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THE FALSE CLAIMS ACT APPLIED TO HEALTH CARE INSTITUTIONS: GEARING UP FOR CORPORATE COMPLIANCE

*Adam G. Snyder**

INTRODUCTION

On December 12, 1995, the Clinical Practices of the University of Pennsylvania (CPUP) entered into a settlement agreement with the United States whereby CPUP agreed to pay a total fine in excess of \$30 million.² The agreement represented a settlement of various claims and allegations under the Civil False Claims Act,³ and other acts, including the Program Fraud Civil Remedies Act⁴ and the Civil Monetary Penalties Law.⁵ One-third of the \$30 million fine will go to "restore" the Medicare Trust Fund. As the dust settles from the CPUP experience, physicians, hospital administrators, and health lawyers are moving forward with an eye toward formal compliance with the various fraud laws.

In 1994, Medicare expenditures reached \$162 billion and are expected to climb as high as \$259 billion by 1998.⁶ Estimates of the General Accounting Office (GAO) indicate that as much as 10 percent of all Government expenditures are being siphoned out of the system due to fraudulent and abusive practices.⁷ Ever since the Attorney General named health care fraud as the second highest priority after violent crime, the

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² SETTLEMENT AGREEMENT, December 12, 1995, p.1.

³ 1 U.S.C. § 3729, *et. seq.* (1995)

⁴ 31 U.S.C. § 3801, *et. seq.*(1995)

⁵ 42 U.S.C. § 1320a-7a. (1995)

⁶ John C. West, *The False Claims Act: Potential Liability for Health Care Providers for Fraud and Abuse and Beyond*, 28 J. HEALTH & HOSP. LAW 15 (1995) (citing Roger C. Henderson, *The Tort of Bad Faith in First Party Insurance Transactions: Refining the Standard of Culpability and Reformulating the Remedies by Statute*, 26 U. MICH. L. REV. 1, 19-20 (1992)).

⁷ *Id.* (citing GAO, *Health Insurance: Vulnerable Payers Lose Billions to Fraud and Abuse*, at 1).

Department of Justice (DOJ) has recovered fines in excess of \$600 million.⁸

Given the Government's stated position, its view on health care fraud, and its success in obtaining settlements, it naturally follows that the number of investigations by the Office of Inspector General (OIG) and the number of prosecutions by the DOJ will continue to increase.⁹ A flurry of new investigations and settlement demands are expected, despite OIG announcements that budget constraints are restricting audit and investigative activities.¹⁰ If actual physical investigations do become limited due to funding, it can be expected that investigations will still be pursued through utilization of computer auditing software.

Astute health care providers with the proper foresight may find shelter from the current regulatory enforcement storm by developing "effective corporate compliance programs."¹¹ Generally, an effective compliance program can detect internal criminal activity, serve as a mitigating factor to a corporate criminal sentence, and, perhaps most importantly, can influence a U.S. Attorney to decide against indicting the corporation.¹²

Implementing a compliance program provides protection to a health care enterprise. In the face of potential prosecution, an effective compliance plan can serve as a "deterrent" to prosecution, and an "incentive" to prosecutors to search for a less compliant organization.

This article will focus on recent developments in the law and in the Government's enforcement efforts that serve as motivators for developing and implementing an "effective corporate compliance program."¹³ Prior to discussing the advantages and disadvantages of implementing a

⁸ See *Id.* (citing BNA, *Justice Announces \$411 Million Recovered in Medical Fraud Probes*, BNA Washington Insider, October 12, 1994).

⁹ Lisa M. Rocelli, *Billing Fraud, Reimbursement Among Top Medicare Legal Issues in 1996*, 5 BNA HEALTH L. REP. at 151 (Feb. 1, 1996).

¹⁰ BNA, *IG Brown Outlines Effects of Budget Problems on Audits, Investigations*, 5 BNA HEALTH L. REP. at 151 (Feb. 1, 1996).

¹¹ BNA, *Advantages of Corporate Compliance Plan in "Age of Fraud" are Touted*, 4 BNA HEALTH L. REP. 42 (Apr. 6, 1996).

¹² Dan K. Webb and Steven F. Molo, *Some Practical Considerations in Developing Effective Compliance Programs: A Framework for Meeting the Requirements of the Sentencing Guidelines*, 71 WASH. U. L. Q. 375, 376 (1993).

¹³ United States Sentencing Commission, GUIDELINES MANUAL § 8A1.2 (Comment, note 3(k)) (1995) (hereinafter "U.S.S.G.").

compliance program, an analysis of current law will be provided. The analysis will focus on recent cases and settlements, between the Federal Government and various institutions, in an effort to illuminate the hazardous nature of the regulatory environment in which hospitals and other health care providers operate.

Next, this article will discuss the development and implementation of health care institutions' compliance plans. This article will attempt to offer insight into ongoing investigations; and the article will consider Intermediary Letter 372, its relevance to compliance programs specifically, and the effect of the recent teaching physician "clarification" regulations that became effective July 1, 1996.¹⁴ The concluding sections serve as a general model for compliance that the DOJ should use to issue a formal policy statement regarding compliance. If a health care institution agrees to take specific steps toward compliance the provider should be free from prosecution absent deliberate attempts to defraud the Government.

CORPORATE LIABILITY AND RELEVANT ENFORCEMENT STATUTES

The first step in developing an effective compliance program is to identify the specific laws and regulations that require compliance and to analyze the scope of potential liability thereunder. These laws and regulations provide a benchmark for assessing a health care institution's current level of corporate compliance.

Corporate criminal liability is a relatively recent development in the United States, largely because corporations were traditionally viewed as entities lacking the ability to entertain a requisite criminal intent.¹⁵ Liability has now been extended to corporations in the civil context under the doctrine of *respondeat superior*. In such a situation, the corporation is liable for the actions of its employees or agents when their conduct is carried out within the scope of employment, or with proper authority and

¹⁴ See 60 Fed. Reg. 63, 135 (Dec. 8, 1995).

¹⁵ Jed S. Rakoff, et al., CORPORATE SENTENCING GUIDELINES: COMPLIANCE AND MATERIAL LITIGATION § 1.02[1] at 1-5 (1995); Leonard Orland, *Reflections on Corporate Crime: Law in Search of Theory and Scholarship*, 17 AM. CRIM. REV. 501, 502 (1980).

for the intended benefit of the corporation.¹⁶

The United States Supreme Court extended the doctrine of *respondeat superior* to the criminal context in *New York Central & Hudson River Railroad v. United States*.¹⁷ As a result, a corporation today may be held criminally liable for the actions of its employees or agents even if the activity undertaken is in complete violation of company policy.¹⁸ The resulting general rule is that a corporation is criminally liable for the criminal actions of its employees or agents if either acted within the scope of their authority with the intent to benefit the corporation.¹⁹

Even if one employee lacks the requisite criminal intent for a specific charge, collective knowledge of several employees may be bundled and imputed to the corporation. Courts analyzing the issue have indicated that the aggregate of several employees' knowledge constitutes knowledge of the corporation as a whole.²⁰

¹⁶ *Id.* (citing Prosser and Keeton, TORTS § 70 (5th ed. 1984)). See *Developments in the Law -- Corporate Crime: Regulating Corporate Behavior Through Criminal Sanctions*, 92 HARV. L. REV. 1227, 1247 (1979).

¹⁷ *New York Cent. & Hudson River R.R. v. United States*, 212 U.S. 481 (1909).

¹⁸ See, e.g., *United States v. Basic Constr. Co.*, 711 F.2d 570, 573 (4th Cir. 1983) (holding a corporation liable for antitrust violations based on employee activities that were in direct conflict with company policy), *cert. denied*, 464 U.S. 956 (1983); *United States v. Hilton Hotel Corp.*, 467 F.2d 1000 (9th Cir. 1972) (holding the corporation criminally liable for the actions of a low-level employee despite the fact that the employee's conduct was generally and specifically prohibited by the United corporation), *cert. denied*, 409 U.S. 1125 (1973).

¹⁹ Charles J. Walsh and Alissa Pyrich, *Corporate Compliance Programs as a Defense to Criminal Liability: Can a Corporation Save Its Soul?*, 47 RUTGERS L. REV. 605, 607 (Winter 1995) (citing Samuel R. Miller, *Corporate Criminal Liability: A Principle Extended to Its Limits*, 38 FED. B.J. 49, 42 (1979); Samuel R. Miller & Lawrence C. Levine, *Recent Developments in Corporate Criminal Liability*, 24 SANTA CLARA L. REV. 41, 42 (1984); Harvey L. Pitt & Karl A. Groskaufmanis, *Minimizing Corporate Civil and Criminal Liability: A Second Look at Corporate Codes of Conduct*, 78 GEO. L.J. 1559, 1571 (1990); Michael E. Tigar, *It Does the Crime But Not the Time: Corporate Criminal Liability in Federal Law*, 17 AM. J. CRIM. L. 211, 214-220 (1990); Steven Walt & William Laufer, *Why Personhood Doesn't Matter: Corporate Criminal Liability and Sanctions*, 18 AM. J. CRIM. L. 263, 266 (1991); *Developments in the Law -- Corporate Crime: Regulating Corporate Behavior Through Criminal Sanctions*, 92 HARV. L. REV. 1227, 1247 (1979).

²⁰ *United States v. Bank of New England*, 821 F.2d 844, 856 (1st Cir. 1987) (quoting *United States v. T.I.M.E. - D.C., Inc.*, 381 F. Supp. 738 (1974) *cert. denied*, 484 U.S. 943 (1987) (holding that a corporation cannot plead innocence by asserting that the information obtained by several employees was not acquired by any one individual who then would have comprehended its full import. Rather, the corporation is considered to have acquired the collective knowledge of its employees and is held responsible for their failure to act accordingly)).

An effective corporate compliance program helps detect criminal violations before they occur and serves as a mitigating factor for sentencing. Some legal scholars and practitioners argue that an effective corporate compliance program should also serve as an actual defense to corporate criminal liability.²¹ However, as the law currently stands, a corporation remains generally criminally liable for the actions of its employees.

Enforcement of Medicare Prohibitions and Related Statutes

The statutory Medicare prohibitions focus on false claim submission and the manner in which referrals are generated prior to claim submission.²² Actions may arise in either a criminal or a civil context. Penalties for violations of the statute may trigger several distinct remedies in varying degrees depending on the nature and scope of the violation. Generally, penalties may include mandatory program exclusion,²³ permissive program exclusion,²⁴ fines,²⁵ and imprisonment.²⁶ In the civil context, fines are typically assessed at \$2,000 per claim submitted, in addition to an assessment that is not more than twice the amount claimed.²⁷ Criminal convictions may be punishable by up to five years imprisonment and fines of up to \$25,000.²⁸

In addition to false claims and referral generation prohibitions, other health care related offenses may trigger the penalties listed above. Specific violations may include false statements or representations with respect to the condition or operation of an institution,²⁹ illegal patient admittance and

²¹ Walsh & Pyrich, *supra* note 18, at 607.

²² 42 U.S.C. § 1320a-7, *et. seq.* (1995).

²³ 42 U.S.C. § 1320a-7(a)(1995).

²⁴ 42 U.S.C. § 1320a-7(b)(1995).

²⁵ 42 U.S.C. § 1320a-7b(a), *et. seq.* (1995).

²⁶ *Id.*

²⁷ 42 U.S.C. § 1320a-7a(a)(1995).

²⁸ 42 U.S.C. § 1320a-7b(1995).

²⁹ 42 U.S.C. § 1320a-7b(c)(1995).

retention practices,³⁰ and violations of assignment terms.³¹

The Medicare prohibitions proscribe several modes of conduct and provide a number of avenues for corporate prosecution. However, health care providers should be aware that there are other general federal statutes capable of providing a basis for prosecution.³² While the federal prosecutor is heavily armed with an arsenal of statutory weapons, the deadliest and most efficient health care fraud fighter that has evolved is the Civil False Claims Act.³³

Enforcement Under The Civil False Claims Act

Originally aimed at Civil War defense contractors, the Civil False Claims Act was enacted in 1863 to cleanse the defense industry of fraudulent practices.³⁴ The general purpose of the Act, then and today, is to "discourage fraud against the Government[.]"³⁵ In recent years, the False Claims Act has been extended beyond the realm of defense contracts to other areas including the health care industry.³⁶

Health care institutions came within the coverage of the False Claims

³⁰ 42 U.S.C. § 1320a-7b(d)(1995).

³¹ 42 U.S.C. § 1320a-7b(e)(1995).

³² Nancy Luque, *Sentencing Guidelines*, HEALTH CARE FRAUD 1994 § G (American Bar Association 1994) (Conspiracy to Defraud the Government with Respect to Claim, 18 U.S.C. § 286; Fictitious or Fraudulent Claims, 18 U.S.C. § 287; Conspiracy to Commit Offense or Defraud United States, 18 U.S.C. § 371; False Statements, 18 U.S.C. § 1001; Mail Fraud, 18 U.S.C. § 1341; Wire Fraud, 18 U.S.C. § 1343; Obstruction of Justice, 18 U.S.C. § 1501; Money Laundering, 18 U.S.C. § 1956-1957; Racketeer Influenced Corrupt Organizations (RICO), 18 U.S.C. § 1962; Forged or Counterfeited Contracts or Documents, 18 U.S.C. § 494-495; and the Program Fraud Civil Remedies Act, 31 U.S.C. § 3801 *et. seq.*

³³ 31 U.S.C. §§ 3729-3733 (1995).

³⁴ Howard M. Pearl, et al., *The False Claims Act and the Medicare-Medicaid Anti-Kickback Statute: An Imperfect Match*, HEALTH CARE FRAUD 1995 § B-29 (American Bar Association) (citing *Rainwater v. United States*, 356 U.S. 590, 592 (1958); John R. Philips, *Qui Tam Litigation*, 14 J. LEGAL MED. 267, 268 n.2 (June 1993); Act of March 2, 1861, 37th Cong., Sess. III, ch. 67, at 696-699).

³⁵ *Robertson v. Bell Helicopter Textron, Inc.*, 32 F.3d 948, 951 (5th Cir. 1994), *cert. denied*, 115 S.Ct. 1110 (1995).

³⁶ Mathew P. Harrington, *Health Care Crimes: Avoiding Overenforcement*, 26 RUTGERS L. J. 111, 122 n. 74 (citing *United States v. Kensington Hospital*, 760 F. Supp. 1120 (E.D. Pa. 1991)).

Act in the wake of allegations that providers “knowingly” submitted “false or fraudulent claim[s] for payment” to the government or that one “knowingly” manufactured a “false record” for the purpose of submitting a claim.³⁷

In 1986, Congress effectively expanded the application of the False Claims Act by increasing the potential civil penalties and by clarifying the definition of “knowingly.”³⁸ Specifically, the statute defines “knowingly” as having actual knowledge of the information, or as acting in deliberate ignorance or reckless disregard as to the truth or falsity of the information.³⁹ Furthermore, in making its case, the Government need not prove or offer evidence of specific intent to defraud.⁴⁰

In the absence of a specific intent requirement, the plaintiff need only show that a defendant acted with “deliberate ignorance” or in “reckless disregard” of the truth.⁴¹ It, therefore, follows that negligence and innocent mistake constitute defenses under the False Claims Act.⁴² As a result of the 1986 amendments, the intent standard was lowered to preclude “ostrich” like behavior where an individual fails to make any inquiry that would reveal the false claim.⁴³

Damages sought under the False Claims Act are indeed serious, including treble damages, mandatory fines of \$5,000 to \$10,000 per claim, and the costs sustained by the Government in bringing the action.⁴⁴ Despite the potential to obtain prohibitively high levels of recovery, the Government need not prove actual damages as a prerequisite to securing

³⁷ 31 U.S.C. § 3279 (a)(1)-(2) (1995).

³⁸ BNA, *Liberalization of False Claims Act Standards, Burden of Proof Being Sought*, 5 BNA HEALTH L. REP. 270 (Feb. 22, 1996) (stating that a defense contracting group is currently seeking a revision of the False Claims Act that would require the plaintiff to prove “actual knowledge” of the falsity of the information).

³⁹ 31 U.S.C. § 3729 (b)(1)-(3)(1995); *United States v. Oakwood Downriver Medical Ctr.*, 687 F. Supp. 302, 305-306 (E.D. Mich. 1988).

⁴⁰ 31 U.S.C. § 3729(b)(1995).

⁴¹ *United States, ex rel. Hagood v. Sonoma County Water Agency*, 929 F.2d 1416, 1421 (9th Cir. 1991).

⁴² *Id.*

⁴³ *United States v. Entin*, 750 F. Supp. 512, 518 (S.D. Fla. 1990) (citing *False Claims Reform Act of 1985*, S. Rep. No. 345, 99th Cong., 2nd Sess., reprinted in 1986 U.S. Code Cong. & Admin. News 5266).

⁴⁴ 31 U.S.C. § 3279(a)(1995).

the per claim recovery.⁴⁵ Under a limited set of circumstances, the court may reduce the penalties to double the damages sustained by the Government.⁴⁶ The court may exercise this limited discretion when full disclosure of all known information is made within thirty days after the defendant obtains the information; full cooperation is rendered to the Government's investigation; and at the time the defendant furnished the information, no action had commenced under the False Claims Act and the defendant had no actual knowledge of the existence of a Government investigation of such violation.⁴⁷

Government Application of The False Claims Act

As described above, application of the False Claims Act to the health care industry can be devastating in terms of penalties and fines. The Justice Department collected \$411 million from health care related civil litigation in 1994, as compared to \$180 million in recovery in 1993.⁴⁸ One case that is often discussed as a classic False Claims action is *United States v. Lorenzo*.⁴⁹ In this case, the Government levied several False Claims allegations against Dr. Lorenzo, a dentist licensed to practice in Pennsylvania and New Jersey.⁵⁰ The allegations centered on the billing practices of Dr. Lorenzo's company, U.S. Mobile Dental Care Systems, Inc., a Pennsylvania corporation formed for the purpose of supplying dental services to nursing home residents.⁵¹

Among the services supplied by Dr. Lorenzo and U.S. Mobile were routine dental exams, which originally included an oral cavity screening for head and neck cancer.⁵² In 1986, U.S. Mobile began to bill Medicare for

⁴⁵ West, *supra* note 5, at 16 (citing *Rex Trailer Co. v. United States*, 350 U.S. 148 (1956); *United States ex rel. Marcus v. Hess*, 317 U.S. 537 (1943); *United States v. Kensington Hosp.*, 760 F. Supp. 1120 (E.D. Pa. 1991); *See also United States ex rel. Hagood v. Sonoma County Water Agency*, 929 F.2d 1416, 1421 (stating that "no damages need be shown in order to recover the penalty.").

⁴⁶ 31 U.S.C. § 3729(a)(1995).

⁴⁷ *Id.*

⁴⁸ Michael M. Mustokoff, *Erroneous Hospital Bills Not Always False Claims; Expect Even More Prosecutions From Justice Department in 1996*, LEGAL INTELLIGENCER, Oct. 18, 1995, at 9.

⁴⁹ *United States v. Lorenzo*, 768 F. Supp. 1127 (E.D. Pa. 1991).

⁵⁰ *Id.* at 1129.

⁵¹ *Id.*

⁵² *Id.*

the cancer screening as a “limited consultation,” separate and distinct from the routine dental exam.⁵³ The Government contended that dentists may not bill Medicare for oral cancer examinations, unless the patient's treating physician makes a referral for that specific purpose.⁵⁴ Dental services are not compensable under Medicare generally unless they are provided in the course of inpatient hospital treatment under Part A of Medicare.⁵⁵

The court in *Lorenzo* determined that the defendant physician had “knowingly” filed 3,683 “false claims” with the Government amounting to \$130,719.10 in actual damages.⁵⁶ As provided in the False Claims Act, the court assessed damages at three times the Government’s actual loss and ordered that the statutory minimum penalty of \$5,000 per false claim filed be assessed. The court ultimately held Dr. Lorenzo responsible for \$18,807,157.30 in fines and penalties;⁵⁷ however, it would have been well within the court's discretion to impose fines and penalties against Dr. Lorenzo in excess of \$37 million, even though the actual damages to the Government amounted to \$130,000.⁵⁸

The case of *United States v. Krizek*⁵⁹ also demonstrates the seemingly disproportionate calculation of penalties relative to the actual damages suffered by the Government.⁶⁰ In *Krizek*, the Government brought an action under the False Claims Act⁶¹ alleging the defendants had falsely billed for Medicare and Medicaid patients.⁶² The general nature of the Government’s allegation was that the defendant physician had “up-coded” patient billings by submitting bills for a higher level of reimbursement than was warranted for the actual level of care rendered.⁶³ The Government also alleged, although it was unable to prove, that Dr. Krizek had

⁵³ *Id.*

⁵⁴ *United States v. Lorenzo*, 768 F. Supp. 1127, 1130 (E.D. Pa. 1991).

⁵⁵ 42 U.S.C. §§ 1395(c) *et. seq.* (1995).

⁵⁶ *Lorenzo*, 768 F. Supp. At 1133.

⁵⁷ *Id.*

⁵⁸ *See* 31 U.S.C. § 3729(a) (1995) stating that the court could have imposed the \$37 Million penalty if it had assessed a penalty of \$10,000 per false claim.

⁵⁹ *United States v. Krizek*, 859 F. Supp. 5 (D.C. 1994).

⁶⁰ *West, supra* note 5, at 17.

⁶¹ 31 U.S.C. §§ 3729-3731 (1994).

⁶² *Krizek*, 859 F. Supp. at 7.

⁶³ *Id.*

submitted bills for services that were not medically necessary.⁶⁴

With respect to the “up-coding” allegations, the Government contended that Dr. Krizek inappropriately used a billing code for 45-50 minute psychotherapy sessions (CPT Code 90844).⁶⁵ Specifically, the Government argued that 24 percent of bills submitted by Dr. Krizek, included the CPT code for a forty-five to fifty minute session when he should have billed for a twenty to thirty minute session. With respect to at least 33 percent of Dr. Krizek’s bill submissions, the Government alleged that Dr. Krizek used the forty to fifty minute session CPT code when he should have billed for a “minimal psychotherapy” session.⁶⁶

Pursuant to its allegations, the Government asked the court to make a finding that Dr. Krizek had submitted 8,002 false claims and assess fines in excess of \$80,750,000.⁶⁷ The court declined to make such a finding, but did recognize that Dr. Krizek had submitted bills on several days where total billings for a single day exceeded twenty hours.⁶⁸ “While Dr. Krizek may have been a tireless worker, it [was] difficult for the court to comprehend how he could have spent more than even ten hours in a single day serving patients.”⁶⁹ Accordingly, the court held the defendant liable under the False Claims Act on days where Dr. Krizek's claims in a single day exceeded the equivalent of nine hours of patient care.⁷⁰

The two cases described above focus on the billing practices of individual physicians. As indicated previously, an institution may be liable for the illegal or fraudulent conduct of its employees. Indeed, the largest amount ever recovered in a health care fraud case settlement involved National Medical Enterprises, Inc. (NME) with a \$379 million price tag.⁷¹ In terms of its civil settlement with the United States Government, NME agreed to pay \$324.2 million in damages for losses it caused to Medicare, Medicaid, the Federal Employee Health Benefit Program, and the Civilian

⁶⁴ United States v. Krizek, 859 F. Supp. 5, 7-8 (D.C. 1994).

⁶⁵ *Id.*

⁶⁶ *Id.*

⁶⁷ *Id.* at 11.

⁶⁸ *Id.* at 12.

⁶⁹ United States v Krizek, 859 F. Supp. 5, 12 (D.C. 1994).

⁷⁰ *Id.*

⁷¹ BNA, *NME to Pay \$379 Million in Penalties Under Settlement with Federal Agencies*, 3 BNA HEALTH L. REP. 917 (July 7, 1994).

Health and Medical Program of the Uniformed Services.⁷² NME also agreed to pay \$16.3 million to various states for Medicaid fraud, \$2.5 to \$5 million to the Public Health Service's Agency for health care policy and research, \$2 million to support a children's mental health program, and \$2.5 million to the National Institute of Mental Health.⁷³ The criminal penalties included fines totaling \$36 million and a seven and one-half year prison sentence for the institution's chief executive officer.⁷⁴ In addition, NME agreed to implement a corporate compliance/integrity program.⁷⁵

With Medicare prohibition rules, the False Claims Act, and other statutes available, the federal prosecutor in false claims cases is armed with what appears to be an arsenal of fraud deterrents. This regulatory gauntlet within which health care providers "operate" is a source of frustration and concern for health care providers and their advocates. One commentator has suggested that "making every false statement a crime ... is like making every attempt at shoplifting cognizable in the federal courts."⁷⁶

While the Government is heavily armed, there is case law that suggests that in some instances prosecutors may only choose one weapon in which to bring to the "fight."⁷⁷ If a prosecutor must choose a particular cause of action under which to pursue fraudulent conduct, the choice is unequivocally going to be the False Claims Act.

Double Jeopardy and Choosing a Cause of Action

In *United States v. Halper*,⁷⁸ the respondent was convicted in an independent proceeding under the federal criminal false-claims statute⁷⁹ for

⁷² *Id.*

⁷³ *Id.*

⁷⁴ *Id.*

⁷⁵ *Id.* (stating that the corporate integrity program included an annual report to the Department of Health and Human Services, an educational program that was to be implemented within 90 days of the settlement agreement, voluntary disclosure upon the discovery of any malfeasance, open access to NME's books, and payment for any investigations in the future).

⁷⁶ Harrington, *supra* note 35, at 152.

⁷⁷ See *United States v. Halper*, 490 U.S. 435 (1989) (holding that imposing exceptional fines under the False Claims Act upon a defendant already convicted of the same offense constitutes a second "punishment" for purposes of Constitutional Double Jeopardy analysis).

⁷⁸ *Id.*

⁷⁹ *Id.* at 438.

submitting sixty-five false claims for Medicare reimbursement. Halper was fined in the amount of \$5,000 and sentenced to prison for a five-year term.⁸⁰ Having only suffered actual damages in the amount of \$585, the Government was compelled to subsequently bring the cause of action against the respondent under the Civil False Claims Act.⁸¹ Based on findings of fact from the criminal proceeding, the Government's motion for summary judgment was granted in the civil proceeding.⁸² Therefore, Halper should have been ordered to pay the statutory penalty of \$130,000.⁸³

Although it was a civil penalty, the lower court viewed the penalty as entirely unreasonable relative to the actual damages of \$585.⁸⁴ The court found the excessive fine to be punitive thus constituting a "second punishment" under double jeopardy analysis.⁸⁵ Adding the Government's cost of litigation to the \$585 actual damages figure, the court imposed a fine of \$16,000 on the respondent.⁸⁶ The key ruling was that multiple punishments for the same conduct are constitutionally prohibited under the Double Jeopardy Clause of the Fifth Amendment.⁸⁷

The critical inquiry in determining the issue of multiple punishments is whether the civil sanction imposed in a particular case contemplates a goal of punishment.⁸⁸ The Supreme Court's specific holding in *Halper* was that under the Double Jeopardy Clause, a defendant who has already been punished criminally may not be subjected to an additional civil sanction that may be characterized as a deterrent or as retribution.⁸⁹

In the wake of *Halper*, the issue of whether a defendant may be prosecuted criminally subsequent to a large civil penalty remains unresolved. However, the undecided nature of the issue is influential to prosecutors choosing a cause of action. Furthermore, a defendant may be

⁸⁰ *Id.* at 437.

⁸¹ *Id.* at 438.

⁸² *United States v. Halper*, 660 F. Supp. 531, 532-533 (S.D.N.Y. 1987).

⁸³ The pre-1986 version of 31 U.S.C. § 3729 called for a \$2,000 penalty for each false claim.

⁸⁴ *United States v. Halper*, 490 U.S. 435, 438-439 (1989).

⁸⁵ *See, Id.*

⁸⁶ *Id.* (citing *United States v. Halper*, 660 F. Supp. at 534).

⁸⁷ *Id.*

⁸⁸ *Id.* at 448.

⁸⁹ *United States v. Halper*, 490 U.S. 435, 448-449 (1989).

able to make an Eighth Amendment Excessive Fines Clause argument even if there has been no prior criminal prosecution.⁹⁰

In addition to the Double Jeopardy and Excessive Fines arguments, there are several reasons why a prosecutor might choose to pursue a health care fraud claim under the Civil False Claims Act as opposed to the Medicare and Medicaid anti-kickback statute or other criminal statutes that may be available.

A prosecutor deliberating over which cause of action to bring necessarily contemplates the level of proof that is required to prevail in the cause of action and the availability of evidence that is required to satisfy that standard. A comparison of the "intent" standard under the Medicare and Medicaid anti-kickback statute and "not knowingly" standard under the False Claims Act is instructive.

As mentioned above, under the False Claims Act, satisfying the "knowingly" standard does not require a showing of specific intent.⁹¹ However, under the Medicare and Medicaid anti-kickback statute provision, the intent standard is generally much harder to meet. The Medicare and Medicaid anti-kickback statute generally prohibit any person from "knowingly" and "willfully" soliciting or receiving any direct or indirect remuneration in return for referring an individual for an item or service for which payment will be sought under Medicare or Medicaid.⁹² The statute also prohibits any person from offering or paying any direct or indirect remuneration to induce the referral of an individual for an item or

⁹⁰ See *Bennis v. Michigan*, 1996 U.S. LEXIS 1565 at *17; *Dep't of Revenue of Montana v. Durth Ranch et al.*, 114 S. Ct. 1937, 1945 (1994) ("A civil forfeiture may violate the Eighth Amendment's proscription against excessive fines"); *Browning-Ferris Indus. v. Kelco Disposal*, 492 U.S. 257, 275 n. 21 (1989) (noting that damages awarded to the Government may raise concerns under the Excessive Fines Clause of the Eighth Amendment); *Austin v. United States*, 509 U.S. 602, 113 S. Ct. 2801 (1993) ("The Eighth Amendment's text is not expressly limited to criminal cases, and its history does not require such a limitation"); *Peterson v. Weinberger*, 508 F.2d 45, 55 (5th Cir. 1975), *cert. denied*, 423 U.S. 830 (1975) (Upholding the District Court's finding that a \$2,000 fine per 120 false claims would be disproportionate and unreasonable as compared to the Government's actual loss).

⁹¹ 31 U.S.C. § 3729(b)(1995) (stating that a showing of deliberate ignorance or reckless disregard may satisfy the "knowingly" standard under the Act).

⁹² 42 U.S.C. § 1320a-7b(1995).

service for which payment will be sought under Medicare or Medicaid.⁹³

The OIG and courts interpreting the “intent” requirement of the statute (“knowingly” and “willfully”) have historically applied a broad standard. In one case, *United States v. Greber*,⁹⁴ the court held that the statute is violated if any portion of any payment is intended to induce a physician to refer a patient, even if the payment is also intended to compensate for legitimate professional service fees.⁹⁵ In this case, Dr. Greber paid physicians an interpretation or consultation fee when the physicians referred patients to his diagnostic services company.⁹⁶

Recently, the Ninth Circuit Court of Appeals applied a narrow interpretation of the statute’s “intent” requirement in *Hanlester Network v. Shalala*.⁹⁷ *Hanlester Network* involved an arrangement between the network, its physician investors, and Smithkline BioScience Laboratories (SKBL).⁹⁸ Specifically, the court focused on the manner in which the Hanlester Network offered limited partnership shares to physician-investors and the ensuing flow of Government reimbursement funds between SKBL and the Hanlester Network.⁹⁹

In *Hanlester Network*, the court construed “knowingly and willfully” to mean that the Government must prove that an individual entered into an arrangement “knowing” that the agreement violated the anti-kickback statute and that the individual had the specific intent to violate the law.¹⁰⁰ Without explicit communication between the parties that specifies an intent to defraud the government, the prosecution will have a difficult time proving violations of the Anti-kickback statute.

⁹³ The reader should note that several safe harbors exist that shelter certain business arrangements from prosecution under the anti-kickback statute. Conversely, the Office of Inspector General (OIG) has issued “Special Fraud Alerts” that describe various conduct that is viewed as “questionable” under the statute. If an arrangement fits squarely within a safe harbor, it may nevertheless represent legal activity if it is not intended to induce referrals. *Id.*

⁹⁴ *United States v. Greber*, 760 F.2d 68 (3d Cir. 1985), *cert. denied*, 474 U.S. 988 (1985).

⁹⁵ *Id.*

⁹⁶ *Id.*

⁹⁷ *Hanlester Network, et. al. v. Shalala*, 51 F.3d 1390 (1995).

⁹⁸ *Id.*

⁹⁹ *Id.*

¹⁰⁰ *Id.*

Although virtually impossible to satisfy an intent requirement that sanctions ignorance of the law as a defense, the scienter requirement might be proved through deposition testimony of employees or through introduction of other “smoking gun” documents. Such documents might contain language specifying “in exchange for referrals” or “compensation per referral” or “as a percentage of referrals,” etc.

In arriving at its decision, the court in *Hanlester Network* relied on the United States Supreme Court's interpretation of “willfulness” in *Ratzlaf v. United States*.¹⁰¹ *Ratzlaf* involved an appeal from a conviction for “willfully” entering into a financial transaction for the purpose of avoiding the reporting requirements of the Bank Secrecy Act.¹⁰² The Supreme Court concluded that “willfulness” means the individual knew the arrangement violated the law.¹⁰³

The OIG viewed the *Hanlester Network* case as “wrongfully decided” and interprets it as extending only to the Ninth Circuit. The OIG's position is that the *Greber* “intent” standard remains good law elsewhere. On November 15th, 1995, the Ninth Circuit Court of Appeals denied the Government's petition to rehear *en banc* the *Hanlester Network* case and the U.S. solicitor general declined to petition the Supreme Court for review of the rehearing denial.¹⁰⁴

Ultimately, the OIG position that the *Hanlester Network* decision only applies to the Ninth Circuit may be somewhat misplaced. On October 3, 1995, a U.S. District Court in Minnesota acquitted an employee of Genentech Inc. of charges under the Anti-kickback statute.¹⁰⁵ This litigation involved the marketing and sales methods surrounding a growth hormone called Protopin.¹⁰⁶ In arriving at his decision, the judge applied the “specific intent” standard of the *Hanlester Network* case.¹⁰⁷ However,

¹⁰¹ *Ratzlaf v. United States*, 114 S. Ct. 655, 657 (1994).

¹⁰² *Id.*

¹⁰³ *Id.*

¹⁰⁴ BNA, *DOJ Refuses to Ask for Supreme Court Review of Hanlester Anti-Kickback Case*, 5 BNA HEALTH L. REP. 200 (Feb. 8, 1996).

¹⁰⁵ *United States v. Neufeld*, 908 F. Supp. 491 (S.D. Ohio 1995).

¹⁰⁶ *Id.*

¹⁰⁷ *Id.* More recently, the Eighth Circuit Court of Appeals applied a “heightened intent” standard when it upheld a conviction under the Anti-kickback statute. See *United States v. Jan*, 93 F 3d 436 (8th Cir. 1996), *reh'g denied*, 1996 U.S. App. LEXIS 27478 (8th Cir., Oct. 22, 1996)

on November 27, 1995, the U.S. District Court for the Southern District of Ohio expressly rejected the *Hanlester Network* scienter standard in *United States v. Neufeld*.¹⁰⁸

In addition to the eased "intent" requirement, potential damages under the False Claims Act appreciably exceed those that are obtainable through other potential remedial measures. At \$5,000 to \$10,000 per false claim, in addition to treble damages, the total fines and penalties accumulate quickly to reach astronomical levels. Faced with the threat of fines and penalties well into the millions of dollars, "[h]ospitals will settle for nominal amounts even if they feel it's like extortion."¹⁰⁹ Furthermore, the standard of proof required in a civil action is "by a preponderance" of the evidence. By selecting to pursue allegedly fraudulent activity under the False Claims Act, the prosecutor evades the daunting task of proving a case "beyond a reasonable doubt."

Considering the burdens on the prosecution, pursuing a cause of action under the False Claims Act, as opposed to seeking a remedy under the Medicare and Medicaid Anti-kickback statute, appears to be a rational decision. Choosing to pursue a False Claims Act action is consistent with a prosecutor increasing the chances of victory and positively effecting the efficient allocation of Government resources.

To this point, the focus of the False Claims Act discussion has been on actions brought by the government. However, as the next section of this article describes, private litigants may also institute civil actions for false claims under the provisions of the Act.¹¹⁰ In considering the liability exposure of any health care institution, the false claims civil action brought by the private individual perhaps poses the greatest threat. An employee's access to practices and records allows for a thorough "investigation" of day to day activities.

Qui Tam Actions Under the False Claims Act

¹⁰⁸ *United States v. Neufeld*, 908 F. Supp. 491 (S.D. Ohio 1995).

¹⁰⁹ BNA, *Billing Fraud, Reimbursement Among Top Medicare Legal Issues in 1996*, 5 BNA HEALTH L. REP. 165 (Feb. 1, 1996).

¹¹⁰ 31 U.S.C. § 3730(b) (1995).

Individuals may bring causes of action under the False Claims Act's "*qui tam*" provision. Short for *qui tam pro domino rege quam pro se ipso in hac parte sequitur*, which means "he who brings the action for the king as well as for himself."¹¹¹ Referred to as "relators," the *qui tam* plaintiff stands to earn substantial compensation if a judgment or settlement results from the information provided.¹¹² Instilling fear in corporate counsel and management everywhere, courts and commentators frequently refer to *qui tam* plaintiffs as "private attorney generals."¹¹³

The concept of earning large monetary rewards for providing information is generally consistent with the statute's purpose of detecting and preventing federal law violations.¹¹⁴ Furthermore, statutory protection is afforded to *qui tam* plaintiffs who are discharged, demoted, suspended, threatened, harassed, or discriminated against as a result of lawfully reporting information about an employer to the Government.¹¹⁵ Relief in this context might include reinstatement and full restoration of seniority, damages, attorney fees, court costs, and double the amount of back pay with interest.¹¹⁶

The *qui tam* plaintiff's complaint must be filed *in camera*, and must remain under seal for at least sixty days.¹¹⁷ The complaint is not served on the defendant until the court orders service, and the Government may intervene and proceed with the action within sixty days after it receives both the complaint and the material evidence and information.¹¹⁸ Whether

¹¹¹ David J. Ryan, *The False Claims Act: An Old Weapon with New Firepower is Aimed at Health Care Fraud*, 4 ANNALS OF HEALTH L. 127, n.2 (1995) (quoting William Blackstone, Commentaries on the Law of England, Book III, 160 (1768)).

¹¹² 31 U.S.C. § 3730(d)(1995).

¹¹³ See *United States ex rel. Pilon v. Martin Marietta Corp.*, 60 F.3d 995, 997 n.2 (2nd Cir. 1995) (citing *United States ex rel. LeBlanc v. Raytheon Co.*, 913 F.2d 17, 19 n.2 (1st Cir. 1990)), See also West, *supra* note 5, at 26 (citing J.A. Minkoff, et al., *Sounding Board: Beyond Advance Directives - Health Care Surrogate Law*, 327 NEW ENG J. MED. 1165-1169 (1992)).

¹¹⁴ *United States ex rel. Barbara Burch v. Piqua Engineering*, 803 F. Supp. 115, 118 (S.D. Ohio 1992) (citing Evan Caminker, *The Constitutionality of Qui Tam Actions*, 99 YALE L. J. 341, 344 (1989)).

¹¹⁵ 31 U.S.C. § 3730(h)(1995).

¹¹⁶ *Id.*

¹¹⁷ 31 U.S.C. § 3730(b)(2)(1995).

¹¹⁸ *Id.*

or not the Government elects to proceed with the action will affect the amount of recovery obtainable by the *qui tam* plaintiff. If the Government proceeds with an action, the *qui tam* plaintiff receives between 15 and 25 percent of the Government's recovery, depending on the extent to which the *qui tam* plaintiff's information substantially contributed to the prosecution of the action.¹¹⁹ The *qui tam* plaintiff is also entitled to recovery of reasonable attorney fees and costs.¹²⁰

If the Government elects not to proceed with the action, the *qui tam* plaintiff may receive an amount between 25 and 30 percent of the total recovery, in addition to recovery of attorney fees and costs.¹²¹ If the *qui tam* plaintiff planned or initiated the activity which gave rise to the complaint and ensuing litigation, the court has discretion to appropriately adjust the level of recovery.¹²² Furthermore, if the *qui tam* plaintiff is criminally convicted for activity that gave rise to the False Claims Act violation, the *qui tam* plaintiff must be dismissed from the civil action as a plaintiff and may not receive any share of the recovery.¹²³ Similarly, in order to receive a monetary award, a *qui tam* plaintiff must be an "original source" to the Government, and have direct and independent knowledge of the information on which the allegations are based.¹²⁴

The financial incentives and procedural protections created by the False Claims Act's *qui tam* provision for private litigants have proven to be effective. In 1987, only \$200,000 was recovered as a consequence of *qui tam* actions.¹²⁵ In 1994, \$378 million was obtained through *qui tam* actions out of a total of \$1.09 billion recovery from all civil fraud cases.¹²⁶ The private plaintiffs in these 1994 cases received a total of \$70 million for their efforts.¹²⁷ As individual recoveries become publicized, the frequency

¹¹⁹ 31 U.S.C. § 3730(d)(1)(1995).

¹²⁰ *Id.*

¹²¹ 31 U.S.C. § 3730(d)(2)(1995).

¹²² 31 U.S.C. § 3730(d)(3)(1995).

¹²³ *Id.*

¹²⁴ 31 U.S.C. § 3730(e)(4)(B)(1995).

¹²⁵ West, *supra* note 5, at 16 (citing BNA, *Government Recovers \$800 Million Through Whistleblower Litigation*, BNA MEDICARE REPORT, Vol.5, No. 45, pp. 1291-1292, Nov. 18, 1994).

¹²⁶ Ryan, *supra* note 110, at 129-130 (citing Josh Chetwynd, *Recoveries by U.S. from Civil Fraud Surged in Fiscal '94*, WALL. ST. J., Oct. 12, 1994, at B3).

¹²⁷ David D. Queen and Elizabeth E. Frasher, *DESIGNING A HEALTH CARE CORPORATE COMPLIANCE PROGRAM* 25 (1995).

of *qui tam* suits under the False Claims Act will undoubtedly increase. Therefore, to prevent the need for private plaintiffs to bring an action under the *qui tam* section of the Act, organizations must attempt to comply with the law and implement appropriate measures.

Defendants facing *qui tam* lawsuits usually argue that the suits against them are unconstitutional because such actions violate the Article III standing requirement, the doctrine of separation of powers, and the Appointment Clause constraints on who may litigate on behalf of the United States. However, parties invoking such constitutional arguments have experienced little, if any, success.¹²⁸

Qui Tam Cases and Potential Expansion of the False Claims Act

The financial incentives and procedural protections afforded *qui tam* plaintiffs undeniably serve to increase the number of *qui tam* suits brought under the False Claims Act and, therefore, the amount of recovery to the Government. However, the scope and reach of the False Claims Act and its *qui tam* provision is an issue currently undergoing judicial review. *Qui tam* plaintiffs are motivated to bring actions within the reach of the False Claims Act in an effort to gain access to *qui tam* provisions and the potential for lottery-size winnings. The direction the courts take with respect to the scope of the False Claims Act will dictate the extent to which institutional health care providers must examine internal practices and implement compliance efforts.

The case of *United States ex rel. Pogue v. American Health Corp. and Diabetes Treatment Centers of America*¹²⁹ is illustrative of the potential expansion of the False Claims Act. Although the plaintiff in *Pogue* signed a release and discharge of all claims and a covenant not to sue, the plaintiff later filed an action under the *qui tam* provision of the False Claims Act against his former employer, Diabetes Treatment Centers of America ("DTCA"), American Healthcorp, Inc. ("AHC"), DTCA's parent company, and West Paces Medical Center ("West Paces"). In addition, the

¹²⁸ *United States ex rel. Schumer v. Hughes Aircraft*, 63 F.3d 1512, 1520 (9th Cir. 1995) ("This circuit has addressed and rejected [each of] these exact [constitutional] arguments").

¹²⁹ *United States ex rel. Pogue v. American Health Corp.*, 1995 U.S. Dist. LEXIS 16710 (Middle District of Tennessee, Sept. 14, 1995) (Opinion altered Jan. 5, 1996).

plaintiff in *Pogue* specifically named five physicians along with various John Doe defendant hospitals and physicians.¹³⁰

Pogue alleged the defendants submitted fraudulent claims to Medicare for reimbursement in violation of the False Claims Act. He specifically alleged that the defendants were involved in a scheme whereby physicians would refer Medicare and Medicaid patients to West Paces in violation of the Anti-kickback¹³¹ and Self-referral¹³² statutes.

The plaintiffs argued that the claims were false and fraudulent maintaining that the Government would have excluded the defendants from the Medicare and Medicaid programs had it been aware of the Anti-kickback and Self-referral violations.¹³³ Therefore, the defendants maintained that the claims submitted were not in violation of any Federal law that would prevent the defendant from participating in the Medicare or Medicaid programs.¹³⁴

The defendants, both the institutions and individuals, filed a motion for summary judgment and alternatively, a motion to dismiss under F.R.C.P. 12(b)(6) for failure to state a claim upon which relief could be granted.¹³⁵ The court first considered the summary judgment motion that was entirely based on the release between the plaintiff and his former employer.¹³⁶ The court denied the summary judgment motion, because the release violated public policy.¹³⁷ However, the court granted the defendant's motion to dismiss on the basis that the plaintiff failed to allege

the claims were actually false or fraudulent, or that the U.S. suffered

¹³⁰ *Id.* at *2.

¹³¹ 42 U.S.C. § 1320a-7b(b) (1995).

¹³² 42 U.S.C. § 1395 (1995) (noting that the prohibition against self-referrals is also referred to as the "Stark" law or amendment).

¹³³ *United States ex rel. Pogue v. American Health Corp.*, 1995 U.S. Dist. LEXIS 16716, at *3 (Middle District of Tennessee, Sept. 14, 1995)(Opinion Altered Jan. 5, 1996).

¹³⁴ *Id.*

¹³⁵ *Id.*

¹³⁶ *Id.*

¹³⁷ *Id.* at 16-17 (ruling that a violation of the anti-kickback or self-referral statutes would not automatically constitute a violation of the False Claims Act).

damages as a result of the alleged "false claims."¹³⁸

At the same time, the plaintiff in *Pogue* also filed a motion to reconsider the motion to dismiss.¹³⁹ Surprisingly, on January 5, 1996, the trial judge overruled his own dismissal order from September 14, 1995.¹⁴⁰ The court first reconsidered the proposition that a plaintiff needs to prove that the Government has suffered harm in order to bring a False Claims Act claim.¹⁴¹ In the motion to reconsider, the court simply recognized a U.S. Supreme Court case precedent holding that no showing of actual damages is necessary as a prerequisite to obtaining recovery under the False Claims Act.¹⁴²

The court further reconsidered whether submitting claims that violate the Anti-kickback or Self-referral statutes constituted a violation of the False Claims Act.¹⁴³ In overruling the dismissal order, the court looked for guidance from other jurisdictions and concluded that the False Claims Act was intended to govern fraudulent acts that result in the government making payments to unintended parties.¹⁴⁴

In reaching its decision, the court in *Pogue* specifically relied on the decision in *United States ex rel. Roy v. Anthony*.¹⁴⁵ In this case, the plaintiff claimed that the defendants were engaged in practices that violated the "Fraud and Abuse Statute" and, therefore, the submission of claims associated with those practices amounted to submitting false or fraudulent

¹³⁸ *United States ex rel. Pogue v. American Health Corp.*, 1995 U.S. Dist. LEXIS 16710, *7-9 (Middle District of Tennessee, Sept. 14, 1995) (Opinion altered Jan. 5, 1996) (citing *United States ex rel. Green v. Northrop Corp.*, 59 F.3d 953 (9th Cir. 1995); *See also Town of Newton v. Rumery*, 480 U.S. 386 (1987) ("[A] promise is unenforceable if the interest in its enforcement is outweighed in the circumstances by a public policy harmed by enforcement of the agreement")

¹³⁹ *Id.*

¹⁴⁰ *Id.* at *16-17 (ruling that a violation of the Anti-kickback or Self-referral statutes would not automatically constitute a violation of the False Claims Act).

¹⁴¹ BNA, *Court Alters on Whether Injury Needed for a Violation of the False Claims Act*, 5 BNA HEALTH L. REP. 10 (Jan. 18, 1996).

¹⁴² *See Id.*; *See also Rex Trailer v. United States*, 350 U.S. 148 (1956); *United States ex rel. Marcus v. Hess*, 317 U.S. 527 (1943); *United States v. Kensington Hosp.*, 760 F. Supp. 1120 (E.D. Pa. 1991); *United States ex rel. Hagood v. Sonoma County Water Agency*, 929 F.2d 1416, 1421 (9th Cir.) ("No damages need be shown in order to recover the penalty").

¹⁴³ *Id.*

¹⁴⁴ BNA, *supra* note 140.

¹⁴⁵ *United States ex rel. Roy v. Anthony*, 914 F. Supp. 1504 (S.D. Ohio 1994).

claims.¹⁴⁶ The court noted that this “vague assertion” created a “tenuous connection” between the False Claims Act and the “Fraud and Abuse Statute.”¹⁴⁷ Tenuous or not, the court deemed the connection to be sufficient to overcome a motion to dismiss.¹⁴⁸

While both *Pogue* and *Roy* underwent judicial review at the federal appellate level,¹⁴⁹ the possibility remains that the False Claims Act will expand to cover other “fraudulent conduct.” This expansion would simply facilitate and expand the ease with which *qui tam* plaintiffs may bring actions under the False Claims Act. An institution embarking on a compliance project should contemplate all areas in which a *qui tam* action could materialize. A successful compliance program will significantly reduce, if not eliminate, the ability of employees to bring actions under the *qui tam* provision of the False Claims Act.

CURRENT ENFORCEMENT EFFORTS

With specific laws identified under which to shape an effective compliance program, the scope of potential liability exposure under these laws must be measured. Corporate vulnerabilities can only be quantified after an assessment of current Government enforcement efforts. The unfortunate experiences of other institutions exposed to Government investigation and prosecution may provide a map with which to build a corporate compliance program.

Developing and implementing a corporate compliance program is usually a condition of settlement agreements entered into between the DOJ and the settling institution. The terms of such compliance agreements have

been characterized as “draconian” compared to components of a “self-

¹⁴⁶ *Id.* at 1507.

¹⁴⁷ *Id.*

¹⁴⁸ *Id.* (“Under the facts alleged, the Plaintiff could produce evidence that would show that the kickbacks allegedly paid to the defendant physicians somehow tainted the claims for Medicare. Additionally, the Plaintiff may establish that his claims for Medicare payments were constructively false or fraudulent. It does not appear beyond doubt that the Plaintiff can prove no set of facts in support of his claim which would entitle him to relief”).

¹⁴⁹ BNA, *Appeals Court Asked to Review Case Involving Anti-kickback Allegations*, 5 BNA HEALTH L. REP. 507 (April 4, 1996).

imposed” compliance strategy.¹⁵⁰

The primary focus of the collaborative efforts between the OIG and the DOJ is on practices that the Government perceives as fraudulent. Recent specific enforcement efforts include the “physical presence requirement” for teaching physicians to submit Part B claims to Medicare,¹⁵¹ the Diagnosis Related Group (DRG) seventy-two hour window project,¹⁵² billing Medicare for procedures that utilize investigational devices not fully approved by the Food and Drug Administration (FDA),¹⁵³ billing for unnecessary services,¹⁵⁴ and general “upcoding.”¹⁵⁵ The first three enforcement efforts are discussed below as the OIG and the DOJ have recently engaged in national uniform programs aimed at these particular practices. General “upcoding” and unnecessary billing will most certainly be examined in most every investigative instance regardless of the investigation's main focus.

Intermediary Letter 372 and the “Physical Presence” Requirement

The Clinical Practices of the University of Pennsylvania (“CPUP”) settlement referred to at the outset of this article was based in part on allegations that during the period from 1989 to 1994, faculty physicians were billing Medicare for services that were actually performed by residents in training. The Government’s general position is that it already subsidizes the residents’ training and salaries through Graduate Medical

¹⁵⁰ See Queen and Frasher, *supra* note 126, at 20.

¹⁵¹ Health Care Financing Administration (HCFA) Payment Policies for Services of Teaching Physicians, 60 Fed. Reg. 63139 (Dec. 8, 1995)(to be codified at 42 C.F.R. 400).

¹⁵² BNA, *Pennsylvania Hospital Settlements Show Willingness to Ensure Proper Billing*, 5 BNA HEALTH L. REP. 331 (March 7, 1996) (stating that the DRG 72-Hour Window Project involves false claims allegations of illegal Medicare billing for non-physician outpatient services provided in conjunction with inpatient admissions).

¹⁵³ BNA, *Sutter Memorial to Pay \$1.3 Million to Settle Medical Device Fraud Charges*, 4 BNA HEALTH CARE POLY REP. 9 (Feb. 26, 1996)(stating the involvement of allegations under the False Claims Act of fraudulent Medicare billing for investigational cardiac device implant procedures that have not received final FDA approval).

¹⁵⁴ BNA, *supra* note 70 (discussing the billing for unnecessary services settlement).

¹⁵⁵ BNA, *Physician Consents to \$98,000 Payment to Settle Charges of Upcoding, Fraud*, 4 BNA HEALTH L. REP. 1727 (Nov. 16, 1995)(defining upcoding as billing for more expensive services than those that were actually rendering).

Education (GME) programs, and thus they should not pay for their treating services.¹⁵⁶ Alleged violations of the proposed regulation would likely constitute violations of the False Claims Act from the purview of the Government. Liability may be attached to the institution under a *respondeat superior* theory as described in previous sections.

Intermediary Letter 372 ("I.L. 372"), issued in 1969, set forth the conditions under which physicians in "teaching settings" were required to satisfy in order to be considered "attending physicians."¹⁵⁷ An "attending physician" was typically qualified to charge Medicare for services in which a resident was involved for the attending's services.

The Health Care Financing Administration (HCFA), via its rule that became effective July 1, 1996, eliminated the I.L. 372 "attending physician" criteria for purposes of determining whether payment should be made for the services of physicians in teaching settings.¹⁵⁸ As a condition to receiving payment under Medicare Part B subsequent to July 1, 1996, a teaching physician must be physically present for a "key portion" of the time during the rendering of the service.

In the case of complex or dangerous procedures, the teaching physician must be present during all "critical portions" of the procedure and must be "immediately available" to be called upon during the entire service or procedure.¹⁵⁹ All documentation in the medical record should reflect the actual physical presence of the physician. HCFA and its agents take the position that "if it was not documented, it did not happen."¹⁶⁰

Physical Presence: New Regulation or Clarification of Old Rule?

¹⁵⁶ 60 Fed. Reg 63135 (1995).

¹⁵⁷ *Id.*

¹⁵⁸ *Id.* at 63139.

¹⁵⁹ *Id.* at 63139-63140 (stating that in the case of surgery, documentation should reflect the exact time in which the teaching physician was actually present and "scrubbed in," or "elbow to elbow" with the resident. In the case of procedures such as endoscopies, the teaching physician evaluation and management services, the teaching physician should bill at a complexity level appropriate for the teaching physician's level of experience).

¹⁶⁰ Stan Weintraub, Health Care Financing Administration, Address to the Association of American Medical Colleges (Feb. 12, 1996).

For reasons that may become more evident after reading the "Preliminary Compliance Program Review" section below, it is important to recognize that HCFA describes the July 1, 1996 "physical presence requirement" as a "mere clarification," as opposed to a "new rule."¹⁶¹ Generally, taking steps to ensure that an institution is conducting business in a manner that is consistent with a prospectively enforceable law yields implications that differ from examining current business practices in an effort to ensure that the institution *has been* complying with the law.

Analyzing the history of the "new rule" that became effective July 1, 1996, reveals several arguments that the new regulation is in fact a "new rule" as opposed to a "mere clarification."¹⁶² In 1967, the Bureau of Health Insurance ("BHI") promulgated a rule that authorized fee-for-service payment when an "attending physician" furnished "personal and identifiable direction" to a resident participating in the care of patients.¹⁶³ The rule, supplanted by Intermediary Letter 372 in 1969, contained no "physical presence" requirement.¹⁶⁴

Intermediary Letter 372 ("I.L. 372") included a provision that the "attending physician" be "present and ready to perform" major surgery and complex procedures.¹⁶⁵ However, I.L. 372 contained no explicit "physical presence" requirement for procedures other than major surgery and complex procedures. In 1970, the BHI issued a letter in the form of questions and answers to Part B intermediaries that arguably established the first "physical presence" rule.¹⁶⁶ However, a "physical presence" requirement has never been consistently enforced during the twenty-five years I.L. 372 has been the law.

As opposed to enacting any "physical presence requirement," Congress has left in place a law that merely requires "sufficient personal and identifiable physicians' services to the patient to exercise full, personal

¹⁶¹ Miller & Chevalier, *The Physical Presence Rule, Past and Future – How HCFA Plans to Get You Coming and Going*, Health Law Alert, Feb. 1996 at 2.

¹⁶² Robert Saner, Powers Pyles Sutter & Verville P.C., Address to the Association of American Medical Colleges (Feb. 12, 1996).

¹⁶³ 20 C.F.R. § 405.521 (1967).

¹⁶⁴ See Intermediary Letter 372 (issued 1969).

¹⁶⁵ *Id.*

¹⁶⁶ See Intermediary Letter 70-2 (issued 1970).

control over the management of the portion of the case” in order to seek payment under Medicare Part B.¹⁶⁷ A clear “physical presence” requirement was articulated in a December 30, 1992 memorandum from the Director of Payment Policy at HCFA, to all the agency’s regional offices.¹⁶⁸ While several Part B carriers implemented the memorandum from Booth, others ignored it entirely.¹⁶⁹

HCFA eventually advised all its intermediaries that a formal rule would be issued and that if a carrier was not enforcing a “physical presence” requirement prior to December 30, 1992, it should not alter its payment policies until the issuance of the final rule.¹⁷⁰ The history, viewed in conjunction with statements in the December 8, 1995 regulation, indicate that “physical presence” would be a formal requirement only as of July 1, 1996.

The preamble to the new rule makes several statements that support the argument that “physical presence” would become an official requirement only after the new regulation became effective. Recognizing that I.L. 372 has never been “applied uniformly by all Medicare carriers,” the preamble states that it should be “replaced,” suggesting that a “new” rule will take its place.¹⁷¹

A tacit admission is contained in the preamble that I.L. 372 required the “attending physician’s” presence during major surgery and complex procedures “but was vague, perhaps necessarily, on the matter of the presence of the physician during other occasions of inpatient service.”¹⁷² While the preamble refers to the “physical presence” requirement in the

¹⁶⁷ 42 U.S.C. § 1395u(b)(7)(A)(i)(I-III) (1995) (“In the case of physicians’ services furnished to a patient in a hospital with a teaching program, ... the carrier shall not provide ... for payment for such services under this part - (i)unless - (I) the physician renders sufficient personal and identifiable physicians’ services to the patient to exercise full, personal control over the management of the portion of the case for which the payment is sought, [and] (II) the services are of the same character as the services the physician furnishes to patients not entitled to benefits under this subchapter”).

¹⁶⁸ Saner, *supra* note 161 (stating that the “Booth Memorandum” says that: “A service furnished by a resident without the presence of the attending physician is not covered as a physician’s service to the individual patient”).

¹⁶⁹ *Id.*

¹⁷⁰ *Id.*

¹⁷¹ 60 Fed. Reg. 63137-63138 (1995).

¹⁷² *Id.* at 63138.

new regulation as a “clarification,”¹⁷³ it also refers to it as a “proposed condition.”¹⁷⁴

As compliance is examined and formally implemented, the “new rule” theory should be considered and assessed in opposition to the “clarification” argument. While “physical presence” is arguably a new requirement, at least “personal and identifiable” and “full, personal control” has always been the requirement. Therefore, the physician who is submitting Part B bills to Medicare while vacationing, would clearly violate both the “old” and “new” rule and would be vulnerable to a False Claims Act cause of action.

A stickier issue may arise, for example, where the teaching physician arrives at the hospital at 3:00 a.m. after the resident has performed at least half of the procedure. In this instance, it is arguable that the physician provided “personal and identifiable” services for which payment could have been sought without being physically present for the entire “key portion” of the service. HCFA has expressed its intention to be flexible with regard to the definition of “key portion,”¹⁷⁵ and has also expressed its view that “physical presence” has always been the rule. However, for the reasons articulated in this section, it is likely that the “physical presence” requirement is only officially and formally effective as of July 1, 1996.

The University of Pennsylvania Settlement

As previously mentioned, the elements of a Government’s imposed compliance program may contain overly burdensome, draconian requirements. The settlement agreement between the CPUP and the United States is illustrative of a typical compliance regimen that the Government will impose as a component of a settlement agreement. One of the allegations included in the settlement agreement referenced “inadequate documentation and violations of billing requirements for services of attending physicians who involve residents in the care of their

¹⁷³ *Id.* at 63140.

¹⁷⁴ *Id.* at 63129.

¹⁷⁵ Bart McCann, M.D., Health Care Financing Administration, Address to the Association of American Medical Colleges (Feb. 12, 1996).

patients.”¹⁷⁶ It should be noted that CPUP and its physicians denied any wrongdoing in entering into the settlement agreement. Furthermore, the agreement dismisses CPUP from the civil action with prejudice but does not foreclose the possibility that the Government will bring a criminal action.¹⁷⁷

The settlement agreement generally covered four broad areas: centralization of billing functions, implementation of internal and external auditing, mandatory education, and implementation of information and reporting telephone lines.¹⁷⁸

CPUP was already moving toward centralization of its billing functions prior to the investigation and ensuing settlement.¹⁷⁹ However, all business and financial functions subsequent to the agreement will be directed by the Chief Financial Officer of CPUP. The centralization will make monitoring easier for CPUP and will allow the Government to investigate with ease in the future. The hallmark of centralization at CPUP is the utilization of inpatient chart abstractors. Under this system, chart abstractors will bill Medicare based on documentation in the chart. Thus, “if it is not documented in the chart, the abstractors [will not] bill it.”¹⁸⁰ Monitoring and auditing is separated into “internal” and “external” for CPUP.¹⁸¹ On the internal side, an office of billing compliance will be established, whereby, the work of each chart abstractor will be reviewed twice per year to ensure the bills being submitted are appropriate and accurate.¹⁸² Physicians’ billing practices for outpatient services will also be audited under the system.¹⁸³ Those physicians who are unable to bring their billing practices within the boundaries of the law will have to pay for

¹⁷⁶ SETTLEMENT AGREEMENT, December 12, 1995, at 3.

¹⁷⁷ *Id.* (Under the terms of the agreement, CPUP waived and “Double Jeopardy” argument that it could potentially make if a criminal action is brought subsequent to the settlement agreement. In doing so it agreed to disregard the decision in *United States v. Halper*, 490 U.S. 435 (1989).

¹⁷⁸ John E. Steiner, Jr., Assistant General Counsel, American Hospital Association, Address to the Metropolitan Chicago Healthcare Council (Mar. 18, 1996).

¹⁷⁹ Mary Stein, Assistant General Counsel, Clinical Practices of the University of Pennsylvania, Address to the Association of American Medical Colleges (Feb. 12, 1996).

¹⁸⁰ *Id.*

¹⁸¹ *Id.*

¹⁸² *Id.*

¹⁸³ *Id.*

extended auditing, and may face suspension from billing Medicare.¹⁸⁴ External audits will be conducted by an independent auditing firm, at CPUP's expense; the auditing firm who will conduct a review of professional fee billings on a yearly basis for the next five years and will report the results to the Government or the intermediary.¹⁸⁵

Standards and policies for these practices will be developed and disseminated through mandatory education.¹⁸⁶ Physicians or employees not attending mandatory educational sessions will be penalized and suspended in some instances.¹⁸⁷ The educational program emphasizes the objective of accurate and complete documentation.¹⁸⁸ In addition, telephone lines will be installed to afford physicians and employees the opportunity to ask billing questions, or to report any aberrant billing practices or other malfeasance.¹⁸⁹ The reporting line is intended to allow the reporting employee to remain anonymous.¹⁹⁰

Compliance is obviously an expensive task to undertake. However, an effective compliance program need not be as formal or expensive as a government-imposed program. Furthermore, the time lines will be much shorter with a Government-imposed program. The best approach is to implement a compliance program before one is ordered to do so.

DRG 72-Hour Window Project

The DRG 72-Hour Window Project refers to an ongoing investigation by the OIG whereby inpatient DRG charges are cross-referenced with non-physician outpatient service charges.¹⁹¹ A False Claims Act allegation is generated if a separate bill was submitted for non-physician outpatient services which were provided in conjunction with inpatient admissions.

¹⁸⁴ *Id.*

¹⁸⁵ *Id.*

¹⁸⁶ *Id.*

¹⁸⁷ *Id.*

¹⁸⁸ *Id.*

¹⁸⁹ *Id.*

¹⁹⁰ *Id.*

¹⁹¹ 42 U.S.C. § 1395ww(a)(4) (1995) (The DRG reimbursement level for a particular service includes all services that are provided by the hospital (or by an entity wholly owned or operated by the hospital) to the patient during the three days immediately preceding the patient's admission date).

The government will assert that prior experience with false claim submission and repayment to the Government is enough to prove the "knowledge" element of a False Claims charge.¹⁹²

Allegations in hand, the Government will make a pre-trial offer to the institution that provides an incentive for settling, rather than retaining defense counsel at great expense.¹⁹³ "Hospitals will settle for nominal amounts even if they feel it's like extortion"¹⁹⁴ and "out of fear of what the Government might find if they really start digging into their record[s]."¹⁹⁵

A hospital will typically become aware that it is the target of an investigation after it receives a settlement demand letter from the DOJ. The letter would likely be addressed to a Finance Manager or Chief Financial Officer. Consider the following letter:

Dear Hospital Chief Financial Officer:

The United States Department of Health and Human Services through the Office of Inspector General has referred a matter concerning North Community Hospital to the Department of Justice for civil prosecution pursuant to the Federal False Claims Act. The matter arises from an audit by the Office of Inspector General through which it has concluded that your institution separately billed Medicare for non-physician outpatient services which were provided in conjunction with inpatient admissions and therefore were reimbursed as part of the DRG.

Through this latest review it has been determined that North Community Hospital requested and received Medicare payments, to which it was not entitled, totalling \$9,708.55 on 29 claims for non-physician outpatient services between November 1, 1990 and December 31, 1991. In addition, Medicare beneficiaries were required to pay coinsurance and deductibles for claims which your hospital should not have processed for payment. Between December 1, 1987 and October 31, 1990, you also billed Medicare for such services. For that period, there were 94 duplicate

¹⁹² BNA, *Pennsylvania Hospital Settlements Show Willingness to Ensure Proper Billing*, 5 BNA HEALTH L. REP. 331 (Feb. 7, 1996).

¹⁹³ *Id.*

¹⁹⁴ BLACK'S LAW DICTIONARY 585 (6th ed. 1990) ("The natural meaning of the word 'extort' is to obtain money or other valuable thing neither by compulsion, by actual force, or by the force of motives applied to the will, and often more overpowering and irresistible than physical force").

¹⁹⁵ BNA, *Billing Fraud, Reimbursement Among Top Medicare Legal Issues in 1996*, 5 BNA HEALTH L. REP. 165 (Feb. 1, 1996) (quoting Dennis M. Barry, Vinson & Elkins, Washington, D.C.).

claims totalling \$29,135.17.

Your hospital had filed similar duplicate claims which were identified in prior reviews covering the period October 1, 1983 through November 30, 1987, of which you should already be aware. Indeed, it is the recurring nature of this long-standing problem which in part motivates this enforcement effort. All of the amounts identified in the first three reviews have been recovered by HCFA through various processes. However, those recoveries have not extinguished the hospital's potential liability for penalties and treble damages under the False Claims Act as a result of its conduct.

Based on the above, it has been determined that your institution should be civilly prosecuted pursuant to that Act. This action will be conducted as a collaborative effort of the offices of the U.S. Attorney for your district. Successful prosecution of such a case will result in the recoupment of the remaining unrecovered payments, the assessment of treble damages, and a mandatory minimum penalty of five thousand dollars (\$5,000) per false claim. The maximum penalty per claim is \$10,000. It should be noted that the assessment of penalties is mandated by the False Claims Act and the Court may not assess a penalty less than \$5,000 per claim. The total financial exposure of your hospital arising from the claims referenced above is \$1,346,531.16. We have enclosed for your use the claim information for these two reviews. Please pay careful attention to the cover memo to this claim information, as it describes some important elements of the process.

In order to expedite and simplify this matter, we are extending to all hospitals the opportunity to settle before litigation. Any settlement at this juncture will save both your institution and the federal Government the burden and expense of litigation, and will provide the hospital an opportunity to resolve this issue on a lasting basis.

The settlement agreement which we are offering is enclosed. As you will note, it requires that your hospital implement measures to curb the submission of duplicate claims, to make a reasonable effort to repay beneficiaries the amount of copayments and deductibles that they were required to expend due to your submission of duplicate claims and to pay civil damages, through December 31, 1991, in the amount of \$58,260.82. The agreement also contains compliance measures and provisions for the

reimbursement of more recent duplicate payments, without penalties, so that this entire issue can be resolved.

If you would like to settle this case before litigation, please contact the undersigned, in writing, at the address indicated within twenty (20) days of the date of this letter. It will not be necessary at that time to enter into the final agreement. We are only seeking a good faith indication on your part that the hospital will consider settlement. When such an

indication is provided, the hospital may take an additional 30 days to sign and return the signed agreement with the initial payment. If we do not hear from you, we will assume you are not interested in a pre-filing settlement and will proceed to file the necessary legal action in the appropriate United States District Court through which we will seek the maximum recovery authorized by law.

Your prompt attention to this important matter would be appreciated.

Very Truly Yours

United States Attorney

Assistant United States Attorney

Assistant U.S. Attorney

This letter resembles a true copy of a settlement demand letter issued by the United States Department of Justice. However, the name of the hospital is changed and the fictitious name of North Community Hospital is used. Additionally, the number of false claims, the amount of total potential damages, and the settlement offer are altered from their original form.

The demand letter calls for a total settlement of \$58,260.82. Considering the cost of litigation and the total liability exposure of \$1,346,531.16, the settlement offer appears attractive. Additionally, entering into the settlement agreement avoids any extensive records investigations or subpoenas *duces tecum*. Furthermore, the parties to the settlement agreement acknowledge that, because of the volume of Medicare claims submitted and the variety of clinical circumstances to which the rule for billing outpatient services may be applicable, it is likely that erroneous claims will be submitted by the institution subsequent to the effective date of the agreement.

If an institution implements certain minimum measures pursuant to a settlement agreement, the U.S. will deem any incorrect claim submitted subsequent to the effective date of the agreement to have been

“inadvertent,” rather than submitted with “deliberate ignorance” or with “reckless disregard.” The minimum measures that the institution must implement include either appropriate computer software, manual pre-submission review, or an optional post-submission testing process.

It is unclear whether an institution will be afforded some type of “prosecutorial immunity” if it implements any of the above minimum measures *sua sponte* prior to settling a specific claim with the DOJ. Implementation of the minimum measures could buttress the argument that any erroneous claims were submitted with “negligence” or as an “innocent mistake,” as opposed to with “deliberate ignorance” or with “reckless disregard.”¹⁹⁶ That is, if the Government is unable to prove the knowledge element of a False Claims cause of action, it has “no case” notwithstanding the formal extension (or lack thereof) of any “immunity” from prosecution. Recall, however, that the typical Government settlement offer, at least in the context of the seventy-two hour window project, is “sweet” enough to extinguish any temptation to resist the allegation.

Medical Device Billing Fraud

The medical device fraud investigative effort is directed at “recouping” DRG reimbursement for procedures involving investigational cardiac devices not yet fully approved by the FDA. Generated from a *qui tam* lawsuit still under seal as of this writing, the general allegation is that 132 U.S. hospitals submitted improper bills for procedures involving the use of unapproved investigational medical devices.¹⁹⁷

The Secretary of the Department of Health and Human Services (“HHS”) issued manual provisions in July 1986 indicating that procedures calling for the use of investigational devices were not “reasonable and necessary” and were not reimbursable by Medicare.¹⁹⁸ The Government, therefore, contends that claims for these procedures constitute violations of the False Claims Act.

¹⁹⁶ Mustokoff, *supra* note 47, at 13.

¹⁹⁷ BNA, *Sutter Memorial to Pay \$1.3 Million to Settle Medical Device Fraud Charges*, 4 BNA HEALTH CARE POLY REP. 9 (Feb. 26, 1996)(citing U.S. *ex re. v. Healthwest Regional Medical Center et al.* (D.C. Wash. filed Mar. 31, 1994).

¹⁹⁸ SETTLEMENT AGREEMENT SUTTER, at 2.

It should be noted that regulations, effective November 1, 1995, set forth the process by which the FDA will assist HCFA in identifying non-experimental investigational devices that may be reimbursable under Medicare.¹⁹⁹ However, the enforcement effort focuses on the period from 1988 to 1994. Of the 132 institutions involved in the lawsuit and investigation, only Sutter Memorial Hospital of Sacramento, California has entered into a settlement agreement that dismisses it from the pending action.²⁰⁰

Obtaining a dismissal with prejudice from the pending administrative and civil proceedings, Sutter agreed to pay the United States \$1,265,487.²⁰¹ Pursuant to the settlement contract, the fine payable is not dischargeable in bankruptcy.²⁰² In addition to the monetary settlement, Sutter agreed to undertake a course of action to prevent fraud and false billing to Medicare.²⁰³ Compliance directives contained in settlement agreements of this nature, while not holding the force of law, may provide general guidance in terms of implementing compliance measures for other institutions in the industry.

The specific compliance provisions generally mandate education and training for bill submission for new and existing physicians and staff, the development and dissemination of an official institutional policy for accurate claims submission, confidential disclosure channels for employees,

and expanded the Government's inspection rights on books, records, and other company documents and supporting materials.²⁰⁴

With the applicable laws identified, and the relevant Government investigations recognized, the health care institution is appropriately

¹⁹⁹ 60 Fed. Reg. 48417 *et. seq.* (Sep. 19, 1995).

²⁰⁰ BNA, *supra* note 194.

²⁰¹ SETTLEMENT AGREEMENT SUTTER.

²⁰² *See* 11 U.S.C. § 523(a)(2), (7) (1995).

²⁰³ SETTLEMENT AGREEMENT SUTTER ("Sutter undertakes on behalf of itself and its subsidiaries to pursue the following course of action from the effective date of this Agreement to prevent fraud, abuse and false billing to Medicare by Sutter, its subsidiaries, its employees, its staff physicians, and third parties whose services are ordered, or certified as medically necessary, by Sutter personnel").

²⁰⁴ SETTLEMENT AGREEMENT SUTTER.

situated to begin designing a formal compliance program.²⁰⁵ Formal compliance programs and their application to health care entities are discussed below.

CLARIFYING CORPORATE COMPLIANCE

With regard to medical claims submission to the Government, a formal compliance program is simply a set of corporate policies that mandate institutional regulatory compliance designed in a manner to detect and prevent legal violations.²⁰⁶ The general underlying goals of a compliance program are to deter corporate internal misconduct and to provide channels for internal policing and reporting malfeasance.²⁰⁷ Indeed, the "hallmark of an effective program to prevent and detect violations of law is that the organization exercised due diligence in seeking to prevent and detect criminal conduct by its employees and other agents."²⁰⁸

The policy directives should clearly state the permissible bounds of employee conduct, and these directives should be tempered with a sensitivity for the general nature of the business and applicable industry standards.²⁰⁹ The preamble to the policy recitation should contain a general disclaiming statement that employee conduct in derogation of company policy is beyond the scope of the employee's authority.²¹⁰ Such a statement may be used as an argument against the application of

²⁰⁵ Although it is beyond the scope of this article, other industries may find corporate compliance efforts appropriate and useful. Furthermore, the health care compliance efforts discussed here are focusing on ensuring accurate claims submission. Compliance efforts directed at other laws like antitrust or environmental regulations may also be appropriate.

²⁰⁶ See Queen & Frasher, *supra* note 126, at 2.

²⁰⁷ Walsh & Pyrich, *supra* note 18, at 645.

²⁰⁸ U.S.S.G. § 8A1.2, comment (n.3(k)).

²⁰⁹ Walsh & Pyrich, *supra* note 18, at 647; Webb and Molo, *supra* note 11, at 391 (quoting Davis S. Machlowitz, *Making a Compliance Program Work: A Practical Guide*, AM. LAW., Mar. 1992, at 16 ("[W]rite policies and procedures in the style of the USA Today, not the Harvard Law Review."); Richard J. MacLaury, *Compliance Programs Under the Robinson-Patman Act and Other Antitrust Law - The Practical Effect of Such Programs or the Absence Thereof*, 37 ANTITRUST L.J. 96, 98 (_____) (stating that an effective compliance policy will be "something a salesman can read and understand").

²¹⁰ Webb and Molo, *supra* note 11, at 390 (citing Karl A. Groskaufmanis, *Corporate Compliance Programs as a Mitigating Factor*, Organizational Sentencing Guidelines 5.0811 (Jed S. Rakoff ed., 1993).

corporate liability in a civil or criminal context.²¹¹ The most important factor with respect to developing a compliance program is that the institution must be reasonably capable of enforcing its compliance policies.

A skeletal framework for the foundation of a compliance program can be derived from the Sentencing of Organizations section of the United States Sentencing Commission Guidelines Manual. Taken to an extreme, ignorance of these Guidelines by a General Counsel may constitute malpractice.²¹² In order to be operating under an “effective program,” the organization must exercise due diligence in pursuing prevention and detection of criminal conduct.²¹³ The program is not necessarily “ineffective” if it fails to prevent or detect a particular offense.²¹⁴ However, “[d]ue diligence requires the organization to take the following **types** (emphasis added) of steps:”

- The organization must have established compliance standards and procedures to be followed by its employees and other agents that are reasonably capable of reducing the prospect of criminal conduct.²¹⁵
- Specific individual(s) within high-level personnel of the organization must have been assigned overall responsibility to oversee compliance with such standards and procedures.²¹⁶
- The organization must have used due care not to delegate substantial discretionary authority to individuals whom the organization knew, or should have known through the exercise of due diligence, had a propensity to engage in illegal activities.²¹⁷

²¹¹ “In derogation of company policy” arguments are unlikely to succeed.

²¹² Webb and Molo, *supra* note 11, at 375 (citing Michele Galen, *Keeping the Long Arm of the Law at Arm's Length*, BUS WK., Apr. 22, 1991, at 104 (quoting Professor John C. Coffee of Columbia University)).

²¹³ U.S.S.G. § 8A1.2, comment (n.3(k)).

²¹⁴ *Id.*

²¹⁵ U.S.S.G. § 8A1.2, comment (n.3(k)(1)).

²¹⁶ U.S.S.G. § 8A1.2, comment (n.3(k)(2)).

²¹⁷ U.S.S.G. § 8A1.2, comment (n.3(k)(3)).

- The organization must have taken steps to communicate effectively its standards and procedures to all employees and other agents, *e.g.*, by requiring participation in training programs or by disseminating publications that explain in a practical manner what is required.²¹⁸
- The organization must have taken reasonable steps to achieve compliance with its standards, *e.g.*, by utilizing monitoring and auditing systems reasonably designed to detect criminal conduct by its employees and other agents and by having in place and publicizing a reporting system whereby employees and other agents could report criminal conduct by others within the organization without fear of retribution.²¹⁹
- The standards must have been consistently enforced through appropriate disciplinary mechanisms, including, as appropriate, discipline of individuals responsible for the failure to detect an offense. Adequate discipline of individuals responsible for an offense is a necessary component of enforcement; however, the form of discipline that will be appropriate will be case specific.²²⁰
- After an offense has been detected, the organization must have taken all reasonable steps to respond appropriately to the offense and to prevent further similar offenses -- including any necessary modifications to its program to prevent and detect violations of law.²²¹

Viewed generally, these guidelines can be categorized as either policy development and delegation of authority, education, auditing and monitoring, or reporting and discipline. An institution may wish to incorporate other specific compliance strategies in addition to those types suggested by these guidelines.²²² Several advantages and some

²¹⁸ U.S.S.G. § 8A1.2, comment (n.3(k)(4)).

²¹⁹ U.S.S.G. § 8A1.2, comment (n.3(k)(5)).

²²⁰ U.S.S.G. § 8A1.2, comment (n.3(k)(6)).

²²¹ U.S.S.G. § 8A1.2, comment (n.3(k)(7)).

²²² BNA, *HCFA Takes More Active Role in Combatting Fraudulent Claims*, 5 BNA HEALTH L. REP. 507 (Apr. 4, 1996) ("Other preventative compliance strategies health care organizations may want to incorporate include: conducting their own internal reviews or audits or employer compensation, related party costs, and billing procedures; retaining experts for accounting and medical reviews;

disadvantages exist relative to implementation of a formal compliance program. While these factors should be considered, the discussion below demonstrates that positive attributes of a program outweigh the negative considerations. It is clear from the discussion that an institution undergoing a governmental investigation will realize greater success if it has implemented an "effective compliance program."

The numerous benefits of implementing a corporate compliance program, as opposed to the steps required for development and implementation, are clear and unambiguous. As a threshold matter, the organization should realize that a self-imposed program will not contain all the harsh provisions of a government-imposed program. If the entity enters into a settlement agreement with the Government to settle a health care fraud claim, a compliance program will inevitably be a condition in the agreement unless such program is already in place.²²³

While it is hopeful that one of the benefits achieved by a compliance program is elimination of corporate wrongdoing, another significant benefit is the substantial reduction in monetary penalties that may be realized if an "effective compliance program" is in place.²²⁴ Nevertheless, if an organization is operating primarily for criminal purposes or by criminal means, the court must set a fine that is of sufficient amount "to divest the organization of all its net assets."²²⁵

If an organization is not operating primarily for criminal purposes or by criminal means, the guidelines provide a set of procedures for determining the fine.²²⁶ Generally, the court determines the base fine;²²⁷ calculates the culpability score,²²⁸ determines the fine range²²⁹ by using minimum and maximum multipliers,²³⁰ and then sets a fine within the

centralizing contract review and approval to detect improper remuneration for referrals or provision of free services; and conducting internal quality assurance reviews").

²²³ BNA, *supra* note 10, ("If a company is found to have violated fraud and abuse statutes, a 'draconian' corporate compliance plan likely will be imposed by the federal Government...").

²²⁴ See U.S.S.G. § 8C.

²²⁵ U.S.S.G. § 8C1.1.

²²⁶ U.S.S.G. § 8C2.4.

²²⁷ *Id.*

²²⁸ U.S.S.G. § 8C2.5.

²²⁹ U.S.S.G. § 8C2.7.

²³⁰ U.S.S.G. § 8C2.6.

range.²³¹

The base fine is calculated by taking the greatest of the amount from the Offense Level Fine Table,²³² the monetary gain to the organization,²³³ or the loss that was caused intentionally, knowingly, or recklessly by the organization.²³⁴ The culpability score starts with five points,²³⁵ then the score increases or decreases after the consideration of “altering factors”. Altering factors that may increase the culpability score generally include the size of the organization, the organization’s involvement in or tolerance of the activity, the historical conduct of the organization, whether the entity violated a court order, and whether the institution obstructed justice.²³⁶ An altering factor that will decrease the culpability score is the presence of an effective compliance program.²³⁷ If the organization has an effective program in place, three points may be subtracted from the culpability score.²³⁸

After determining the culpability score, the court determines the fine range by multiplying the base fine by the maximum and minimum multipliers. Finally, a fine is selected within the fine range based upon various factors that generally attempt to pinpoint the seriousness of the offense within the applicable range.²³⁹

A practical example best demonstrates the reducing effect that an effective compliance program can have on criminal fines. Consider again North Community Hospital (NCH). Without considering the relevant offense, assume that NCH has been convicted of an offense that has an “Offense Level” of 25. The applicable fine for an “Offense Level” of 25 is \$2,800,000. If the starting “Culpability Score” is 5, and no aggravating or mitigating circumstance applies, then the “Minimum Multiplier” is one and the “Maximum Multiplier” is two. Therefore, the fine range is from \$2,800,000 to \$5,600,000. However, if NCH had an “effective compliance

²³¹ U.S.S.G. § 8C2.8.

²³² U.S.S.G. § 8C2.4(a)(1),(d).

²³³ U.S.S.G. § 8C2.4(a)(2).

²³⁴ U.S.S.G. § 8C2.4(a)(3).

²³⁵ U.S.S.G. § 8C2.5(a).

²³⁶ U.S.S.G. § 8C2.5(b)-(e).

²³⁷ U.S.S.G. § 8C2.5(f).

²³⁸ *Id.*

²³⁹ U.S.S.G. § 8C2.8(a)(1)-(10).

program” in place, then the “culpability score” is reduced to two, the “Minimum Multiplier” is four, and the “Maximum Multiplier” is eight. With the compliance program, the applicable fine range is from \$1,120,000 to \$2,240,000. Therefore, if NCH had an “effective compliance program” in place, it would realize a fine *reduction* ranging from \$1,680,000 to \$3,360,000.

As stated previously, the Government may not seek criminal prosecution due to the ease with which it can bring a claim under the Civil False Claims Act. However, under the False Claims Act, a compliance program does not help reduce criminal fines. Nevertheless, several other valuable benefits may accrue to the organization as a result of the implementation of an effective compliance program.

The most successful compliance programs will undermine the ability of employees to bring claims under the False Claims Act as *qui tam* relators. An effective compliance program requires “publicizing a reporting system whereby employees and other agents could report criminal conduct.”²⁴⁰ An employee may therefore feel compelled to comply with company policy and bring any perceived misconduct to the attention of the management before the questioned conduct is reported to the Government. By implementing a compliance program, the *qui tam* plaintiff will be unable to “claim the moral high ground by asserting that [his] employer [was] ... indifferent to quality control.”²⁴¹

Moreover, while the aim of the compliance program might be to avoid fraudulent submission of Part A Medicare claims, implementation may create a heightened employee awareness of the billing process that can result in realizing economies of scale or other efficiencies. The heightened awareness of the billing process can result in general cost savings and possibly prompt realization of practices that result in actual under-billing. The educational and reporting mechanisms may provide a system by which management and staff can communicate with each other and respond quickly to lawsuits and investigations.²⁴² Furthermore, the development of a corporate compliance program may promote a positive corporate image

²⁴⁰ U.S.S.G. § 8A1.2, comment (n.3(k)(5)).

²⁴¹ Queen & Frasher, *supra* note 126, at 25.

²⁴² Webb & Molo, *supra* note 11, at 377.

in the eyes of the general public, potential donors, and bondholders.²⁴³

Disadvantage of Program Implementation

If there are negative implications associated with developing a compliance program, they pale in comparison to the numerous benefits that should accrue. There are two primary disadvantages associated with implementing a compliance program.²⁴⁴

The first disadvantage is that a compliance program may actually encourage a prosecutor to bring a criminal or civil action under certain circumstances. For instance, the presence of a compliance policy that is not fully implemented or enforced can be deadly. The program's parameters may provide a benchmark against which a prosecutor will argue that a corporation was "reckless" by not enforcing its own compliance program. The prosecutor in a Civil False Claims action might argue that an entity had "knowledge" that it was filing false claims *because* it had a compliance program. That is, if it were not filing false claims, it would not have developed a policy to combat the problem.²⁴⁵ The plan will either be deemed "non-effective" at sentencing, or will be used by the prosecutor as evidence that a standard was not met.²⁴⁶ The second disadvantage is the possibility that damaging evidence will be generated over the course of developing a compliance program. Despite the possible negative implications of implementation, the "better course of action" is to develop and enforce an "effective compliance program."²⁴⁷

²⁴³ *Id.* ("[T]he dissemination of a positive corporate ethos that deters misconduct ultimately saves a company money").

²⁴⁴ *Yates v. Avco Corp.*, 819 F.2d 630, 636 (6th Cir. 1987) (concluding that sexual harassment was foreseeable, the court noted that had it not been, Avco would not have had a policy attempting to deal with it).

²⁴⁵ Dan K. Webb et al., CORPORATE INTERNAL INVESTIGATIONS §16.04[1], at 16-11 (citing *Principles of Federal Prosecution*, at 9-27.110).

²⁴⁶ *Id.* § 16.04[1][a] ("Factors considered in determining whether a substantial federal interest would be served include: Federal law enforcement priorities, the nature and seriousness of the offense, the deterrent effect of prosecution, the corporation's culpability in connection with the offense, the entity's history of criminal activity, the corporation's level of cooperation in the Government's prosecution, and the likely sentence or other consequences if the person is convicted").

²⁴⁷ *Id.* §16.04[1][b] (discussing in what jurisdiction the defendant is most likely to be appropriately punished).

PROGRAM DEVELOPMENT

The steps required for development of an “effective compliance program” can be brief, confusing and ambiguous. The precise actions necessary for an effective compliance program vary depending on the size of the organization, the likelihood that certain offenses may occur because of the nature of the business, and the history of the organization.²⁴⁸ The entity should have in place a general two-step process in which to create a program to prevent and detect violations of the law. The general two-step process should be conducted pursuant to a board resolution or a directive from senior management.²⁴⁹ The first general step in the process is conducting a “preliminary compliance program review.”²⁵⁰ The second general step is the development and implementation of the plan.

The Preliminary Compliance Program Review

The purpose of conducting a preliminary compliance program review (hereinafter “audit”) is to gauge current compliance with the law, identify areas that are ripe for change, and to estimate current liability exposure. The preliminary audit should be defined in terms of scope, who will oversee the audit, what areas will be audited, and what mechanisms will be applied to ensure application of the attorney-client privilege and the attorney work product doctrine.²⁵¹ The general nature of the audit should be with an eye toward complying with the law in the future, as opposed to excavating the past in an attempt to uncover fraudulent practices.

The scope of the audit, who will oversee the audit, and who will be audited will fluctuate depending on which practices of the organization are analyzed. Furthermore, the specific laws that the compliance program will address will effect the nature of the audit. The most important aspect of conducting the preliminary audit is ensuring that an attorney-client privilege is preserved or that the protection of the work product doctrine

²⁴⁸ *Id.* § 16.04[1][c].

²⁴⁹ Walsh & Pyrich, *supra* note 18, at 670 (citing 21 ENVTL. L. REP. 35, 399 (July 1, 1991)).

²⁵⁰ *Id.* at 671.

²⁵¹ 48 C.F.R. § 203.7001 (1995).

is available. The organization may also attempt to invoke the "self-evaluative" privilege. However, the "self-evaluative" privilege has not survived Government's attempts to obtain internal audit reports.²⁵²

The general rule for the attachment of an attorney-client privilege is that confidential communications are privileged if they are made in confidence, between a client or potential client and a lawyer, and are made for the purpose of obtaining legal advice.²⁵³ The work product doctrine protects against the disclosure of an attorney's mental impressions made in anticipation of litigation.²⁵⁴

In terms of conducting a preliminary internal review, general counsel or outside counsel should generally oversee the audit to maximize the potential for full employee disclosure.²⁵⁵ Both inside and outside counsel may direct the audit in such a manner that maximizes the protection of the attorney-client privilege. Inside counsel may be more sensitive to peculiarities of the institution in terms of conducting business, whereas outside counsel may be in a position to render valuable advice based on its experience with corporate compliance. While cost may also be an issue, outside counsel should be used if possible to eliminate the Government's

argument that inside counsel rendered unprotected business advice, as opposed to protected legal advice.

In formulating a preliminary review plan, counsel may wish to retain the services of an independent audit consultant. Communications between the client and an agent of the attorney will be protected if all requirements for the privilege are satisfied and the agent was necessary or beneficial to

²⁵² Dan K. Webb et al., *supra* note 244, at 16-25.

²⁵³ *Id.*

²⁵⁴ See discussion, *supra* p. 4.

²⁵⁵ *United States v. Hilton Hotel Corp.*, 467 F.2d 1000, 1007 (9th Cir. 1972), *cert. denied*, (holding the corporation criminally liable for the actions of a low-level employee despite the fact that the employee's conduct was generally and specifically prohibited by the corporation) 409 U.S. 1125 (1973); *But cf. Holland Furnace Co. v. United States*, 158 F.2d 2, 8 (6th Cir. 1946) (holding that the company was not criminally liable for its salesman's violation of a War Production Board order because it "would carry corporate responsibility beyond the holding in any case which has been cited and beyond the boundary to which we think corporate criminal responsibility should be carried").

the attorney in rendering legal advice.²⁵⁶ Indeed, the audit consultant may possess unique intelligence relative to industry practice, an item which must be considered under the Sentencing Guidelines.²⁵⁷ Therefore, communications made between an independent auditor and counsel are protectable under the attorney-client privilege.

However, if an independent consultant is used in the preliminary review phase, they should not be retained to assist in the prospective implementation phase of the compliance effort. If the consultant was retained to assist in all aspects of the development of the program, then an organization would be seeking unprotected accounting or consulting advice, as opposed to protected legal advice, potentially leaving the audit or audit findings unprotected.²⁵⁸

In terms of conducting the preliminary review, it is recommended that organization abstain from documenting or memorializing findings. If an organization insists on conducting a formal review, the guidelines below should be followed:

- A memo should be created that requests legal advice.
- Employees should be notified in writing that counsel will contact them.
- An attorney should generally supervise all phases of the audit.
- Experts or investigators should report to counsel for direction and

²⁵⁶ Walsh & Pyrich, *supra* note 18, at 664-665 (citing Robert E. Bloch, *Compliance Programs and Criminal Antitrust Litigation: A Prosecutor's Perspective*, 57 ANTITRUST L. J. 223, 226 (1988) ("The basic question is whether the existence of a corporate compliance program is legally relevant in determining corporate liability. In my judgment, the answer is no"); John H. Shenefield & Richard J. Favertto, *Compliance Programs as Viewed from the Antitrust Division*, 48 ANTITRUST L. J. 73, 79 (1979) ("The existence of a corporate compliance program is, as a matter of law, irrelevant...").

²⁵⁷ FED R. EVID. 401.

²⁵⁸ *Hanlester Network v. Shalala*, 51 F.3d 1390, 1400 (19__) (citing *United States v. Beusch*, 596 F.2d 871, 877-878 (19__) ("Merely stating or publishing instructions and policies without diligently enforcing them is not enough to place the acts of an employee who violates them outside the scope of his employment"); *United States v. Basic Constr. Co.*, 711 F.2d 570, 573 (19__), *cert. denied*, 464 U.S. 956 (1983) (holding that the trial court properly allowed the jury to consider Basic Construction's antitrust compliance policy for the purpose of determining whether the employees were acting for the benefit of the corporation).

oversight.

- Mark all documents “Privileged and Confidential - Attorney Work Product/Attorney-Client privileged.”
- A separate file should be maintained by the attorney.
- Reports from witness interviews should only contain the mental impressions of the attorney as opposed to witness quotes.
- Reports to management should be presented as legal advice.²⁵⁹

In the course of conducting the preliminary review, it is likely that instances of malfeasance or misconduct will be uncovered. Therefore, an issue arises with respect to whether the institution should simply correct the errant conduct or should fully disclose the discovery to the Government.

Voluntary Disclosure

The issue of whether a health care entity should voluntarily disclose any discovered misconduct arises frequently. The issue does not easily lend itself to the application of a consistent, general rule. Each discovery should be evaluated by counsel and the disclosure decision should be made on a case-by-case basis.

If a health care entity discovers that it has been submitting “false” claims for payment to the Government it could face penalties of up to \$10,000 per claim plus three times the amount of damages which the Government sustains.²⁶⁰ However, if the entity furnishes Government officials with all relevant information within thirty days of discovery, fully cooperates with any Government investigation, and no prosecution or investigation has commenced against the entity, the potential penalties are reduced down to as little as double damages.²⁶¹ In addition to its potential

²⁵⁹ Walsh & Pyrich, *supra* note 18, at 666 n. 259.

²⁶⁰ Webb & Molo, *supra* note 11, at 379.

²⁶¹ *Id.*

penalty reducing function under the False Claims Act, voluntary disclosure may have a fine reducing effect under the Federal Sentencing Guidelines.

Under the Guidelines, if the organization “(A) prior to an imminent threat of disclosure or Government investigation; and (B) within a reasonably prompt time after becoming aware of the offense, reported the offense to appropriate Governmental authorities, fully cooperated in the investigation, and clearly demonstrated recognition and affirmative acceptance of responsibility for its criminal conduct,” then five points are subtracted from the culpability score.²⁶²

In the example above, North Community Hospital (NCH) realized a significant reduction in criminal fines because of the existence and operation of its compliance program. Recall that NCH had already been convicted of an offense with an “Offense Level” of twenty-five, and a “Culpability Score” of five. Also recall that an “Offense Level” of twenty-five carries with it a “Base Fine” of \$2,800,000. The fine range for an offense with an “Offense Level” of twenty-five and a “Culpability Score” of 5 is \$2,800,000 to \$5,600,000. If NCH had discovered and properly disclosed the misconduct to the Government, it could have reduced its “Culpability Score” to zero. The “Minimum Multiplier” would have been reduced to .05 and the “Maximum Multiplier” would have been reduced to point twenty. Assuming proper voluntarily disclosure, the fine range would be between \$140,000 and \$560,000. Therefore, with voluntary disclosure, NCH could realize a fine reduction ranging from \$2,660,000 to \$5,040,000.

In addition to providing a penalty reducing effect, voluntary disclosure plays into the exercise of prosecutorial discretion. Voluntary disclosure of misconduct may significantly influence a prosecutor not to indict.²⁶³ Furthermore, defense contractors have experienced great success

²⁶² *Id.*

²⁶³ U.S.S.G. § 8A1.2, comment (n.3(k)(i)-(iii)) (“Among the relevant factors are: (i) Size of the organization – The requisite degree of formality of a program to prevent and detect violations of law will vary with the size of the organization: the larger the organization, the more formal the program typically should be. A larger organization generally should have established written policies defining the standards and procedures to be followed by its employees and other agents; (ii) Likelihood that certain offenses may occur because of the nature of its business – If because of the nature of an organization’s business there is a substantial risk that certain types of offenses may occur, management must have taken steps to prevent and detect those types of offenses. For example, if an organization

under the Department of Defense Voluntary Disclosure Program.²⁶⁴

In 1989, seventy-three companies disclosed 164 instances of criminal conduct. Of the 164 instances, only nine were prosecuted with eight being instances in which the Government had evidence of malfeasance prior to disclosure.²⁶⁵ Currently, there is no voluntary disclosure program in place for hospitals that resembles the Department of Defense program. However, the HHS Inspector General, has expressed an interest in developing a similar disclosure program to the one she established while she was the Defense Department Inspector General.²⁶⁵

The incentive to voluntarily disclose is significant at least in terms of a monetary reduction in penalties. Furthermore, prosecutorial discretion provides an incentive to voluntarily disclose. However, each disclosure should be considered carefully by counsel on a case-by-case basis prior to making any disclosures to the Government. Having conducted a preliminary review and having assessed any voluntary disclosure possibilities, the organization is ready to prospectively address the

handles toxic substances, it must have established standards and procedures designed to ensure that those substances are properly handled at all times. If an organization employs sales personnel who have flexibility in setting prices, it must have established standards and procedures designed to ensure that those substances are properly handled at all times. If an organization employs sales personnel who have flexibility in setting prices, it must have established standards and procedures designed to prevent and detect price-fixing. If an organization employs sales personnel who have flexibility to represent the material characteristics of a product, it must have established standards and procedures designed to prevent fraud; (iii) Prior history of the organization – An organization's prior history may indicate types of offenses that it should have taken actions to prevent. Recurrence of misconduct similar to the which an organization has previously committed casts doubt on whether it took all reasonable steps to prevent such misconduct.

An organization's failure to incorporate and follow applicable industry practice or the standards called for by any applicable governmental regulation weighs against a finding of an effective program to prevent and detect violations of law").

²⁶⁴ Queen & Frasher, *supra* note 126, at 33 ("A board resolution...documents the date on which your organization committed itself to creating a comprehensive compliance program....[I]f your organization is implicated in wrongdoing before completion to the program, you can at least argue that your good intentions were not merely in response to Government's investigation. The resolution is the first step in extending the attorney-client privilege to the entire process of compliance program design. The resolution should expressly identify the purpose of the legal representation as securing legal advice for use in creation and implementation of a corporate compliance program").

²⁶⁵ Antitrust Risks and Compliance Procedures, MATERIALS ON ANTITRUST COMPLIANCE 1994 § 1.019 (1994) (offering that the term "preliminary compliance program review be used as opposed to the term "audit").

²⁶⁶ Queen & Frasher, *supra* note 126, at 41.

installation and application of its compliance program.

Considerations for Program Implementation

The directive from senior management or the board resolution to develop a compliance program should have provided for the assembly of a duly qualified "compliance committee." Counsel should be present at all meetings of the committee to ensure that the committee is creating an "effective compliance program" and to "render legal advice." In addition, counsel should apprise the committee of ongoing developments in the law, respond to specific legal questions from the committee, respond to reports of program violations, and assess voluntary disclosure if misconduct is discovered. All members of the committee should consider the peculiarities of the health care industry as the program is developed. That is, while the Sentencing Guidelines provide a framework for development of the program, they were not designed with health care institutions in mind.

In the context of claims submission, the individual chairing the committee should preferably be a physician that serves a dual medical/management role. This type of chairperson fully understands the business environment in which the hospital operates as well as the route of the medical chart from patient visit to claim submission. Depending on the size of the committee, the organization may wish to promulgate its compliance plan utilizing sub-committees. The committee should at least address policy development and delegation of authority, education, auditing and monitoring, and prevention, reporting and discipline.

Counsel should generally abstain from involvement in the development of written policies, except for legal review and analysis. For example, counsel is probably not qualified to develop a policy for what constitutes a "key portion" of a medical procedure. Additionally, as a counsel's role becomes more of a management role and less of a legal advisor, any attorney-client privilege may be jeopardized. When an attorney is rendering both legal and business advice, courts will extend the privilege if legal advice was the predominant aspect of the

communication.²⁶⁷

Policy Development and Delegation of Authority

The Federal Sentencing Guidelines charge that compliance standards and procedures be developed that are “reasonably capable of reducing the prospect of criminal conduct.”²⁶⁸ The policies developed by the committee or sub-committee must be narrowly-tailored to specifically identified problem areas in order to be capable of reducing the possibility of legal violations. The phrase “[i]t is the policy of this hospital to ensure that all claims submitted to the Government for payment will comply with all laws and regulations” is probably insufficient to satisfy the requirement. However, in the context of the “physical presence” requirement, it is probably sufficient to implement a policy that “all teaching physicians submitting part B claims to Medicare for services in which a resident assisted in the provision of the service must be physically present during the key portion of the procedure.”

In terms of policy oversight, “high-level” personnel of the organization must be assigned supervisory responsibility.²⁶⁹ “High-level personnel of the organization” includes a director, an executive officer, an individual in charge of a major business or functional unit of the organization, such as sales, administration, or finance.”²⁷⁰ Effectively, this means that oversight may be the responsibility of anyone who has the

authority and ability to exercise substantial control over a particular function.

In terms of compliance with claims submission rules, oversight should be the responsibility of high level personnel within a medical records division. Documentation is a key factor in submitting an accurate claim to

²⁶⁷ Thomas W. Hyland and Molly Hood Craig, *Attorney-Client Privilege and Work Product Doctrine in the Corporate Setting*, DEF. COUNS. J., Oct. 1995, at 561 (citing Vincent C. Alexander, *The Corporate Attorney-Client Privilege: A Study of the Participants*, 63 ST. JOHN'S L. REV. 191, 338, n.490-491 (1989)).

²⁶⁸ U.S.S.G. § 8A1.2, comment (n.3(k)(1)).

²⁶⁹ U.S.S.G. § 8A1.2, comment (n.3(k)(2)).

²⁷⁰ U.S.S.G. § 8A1.2, comment (n.3(k)(b)), § 8C2.5, comment (n.3).

the Government, and medical records personnel will best understand the path of a medical chart and its notations.

In terms of screening current and prospective employees and agents, the organization must exercise due care in delegating substantial authority to individuals who have a propensity to engage in illegal activities.²⁷¹ This guideline requires at a minimum that the institution conduct background checks of individuals who will exercise substantial authority. In the context of claims submission, this group would likely include all high-level managers in departments related to billing, physicians and any other employee or agent involved in submitting a bill to the Government for payment.

In the health care context, the classification of individuals who are delegated substantial authority likely includes third-party billing consultants. Third-party billing consultants that are compensated based on a percentage of revenues or revenue increases should be eliminated from an institution's claims submission process. At the very least, compensation paid to billing consultants should reflect an hourly rate or an appropriate flat fee. If the billing consultant is compensated based on a percentage of revenue from Medicare Claims, it is likely that the consultant would have the "propensity to engage in illegal activity" by "gaming" the Medicare reimbursement system.²⁷²

Removing third party billing consultants from the submission process is also consistent with the overall compliance charge of exercising "due diligence in seeking to prevent and detect criminal conduct" by employees and other agents." While billing consultants may be extremely proficient in maximizing reimbursement on behalf of health care organizations, they also may attract the attention of Government investigators or prosecutors. Metzinger Associates, a New Jersey-based billing consultant, was charged with causing over 180 hospitals in 17 different states to submit false claims. Following an investigation of Metzinger, the Government announced its intention to analyze each client-hospital's billing practices to ensure

²⁷¹ U.S.S.G. § 8A1.2, comment (n.3(k)(3)).

²⁷² Eugene W. Lorenz and Marleeta K. Jones, *ST. ANTHONY'S DRG GUIDEBOOK 1996*, at V (stating that billing consultants are likely to exhibit practices consistent with the book's "Keys to a Financially Successful DRG Program" which include decreasing the length of stay, decreasing resource utilization, discharging a patient "early," and increasing the number of pre-admission tests).

compliance with the law,²⁷³ suggesting that if the hospitals implemented a policy to internalize all claim submission procedures, the Government investigators would not be paying a visit.

Education

“Education requires that the organization must have taken steps to communicate effectively its standards and procedures to all employees and other agents[.]”²⁷⁴ It can be reasoned that “communicate effectively” means requiring attendance at all educational sessions and disseminating publications that explain compliance requirements in a practical manner.²⁷⁵ Put simply, education should accomplish the goal of notifying and explaining how the new policies function and how they will be implemented.

New and existing employees should be required to attend an educational seminar. If an individual fails to satisfy the attendance requirement within the time period (with reasonable opportunities to attend), they should be required to fund the training at their own expense and on their own time. If the attendance requirement is not satisfied within a required time, billing privileges should be suspended. Recall that part of the requirement for an “effective compliance program” is that it is “reasonably enforced.” Requiring attendance with graduated penalties for failure to attend should ensure full attendance by all those whose attendance is required.

The key to a successful educational program is to implement a uniform, systematic, institution-wide training course. Piecemeal, sporadic, informal “meetings” will likely be insufficient in terms of satisfying the “due diligence” requirement.

Auditing and Monitoring

²⁷³ Mustokoff, *supra* note 47, at 14.

²⁷⁴ U.S.S.G. § 8A1.2, comment (n.3(k)(4)).

²⁷⁵ *Id.*

In the context of claims submission compliance efforts, auditing and monitoring represent what is likely the most costly component since hiring or retaining new personnel to conduct these new functions will likely be a necessity. However, centralizing all billing functions may facilitate periodic reviews of claim submissions. In doing so, economies of scale may be realized that result in cost savings to “subsidize” the additional labor expenses.

In terms of reviewing physician billing practice patterns, the CPUP settlement offers mechanical guidance. The compliance effort at CPUP calls for an annual review of physicians' billing practices for outpatient services. Each year, a sampling of every physician's charts will be reviewed for billing compliance. The results of the review will be shared with the physician and the physician's department chair. It should be noted that the feedback at this stage also serves to satisfy the educational requirement of the previous section.

If a physician is not found to be in full compliance on the first review, additional review will be necessary where more charts are analyzed. If after the second review it is determined the physician is in full compliance, then the physician is reviewed again in ninety days after having some proscribed educational counseling. If the physician is not in compliance after this expanded review, then the physician must undergo a concurrent review. Concurrent review requires a review of every bill submitted for payment for a period of thirty days and then until the physician is in compliance for ten days. After completion of concurrent review, a follow-up will be conducted after a ninety day period. While concurrent review is a costly proposition, the expense is borne by the monitored physician.

Although not absolutely necessary, institutions should also consider retaining an outside auditor to conduct an annual or bi-annual review to ensure claims submission compliance. Claims that are submitted are the pinnacle of a compliance program. The claim is what the Government will review before deciding which entities to investigate and prosecute. Auditors need to recognize what the Government looks for in deciding who should be investigated. Some red flags might be a physician who bills Medicare every day of the calendar year, a physician who submitted bills while on vacation, or a physician who consistently bills at a level that is high in complexity. An organization contemplating compliance may also

wish to consider the possibility of a post-submission testing process.

Prevention, Reporting Misconduct, and Discipline

Under the guidelines, an “effective compliance program” must include a publicized “reporting system whereby employees and other agents could report criminal conduct by others within the organization without fear of retribution.” If auditing and monitoring represents the most daunting task, this is perhaps the simplest. All that is necessary is designating a phone line as the “reporting” line and publicizing its existence to employees. It is also recommended that a separate phone line be dedicated to answering billing questions that may arise.

In terms of reporting misconduct, the legal office is perhaps best positioned to monitor the phone line. An organization will want a quick legal review of the reported information to determine if a significant legal problem exists. The individual reporting should have the choice of remaining anonymous, or of disclosing his or her identity. If an individual has specific billing questions, the finance department or a unit of finance is probably best situated to competently answer complex procedural questions.

In order to properly function, the compliance program must have teeth. The guidelines require that “standards must have been consistently enforced through appropriate disciplinary mechanisms.”²⁷⁶ An institution should guard against limiting disciplinary actions in terms of their character. For example, only using the threat of revocation or suspension of staff privileges as potential punishments is probably insufficient. A minor billing error should not, and would not, result in a physician being stripped of his or her livelihood. Minor billing errors, however, should not

go unpunished. The punishment simply needs to be tempered and structured to fit the offense.

CONCLUSION

²⁷⁶ U.S.S.G. § 8A1.2, comment (n.3(k)(6)).

Notwithstanding its budgetary constraints, the Federal Government is aggressively pursuing health care fraud cases. In its program, the Government has selected the Civil False Claims Act as its weapon of choice. As investigations and prosecutions proliferate, a health care entity can best protect itself by developing and implementing a corporate compliance program.

Influencing entities to engage in compliance efforts should represent a valued public policy. However, the lack of clarity embodied in the Federal Sentencing Guidelines will represent a barrier to compliance participation. It is imperative that the DOJ, the HCFA, and the OIG coordinate, develop, and issue an enforcement policy statement. The statement should include the minimum necessary steps for a health care compliance program.

An official position announced by the Government would provide an incentive for entities to develop formal compliance programs. Subsequent to issuing policy statements in the past, the Government has experienced success with defense Contractors and entities attempting to comply with environmental regulations.