse Services (OASAS) and for paying the company a monthly fee above fair market value as an alleged kickback to obtain patients for the program. While the case is currently pending against several hospitals, one hospital has settled the False Claims Act claim for an amount in excess of \$13 million.

Case Two: Ego and Egotism

Dr. Roland Borrasi owned Integrated Health Centers, a group of health care providers in Romeoville, Illinois. Integrated mostly provided services at area nursing homes and hospitals. As a “player” in the area, Dr. Borrasi became acquainted with Wendy Mamoon, the CEO, and Mahmood Baig, director of operations, at Rock Creek Center, a licensed inpatient psychiatric hospital. Subsequently, Dr. Borrasi and other Integrated employees were placed on the payroll of Rock Creek and paid approximately \$650,000 over a three-year period. The Hospital also gave Integrated physicians, including Borrasi, individual titles, developed job descriptions, and required timesheets to be submitted. During this period the referrals from Borrasi’s practice to the hospital increased dramatically. For example, in 2001 alone, Borrasi referred approximately 484 Medicare patients to Rock Creek.

During the course of the investigation, several of Borrasi’s employed physicians and Rock Creek’s Director of Operations Baig cooperated with the government and testified at trial against Borrasi and CEO Mamoon saying they never performed their assigned duties and that their reports and timesheets were fictitious. Specifically, Mr. Baig testified that neither he, nor Mamoon or Borrasi, expected the Integrated employees to perform any administrative duties and that administration did not expect Borrasi to perform any duties, such as the “service medical director.” This testimony supported the position of the government that Borrasi and CEO Mamoon violated the anti-kickback statute (*i.e.*, paying kickbacks to Integrated for patient referrals to Rock Creek).

The jury returned a guilty verdict against both defendants. Borrasi received a sentence of 72 months (six years) incarceration, and due to extraordinary circumstances, Mammon received six months. On appeal the Seventh Circuit affirmed these two convictions holding that if *one purpose* of the payment was to induce future referrals (even if some professional time was actually expended), the anti-kickback statute was violated.

The conviction of Dr. Borrasi and its six-year prison term was only the start of his problems. Dr. Borrasi will be excluded from the Medicaid and Medicare programs for a minimum of five years, and there is a strong possibility he will lose his license to practice medicine in Illinois.

Case Three: Loophole Exploitation

Forest Pharmaceuticals Inc., a subsidiary of Forest Labs Inc., was sentenced to pay a criminal fine of \$150 million and forfeit \$14 million of assets for its pleas to the felony of obstructing justice and two misdemeanor counts of distributing a misbranded drug and distributing an unapproved drug. The criminal fines and civil settlement to resolve False Claims Act violations totaled over \$313 million.

The Department of Justice press release dated March 2, 2011, outlines the evidence against Forest:

- Distributing Levothroid for treatment of hypothyroidism without first obtaining FDA approval.
- When the FDA permitted distribution of the drug subject to a gradual distribution phase down pending FDA approval, Forest made a “deliberate decision” to continue distribution far in excess of the FDA-permitted amount.
- When the FDA issued a letter on August 7, 2003, directing it was no longer entitled to distribute unapproved Levothroid, Forest directed its employees at one plant to work overtime to ship as much unapproved Levothroid as possible.
- Forest also obstructed an FDA inspection in November 2003 when management

was aware of serious equipment malfunctions that resulted in testing conditions for hundreds of days that did not comply with FDA regulations. Management also brought in a portable humidifier to control humidity in the testing room and lied to FDA inspectors about its use.

Forest's plea also covers the drug Celexa. Here, Forest promoted off-label use of the drug for children and adolescents suffering from depression when the medication was only approved for adults. In connection with its off-label promotion, Forest aggressively pushed the results of a double-blind/placebo controlled Forest study on Celexin while suppressing the negative results of the same type of controlled test in Europe.

Based upon Forest's plea on April 12, 2011, the OIG notified Forest Lab's CEO and president, Howard Solomon, that it was considering excluding him from Medicare under the OIG's B-15 authority. Mr. Solomon is 82 years old and is the chairman of the board, president, and CEO of Forest Labs. He has been CEO since 1977. Solomon currently ranks 27th on the Forbes Executive Pay list for 2011 with a total compensation package of \$27.10 million (one spot ahead of Les Moonves, the CEO of CBS).¹⁴

Mr. Solomon will have the opportunity to respond to the OIG's "Intent to Exclude Letter" and set forth why the OIG should not use its discretion to exclude him. In the event the OIG uses its B-15, Solomon can appeal to HHS' Administrative Law Judge. An adverse decision is appealed to HHS' Departmental Appeals Board (DAB). Judicial review starting in federal district court is also available after the final DAB decision.

AVOIDING RISKY BUSINESS

"The buck stops here!" President Truman's mantra reminds us today that the CEO, as well as boards of trustees, still need to have their radar tuned to a very selective frequency to increase their overall awareness. With reliance on senior management, the C-suite is vulnerable to egregious acts committed from within the executive cir-

cle, as well as from those for whom they are responsible. Several problem situations are described below, and with the benefit of hindsight, the telltale warning signs will be noted and suggestions made as to how these problems might have been uncovered sooner, and/or if they were preventable in the first place.

Instituting Tighter Internal Controls

In the case of a hospital purchasing bid-rigging fraud, Mario Perciavalle, a former associate director of plant services at the Mount Sinai Medical Center and School of Medicine, pled guilty to three counts in an April 2010 indictment. The defendant falsely submitted intentionally high non-competitive bids to make it appear that a legitimate bidding process was conducted. In addition, the defendant asked for and accepted bribes from one of the companies that was later awarded the contract, and became a co-conspirator.¹⁵

While the fraud and conspiracy took place from June 2004 to September 2005, it might have been possible to have detected some of the irregularities by requiring each invited vendor to submit its bid in both hardcopy and electronic formats. Although it might be more efficient to have all of the bids submitted to one individual (in this case the defendant), having it sent both in hardcopy and electronic formats to a small selection committee might have made the fraud harder, if not impossible, to carry out. The electronic email versions would have been more difficult to have fabricated the bidder's email account along with sending the attached file containing the bid.

Similarly, by ensuring that each member of a (small) selection committee received the documents, any collusion would have required more people being involved, thereby increasing the risk. There would be a stronger likelihood that one or more selection committee members would have taken their "duty to report" seriously and advised their supervisor or compliance officer of a problem.

Additionally, having bidder conferences (sometimes at the outset, upon release of a request for proposal (RFP), or at a question and answer session) may have allowed more vendor-hospital interaction and communication that would have required vendor presence and reduced the likelihood of phantom bidders being introduced. In this instance, the chief financial officer, regarding the procurement and purchasing function, and senior facilities executive, for the direct functional responsibility, should have had more safeguards. The senior internal audit officer also should have examined the process to detect operational weaknesses and suggested more oversight controls and reviews.

Striking a Balance

Throughout the health care provider community, there is an ongoing push to fund research and develop the remedies to today's diseases and ailments. Much has been written about the relationship between pharma and providers. With federal settlements against some of the largest pharmaceutical companies running into the millions of dollars, health care providers face the continuing challenge of monitoring and managing their relationships with these companies.

In its April 29, 2009 report released on "Conflict of Interest in Medical Research, Education, and Practice," the Institute of Medicine of the National Academies concluded:

The committee recommends the implementation of policies and procedures that will reduce the risk of conflicts that can jeopardize the integrity of scientific investigations, the objectivity of medical education, the quality of patient care, and the public's trust in medicine.¹⁶

Even with this lofty goal, including the "Massachusetts law that put into effect regulations banning gifts to doctors from drug and medical device companies, as well as requiring the companies to disclose most

consulting payments made to doctors,"¹⁷ the reality is the CEOs, chief medical officers, and clinical chiefs need to ensure that clearly worded protocols and policies are understood and that the process is both manageable and subject to effective oversight monitoring to ensure compliance.

Even when health care providers implement procedures and safeguards, the public's perception often reveals a different reality. In reporting by Sandra Yin, public survey results indicate large numbers of respondents negatively commenting on the relationship of pharmaceutical companies and doctors, including the preferred use of medications over other forms of treatment, and knowledge that drug companies often provide payment in the form of testimonials, speaking engagements, and meals for doctors and their staffs.¹⁸ She goes on to report that pharma company physician spokespeople have been found to have professional issues related to purported credentials and exaggerated clinical treatment experience.¹⁹ Health care providers will need to be especially careful in this area to ensure that its standards of conduct are well understood and being followed.

CEOs Behaving Badly

The case of Georgia's Archbold Medical Center CEO, Ken Beverly, who has been accused of falsifying documents in order to pocket \$9 million in Medicaid funds,²⁰ and David P. Rosen, the former CEO of the Medisys Health Network (New York), accused of participating in bribery schemes,²¹ raises the specter that if the CEO has abandoned both mission and ethics, then the boards of trustees appear to be the last line of defense.

While the B-15 exclusion provides one way in which bad actors and bad organizations will face the ultimate punishment, boards are beginning to face closer scrutiny. Even before CEO Rosen was fired, when the charges were first being brought, "New York's Department of Health authorized the attorney general's office to launch a probe into the actions of trustees...of Me-

disys Health Network...[for] breach of its fiduciary duties."²² This inquiry was started about the time the first rumblings of questionable CEO behavior were surfacing. Hospital boards need to take a page from other industry boards. In its 2011 survey of boards of directors, the firm EisnerAmper identified this key concern:

Directors identified the various risks that were most important to their boards with 69 percent identifying reputational risk as most important. The percentage skyrockets with the addition of their concerns about the elements of reputational risk including IT risks, product risk, outsourcing risk, privacy and data security, and risk due to fraud.²³

The take-away for hospital boards: Warning: Danger — Rough Road Surface Ahead! Proceed with caution and become more involved and aware.

When All Else Fails

A juror in a medical malpractice suit solicited a bribe from the plaintiff for influencing the jury verdict. The plaintiff advised his lawyer, who in turn advised the judge and subsequently the Nassau County, NY, District Attorney, and an arrest was then made.²⁴ In this instance, all of the affected innocent parties turned out to be “good actors;” however, in the case of an anesthesiologist-turned-auditor for an insurance company, his review uncovered issues with a hospital system’s alleged abuse of anesthesia billing codes. Dr. Benton Forman found inconsistencies with the 25-hospital Sutter Health system’s use of codes when reviewing claims for Guardian Life Insurance. In eventually relating these problems to the California Insurance Commissioner, a *qui tam* lawsuit was filed and is now underway. While the case is yet to be adjudicated, the continued presence of whistleblowers serves as an ultimate check and balance on a system that needs to tighten its compliance oversight.²⁵

DOES THE QUALITY GO IN BEFORE THE CODE GOES ON?

In 1927, Zenith made famous its slogan: “The Quality Goes In Before the Name Goes On.”²⁶ Ford Motor Company made its “Quality Is Job 1” a household slogan in the 1980s as it introduced revolutionary new products and used total quality management (TQM) to drive down costs and capture market share.²⁷ TQM and Six Sigma have been part of health care’s process reengineering and redesign for many years. And in much the same way that industry giants such as Ford and Zenith (now wholly owned by LGE) compete for market share, hospitals and health care systems often may be viewed as waging a “war” to be the best.

In a world where advertisements adorn sports arenas and highway billboards touting the best in care, the consumer needs to be challenged to find the best care available to them. If you’ve ever seen a Las Vegas tourist magazine, you’d be surprised that virtually every restaurant, show, or hotel has won some award. It is truly becoming: *Caveat Emptor* (Let the Buyer Beware)!

As for quality and coding, health care providers seem to be caught in an endless loop as they seek to justify medical necessity and appropriate levels of care. Recovery audit contractors (RACs) continue to uncover instances of providers failing to either properly document or code the care that was rendered. “Most of the denials involved hospital stays lasting less than one day, and most had to do with an inappropriate care setting triggering the denial, not that the care itself was completely unnecessary.”²⁸

With RAC as a backdrop, health care providers are simultaneously wrestling to demonstrate that it meets the “meaningful use” criteria associated with obtaining funding for the development and implementation of the electronic medical record (EMR). They are also faced with preparing for the major coding changes that are expected with the introduction of ICD-10 in

2013. When coupled together, one can only wonder, when extrapolating today's RAC and other audit performance weaknesses, if having the EMR will allow auditors to find the errors that much more quickly.

Physician education and awareness is needed to ensure that these caregivers understand what is needed in the hospital medical record to support their clinical judgments. Without proper coding and documentation, not only will claims be subject to review and penalty, but there is also the likelihood that costs, cost reporting, and financial reporting will lead to inaccuracies and openings to exploit loopholes.

AVOIDING RISKS: LESSONS LEARNED

With technological advances continuing at a feverish pace, the C-suite will be faced with decisions to keep their organizations at the cutting-edge of medical science and operational efficiency. While faced with these challenges, the C-suite executives need to ratchet up the organization's protection against data breaches. With these numbers continuing to increase, one can only ask if it is necessary to have so many laptops — especially those that are prone to leaving the facility? This problem may only become exacerbated with the popularity and expanded use of electronic tablets that may be more difficult to secure as the practice of medicine goes even more digital.

Similarly, the increasing incidences of employees trolling medical records when unauthorized poses a continuing threat, as does the presence of hospitals and health systems now joining the ranks of social media networks to increase their presence and market share. Unless the C-suite executives and boards begin to tighten these various portals, there will be an ever-increasing level of risk for fraud and abuse.

Finally, appearance matters. It is not enough that with all of the risks noted above (and these are but a smattering of the many that are out there), C-suite occupants must set the standard, both in personal conduct and performance. CEOs have been driven

from office by criminal scandal as well as individual indiscretions and involvement with subordinates. CEO compensation continues to be a lightning rod and focal point, too. It is also often the study and reporting of others that raises concern.

...[T]he [2009] University of Connecticut School of Business study that showed hospitals that provide more charity care actually pay their CEOs less, while hospitals that provide less care for indigent patients pay their CEOs more. That's the kind of ammunition that could draw blood down the line.²⁹

And while the study itself goes on to point out its limitations both in terms of geography and metrics, it casts a shadow nonetheless. The bad examples of the few should continue to serve as a reminder to the many that most of the risks are avoidable and preventable — including the addition of an orange jumpsuit to one's wardrobe.

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