

A Forensic Accountant's Guide to the Most Potent Federal Laws Used Against Healthcare Fraud

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Introduction

Healthcare expenses in the U.S. are estimated to grow at an average annual rate of 5.4 percent for 2019-28 and reach \$6.2 trillion by 2028 (CMMS, 2020). In 2018, Americans spent \$3.65 trillion on health care, or about \$10,750 per person (Persinos, 2019). That represents an increase of 4.4 percent over 2017 (Persinos, 2019). Price growth for medical goods and services is projected to accelerate, averaging 2.4 percent per year for 2019–28 (CMMS, 2020). Given this explosion in healthcare spending, it is no surprise that fraudsters view healthcare as a lucrative field for illegal activity. The Federal Bureau of Investigation (FBI) states that the costs associated with healthcare fraud amount to tens of billions of dollars a year (DOJ, 2018a), and these costs are estimated to increase in future years as people live longer (FBI, 2012). In 2016, the U.S. Government Accountability Office (GAO) found that although there have been convictions for multimillion dollar schemes that defrauded the federal healthcare system, there are no reliable estimates of the magnitude of fraud across the various federal programs and the healthcare industry overall (GAO, 2016). An important factor causing unreliable estimates is that healthcare fraud in America exists in a complex environment made up of many schemes committed by different groups of fraudsters (Flasher and Lamboy-Ruiz, 2017).

Due to the troublesome increase in healthcare fraud, the U.S. federal government has stepped up its efforts to combat it. For example, Medicare Fraud Strike Forces (“Strike Forces”) have been in action for over ten years. These Strike Forces are modeled on a cross-agency collaborative approach to investigations and resources, including a partnering of the FBI, the Department of Health and Human Services’ Office of Inspector General (“HHS-OIG”), the Centers for Medicare and Medicaid Services (“CMS”), the Center for Program Integrity (“CPI”), U.S. Attorney’s offices, law enforcement agencies, and sometimes the Drug Enforcement Agency (“DEA”) and Internal Revenue Service (“IRS”)(DOJ, 2018b). Another example of the federal government’s anti-fraud effort is the increased budget for the Healthcare Fraud and Abuse Control Program. The 2018 budget was increased to \$2.1 billion in total mandatory and discretionary investments, \$152 million more than was allocated for fiscal year 2017 (HHS, 2017). While the FBI is the primary investigative agency in the fight against healthcare fraud, it coordinates its efforts with HHS-OIG, the DEA, the IRS’s Criminal Investigation Division, and various state and local agencies (FBI, 2012).

According to the DOJ, in fiscal year 2019, the department obtained more than \$3 billion in settlements and judgments from civil cases involving fraud and false claims against the government (DOJ, 2020). Despite the government’s continued efforts to combat healthcare fraud in the last few years, the threat remains high. This threat is evidenced by record-setting dollar amounts in recent healthcare fraud scheme takedowns, including opioid-related schemes (DOJ, 2018c). As an example, on April 9, 2019, the FBI, HHS-OIG, and DOJ dismantled one of the largest healthcare frauds in U.S. history (DOJ, 2019). The investigation resulted in charges against 24 individuals, including CEOs, COOs, three licensed medical professionals, employees of five telemedicine companies, and owners of durable medical equipment companies (DOJ, 2019). The schemes centered on over-prescription of medically unnecessary back, shoulder, wrist and knee braces (DOJ, 2019). Purportedly, an international telemarketing network with call centers located in the Philippines and Latin America would reach out to Medicare patients and convince the patients to get free or low-cost braces (DOJ, 2019). Sometimes doctors would write prescriptions without even speaking to the patient (DOJ, 2019). Overall, the schemes resulted in more than \$1.2 billion in losses (DOJ, 2019). The proceeds of these schemes were allegedly laundered through shell corporations and used to purchase luxury automobiles, yachts, and real estate both in the U.S. and abroad (DOJ, 2019).

Healthcare fraud impacts both the public and private sectors. The costs of healthcare fraud are borne by all Americans: (1) insurance policyholders who have to pay higher premiums and out-of-pocket expenses as well as reduced benefits and coverage; (2) businesses that have to pay more to purchase healthcare for their employees; and (3) taxpayers who have to pay more to cover healthcare expenditures in public health plans. Healthcare fraud results in not just monetary losses but hampers the healthcare delivery system diminishing the resources available for legitimate healthcare needs (Ahadiat and Gomaa, 2018).

To detect and combat healthcare fraud, one must comprehend the laws available to counter healthcare fraud schemes (VanCapelleven et al., 2016). The fight against healthcare fraud involves the use of both civil and criminal laws. The federal legal framework creates incentives for the DOJ to favor civil actions rather than criminal prosecutions. Financial recoveries (damages) in healthcare fraud cases are often higher in civil actions than criminal cases (Grioux, 2018; Nalven, 1994). Also, in civil cases, “a preponderance of the evidence” is a lower standard of proof than “beyond a reasonable doubt” in criminal cases.

Forensic accountants, federal and state healthcare investigators, hospital administrators, regulators, and others who investigate healthcare fraud must have a basic understanding of the federal laws that serve as the groundwork for healthcare civil and criminal lawsuits. Without a basic knowledge of these laws, any healthcare fraud investigation is an exercise in futility. The forensic accountant or investigator must know what evidence to collect or seek to help prove in a court of law each and every element of a specified health care offense. The research question this article analyzes is what do healthcare forensic accountants, investigators, law enforcement personnel, regulators, hospital administrators, and health insurance personnel (especially claims adjusters) need to know about federal healthcare fraud laws to help combat the rising epidemic of this type of fraud? Hence, the purpose of this article is to examine the most prominent federal civil and criminal healthcare laws to educate healthcare forensic accountants and others with the knowledge necessary to help combat fraud in the healthcare arena.

The article is divided into three major sections. The first section focuses on federal civil laws used to combat healthcare fraud. The focus in the first section is on the Federal False Claims Act (FCA), the law which has resulted in the largest healthcare fraud recoveries. The civil law section also discusses the Affordable Care Act, and the Stark law. The second major section addresses federal criminal laws utilized to fight healthcare fraud. This section evaluates a statute that prohibits false statements to obtain healthcare benefits, the Anti-Kickback statute, the Health Insurance Portability and Accountability Act (HIPAA), and the mail and wire fraud statutes. The third section discusses common law actions that can be used by both government and private healthcare insurance programs against fraudsters. The last section concludes the article.

Civil Laws

Federal False Claims Act—The Most Significant Federal Law to Combat Healthcare Fraud

The Federal False Claims Act (FCA)¹ was originally enacted in 1863 to protect the federal government from fraud perpetrated by unscrupulous Civil War contractors. Today the law is aimed at those responsible for the \$100 billion or more in fraudulent activity diverted every year from the federal healthcare, defense, and other programs (Crain et al., 2015). “In addition to ... monetary losses, fraud also ... erodes public confidence and raises questions about the government’s ability to manage its programs” (Phelps, 1999).

Today the FCA has become the primary law used to pursue healthcare fraud. The current version of the FCA makes liable “[a]ny person who ... knowingly presents or causes to be presented ... a false or fraudulent claim [to the US government] for payment or approval.”² The law also imposes liability for making “false record[s] or statement[s]

¹ 31 U.S.C. §§3729-3733 (2018).

² 31 U.S.C. §3729(a)(1)(2018).

³ §3729 (a)(2)(2018). Sections 3729(a)(1) and (2) are the most frequently used provisions of the FCA. Section 3729(a) states in relevant part: Any person who-

- (A) Knowingly presents, or causes to be presented, ... a false or fraudulent claim for payment or approval;
- (B) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
- (C) Conspires to commit a violation of subparagraph (A), (B), (C), (D), (E), (F), or (G);

[designed] to conceal, avoid, or decrease an obligation to pay or transmit money or property to the [United States] government.”³

Many FCA violations involve submission of false information while presenting payments to the federal government. One instance of a false claim happened in *U.S. v. Merck-Medco Managed Care, LLC*⁴ in which plaintiffs alleged Medco made false statements, cancelled or destroyed mail order prescriptions to avoid paying penalties for delays in filling orders, created false records showing that doctors had been contacted to discuss issues (when no contacts occurred), billed the federal government for prescriptions not authorized by law, and fraudulently induced physicians to authorize drug switches. The Eastern District of Pennsylvania federal court held that there was sufficient potential harm to the U.S. to support an FCA claim. Another example of a false health care claim occurred in *U.S. v. Cabrera-Diaz*⁵, where Dr. Manuel Cabrera-Diaz and his secretary, Esther Arbona, filed overpayment claims for anesthesia services for \$237,000 and \$211,000 in 1994 and 1995, respectively, under Medicare Part B. The federal district court in Puerto Rico ruled that an audit revealed 455 of 461 claims were overstated, falsely reported, or undocumented, demonstrated that the physician and billing secretary had knowledge of the falsity of the claims, treble damages would be assessed, the physician and secretary were jointly liable, and default judgment was entered.

One feature which makes the FCA such a powerful enforcement tool against healthcare fraud is the *qui tam* legal action or lawsuit. This feature or legal provision allows private citizens to file civil fraud claims or cases against alleged fraudsters on behalf of the U.S. government (*Black's Law Dictionary*, 1999). In 2019, 633 *qui tam* lawsuits were filed (DOJ, 2020).

A *qui tam* plaintiff, also called a *qui tam* relator or a whistleblower, is a private citizen who files a civil lawsuit against an alleged fraudster, in the role of a private attorney general, on behalf of himself or herself and the U.S. government. If the federal government chooses not to pursue or join in the lawsuit, the relator initiating the case is entitled to “not less than 25 percent and not more than 30 percent of the proceeds of the action or settlement and shall be paid out of such proceeds” if there is a settlement or verdict in the plaintiff’s favor.⁶ In addition, the *qui tam* plaintiff is entitled to collect from the defendant reasonable attorneys’ fees, and expenses from bringing the lawsuit.⁷ If the federal government joins the *qui tam* lawsuit, then the *qui tam* relator is still entitled to “at least 15 percent but not more than 25 percent of the proceeds of the action or settlement of the claim, depending upon the extent to which the person substantially contributed to the prosecution of the action.”⁸

Because the FCA’s damages and penalty provisions tend to generate large dollar settlements and judgments, plaintiffs’ recoveries can involve substantial amounts (Pacini and Hood, 2007). In 2009, Pfizer, Inc. and its subsidiary, Pharmacia and Upjohn Company, Inc. agreed to pay \$2.3 billion, one of the largest healthcare fraud settlements in history for violation of the Food, Drug, and Cosmetic Act and to pay \$1 billion under the FCA for illegally promoting various drugs, including Bextra, Geodon, Zyvox, and Lyrica (DOJ, 2009). Global healthcare company Glaxo Smith Kline agreed to plead guilty and pay \$3 billion to resolve criminal and civil liability from the unlawful promotion of certain drugs and

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- (D) Has possession, custody, or control of property or money used, or to be used, by the Government and knowingly delivers, or causes to be delivered, less than all of that money or property;
 - (E) Is authorized to make or deliver a document certifying receipt of property used, or to be used, by the Government and, intending to defraud the Government, makes or delivers the receipt without completely knowing that the information on the receipt is true;
 - (F) Knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the Government, or a member of the Armed Forces, who lawfully may not sell or pledge property; or
 - (G) Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government,

Is liable to the United States Government for a civil penalty

⁴ 336 F. Supp. 2d 430 (E.D. Pa. 2004).

⁵ 106 F. Supp. 2d 234 (D.P.R. 2000).

⁶ 31 U.S.C. §3730(d)(2)(2018).

⁷ 31 U.S.C. §3730(d)(2)(2018).

⁸ 31 U.S.C. §3730(d)(1)(2018).

report safety violations, including \$2 billion to resolve civil liabilities (including off-label promotion and kickbacks) under the FCA related to Paxil, Wellbutrin, and Avandia. The off-label settlement resolved four lawsuits in federal district court in Massachusetts under the *qui tam* provisions of the FCA (DOJ, 2012). In 2013, Johnson and Johnson agreed to pay the federal government more than \$2.2 billion to resolve commercial and civil liability relating to prescription drugs Risperdal, Invega, and Natrecor based on an alleged violation of the FCA (DOJ, 2013).

The FCA *qui tam* provision contains two features that make it quite successful as a regulatory and external corporate governance tool. First, the law facilitates the dissemination of inside information on fraud. Complex financial crimes often cannot be detected without the assistance of those who possess knowledge of them. Convincing people to inform or turn on their employer, co-workers, and partners is not an easy task (Phelps, 1999). Second, the FCA provides a means for knowledgeable *qui tam* plaintiffs to supplement the strained resources of government attorneys and litigators (Barger, 2005).

A *qui tam* relator who sues under the FCA does so both in an individual capacity and on behalf of the U.S. government. A copy of the complaint and written disclosure of substantially all material evidence and information possessed by the *qui tam* plaintiff must be filed in camera (judge's chambers) and a copy must be sent to the Department of Justice (DOJ).⁹ "The purpose of the written disclosure requirement is to provide the U.S. with enough information on alleged fraud to be able to make a well-reasoned decision on whether it should participate in the filed lawsuit or allow the relator to proceed alone."¹⁰

Although FCA lawsuits have grown during the last 30 years, the federal government has declined to intervene in almost two-thirds of said lawsuits (Baker, 2011). When the federal government decides not to get involved, a case is much less likely to result in a recovery (Baker, 2011). Since 1986, FCA recoveries have totaled over \$62 billion (DOJ, 2020).

Much of the money recovered has involved healthcare fraud claims, which include providers (e.g., hospitals, nursing homes, and physicians), pharmaceutical firms, medical device makers, and suppliers (Farringer, 2018).

Of the more than \$3 billion in settlements and judgments recovered by the DOJ in 2019, \$2.6 billion involves matters in the health care industry, including drug and medical device manufacturers, managed care providers, hospitals, pharmacies, hospice organizations, laboratories, and physicians (DOJ, 2020). Fiscal year 2019 is the tenth consecutive year that the DOJ's civil health care fraud settlements and judgments have exceeded \$2 billion (DOJ, 2020).

Elements of a Qui Tam Claim

Most FCA *qui tam* healthcare fraud cases are brought under 31 U.S.C. §3729(a)(1)(A) or (a)(1)(B). In 2009, Congress enacted into law the Fraud Enforcement and Recovery Act (FERA),¹¹ which expanded liability exposure under the FCA. After the FERA amendments, a false claim can be presented to anyone for payment, as long as the federal government has or will provide part or all of the money to pay the claim, for potential liability to attach.¹² Legal claims filed under §3729(a) require proof of several elements to establish a violation of the FCA: (1) a "claim" must be made; (2) the claim must be made "knowingly" or with "knowledge"; (3) the claim must be "false" or "fraudulent"; (4) the claim must be material (while not in the statute, many courts require proof of materiality); (5) causation; and (6) the claim must have resulted in damage to the federal government. We discuss below some of the most important, and debatable, elements.

A. "Claim"

The determination of whether an actual "claim" has been made is often not a simple task but is easier than before the amendments enacted by FERA. After FERA, a "claim" is "any request or demand, whether under a contract or otherwise, for money or property and whether the United States has title to the money or property."¹³ "Claim" includes any demand for money or property if it is to be spent or used on behalf of the federal government or to advance a

⁹ 31 U.S.C. §3730(b)(2)(2018).

¹⁰ U.S. *ex. rel.* Bagley v. TRW, Inc., 212 F.R.D. 554, 555 (C.D. Cal. 2003)(quoting U.S. *ex. rel.* Woodward v. Country View Care Center, Inc., 797 F. 2d 888, 892 (10th Cir. 1986).

¹¹ Pub. L. No. 111-21, 123 Stat. 617 (2009)(codified as amended in various sections of 18 and 31 U.S.C.).

¹² 31 U.S.C. §3729(a)(1)(A)(2018).

¹³ 31 U.S.C. §3729(b)(2)(A)(2018).

government program or interest.¹⁴ In some circumstances, lawyers and other parties must look to sources outside the FCA to ascertain whether a “claim” has been adequately set forth.

For instance, regulations and statutes define what is a “claim” for payment under Medicare. Under Part B, the federal government promises to pay only costs that are “reasonable and necessary.”¹⁵ Hence, requesting the government to pay for medical tests under Medicare without the required physician supervision under Part B is equivalent to asking for payment for something that is not a contractual claim under Part B (Al-Salihi, 2015). Lack of compliance with Part B’s regulations would potentially fail the “claim” requirement under Part B (Al-Salihi, 2015). An example of a valid “claim” for FCA purposes is *U.S. v. Berkeley Heartlab, Inc.*¹⁶ in which plaintiffs alleged that Berkeley concocted and implemented three separate schemes that are FCA “claims”: (1) a processing and handling kickback scheme which involved paying physician groups a kickback disguised as a “draw” or “processing and handling fee” to make more referrals and order more blood tests; (2) unnecessary genetic testing on patient blood samples; and (3) a scheme to waive copays and deductibles to induce doctors to order more tests. A federal district court ruled that all three schemes constituted FCA violations. Another instance of a legitimate “claim” occurred in *U.S. ex. rel. Bilotta v. Novartis Pharmaceuticals Corp.*,¹⁷ where plaintiffs alleged that Novartis bribed doctors from January 2002 through November 2011 to induce them to prescribe Novartis’ cardiovascular drugs. Novartis’ inducement took the form of “sham” speaker events at which few or no slides were shown. The events served mostly as upscale social outings. The Southern District Court of New York ruled that this conduct amounted to an FCA violation.

The FCA does not attach liability to the underlying fraudulent activity or the government’s wrongful payment, but to the “claim for payment or approval.” In deciding whether a false statement is a claim or demand for payment or approval, a court should determine whether the statement had the practical effect of inducing wrongful payment.¹⁸

An FCA claim must allege that the defendant submitted either a legally fraudulent or legally false claim.¹⁹ A legally false claim occurs when a government funds recipient has certified compliance with a regulation or law as a condition, but knowingly failed to comply.²⁰ A factually false claim involves a reimbursement request containing an improper listing of services rendered or goods provided.²¹

Also, Federal Rule of Civil Procedure (FRCP) 9(b) requires a *qui tam* plaintiff to state with particularity the facts constituting fraud. It is significant to note that, since most FCA cases end in settlement (Latham, 2008), the decision on whether FRCP 9(b) has been met holds much importance in the outcome of a given FCA lawsuit.

B. “False” or “Fraudulently”

The U.S. Supreme Court has stated that the FCA is not designed to combat every kind of fraud committed against the federal government.²² The words “false” and “fraudulent” are not defined by Congress in the FCA. These terms have been held by the U.S. Supreme Court, in *Universal Health Care Services, Inc. v. U.S. ex. rel. Escobar*,²³ to have meaning based on common law fraud concepts. For instance, because the FCA employs the disjunctive “or,” no need exists for a *qui tam* relator to demonstrate a claim is both false and fraudulent. Either one will suffice (Helmer and Popham, 2003).

Historically, most healthcare FCA cases have involved direct “factually false” claims requesting payment for more expensive categories of care than were provided or services that were never provided (Krause, 2017).²⁴ *Qui tam*

¹⁴ 31 U.S.C. §3729(b)(2)(2018).

¹⁵ 42 C.F.R. §411.15 and 415.50-.70 (2018).

¹⁶ 225 F. Supp. 3d 487 (D.S.C. 2016).

¹⁷ 50 F. Supp. 3d 497 (S.D.N.Y. 2014).

¹⁸ *U.S. v. Rivera*, 55 F. 3d 703, 709-710 (1st Cir. 1995); *U.S. v. Richard Dattner Architects*, 972 F. Supp. 738, 746-47 (S.D.N.Y. 1997).

¹⁹ *Foglia v. Renal Ventures Mgmt., LLC*, 830 F. Supp. 2d 8, 16 (D.N.J. 2011).

²⁰ *Universal Health Services, Inc. v. U.S. ex. rel. Escobar*, 136 S. Ct. 1989 (2016).

²¹ *U.S. ex. rel. Connor v. Salina Reg’l. Health Ctr., Inc.*, 543 F. 3d 1211, 1217 (10th Cir. 2008).

²² *U.S. v. McNinch*, 356 U.S. 595 (1958).

²³ 136 S. Ct. 1989 (2016).

²⁴ *U.S. ex. rel. Connor v. Salina Regional Health Ctr., Inc.*, 543 F. 3d 1211, 1217 (10th Cir. 2008).

relators also have employed the law against “legally false” claims, where services or items were provided but the one seeking payment has untruthfully certified compliance with a statute, regulation, or contractual provision.²⁵

Two distinct theories of legal falsity are valid in federal courts. One theory is known as express certification, which occurs when a party offers a false certification about a program condition, such as signing a false certification statement on a document.²⁶ A second theory is known as implied certification. This theory serves as a basis for liability when two conditions are met: the claim does not merely request payment, but also makes specific representations about the goods or services provided and the defendant’s failure to disclose noncompliance with material statutory, regulatory, or contractual requirements leads to half-truths.²⁷ A misrepresentation must be material to the government’s payment decision.²⁸

C. Made “Knowingly” or “Know”

The FCA statute indicates that the presenter of information meets the “knowingly” or “knowledge” requirement if he or she “has actual knowledge ... acts in deliberate ignorance of the truth or falsity ... or acts in reckless disregard of the truth or falsity of the information” presented.²⁹ The law further provides that “no proof of specific intent to defraud” is necessary.³⁰ The requisite intent is the presentation of what is known to be false.³¹

Although the FCA does not provide a definition of “reckless disregard,” the concept embodies a conscious indifference to the falsity of a claim (Al-Salihi, 2015). Negligence and innocent mistake, however, are not sufficient to establish liability.³² An interesting application of the “knowingly” requirement in a healthcare fraud scenario occurred in the *U.S. v. Lorenzo*³³ case. In that case, Dr. Lorenzo and several other dentists performed oral cancer screenings as part of routine dental examinations at nursing homes in Pennsylvania and New Jersey. The cancer screenings, after being billed to Medicaid, were then billed to Medicare as limited consultations. The evidence showed that Lorenzo knew that Medicare rules did not allow procedures during routine screenings to be deemed “limited consultations.” The federal district court found that Lorenzo, at the very least, acted in reckless disregard of the truth or falsity of the claims made.

By not requiring proof of specific intent to defraud, Congress and the federal judiciary have extended liability to virtually anyone associated with a false or fraudulent claim. Healthcare providers and others thus have a strong incentive to make sure their payment claims are accurately presented. The knowledge requirement makes it risky for individuals to look the other way with regard to a fraudulent claim (Frieden, 1998).

D. “Materiality”

Based on a straightforward reading of the FCA statute (§3729), the term “material” modifies the “false record” offered in support of a false claim, not the false claim itself. The false record or statement supporting the false claim must operate in a material way as a supporting document. Thus, the “materiality” requirement is germane only to an §3729(a)(1)(B) cause of action, not an §3729(a)(1)(A) lawsuit or legal claim.

Whatever a healthcare provider or contractor is allegedly lying about does not have to be material to lead to §3729(a)(1)(A) or §3729(a)(1)(B) liability. A threshold requirement exists that any record used to support the accuracy of a false claim must actually support that claim (Al-Salihi, 2015). Although a trivial false claim can give rise to FCA

²⁵ *U.S. ex. rel. Connor v. Salina Regional Health Ctr., Inc.*, 543 F. 3d 1211, 1217 (10th Cir. 2008).

²⁶ *U.S. ex. rel. Connor v. Salina Regional Health Ctr., Inc.*, 543 F. 3d 1211, 1217 (10th Cir. 2008).

²⁷ *Universal Health Services, Inc. v. U.S. ex. rel. Escobar*, 136 S. Ct. 1989, 2001 (2016).

²⁸ *Universal Health Services, Inc. v. U.S. ex. rel. Escobar*, 136 S. Ct. 1989, 2001 (2016).

²⁹ §3729(b)(1)(A)(2018).

³⁰ §3729(b)(1)(B)(2018).

³¹ *U.S. ex. rel. Hagood v. Sonoma County Water Agency*, 929 F. 2d 1416, 1421 (9th Cir. 1991).

³² *U.S. v. Oakwood Downriver Med. Ctr.*, 687 F. Supp. 302, 305 (E.D. Mich. 1988). Congress added “reckless disregard” or “deliberate ignorance” to the FCA in 1986. The Senate Report that accompanied the change showed an intent to hold liable “only those who act in gross negligence, who failed to make such inquiry as would be reasonable and prudent to conduct under the circumstances” (S. Rep. No. 99-345, 1986).

³³ 768 F. Supp. 1127 (E.D. Pa. 1991)

liability, some courts have judicially grafted the term “material” on to a §3729(a)(1)(A) analysis (or claim).³⁴ This approach interprets §3729(a)(1)(A) as meaning that a healthcare provider faces FCA liability if he or she “knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval” which is “material.” In reality, §3729(a)(1)(A) does not state this requirement.

In those cases (or courts) that apply “materiality” to §3729(a)(1)(A) claims, the term is defined as whether the false or fraudulent claim has a “natural tendency to influence agency action or is capable of influencing agency action.”³⁵ Contemporary courts that use a materiality standard for §3729(a)(1)(A) claims use a case-by-case fact-intensive analysis to determine whether a given condition of payment is material.³⁶ In the end, the insertion of materiality into a §3729(a)(1)(A) analysis obfuscates what is really a clear standard (Al-Salihi, 2015).

A guilty fraudster under the FCA is liable to the federal government for a civil penalty of not less than \$5,000 and not more than \$10,000, plus treble damages which the government incurs because of the fraud.³⁷ See Exhibit A for a summary and brief analysis of the FCA.

FCA Healthcare Fraud Lawsuits Facilitated by the Affordable Care Act (ACA)

Prior to the Patient Protection and Affordable Care Act of 2010 (PPACA),³⁸ as modified by the Health Care Education and Reconciliation Act of 2010,³⁹ the FCA had a strong restriction on filing a *qui tam* lawsuit, known as the public disclosure bar. The FCA used to have a two-pronged test to determine whether a federal court could hear a *qui tam* case. First, the court had to determine whether the fraud allegations were based on publicly disclosed material.⁴⁰ If so, the court then had to evaluate whether the relator was an original source of the disclosure. In order to establish subject matter jurisdiction, the *qui tam* plaintiff had to prove, by a preponderance of the evidence, that the suit was not based upon a prior public disclosure, or, if it was, that he or she was an original source of the information.⁴¹ The FCA outlined three means by which prior public disclosure could happen: (1) in a civil, criminal, or administrative hearing;⁴² (2) in a Congressional, administrative or GAO report, audit, or investigation;⁴³ or (3) in the media.⁴⁴ Generally, the courts broadly construed what types of disclosures were public and thus barred *qui tam* claims, even though some disputes existed among the courts (Phelps, 1999).

In the Affordable Care Act, Congress lowered the disclosure bar so that only facts that are “substantially the same” as the facts disclosed in the prior proceeding would lead to the bar being imposed.⁴⁵ The bar now applies if the information on which the *qui tam* suit is based has been disclosed in a federal proceeding in which the government is a participant.⁴⁶ The public disclosure bar does not apply when the *qui tam* relator is an “original source” of the information.⁴⁷ Before the Affordable Care Act, the public disclosure bar prevented many *qui tam* suits that involved public information, as broadly interpreted. This change to the FCA has enhanced its potency as a weapon against healthcare fraud.

The Stark Law

³⁴ U.S. ex. rel. Hutcheson v. Blackstone Med., Inc., 647 F. 3d 377, 394 (1st Cir. 2011)(analysis of “material” in terms of the claim itself).

³⁵ U.S. v. Norris, 749 F. 2d 1116, 1122 (4th Cir. 1984).

³⁶ U.S. v. Sci. Application Int’l. Corp., 626 F. 3d 1257, 1269 (D.C. Cir. 2010).

³⁷ 31 U.S.C. §3729(a)(1)(G)(2018).

³⁸ Pub. L. No. 111-148, 124 Stat. 119 (2010)(amending various sections of the U.S. Code including the FCA and the Anti-Kickback Statute).

³⁹ Pub. L. No. 111-152, 124 Stat. 1029 (2010).

⁴⁰ U.S. ex. rel. Springfield Terminal Ry. Co. v. Quinn, 14 F. 3d 645, 651 (D.C.Cir. 1994).

⁴¹ U.S. v. Alcan Elec. and Eng’g., Inc., 197 F. 3d 1014, 1018 (9th Cir. 1999); U.S. ex. rel. Biddle v. Bd. Of Trustees of the Leland Stanford, Jr. University, 161 F. 3d 533, 535 (9th Cir. 1998).

⁴² U.S. ex. rel. Siller v. Becton Dickinson and Co., 21 F. 3d 1339, 1350 (4th Cir. 1994).

⁴³ U.S. ex. rel. Schwedt v. Planning Research Corp., 39 F. Supp. 2d 28 (D.D.C. 1999).

⁴⁴ U.S. ex. rel. Stinson, Lyons, Gerlin and Bustamonte v. Prudential Ins. Co., 944 F. 2d 1149 (3rd Cir. 1991).

⁴⁵ 124 Stat. 901 (amending 31 U.S.C. §3730(e)(4)).

⁴⁶ 124 Stat. 901 (amending 31 U.S.C. §3730(e)(4)).

⁴⁷ Pub. L. No. 101-239, §6204, 103 Stat. 2236 (codified, as amended, at 42 U.S.C. §1395nn (2018)).

In 1989, as part of the Omnibus Budget Reconciliation Act,⁴⁸ Congress enacted into law Stark I to counteract the growing cost of health care attributable to physician self-referrals (Grioux et al., 2018). Stark I prohibited physician referrals under Medicare for clinical lab services when the referring physician has a financial relationship with the lab unless the terms of certain statutory or regulatory exceptions are met.⁴⁹ As part of the Omnibus Budget and Reconciliation Act of 1993, Stark I was expanded into Stark II (Bucy et al. 2002). Stark II extended the Stark I legislation to Medicaid patients and to “designated health services (DHS)” other than clinical laboratory services (Bucy et al., 2002).

For purposes of the Stark Law, DHS include the following:

1. Clinical laboratory services.
2. Physical therapy services.
3. Occupational therapy services.
4. Radiology services, including magnetic resonance imaging (MRI), computerized axial tomography scans, and ultrasound services.
5. Radiation therapy services and supplies.
6. Durable medical equipment and supplies.
7. Parental and enteral nutrients, equipment, and supplies.
8. Prosthetics, orthotics, and prosthetic devices and supplies.
9. Home health services.
10. Outpatient prescription drugs; and
11. Inpatient and outpatient hospital services.⁵⁰

In general, the Stark Law (I and II collectively) and its accompanying regulations forbid a physician (or an immediate family member) who has a “financial relationship” with a medical facility (e.g., a hospital) from making a “referral” to that facility for the furnishing of certain DHS for which payment can be made by the federal government.⁵¹ A medical facility may not submit for payment a Medicare or Medicaid claim for service provided pursuant to a prohibited referral. The federal government may not make payments on a prohibited claim and medical facilities must reimburse any payments that are mistakenly made by the federal government.⁵²

The Stark Law took years to take effect: Stark I did not go into force until January 1, 1992 (Bucy et al., 2002). Enforcement of Stark II took effect on January 1, 1995 (Bucy et al., 2002). The final regulations for Stark II became effective on January 4, 2002 (Bucy et al., 2002). Phase III regulations were published in September 2007, and the enhanced clarity of these regulations lessened the regulatory burden on the healthcare industry (Sutton, 2011). The Stark Law is complex but its violation can carry severe penalties.

Determination of whether a Stark Law violation has happened entails a multi-step analysis. The first step is to ascertain whether the person or entity involved has made a “referral.” The latter is a request by a physician for, or ordering of, or the certifying or recertifying of the need for, as well as the establishment of a plan of care by a physician that includes the provision of a DHS for which payment may be made under Medicare or Medicaid.⁵³ While the Stark regulations do not expressly include any DHS provided by the referring physician, they do implicate referrals made within a physician’s group practice.⁵⁴ The next step in the analysis is definition of the word “physician.”

A “physician” means a Doctor of Medicine or Osteopathy, a Doctor of Dental Surgery or dental medicine, a Doctor of Podiatric Medicine, a Doctor of Optometry, or a Chiropractor.⁵⁵ Nurse practitioners, physician’s assistants, and physical therapists do not fall within the definition.

⁴⁸ 42 U.S.C. §1395nn (2018).

⁴⁹ 42 U.S.C. §1395nn(h)(6)(2018).

⁵⁰ U.S. ex. rel. Drakeford v. Tuomey Healthcare Systems, Inc., 675 F. 3d 394, 397-8 (4th Cir. 2012); 42 U.S.C. §1395nn(a)(1)(2018).

⁵¹ U.S. ex. Rel. Drakeford v. Tuomey Healthcare Systems, Inc., 675 F.3d. 394, 397-8 (4th Cir. 2012); 42 U.S.C. §1395nn(a)(1) (2018).

⁵² 42 U.S.C. §1395nn(g)(1) (2018).

⁵³ 42 C.F.R. §411.351 (2018).

⁵⁴ 42 C.F.R. §411.351 (2018).

⁵⁵ 42 C.F.R. §411.351 (2018).

One of the most significant determinations under the Stark Law is whether a “financial relationship” exists between a physician (or an immediate family member) and the entity to which the referral has been made. A “financial relationship” can fall into one or more of three categories: (1) an ownership interest; (2) an investment interest; or (3) a compensation agreement between the physician (or immediate family member) and the entity.⁵⁶ Stark regulations specify that a financial relationship may be “direct” or “indirect.”⁵⁷ A “direct” financial relationship exists “if remuneration passes between the referring physician (or immediate family) and the entity furnishing” DHS “without any intervening persons or entities.”⁵⁸ An “indirect financial relationship” is present when three criteria are met. First, an unbroken chain of persons or entities must exist between the referring physician and the entity rendering DHS.⁵⁹ Second, the referring physician must receive aggregate compensation that takes into consideration the volume or value of referrals or other business generated by the referring physician for the receiving entity.⁶⁰ Third, the entity providing DHS must have actual knowledge (or act in reckless disregard or in deliberate ignorance of) the fact that the referring physician (or immediate family member) receives aggregate compensation that considers the volume or value of referrals.⁶¹

The last step is to consider the meaning of the word “entity.” “Entity” means “a physician’s sole practice or a practice of multiple physicians or any other person, sole proprietorship, public or private agency or trust, corporation ... that furnishes DHS. An entity does not include the referring physician ... but does include his or her medical practice.”⁶² This definition means that the physicians or physician group practices that perform DHS must now meet an exception to the Stark Law (Sutton, 2011).

In cases where a physician has made a referral for DHS to an entity with which he or she has a financial relationship, the next question is whether an exception to the law applies. Exceptions fall into three categories: (1) exceptions applicable to both physician ownership/investment interests and compensation arrangements; (2) exceptions for ownership or investment interests only; and (3) exceptions for compensation arrangements only.⁶³

The first exceptions category includes doctors’ services where referrals are between members of the same group practice,⁶⁴ certain ancillary services rendered within the same office of a group practice (the most commonly used exception)⁶⁵ (Sutton, 2011), and certain prepaid health plans.⁶⁶ The second exceptions category includes ownership interests in publicly traded securities, healthcare facilities in rural areas or Puerto Rico, and hospitals meeting certain requirements.⁶⁷ The third exceptions category covers the rental of office space and equipment, genuine employment relationships, personal services arrangements, physician recruitment activities and payments by doctors for certain items and services.⁶⁸

The federal regulations that relate to these exceptions are complex and require intensive analysis. Some of the matters which must be analyzed include, for example, whether doctors in a group practice spend the required number of hours with patients per week providing non-DHS services,⁶⁹ and whether the amount of space leased exceeds the amount deemed “reasonable and necessary” for legitimate business purposes.⁷⁰

⁵⁶ 42 U.S.C. §1395nn(a)(2) (2018).

⁵⁷ 42 C.F.R. §411.354(a)(1) and (2) (2018).

⁵⁸ 42 C.F.R. §411.355(a)(2) (2018).

⁵⁹ 42 C.F.R. §411.354(b)(5)(i) and (c)(2)(i) (2018).

⁶⁰ 42 C.F.R. §411.354(c)(2)(i) (2018).

⁶¹ 42 C.F.R. §411.354(c)(2)(iii) (2018).

⁶² 42 C.F.R. §411.351 (2018).

⁶³ 42 U.S.C. §1395nn(b)-(e) (2010).

⁶⁴ 42 U.S.C. §1395nn(1) (2010).

⁶⁵ 42 U.S.C. §1395nn(b)(2) (2010).

⁶⁶ 42 U.S.C. §1395nn(b)(3) (2010).

⁶⁷ 42 U.S.C. §1395nn(c)-(d) (2010).

⁶⁸ 42 U.S.C. §1395nn(e)(1-8) (2010).

⁶⁹ 42 C.F.R. §411.355(b)(2)(A)(2) (2009).

⁷⁰ 42 C.F.R. §411.357(a)(3) (2009).

Penalties for violations of the Stark Law can be severe. Claims filed for services in violation of self-referrals means nonpayment.⁷¹ Moreover, if one collects money in violation of the Stark Law, the money must be refunded. Improper claims may result in civil monetary penalties up to \$15,000 per violation and exclusion from participating in Medicaid and Medicare programs.⁷² Also, a civil penalty not to exceed \$100,000 applies to cross-referral arrangements when a physician or entity “knows or should know” that the arrangement serves to assure referrals by the physician to the entity.⁷³

In February 2018, the Bipartisan Budget Act outlined changes to the Stark Law. Holdovers in personal services arrangement exceptions and equipment exceptions are now indefinite; previously, they had been limited to six months (Hardiman, 2018).

Federal Criminal Laws to Combat Healthcare Fraud

False Statements to Obtain Health Benefits or Payments

A relatively obscure federal statute, 42 U.S.C. §1320a-7b(a), makes it a crime to make a false statement or representation in any application or claim for benefits under a federal health care program. Under this statute, the federal government must prove beyond a reasonable doubt that: (1) the defendant made, or caused to be made, a statement or representation of material fact in an application for payment or benefits under a federal healthcare program; (2) the statement or representation was false; and (3) the defendant knowingly and willfully made the false statement or representation.⁷⁴

The first element requires that a statement or representation of fact be material to be actionable. In one case, a company named Family Healthcare Group, Inc. did business in Houston, Texas. The company was approved as a Medicare provider in 2005. Family Healthcare provided home health care to individuals by skilled nurses. Family Health Care was paid about \$5.2 million for home health care services between April 2006 and August 2009. Evidence at trial showed that Family Health Care billed Medicare for services to beneficiaries who were ineligible for home health care, not in need of skilled nursing, or received services that were inadequate and misrepresented in the documented nursing reports. Nursing notes were subject to audit by Medicare. The jury found that the nursing notes were material.⁷⁵ The government does not have to prove actual reliance on the false statement by the respective federal agency.⁷⁶

The second element of the offense requires the defendant to utter or make a false statement or representation. The false statement or representation must have been submitted to the respective federal agency for payment. An example would be billing Medicaid for procedures not actually performed. In one case, Dr. Boesen specialized in the medical and surgical treatment of the ears, nose and throat. Between 2000 and 2002, Boesen’s clinic was regularly billing federal health care agencies for nasal endoscopy with debridement, cholesteatoma removal, and otoacoustic emissions tests that were not actually done.⁷⁷ A second case involved Dr. Peter Larm, an allergist who was convicted of Medicaid fraud for submitting false claims for “office visits” where he neither saw or examined patients nor personally rendered services. Larm even submitted claims for administration charges for injections which the patients administered themselves.⁷⁸

The third element of the offense is that the accused “knowingly and willfully” makes or causes to be made any false representation. “Knowingly” refers to the fact that proof must exist that the accused possessed knowledge of the facts that constitute the offense. The “knowing and willful” element is met if the defendant is aware that his or her

⁷¹ 42 U.S.C. §1395nn(g) (2010).

⁷² 42 U.S.C. §1395nn(g) (2010).

⁷³ 42 U.S.C. §1395nn(g) (2010).

⁷⁴ *U.S. v. Laughlin*, 26 F. 3d 1523 (10th Cir. 1994); 42 U.S.C §1320a-7b (2018).

⁷⁵ *U.S. v. Njoku*, 737 F.3d 55 (5th Cir. 2013).

⁷⁶ *Neder v. U.S.*, 527 U.S. 1 (1999).

⁷⁷ *U.S. v. Boesen*, 541 F.3d 838 (8th Cir. 2008).

⁷⁸ *U.S. v. Larm*, 824 F.2d 780 (9th Cir. 1987).

conduct is unlawful without knowledge of the specific law violated.⁷⁹ Also, the accused must know that the statement is false at the time it is made or submitted.⁸⁰

Federal Anti-Kickback Statute

The federal Anti-Kickback Statute⁸¹ is a criminal statute that prohibits knowingly and willfully paying or receiving any compensation directly or indirectly, in cash or in kind, in exchange for prescribing, purchasing, or recommending any service, treatment or item for which payment will be made by Medicaid, Medicare, or any other federally funded program (Rheiner, 2015). The anti-kickback statute is broadly drafted and establishes liability for individuals and entities on not only kickbacks and bribes, but also an array of economic relationships that can be more complex than a simple payment for services (Pyle III, 2007). The purpose of the anti-kickback statute is to prevent drains on the public treasury. Moreover, in recent years, the pace of anti-kickback statute enforcement has remained high. For example, in April 2015, Health Diagnostics Laboratory and Singulex, Inc., cardiovascular testing companies, collectively paid \$48.5 million to settle allegations that they violated the anti-kickback statute by paying compensation to doctors in exchange for patient referrals (DOJ, 2015a). In another case, in October 2015, Millennium Health, a urine testing company, agreed to pay \$256 million to settle allegations that it provided free point of care testing cups for urine drug testing to doctors on the condition that the physicians agree to return the urine specimens to Millennium for additional costly tests (DOJ, 2015b). Since the Stark law and the anti-kickback statute both address “referrals,” Exhibit B summarizes both laws and clarifies their differences.

Federal courts expanded the scope of the anti-kickback statute by establishing the “one-purpose test.”⁸² This test holds that if one purpose of a payment were to induce future referrals, the arrangement violated the anti-kickback statute. Although the anti-kickback statute does not make provision for private civil suits by individuals, the FCA provides a vehicle whereby individuals may bring *qui tam* actions⁸³ alleging violations of the anti-kickback statute. For a criminal conviction under the anti-kickback statute, the government must prove beyond a reasonable doubt that the defendant: (1) knowingly and willfully; (2) solicited, received, paid, or offered to pay remuneration; (3) in return for, or to induce, the referral or generation of program-related business.⁸⁴ The “knowing and willful” element is met by demonstrating the defendant was aware his or her conduct was unlawful and acted voluntarily and purposely. Further clarification of this element was provided in *U.S. v. Mathur*⁸⁵ which states, “with respect to violations of this section, a person need not have actual knowledge of this section as specific intent to commit a violation of this section.”

The broad scope of the one-purpose test has the potential to create liability under the anti-kickback statute for actions that are relatively innocuous commercial arrangements (Kirman and Wyman, 2015). Parties can be liable under the anti-kickback statute even if their actions cause no tangible harm to patients.⁸⁶ For example, if a hospital offers a physician any remuneration to join its staff, intending that the doctor will refer Medicare patients to the hospital, it risks violating the one-purpose test.⁸⁷

The broad scope of potential liability under the law gave rise to sufficient concern in Congress that numerous “safe harbors” or statutory exceptions were created. Safe harbors protect from prosecution specific practices that would otherwise violate the statute.⁸⁸ The Office of Inspector General (OIG) has listed over twenty-five regulatory safe harbor provisions and one statutory provision⁸⁹ that protect doctors from liability under the anti-kickback statute. Each transaction or alleged activity that falls within a safe harbor must be evaluated on a case-by-case basis to ascertain

⁷⁹ *U.S. v. Starks*, 157 F.3d 833 (11th Cir. 1998).

⁸⁰ *U.S. v. Njoku*, 737 F.3d 55 (5th Cir. 2013).

⁸¹ 42 U.S.C. §§ 1320a-7b(b)(2017).

⁸² *U.S. v. Greber*, 760 F.2d 68 (3rd Cir. 1985).

⁸³ 31 U.S.C. §3730(d)(2)(2018).

⁸⁴ 42 U.S.C. §1320a-7b(2017); *U.S. v. Vernon*, 723 F.3d 1234 (11th Cir. 2013).

⁸⁵ 2012 WL 4742833, at *15 (D. Nev. Sept. 13, 2012).

⁸⁶ *U.S. v. Jain*, 93 F.3d 436 (8th Cir. 1996).

⁸⁷ *Polk Cnty., Tex. v. Peters*, 800 F. Supp. 1451 (E.D. Tex. 1992).

⁸⁸ 42 C.F.R. §1001 (2017).

⁸⁹ 42 C.F.R. §1001.952(a)-(y) (2017).

whether it constitutes an anti-kickback violation (Crain, Hopwood, Pacini, and Young, 2015). The following is a partial list of the safe harbor provisions:

1. Investment safe harbor. Protects an investor who holds a security issued by an entity, provided he or she satisfies certain statutory requirements. This safe harbor applies to three types of securities: investments in large entities, in small entities, and in medically underserved areas.
2. Sale of physician practices. Divided into two sections: sales to another practitioner and sales to a hospital or other entity. Each type of sale has different criteria.
3. Practitioner recruitment safe harbor. Designed to allow areas that have difficulty attracting doctors to offer incentives to potential practitioners. Various conditions must be met.
4. Space rental, equipment rental, and personal services and management contracts. These safe harbors prevent prosecution of such contracts if payments thereunder meet the following criteria: (1) the written contract covers all of the property or services exchanged between the parties; (2) the contract is in writing and is signed by all the parties; (3) the schedule of use, length of each use, and exact rent is set for those property or services that are used only periodically; (4) the contract is for at least one year; (5) the payments are equal to fair market value and are set in advance; and (6) the space or amount of services is no more than necessary for a reasonable business purpose.
5. Referral services safe harbor. Protects organizations that operate referral services for a fee, such as professional societies or consumer groups. The safe harbor does not extend to situations where the operator of the referral service adjusts the fees that it charges participating doctors based on the number of referrals the physician makes to the operator of the service.
6. Referral arrangements for specialty services. Designed to allow a practitioner to refer a patient to another party for the provision of a specialty service under an agreement that the patient will be referred back at a specified time or under certain conditions.
7. Ambulance replenishing. Under the law, “remuneration does not include any gift or transfer of drugs or medical supplies (including linens) by a hospital or other receiving facility to an ambulance provider for the provider (or first responder) in connection with the transport of a patient by ambulance to the hospital or other receiving facility if all the criteria in this safe harbor are met.
8. Health centers. Under the law, “remuneration” does not include the transfer of any goods, items, services, donations, or loans (whether in cash or in-kind), or combination thereof from an individual or entity to a health center, as long as nine specified standards are met.⁹⁰

These regulatory safe harbors are drawn narrowly. If an agreement does not meet the exact requirements of a safe harbor regulation, it is not immunized from liability under the anti-kickback statute (Rheiner, 2015). An agreement is subject to the one-purpose test if it does not precisely fit into a safe harbor, even if it is in substantial compliance with the requirements of the regulation. Many arrangements will not fit into the specific requirements of a certain given safe harbor, but the Department of Health and Human Services (HHS) has no reason to challenge these agreements if they create no risk of tangible harm to patients or drain on the public treasury.

Health Insurance Portability and Accountability Act (HIPAA)

In 1996, Congress passed the Health Insurance Portability and Accountability Act (HIPAA).⁹¹ HIPAA is intended to protect the insured by improving portability of healthcare insurance coverage and reducing fraud and abuse in healthcare (Khansa et al., 2012). HIPAA expanded the fight against healthcare fraud in numerous ways. First, HIPAA widened the coverage of the anti-kickback statute to include all federal healthcare programs.⁹² Second, HIPAA expanded the definition of a kickback. Controversy existed at one time as to whether waiving a copayment or deductible constituted remuneration to induce patients to utilize a given provider (Eddy, 2000). One provision of HIPAA specifically states that

⁹⁰ 42 C.F.R. §1001.952 (2018).

⁹¹ Pub. L. No. 104-191, 110 Stat. 1936 (1996) (codified as amended at 42 U.S.C. §1320a-7c).

⁹² 42 U.S.C. §1320a-b applies to anything “under a health care program.”

waiving a copayment is a kickback unless it is done for a documented financial need or represents failure to collect after reasonable efforts.⁹³ HIPAA also extends this exception to all federal healthcare programs except the Federal Employee Health Benefit Program. Under HIPAA and the anti-kickback statute, remuneration includes the routine or partial waiver of coinsurance and deductibles as well as the transfer of items or services for free or less than market value.⁹⁴ There is a safe harbor for waivers not routinely offered.

HIPAA also changed the money laundering, asset forfeiture and injunctive relief statutes to cover “federal health care offenses” (Eddy, 2000). HIPAA amended a federal criminal forfeiture statute with mandatory forfeiture language that states a court “shall order a person [convicted of a federal health care offense] to forfeit property, real or personal, that constitutes or is derived, directly or indirectly, from gross proceeds traceable to the commission of the offense.”⁹⁵ One example is the case involving Mashiyat Rashid, who plead guilty to conspiracy to commit healthcare fraud and wire fraud, and money laundering (DOJ, 2018d). Rashid and his associates prescribed over six million dosages of medically unnecessary opioids to patients in Michigan and Ohio who were already suffering from addiction. Rashid agreed to the entry of a forfeiture money judgment in excess of \$51 million, commercial real estate, residential real estate, luxury clothes, and a Lamborghini and Rolls Royce Ghost (DOJ, 2018d).

The use of criminal forfeiture represents a step forward in healthcare fraud cases but civil forfeiture would provide federal law enforcement authorities the power to seize the assets or funds of healthcare fraudsters sooner and, thereby, reducing the chance that assets or funds could be dissipated or moved. HIPAA also expanded the fraud injunction statute, authorizing the federal government to commence a civil lawsuit to enjoin the commission of a federal healthcare offense and to freeze the assets of fraudsters disposing or trying to dispose of assets acquired as a result.⁹⁶

In one case, *U.S. v. Sriram*,⁹⁷ the federal government filed suit against Dr. Krishnaswami Sriram for fraudulently acquiring over \$1 million through false Medicare claims. Besides asserting claims for civil penalties and treble damages under the FCA, the government sought and obtained a preliminary injunction against Sriram and froze certain assets (worth over \$1.6 million).

HIPAA has had other significant effects in the fight against healthcare fraud. HIPAA is the first federal statute that creates a federal crime of healthcare fraud committed against private health care plans.⁹⁸ HIPAA also created five new healthcare crimes, four of which were felonies and one a misdemeanor. The first felony is known simply as healthcare fraud.⁹⁹ For a conviction, this law requires the government to prove beyond a reasonable doubt that the defendant (1) knowingly and willfully executed, or attempted to execute, a scheme or artifice (2) to defraud a healthcare benefit program (3) in connection with the delivery of or payment for health care, benefits, items or services. One example is found in *U.S. v. Morgan*,¹⁰⁰ in which the defendant was convicted of twelve counts of healthcare fraud to defraud Medicare by signing Certificates of Medical Necessity (CMNs) for motorized wheelchairs for patients that the defendant did not examine and who were not medically eligible for wheelchairs.

A second crime created by HIPAA is theft or embezzlement in connection with healthcare.¹⁰¹ This crime requires that the government prove beyond a reasonable doubt that the defendant knowingly and willingly embezzled, stole, intentionally misapplied, or otherwise converted any of the property or assets of a healthcare program. The law allows federal prosecutions of embezzlements from private health plans.¹⁰²

⁹³ 42 U.S.C. §1320a-7a(i)(6)(Supp. III 1997).

⁹⁴ 42 U.S.C. §1320a-7a(i)(6)(Supp. III 1997).

⁹⁵ 42 U.S.C. §1320a-7b(a)(6)(Supp. III 1997).

⁹⁶ 18 U.S.C. §1345 (2018); 18 U.S.C. §982(a)(7) (2018).

⁹⁷ 147 F.Supp. 2d 914 (N.D. Ill. 2001).

⁹⁸ Pub. L. No. 104-191, 241-247, 249, 110 Stat. 1936, 2016-2021 (1997).

⁹⁹ 18 U.S.C. §1347 (2018).

¹⁰⁰ 505 F.3d 332 (5th Cir. 2007).

¹⁰¹ 18 U.S.C. §669 (2018).

¹⁰² *U.S. v. Lucien*, 347 F.3d 45 (2nd Cir. 2003).

A third felony under HIPAA is false statements relating to healthcare matters.¹⁰³ To convict a person of making false statements relating to healthcare matters, the government must prove beyond a reasonable doubt that the person (1) knowingly and willingly made false statements or representations (2) in connection with the delivery of or payment for healthcare benefits, items, or services and (3) in a matter involving a healthcare benefit program.¹⁰⁴

A fourth felony created by HIPAA is obstruction of criminal health investigations.¹⁰⁵ A conviction requires that the government prove beyond a reasonable doubt that the defendant willfully prevented, obstructed, misled, delayed, or attempted to prevent, obstruct, mislead, or delay, the communication of information or records relating to a violation of a federal healthcare offense to a criminal investigator.¹⁰⁶

Penalties for these various crimes include fines, which vary according to the damage to the particular federal program, and prison sentences, up to a maximum term of five to ten years (Eddy, 2000).

Mail and Wire Fraud Statutes

The federal government can prosecute healthcare providers using mail and wire fraud statutes.¹⁰⁷ Prosecutors can also pursue charges under one of HIPAA's specialized mail and wire fraud provisions tailored to health care fraud.¹⁰⁸ The prosecution of an individual or entity for mail or wire fraud requires the government to prove beyond a reasonable doubt that the defendant (1) intentionally participated in a scheme or artifice to defraud and (2) used the mails or wires to perpetrate the scheme.¹⁰⁹ The federal government need not prove that a defendant personally mailed a document but only that he or she committed "an act with knowledge that the use of the mails [would] follow in the ordinary course of business, or where such use [could] reasonably be foreseen, even though not actually intended."¹¹⁰ The wire fraud statute requires that the crime involve the use of wire (including the Internet), radio, or television communication in pursuit of the scheme.¹¹¹

In one example of the application of these statutes, Dr. Henry Sherman of East Orange, N.J., was convicted of mail fraud for billing insurance companies (using the postal system) for many times the actual number of office visits made by each patient and for equipment he did not provide.¹¹² Other conduct which would qualify as a scheme or artifice to defraud for mail or wire fraud prosecution include creating false descriptions of services rendered and making false representations that services were medically necessary.¹¹³

A person convicted of mail or wire fraud may be subject to a fine, a prison term of up to 20 years, or both.¹¹⁴

Federal Statutes Are Not the Only Means Available to Combat Healthcare Fraud

Although used quite infrequently, common law, not statutory, actions are available to the government and private health insurers, to supplement statutory remedies, as long as the statute does not preclude such actions.¹¹⁵ The government and private health insurers may sue an alleged healthcare fraudster using common law legal theories such as unjust enrichment and payment by mistake.¹¹⁶

Unjust enrichment is an obligation or remedy created by the law to compensate for the unjust retention of a benefit conferred by another. The federal or state government, or a private health insurer which has been defrauded by a

¹⁰³ 18 U.S.C. §1035 (2018).

¹⁰⁴ U.S. v. Hunt, 521 F.3d 636 (6th Cir. 2008).

¹⁰⁵ 18 U.S.C. §1518a (2018).

¹⁰⁶ U.S. v. Franklin-El, 554 F.3d 903 (10th Cir. 2009).

¹⁰⁷ 18 U.S.C. §1341 (2018); 18 U.S.C. §1343 (2018).

¹⁰⁸ 18 U.S.C. §1347 (2018).

¹⁰⁹ 18 U.S.C. §1341 (2018); 18 U.S.C. §1343 (2018).

¹¹⁰ U.S. v. Peterson, 223 F.3d 756 (3rd Cir. 2000).

¹¹¹ 18 U.S.C. §1343 (2018).

¹¹² 160 F.3d 967 (3rd Cir. 1998).

¹¹³ U.S. v. Shetty, 76 Fed. Appx. 842 (9th Cir. 2003).

¹¹⁴ 18 U.S.C. §1341 (2018); 18 U.S.C. §1343 (2018).

¹¹⁵ U.S. v. Berkeley Heartlab, Inc., 225 F. Supp. 3d 487 (D.S.C. 2016).

¹¹⁶ U.S. ex. rel. Drakeford v. Tuomey, 792 F. 3d 364 (4th Cir. 2015).

healthcare provider or other party must prove four elements by a preponderance of the evidence to recover under a theory of unjust enrichment: (1) a plaintiff conferred a benefit on the defendant; (2) a defendant had knowledge of the benefit; (3) a defendant accepted or retained the benefit; and (4) the circumstances make it unjust to retain the benefit without compensating.¹¹⁷ Unjust enrichment is its own cause of action.

For example, in *Berkeley Heartlab, Inc.*, the federal government claimed that Medicare and Tricare (health insurance program for veterans) paid HDL, a laboratory blood testing company, over \$325 million for improper tests and that HDL's CEO, Mallory, was unjustly enriched by more than \$25 million. HDL and Mallory failed to have the unjust enrichment theory dismissed by a South Carolina federal district court. In another case, the Fourth Circuit Court of Appeals held "that it is appropriate for a federal court to weave into the statutory fabric of ERISA (Employment Retirement Income Security Act) the federal common law remedy of unjust enrichment."¹¹⁸

Another common law theory that is used by the government (and may be used by private health insurers) is payment by mistake. Under this common law theory, a plaintiff may recover funds it mistakenly, erroneously, or illegally paid a party who received the monies without right.¹¹⁹ Parties receiving funds from the federal government (or private insurer) under mistake of fact or law are liable to return the funds.¹²⁰ The required elements for a common law payment by mistake claim are: (1) a payment was made; (2) the payment was made based on a mistake, error, or it was illegally made; and (3) the party receiving the payment did not have the right to

the payment.¹²¹

As an illustration, in *U.S. v. Anderson*,¹²² the defendant (Anderson), acting individually and through his company, PCM Management, LLC, perpetrated a scheme to falsely obtain money from government health care programs by creating a group of four pain management clinics purportedly owned by a string of sham physician owners. The clinics submitted false payment claims to Medicare. The defendants were sued under separate counts under the FCA, unjust enrichment and payment by mistake.

Although the common law theories of unjust enrichment and payment by mistake are occasionally used alongside federal statutory theories, we propose these theories should be employed more often. The elements are often easier to prove than statutory claims and provide plaintiffs with more tools to combat healthcare fraud.

Conclusion

Despite growing efforts by the U.S. government, law enforcement agencies, federal and private health insurance programs and increased legislation to battle healthcare fraud, the latter remains a widespread problem. Medicare, Medicaid, and other federal healthcare programs have been and continue to experience tens of billions of dollars in fraudulent claims. Fraud schemes committed by healthcare providers, pharmaceutical firms, medical device makers, organized crime and others cost more than just money; these frauds erode the public's trust in a system that should engender confidence.

The fight against healthcare fraud is important for American society. Every dollar saved or recovered from fraud can be used to ensure people have access to better healthcare services. Significant fines and damages have been collected and more prison sentences meted out in recent years for healthcare fraud offenses.

Society and the federal government have powerful statutory and common law weapons to combat healthcare fraud. This article analyzes the most important federal civil and criminal laws utilized to fight healthcare fraud, including the FCA, PPACA, the Stark Law, a law against false statements to obtain health benefits or payments, the federal anti-kickback statute, HIPAA, the mail and wire fraud statutes, and various common law actions.

¹¹⁷ *Commerce P'ship v. Equity Contracting Co.*, 695 So. 2d 383 (Fla. 4th DCA 1997).

¹¹⁸ *Provident Life and Accident Insurance Company v. Waller*, 906 F. 2d 985 (4th Cir. 1990).

¹¹⁹ *U.S. v. Medica Rents Co. Ltd.*, 2008 WL 3876307, at *3 (5th Cir. 2008).

¹²⁰ *U.S. v. The Estate of Williams Cole*, 620 F. Supp. 126 (W.D. Mich. 1985).

¹²¹ *U.S. v. Life Care Centers of America*, 2014 WL 11429265 (E.D. Tenn. 2014).

¹²² 271 F. Supp. 3d 950 (M.D. Tenn. 2017).

The analysis of these various criminal and civil laws has some takeaways. Existing laws provide powerful tools for forensic accountants and law enforcement to fight and minimize healthcare fraud. It is incumbent that those involved in investigating and pursuing healthcare fraud educate themselves or become familiar with the laws explained in this article to facilitate healthcare fraud investigations and prosecutions and minimize the negative consequences of healthcare fraud on public confidence and the federal treasury. Another takeaway is that the FCA is one of the most potent federal laws available to combat healthcare fraud because of its *qui tam* feature. Also, greater collaboration between various federal agencies and task forces, state healthcare regulators and private healthcare forensic accountants may result in even more successful prosecutions and greater recoveries in healthcare fraud actions.

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Exhibit A: Federal False Claims Act

Prohibition:	Imposes civil liability on any person who knowingly presents or causes to be presented a false or fraudulent claim to the U.S. government for payment or approval.
Type of law:	Civil
Standard of proof:	Preponderance of the evidence
Special feature (s):	Qui tam lawsuits. Allows private citizens (whistleblowers) to file a civil lawsuit against an alleged fraudster, in the role of a private attorney general, who commits an alleged fraud against the federal government. The <i>qui tam</i> relator receives 15 to 30 percent of any damages awarded and attorneys' fees in a settlement or trial verdict.
Elements of <i>Qui tam</i> Claim	"Claim" includes any demand for money or property if it is to be spent or used on behalf of the federal government or to advance a federal government program.
"False or fraudulently"	Most healthcare FCA cases involve direct "factually false" claims but the FCA has also been used against "legally false" claims. The latter occurs where services or items were provided but the one seeking payment has untruthfully certified compliance with a regulation or contractual provision.
Made "Knowingly" or "Know"	An alleged perpetrator meets the "knowingly" requirement if he or she has actual knowledge, acts in reckless disregard of the truth or falsity of the information presented for payment or approval.
Materiality	The term "materiality" applies to the "false record" offered in support of a false claim. "Materiality" is defined by many federal courts as whether a false or fraudulent claim has a natural tendency to influence agency action or is capable of influencing agency action.
Causation	The causation element is satisfied if one presents or causes to be presented a false or fraudulent claim to the federal government for payment or approval.

Exhibit B: The Anti-Kickback Statute and the Stark Law

	The Anti-Kickback Statute (42 USC Section 1320a-7b[b])	Stark Law (42 USC Section 1395nn)
Prohibition	Prohibits offering, paying for, soliciting, or receiving anything of value to induce or reward referrals or generate federal healthcare program business	Prohibits a physician from referring Medicare patients for designated health services to an entity with which the physician (or immediate family member) has a financial relationship, unless an exception applies Prohibits the designated health service entity from submitting claims to Medicare for those services resulting from a prohibited referral
Referrals	Referrals from anyone	Referrals from a physician
Items or Services	Any items or services	Designated health services
Intent	Intent must be proven (knowing and willful)	No intention standard for overpayment (strict liability) Intent required for civil monetary penalties for knowing violations
Penalties	Criminal: • Fines up to \$25,000 per violation • Up to five-year prison term per violation Civil or Administrative: • False Claims Act liability • Civil monetary penalties and program exclusion • Up to \$50,000 civil monetary penalty per violation • Civil assessment of up to three times amount of kickback	Civil: • Overpayment or refund obligation • False Claims Act liability • Civil monetary penalties and program exclusion for knowing violations • Potential \$15,000 civil monetary penalty for each service • Civil assessment of up to three times the amount claimed
Exceptions	Voluntary safe harbors	Mandatory exceptions
Federal Healthcare Programs	All	Medicare or Medicaid

Source: Crain, Hopwood, Pacini and Young. 2015. Essentials of Forensic Accounting p.532