New Government Scrutiny
Demands New Strategies for
Health Care Clients

T. Mills Fleming
Partner and Chair, Health Care Practice Group
Hunter, Maclean, Exley & Dunn PC

ASPATORE
Introduction

With the continuing passage of a host of new laws, health care compliance is now more challenging than ever. As set forth in the Department of Health and Human Services (HHS) and Department of Justice (DOJ) Health Care Fraud and Abuse Control Program Annual Report for Fiscal Year 2010, FY 2010 was a record year for health care fraud enforcement in the United States, and 2011 promises to be just as busy.

HHS’s Office of Inspector General (OIG) has submitted its Semiannual Report to Congress, addressing the first six-month period of fiscal year (FY) 2011 (October 1, 2010, to March 31, 2011). The report describes the results of OIG reviews and legal and investigative outcomes and provides recommendations.

During the semiannual reporting period, the OIG reports recoveries of about $3.4 billion, consisting of $222.4 million in audit receivables and $3.2 billion in investigative receivables. OIG also reports exclusions of 883 individuals and entities from participation in federal health care programs, including 349 criminal actions against individuals or entities that engaged in crimes against HHS programs and 197 civil actions.

During the reporting period, Medicare Fraud Strike Force efforts have resulted in the filing of charges against 213 individuals or entities, 107 convictions, and $63.9 million in investigative receivables. In February 2011, Strike Force teams arrested more than 100 defendants in nine cities for their alleged participation in Medicare fraud schemes involving more than $225 million in false billing. The defendants are accused of various health care-related crimes ranging from violating the anti-kickback statute to money laundering to aggravated identity theft.

With these increased enforcement efforts, health care entities—from hospitals to physicians, to corporate executives, to boards—must understand the laws governing these areas and adhere to good governance practices to avoid not only corporate, but also individual, exposure.

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A Potent Combination: False Claims Act, Stark Law, Anti-Kickback Statute

Taken individually, the False Claims Act, the Stark Law, and the anti-kickback statute each presents health care providers with significant challenges. When the government uses these laws in various combinations, the resulting compliance issues can be a nightmare. Enforcement under the False Claims Act has become a major tool for the government to investigate hospitals and health systems.

To appreciate why the False Claims Act has become such a tool, one needs to understand the breadth of this law and the ways it integrates with the Stark Law and the anti-kickback statute.

The False Claims Act (FCA), 31 U.S.C. §§ 3729-3733, prohibits false or fraudulent claims for payment to the federal government. Under the FCA, liability attaches to a “false or fraudulent claim for payment” or a “false record or statement [made] material to a false or fraudulent claim.” 31 U.S.C. § 3729(a)(1). The qui tam provisions of the FCA allow a private citizen (called a relator) to bring a civil claim under the statute “for the person and for the United States Government...in the name of the Government.” 31 U.S.C. § 3730(b)(1). Falsely certifying compliance with the Stark or anti-kickback statute in connection with a claim submitted to a federally funded insurance program is actionable under the FCA. PPACA § 6402(f) (to be codified at 42 U.S.C. § 1320a-7b(g)); United States ex rel. Wilkins v. United Health Group, et al., No. 10-2747, 2011 WL 2573380 (3d Cir. June 30, 2011); United States ex rel. Koveszke v. Carlisle HMA Inc., et al., 554 F.3d 88 (3d Cir. 2009).

Since the FCA can “bootstrap” both a Stark and an anti-kickback statute violation, this combination allows the government to claim treble damages. What makes this combination more treacherous is that the Stark Law, which took the government over a decade to issue a series of regulations, is a very technical statute, with a myriad of twists and turns, exceptions, and definitional issues, and a violation of it creates strict liability. In other words, good faith or substantial compliance does not insulate a provider from liability. Similarly, the anti-kickback statute, 42 U.S.C. § 1320a-7b(b) is a criminal statute that prohibits payments as inducement for referrals of
Medicare and Medicaid beneficiaries and beneficiaries of other federal health care payment programs. Because it is an intent-based statute, good faith or substantial compliance can be a defense to an alleged anti-kickback statute violation.

**An Increased Enforcement Environment**

The current enforcement environment is notable for its increased criminal prosecutions, with the DOJ’s opening 1,116 new criminal health care fraud investigations involving 2,095 potential defendants in FY 2010 alone, and more resources are being provided by Congress. The Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative, launched in May 2009 by Attorney General Eric Holder and Secretary of the Department of Health and Human Services Kathleen Sebelius to better enforce the FCA, saw the Medicare strike force charge 111 individuals for more than $225 million in false billings in February 2011. According to the January 2011 Health Care Fraud and Abuse Control Program (HCFAC) report, the DOJ reported that it has recovered some $2.5 billion in health care fraud settlements and judgments for fiscal year 2010. Since January 2009, DOJ recovered $4.6 billion and more than $3 billion in cases brought under the Food and Drug Cosmetics Act (FDCA).

**Associated Legislative Activity around Heightened Enforcement**

In addition to the heightened enforcement, there has been legislative activity related to health care fraud enforcement and, most notably, the enactment of three sweeping laws that also amended other health care statutes: the Fraud Enforcement Recovery Act of 2009 (FERA), enacted in May 2009; the Patient Protection and Affordable Care Act (PPACA), enacted on March 23, 2010; and the Dodd-Frank Financial Reform bill, passed on July 21, 2010.

With respect to health care fraud enforcement, the FCA amendments contained in FERA effectively reverse the unanimous decision of the Supreme Court in *Allison Engine Co. v. United States ex rel. Sanders*, 128 S. Ct. 2123 (2008). *Allison Engine* made clear that to establish liability under Section 3729(a)(2) of the FCA, the government must prove that a defendant, when using a false record or statement “to get” a false claim paid or approved “by the government,” intended for the government itself to pay the claim. FERA eliminates the intent requirement with the removal of both the “to get” and “by the government” language from Section 3729(a)(2). *United States ex rel. Wilkins v. United Health Group, et al.*, No. 10–2747, 2011 WL 2573380 (3d Cir. June 30, 2011).

With respect to overpayment obligations, FERA amends the “reverse false claims” provisions of the FCA to expand liability to “knowingly and improperly avoid[ing] or decrease[ing] an obligation to pay or transmit money or property to the government.” In other words, to establish a “reverse false claim” violation, it is no longer required that the defendant be shown to have taken an “affirmative act”—that is, creating a false statement or record, to “conceal, avoid or decrease” the obligation to repay the government. Instead, the mere ongoing possession of an overpayment, if there is an “obligation” to repay, can now be grounds for an FCA violation.

Although FERA expanded the scope of the reverse false claims provisions, FERA did not clarify the meaning of “obligation” and whether there was a specific duty to return “overpayments.” The PPACA answered these questions and linked the retention of overpayments to FCA liability. Under the PPACA, “overpayments” are defined as governmental funds that a person receives or retains to which that person is not entitled. Such persons must “report and return” any overpayments within sixty days after either the date on which the overpayment was identified or the date any corresponding cost report was due, whichever is later.

In addition to obligating a health care provider to report an overpayment, the PPACA also imposed broader obligations for providers to self-disclose actual or potential violations of the Stark Law through what is called the “Self-Referral Disclosure Protocol” (SRDP). The SRDP cannot be used to obtain a CMS determination as to whether an actual or potential violation of Stark has occurred. In other words, the SRDP is separate from the CMS Stark advisory opinion process and is intended to facilitate the resolution of only matters that, in the disclosing party’s reasonable assessment, are actual or potential violations of the Stark Law. Conduct that raises potential liabilities under other federal criminal, civil, or administrative laws should be reported under the OIG’s CMS Self-Disclosure Protocol. Therefore, a
settlement with CMS does not preclude the provider from liability under the FCA or other statutes.

While the PPACA imposed stricter requirements on self-disclosure by providers, it eased the ability of “whistleblowers” to report the provider for alleged wrongdoing, even when the information was available to the public. Prior to the PPACA’s enactment, the text of the FCA’s public disclosure bar, 31 U.S.C. §§ 3730(e)(4)(A) and (B), read:

(4)

A. No court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

B. For purposes of this paragraph, “original source” means an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section which is based on the information.

Pursuant to this version of the statute, courts have determined that a relator is precluded by the public disclosure bar from bringing a quii tam action when, for example:

1. a relator’s complaint against a hospital is based on the contents of a published magazine article describing an FBI investigation of the hospital’s fraudulent practices; (Bannon, 406 F. Supp. 2d at 910-12)
2. a relator bases her complaint on information gained from an administrative audit or report of the Centers for Medicare and

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Medicaid Services2 or a response to the relator’s request under the Freedom of Information Act; (United States ex rel. Reagan v. East Texas Medical Center Regional Healthcare System, 384 F.3d 168 (5th Cir. 2004)) or

3. a relator’s complaint reflects information already disclosed in civil litigation in state court.3

Despite this guidance regarding what constitutes a public disclosure, the state of the law is in flux due to the recent enactment of PPACA. On March 23, 2010, PPACA declared: “Section 3730(e) of title 31, United States Code, is amended by striking paragraph (4) and inserting the following:”

(4)

A. The court shall dismiss an action or claim under this section, unless opposed by the Government, if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed:

i. in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party;
ii. in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or
iii. from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

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2 Glaser v. Wound Care Consultants Inc., 570 F.3d 907 (7th Cir. 2009) (“For purposes of § 3730(e)(4), a ‘public disclosure’ occurs when ‘the critical elements exposing the transaction as fraudulent are placed in the public domain.’... A public disclosure bring[s] to the attention of the relevant authority that there has been a false claim against the government.” (quoting US ex rel. Feingold v. AdminaStar Fed. Inc., 324 F.3d 492, 495 (7th Cir. 2003))).
3 Reagan, 384 F.3d at 174. (“Any information disclosed through civil litigation and on file with the clerk’s office should be considered a public disclosure of allegations in a civil hearing for the purposes of section 3730(e)(4)(A).”)
B. For purposes of this paragraph, “original source” means an individual who either (1) prior to a public disclosure under subsection (e)(4)(a), has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based, or (2) [sic] who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section.

The language of the public disclosure bar has not changed since March 23, 2010. A notable difference between the pre-PPACA and post-PPACA language is that, before the enactment of PPACA, courts sought to determine whether the relator’s complaint was “based upon” a public disclosure. After PPACA, the public disclosure bar applies if “substantially the same” allegations or transactions alleged in the action were publicly disclosed.

This distinction is noteworthy because many courts found the decision of whether the bar precluded a qui tam action on an analysis of the phrase “based upon.” For instance, the Seventh Circuit Court of Appeals in Mathews v. Bank of Farmington, 166 F.3d 853, 863 (7th Cir. 1999), reasoned that “based upon” is not synonymous with ‘identical to’ or ‘similar to,’ but can be substituted for ‘derived from’ wherever it occurs.” The Fourth Circuit Court of Appeals applied an even stricter interpretation of “based upon,” determining that jurisdiction was lacking only when the relator “actually derived” his claim from a public disclosure. US ex rel. Siller v. Becton Dickinson & Co., 21 F.3d 1339, 1348 (4th Cir. 1994). In contrast, the Eleventh Circuit Court of Appeals determined that “the language is most naturally read to preclude suits based in any part on publically disclosed information.” Cooper v. Blue Cross & Blue Shield of Florida Inc., 19 F.3d 562, 567 (11th Cir. 1994) (emphasis in original).

The Eleventh Circuit Court of Appeals reinforced this interpretation in US ex rel. Brown v. Walt Disney World Co., 361 Fed. Appx. 66 (11th Cir. 2010), in which the court noted that the basis for one of the plaintiff’s claims, the defendant’s de-annexation of residential housing parcels, “had been the subject of newspaper articles.” Even though the plaintiff argued that “single, isolated exhibits included with her complaint [did] not constitute publicly disclosed information,” the court reasoned that “the FCA precludes suits based in any part on publicly disclosed information.” Id. at 68. Although the Eleventh Circuit Court of Appeals adheres to a broad application of the “based upon” standard, the post-PPACA “substantially the same” language clearly demands a fresh analysis and has yet to be widely interpreted.

Other significant changes to the public disclosure bar include the replacement of the “jurisdictional” bar with a more lenient, discretionary option to be exercised by the government. Also, the amendments inserted the term “Federal” before the “criminal, civil, or administrative hearing” provision. One district court summarized the PPACA amendments to the public disclosure bar as follows:

The major changes effected by the 2010 amendments ... are to clarify that the public disclosure bar only applies if the ‘criminal, civil, or administrative hearing’ at which disclosure occurred was a federal proceeding and to make

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4 Current through May 31, 2011.
5 The “actually derived” analysis employed by the Fourth Circuit Court of Appeals is the narrowest interpretation of all circuit courts.

6 The district court further noted that the defendant’s practice of de-annexing residential parcels had not only been “the subject of newspaper articles for many years,” but the de-annexation had been disclosed in other “news media,” including the Wikipedia website. 2008 US Dist. Lexis 116832, *11. Interestingly, neither the district court nor the Eleventh Circuit Court of Appeals elaborated on the content of the “newspaper articles,” foregoing an analysis of the specificity required to preclude a suit based on a public disclosure.

7 Several district courts have declined to interpret the post-PPACA language of the public disclosure bar, reasoning that “[a]lthough § 3730(e)(4) was amended on March 23, 2010, the pre-amendment version of the statute applies in [the present] case because the Supreme Court has already determined that the amended statute does not apply retroactively,” US ex rel. Davis v. Prince, 753 F. Supp. 2d 569, 578 (E.D. Va. 2011). See also US ex rel. Rosner v. WB/Starler IP Owner LLC, 793 F. Supp. 2d 396, 402 (S.D.N.Y. 2010); US ex rel. Lancaster v. Boeing Co., 701 F. Supp. 2d 888 (W.D. Tex. 2010); US ex rel. Dekort v. Integrated Coast Guard Systems, 705 F. Supp. 2d 519, 553 n.13 (N.D. Tex. 2010). These cases refer to the Supreme Court’s recent decision in Graham County Soil & Water Conservation Dist. v. United States ex rel. Wilson, 130 S.Ct. 1396, 1400 n. 1 (2010), to support their contention that the amended version of the public disclosure bar has no retroactive effect.
the bar applicable only if the [U.S.] government or its agent was a party to that hearing. Moreover, the amendment adds that the bar does not apply if the government opposes dismissal of the action. Furthermore, Congress changed the language of this provision to state that a case based upon certain information must be dismissed rather than allowing the section to continue to state that "[n]o court shall have jurisdiction" over such cases.


The PPACA amendments also revised Section 3730(e)(4)(B), adding the requirement that the original source's independent knowledge must "materially add" to the publicly disclosed allegations unless the original source voluntarily disclosed the information to the government prior to the public disclosure.

In Schindler v. United States, 131 S. Ct. 1885 (2011), the most recent case in which the Supreme Court interpreted the FCA public disclosure provisions, the Court emphasized the broad scope of the public disclosure bar, particularly the statutory reference to "news media." Schindler, 131 S. Ct. at 1891-92. However, the Court noted that, although PPACA amended the public disclosure bar, the Schindler opinion refers to the statute as it existed when the suit was filed. 9 Thus, the decision did not address the potential effects of replacing the jurisdictional bar with a more discretionary standard or any other consequences of the May 23, 2010, amendments.

No Strength in Numbers: The Government Pursues Individuals

A sea change in health care enforcement is the government’s focus on holding individuals accountable in health care fraud investigations.

8 This Tennessee district court stands virtually alone in interpreting the PPACA amendments to the FCA public disclosure bar. As of June 14, 2011, nearly all courts have chosen to apply the language of the statute at the time the action was filed, thereby eliminating the need for new interpretation.

9 The district court entered an order in Kirk v. Schindler Elevator Corp., 606 F. Supp. 2d 448 (S.D.N.Y. 2009), on March 30, 2009. Thus, the Schindler opinion analyzes the pre-PPACA public disclosure language.

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Executives of health care companies are under scrutiny—a likely fallout from the Enron scandal and the prosecution of Enron’s chief executive, Kenneth Lay.

While the enforcement focused on the for-profit world, that philosophy has now drifted into the tax-exempt arena of hospitals. This effort was undertaken over the last several years, driven primarily by Senate Finance Committee Chairman Charles Grassley (R-Iowa). As Grassley noted in 2005, “Non-profit hospitals receive billions in tax breaks at the federal, state and local level. The public has a right to expect significant, measurable benefits in return.”

Grassley’s efforts resulted in the IRS’s considering the need for additional guidance on the qualifications a hospital must satisfy to exist as a tax-exempt organization—including a possible “bright line facts and circumstances” approach. See Simon Brown, IRS Considering Bright-Line Standards for Hospital Tax Exemption, 2009 EAT 87-5, May 8, 2009.

In February 2009, the IRS issued the results of its study of nonprofit hospitals begun in 2006. The study was conducted so that the IRS and other stakeholders could better understand nonprofit hospitals and their community benefit and executive compensation practices and reporting. The report is based on the responses to questionnaires the IRS sent to a sample of more than 500 nonprofit hospitals. As part of the study, the IRS also examined twenty nonprofit hospitals regarding their executive compensation practices. See http://www.irs.gov/pub/irs-tege/frepthosproj.pdf.

Two Pivotal Enforcement Cases

There have been several recent enforcement actions taken against senior executives in health care systems, pharmaceutical companies, large managed care companies, and related companies. The enforcement actions have affected chief executive officers (CEOs), chief financial officers (CFOs), and general counsel. Actions against these individuals include criminal prosecution, exclusion from participation in the Medicare and Medicaid programs, False Claims Act cases, and civil monetary penalty enforcement. Liability is based on a number of different theories, but it appears to arise
primarily from US Supreme Court cases that address liabilities of corporate officers with responsibility to prevent or correct alleged misconduct.

Two cases define this focus on corporate officials. *US v. Dotterweich*, 320 U.S. 277 (1943) and *US v. Park*, 421 U.S. 658 (1975) are interpreted as permitting the prosecution of corporate officers for certain misdemeanor criminal offenses without having to prove intent or involvement in the wrongdoing. In *Dotterweich* the Court addressed whether “the manager of a corporation, as well as the corporation itself, may be prosecuted under the Federal Food, Drug, and Cosmetic Act of 1938 for the introduction of misbranded and adulterated articles into interstate commerce.” The jury had disagreed as to the corporation, a jobber purchasing drugs from manufacturers and shipping them in interstate commerce under its own label, but had convicted Dotterweich, the corporation’s president and general manager. The Court of Appeals reversed the conviction on the ground that only the drug dealer, whether corporation or individual, was subject to the criminal provisions of the act, and that where the dealer was a corporation, an individual connected therewith might be held personally only if he was operating the corporation “as his ‘alter ego.’”

In reversing the judgment of the Court of Appeals and reinstating Dotterweich’s conviction, this Court looked to the purposes of the act and noted that they “touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection.” It observed that the act is of “a now familiar type” that “dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing. In the interest of the larger good it puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger.”

Similarly, in *Park*, the government charged Acme and its CEO with violations of the Federal Food, Drug, and Cosmetic Act. Each count of the information alleged that the defendants had received food that had been shipped in interstate commerce and that, while the food was being held for sale in Acme’s Baltimore warehouse following shipment in interstate commerce, they caused it to be held in a building accessible to rodents and to be exposed to contamination by rodents.

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As the Court noted in *Park*, “Dotterweich and the cases which have followed reveal that in providing sanctions which reach and touch the individuals who execute the corporate mission—and this is by no means necessarily confined to a single corporate agent or employee—the Act imposes not only a positive duty to seek out and remedy violations when they occur but also, and primarily, a duty to implement measures that will insure that violations will not occur. The requirements of foresight and vigilance imposed on responsible corporate agents are beyond question demanding, and perhaps onerous, but they are no more stringent than the public has a right to expect of those who voluntarily assume positions of authority in business enterprises whose services and products affect the health and well-being of the public that supports them...Viewed as a whole, the charge did not permit the jury to find guilt solely on the basis of respondent’s position in the corporation; rather, it fairly advised the jury that to find guilt it must find respondent ‘had a responsible relation to the situation,’ and ‘by virtue of his position...had...authority and responsibility’ to deal with the situation. The situation referred to could only be ‘food...held in insanitary conditions in a warehouse with the result that it consisted, in part, of filth or...may have been contaminated with filth.’”

It is expansive enough to make the spokes in a system liable, not just the hub. Even if the entire organization is not involved, partial responsibility could have the same effect as a conspiracy to commit the crime.

**Treachurous Ground for Hospitals, Doctors, and Boards**

In a hospital setting, the biggest area of regulatory and compliance exposure is not only physician compensation, but also any agreement between a hospital and a doctor. Myriad laws, such as Stark and the anti-kickback statute, and tax-exempt laws, which prohibit anything inuring to the benefit of a private party, are significant pillars you have to deal with in terms of finding a regulatory balance relative to contractual relationships with physicians. Any time money flows from a doctor to a hospital, it has to fall within an exception under the Stark Law (e.g., a lease for office space) or the anti-kickback statute safe harbor (e.g., a medical director arrangement for identifiable services).

Depending on the particulars of the arrangement, clients should be counseled on the availability of obtaining an advisory opinion (or, in the
case of certain tax issues, a private letter ruling) from the federal government. Such an opinion provides significant protection from the government, but also from potential whistleblowers.

*Minding the Board’s Business*

I am not suggesting that HIPAA is not important, but the government is focusing less on the law because the dollars are not there. A HIPAA violation nets the government a miniscule settlement when compared with a False Claims Act, Stark, or the anti-kickback statute, when you consider boards, conflicts of interest, and the directors executing their duty for purposes of ensuring that they are disinterested directors and will assess issues before they vote. The law says that if a board exercises its business judgment about an arrangement, and the directors are disinterested, then the burden of proof shifts to the government to show the arrangement was improper or illegal. This represents a significant benefit that boards enjoy.

*Spitzer’s Leading-Edge Use of the State Non-Profit Code*

Former New York State Attorney General Elliott Spitzer used the state non-profit code to prosecute directors because they had breached fiduciary duties and obligations in terms of executive compensation. He was one of the first state attorneys general to use state statutes to prosecute directors instead of pursuing under federal law. As the attorney general, Spitzer was New York’s lead state law enforcement agent, and he used the state statutes, which had probably been on the books for decades. Therefore, officers, directors, and their legal counsel need to be well-versed on both state and federal statutes.

*Community Need versus Fair Market Value for Physician Salaries*

My experience with health care clients shows me that they want to comply with the law. In other words, no one wants to go to jail or even be in violation. Unfortunately, there are many gray-area issues.

For example, a rural hospital has to recruit an orthopedic surgeon to its service area. The hospital plans to guarantee the orthopedic surgeon $800,000 annually. If you refer to salary surveys, that level of compensation is likely considered in excess of normal circumstances and beyond fair market value. The law says fair market value is measured on both objective and subjective factors. Your client may be able to say that the salary is legitimate because it had tried to recruit someone for the past five years and was unable to attract a doctor at the original salary. There is a community need, and paying the higher salary has enabled the hospital to meet the need.

Objectively, paying an orthopedic surgeon $800,000 may be “unreasonable” for objective, fair-market-value purposes, but the hospital may be able to provide other data that shows that it is reasonable under particular circumstances. Such circumstances can include strategic importance of the clinical service; quality levels and clinical outcomes for each physician; physician’s reputation, training, skills, honors, awards, etc.; physician’s leadership and program development skills; recruitment and retention issues for the physician’s specialty; and the grant support and/or external funding that each physician can obtain for the hospital.

This is a gray area within which health care executives have to take a risk. If people have to travel an hour (also referred to as “outmigration”) to get care for certain procedures, then the issue becomes far less black and white than an objective assessment of fair market value. Management must balance those issues and one of the most recent results of diminishing insurance coverage and lack of primary care physicians: the unfunded mandate of the Emergency Medical Treatment and Active Labor Act (EMTALA). EMTALA requires that any time an individual presents for treatment at a hospital’s emergency room, the facility must provide stabilizing treatment, regardless of the patient’s ability to pay.

In one emergency department at a major hospital, annual visits have increased 15 percent to 20 percent annually. That is an exponential increase, and some emergency rooms that were designed to treat 30,000 to 40,000 people a year are now treating more than 100,000 a year. This care costs a great deal of money, and the challenge for hospitals is to recover some of that cost through other health care ventures and operational efficiency. To make matters worse for hospitals, physicians are opening their own surgery centers, affecting the revenue hospitals generate from inpatient and outpatient surgeries. As doctors start to perform surgery in their own
facilities, it forces the hospital to employ other physicians to care for those presenting at the emergency departments, since physicians are now choosing not to be on hospital call schedules.

Health Care Lawyers Must Specialize

When I graduated from law school twenty-one years ago, there was not a health care law class. When I started in health care law, most of the work was related to medical malpractice defense. Within a short time, regulatory issues came into prominence, along with end-of-life issues. The Karen Ann Quinlan case triggered legislation, in many states, that dealt with when it is lawful to stop providing care. The next wave brought fraud, abuse, and anti-kickback matters, followed by Stark. Various presidents brought new legislation, Medicare Secondary Payer Act of 1980, Medicare Catastrophic Coverage Act of 1988, Medicare Catastrophic Coverage Repeal Act of 1989, Balanced Budget Act of 1997, Medicare Prescription Drug, Improvement, and Modernization Act, and Patient Protection and Affordable Care Act and Health Care and Education Reconciliation Act of 2010.

Recall also that President Bill Clinton attempted an overhaul of Medicare through his health care reform plan in 1993 and 1994 but was unable to get the legislation passed by Congress.

None of these laws, however, has deterred the government from aggressively prosecuting hospitals, physicians, drug companies, and health care executives, and the government’s latest data on case settlements proves this point. For example, in FY 2009 alone, approximately $2.5 billion was deposited in FY09 to the Medicare Trust Fund—an increase of more than half a billion dollars over the prior year’s total; $1.6 billion in judgments and settlements were won or negotiated; the Justice Department’s Criminal Division, in cooperation with US attorneys’ offices around the country, opened more than 1,000 new criminal health care fraud investigations and had more than 1,600 health care fraud criminal investigations pending; the department indicted an “all-time high” number of health care fraud defendants—more than 800—in nearly 500 cases filed and obtained close to 600 convictions; and the Justice Department’s Civil Division opened nearly 900 new civil health care fraud investigations and had more than 1,100 pending cases.

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Today, health care attorneys specialize in reimbursement, Medicare contracting, regulatory analysis, Stark analysis, and tax issues. Many hospitals have capital because they floated tax-exempt bonds to pay for it, and you cannot use the funds for private use. For example, if a hospital builds a building with tax-exempt bonds, it cannot allow a private doctor to run his office out of that location. The details that seem to be insignificant can cause the most trouble. And in an environment with more enforcement, more regulations, and more scrutiny, it can become very complex. It does not take a major violation to trigger an investigation.

Negotiating the Enforcement Landscape: Triggers, Client Strategies, and Challenges

The regulations are complex; the investigations are rigorous; and the outcome for a health care provider depends as much on the skill with which its response is undertaken as the severity of the charges or the preparation by the client. Understanding the factors that trigger the investigation, the fundamental steps for dealing with it, and the common challenges will go a long way toward a successful result.

The Key Question: What Caused the Investigation in the First Place?

Physician and hospital relationships are, without a doubt, the most common reason for an investigation. Any time money passes between a hospital and a doctor, the government wants to be sure that referrals are not involved. Even arrangements that would fall under safe harbor provisions are now being challenged on a fair market value basis—e.g., if you pay your doctor employee above market average, the government may view that as excessive and investigate. The determination is subject to opinions. You hire a consultant and do a spot check on compensation levels. There are separate business judgment factors that will justify paying a doctor at a certain level. However, the government will take the position that even if you are falling within one of these expectations, there is the suspicion that you are doing it to garner referrals. That wipes out the employment exception because if even one purpose out of 100 is to garner referrals, your client has violated the law.

The best prevention against a trigger is to do a thorough job of ensuring that everything is documented, reviewed, and approved. This will help
verify that you are paying fair market value, and the arrangement is commercially reasonable.

Another common trigger is when hospitals join, or hospitals and doctors join, to negotiate with managed care companies. The managed care companies assert that the doctors and hospitals cannot join like that because they are price-fixing and would have too much of a monopoly. This situation leads to further battles beyond the government’s investigation.

*Client Actions at the Outset of an Investigation*

Most investigators begin by the issuance of a subpoena. The first thing you need to do is establish some kind of contact with the government agency that has issued the subpoena—typically, a special agent or the US attorney who is dealing with the matter.

On the client side, you must ensure that the client does not destroy documents. Send the client a letter that instructs it to retain all files. The next step is to interview relevant people who may have information about the alleged infraction. Many times, the subpoena will not state specifically that the client violated a particular aspect of the law. However, you should get an idea of what the government is seeking and develop your facts through the interviews as soon as possible. The subpoena gives you an idea of what the government is asking for, and you must issue a litigation hold notice to your client. Destruction of documents will result in an obstruction of justice charge.

When you respond to the subpoena, you must ensure that you are not releasing any privileged information. This is electronic as well as printed information; there is a host of information stored online, and you have to preserve that and be able to produce the correct information when it is requested. The government will use that to assess whether it believes there is a need for an additional investigation or an additional document review. If the investigation deals with a whistleblower (which the government does not have to disclose), and the government decides not to prosecute, then the whistleblower can proceed on his or her own. At this point, the case becomes a federal case and a public document.

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*The Execution of a Federal Case*

A federal investigation follows the typical path of discovery, depositions, additional review of information, motions to dismiss or compel information, and then movement toward trial or a motion to settle. The government pursues a number of different theories, depending on the facts.

Typically, it will have someone on the inside who is feeding it the information, and investigators like to see whether that information is valid or reasonable. The investigators will try to discern the organization’s position on an issue by examining memos, statements, or other materials. The investigators want to see whether the statement is taken out of context or whether it is reflective of a larger problem. The government does not have to stop with the information it requested. It can subpoena for other materials and create an extensive investigation.

*Conferences with Counsel*

Investigators will try to meet with counsel for the hospital or physician group to get a better flavor for the case. They will provide the client with the opportunity to talk about why it has not done anything wrong. The government will rebut that, and comes back and states why it thinks it was wrong. If you cannot convince the investigators after a few rounds of back and forth, you go to trial.

*Common Challenges for Lawyers and Clients in the Health Care Enforcement Process*

For hospitals, the biggest challenge is gathering the documents relevant to the issue. The hospital comprises thousands of people, and you may have somebody like an accounting clerk doing a routine task. That simple act may have a major effect on something else in another area of the hospital in terms of enforcement and liability, so often the challenge is making sure you get the complete story from your client’s staff members.

You should also ensure that the hospital adopts a consistent approach to compliance, as well as all your legal issues. For example, contracting is a
problem because many hospitals have multiple attorneys from different firms opining on a host of different issues. Large health care clients have a tendency to opinion-show, which can get you, and them, into problems very quickly. One firm thinks that the client can do something based on XYZ, while another believes that the client can and should do ABC.

One Voice, One Compliance Strategy

You have to develop a consistent approach, follow OIG work plans, and have a compliance officer who understands the legal hot spots. This enables the client (and counsel) to speak with one voice on the issue. If you have multiple views on one issue, the government will sit back and thank you for proving its case. Investigators believe that the hospital, like any other company, ought to be run on a consistent basis. However, if you have different divisions for doing different things that are not part of the same strategic plan, you create more issues.

Best Practices for Health Care Lawyers

Stay current on the law, but more important, the trends related to allegations and where the government is focusing its efforts. Health care laws change by the month, and if you think you have your hiring covered under Stark, but then find out that you have stepped on a landmine relative to PPCPA, it is worthwhile to understand how the laws interact.

It is also important to understand how the government approaches its civil and criminal enforcement actions. You should read the OIG opinions and trade journals, go to the seminars and hear the government officials talk about their enforcement initiatives, understand the primary areas of enforcement and how they relate to provider audits and False Claims Act issues and hospital physician relations.

State statutes also factor into enforcement. Most states have their own false claims legislation, and most have fraud control units. Even if your client settles a federal case, there may still be exposure under a state statute. For example, your client can be charged with submitting a false claim under federal law, but you can carry just as much liability on the state side.

Mitigating Federal Charges by Challenging Definitions

There are a number of areas in which you can try to mitigate cases that the government has filed. One is under the False Claims Act. You have to distinguish between what is called a condition of participation versus a condition of payment. Under a condition of participation, you may be able to get a false claims act dismissed. For example, if you have a whistleblower situation and the information has already been made public, you can get a case dismissed on that basis. On a charge of a false claim, you can challenge on the definition of false. If you have a relator, for example, from inside the hospital, you can claim that he has unclean hands himself. If there was a knowing violation of the statute, it can change a case. That is one of the big frontiers under liability; there have been cases within which relators have failed to allege that when a defendant signed an enrollment form, he knew it was a false claim. This presents opportunities to defend against these types of actions, such as Rule (9) (b) motions.

Time Is Money: Strategies for Saving Both

Hospitals are far deeper into compliance than they ever wanted to be. They are still in the health care business, but they have to devote so much time and resources to compliance that it erodes their margins. Hospitals are run on very thin operating margins, and they do not have much extra money to spend on compliance issues. When you consider a 2 percent to 3 percent operating margin, it does not leave much extra capital left over for scanning equipment and linear expanders and cotton balls. Medical supplies are expensive.

One hospital I know of spent millions on a settlement and ended up paying the lawyers to defend the case, as well. It was a huge cost for the hospital. The Tuomey case in South Carolina starts with a $49 million verdict, has interest piled on it, and will require payment of the fine and the accrued interest if the appeal fails.

Protecting Clients against Whistleblowers

The False Claims Act provides that once a qui tam action is filed, the relator and the defendant may not settle or voluntarily dismiss the action. 31 U.S.C.
§ 3730(b)(1). The statute does not, however, address whether a relator may release *qui tam* claims prior to the filing of a complaint. As a result, an ambiguity exists as to the enforceability of pre-filing releases of *qui tam* claims. Courts that have addressed the issue have reached different conclusions based on the contractual terms of the release, public policy considerations, and the specific facts and circumstances related to any pre-filing disclosure and/or investigation of the allegations.

In *US ex rel. Whitten v. Triad Hospital Inc.*, the Eleventh Circuit was confronted with the issue, but elected to decide the case solely on narrow contractual grounds. Ted Whitten worked for the Glynn Brunswick Memorial Hospital Authority in a number of positions, including compliance officer. Quorum Health Group Inc. provided the Authority with management services, including a CEO and a CFO, to manage the hospitals’ day-to-day operations. Whitten left his employment with the Authority shortly after the Authority terminated its relationship with Quorum and entered into a severance agreement, which released the Authority and its agents from “any and all claims.”

Whitten subsequently brought a *qui tam* action under the FCA against Triad Hospitals Inc., as Quorum’s successor, alleging that Quorum was responsible for presenting false claims to the federal government for payment under the Medicare, CHAMPUS, and Tricare programs. Quorum moved to dismiss, arguing among other things that the severance agreement Whitten entered into with the Authority barred his suit as a *qui tam* relator. The US District Court for the Southern District of Georgia granted Quorum’s motion to dismiss. In doing so, the court refused to set aside the release of Whitten’s right to serve as a relator in a *qui tam* action as against public policy. According to the court, the public policy interest of encouraging disclosure of allegations of fraud against the government is adequately served “by a rule that prohibits a litigant who has agreed to release his right to serve as a relator from maintaining a *qui tam* action if the government declines to intervene in the action.” Thus, the court found that an employee’s release of *qui tam* claims in a severance agreement would be enforceable and does not violate public policy, at least when the government declines to intervene in a *qui tam* action.

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In reaching this conclusion, the court declined to follow the Ninth Circuit’s ruling in *Green* (discussed below) that a relator’s pre-filing release of *qui tam* claims was unenforceable on public policy grounds. The court reasoned that the *Green* court “did not consider whether a relator who has signed a release ought to be able to maintain a *qui tam* action in cases where the government has declined to intervene.” The court further explained that enforcing *qui tam* releases when the government fails to intervene in a *qui tam* action “has the merit of encouraging those with relevant information to come forward, without unduly rewarding litigants that seek to renegotiate on their agreements ... When a court enforces a valid, uncoerced private agreement, without inordinately hampering the disclosure of harm to the public fisc, such a result is not in any measure inconsistent with public policy.”

On appeal, the Eleventh Circuit avoided the broader enforceability issue of *qui tam* releases and relied on contract law to determine whether the release in Whitten’s severance agreement prevented him from suing Quorum. The court found that the contract referred to Quorum as a separate entity that was not intended by the parties to be one of the releasees. The court reversed and remanded the case, concluding that the language of the severance agreement released only the Authority, not Quorum. The Eleventh Circuit thus left open the issue as to whether a pre-filing release of *qui tam* claims would be enforceable as a matter of public policy.

**Other Jurisdictions**

The Ninth Circuit has addressed the enforceability of pre-filing releases of *qui tam* claims on several occasions. Perhaps the most frequently cited case is *US ex rel. Green v. Northrop Corp.* Michael Green, under Northrop’s employment as a criminal investigator, exposed evidence that Northrop “double-charged” the US Air Force for equipment. Upon his termination, Green filed a wrongful discharge claim in state court alleging that he had been fired for raising issues about Northrop’s billing practices. To settle the case, Northrop paid Green $190,000 in exchange for Green’s agreement to “forever discharge Northrop ... from any and all claims.” Green, nonetheless, filed a *qui tam* action against Northrop in federal court nine months after signing the release.
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In considering the case, the court expressed concern that a pre-filing release of *qui tam* claims would undermine the fundamental purpose of the FCA’s *qui tam* provisions—to incentivize insiders to disclose fraud against the government. The Ninth Circuit adopted a balancing test to determine the enforceability of *qui tam* releases, analyzing whether the interest in “enforcement is outweighed in the circumstances by a public policy harmed by enforcement of the agreement.”

The court found that the significant public interest in deterrence and restitution of fraud against the government outweighed the interest of encouraging the settlement of litigation. The court reasoned that, if pre-filing releases of *qui tam* claims were permitted, the following would occur:

1. Employers would likely settle with whistleblowers for a lesser amount than they would pay as a result of successful *qui tam* claim.
2. A rational employee would be willing to settle for a lesser amount than total liability and keep 100 percent of the proceeds, rather than file a *qui tam* action, where the whistleblower’s maximum recovery is 30 percent.
3. The government, who is the wronged party, may never learn of the illegal act and would recover nothing.

The court therefore found that enforcing a pre-filing release of *qui tam* claims would “impair a substantial public policy,” and held that such releases, when entered into without the government’s knowledge or consent, cannot be enforced to bar a subsequent *qui tam* claim.

Two years later, the Ninth Circuit revisited the issue in *US ex rel. Hall v. Teledyne Wah Chang Albany* and created an exception to *Green*. This exception applies when the government has investigated and declined to intervene in an employee’s *qui tam* action prior to that employee’s execution of a *qui tam* release. Christopher Hall, an engineer involved in the manufacture of nuclear reactor components for Teledyne, alleged that Teledyne’s manufacturing process did not meet government specifications. When Hall reported this concern to Teledyne management, Teledyne investigated the issue and determined that his claims were unfounded. Teledyne nonetheless reported the claim to the Nuclear Regulatory Commission (NRC), as well as the results of its investigation. NRC then conducted its own investigation and determined that the nuclear reactor components met specifications.

Hall later executed a broadly worded general release when settling a number of employment-related claims against Teledyne. Months after signing the release, Hall filed a *qui tam* action, alleging again that Teledyne’s manufacturing process did not meet government specifications. The government investigated Hall’s claim, again concluding that the products met specifications, and declined to intervene in the *qui tam* action. In analyzing the enforceability of the *qui tam* release, the court noted “the concerns that led us to deny enforcement in *Green* are not present. The federal government was aware of Hall’s allegations regarding false certifications. Therefore, the public interest in having information brought forward that the government could not otherwise obtain is not impaired.” The court thus concluded that a *qui tam* release is enforceable if the defendant can prove that, prior to the execution of the release, the federal government (1) was notified of the relator’s allegations and (2) fully investigated the allegations.

Most courts considering the enforceability of *qui tam* releases executed prior to filing an FCA suit apply the analytical framework established by the Ninth Circuit in *Green* and *Hall*.

The Fourth Circuit recently recognized the enforceability of a *qui tam* release where the government had knowledge of the allegations prior to the execution of the release. In *US ex rel. Radcliffe v. Purdue Pharma*, the Department of Justice (DOJ) had already begun a criminal investigation of alleged unlawful marketing practices for OxyContin when Radcliffe, a former employee of Purdue Pharma, filed a *qui tam* action based on the same allegations. The DOJ reached a settlement in the criminal investigation and declined to intervene in Radcliffe’s *qui tam* action. The Fourth Circuit looked to the Ninth Circuit’s decision in *Hall* and adopted the Ninth Circuit’s balancing test to evaluate the public policy interest in *qui tam* actions. The court weighed the policy interest served by enforcing settlements against the public interest in pursuing fraud against the federal government. The court found that, where the government is aware of claims prior to the filing of a *qui tam* action, “public policies supporting the private settlement of suits heavily favor enforcement of a pre-filing release.”
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The court reasoned that enforcing pre-filing releases when the government is already aware of the allegations promotes a broader public interest of avoiding parasitic and opportunistic qui tam suits.

The DOJ also filed an amicus brief in Radcliffe, supporting the enforcement of the qui tam release. The DOJ also asserted that, when determining whether a qui tam release is enforceable, the proper focus of the government knowledge inquiry is whether the allegations of fraud were sufficiently exposed to the government prior to the filing of a qui tam action, not whether the government’s investigation was already completed (as Radcliffe argued based on Hall). The Fourth Circuit agreed with the DOJ’s position, thus concluding that a full investigation is not required prior to the filing of a qui tam action for a release to be enforceable. As a result, the Fourth Circuit’s conclusion concerning the enforceability of qui tam releases is broader than that of the Ninth Circuit.

In United States ex rel. Ritchie v. Lockheed Martin Corp., the Tenth Circuit concluded that qui tam releases are enforceable when allegations are disclosed to the government by the defendant prior to the relator signing a release of qui tam claims. Unlike in Hall, the public interest in supplementing federal enforcement was still present because the government had not concluded its investigation when the release of qui tam claims was signed. Nevertheless, that interest did not outweigh the interests served by enforcing the release, including disclosure of fraud allegations and encouraging settlements.

The Eighth Circuit has also weighed in on the issue. In United States ex rel. Gebert v. Transport Administrative Services, the court held that a pre-filing release of a qui tam claim is enforceable when the release is entered into during bankruptcy proceedings. The court found that the public policy concerns that the Ninth Circuit addressed in Green were not present here because the claim belonged to the bankruptcy estate, not the relators, and the proceeds of the release would flow to the estate, rather than to the relators.

In United States ex rel. Jimenez v. Health Net Inc., a federal district court in Colorado reached a conclusion as to the enforceability of qui tam releases on contractual grounds. The court held that when an employee signs a release stating that he or she has not filed an FCA claim, and that statement is false, the release may be upheld, since the employee breached the terms of the agreement. The court concluded that relators cannot accept severance pay, execute releases from filing future claims, and then seek recovery under the FCA, without at least returning the severance pay.

Summary of when qui tam releases are enforceable:

- **Fourth Circuit (Radcliffe):** Prior to filing of qui tam action, sufficient disclosure of the allegations is provided to the government. A full investigation of the allegations by the government is not required, however, for a pre-filing release to be enforceable.
- **Eighth Circuit (Gebert):** The release is entered into during bankruptcy proceedings, such that the qui tam claim belongs to the bankruptcy estate, not the relators.
- **Ninth Circuit (Hall):** Prior to execution of release, the government is notified of allegations and fully investigates allegations.
- **Tenth Circuit (Ritchie):** The defendant discloses the allegations to the government prior to the relator signing a release of qui tam claims.
- **Eleventh Circuit:** Unclear, but see Whitten at district court level (holding that release is enforceable if government declines to intervene in qui tam action).
- **Colorado (Jimenez):** The employee signs a release stating that he or she has not filed an FCA claim and that statement is false, resulting in a breach of contract.

Additional Protection for the Employer

The climate for qui tam releases is uncertain; there is no guarantee that a release for future qui tam claims is, in fact, final. An employer can, however, take additional precautions, such as including a representation and warranty section in a release agreement, to protect against a qui tam action. A representation and warranty section should require the employee to:

- Confirm under oath that he has not commenced a qui tam action;
- Affirmatively disclose any and all known compliance issues with specificity;
If any issue exists, describe how he has firsthand knowledge of the issue; 
Identify to whom the issue was reported; and 
Indicate why he feels these claims have not been cured.

Another option is to ask an employee to release a claim to monetary compensation—either directly or indirectly—from a qui tam suit, rather than releasing the employer from the claim itself. This release would relieve the employer of some financial exposure should the employee later file a qui tam action in which the government decides to intervene.

The Big Five: Compliance Issues Most Likely to “Trip Up” a Client

A large number of compliance issues can arise from complex legislation, but a handful vexes most health care clients, regardless of their size or location. These are:

1. **Billing practices:** There are significant risk areas, such as billing for services that were not rendered or billing for medically unnecessary services. Your client can be charged with upcoding or filing false cost reports, duplicate billings, and failure to refund credit balances.

2. **Medical decision-making:** Admitting patients from the emergency department to get the extra revenue from classifying the patient as inpatient gets into some nuanced issues about medical decision-making. Often this relates to how much revenue is derived from decision A versus decision B—for example, an OB/GYN getting paid more to do a Caesarian section (C-section) than a standard delivery. While OB/GYNs would opt to do more C-sections, hospitals have to track and monitor that activity to ensure that it is medically necessary. The doctors will argue that there are fewer complications, but others will argue that they are doing it only to make more money. It is a gray area.

3. **Durable medical equipment:** This issue goes beyond hospitals and physicians and gets into discounts and free items, equipment and space rental practices, and marketing practices.

4. **Professional courtesy:** Doctors used to waive a co-payment or a charge when they would treat another physician. That is gone. Today, the provider has to charge for all services—even an ambulance.

5. **Quality of care:** This is a provision in the new PPCPA. In accountable care organizations, the government wants to reward the efficient provision of care. For example, when a patient is admitted, the hospital is paid for that patient regardless of whether she stays there for three weeks or three days. The hospital will want the person out sooner rather than later. Not long ago, if the patient stayed longer, the government paid more. Today, the longer patients stay, the more costly it is, so the government has capped what they will pay for certain things. That has spawned average length of stay, which is a statistic that hospitals track carefully. They do this to understand how many employees it takes to staff a bed. The government is getting into these measures because they want not only affordable care, but efficient and quality care, as well.

The Government Defines Quality Care: A Quandary for Providers

That the government came out with a fact sheet titled “Improving Quality of Care for Medicare Patients, Accountable Care Organizations” is an indication that it is looking at this topic as the next big wave of providing quality, affordable care. That is the origin of the name Affordable Care Act, but what is interesting is that it was one of the first times the government has ever issued a directive not only from Medicare and Medicaid, but also from the Department of Health and Human Services and the Federal Trade Commission.

As a result, the affordable care organizations (ACOs) are now concerned about anti-trust issues. The FTC came out with its own anti-trust enforcement policy relating specifically to ACOs, which is the first in more than fifteen years. The ACOs are telling hospitals and doctors that they need to work together to provide affordable health care. That raises anti-trust issues, so the FTC issues a policy statement that determines when it is lawful for this kind of collaboration to occur.

These are all considered major regulatory guidance for the government, and it will continue to be involved with quality measures. The regulation of health care and telling doctors what they can and cannot do strikes some people as right and others as wrong. The government’s position is simple: if we pay for it, then we will have a say in the way it is delivered.
Developing a Sustainable Compliance Program for Clients

The compliance program must address the challenges that were described earlier in the chapter. At a minimum, you must ensure that the client has a compliance officer to oversee the in-house compliance efforts. A compliance committee, typically a committee of the board, can provide regular review of the program. Auditing and billing are critically important, and there has to be a confidential disclosure program and hotline that makes it possible to call the compliance officer and report that there is a problem. The compliance officer will deal with a set of issues common to most providers: anti-kickback statute, billings, claims, auditing and cost reporting, credit balances, and medical necessity issues. The client has to ensure that contractors are compliant. That may require screening. Employees must be vetted, as well.

The Importance of the Self-Disclosure Protocol

The government truly wants the client to do its own policing, and the client must determine when it is appropriate to report to the government. This requires continuous training and education on billing practices, contracts, cost reporting, and more. The goal is to foster a culture of compliance so that it becomes part of the DNA of the organization.

If the government believes the client is in violation and holds it accountable, it will require the client to enter into either a corporate integrity agreement or a certification of compliance agreement. The former is a bit more onerous, the latter less so. Either requires the client to take all of the steps described earlier to have a fully functional compliance system in place. If people know about the program, and if the program has discipline and people who are informed and trained, then at the earliest sign of a problem, staff members will know to report to the compliance officer. A small problem can remain that way, instead of becoming something the government pursues.

The government wants to see annual reviews (at a minimum). For example, a statistical analysis sample of claims helps assess that billings are reasonable and in order. Independent audits and internal controls will cause red flags to go up earlier rather than later.

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When Compliance Programs Fail

Compliance programs fail for a variety of reasons, but the most common is that the plan is either not comprehensive enough or emphasizes form over function. The plan has to be a living, breathing document. It has to work well and has to be managed by someone who owns the process. If it is sitting on a shelf and never enforced, then the client will be guilty by association. A compliance officer who is caught in the weeds can also cause a problem. This individual focuses on relatively minor issues. Chasing rabbits, such as a minor HIPAA issue, is a distraction that prevents the organization from focusing on issues that expose it to liability.

Patient liability is also a common downfall for compliance programs. For example, if the client is careless with records and discloses that an individual was tested for AIDS, it can have a far-reaching impact on that individual—even if the test results are negative. This is one of the areas within which the client must be scrupulous about record-keeping and about adhering to the compliance program.

Conclusion

Health care enforcement will increase and continue to evolve. There is no slowdown in government enforcement efforts. PPCPA is a paradigm shift for hospital/physician relationships, and it represents what health care will look like going forward. As more people are eligible for government-funded health care, it shortens the timeframe within which you can predict with certainty the future of health care.

For example, in the middle of the 1990s, all the prognosticators said that health care would shift to outpatient, and hospitals would close because they did not need the beds. The opposite happened. There has been a big shift to outpatient care, but inpatient care is still very strong because people still get sick regardless of what laws are passed or how the regulatory and enforcement environments unfold. People will get cancer regardless of whether the PPCPA is enacted and will need the care for it.

I am not suggesting that those prognostications were disingenuous, but simply that it was an educated guess. The advancement in medical technology
enables delivery of care in a more efficient manner, but it has also caused a proliferation in surgery centers, within which you can have a knee replacement without spending a month in the hospital. It used to be that childbirth came along with a two-week stay in the hospital. Today, baby and mom are discharged forty-eight hours from birth.

The Impact of Prescription Drugs

One class of drug—the statins—has had the biggest impact on health care. Drugs such as Zocor and Lipitor clean the plaque out of people’s arteries. Before these drugs were invented, people were having open-heart surgery to clean out the vessels. That procedure has been cut in half because the need for arterial bypasses is diminished. The drug essentially does for arteries what Drano does for clogged sinks.

Twenty years ago, a cardiothoracic surgeon made $800,000 a year. Today, a client can probably pick one up for $250,000. Another good example of how technology has changed medicine is laparoscopic surgery. The need for massive incisions, which would cause infections and require a longer recovery time, is gone.

Advice for Compliance Practitioners

Stay on top of the law, and do a tremendous amount of reading. Lawyers have to be practical in their advice. Lawyers and compliance officers often forget that the hospital has to operate and save lives. A hospital can focus so much on compliance that it puts itself out of business.

Know the risk areas, and get the government to weigh in on an advisory opinion. Maintain a sense of practicality that strikes a balance between being compliant and being able to survive on a razor-thin margin. I do not think that the government wants to put hospitals out of business, but the regulations have made their operation quite challenging. Whether a hospital is dealing with a patient care issue or a medical issue, boards and hospitals are in a gray area when they are deciding the right thing to do.

This is not a practice area in which one should dabble. Either you know it or you do not.

Key Takeaways

- Counsel your clients to get an advisory opinion from the government. The client can vet the proposed arrangement with government investigators and be in a better position to live with the consequences. The advisory opinion also imbues the arrangement—and the client—with immunity.
- Review all contractual arrangements that a client makes with a provider. If everything is documented, reviewed, and approved, it will increase the likelihood that the arrangement is reasonable and reflects fair market value.
- Discourage your client from “opinion shopping.” This can expose the client to contradictory advice, but it also encourages the client to be inconsistent in its approach to compliance and all legal matters.
- Ensure that your client gets a waiver of claims from every exiting employee who receives a severance package. This will prevent the employee from filing a false claims complaint after termination. The courts are allowing this in agreements.
- Help your client create a culture of compliance that becomes part of the “DNA” of the organization. The government does not want to put hospitals out of business and prefers that they self-polic and self-report. Training and education for employees on a continuous basis are mandatory for this level of compliance.

T. Mills Fleming, a partner with Hunter, Maclean, Exley & Dunn PC, chairs the firm’s Health Care Practice Group. Past president of the Georgia Academy of Health Care Attorneys, he is a member of the American Health Lawyers Association. His practice concentrates on the general representation of health care systems, specialized regulatory support to health care entities, and specialized projects involving compliance planning, qui tam/FCA investigations, health care industry restructuring, tax-exempt entities and intermediate sanctions, reimbursement, fraud and abuse, managed care, and health care policy. He also assists clients with compliance self-assessments and remedial actions, Stark Law compliance assessments, and the development of multi-provider joint ventures.
Mr. Fleming is included in the most recent editions of The Best Lawyers in America. He writes and speaks frequently on health care law issues and is co-editor of the Georgia Hospital Association's Hospital Law Manual, 5th ed. (2006). He wrote an article on the final HIPAA privacy rules for the American Bar Association's American Law Institute and has presented on the Sarbanes-Oxley Act at the Georgia Academy of Health Care Attorneys' Annual Meeting.

Mr. Fleming's practice also focuses on immigration and nationality law. His practice includes extensive visa work, handling both temporary and permanent visa cases and J-1 waivers, as well as advice regarding compliance with the I-9, discrimination, and document abuse provisions of the Immigration Reform and Control Act of 1986. He is a member of the American Bar Association-affiliated American Immigration Lawyers Association. A frequent lecturer and presenter on immigration topics, he advises employers regarding best practices on employment-related issues.

Mr. Fleming earned a BA and a JD from the University of Florida. He began his legal career at HunterMaclean, served for three years as general counsel with a large hospital system, and returned to HunterMaclean in 1995. He is admitted to practice in the US District Court for the Southern District of Georgia and the State of Georgia.