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Investigating Healthcare Fraud: Its Scope, Applicable Laws, and Regulations

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INVESTIGATING HEALTHCARE FRAUD: ITS SCOPE, APPLICABLE LAWS, AND REGULATIONS

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ABSTRACT

Healthcare costs are not only an enormous strain on the U.S. economy but are expected to increase in the foreseeable future. Not surprisingly, clever fraudsters view the healthcare industry as a lucrative and attractive hotspot for illegal activity. Although federal and state governments have increased their funding and prosecution efforts relating to healthcare fraud, this fraud continues to be a major threat to the U.S. economy and every patient and consumer. The impact of healthcare fraud is substantial and far-reaching. Healthcare fraud in the U.S. affects not only the government, but also insurance companies, patients, healthcare providers, and consumers. This Article examines the types of healthcare fraud and the major federal laws used to combat this type of fraud.

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INTRODUCTION

Healthcare costs are a significant drain on the U.S. economy.¹ According to the Centers for Medicare and Medicaid Services (CMS), health expenditures in the U.S. are estimated to grow by an average annual rate of 5.8 percent between 2015 and 2025 and are projected to reach \$5.4 trillion in 2025, up from \$3 trillion in 2014.² In 2018, eighteen percent of the national economy was spent on healthcare.³ It is no surprise that this large volume of economic activity has led fraudsters to view healthcare as a lucrative field for illegal activity.⁴ The Federal Bureau of Investigation (FBI) states that the costs associated with healthcare fraud amount to tens of billions of dollars a year⁵ and are estimated to increase in the future as people live longer, which in turn will increase the demand for Medicare benefits.⁶

The impact of healthcare fraud is significant and wide reaching.⁷ The following parties may face the financial consequences: (1) insurance holders who pay higher premiums and out-of-pocket expenses while receiving reduced benefits and coverage; (2) businesses that pay increasing premiums to provide healthcare

¹ Centers for Medicare and Medicaid Services (2016), *National Health Expenditures 2017 Highlights*, <https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/downloads/highlights.pdf> [<https://perma.cc/AUX2-CNU9>].

² *Id.*

³ Peter G. Peterson Found., *Key Drivers of the Debt*, <https://www.pgpf.org/the-fiscal-and-economic-challenge/drivers> [<https://perma.cc/PTA5-5QR7>].

⁴ See generally *Consumer Info & Action*, NAT'L HEALTHCARE ANTI-FRAUD ASS'N (2016), <https://www.nhcaa.org/resources/health-care-anti-fraud-resources/consumer-info-action.aspx> [<https://perma.cc/K2L8-UNFB>].

⁵ *Rooting Out Healthcare Fraud is Central to the Well-Being of Both Our Citizens and The Overall Economy* (2016), FED. BUREAU OF INVESTIGATION, <https://www.fbi.gov/about-us/investigate/white-collar/health-care-fraud> [<https://perma.cc/QB3G-VHW9>]. In fiscal year 2017, the Department of Justice recovered \$2.4 billion from healthcare fraud at the federal level. *Justice Department Recovers Over \$3.7 Billion From False Claims Act Cases in Fiscal Year 2017*, U.S. DEP'T OF JUST. (Dec. 21, 2017), <https://www.justice.gov/opa/pr/justice-department-recovers-over-37-billion-false-claims-act-cases-fiscal-year-2017> [<https://perma.cc/W75K-6WJ2>].

⁶ *Federal Crimes Report 2010–2011*, FED. BUREAU OF INVESTIGATION (2012), <https://www.fbi.gov/stats-services/publications/financial-crimes-report-2010-2011> [<https://perma.cc/VP7Y-VR2X>].

⁷ See NAT'L HEALTHCARE ANTI-FRAUD ASS'N, *supra* note 4.

to their employees, resulting in an overall increased cost of doing business; and (3) taxpayers who pay more to cover healthcare expenditures in public health plans.⁸ Beyond monetary damages, healthcare fraud can also place patients at risk of serious physical harm, unnecessary procedures, unapproved drugs, or overprescribed diagnostic tests and antibiotics.⁹ The vast amounts of sensitive medical and financial information included in each patient's medical records are an area also tempting to fraudsters.¹⁰

Due to troublesome increases in healthcare fraud, U.S. federal and state law enforcement agencies have made healthcare fraud prosecution a primary focus.¹¹ Under the Patient Protection and Affordable Care Act (PPACA) of 2010, for example, the Obama Administration provided an additional \$350 million for healthcare fraud prevention and enforcement efforts.¹²

While the FBI is the primary investigative agency in the fight against healthcare fraud, it coordinates its efforts with the Health and Human Services Office of the Inspector General (HHS-OIG), the Food and Drug Administration (FDA), the Drug Enforcement Administration (DEA), the Internal Revenue Service (IRS) Criminal Investigation Division, and various state and local agencies.¹³ However, despite more funding and a more focused and integrative effort by multiple government entities in

⁸ *Id.*

⁹ *Id.*

¹⁰ See *Health Care Fraud Unit*, U.S. DEP'T OF JUST., <https://www.justice.gov/criminal-fraud/health-care-fraud-unit> [<https://perma.cc/9XF6-RBYH>].

¹¹ *Id.* For example, Medicare Fraud 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 & Medicaid Services (CMS) Center for Program Integrity (CPI), U.S. Attorney's offices, law enforcement agencies and sometimes the Drug Enforcement Agency and Internal Revenue Service. See *id.*

¹² The Patient Protection and Affordable Care Act, Pub. L. No. 111-48, 124 Stat. 119 (2010) (amending various sections of the U.S. Code including the False Claims Act and the Anti-Kickback statute); *The Affordable Care Act and Fighting Fraud* (2016), U.S. DEP'T OF HEALTH AND HUM. SERVS., <https://www.cms.gov/newsroom/fact-sheets/health-care-fraud-and-abuse-control-program-protects-consumers-and-taxpayers-combating-health-care> [<https://perma.cc/98N9-AEUC>].

¹³ *Federal Crimes Report 2010–2011*, *supra* note 6.

the last few years, the threat of healthcare fraud remains high.¹⁴ This is evidenced by record-setting dollar amounts in recent healthcare fraud scheme takedowns, including opioid-related schemes.¹⁵

The goal of this analysis is to shed light on healthcare fraud schemes as well as present solutions to help control it. An analysis of the scope of such fraud schemes highlights the importance of effectively combating them. Educating the public is an important step towards detecting and preventing this fraud in the first place.

This Article proceeds in two parts. In Part I, the scope of healthcare fraud is introduced through the explanation of various schemes and review of recent cases. In Part II, major federal civil and criminal laws and related regulations applicable to healthcare fraud are analyzed.

I. TYPES OF HEALTHCARE FRAUD SCHEMES

The largest anti-healthcare fraud organization, the National Health Care Anti-Fraud Association (“NHCAA”), defines healthcare fraud in general terms as an intentional deception or misrepresentation that could result in unauthorized benefit.¹⁶ There are different types of healthcare fraud schemes that exist. While the following discussion is not intended to be all-inclusive, it highlights the most prevalent healthcare fraud schemes. These include billing schemes, kickbacks, medical identity theft, fraud against Medicare and Medicaid, hospital fraud, fraud by service providers, and fraud by pharmaceutical companies.¹⁷

A. Billing Schemes

According to the NHCAA, most healthcare fraud is committed by organized criminals and the small minority of healthcare

¹⁴ *See id.*

¹⁵ On its website, the Department of Justice lists many of its charges, the number of defendants, and the amount of falsely billed healthcare claims. Many of the recent cases involved pharmacies, drug diversion, and controlled substances. *Largest Health Care Fraud Enforcement Action in Department of Justice History Resulted in 76 Doctors Charged and 84 Opioid Cases Involving More Than 13 Million Illegal Dosages of Opioids*, U.S. DEP’T OF JUST. (2018), <https://www.justice.gov/criminal-fraud/health-care-fraud-unit/june-2015-takedown> [<https://perma.cc/LXR7-C6KH>].

¹⁶ NAT’L HEALTHCARE ANTI-FRAUD ASS’N, *supra* note 4.

¹⁷ *Id.*

providers that are dishonest.¹⁸ Common examples of billing fraud include:

1. billing for services or equipment not rendered;
2. billing for unnecessary services or equipment;
3. double billing for the same service or equipment;
4. billing for phantom patients, or patients who are deceased;
5. billing for old services as if they were new;
6. “unbundling,” that is, billing separately for services or equipment included in a combined or bundled rate;
7. “upcoding,” that is, billing for a service or piece of equipment at a higher rate than was actually provided;
8. attempting to get reimbursed for non-covered services by fraudulently labeling them as covered services; and
9. billing for a canceled service, that is, a medication, procedure, or service that was prearranged and then canceled is still billed.¹⁹

As seen by the above list, billing schemes can be very diverse. Some cases of billing fraud can be easily detected if a patient is aware of this type of fraud and carefully reviews their benefits statements. Other types of billing fraud are not easily identified. For example, if a patient reviews a hospital bill, a double-billing error might be readily apparent, while overbilling might not be as easily detectable.

In the largest healthcare fraud enforcement action to date, 601 individuals—including 165 doctors, nurses, and other licensed medical professionals—were charged for their alleged participation in a false billing scheme amounting to more than \$2 billion.²⁰

¹⁸ *What Does Health Care Fraud Look Like*, NAT'L HEALTHCARE ANTI-FRAUD ASS'N, <https://www.nhcaa.org/news/what-does-health-care-fraud-look-like.aspx> [<https://perma.cc/HQV5-3UQG>].

¹⁹ *Id.*; Ron Cresswell, *Health Care Fraud: 5 Common Health Schemes*, ACFEINSIGHTS (Dec. 12, 2018), <https://acfeinsights.squarespace.com/acfe-insights/2018/12/12/health-care-fraud-5-common-billing-schemes> [<https://perma.cc/JB8R-DUFR>].

²⁰ Press Release, U.S. Dep't of Just., National Health Care Fraud Takedown Results in Charges Against 601 Individuals Responsible for Over \$2 Billion in

Allegedly, the defendants took part in schemes to submit claims to Medicaid, Medicare, TRICARE (a health insurance program for veterans of the Armed Forces and their family members), and private insurance companies for medically unnecessary treatments and, often, never provided.²¹ In these schemes, patient recruiters, beneficiaries, and other co-conspirators purportedly paid cash in return for supplying beneficiary information to providers.²² With this information, the providers could then submit fraudulent bills to Medicare.²³ Particularly significant in this case is the number of medical professionals charged, as almost every healthcare fraud scheme involving Medicare or Medicaid requires the participation of a corrupt medical professional.²⁴

B. Kickbacks

Another common fraudulent scheme is the payment of “kickbacks” in return for influencing the provision of healthcare.²⁵ Kickbacks can corrupt a medical provider’s decision-making and make profit, rather than a patient’s welfare, the healthcare provider’s primary goal.²⁶ Kickbacks can lead to inappropriate medical care, including incorrect hospitalization, surgery, tests, medications, and equipment.²⁷ Some of the largest kickback cases have occurred in the U.S. Department of Veterans Affairs (VA).²⁸

The Veterans’ Health Administration [of the VA] is the largest integrated health care system in the United States, providing

Fraud Losses (June 28, 2018), <https://www.justice.gov/opa/pr/national-health-care-fraud-takedown-results-charges-against-601-individuals-responsible-over> [<https://perma.cc/T5VG-Q5JG>].

²¹ *Id.*

²² *Id.*

²³ *Id.*

²⁴ *Id.*

²⁵ Fried et al., *Individual and Institutional Corruption in European and US Healthcare: Overview and Link of Various Corruption Typologies* (2018), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5940713/> [<https://perma.cc/947B-Y6S8>].

²⁶ *Id.*

²⁷ *See id.*

²⁸ *See Former Department of Veterans Affairs Official Sentenced to 46 Months In Prison for Taking \$1.2 Million in Kickbacks*, U.S. DEP’T OF JUST. (2015), <https://www.justice.gov/usao-nj/pr/former-department-veterans-affairs-official-sentenced-46-months-prison-taking-12-million> [<https://perma.cc/9HFT-NP95>].

care at 1,255 health care facilities, including 170 VA Medical Centers and 1,074 outpatient sites of care of varying complexity (VHA outpatient clinics) to over 9 million veterans enrolled in the VA health care program.²⁹

If you consider that kickback schemes involving specific contracts and referrals, this system presents a huge opportunity for fraudsters.³⁰ In the below example, an indictment alleges that defendants made materially false statements and omissions in the course of applying for a \$59 million contract with the VA.³¹ Contracts that large are not common in most healthcare systems.³² But a contract with the VA national system can be worth tens of millions of dollars.³³

Former VA podiatry chief Anthony Lazzarino and Sunrise Shoes CEO Peter Wong were charged with healthcare fraud, conspiracy to pay and receive kickbacks on medical referrals, and conspiracy to commit wire fraud.³⁴ The indictment alleged that between March 2008 and February 2015, Lazzarino and Wong engaged in a scheme to defraud the VA by billing the VHA for custom work and services that were prescribed but not supplied in shoes delivered to veterans.³⁵ Specifically, the two men teamed up to bill the VA for nearly \$1.7 million worth of specialized shoes, some of them costing as much as \$1,682 a pair, while veterans received only “off-the-shelf” products from Sunrise Shoes.³⁶

In addition, the indictment alleges that Lazzarino referred patients directly to Sunrise Shoes, in violation of VA policy, and agreed with Wong to offer kickbacks in return for such referrals.³⁷ Specifically, Lazzarino made sure veterans were steered to Sunrise

²⁹ *Veterans Health Administration*, DEP'T OF VETERANS AFF., <https://www.va.gov/health/aboutvha.asp> [<https://perma.cc/7SGY-76JD>].

³⁰ *See A Roadmap for New Physicians: Fraud & Abuse Laws*, OFF. OF INSPECTOR GEN., <https://oig.hhs.gov/compliance/physician-education/01laws.asp> [<https://perma.cc/9JX4-HXWC>].

³¹ Sealed Indictment at 11–12, Lazzarino, No.2:16-CR-0237 TLN (E.D. Cal. Dec. 15, 2016), ECF No.1.

³² *Id.*

³³ As discussed earlier in this section, the Veterans' Health Administration [of the VA] is the largest integrated healthcare system in the United States.

³⁴ Sealed Indictment at 18, Lazzarino, No.2:16-CR-0237 TLN (E.D. Cal. Dec. 15, 2016), ECF No.1.

³⁵ *Id.* at 3–4.

³⁶ *Id.* at 3–5.

³⁷ *Id.* at 6–10.

by handing them the store's business card and making disparaging comments about other vendors.³⁸

Further, the indictment alleges that Lazzarino and Wong agreed to make materially false statements and omissions to the VA regarding where the shoes were manufactured in the course of applying for a contract with the VA.³⁹ At the time of this writing, neither party has been convicted on these alleged charges.⁴⁰ "If convicted, Lazzarino and Wong face a maximum statutory penalty of 10 years in prison and a \$250,000 fine for each health-care fraud count, and five years in prison and a \$250,000 fine for each of the two conspiracy counts."⁴¹

C. Medical Identity Theft

Increased cybersecurity threats and identity theft have led to a rise in an expensive and dangerous offspring in the healthcare sector: medical identity theft.⁴² According to the Department of Health and Human Services, medical identity theft is one of the fastest-growing areas of healthcare fraud.⁴³ In this type of fraud, medical information is often stolen by employees at medical facilities to sell on the black market for a profit or by an uninsured individual who needs medical treatment.⁴⁴ Thieves may also hack into pacemakers, insulin pumps, medical databases or even break into medical facilities.⁴⁵ Medical identity thieves

³⁸ *Id.* at 4.

³⁹ *Id.* at 3–5.

⁴⁰ *Id.* at 17–18.

⁴¹ Press Release, U.S. Dep't of Just., Former VA Podiatry Chief and Sunrise Shoes CEO Indicted for Health Care Fraud Scheme (Dec. 16, 2016), <https://www.justice.gov/usao-edca/pr/former-va-podiatry-chief-and-sunrise-shoes-ceo-indicted-health-care-fraud-scheme> [<https://perma.cc/LS5Q-N9ZE>].

⁴² Michael Ollove, *The Rise of Medical Identity Theft in Healthcare*, KAISER HEALTH NEWS (Feb. 7, 2014), <https://khn.org/news/rise-of-identity-theft/> [<https://perma.cc/PFX3-4LGY>].

⁴³ *Id.*

⁴⁴ *Id.*

⁴⁵ *By the Numbers: Fraud Statistics*, COALITION AGAINST INS. FRAUD (2016), <http://www.insurancefraud.org/statistics.htm> [<https://perma.cc/W4NW-45MW>]. See generally Katherine Booth Wellington, *Cyberattacks on Medical Devices and Hospital Networks: Legal Gaps and Regulatory Solution*, 30 SANTA CLARA COMP. & HIGH TECH. L.J. 139 (2014).

often use false or stolen personal medical data to create claims and bill the victim's health insurance company.⁴⁶

Not only is medical identity theft very costly for the victim, it also causes great stress.⁴⁷ According to a survey by the Ponemon Institute, 65 percent of victims paid an average of \$13,500 to repair the harm done by this type of theft.⁴⁸ In addition to the significant costs, it is time-consuming to resolve medical identity theft.⁴⁹ In another survey by Ponemon Institute, victims of medical identity theft spent 200 hours correcting their compromised data.⁵⁰ But worse, a victim's medical history can be permanently altered, with diseases or injuries the victim never had falsely entered into records, further harming the victim by having the wrong medical information (for example, incorrect blood type) on file.⁵¹

Unfortunately, many people who are victims of medical identity theft may not find out until months later.⁵² "Few consumers [even] know what medical identity theft is or how much this crime can damage their credit and health."⁵³ Only 15 percent of adults state that they are familiar with medical identity theft.⁵⁴ Of those, only 38 percent could correctly define "medical identity."⁵⁵ Targets of medical identity theft particularly include the elderly and disabled, who are less likely to notice that anything is wrong.⁵⁶ Individuals can protect their information from being stolen in the first place by being careful when discarding items containing health information, such as billing statements and prescription bottles.⁵⁷ The explanation of benefits documents should also be carefully reviewed to spot potential red flags.⁵⁸

⁴⁶ Wellington, *supra* note 45, at 151.

⁴⁷ COALITION AGAINST INS. FRAUD, *supra* note 45.

⁴⁸ *Fifth Annual Study on Identity Theft* (2016), PONEMON INST., http://medi dfraud.org/wp-content/uploads/2015/02/2014_Medical_ID_Theft_Study1.pdf [<https://perma.cc/8X5D-6DS3>].

⁴⁹ *Id.*

⁵⁰ *Id.*

⁵¹ *Id.*

⁵² COALITION AGAINST INS. FRAUD, *supra* note 45.

⁵³ *Id.*

⁵⁴ *Id.*

⁵⁵ *Id.*

⁵⁶ Michelino Mancini, *Medical Identity Theft in the Emergency Department: Awareness is Crucial*, NCBI (Sept. 24, 2014), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4251251/> [<https://perma.cc/B5C6-FCYH>].

⁵⁷ PONEMON INST., *supra* note 48.

⁵⁸ *Id.*

“Most cases of medical identity theft occur through the emergency department [in hospitals].”⁵⁹ Doctors working in hospitals can also be victims of medical identity theft, for example, when blank prescription forms are stolen and then sold in the black market.⁶⁰ In 2011, the Latin Kings gang from New York was found to be trafficking stolen prescription forms with forged signatures.⁶¹ These prescriptions, mostly for the addictive painkiller Oxycodone, were sold by the gang nationwide for \$100 to \$300 to users seeking drugs.⁶² The prescriptions were stolen from local New York hospitals due to poor controls and safeguards, and the incident was part of a large national trafficking scheme involving up to 1.4 million prescription forms.⁶³

In an attempt to address medical identity theft, new technologies have been developed that can help health insurers reduce the chance of being defrauded.⁶⁴ Most insurers use basic tools such as automated red flags and business rules.⁶⁵ But advanced

⁵⁹ John Dumfries, *Healthcare Fraud and Medical Identity Theft in Canada and USA* (Oct. 9, 2012), THE INST. OF INTERNAL AUDITORS CAN., http://www.wsu.com/iia/healthcare_fraud_bw.pdf [<https://perma.cc/T9B4-DYL9>] (alteration in quote).

⁶⁰ See Shantanu Agrawal & Peter Budetti, *Physician Medical Identity Theft*, 307 JAMA 459 (Feb. 1, 2012), <https://jamanetwork.com/journals/jama/article-abstract/1104942> [<https://perma.cc/7RZR-GCFG>] (“Medical identity theft is the appropriation or misuse of a patient’s or physician’s unique medical identifying information to obtain or bill public or private payers for fraudulent medical goods or services. For physicians, this information includes the National Provider Identifier (NPI), Tax Identification Number (TIN), and medical licensure information.”).

⁶¹ Robert Lewis & Will Van Sant, *NY: Up to 1.4M Prescription Forms Stolen*, NEWSDAY (Oct. 23, 2011, 12:01 AM), <http://www.newsday.com/news/health/ny-up-to-1-4m-prescription-forms-stolen-1.3265916> [<https://perma.cc/R85Y-W2F5>].

⁶² *Id.*

⁶³ *Id.*

⁶⁴ For an example of technology being used to help to detect hospital fraud, see, e.g. Joan H. Krause, *Following the Money in Health Care Fraud: Reflections on a Modern-Day Yellow Brick Road*, 36 AM. J.L. SCI. 343, 349 (2010) (“Health Outcomes Technologies was a software company that developed computer-based health outcomes measurement and disease management systems. Using this technology, the company was able to identify hospitals that had billed for bacterial pneumonia at rates far in excess of the national average....”).

⁶⁵ COALITION AGAINST INS. FRAUD, THE STATE OF INSURANCE FRAUD: A STUDY OF INSURER USE, STRATEGIES AND PLANS FOR ANTI-FRAUD TECHNOLOGY 4 (Nov. 2016), http://www.insurancefraud.org/downloads/State_of_Insurance_Fraud_Technology2016.pdf [<https://perma.cc/39KB-NETS>].

tools (such as link analysis, predictive modeling, text mining, and geo-mapping) are not as commonly used by insurers.⁶⁶ More than half of insurers cite a lack of IT resources as the main stumbling block in implementing anti-fraud technology.⁶⁷

D. Hospital Frauds

Lack of oversight and an overly complex system has led to the widespread occurrence of healthcare-related fraud in the hospital industry.⁶⁸ The types of fraud committed relating to hospitals are multifold.⁶⁹ These frauds can be divided into frauds committed “by” hospitals and frauds committed “against” hospitals.⁷⁰ Some of the more typical schemes of both types are discussed next.

1. Unnecessary Procedures

When hospitals commit fraud, it is often in the form of unnecessary procedures.⁷¹ These frauds can be attributed to several different reasons.⁷² For example, hospitals desire to improve their reputation by having completed a large number of procedures and,

⁶⁶ *Id.* at 4.

⁶⁷ *Id.* at 6.

⁶⁸ See Passard Dean, Josseibel Vazquez-Gonzalez & Lucy Fricker, *Causes and Challenges of Healthcare Fraud in the US*, 4 INT’L J. BUS. SOC. SCI. No. 14 at 1–3 (Nov. 2013), https://ijbssnet.com/journals/Vol_4_No_14_November_2013/1.pdf [<https://perma.cc/2SGX-DY24>] (discussing the “complex environment of the healthcare industry” and “low perceived risk of getting caught” as factors contributing to the “widespread problem” of healthcare fraud in the United States).

⁶⁹ See Dana McWay & Seena Kurian, *Busting Bad Medicine: A Call to Action Addressing Healthcare, Fraud, Waste, and Abuse*, 88 J. AM. HEALTH INFO. MGMT. ASS’N 32 no. 10 (Oct. 2017), <http://library.ahima.org/doc?oid=302311#.XY5TmEZKhyw> [<https://perma.cc/QH8Z-M5K2>] (discussing common types of healthcare fraud committed by providers).

⁷⁰ See James Byrd, Paige Powell & Douglas Smith, *Health Care Fraud: An Introduction to a Major Cost Issue*, 14 J. ACCT. ETHICS & PUB. POL’Y, 521, 528 (2013), <https://ssrn.com/abstract=2285860> [<https://perma.cc/T7VZ-QXVE>] (“In addition to fraud committed by health care providers, individuals commit frauds against providers and insurers...”).

⁷¹ See McWay & Kurian, *supra* note 69 (listing “[b]illing for services that were not medically necessary” as one of the common types of healthcare fraud).

⁷² See generally Dean et al., *supra* note 68 (exploring multiple aspects of the healthcare industry that makes it prone to fraud); see also Byrd et al., *supra* note 70, at 529 (stating that motivations to commit fraud in the healthcare industry “are as varied as the number of providers and health care patients”).

therefore, appearing to be more proficient at performing them.⁷³ Stringent regulations from the federal Medicare and Medicaid programs also represent reasons for doctors and hospitals to commit fraud against their patients.⁷⁴ But perhaps the largest pressure is the desire to meet financial goals and create the additional revenues generated by billing for these procedures.⁷⁵ When profits are a factor, hospitals can habitually upgrade patients to more expensive therapies even when lower cost alternatives offer a better outcome for the patient.⁷⁶ Also, as the demand for hospital services has declined with individuals seeking less costly alternatives, hospitals have sought additional ways of generating revenues.⁷⁷ Unnecessary aggressive chemotherapy, cancer treatments, infusion therapies, and cardiac procedures are some examples of unnecessary procedures performed by hospitals.⁷⁸ The following

⁷³ See United States *ex rel.* Riley v. St. Luke's Episcopal Hosp., 355 F.3d 370, 374 (5th Cir. 2004) (Complainant stated that “in apparent pursuit of prestige by being industry leaders in terms of number of heart transplants performed, Defendants performed unnecessary heart transplants”); REBECCA SALTIEL BUSCH, HEALTHCARE FRAUD, AUDITING AND DETECTION GUIDE 9 (John Wiley & Sons, Inc., 2d ed. 2012) (listing “[c]ompetitive advantage” as one of the targets of healthcare fraud).

⁷⁴ Byrd et al., *supra* note 70, at 527–28 (stating that to avoid “fines or penalties” or “closure of a facility” by Centers for Medicare and Medicaid Services, a provider may conduct “unnecessary services”).

⁷⁵ Aaron E. Carroll, *The High Costs of Unnecessary Care*, 318 JAMA no. 9 1748, 1749 (2017), <https://jamanetwork.com/journals/jama/fullarticle/2662877> [<https://perma.cc/R4XW-NQFR>] (noting a “recent survey found that more than 70 [percent] of physicians believe that physicians are more likely to perform unnecessary procedures when they profit from them” and the reimbursement system that increases revenue for healthcare providers when they provide more care).

⁷⁶ Shefali Luthra, *Infusion Treatments—Needed or Not—Can Deplete Patients' Wallets*, KAISER HEALTH NEWS (AUG. 2, 2019), <https://khn.org/news/infusion-treatments-for-low-iron-can-deplete-patients-wallets/> [<https://perma.cc/2CTL-PX7Z>] (noting how Medicare and private insurance's reimbursement system gives providers an incentive to pick the newer, more expensive option).

⁷⁷ See Melanie Evans, *U.S. Hospital Profits Fall as Labor Costs Grow and Patient Mix Shifts*, WALL ST. J. (Apr. 23, 2018, 11:00 AM), <https://www.wsj.com/articles/u-s-hospital-profits-fall-as-labor-costs-grow-and-patient-mix-shifts-1524495601> [<https://perma.cc/U4FP-83PU>].

⁷⁸ See Luthra, *supra* note 76 (finding hospital use of unnecessary infusions); Mustaqeem Siddiqui & Vincent Rajkumar, *The High Cost of Cancer Drugs and What We Can Do About It*, 87 MAYO CLINIC STET. 935, 938 (Oct. 2012), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3538397/pdf/main.pdf> [<https://perma.cc/L6QJ-5Z6X>] (“Physicians receiving more generous Medicare reimbursements ... used more costly [cancer] treatment regimens.”).

case demonstrates how one hospital extracted funds illegally from Medicare and Medicaid by performing unnecessary procedures on its patients.

In 2014, Saint Joseph London Hospital agreed to pay the U.S. government \$16.5 million to settle “civil allegations that it submitted false or fraudulent claims to the Medicare and Kentucky Medicaid programs for a variety of medically unnecessary heart procedures.”⁷⁹ Between 2008 and 2011, “several doctors working at the hospital performed numerous invasive cardiac procedures”—“which included coronary stents, pacemakers, coronary artery bypass graft surgeries (“CABGS”), and diagnostic catheterizations”—“on Medicare and Medicaid patients who did not need them.”⁸⁰

To better understand this example of hospital fraud, it helps to consider a specific case of a doctor involved in the Saint Joseph London case. One of the doctors at that hospital, Dr. Anis Chalhoub, was sentenced by U.S. District Court “to serve 42 months in federal prison” and pay monetary fines and damages for health-care fraud.⁸¹

In April 2018, a federal jury returned a guilty verdict, after hearing evidence that Dr. Chalhoub defrauded Medicare, Medicaid, and other insurers by implanting medically unnecessary pacemakers in his patients and causing the unnecessary procedures and follow-up care to be billed to health insurance programs. Between 2007 and 2011, Dr. Chalhoub implanted approximately 234 pacemakers in patients at St. Joseph London hospital. The evidence at trial showed that dozens of those patients’ pacemakers were medically unnecessary under well-established national guidelines and Medicare coverage rules. A number of patients testified at trial that Dr. Chalhoub pressured them into getting the procedures [and misled them] about their health conditions. For instance, several patients recalled Dr. Chalhoub telling them that they might die without a pacemaker. Sinus

⁷⁹ Press Release, U.S. Dep’t of Justice, Saint Joseph London Hospital to Pay \$16.5 Million to Settle False Claims Act Allegations of Unnecessary Heart Procedures (Jan. 28, 2014), <https://www.justice.gov/usao-edky/pr/saint-joseph-london-hospital-pay-165-million-settle-false-claims-act-allegations> [<https://perma.cc/P8NQ-Q9Z3>].

⁸⁰ *Id.*

⁸¹ Press Release, U.S. Dep’t of Justice, London Cardiologist Sentenced to 42 Months for Health Care Fraud (Oct. 31, 2018), <https://www.justice.gov/usao-edky/pr/london-cardiologist-sentenced-42-months-health-care-fraud> [<https://perma.cc/SC9Y-ZVAQ>].

node dysfunction, the diagnosis Dr. Chalhoub gave the patients, is a non-fatal condition. The jury also heard evidence that Medicare, Medicaid, and other insurers suffered hundreds of thousands of dollars in losses from Dr. Chalhoub's unnecessary procedures.⁸²

A so-called "hospital-physician transaction," which is any cooperation between a hospital and a physician, can also have the potential for healthcare fraud.⁸³ According to the Stark Law and the False Claims Act (both discussed below), hospitals are prohibited from submitting claims to Medicare for patients referred to the hospital by physicians who have a "prohibited financial relationship" with the hospital.⁸⁴ These parties could potentially negotiate for a transaction for less or more than fair market value.⁸⁵ A legitimate hospital-physician relationship is one where the physician is paid fair market value, meaning the amount paid in an arm's-length transaction.⁸⁶ Hospital-physician transactions can be complex, such that illegal activities are not always clear-cut.⁸⁷

In the following case, involving an illegal hospital-physician transaction, however, the transactions were clearly not paid at fair market value.⁸⁸ The U.S. Department of Justice (DOJ) obtained

⁸² *Id.*

⁸³ See Leigh Walton et al., *Hospitals Employing Physicians: A Practical Guide to Buying Physician Practices and Compensating Employed Doctors*, 22 HEALTH L. 1, 5 (2009) ("In an effort to prevent fraud and abuse in the health-care system, federal and state laws impose significant restrictions on the manner in which hospitals compensate physicians for the items and services they provide to the hospital.").

⁸⁴ See generally 42 U.S.C. § 1395nn (2012) (also called the Stark Law); False Claims Act (FCA), 31 U.S.C. §§ 3729–3733 (2012).

⁸⁵ See Walton et al., *supra* note 83, at 9 (stating to avoid considerations of fraud "it is critical that a hospital purchasing a physician practice buy the practice for a price that does not exceed fair market value").

⁸⁶ Lisa Ohrin, Daryl Johnson Macc & Lawrence Vernaglia, *Fair Market Value and Commercial Reasonableness in Hospital/Physician Transactions: What's the Difference?*, Roundtable Webinar Discussion, American Health Lawyers Association (Jan. 3, 2012), https://www.healthlawyers.org/Events/Webinars/RoundtableDiscussions/2011/Documents/roundtable_discussion_slides_010312.pdf [<https://perma.cc/4A3Q-TFGY>].

⁸⁷ See Walton et al., *supra* note 83, at 9.

⁸⁸ Press Release, U.S. Dep't of Justice, United States Resolves \$237 Million False Claims Act Judgment against South Carolina Hospital that Made Illegal Payments to Referring Physicians (Oct. 16, 2015), <https://www.justice.gov/opa/pr/united-states-resolves-237-million-false-claims-act-judgment-against-south-carolina-hospital> [<https://perma.cc/JJM4-SGA4>].

a \$237 million judgment against South Carolina-based Tuomey Healthcare System Inc., which was accused of having a referral agreement with physicians.⁸⁹ Tuomey entered into contracts with 19 physicians that required the physicians to refer their outpatient procedures to Tuomey to avoid losing lucrative outpatient procedure referrals to a surgery center.⁹⁰ In exchange, Tuomey paid the physicians “compensation that far exceeded fair market value and included part of the money it received from Medicare for the referred procedures”.⁹¹ The DOJ “reached a \$1 million settlement with Ralph J. Cox III”, the former CEO of Tuomey Healthcare System, for his involvement in the hospital’s illegal Medicare and Medicaid billings for services referred by physicians with whom the hospital had improper financial relationships.⁹² “Under the terms of the settlement agreement”, Cox was also “excluded from participating in federal healthcare programs, including management or administrative services paid for by federal healthcare programs, for four years.”⁹³

2. *Embezzlement*

Healthcare frauds are also committed against hospitals.⁹⁴ These often take the form of embezzlement, where an unauthorized benefit is shifted from the hospital to the fraudster.⁹⁵ Employees, from secretaries to CEOs, can become fraudsters and embezzle funds from hospitals just as easily as they can in any other business.⁹⁶ When people are placed in positions of trust over large sums of money, such as is the case in hospitals, the risk of embezzlement is amplified.⁹⁷ Also, hospitals are often not-for-profit

⁸⁹ *Id.*

⁹⁰ *Id.*

⁹¹ *Id.*

⁹² *Id.*

⁹³ *Id.*

⁹⁴ See Byrd et al., *supra* note 70, at 529.

⁹⁵ See generally Deborah R. Mathis & Michael S. Lewis, *Employee Embezzlement: A Growing Problem*, 25 J. MED. PRAC. MGMT. 146 (2009) (discussing embezzlement in healthcare).

⁹⁶ Press Release, U.S. Dep’t of Justice, Ex-CEO of Imperial Valley Hospital Pleads Guilty to Fraud and Embezzlement (July 31, 2013), <https://archives.fbi.gov/archives/sandiego/press-releases/2013/ex-ceo-of-imperial-valley-hospital-pleads-guilty-to-fraud-and-embezzlement> [<https://perma.cc/ZJU9-2X8Q>].

⁹⁷ See Joseph T. Wells, *Why Employees Commit Fraud*, J. ACCT. (Feb. 1, 2001), <https://www.journalofaccountancy.com/issues/2001/feb/whyemployees>

organizations, which means an increased risk of embezzlement, as hospitals often have fewer employees and less segregation of duties.⁹⁸ The following two cases highlight how employees of hospitals embezzled funds from employers through various methods.

In the first case, William Roe, CFO of Danbury Hospital in Hartford, Connecticut, set up a fake software company and then approved payments totaling \$95,000 for services never performed.⁹⁹ He also fraudulently received \$46,166 when he altered the appraisal value of his home when Danbury Hospital agreed to pay the difference between the sales price and the appraised value as part of his hiring agreement as CFO.¹⁰⁰ He was sentenced to 33 months in prison.¹⁰¹ Interestingly, prior to working at Danbury Hospital, Roe worked for St. Rita Hospital in Ohio where he stole \$75,000 using the same software company scheme.¹⁰² If the earlier hospital had decided to prosecute, perhaps the crimes at the second hospital would have been prevented.

In the second case, Eduora McDaniel, a VA employee, and Angela Hunter, co-owner of Divine Iron Works, generated purchase orders for fictitious goods and services.¹⁰³ “They [allegedly] entered into an agreement to split the VA’s payments for goods and services Hunter’s company never provided.”¹⁰⁴ Divine Iron Works “was effectively defunct from January 2011 to December

commitfraud.html [<https://perma.cc/HJ9X-PUJQ>] (“If one person controls both the books and the assets, the ability to commit fraud is limited only by that person’s imagination.”).

⁹⁸ See Mathis & Lewis, *supra* note 95, at 147 (“Practices that are able to segregate duties ... will be less vulnerable to embezzlement.”).

⁹⁹ John Pirro, *Former Danbury Hospital Exec Faces Sentencing for Embezzlement*, NEWS TIMES (July 10, 2011), <http://www.newstimes.com/news/article/Former-Danbury-Hospital-exec-faces-sentencing-for-1460230.php> [<https://perma.cc/GW74-BD78>].

¹⁰⁰ *Id.*

¹⁰¹ Edmond Mahoney, *Former Danbury Hospital CFO Sentenced In Fraud*, HARTFORD COURANT (July 11, 2011), <https://www.courant.com/health/hc-xpm-2011-07-11-hc-hospital-fraud-0712-20110711-story.html> [<https://perma.cc/N2RK-YH72>].

¹⁰² *Id.*

¹⁰³ Press Release, U.S. Dep’t of Justice, VA Employee and Former Vendor Charged with Fraud in Alleged Bogus Invoice Scheme (June 12, 2018), <https://www.justice.gov/usao-sdtx/pr/va-employee-and-former-vendor-charged-fraud-alleged-bogus-invoice-scheme> [<https://perma.cc/YW2T-TU4M>].

¹⁰⁴ *Id.*

2014 and provided no actual goods or services.”¹⁰⁵ “[A]s a VA prosthetics representative, McDaniel had the authority to obtain prosthetic goods and services if a [VA] physician found them medically necessary” and she had a government-issued Visa credit card for this purpose.¹⁰⁶ “McDaniel [allegedly] created bogus purchase orders for Hunter’s company, which Hunter used to obtain payment on McDaniel’s government credit cards.”¹⁰⁷

3. *Unauthorized Practice*

Practicing, attempting to practice or offering to practice a regulated healthcare profession without a valid license can be a felony offense carrying minimum mandatory jail penalties (for example, see Florida Statute § 456.065(2)(d)).¹⁰⁸ The following case illustrates how an unlicensed individual posing as a licensed medical professional can endanger patients’ health.

Juan Manuel Perez falsely held himself out as a Licensed Vocational Nurse (LVN).¹⁰⁹ In January 2015, Perez obtained employment with Cleveland Health Care LLC in McAllen, Texas, falsely claiming to be a LVN.¹¹⁰ Perez presented a license number, which allegedly belonged to another individual with the same name.¹¹¹ However, Perez was not licensed by the Texas Board of Nursing and was never an LVN.¹¹² From January 2015 through July 2016, Perez conducted patient home visits and provided medical services while employed with Cleveland Health Care.¹¹³ Perez later utilized the stolen identification to gain employment with various other area healthcare institutions, including Harlingen Medical Center and Valley Baptist Medical Center.¹¹⁴ Perez

¹⁰⁵ *Id.*

¹⁰⁶ *Id.*

¹⁰⁷ *Id.*

¹⁰⁸ See FLA. STAT. ANN. § 456.065(2)(d) (West 2001).

¹⁰⁹ Press Release, U.S. Dep’t of Just., San Benito Man Heads to Prison for Posing as Licensed Vocational Nurse (Jan. 31, 2017), <https://www.justice.gov/usao-sdtx/pr/san-benito-man-heads-prison-posing-licensed-vocational-nurse> [<https://perma.cc/4FAV-GN52>].

¹¹⁰ *Id.*

¹¹¹ *Id.*

¹¹² *Id.*

¹¹³ *Id.*

¹¹⁴ Press Release, U.S. Dep’t of Just., San Benito Man Arrested for Posing as LVN (Aug. 15, 2016), <https://www.justice.gov/usao-sdtx/pr/san-benito-man-arrested-posing-lvn> [<https://perma.cc/9BUK-HTJT>].

received a mandatory 24-month prison sentence in connection with identity misappropriation.¹¹⁵

4. *Pharmaceutical and Durable Medical Equipment Fraud*

Some of the largest and most complex fraud cases are those involving pharmaceuticals and durable medical equipment.¹¹⁶ Nationally, there has been a focus on the misuse of and addiction to opioids and other narcotics.¹¹⁷ In fact, in one month (June 2018), the Attorney General and the Department of Health and Human Services announced that 162 defendants, including 76 doctors, had been charged for their roles in schemes involving opioids and other narcotics.¹¹⁸ The year-over-year trends are staggering: the DOJ reported that while 90 defendants were charged in 2014, 301 defendants were charged in 2016, and 601 defendants were charged in 2018.¹¹⁹ Opioid-related fraud losses grew from \$260 million in 2014 to \$2 billion in 2018.¹²⁰

Over half of the states reported narcotic-related fraud cases from 2018.¹²¹ Examples include an indictment in California, where two podiatrists were accused of providing pre-printed prescriptions, regardless of need, in exchange for kickbacks, prostitutes, and expensive meals.¹²² These prescriptions allegedly amounted to more than \$250 million in fraudulent claims.¹²³ An additional indictment in Texas claimed that fraudulent prescriptions were used to order over one million pills of hydrocodone and oxycodone.¹²⁴ In this instance, 48 individuals, including a pharmacy chain owner

¹¹⁵ *Id.*

¹¹⁶ See, e.g., Opioid Crisis Response Act of 2018, Pub. L. No. 115-271, 132 Stat. 4012 (2018), available at <https://oig.hhs.gov/fraud/enforcement/criminal/> [<https://perma.cc/9BUK-HTJT>].

¹¹⁷ *Id.*

¹¹⁸ National Health Care Fraud Takedown Results in Charges Against 601 Individuals Responsible for Over \$2 Billion in Fraud Losses, *supra* note 20.

¹¹⁹ *Documents and Resources from the June 28, 2018 National Health Care Fraud and Opioid Takedown Press Conference*, U.S. DEP'T OF JUST. (June 28, 2018), <https://www.justice.gov/opa/documents-and-resources-june-28-2018> [<https://perma.cc/H6PF-Z75Q>].

¹²⁰ *Id.*

¹²¹ National Health Care Fraud Takedown Results in Charges Against 601 Individuals Responsible for Over \$2 Billion in Fraud Losses, *supra* note 20.

¹²² *Id.*

¹²³ *Id.*

¹²⁴ *Id.*

and pharmacist, were charged with fraud.¹²⁵ In a 2018 case, a Delaware physician was charged with unlawfully prescribing more than two million units of oxycodone.¹²⁶ In total, 30 states and 58 federal districts reported cases in 2018.¹²⁷

Fraudsters have also targeted durable medical equipment (DME).¹²⁸ DME is medical equipment that is prescribed by a treating physician to be used in the home or homelike setting on a repeated basis, such as walkers, wheelchairs, and back braces.¹²⁹ Fraud related to DME is not new; according to the Government Accounting Office, DME and medical facilities accounted for 41 percent of all criminal case subjects in 2005 and about 40 percent of all criminal cases brought under the FCA in 2010.¹³⁰

Fraud related to DME has evolved with healthcare. Over the past decade, healthcare services have moved from inpatient settings to clinic settings and then to telemedicine, which allows providers to diagnose and prescribe medicine to patients via telephone and video.¹³¹ In April 2019, the DOJ reported the indictment of 24 defendants, including CEOs and COOs of five telemedicine companies, the owners of dozens of DME companies and three licensed medical professionals.¹³² In short, the government believed

¹²⁵ *Id.*

¹²⁶ *Id.*

¹²⁷ *Documents and Resources from the June 28, 2018 National Health Care Fraud and Opioid Takedown Press Conference*, *supra* note 119.

¹²⁸ For example, in 2011, one of the largest national DME suppliers, Hill-Rom Company, paid \$41.8 million to settle allegations that it submitted false claims over an eight-year period related to medical bed equipment. *Hill-Rom Company, Inc. Will Pay \$41.8 Million to Resolve Federal Healthcare Fraud Investigation*, U.S. DEP'T OF JUST. (Sept. 27, 2011), <https://www.justice.gov/archives/usao/tne/news/2011/September/092711A%20Hill-Rom%20Settlement.html> [<https://perma.cc/J2PK-K9PZ>].

¹²⁹ *Durable Medical Equipment (DME)*, HEALTHCARE.GOV, <https://www.healthcare.gov/glossary/durable-medical-equipment-dme> [<https://perma.cc/88C8-H7N7>].

¹³⁰ *Health Care Fraud: Types of Providers Involved in Medicare, Medicaid, and the Children's Health Insurance*, U.S. GOV'T ACCOUNTABILITY OFF. (Sept. 2012), <https://www.gao.gov/products/GAO-12-820> [<https://perma.cc/8KR6-AW7V>].

¹³¹ *The Ultimate Telemedicine Guide: What is Telemedicine?*, EVISIT (May 25, 2018), <https://evisit.com/resources/what-is-telemedicine/> [<https://perma.cc/J5E2-PAVN>].

¹³² Press Release, U.S. Dep't of Just., Federal Indictments & Law Enforcement Actions in One of the Largest Health Care Fraud Schemes Involving Telemedicine and Durable Medical Equipment Marketing Executives Results in Charges

that the indicted medical providers worked with telemedicine companies to provide elderly and disabled Medicare beneficiaries with unneeded back, shoulder, and knee braces, resulting in a loss to Medicare of over one billion dollars.¹³³ Allegedly, the telemarketers phoned Medicare beneficiaries, promised free or low-cost orthopedic braces, had physicians who had not treated or evaluated the patients sign prescriptions for the braces, then sold the prescriptions to DME companies who shipped the braces and billed Medicare.¹³⁴ It is believed that the fraudsters then laundered the money through shell companies to purchase cars, yachts, and property in the United States and abroad.¹³⁵

In summary, the forms of healthcare fraud are vast. Many of the fraud cases described above involve similar and overlapping themes. No matter the parties involved, the schemes often include behavior such as billing for services never provided, misstatements of facts, giving kickbacks, stealing information, and committing wire fraud.¹³⁶ The following section discusses the laws enacted to control fraud in the medical industry.

II. MAJOR FEDERAL CIVIL AND CRIMINAL LAWS THAT RELATE TO HEALTHCARE FRAUD

A. *Federal False Claims Act*

The Federal False Claims Act (FCA)¹³⁷ was originally enacted in 1863 to protect the federal government from fraud perpetrated by unscrupulous Civil War contractors.¹³⁸ Today the law is aimed at those responsible for the \$100 billion or more in

Against 24 Individuals Responsible for Over \$1.2 Billion in Losses (Apr. 9, 2019), <https://www.justice.gov/opa/pr/federal-indictments-and-law-enforcement-actions-one-largest-health-care-fraud-schemes> [<https://perma.cc/NX5A-RUG9>].

¹³³ *Id.*

¹³⁴ *Id.*

¹³⁵ *Id.*

¹³⁶ Federation of American Scientists, *Bribery, Kickbacks, and Self-Dealing: An Overview of Honest Services Fraud and Issues for Congress*, CONG. RES. SERV. (Jan. 30, 2019), <https://fas.org/sgp/crs/misc/R45479.pdf> [<https://perma.cc/3WQ6-D89M>].

¹³⁷ 31 U.S.C. §§ 3729–3733 (2018).

¹³⁸ *The False Claims Act*, U.S. DEP'T OF JUST., <https://www.justice.gov/civil/false-claims-act> [<https://perma.cc/6A8S-ACLR>].

fraudulent activity diverted every year from federal healthcare, defense, and other programs.¹³⁹ “In addition to ... monetary losses, fraud also ... erodes public confidence and raises questions about the government’s ability to manage its programs.”¹⁴⁰

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 U.S. government] for payment or approval.”¹⁴¹ The law also imposes liability for making “false record(s) or statement(s) ... [designed] to conceal, avoid, or decrease an obligation to pay or transmit money or property to the [United States] government.”¹⁴²

¹³⁹ M. CRAIN, W. HOPWOOD, C. PACINI & G. YOUNG, *THE ESSENTIALS OF FORENSIC ACCOUNTING* 525 (2015).

¹⁴⁰ J. Morgan Phelps, *The False Claims Act’s Public Disclosure Bar: Defining the Law Between Parasitic and Beneficial*, 49 *CATH. U. L. REV.* 247, 247 (1999).

¹⁴¹ 31 U.S.C. § 3729(a)(1) (2018).

¹⁴² *Id.* § 3729(a)(2). Sections 3729(a)(1) and (2) are the most frequently used provision 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);
- (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,

Many FCA violations involve submission of false information while presenting payments to the federal government.¹⁴³ Two examples of false healthcare claims can be found in *U.S. v. Rogan*¹⁴⁴ and *U.S. v. Cabrera-Diaz*.¹⁴⁵ Using a unique characteristic of the FCA known as the *qui tam* action, private citizens, rather than government attorneys, are allowed to challenge FCA violations.¹⁴⁶

A *qui tam* plaintiff, also referred to as a *qui tam* relator or a whistleblower, is a private citizen who files a civil lawsuit against an alleged fraudster on behalf of himself and the US government.¹⁴⁷ If the government does not pursue the action, the relator pursuing 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.”¹⁴⁸ In addition, the *qui tam* plaintiff is entitled to collect from the defendant reasonable attorneys’ fees, and expenses from pursuing the claim.¹⁴⁹ In the event the defendant retaliates against the plaintiff through discharge, demotion, suspension, harassment, or discrimination in any other manner, the plaintiff shall be entitled “to all relief necessary to make the [plaintiff] whole.”¹⁵⁰ If the federal government intervenes in the lawsuit initiated by the *qui tam* relator, the latter 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.”¹⁵¹

(H) Is liable to the United States Government for a civil penalty....

¹⁴³ *The False Claims Act: A Primer*, U.S. DEP’T OF JUST., https://www.justice.gov/sites/default/files/civil/legacy/2011/04/22/C-FRAUDS_FCA_Primer.pdf [<https://perma.cc/U6J4-5ZBR>].

¹⁴⁴ See 459 F. Supp. 2d 692, 692 (N.D. Ill. Oct. 27, 2005). This case involved alleged falsification of annual reports to Medicare.

¹⁴⁵ See 106 F. Supp. 2d 234, 234 (D.P.R. 2000). This case involved alleged false claims submitted to Medicare for anesthesia services.

¹⁴⁶ “*Qui tam*” is a term derived from the Latin phrase “*qui tam pro domino rege quam pro se, ipso in hac parte requites*,” which means, “who as well for the king as himself sues in this matter.” BLACK’S LAW DICTIONARY 1262 (7th ed. 1999).

¹⁴⁷ *Id.*

¹⁴⁸ 31 U.S.C. § 3730(d)(2) (2018).

¹⁴⁹ *Id.*

¹⁵⁰ *Id.* § 3730(h)(1).

¹⁵¹ *Id.* § 3730(d).

Because the FCA's damages and penalty provisions tend to generate large dollar settlements and judgments, relators' recoveries can involve substantial amounts.¹⁵² The following are a few examples: In 2013, Johnson and Johnson agreed to pay the federal government more than \$2.2 billion to resolve commercial and civil liability under the FCA related to the prescription drugs Risperdal, Invega, and Natrecor.¹⁵³ Pfizer, Inc. and its subsidiary, Pharmacia & 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.¹⁵⁴ Global healthcare company GlaxoSmithKline agreed to plead guilty and pay \$3 billion to resolve criminal and civil liability from the unlawful promotion of certain drugs and 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.¹⁵⁵ The off-label settlement resolves four lawsuits pending in federal district court in Massachusetts under the *qui tam* provisions of the FCA.¹⁵⁶

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 of fraud.¹⁵⁷ Complex financial crimes often cannot

¹⁵² James F. Barger, Jr. et al., *States, Statutes, and Fraud: An Empirical Study of Emerging State False Claims Acts*, 80 TUL. L. REV. 465, 476 (2005).

¹⁵³ Press Release, U.S. Dep't of Just., Johnson & Johnson to Pay More Than \$2.2 Billion to Resolve Criminal and Civil Investigations (Nov. 4, 2013), <https://www.justice.gov/opa/pr/johnson-johnson-pay-more-than-22-billion-resolve-criminal-and-civil-investigations> [<https://perma.cc/XV2P-47HQ>].

¹⁵⁴ Press Release, U.S. Dep't of Just., Justice Department Announces Largest Health Care Fraud Settlement in Its History (Sept. 2, 2009), <https://www.justice.gov/opa/pr/justice-department-announces-largest-health-care-fraud-settlement-its-history> [<https://perma.cc/5VKX-FBQE>].

¹⁵⁵ Press Release, U.S. Dep't of Just., GlaxoSmithKline to Plead Guilty and Pay \$3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data (July 2, 2009), <https://www.justice.gov/opa/pr/glaxosmithkline-plead-guilty-and-pay-3-billion-resolve-fraud-allegations-and-failure-report> [<https://perma.cc/4RXA-7BFX>].

¹⁵⁶ *Id.*

¹⁵⁷ Carl Pacini & Michael B. Hood, *The Role of Qui Tam Actions Under the False Claims Act in Preventing and Deterring Fraud Against Government*, 15 U. MIAMI BUS. L. REV. 273, 276 (2007).

be detected without the assistance of those who have knowledge of them.¹⁵⁸ However, convincing people to inform or turn on their employer, co-workers, and partners is not an easy task.¹⁵⁹ Second, the statute provides a means for knowledgeable *qui tam* plaintiffs to supplement the strained resources of government attorneys and investigators.¹⁶⁰ This resource supplement is accomplished through the required statutory procedures or protocol.¹⁶¹

A *qui tam* relator who sues under the FCA does so both in an individual capacity and on behalf of the US government.¹⁶² 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 and a copy must be sent to the Department of Justice (DOJ).¹⁶³ “The purpose of the written disclosure requirement is to provide the United States 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.”¹⁶⁴

Although FCA lawsuits have grown during the past decades, the federal government has declined to intervene in almost two-thirds of said lawsuits.¹⁶⁵ When the federal government decides to not get involved, a case is much less likely to result in a recovery.¹⁶⁶ From 1987 to September 30, 2017, FCA recoveries totaled over \$36 billion.¹⁶⁷ Over \$28 billion, or close to 79 percent of that total, has occurred when the US government intervened.¹⁶⁸ Much of the \$36 billion recovered has involved health-care fraud claims, which includes providers (e.g., hospitals, nursing

¹⁵⁸ *Id.* at 276–77.

¹⁵⁹ Phelps, *supra* note 140, at 248.

¹⁶⁰ Barger, Jr. et al., *supra* note 152, at 475–76.

¹⁶¹ *Id.* at 476.

¹⁶² *Id.*

¹⁶³ 31 U.S.C. § 3730(b)(2) (2018).

¹⁶⁴ United States *ex rel.* Bagley v. TRW, Inc., 212 F.R.D. 554, 555 (C.D. Cal. 2003) (quoting United States *ex rel.* Woodward v. Country View Care Ctr., Inc., 797 F.2d 888, 892 (10th Cir. 1986)).

¹⁶⁵ D. Baker, Comment, *A Whole New World of False-Claims-Act Liability: The 2009 Amendments and Learning Where to Draw the Line*, 61 CATH. U. L. REV. 201, 228 (2011).

¹⁶⁶ *Id.*

¹⁶⁷ U.S. DEP’T OF JUST.: CIVIL DIVISION, FRAUD STATISTICS—HEALTH AND HUMAN SERVICES 2017 (Dec. 19, 2017), <https://www.justice.gov/opa/press-release/file/1020116/download> [<https://perma.cc/TUF5-7LZN>].

¹⁶⁸ *Id.*

homes, physicians), pharmaceutical firms, medical device makers, and suppliers.¹⁶⁹

In the fiscal year ended September 30, 2016, the DOJ recovered more than \$4.7 billion in FCA civil cases.¹⁷⁰ Of the \$4.7 billion recovered, 53 percent (or over \$2.5 billion) came from the health-care industry.¹⁷¹ In the fiscal year ended September 30, 2017, the DOJ recouped more than \$3.7 billion in FCA civil cases.¹⁷² Of that amount, over 64 percent (or \$2.4 billion) involved healthcare industry claims.¹⁷³ The FCA has become the primary law used to pursue healthcare fraud.¹⁷⁴

1. Qui Tam *Elements*

The FCA applies to a wide range of misconduct that is potentially harmful to the federal treasury.¹⁷⁵ In 2009, Congress enacted into law the Fraud Enforcement and Recovery Act (FERA),¹⁷⁶ which expanded liability exposure under the FCA. Prior to the enactment of FERA, liability did not attach under Section 3729(a)(1) unless a defendant presented a false claim for payment or approval to an “employee of the United States government or a member of the Armed Forces of the United States.”¹⁷⁷ Today, the 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.¹⁷⁸

¹⁶⁹ Deborah R. Farringer, *From Guns That Do Not Shoot to Foreign Staplers: Has the Supreme Court’s Materiality Standard Under Escobar Provided Clarity for the Health Care Industry About Fraud Under the False Claims Act?*, 83 BROOK. L. REV. 1227, 1236 (2018).

¹⁷⁰ Press Release, U.S. Dep’t of Just., Justice Department Recovers Over \$4.7 Billion From False Claims Act Cases in Fiscal Year 2016 (Dec. 14, 2016), <http://www.justice.gov/opa/pr/justice-department-recovers-over-47-billion-false-claims-act-cases-fiscal-year-2016> [<https://perma.cc/RMR4-8CFD>].

¹⁷¹ *Id.*

¹⁷² Press Release, U.S. Dep’t of Just., Justice Department Recovers From False Claims Act Cases in Fiscal Year 2017 (Dec. 21, 2017), <https://www.justice.gov/opa/pr/justice-department-recovers-over-37-billion-falseclaims-act-cases-fiscal-year2017> [<https://perma.cc/Q35Y-JFKS>].

¹⁷³ *Id.*

¹⁷⁴ *See generally id.*

¹⁷⁵ *See generally* 31 U.S.C. § 3729 (2012).

¹⁷⁶ Fraud Enforcement and Recovery Act of 2009, Pub. L. No. 111-21, 123 Stat. 1617 (2009) (codified as amended in 18 and 31 U.S.C.).

¹⁷⁷ 31 U.S.C. § 3729(a)(1) (2006).

¹⁷⁸ 31 U.S.C. § 3729(a)(1)(A) (2012).

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. As amended by FERA, a “claim” is “any request or demand, whether under a contract or otherwise, for money or otherwise, for money or property and whether the United States has title to the money or property.”¹⁷⁹ “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 government program or interest.¹⁸⁰ In some circumstances, lawyers and other parties must look to sources outside the FCA to ascertain whether a “claim” has been adequately set forth.¹⁸¹

For instance, regulations and statutes define what is a “claim” for payment under Medicare. Under subparts of title 42 of the Code of Federal Regulation, the federal government promises to pay only costs that are “reasonable and necessary.”¹⁸² 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 payable under part B.¹⁸³ Lack of compliance with Part B’s regulations would potentially fail the “claim” requirement under Part B.¹⁸⁴

The FCA does not attach liability to the underlying fraudulent activity or to the government’s wrongful payment, but to the “claim for payment or approval.”¹⁸⁵ 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.¹⁸⁶

¹⁷⁹ *Id.* § 3729(b)(2)(A).

¹⁸⁰ *Id.* § 3729(b)(2).

¹⁸¹ *See* 42 C.F.R. §§ 411.15(4)(k), 415.50–70 (2018).

¹⁸² *Id.*

¹⁸³ Kamal Al-Salihi, *Keeping It Simple: Finding Falsity Under the False Claims Act*, 36 WHITTIER L. REV. 431, 448 (2015).

¹⁸⁴ *Id.*

¹⁸⁵ 31 U.S.C. § 3729(a)(1)(A) (2012).

¹⁸⁶ *United States v. Rivera*, 55 F.3d 703, 709–10 (1st Cir. 1995); *United States v. Richard Dattner Architects*, 972 F. Supp. 738, 746–47 (S.D.N.Y. 1997).

An FCA claim must allege that the defendant submitted either a legally fraudulent or legally false claim.¹⁸⁷ 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.¹⁸⁸ A factually false claim involves a reimbursement request containing an improper listing of services rendered or goods provided.¹⁸⁹ Moreover, Federal Rule of Civil Procedure (FRCP) 9(b) requires a *qui tam* plaintiff to state with particularity the facts constituting fraud.¹⁹⁰ It is significant to note that, since most FCA cases end in settlement,¹⁹¹ the decision on whether FRCP 9(b) has been met holds much importance in the upshot of a given FCA lawsuit.¹⁹²

b. Made “Knowingly” or “Know”

Section 3729(b)(1)(A) indicates that the presenter of information satisfies 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.¹⁹³ The statute further provides that “no proof of specific intent to defraud” is necessary.¹⁹⁴ The requisite intent is the presentation of what is known to be false.¹⁹⁵

Although the FCA does not provide a definition of reckless disregard, the concept embodies a conscious indifference to the

¹⁸⁷ *Foglia v. Renal Ventures Mgmt.*, 830 F. Supp. 2d 8, 16 (D.N.J. 2011); *see also* *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 305 (3rd Cir. 2011).

¹⁸⁸ *Mikes v. Straus*, 274 F.3d 687, 701 (2d Cir. 2001).

¹⁸⁹ *United States ex rel. Conner v. Salina Reg'l Health Ctr., Inc.*, 543 F.3d 1211, 1217 (10th Cir. 2008).

¹⁹⁰ FED. R. CIV. P. 9(b).

¹⁹¹ *Latham's Lauer on Defending False Claims Act Cases*, 22 CORP. CRIM. REP. 8, 3 (Feb. 25, 2008), <http://www.lw.com/mediacoverage/lathams-lauer-on-defending-false-claims-act-cases> [<https://perma.cc/QE3U-7PFK>].

¹⁹² Taylor Chenery & Nicholas A. Deuschle, *Supreme Court Asked to Review Pleading Standard and Constitutionality of FCA*, BASS, BERRY & SIMS P.L.C.: INSIDE THE FCA (Feb. 22, 2019), <https://www.insidethefca.com/fca-pleading-standard-constitutionality/> [<https://perma.cc/TB7V-BP42>].

¹⁹³ 31 U.S.C. § 3729(b)(1)(A) (2012).

¹⁹⁴ *Id.* § 3729(b)(1)(B).

¹⁹⁵ *United States ex rel. Hagood v. Sonoma Cty. Water Agency*, 929 F. 2d 1416, 1421 (9th Cir. 1991).

falsity of a claim.¹⁹⁶ Negligence and innocent mistake, however, are not sufficient to establish liability.¹⁹⁷ An interesting application of the “knowingly” requirement in a healthcare scenario occurred in *United States v. Lorenzo*.¹⁹⁸ It is a fine application of reckless disregard meeting the knowledge requirement of the FCA.

By not requiring proof of specific intent to defraud, Congress and the judiciary have extended liability to almost anyone associated with a false or fraudulent claim. Healthcare providers and others who submit claims for payment to the government thus have a strong incentive to make sure their claims are accurately presented. The knowledge requirement makes it risky for individuals to look the other way with regard to a fraudulent claim.¹⁹⁹

The knowledge requirement is not always a simple question of whether the *qui tam* defendant knew of the truth or falsity of a representation.²⁰⁰ Because many entities entailed in FCA litigation are large, multidimensional firms, some courts judicially impose a second test: not only must there exist an affirmative recognition of falsity, such falsity must be consciously presented to the government.²⁰¹

c. “False” or “Fraudulently”

The Supreme Court has stated that the FCA is not designed to reach every kind of fraud committed against the government.²⁰² The words “false” and “fraudulent” are not defined by Congress

¹⁹⁶ Al-Salihi, *supra* note 183, at 446.

¹⁹⁷ *United States v. Oakwood Downriver Med. Ctr.*, 687 F. Supp. 302, 305 (E.D. Mich. 1988).

¹⁹⁸ *United States v. Lorenzo*, 768 F. Supp. 1127, 1129 (E.D. Pa. 1991). 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. *Id.* at 1129. The cancer screenings, after being billed to Medicaid, were then billed to Medicare as limited consultations. *Id.* at 1129–30. The evidence showed that Lorenzo knew that Medicare rules did not allow procedures during routine screenings to be deemed “limited consultations.” *Id.* at 1131. The district court found that Lorenzo, at the very least, acted in reckless disregard of the truth or falsity of the claims made. *Id.* at 1132.

¹⁹⁹ Christopher Frieden, *Protecting the Government’s Interests: Qui Tam Actions Under the False Claims Act and the Government’s Right to Veto Settlements of Those Actions*, 47 EMORY L. J. 1041, 1057–58 (1998).

²⁰⁰ *Id.* at 1057.

²⁰¹ *Hindo v. Univ. of Health Sci.*, 65 F.3d 608, 613 (7th Cir. 1995).

²⁰² *United States v. McNinch*, 356 U.S. 595, 598 (1958).

in the FCA.²⁰³ These terms have been held by the Supreme Court, in *Universal Health Services, Inc. v. United States ex rel. Escobar*,²⁰⁴ to have meaning based on common law fraud concepts. For example, because the FCA uses the disjunctive “or,” no need exists for a *qui tam* plaintiff to prove a claim is both false and fraudulent. Either will do.²⁰⁵

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.²⁰⁶ *Qui tam* plaintiffs also began to employ the law against “legally false” claims, where services or items were provided but the one seeking payment had untruthfully certified compliance with a statute, regulation, or contractual provision.²⁰⁷

The federal courts have sanctioned two distinct theories of legal falsity.²⁰⁸ Express certification occurs when a party makes a false certification concerning a program condition, such as signing a false certification statement on a document.²⁰⁹ Some federal courts have extended legal falsity to include implied certification.²¹⁰ In *Escobar*, the U.S. Supreme Court stated:

[W]e hold that the implied certification theory can be a basis for liability, at least where two conditions are satisfied: first, the claim does not merely request payment, but also makes specific representations about the goods or services provided; and second, the defendant’s failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths.²¹¹

²⁰³ 31 U.S.C. § 3279 (2009).

²⁰⁴ 136 S. Ct. 1989 (2016).

²⁰⁵ James B. Helmer, Jr. & Julie Popham, *Materiality and the False Claims Act*, 71 U. CIN. L. REV. 839, 845 (2003).

²⁰⁶ *United States ex rel. Conner v. Salina Reg’l Health Ctr., Inc.*, 543 F.3d 1211, 1217 (10th Cir. 2008); Joan H. Krause, *Reflections on Certification, Interpretation, and the Quest for Fraud That “Counts” Under the False Claims Act*, 2017 U. ILL. L. REV. 1811, 1816 (2017).

²⁰⁷ *Conner*, 543 F.3d at 1217.

²⁰⁸ *Id.*

²⁰⁹ *Id.* at 1217–18.

²¹⁰ *Universal Health Serv., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 1995 (2016).

²¹¹ *Id.* at 2001.

The Court further held that a misrepresentation must be material to the government's payment decision.²¹²

The Supreme Court tried to shed further light on the meaning of "materiality" in this context.²¹³ "We need not decide whether § 3729(a)(1)(A)'s materiality requirement is governed by § 3729(b)(4) or derived directly from the common law. Under any understanding of the concept, materiality look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation."²¹⁴ On the other hand, if the government "pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material."²¹⁵

The *Escobar* case left open a number of important questions, including the "threshold question of whether we now have a coherent test defining implied certification."²¹⁶ The confounding new questions will generate more litigation over the implied certification theory.²¹⁷

It seems that the emphasis of the *Escobar* decision is the new focus on the government's behavior and the defendant's knowledge of such behavior.²¹⁸ Lower federal court cases appear to indicate a shift toward a materiality standard which requires evidence that the government was in fact influenced—that is, it knew of the noncompliance and chose to pay the claim anyway.²¹⁹

d. Materiality

Based on a straightforward reading of the FCA statute, the term "material" modifies the "false record" offered in support of a false claim, not the false claim itself.²²⁰ The false record or statement supporting the false claim has to operate in a material way as a supporting document.²²¹ Thus, the "materiality" requirement is

²¹² *Id.* at 2002.

²¹³ *Id.* at 2003.

²¹⁴ *Id.* at 2002.

²¹⁵ *Id.* at 2003.

²¹⁶ Krause, *supra* note 206, at 1830.

²¹⁷ *Id.*

²¹⁸ Farringer, *supra* note 169, at 1258.

²¹⁹ *United States ex rel. Kelly v. Serco, Inc.*, 846 F.3d 325, 332 (9th Cir. 2017); Farringer, *supra* note 169, at 1258.

²²⁰ 31 U.S.C. § 3729(a)(1)(B) (2012).

²²¹ Al-Salihi, *supra* note 183, at 449.

germane only to a section 3729(a)(1)(B) cause of action, not a section 3729(a)(1)(A) lawsuit or legal claim.²²²

Whatever a healthcare provider or contractor is allegedly lying about does not have to be material to lead to section 3729(a)(1)(A) or section 3729(a)(1)(B) liability. A threshold requirement exists that any record used to undergird the accuracy of a false claim must actually support that claim.²²³ Although a trivial false claim can give rise to FCA liability, some courts have judicially grafted the term “material” on to a section 3729(a)(1)(A) analysis (or claim).²²⁴ This approach interprets section 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.”²²⁵ In reality, section 3729(a)(1)(A) does not state this requirement.²²⁶

In those cases that apply “materiality” to section 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.²²⁷ Contemporary courts that use a materiality standard for section 3729(a)(1)(A) claims use a case-by-case fact-intensive analysis to ascertain whether a particular condition of payment is material.²²⁸ In the end, the insertion of materiality into a section 3729(a)(1)(A) analysis muddies what is actually a clear standard.²²⁹

A guilty fraudster under the FCA is liable to the federal government for a civil penalty of not less than \$5000 and not more than \$10,000, plus treble the amount of damages which the government sustains because of the fraudulent act.²³⁰

²²² *Id.*

²²³ *Id.* at 450.

²²⁴ United States *ex rel.* Hutcheson v. Blackstone Med., Inc., 647 F.3d 377, 394–95 (1st Cir. 2011) (providing an analysis of “material” in terms of the claim itself).

²²⁵ *Id.* at 389.

²²⁶ See generally 31 U.S.C. § 3729 (2012).

²²⁷ *Hutcheson*, 647 F.3d at 394 (citations omitted).

²²⁸ See United States v. Sci. Application Int’l. Corp., 626 F.3d 1257, 1269 (D.C. Cir. 2010).

²²⁹ Al-Salihi, *supra* note 183, at 451.

²³⁰ 31 U.S.C. § 3729(a)(1)(G) (2012).

B. FCA Healthcare Fraud Lawsuits Facilitated by the Affordable Care Act

Before the Patient Protection and Affordable Care Act of 2010 (ACA),²³¹ as modified by the Health Care Education and Reconciliation Act of 2010,²³² the FCA had a strong limitation on filing a *qui tam* lawsuit, known as the public disclosure bar.²³³ The FCA used to possess a two-part test to determine whether a federal court could hear a *qui tam* case.²³⁴ First, the court had to ascertain whether the fraud allegations were based on publicly disclosed material.²³⁵ If so, the court then had to assess whether the relator was an original source of the disclosure.²³⁶ 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.²³⁷ The FCA outlined three ways in which prior public disclosure could occur: (1) in a civil, criminal, or administrative hearing;²³⁸ (2) in a Congressional, administrative, or GAO report, audit, or investigation;²³⁹

²³¹ Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010) (amending various sections of the U.S. Code including the FCA and Anti-Kickback Statute).

²³² Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (2010).

²³³ United States *ex rel.* Springfield Terminal Ry. Co. v. Quinn, 14 F.3d 645, 652 (D.C. Cir. 1994).

²³⁴ *Id.* at 651.

²³⁵ *Id.*

²³⁶ *Id.* at 653.

²³⁷ United States v. Alcan Elec. & Eng'g, Inc., 197 F.3d 1014, 1018 (9th Cir. 1999); United States *ex rel.* Biddle v. Bd. of Trustees of the Leland Stanford, Jr. Univ., 161 F.3d 533, 535 (9th Cir. 1998).

²³⁸ "Hearing" encompassed both civil complaints and criminal indictments. United States *ex rel.* Siller v. Becton Dickinson & Co., 21 F.3d 1339, 1350 (4th Cir. 1994). With regard to administrative hearings, the issue of what constituted a "hearing" and thus a "public disclosure" was not so cut and dry. *See, e.g.*, A-1 Ambulance Serv. Inc. v. California, 202 F.3d 1238, 1244 (9th Cir. 2000); United States *ex rel.* Garibaldi v. Orleans Parish Sch. Bd., 21 F. Supp. 2d 607, 614-15 (E.D. La. 1998).

²³⁹ In United States *ex rel.* Schwedt v. Planning Research Corp., 39 F. Supp. 2d 28, 31-32, 34 (D.D.C. 1999), an audit report prepared by the Office of Inspector General and reviewed by an outside accounting firm indicated

or (3) in the media.²⁴⁰ Generally, the courts broadly construed what types of disclosures were public and thus barred *qui tam* suits,²⁴¹ even though some disputes existed among the courts.²⁴²

In the ACA, 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.²⁴³ 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.²⁴⁴ The public disclosure bar does not apply when the *qui tam* plaintiff is an “original source” of the information’s provenance.²⁴⁵ Before the ACA, the public disclosure bar prevented many *qui tam* claims that involved public information, as broadly construed.²⁴⁶ This change to the FCA has enhanced its potency as a weapon against healthcare fraud.²⁴⁷

C. Federal Anti-Kickback Statute

The federal Anti-Kickback Statute²⁴⁸ 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.²⁴⁹ The anti-kickback statute is broadly drafted and establishes liability for

that a government contractor had submitted flawed products while certifying their completeness. The district court held that a *qui tam* suit was based upon a public disclosure and was thus barred.

²⁴⁰ United States *ex rel.* Stinson v. Prudential Ins. Co., 944 F.2d 1149, 1149 (3d Cir. 1991) (construing the term “hearing” to incorporate more than just formal proceedings; it includes any information disclosed in connection with criminal, civil, or administrative litigation).

²⁴¹ See *Springfield Term. Ry. Co.*, 14 F.3d at 654.

²⁴² Phelps, *supra* note 140, at 260.

²⁴³ 31 U.S.C. § 3730(e)(4)(A).

²⁴⁴ 31 U.S.C. § 3730(e)(4)(A)(iii); 31 U.S.C. § 3730(e)(4)(B).

²⁴⁵ *Id.*; J. Hammond, *What Exactly Is Healthcare Fraud After the Affordable Care Act?*, 42 STETSON L. REV. 35, 53 (2012).

²⁴⁶ Hammond, *supra* note 245, at 53.

²⁴⁷ See *id.*

²⁴⁸ 42 U.S.C. §§ 1320a-7b(b) (2017).

²⁴⁹ D. Rheiner, *Kickbacks and Contradictions: The Anti-Kickback Statute and Electronic Health Records*, 17 VAND. J. ENT. & TECH. L. 493, 500 (2015).

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.²⁵⁰ The purpose of the anti-kickback statute is to prevent drains on the public treasury.²⁵¹

In 1985, the Third Circuit Court of Appeals significantly expanded the scope of the anti-kickback statute in *U.S. v. Greber*.²⁵² The court established the “One Purpose Test,” holding that if one purpose of a payment was to induce future referrals, the arrangement violated the anti-kickback statute.²⁵³ Although the anti-kickback statute does not afford a private right of action, the FCA²⁵⁴ provides a vehicle whereby individuals may bring *qui tam* actions²⁵⁵ alleging violations of the anti-kickback law. For a 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, a referral or generation of program-related business.²⁵⁶ The “knowing and willful” element is met by demonstrating the defendant was aware his conduct was unlawful and acted voluntarily and purposely.²⁵⁷ Further clarification of the first element was provided in *U.S. v.*

²⁵⁰ F.T. Pyle III, Comment, *The Federal Anti-Kickback Statute Has No Preemptive Power, or Does It? Florida’s Supreme Court Holds Florida’s Medicaid Anti-Kickback Statute Unconstitutional*, 112 PENN ST. L. REV. 631, 636 (2007).

²⁵¹ *United States v. Bay State Ambulance & Hosp. Rental Serv.*, 874 F.2d 20, 32 (1st Cir. 1989).

²⁵² *See United States v. Greber*, 760 F.2d 68, 71 (3d Cir. 1985).

²⁵³ *Id.* at 69.

²⁵⁴ *See generally* 31 U.S.C. §§ 3729–3733 (2012).

²⁵⁵ A *qui tam* plaintiff, also referred to as a *qui tam* relator, or a whistleblower, is a private citizen who files a civil lawsuit against an alleged fraudster on behalf of himself and the U.S. government. If the government does not pursue actions, the relator pursuing the case is entitled to “not less than 25 percent and not more than 30 percent of the proceeds of the action or settlement.” 31 U.S.C. § 3730(d)(2).

²⁵⁶ 42 U.S.C. § 1320a-7b(b); *United States v. Vernon*, 723 F.3d 1234, 1251–52 (11th Cir. 2013).

²⁵⁷ *Vernon*, 723 F.3d at 1256 (“[T]his court concluded ... the word ‘willfully’ ‘means the act was committed voluntarily and purposely with the specific intent to do something the law forbids, that is, with a bad purpose, either to disobey or disregard the law.’”). In 18 U.S.C. § 1347(b) (2012) it 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.”

Mathur,²⁵⁸ 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.”²⁵⁹

The broad scope of the One Purpose Test has the potential to create liability under the anti-kickback statute for actions that are commonly accepted commercial arrangements.²⁶⁰ Parties can also be liable under the Anti-Kickback Statute even if their actions cause no tangible harm to patients.²⁶¹ 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.²⁶²

The broad scope of potential liability under the statute gave rise to sufficient concern in Congress that numerous “safe harbors” or statutory exceptions were created.²⁶³ The Office of Inspector General (OIG) has listed over twenty-five regulatory safe harbor provisions and one statutory provision²⁶⁴ that protect physicians 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 whether it constitutes an anti-kickback violation.²⁶⁵

The following list is a partial enumeration of some of the safe harbor provisions:

²⁵⁸ *United States v. Mathur*, 2012 WL 4742833, at *15 (D. Nev. Sept. 13, 2012) (“[T]he [Affordable Care Act] has not removed a specific intent requirement from the Anti-Kickback Act ... the government must still show that a criminal defendant acted ‘knowingly and willingly’ in offering or paying remunerations in exchange for patient referrals. [The Act] simply clarified that the government is not required to show a criminal defendant specifically knew the Anti-Kickback Act prohibited offering or paying consideration to induce referrals and intended to violate the law.”).

²⁵⁹ *Id.*

²⁶⁰ James G. Sheehan & Jesse A. Goldner, *Beyond the Anti-Kickback Statute: New Entities, New Theories in Healthcare Fraud Prosecutions*, 40 J. HEALTH L. 167, 171 (2007).

²⁶¹ *United States v. Jain*, 93 F.3d 436, 442 (8th Cir. 1996).

²⁶² *Polk Cnty. v. Peters*, 800 F. Supp. 1451, 1456 (E.D. Tex. 1992).

²⁶³ Safe harbors protect from prosecution-specific practices that would otherwise violate the Anti-Kickback Statute. *See, e.g.*, 42 C.F.R. § 1001.952(e)(iv)(B) (2017).

²⁶⁴ *See generally* 42 C.F.R. § 1001.952(a)–(y).

²⁶⁵ CRAIN ET AL., *supra* note 139, at 530.

1. Investment safe harbor. This 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.²⁶⁶
2. Sale of physician practices. This is divided into two sections: sales to another practitioner and sales to a hospital or other entity. Each type of sale has different criteria.²⁶⁷
3. Practitioner recruitment safe harbor. This is designed to allow areas that have difficulty attracting doctors to offer incentives to potential practitioners. Various conditions must be met.²⁶⁸
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.²⁶⁹
5. Referral services safe harbor. This 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

²⁶⁶ 42 C.F.R. § 1001.952(a) (2017).

²⁶⁷ *Id.* § 1001.952(e).

²⁶⁸ *Id.* § 1001.952(n).

²⁶⁹ *Id.* § 1001.952(c).

of referrals the physician makes to the operator of the service.²⁷⁰

6. Referral arrangements for specialty services. This is 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.²⁷¹
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.”²⁷²

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.²⁷³

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.”²⁷⁴ “[A]n agreement is subject to the One Purpose Test if it does not fit precisely into a safe harbor, even if it is in substantial compliance with the requirements of the regulation.”²⁷⁵ Many arrangements will not fit into the specific requirements of a certain specific harbor but the Department of Health and Human Services “[HHS] has no motivation to challenge these agreements if they create no risk of tangible harm to patients or drain on the public fisc”.²⁷⁶

²⁷⁰ *Id.* § 1001.952(f).

²⁷¹ *Id.* § 1001.952(s).

²⁷² *Id.* § 1001.952(v).

²⁷³ *Id.* § 1001.952(w).

²⁷⁴ Rheiner, *supra* note 249, at 505.

²⁷⁵ *Id.*

²⁷⁶ *Id.*

D. False Statements to Obtain Health Benefits or Payments

A little-known 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 healthcare program.²⁷⁷ 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.²⁷⁸

The first element requires that a statement or representation of fact be material to be actionable.²⁷⁹ Materiality is a mixed question of law and fact.²⁸⁰ The customary common law test of materiality in false statement laws is whether the statement “has a natural tendency to influence, or was capable of influencing, the decision of the decision-making body to which it was addressed.”²⁸¹ The government does not have to prove actual reliance on the false statement by the respective federal agency.²⁸²

The second element of the offense requires the defendant to utter or make a false statement or representation.²⁸³ The false statement or representation must have been submitted to the

²⁷⁷ 42 USC § 1320a-7b(a) (2018).

²⁷⁸ *Id.* United States v. Laughlin, 26 F.3d 1523, 1527 (10th Cir. 1994).

²⁷⁹ United States v. Njoku, 737 F.3d 55, 61–62 (5th Cir. 2013). In *Njoku*, 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 healthcare to individuals by skilled nurses. Family Health Care was paid about \$5.2 million for home healthcare services between April 2006 and August 2009. Evidence at trial showed that Family Healthcare billed Medicare for services to beneficiaries who were ineligible for home healthcare, 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. *Id.* at 66–67.

²⁸⁰ United States v. Gaudin, 28 F.3d 943,944, 948 (9th Cir. 1994).

²⁸¹ *Kungys v. United States*, 485 U.S. 759, 770 (1988).

²⁸² *Neder v. United States*, 527 U.S. 1, 9 (1999); *United States v. Rowe*, 56 F.2d 747, 749 (2d Cir. 1932).

²⁸³ *Laughlin*, 26 F.3d at 1526.

respective federal agency for payment.²⁸⁴ Examples include: billing Medicaid for procedures not actually performed,²⁸⁵ submitting claims for patients never examined,²⁸⁶ submitting claims for services not personally rendered,²⁸⁷ and submitting claims for services rendered by another party.²⁸⁸

The third element of the offense is that the accused “knowingly and willfully” make or causes to be made any false representation.²⁸⁹ “Knowingly” refers to the fact that proof must exist that the accused possessed knowledge of the facts that constitute the offense.²⁹⁰ The “knowing[] and willful[]” element is satisfied if the accused is aware his or her conduct is unlawful without any knowledge of the specific statute violated.²⁹¹ Moreover, the accused must know that the statement is false at the time it is made or submitted.²⁹²

E. The Stark Law

In 1989, as part of the Omnibus Budget Reconciliation Act, Congress enacted into law Stark I²⁹³ to counteract the growing cost of healthcare attributable to physician self-referrals.²⁹⁴ Stark I

²⁸⁴ *Id.*

²⁸⁵ *United States v. Boesen*, 541 F.3d 838, 843 (8th Cir. 2008). In this 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 healthcare agencies for nasal endoscopy with debridement, cholesteatoma removal, and otoacoustic emissions tests not actually done.

²⁸⁶ *United States v. Larm*, 824 F.2d 780, 782 (9th Cir. 1987). In this case, Dr. Peter Larm, an allergist, was convicted of Medicaid fraud for submitting false claims for “office visits” where he neither saw or examined the patients nor personally rendered the services.

²⁸⁷ *Id.* In *Larm*, the allergist also submitted claims for administration charges for injections which the patients administered themselves. *Id.*

²⁸⁸ *United States v. Davis*, 471 F.3d 783, 785 (7th Cir. 2006). In this case, Davis, a psychologist, billed Medicaid for psychological services provided by employees in his employ who were not qualified to deliver them. *Id.*

²⁸⁹ *Laughlin*, 26 F.3d at 1526.

²⁹⁰ *Bryan v. United States*, 524 U.S. 184, 184 (1998).

²⁹¹ *United States v. Starks*, 157 F.3d 833, 837–38 (11th Cir. 1998) (alteration in quote).

²⁹² *United States v. Njoku*, 737 F.3d 55, 66–67 (5th Cir. 2013).

²⁹³ *See generally*, Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101-239, § 6204 (codified, as amended, at 42 U.S.C. § 1395nn (2018)).

²⁹⁴ W. Grioux, J. Maul, A. Delaplane, F. Hane, D. Josephy, N. Pfeiffer & P. Safirstein, *Health Care Fraud*, 55 AM. CRIM. L. REV. 1333 (2018).

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.²⁹⁵ As part of the Omnibus Budget and Reconciliation Act of 1993, Stark I was expanded into Stark II.²⁹⁶ Stark II extended the Stark I legislation to Medicaid patients and to “designated health services” (DHS) other than clinical laboratory services.²⁹⁷

In general, the Stark Law (I and II collectively) and its accompanying regulations prohibit 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.²⁹⁸ A medical facility may not submit for payment a Medicare or Medicaid claim for service provided pursuant to a forbidden referral.²⁹⁹ The federal government may not make payments pursuant to a prohibited claim and medical facilities must reimburse any payments that are mistakenly made by the federal government.³⁰⁰

The Stark Law took years to take effect: Stark I did not go into force until January 1, 1992.³⁰¹ Enforcement of Stark II took effect on January 1, 1995.³⁰² The final regulations of Stark II became effective on January 4, 2002.³⁰³ Phase III regulations were published in September 2007, and the enhanced clarity of said regulations reduced the regulatory burden on the healthcare industry.³⁰⁴ The Stark law is complex, but its violation can carry severe penalties.³⁰⁵

²⁹⁵ 42 U.S.C. § 1395nn(a)(1)(A) (1992).

²⁹⁶ P. BUCY ET AL., HEALTH CARE FRAUD: ENFORCEMENT AND COMPLIANCE, 4.05 [1] and [6] (9th ed. 2002) (citing Omnibus Budget Reconciliation Act of 1993, Pub. L. No. 103-66).

²⁹⁷ *Id.*

²⁹⁸ 42 U.S.C. § 1395nn(a)(1)(A) (2018); United States *ex rel.* Drakeford v. Tuomey Healthcare Sys., Inc., 675 F.3d 394, 397–98 (4th Cir. 2012).

²⁹⁹ *Drakeford*, 675 F.3d at 397–98.

³⁰⁰ 42 U.S.C. § 1395nn(g)(1) (2018).

³⁰¹ BUCY ET AL., *supra* note 296, at 2–129 n.182.

³⁰² *Id.* at 4–89.

³⁰³ *Id.*

³⁰⁴ Patrick A. Sutton, *The Stark Law in Retrospect*, 20 ANNALS HEALTH L. 15, 25 (2011).

³⁰⁵ *Id.* at 34.

Determination of whether a Stark law violation has occurred entails a multistep analysis. The first step is to ascertain whether the person or entity involved has made a “referral.” The latter is “the 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.³⁰⁶ 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.³⁰⁷

The second step in the analysis is defining “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.³⁰⁸ Nurse practitioners, physician’s assistants, and physical therapists do not fall within the definition.³⁰⁹ Another step in the analysis is specifying DHS. The latter includes 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.
11. Inpatient and outpatient hospital services.³¹⁰

One of the most significant determinations under the Stark law is whether a “financial relationship” exists between a physician

³⁰⁶ 42 C.F.R. § 411.351 (2018).

³⁰⁷ *Id.*

³⁰⁸ *Id.*

³⁰⁹ *Id.*

³¹⁰ 42 U.S.C. § 1395nn(h)(6) (2018).

(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 arrangement between the physician (or immediate family member) and the entity.³¹¹ Stark regulations specify that a financial relationship may be “direct” or “indirect.”³¹² A “direct” financial relationship exists “if remuneration passes between the referring physician (or a member of his or her immediate family) and the entity furnishing DHS without any intervening persons or entities”³¹³ An “indirect financial relationship” is present when three criteria are met.³¹⁴ First, an unbroken chain of persons or entities must exist between the referring physician and the entity rendering DHS.³¹⁵ Next, 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.³¹⁶ 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 takes into account the volume or value of referrals.³¹⁷ Some exceptions apply to the financial relationship prohibition.³¹⁸

The last step is to consider the meaning of the word “entity” on the receiving end of a referral. “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

³¹¹ *Id.* § 1395nn(a)(2).

³¹² 42 C.F.R. § 411.354(a)(1)–(2) (2018).

³¹³ *Id.* § 411.354(a)(2).

³¹⁴ *Id.* §§ 411.354(b)–(c).

³¹⁵ *Id.* §§ 411.354 (b)(5)(i), (c)(2)(i).

³¹⁶ *Id.* § 411.354(c)(2)(ii).

³¹⁷ *Id.* § 411.354(c)(2)(iii).

³¹⁸ Exceptions to the Stark law “financial relationship” element fall into three general categories: 1) all-purpose ownership and compensation arrangements; 2) ownership and investment exceptions; and 3) direct and indirect compensation arrangement exceptions. The latter categories are the target for critics of the statute’s complexity and focus of the statute itself. Paula Tironi, *The “Stark” Reality: Is the Federal Physician Self-Referral Law Bad for the Health Care Industry?*, 19 ANNALS HEALTH L. 235, 238 (2010).

referring physician ... but does include his or her medical practice.”³¹⁹ This definition means that physicians or physician group practices that perform DHS must now meet an exception to the Stark law.³²⁰

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.³²¹

The first exceptions category includes doctors’ “services where referrals are between members of the same group practice,³²² certain ancillary services rendered within the same office of a group practice [(this is the most commonly used exception)],³²³ and certain prepaid health plans.”³²⁴ The second exceptions category includes ownership interests in publicly traded securities, healthcare facilities in rural areas or Puerto Rico, and hospitals meeting certain requirements.³²⁵ 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.³²⁶

The federal regulations that relate to these exceptions are complex and require intensive analysis. Some of the matters which must be scrutinized include, for example, whether doctors in a group practice spend the required number of hours with patients per week providing non-DHS services,³²⁷ and whether the amount of space leased exceeds the amount deemed “reasonable and necessary” for legitimate business purposes.³²⁸

³¹⁹ 42 C.F.R. § 411.351 (2018) (alteration in quotation).

³²⁰ Sutton, *supra* note 304, at 27–28; Grioux et al., *supra* note 294, at 1368.

³²¹ 42 U.S.C. §§ 1395nn(b)–(e) (2010).

³²² Sutton, *supra* note 304, at 30 (referencing 42 U.S.C. § 1395nn(b)(1) (2010)).

³²³ *Id.*

³²⁴ *Id.*

³²⁵ 42 U.S.C. §§ 1395nn(c)–(d) (2010).

³²⁶ *Id.* §§ 1395nn(e)(1)–(8).

³²⁷ *Id.* § 411.355(b)(2)(A)(2) (2009).

³²⁸ Sutton, *supra* note 304, at 30 (referencing 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 mean non-payment.³²⁹ Moreover, if one collects money in violation of the Stark law, the money must be refunded.³³⁰ Improper claims may result in civil monetary penalties up to \$15,000 per violation and exclusion from participating in Medicaid and Medicare programs.³³¹ 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.³³²

In February 2018, the Bipartisan Budget Act outlined changes to the Stark law.³³³ Holdovers in personal services arrangement exceptions and equipment exceptions are now indefinite; previously they had been limited to six months.³³⁴

F. Health Insurance Portability and Accountability Act (HIPAA)

In 1996, Congress passed the Health Insurance Portability and Accountability Act (HIPAA),³³⁵ which expanded the fight against healthcare fraud in numerous ways. First, HIPAA expanded the coverage of the Anti-Kickback Statute to include all federal healthcare programs.³³⁶ Next, HIPAA widened the definition of a kickback.³³⁷ Controversy existed at one time as to whether waiving a copayment or deductible constituted remuneration to induce patients to utilize a given provider.³³⁸ Section 231 of HIPAA specifically states that waiving a copayment is a

³²⁹ 42 U.S.C. § 1395nn(g)(1) (2010).

³³⁰ *Id.* § 1395nn(g)(2).

³³¹ *Id.* § 1395nn(g)(3).

³³² *Id.* § 1395nn(g)(4).

³³³ See Kristina Sherry et al., *2018 Changes to the Federal Physician Self-Referral Law*, NELSON HARDIMAN NEWSROOM (March 20, 2018), <https://www.nelsonhardiman.com> [<https://perma.cc/B2VJ-5QH>].

³³⁴ *Id.*

³³⁵ Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (1996) (codified as amended at 42 U.S.C. § 1320a-7c).

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

³³⁷ See 42 U.S.C. § 1320a-7b(7).

³³⁸ A. Craig Eddy, *The Effect of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) on Health Care Fraud in Montana*, 61 MONT. L. REV. 175, 199 (2000).

kickback unless it is done for a documented financial need or represents failure to collect after reasonable efforts.³³⁹ HIPAA also extends this to all federal healthcare programs except the Federal Employee Health Benefit Program.³⁴⁰ 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.³⁴¹ There is a safe harbor for waivers not routinely offered.³⁴²

HIPAA also changed the money laundering, asset forfeiture and injunctive relief statutes to cover “federal health care offenses.”³⁴³ Significantly, HIPAA amended a federal criminal forfeiture statute with a new section containing mandatory forfeiture language that states a court “shall order the 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.”³⁴⁴ 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, reducing the chance that assets or funds could be dissipated or moved. HIPAA also widened 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.³⁴⁵

In *United States v. Sriram*, the federal government filed suit against Dr. Krishnaswami Sriram for fraudulently acquiring over \$1 million in false Medicare claims.³⁴⁶ Besides asserting claims for civil penalties and treble damages under the FCA, the

³³⁹ 42 U.S.C. § 1320a-7a(i)(6) (2018).

³⁴⁰ *Id.* § 1320a-7b(f). The expressed definition includes “any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government (other than the health insurance program under chapter 89)” *Id.*

³⁴¹ 42 U.S.C. § 1320a-7a(i)(6) (2018).

³⁴² *Id.*

³⁴³ Eddy, *supra* note 338, at 198.

³⁴⁴ *Id.* (referencing 18 U.S.C. § 982(a)(7) (2018)).

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

³⁴⁶ *United States v. Sriram*, 147 F. Supp. 2d 914, 916 (N.D. Ill. 2001).

government sought and obtained a preliminary injunction against Sriram and froze certain assets (over \$1.6 million).³⁴⁷

HIPAA has also 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 healthcare plans.³⁴⁸ HIPAA also created five new healthcare-related crimes, four of which were felonies and one a misdemeanor.³⁴⁹ The new crimes created are: (1) healthcare fraud;³⁵⁰ (2) theft or embezzlement in connection with healthcare;³⁵¹ (3) false statements relating to healthcare matters;³⁵² and (4) obstruction of

³⁴⁷ *Id.* at 949.

³⁴⁸ Pub. L. No. 104-191, 241–247, 249, 110 Stat. 1936 (1997) (codified at 18 U.S.C.A. § 24).

³⁴⁹ Grioux et al., *supra* note 294, at 1372.

³⁵⁰ 18 U.S.C. § 1347 (2018). For conviction, this statute 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 to 2) defraud a healthcare benefit program or to obtain by false or fraudulent pretenses any money or property under the custody or control of a healthcare benefit program and 3) in connection with the delivery of or payment for healthcare benefits, items, or services. Examples include *United States v. Morgan*, 505 F.3d 332, 335 (5th Cir. 2007) (defendant convicted of twelve counts of healthcare fraud to defraud Medicare by signing a Certificate of Medical Necessity (CMN) for motorized wheelchairs for patients that the defendant did not examine and who were not medically eligible for wheelchairs); *United States v. Hunt*, 521 F.3d 636, 640 (6th Cir. 2008) (conviction for healthcare fraud where the doctor submitted claims to Medicare for tests that had not been determined to be medically necessary since the defendant had not examined the patients); *United States v. Gelin*, 712 F.3d 612, 614 (1st Cir. 2013) (two defendants convicted of violating § 1347 from making false claims to and obtaining payment from, insurers participating in Massachusetts' no-fault auto insurance program. Congress did not limit the scope of § 1347 to health insurers).

³⁵¹ 18 U.S.C. § 669 (2018). For a conviction under this section, the government must 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. This statute allows federal prosecutions of embezzlements from private health plans. *United States v. Lucien*, 347 F.3d 45, 51–52 (2d Cir. 2003).

³⁵² 18 U.S.C. § 1035 (2018). To convict a person of making false statements relating to healthcare matters, the government must prove beyond a reasonable doubt that the 1) person 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. *United States v. Hunt*, 521 F.3d 636, 647–48 (6th Cir. 2008).

criminal healthcare investigations.³⁵³ The penalties include a maximum prison term of five to ten years.³⁵⁴

CONCLUSION

Despite increasing efforts by the U.S. government, law enforcement agencies, and federal and private health insurance programs, healthcare fraud remains a widespread problem. Countless individual victims have had to deal with the consequences, such as false information added to their medical records, damaged credit ratings, and unnecessary medical bills. Moreover, Medicare, Medicaid and other federal healthcare programs have been and continue to be hit by tens of billions of dollars in fraudulent claims. Fraud schemes committed by healthcare providers, organized crime, and others cost more than just money; these frauds shake the public's trust in a system that should engender confidence.

Society and the federal government are not without powerful statutory weapons to fight healthcare fraud. This Article analyzes the major federal civil and criminal laws relied on to combat healthcare fraud, including the Federal False Claims Act (FCA), the Patient Protection and Affordable Care Act (PPACA) of 2010, the Stark Law, a law against false statements to obtain health benefits or payments, the federal Anti-Kickback Statute, the Health Insurance Portability and Accountability Act (HIPAA), and the mail and wire fraud statutes.

The FCA is a civil law but represents the single most potent federal law available to combat healthcare fraud. One factor that makes the FCA so powerful is the *qui tam* legal action in which a private citizen can obtain a monetary reward of fifteen to thirty percent of any settlement or verdict in a healthcare fraud case committed against the United States.³⁵⁵ The PPACA loosened the public disclosure bar formerly faced by *qui tam*

³⁵³ 18 U.S.C. § 1518a (2018). 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. *See United States v. Franklin-El*, 554 F.3d 903, 909 (10th Cir. 2009).

³⁵⁴ Eddy, *supra* note 338, at 197.

³⁵⁵ *See supra* Section II.A.

plaintiffs.³⁵⁶ This PPACA feature has enhanced the FCA as a weapon to combat healthcare fraud. The Stark Law is a federal civil law aimed at preventing and deterring physician self-referrals for certain designated health services.³⁵⁷

A less well-known federal statute makes it a crime to make a false statement or representation in any claim for benefits under a federal healthcare program. The federal Anti-Kickback Statute is a criminal law that prohibits paying or receiving anything of value in exchange for prescribing, purchasing, or recommending any medical treatment or item paid for with federal money.³⁵⁸ HIPAA established several new federal healthcare fraud crimes, including private insurance plan healthcare fraud, healthcare embezzlement, false statements relating to healthcare, and obstruction of criminal health investigations.³⁵⁹ Federal mail and wire fraud statutes have also been utilized to prosecute healthcare fraudsters.

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. The most current report from the DOJ states that, during fiscal year 2014, the Federal government won or negotiated over \$2.3 billion in healthcare fraud settlements and judgments.³⁶⁰ Also in fiscal year 2014, 734 defendants were convicted of healthcare fraud-related crimes, 782 new civil healthcare fraud investigations were opened, and 957 healthcare fraud matters were pending.³⁶¹ Despite these recent successes, the battle must continue until healthcare fraud is a vanishingly rare occurrence.

³⁵⁶ *Id.*

³⁵⁷ *See supra* Section II.E.

³⁵⁸ *See supra* Section II.C.

³⁵⁹ *See supra* Section II.F.

³⁶⁰ U.S. DEP'T OF JUSTICE, HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM FY 2014 1 (2015).

³⁶¹ *Id.*