Keeping the Healthcare Industry Accountable

Yoori Chung

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Keeping the Healthcare Industry Accountable

By Yoori Chung

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I. INTRODUCTION

How does the federal government regulate and mitigate health care fraud in one of the largest industries of the economy? Physicians, specifically, have a myriad of opportunities to cultivate business relationships that “may raise fraud and abuse concerns,”1 whether it is with fellow physicians, other providers, or pharmaceutical and medical device companies.2 Although medical service providers, including health care professionals, facilities, equipment suppliers, and prescription drug suppliers should be primarily focused on what is best for the patient and the health of the consumer, the “growing commercialization of health care” inevitably brings economic gain as a competing focus.3 The influence of external factors, such as financial incentives to recommend a certain

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1 Yoori Chung is a Juris Doctor, 2019 candidate at Pepperdine University School of Law. Yoori received her Bachelor of Arts in Social Welfare and Bachelor of Arts in Ethnic Studies from the University of California Berkeley. She was a state-registered HICAP counselor for two years with the Center for Health Care Rights prior to law school as well as a certified law clerk with the Licensing Litigation section in the Office of the Attorney General of the California Department of Justice. I would like to thank my editor, Charles Melcombe, for his patience and thorough review of my work, as well as my partner, John Kim, for the constant love and support throughout my career. I especially would like to thank my parents, Simon and Rocio Chung. I would not be who I am today without you.


3 See Off. of Inspector Gen., A Roadmap for New Physicians: Fraud & Abuse Laws (2018), https://oig.hhs.gov/compliance/physician-education/01laws.asp (“As a physician, you are an attractive target for kickback schemes because you can be source of referrals for fellow physicians or other health care providers and suppliers. You decide what drugs your patients use, which specialists they see, and what health care services and supplies they receive.”) [hereinafter OIG, Roadmap].

4 Claire Andre and Manuel Vasquez, A Healthy Bottom Line: Profits or People, ISSUES IN ETHICS, Summer 1988, https://www.scu.edu/ethics/focus-areas/bioethics/resources/a-healthy-bottom-line-profits-or-people/.
product, puts the safety and welfare of all health care consumers at risk.\(^4\)

In the following, Part I describes the varying forms of health care fraud and the context in which issues of fraud are raised and enforced.\(^5\) Part II discusses how these existing laws and statutes are utilized to identify and recover taxpayer dollars from individuals and organizations participating in unlawful inducement and fraudulent activities.\(^6\) Part III explores how we can continue to encourage health care fraud reporting.\(^7\) Part IV investigates changes in enforcement trends and whether these trends will continue.\(^8\) Finally, Part V investigates different avenues and the future of government health care fraud enforcement.\(^9\)

II. INTRODUCTION TO HEALTH CARE FRAUD

Health care fraud is a major issue that costs federal and state governments millions of dollars each year.\(^10\) Medical providers carry

\(^{4}\) National Health Care Anti-Fraud Association, *The Challenge of Health Care Fraud*, https://www.nhca.org/resources/health-care-anti-fraud-resources/the-challenge-of-health-care-fraud.aspx. In June[\(^])\] 2002, for example, a Chicago cardiologist was sentenced to 12-1/2 years in federal prison and was ordered to pay $16.5 million in fines and restitution after pleading guilty to performing 750 medically unnecessary heart catheterizations, along with unnecessary angioplasties and other tests as part of a 10-year fraud scheme. Three other physicians and a hospital administrator also pleaded guilty and received prison sentences for their part in the scheme, which resulted in the deaths of at least two patients. The physicians and hospital induced hundreds of homeless persons, substance abusers, and elderly men and women to feign symptoms and be admitted to the hospital for the unnecessary procedures. How? By offering them incentives such as food, cash, and cigarettes. There were 750 people who had needles stuck into their hearts purely for profit, not because they needed it, said one of the federal prosecutors. *Id.*

\(^{5}\) See infra notes 10–30 and accompanying text.

\(^{6}\) See infra notes 31–96 and accompanying text.

\(^{7}\) See infra notes 97–150 and accompanying text.

\(^{8}\) See infra notes 151–194 and accompanying text.

\(^{9}\) See infra notes 195–236 and accompanying text.

out an uncanny 72% of health care fraud, but other major types of health care fraud include patient fraud and insurer fraud in a variety of forms.\textsuperscript{11} Traditional health care fraud consists of false billing and filing for services providers did not perform or patients did not receive, or “undervaluing the amount owed by the insurer to a health care provider under the terms of its contract,”\textsuperscript{12} among others. Non-traditional health care fraud involves accepting kickbacks\textsuperscript{13} for patient referrals, marketing illegally, and incentivizing health care providers to make certain clinical judgments in return for unlawful remuneration.\textsuperscript{14} Combating health care fraud through civil and criminal enforcement allows the federal government not only to recover taxpayer dollars for the federal programs that were defrauded, but also to keep health care providers compliant to regulations and accountable to all.\textsuperscript{15}

The primary fraud and abuse laws protecting patients and combating dishonest health care professionals are the False Claims Act (FCA), the Anti-Kickback Statute (AKS), and the Physician Self-Referral Law (Stark Law).\textsuperscript{16} "Government agencies, including the U.S. Department of Justice (DOJ), the U.S. Department of Health and Human Services (HHS), the HHS Office of Inspector General (OIG), and the Centers for Health and Human Services (CMS),

\textsuperscript{11} Id.

\textsuperscript{12} Id.

\textsuperscript{13} “Remuneration [also known as kickbacks] includes anything of value and can take many forms beside cash, such as free rent, expensive hotel stays and meals, and excessive compensation for medical directorships or consultancies.” See OIG, Roadmap, supra note 2.

\textsuperscript{14} “If the [marketer’s] compensation is in any way tied to results—the number of prescriptions flowing to the client or the increased number of patients the pain clinic gets, for example—the government is taking the position that such marketing constitutes kickbacks.” Kristen Rasmussen and Sue Reisinger, Feds’ Crackdown on Health Care Fraud: What Lawyers Need to Know, LAW.COM (Sept. 1, 2017), https://www.law.com/insidecounsel/sites/insidecounsel/2017/09/08/feds-crackdown-on-health-care-fraud-what-lawyers-need-to-know/ (quoting Patrick Cotter, a former federal prosecutor).


\textsuperscript{16} See CMS, Avoiding Medicare Fraud & Abuse, supra note 1, at 3.
enforce these laws.”17 The FCA,18 originally enacted in 1863,19 is the Department of Justice’s primary tool for fraud recoveries, but as Assistant Attorney General West stated, “[n]owhere is this more apparent than in our success in fighting health care fraud.”20 In 1986, Congress21 substantially strengthened the civil FCA by revising qui tam provisions and incentivizing individuals “to come forward with allegations of fraud.”22 The Fraud Enforcement and Recovery Act of 2009, signed by then President Obama, “provide[s] federal investigators and prosecutors with significant new tools and resources, both civil and criminal, with which to combat mortgage fraud, securities and commodities fraud, and related offenses.”23 Although health care fraud is not mentioned, provisions of this legislation led the way to establishing the anti-fraud legislation primarily utilized in combating health care fraud today.24

A qui tam action is “a suit filed by an individual on behalf of the government,” while “the person bringing the action is referred to as a

17 Id. at 4.
19 The False Claims Act was originally enacted for reasons unrelated to health care. In 1863, Congress was “concerned that suppliers of goods to the Union Army during the Civil War were defrauding the Army.” Id.
20 Off. of Pub. Affairs, Dep’t of Justice, Department of Justice Recovers $3 Billion in False Claims Cases in Fiscal Year 2010, JUSTICE.GOV (Nov. 22, 2010), https://www.justice.gov/opa/pr/department-justice-recoveres-3-billion-false-claims-cases-fiscal-year-2010 [hereinafter DOJ, Fiscal Year 2010] (refers to the FCA over a two-year period during Eric Holder’s tenure; however, all following fiscal year reports continue to show large annual recoveries under the statute).
21 “In 1986, Senator Charles Grassley and Representative Howard Berman led the successful efforts in Congress to amend the False Claims Act to, among other things, encourage whistleblowers to come forward with allegations of fraud” and later supported the Fraud Enforcement and Recovery Act of 2009.” Id.
22 Id.
24 Id.
'relator.' When President Barack Obama signed the Patient Protection and Affordable Care Act (ACA) into law in 2010, the passage of the ACA included additional inducements, further incentivizing and protecting whistleblowers to disclose fraud to the government, in addition to bolstering the provisions of the federal health care AKS. The DOJ emphasized that "fighting fraud committed against public health care programs is a top priority for the Obama Administration." Under Attorney General Eric Holder, the DOJ reclaimed "the largest two-year recovery of taxpayer dollars in the history of the Justice Department" and since 1986 to 2010, "qui tam cases have exceeded $18 billion, and relators have obtained more than $2.8 billion in awards."

III. ANTI-FRAUD AND ANTI-ABUSE LEGISLATION

Since its enactment in 1863, the FCA has been amended and interpreted by multiple federal courts for a myriad of purposes. The majority of FCA cases have shifted from lawsuits involving fraudulent billing leading to overpayments by the government to consist mostly of AKS and Stark Law violations. While the FCA

25 See DOJ, A Primer, supra note 18, at 2.
26 Id. Whistleblowers are also known as relators. Id.
30 See DOJ, A Primer, supra note 18, at 1.
31 "Stark Law[] prohibits a physician from referring for certain designated health services payable by Medicare or Medicaid to an entity where the physician (or an immediate family member) has an ownership/investment interest or a
targets fraud in general, the AKS specifically protects federal health care programs. The AKS “prohibits the knowing and willful offer, payment, solicitation, or receipt of any remuneration” for medically related services paid through a federal health care program. For example, “the payment of remuneration to induce the use of medical devices covered by Medicare, Medicaid, and other federally-funded health care programs, including the Department of Veteran Affairs (VA)” is prohibited. A conflict of interest and an obstacle to moral and ethical professionalism exists when physicians and medical service providers can have their judgments and recommendations motivated by profits. The growing tension between patient-centered care and profits contributes to an increase in federal health care fraud enforcement under existing legislation and amendments.

In a kickback case involving a medical device, Shire Pharmaceuticals, LLC (Shire) and Advanced BioHealing (ABH), a company Shire acquired in 2011, settled FCA allegations that they

compensation arrangement, unless an exception applies.” See CMS, Avoiding Medicare Fraud & Abuse, supra note 1, at 5.


35 Remuneration, OXFORD DICTIONARY (2018), https://en.oxforddictionaries.com/definition/remuneration (“money paid for work or a service,” but extensive legal authority establishes remuneration includes anything of value; see CMS, Laws Against Health Care Fraud, supra note 34, at 2 including that “payments [] are above fair market value for the services provided”).

36 See DOJ, Shire, supra note 33.

37 Patients, clinicians, organizations within health care, policy makers, and public health practitioners may all have different, but legitimate views and meanings of patient-centered care. Here, patient-centered care prioritizes the patient over the bottom line.
“employed kickbacks and other unlawful methods to induce clinics and physicians to use or overuse its product ‘Dermagraft,’ a bioengineered human skin substitute approved by the FDA for treatment of diabetic foot ulcers.” The alleged kickbacks include unlawful inducements of “lavish dinners, drinks, entertainment and travel; medical equipment and supplies; unwarranted payments for purported speaking engagements and bogus case studies; and cash, credits and rebates.” The United States stated that ABH and Shire’s failure to comply with AKS provisions “submitted or caused to be submitted to federally-funded health care programs hundreds of millions of dollars of false claims for Dermagraft,” and thus violated FCA as well. This settlement recovery demonstrates how federal laws protect health care consumers, “by making illegal the payment of remuneration to induce the use of medical devises covered by federally-funded health care programs.”

In order to comply with health care fraud and abuse laws, physicians in their relationships with patients or payers, should properly document patient interactions for themselves and patients, but also for those “who may rely on [their] records for patients’ medical histories.” Fraud often occurs in business relationships that “can improperly influence or distort physician decision-making and result in the improper steering of a patient to a particular therapy or service where a physician has a financial interest.” To avoid serious legal risks under the AKS and Stark Law, physicians should avoid “excessive and medically unnecessary referrals . . . [that] can expose beneficiaries to harm from unnecessary services.” Next, in physician relationships with vendors such as pharmaceutical and medical device industries, physicians should avoid “sham consulting

38 See DOJ, Shire, supra note 33.
39 Id.
40 Id.
41 Id.
42 See CMS, Avoiding Medicare Fraud & Abuse, supra note 1, at 9.
43 Id.
44 “The Stark law is a strict liability statute, which means proof of specific intent to violate the law is not required. The Stark law prohibits the submission, or causing the submission, of claims in violation of the law’s restrictions on referrals.” See OIG, Roadmap, supra note 2.
45 See CMS, Avoiding Medicare Fraud & Abuse, supra note 1, at 9.
agreements and other arrangements” offered to “buy physician loyalty to [the vendor’s] products” and brand.46 Because practicing physicians are frequently exposed to consulting and promotional speaking opportunities for drugs and medical devices, they must also be more vigilant in “evaluat[ing] the link between the [provided] services and the compensation.”47 Finally, practicing physicians can avoid issues pertaining to fraud by understanding the existing laws and educating themselves on how to stay compliant.48

The HHS, the federal agency charged with interpreting the AKS, noted that the inclusion of “remuneration” and “to induce” in the statute “demonstrate congressional intent to create a very broadly worded prohibition.”49 It can be argued that Congress intended to widen the range of prohibited conduct, not constrict it.50 The AKS, originally enacted in Section 1128(B)(b) of the Social Security Act in 1972,51 was not able to prevent the rise of Medicare and Medicaid fraud. The Medicare-Medicaid Anti-Fraud and Abuse Amendments in 197753 “increased the severity of penalties from a misdemeanor to a felony”54 to further discourage fraudulent activity and abuse of federal health care programs.

46 Id. at 11.
47 Id.
48 Id. at 3.
50 “[P]rohibited conduct includes not only remuneration intended to induce referrals of patients, but remuneration also intended to induce the purchasing, leasing, ordering or arranging for any good, facility, service, or item paid for by Medicare or State health programs.” Id.
51 42 U.S.C.A § 1320a-7b (West 2015).
53 “This bill was enacted after being signed by the President on October 25, 1977.” Medicare-Medicaid Anti-Fraud and Abuse Amendments (1977 - H.R. 3), GOVTRACK.US, https://www.govtrack.us/congress/bills/95/hr3 (“An Act to strengthen the capability of the Government to detect, prosecute, and punish fraudulent activities under the Medicare and Medicaid programs, and for other purposes.”).
54 Id.
The government prohibits kickbacks to prevent "overutilization, increased program costs, corruption of medical decision-making, patient steering, [and] unfair competition."\textsuperscript{55} It may be that the recommended decision that results in a kickback is not necessarily harmful, and even beneficial, to the patient. However, "the element of corruption"\textsuperscript{56} is met by physicians receiving payments for their recommendations. In \textit{United States v. Greber},\textsuperscript{57} the United States Court of Appeals for the Third Circuit recognized the risk of external influences such as financial incentives and rewards in clouding physicians' judgment and manifesting into referrals that may not be in the best interest of the patient, even if it may not be the worst. \textit{Greber} emphasized that it was Congress' intent to prevent "[t]he potential for increased costs to the Medicare-Medicaid system and misapplication of federal funds."\textsuperscript{58} \textit{Greber} widened the reach of the 1977 Medicare Anti-Fraud amendment "[b]y including such items as kickbacks and bribes" and "[t]hat a particular payment was a remuneration (which implies that a service is rendered) rather than a kickback, d[id] not foreclose the possibility that a violation nevertheless could exist."\textsuperscript{59}

In \textit{Allison Engine Co. v. United States ex rel. Sanders}, the Court held that "a plaintiff asserting a § 3729(a)(2) claim . . . must prove that the defendant intended that the false statement be material to the Government's decision to pay or approve the false claim."\textsuperscript{60} The Court further stated that "[r]ecognizing a cause of action under the FCA for fraud directed at private entities would threaten to transform the FCA into an all-purpose antifraud statute."\textsuperscript{61} The Court was aware that broad causes of action should be avoided, but it was up to

\textsuperscript{55} \textit{See} OIG, \textit{Roadmap, supra} note 2.

\textsuperscript{56} \textit{United States v. Hancock}, 604 F.2d 999, 1001 (7th Cir. 1979).

\textsuperscript{57} \textit{United States v. Greber}, 760 F.2d 68, 72 (1985) (holding that "if the payments were intended to induce the physician to use [certain] services, the [AKS] was violated, even if the payments were also intended to compensate for professional services").

\textsuperscript{58} \textit{Id.} at 72 (citing \textit{Hancock}, 604 F.2d at 1001).

\textsuperscript{59} \textit{Id.} at 71 (concluding that if even one purpose of a payment made is for a referral of business, the payment is deemed to be illegal).

\textsuperscript{60} \textit{Allison Engine Co. v. United States ex rel. Sanders}, 553 U.S. 662, 665 (2008) (case is superseded by statute but not preempted).

\textsuperscript{61} \textit{Id.} at 672.
government agencies and lawmakers to clarify how to pursue and enforce these claims.

A health care provider who commits any Medicare or Medicaid fraud is committing fraud against the federal government and this violation is punishable as a federal crime as well as subject to civil litigation.62 Failure to comply with the AKS may establish a violation under the False Claims Act. 63 However, there appears to be little federal regulation that applies to physicians in private practice if they, as providers who do not participate in Medicare, Medicaid, or VA programs, do not accept any federal funding. Private practitioners may be excluded from AKS and FCA governance entirely. Additional legislation providing accountability to all medical service providers, regardless of federal health care program participation, is recommended and should be further explored. The legislature has successfully responded in the past and must continue to do so as the need arises.

In 2009, “Attorney General Holder and Secretary Sebelius formed a new interagency task force”64 to prioritize health care fraud enforcement and to build upon existing partnerships that already exist between the two agencies.65 The Health Care Fraud Prevention and Enforcement Action Team’s (HEAT) goals are “to increase coordination and optimize criminal and civil enforcement[,]”66 to “protect the Medicare Trust Fund for seniors and the Medicaid program for the country’s neediest citizens,” and ultimately to “result in higher quality health care at a more reasonable price” for all.67 This collaborative effort “commenced more health care fraud investigations, [] larger fines and judgments, and [the recovery] of

63 CMS, Laws Against Health Care Fraud, supra note 34, at 2.
64 DOJ, Fiscal Year 2010, supra note 20.
65 DOJ, HEAT, supra note 62.
more taxpayers lost to health care fraud than in any other two-year period."\textsuperscript{68} Joint health care fraud enforcement is working.\textsuperscript{69}

In a letter written to Representative Jim McDermott, then HHS Secretary Kathleen Sebelius stated that “[t]he department of Health and Human Services does not consider QHPs,\textsuperscript{70} other programs related to the Federally-facilitated Marketplace, and other programs under Title I of the Affordable Care Act to be federal health care programs.”\textsuperscript{71} This interpretation is striking because the HHS and DOJ seem to be leaving a lot of taxpayer dollars potentially being fraudulently paid out in the health care industry without enforcement. She further explains that “[t]his conclusion was based upon a careful review of the definition ‘Federal health care program’ and an assessment of the various aspects of each program under Title I of the [ACA] and consultation with the Department of Justice.”\textsuperscript{72} However, Secretary Sebelius highlights that “[t]he Department [of Health and Human Services] is taking strong measures to protect consumers and to ensure robust oversight of these critical [ACA] programs” and

\textsuperscript{68} DOJ, Fiscal Year 2010, supra note 20.

\textsuperscript{69} DOJ, HEAT, supra note 62.

“In FY2009, the [DOJ], including its 94 U.S. Attorneys’ Offices, HHS’s Office of the Inspector General, and the Centers for Medicare and Medicaid Services (CMS) worked together to file charges involving criminal health care fraud violations against more than 800 defendants, secure 583 criminal convictions, open 866 new civil health care fraud investigations, obtain 337 civil administrative actions against individuals and organizations who were committing Medicare Fraud, and recovered more than $2.5 billion in criminal, civil, and administrative actions . . . .”

\textit{Id.}


\textsuperscript{71} \textit{Id.} See also Robert Radick, Forbes, \textit{The Anti-Kickback Statute and the Affordable Care Act: A Law Enforcement Tool Suddenly Goes Missing}” (Nov. 13, 2013), https://www.forbes.com/sites/insider/2013/11/13/the-anti-kickback-statute-and-the-affordable-care-act-a-law-enforcement-tool-suddenly-goes-missing/#1f8e48bc1ceac (“that insurance offered through the Affordable Care Act’s new health insurance exchanges do not constitute ‘Federal health care programs’ and thus are not within the scope of the federal anti-kickback statute”).

\textsuperscript{72} Letter from Kathleen Sebelius, supra note 70, at 1.
analyzes the proposals and finalized compliance standards to oversee QHPs.\textsuperscript{73}

Here, there appears to be room for the federal government to partner with states to regulate “plans in the Federally-facilitated Marketplace”\textsuperscript{74} as well as for states to enact similar legislation to pursue fraud and abuse within their own state health insurance exchanges. Some states already have their own false claims acts and anti-kickback laws.\textsuperscript{75} Nonetheless, the federal government can work with all states to ensure every state is equipped to identify and reduce health care fraud and abuse within their jurisdiction.\textsuperscript{76} Medicaid is considered a federal health care program\textsuperscript{77} for the purposes of federal regulation. With similar reasoning, health insurance exchanges through the ACA should be considered a federal health care program. States determine how to administer QHPs\textsuperscript{78} “according to federal requirements”\textsuperscript{79} and can be further incentivized to recover taxpayer dollars as well as combat health care fraud within their jurisdiction.

There must be an increased urgency for the federal government to curb and prevent health care professionals from reaching clinical judgments with outside influences.\textsuperscript{80} Although the DOJ has placed

\textsuperscript{73} Id.

\textsuperscript{74} Id.

\textsuperscript{75} “The acts usually mirror the federal False Claims Act, which applies only to federal funded programs. Federal law provides states a financial incentive to enact false claims acts that include specific provisions.” NCSL, \textit{Combating Health Care Fraud and Abuse}, supra note 10, at 2.

\textsuperscript{76} Id.

\textsuperscript{77} “Medicaid is administered by states, according to federal requirements. The program is funded jointly by states and the federal government.” Medicaid, MEDICAID.GOV, (2018), https://www.medicaid.gov/medicaid/index.html.

\textsuperscript{78} “The term “‘qualified health plan’ means a health plan that . . . is licensed and in good standing to offer health insurance coverage in each State in which such issuer offers health insurance coverage [and] . . . shall be deemed to include a . . . a multi-State plan” 42 U.S.C.S. § 18021 (LexisNexis 2010).

\textsuperscript{79} Medicaid, \textit{supra} note 77.

"renewed emphasis" on nonmonetary remediation, such as requiring companies "to make clear, public statements about their misconduct as part of their FCA settlements"\textsuperscript{81} to emphasize corporate accountability, it is apparent that the federal government’s priority remains the recovery of taxpayer dollars and understandably so. People like to hear numbers and see results. However, as Principal Deputy Assistant Attorney General Benjamin C. Mizer stated, "[p]atients deserve the unfettered, independent judgment of their health care professionals."\textsuperscript{82} On the same vein, the U.S. Attorney David Rivera for the Middle District of Tennessee emphasized that “[t]he best interest of the patient is, and must be, the primary factor in a physician’s decision regarding patient care.”\textsuperscript{83} There is room for a cooperative effort by state medical boards\textsuperscript{84} and the federal government to strengthen enforcement of ethical requirements and repercussions, beyond ordering the payment of fines.

Today, there are serious consequences for violating the Anti-Kickback Statute. Criminal penalties “may include fines, imprisonment, or both,” while civil penalties “may include three times the amount of the kickback plus up to $74,792 (in 2017) per kickback,” in addition to exclusion from federal health care of FCA by paying kickbacks to induce physicians to prescribe Daiichi drugs, including Azor, Benicar, Tribenzor and Welchol).

\textsuperscript{81} Teichert, \textit{Renewed Emphasis}, supra note 16.

\textsuperscript{82} DOJ, \textit{Shire}, supra note 33.

\textsuperscript{83} Id.

\textsuperscript{84} The Medical Board of California’s mission is “to protect health care consumers through the proper licensing and regulation of physicians and surgeons and certain allied health care professions and through the vigorous, objective enforcement of the Medical Practice Act, and to promote access to quality medical care through the Board’s licensing and regulatory functions.” The Medical Board of California (2018), http://www.mbc.ca.gov/. Other state medical boards have similar mission statements related to the interests of the public. See New Mexico Medical Board (2018), http://www.nmmb.state.nm.us/ (“in the interest of the public health, safety and welfare and to protect the public from improper, unprofessional, incompetent and unlawful practice of medicine”). See also Nevada State Board of Medical Examiners (2018), http://medboard.nv.gov/About/About/ (“the Board will place the interests of the public before the interests of the medical profession and encourage public input and involvement to help educate the public as we improve the quality of medical practice in Nevada”).
programs. However, the health care industry has yet to see the end of FCA expansion. "One of the nation’s largest vendors of electronic health records software, eClinicalWorks (ECW), and certain of its employees will pay a total of $155 million to resolve a False Claims Act lawsuit alleging that ECW misrepresented the capabilities of its software." Special Agent in Charge, Phillip Coyne of HHS-OIG, stated that:

Electronic health records have the potential to improve the care provided to Medicare and Medicaid beneficiaries, but only if the information is accurate and accessible . . . . Those who engage in fraud that undermines the goals of EHR or puts patients at risk can expect a thorough investigation and strong remedial measures such as those in the novel and innovative Corporate Integrity Agreement in this case.

Legislation, such as the AKS, Anti-Bribery statute, and the Federal Acquisition Regulations, prohibits different types of remuneration, including "bribes to government officials or employees, including VA physicians, to obtain a contract or favorable treatment under a supply contract." Consequences for individuals and organizations who violate existing fraud and abuse laws include the "non-payment of claims, Civil Monetary Penalties (CMPs), exclusion from all Federal health care programs (including Medicare), and criminal and civil liability." It may be in the government’s best interest to


87 Id.

88 DOJ, Shire, supra note 33 (legislation punishing remuneration as federal felonies).

89 CMS, Avoiding Medicare Fraud & Abuse, supra note 1, at 4.
extend the consequences to individuals and their personal rights to practice. The HHS OIG, a government agency able to enforce health care fraud and abuse laws, must exclude from participation in all Federal health care programs individuals and entities convicted of any of the following:

- Medicare or Medicaid fraud, as well as any other offenses related to the delivery of items or services under Medicare or Medicaid
- Patient abuse or neglect
- Felony convictions for other health care-related fraud, theft, or other financial misconduct
- Felony convictions for unlawful manufacture, distribution, prescription, or dispensing of controlled substances.90

The increasing severity of the consequences for AKS violations have made an impact. The gravity of the ramifications may have deterred some individuals and organizations from committing or participating in fraudulent activities but may have also led certain health care providers to reconsider their provided services. It is possible that some “hospitals have been shutting down their ambulance medication and supplies restocking programs lately over concern that they may violate the AKS, the premise being that the hospital is restocking in exchange for the ambulance services bringing patients to the hospital.”91 In 2002, the OIG finalized a rule “[e]stablishing a new safe harbor for ambulance restocking arrangements . . . [an activity that is] commonplace in many parts of the country.”92 Although “safe harbors”93 exist specifically to protect

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90 Id. at 5. This list is in addition to other permissive exclusions the OIG has the discretion to impose. Id.
91 Becker’s Hospital Review, 20 Things, supra note 32.
93 “The ‘safe harbor’ regulations describe various payment and business practices that, although they potentially implicate the Federal [AKS], are not treated as offenses under the statute.” Safe Harbor Regulations, Office of Inspector General (2018), https://oig.hhs.gov/compliance/safe-harbor-
ambulance replenishing, some hospitals have ceased the practice anyway to cut costs\textsuperscript{94} and to avoid the possibility of AKS violations altogether.\textsuperscript{95} The unwanted impact of increased enforcement is a type of chilling effect on providers who want to do the right thing and are hesitant on how to effectively do so. In an effort to be extra cautious, they may cut services and accessibility to much needed patient supplies and services, to their detriment.\textsuperscript{96}

IV. FURTHER INCENTIVIZE AND PROTECT WHISTLEBLOWERS

The government’s creative pursuits under the FCA in addition to significant incentives for whistleblowers will continue to shape the healthcare industry and keep it accountable. Healthcare IT News titled a segment of their article “Enter the Bounty Hunters”\textsuperscript{97} noting that the potential of high value settlements and collections will encourage other whistleblowers to report allegations of fraud.\textsuperscript{98} The writer balances this perspective by stating, “[t]hat is not to call [a whistleblower] a bounty hunter” because “as the healthcare attorney Ramsey noted whistleblowers, particularly in healthcare where patient lives are at stake, are usually in it for more than the money.”\textsuperscript{99} Like many other solutions, there will be flaws in the application. This

\begin{itemize}
  \item regulations/index.asp; see 42 C.F.R. § 1001.952 (2016) (listing exceptions such as investment interests, space rental, equipment rental, personal services and management contracts among other safe harbors).
  \item Becker’s Hospital Review, 20 Things, supra note 32.
  \item Id.
  \item Id. (discussing the significant growth in valuation firms in the health care sector and the new market for law firms providing legal advice under the AKS and the FCA).
  \item Id. (“[W]hile whistleblower Brendan Delaney has collected $30 million from the eClinical Works settlement and there is reason to think other whistleblowers might step forward and federal investigators might pursue additional vendors.”)
  \item Id. “Most of the cases resulting in recoveries were brought to the government by whistleblowers under the False Claims Act, the federal government’s primary weapon in the battle against fraud.” DOJ, Fiscal Year 2010, supra note 20.
\end{itemize}
seems to be a risk the government is willing to take and one that has not been highlighted as a bigger problem but may become an issue in the future.

The existence and protection of whistleblowers is essential to the success of the FCA settlements and recoveries. Due to the increased significance and need for whistleblowers, the legislature should respond with additional protections. "When plaintiffs show that they have a viable case, although beginning as a False Claims Act case, the government can step in and take over the litigation, which often results in a settlement that the government uses to cover its losses, and a monetary reward for the whistleblower." However, the relator may receive nothing at all, which allows room for discretion and fairness. Protections will not be allowed for a whistleblower who makes the government aware of its fraudulent conduct. The health care industry is a natural target for the FCA, because it is an industry with large amounts of money susceptible to high levels of fraud, along with mortgage fraud. The FCA remains the government’s primary civil enforcement tool. “We would not have been able to pursue those cases but for the whistleblower filing the case and tipping us off,” Brooker says. Strong examples of this trend involve cases related to hospice care and pharmaceutical off-label marketing-promoting drugs for uses unapproved by the U.S. Food and Drug Administration. For example, “a record $2.3 billion settlement with Pfizer Inc. for off-label marketing in 2009.” In addition, “seven of the top ten FCA health care cases since 2000

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100 Id. “[W]hile whistleblowers . . . many of whom face considerable personal risk in coming forward with allegations of fraud – are entitled to recover between 15 and 30 percent of the proceeds of a successful suit.” Id. (absent is a discussion of what happens to whistleblowers involved in successful suits).

101 “Whistleblowers are setting policy priorities.” Rasmussen & Reisinger, supra note 14.

102 Id. See also, DOJ, A Primer, supra note 18, at 2–3 (“Under certain circumstances, the relator’s share may be reduced to no more than ten percent. If the relator planned and initiated the fraud, the court may reduce the award without limitation.”).

103 Rasmussen & Reisinger, supra note 14.

104 Id.

105 Id.
involve pharmaceutical companies\textsuperscript{106} in their attempt to have physicians prescribe more of their medications.

Pharmaceutical companies have incredible power in our federal government. The DOJ and HHS interpretation to exclude QHPs from federal health care program “will allow pharmaceutical companies to provide co-payment assistance to Affordable Care Act beneficiaries who cannot afford the co-payments for expensive brand name drugs.”\textsuperscript{107} This conclusion may “mean that pharmaceutical companies can provide such assistance to beneficiaries who purchase their insurance on the government exchanges.”\textsuperscript{108} This is a giant loophole to the existing anti-fraud and anti-abuse legislation, such as the FCA and the Anti-Kickback Statute. This exposes the federal government to larger opportunities for criminal activity and exploitation of sick and needy individuals.

The alleged increase in illegal kickbacks and unlawful remuneration includes, but is not limited to, discounted lease payments, gift cards, exorbitant speaking fees, and “incentivizing a health care provider to make certain clinical judgments, whether it’s prescribing certain drugs or services to a patient, in return for remuneration, [is] fraud.”\textsuperscript{109} Simply, “[i]f the [marketer’s] compensation is in any way tied to results – the number of prescriptions flowing to the client . . . ” the government holds the position that such marketing constitutes kickbacks.\textsuperscript{110} Companies should therefore immediately undertake a thorough review of their marketing techniques as well as key government billing and record keeping practices, Cotter says.\textsuperscript{111}

Increasingly in recent years, the Justice Department relies on data analysis, including predictive analytics, to help determine which cases to investigate and prosecute.\textsuperscript{112} Identifying points of weakness and areas of improvement is the first step to understanding how

\textsuperscript{106} Id.
\textsuperscript{107} Radick, Tool Goes Missing, supra note 73.
\textsuperscript{108} Id. (“[a]lthough the practice of providing payment assistance for those who purchase particular medications has been considered an illegal kickback under federal programs such as Medicare and Medicaid”).
\textsuperscript{109} Rasmussen & Reisinger, supra note 14.
\textsuperscript{110} Id.
\textsuperscript{111} Id.
\textsuperscript{112} Id.
healthcare providers, insurance organizations, and third-party payers can operate at a higher level of efficiency and compliance.

Inappropriate payments by insurance organizations or third-party payers occur because of errors, abuse and fraud. The scale of this problem is large enough to make it a priority issue for health systems. Traditional methods of detecting health care fraud and abuse are time-consuming and inefficient. Combining automated methods and statistical knowledge lead to the emergence of a new interdisciplinary branch of science that is named Knowledge Discovery from Databases (KDD). Data mining is a core of the KDD process. Data mining can help third-party payers such as health insurance organizations to extract useful information from thousands of claims and identify a smaller subset of the claims or claimants for further assessment.\(^{113}\)

There are “studies that performed data mining techniques for detecting health care fraud and abuse, using supervised and unsupervised data mining approaches.”\(^{114}\) These studies conclude that there is a need and demand for innovative approaches.

In traditional methods of health care fraud and abuse detection, a few auditors handle thousands of paper health care claims. In reality, they have little time for each claim, focusing on certain characteristics of a claim without paying attention to the comprehensive picture of a provider’s behavior (Rashidian et al... 2012). This method is time-consuming and inefficient.\(^{115}\)

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114 Id.

115 Id.
With the advances of technology today, data mining of this sort may be an advantage the DOJ can utilize for future health care fraud enforcement efforts.

In addition to data mining, health care providers can “reduce exposure to claims fraud” with integration of public records.\textsuperscript{116}

The United States now spends about $2.6 trillion annually on health care and with the reform initiatives under the ACA, the number of Americans insured and the amount spent will grow dramatically, potentially leading to even greater fraud, waste and abuse in the system. The U.S. Department of Health and Human Services (HHS) estimated that, in 2013, it improperly spent about $65 billion in taxpayer funds through waste, errors and fraud – a figure that was primarily fueled by an estimated $60 billion in overpayments to Medicare and Medicaid . . . . A recent analysis of a national health care payer’s claims data illustrated the risk. It’s bad enough to find a provider who billed $2 million in a single year (and was paid more than $600,000) without any medical licensure in the state in which he appeared to practice.\textsuperscript{117}

Public records can be utilized to take “a proactive approach to uncovering derogatory attributes linked to providers and other individuals interacting across the health care system, reducing a payer’s exposure to fraud and abuse before it affects the organization’s bottom line, regulatory compliance and patient safety.”\textsuperscript{118} Every party in the healthcare industry stands to benefit from resourceful and forward-thinking regulation.

Public records provide insight into an individual’s background that may not ever be of notice but should


\textsuperscript{117} Id.

\textsuperscript{118} Id.
be. Drawn from thousands of data sources, the information that can be aggregated and analyzed provides an amazing opportunity to understand the risk triggers and possible motives for aberrant behaviors of individuals interacting within the healthcare ecosystem.\footnote{119}

This proposed approach would attack the problem of health care fraud from a different angle and from the perspective of the patient and the consumer’s personal information. “Some of the issues that can be detected with public records include: deceased providers, license status, sanctions – both state and specialty boards, criminal convictions, high risk indicators for address and SSN, financial information such as liens, bankruptcies and judgments, [and] provider business ID verification.”\footnote{120} “While the public records, in and of themselves, may not warrant the denial of a claim, or provide reason enough for investigation, they can help to strengthen the case and provide greater assurance that the provider in question should be looked into further.”\footnote{121} This reveals another opportunity for state medical boards to cooperate with the federal government.

Another motivation to screen and protect public records is that “[s]tealing patients’ identities is lucrative.”\footnote{122} “Medical records are worth more to crooks than credit-card numbers.”\footnote{123} “They contain more information, and can be used to obtain prescriptions for controlled drugs.”\footnote{124} “Usually, it takes victims longer to notice that their details have been pinched”\footnote{125} “The Government Accountability Office has recommended that the CMS remove Social Security

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\begin{itemize}
\item \textit{Id.}
\item \textit{Id.}
\item \textit{Id.}
\item \textit{Id.}
\item \textit{Id.}
\item \textit{Id.}
\end{itemize}
numbers from Medicare cards to prevent fraud.”126 “It has yet to do so.”127

The Justice Department expects to expand to issues such as opioid overprescribing, which is a hot topic in the national conversation.128 The federal government charged some defendants in the big July takedown with felony drug charges, such as dispensing of controlled substances, but not with traditional health care fraud allegations such as false billing.129 This shift represents a change in priorities for the department toward illicit opioid distribution prosecution under the Trump administration, as opposed to white-collar fraud.130 The DOJ has made attempts to be creative in pursuing, criminally and civilly, any entity that touches opioids in any way.131 “In April 2016, at the height of the deadliest drug epidemic in U.S. history, Congress effectively stripped the Drug Enforcement Administration (DEA) of its most potent weapon against large drug companies suspecting of spilling prescription narcotics onto the nation’s streets.”132 Congress and the legislature must work together to address the growing opioid problem.133 Companies in any way associated with producing and distributing or

126 Id.
127 Id.
128 Id. “The U.S. Justice Department will enlist federal prosecutors to help fight the nation’s opioid crisis by sharing information on overprescribing doctors and coordinating with public health officials to address addiction” Justice Department Opioid Epidemic, FORTUNE.COM (Sept. 16, 2016), http://fortune.com/2016/09/16/justice-department-opioid-epidemic/.
129 Rasmussen & Reisinger, supra note 14.
130 Id.
131 Id.
133 Benjamin Oreskes, Congresswoman Demands Investigation Into Law That Stymied DEA on Opioid Enforcement, LOS ANGELES TIMES, (Oct. 19, 2017), http://www.latimes.com/local/lanow/la-na-opioids-follow-up-20171018-story.html (Judy Chu was reassured by then-head of the DEA Chuck Rosenberg, that recently passed legislation related to the oversight of how opioids are distributed, which she cosponsored, “did not interfere with the DEA’s ability to successfully stop bad actors,” but it did).
prescribing opioid medications need to carefully assess their compliance programs.\textsuperscript{134} Policies and procedures should be a living document and revisited often, and they should notify employees of updated or changed regulations.\textsuperscript{135} Pursuing white-collar fraud and illegal opioid distribution are not mutually exclusive goals as the two often coincide.\textsuperscript{136}

Very recently, Purdue Pharma, “[t]he manufacturer of the powerful painkiller OxyContin announced [] that it will stop promoting its opioid drugs to doctors after years of criticism and mounting lawsuits.”\textsuperscript{137} This article specifically notes that the “remaining question is whether other opioid makers will follow suit and cease marketing the drugs to doctors.”\textsuperscript{138} We may have to wait and see.

[Senator Claire McCaskill] launched an investigation in the sales and marketing practices of opioid manufacturers . . . to determine the role that manufacturers have played in the country’s opioid crisis. The investigation has already shown that a major pharmaceutical company lied and bypassed normal processes to push opioids on to patients who didn’t need them.\textsuperscript{139}

Kickbacks, remuneration, fraud, and aggressive marketing techniques all have one thing in common—money. Individuals and organizations are trying to make as much money as possible while

\textsuperscript{134} Id.
\textsuperscript{135} Id.
\textsuperscript{136} Id.
\textsuperscript{138} Id.
the lives of patients and health care consumers lay in the balance. The federal government is combating this by attempting to obtain large recoveries from individuals and to hold them responsible.\textsuperscript{140} This is a reaction and not proactivity. How do we improve our health care system and the care it delivers while encouraging individuals and companies to operate honestly and remain competitive? This is the question legislators continue to strive to answer.

The FCA is the only enacted legislation that includes a qui tam provision.\textsuperscript{141} Other statutes such as Truth in Negotiation Act or the Public Contracts Anti-Kickback Act do not give relators the legal right to assert in their complaint.\textsuperscript{142} In practice, there are five potential options for the Department of Justice in a FCA allegation.\textsuperscript{143} The DOJ can:

1) intervene in one or more counts of the pending qui tam action 2) decline to intervene in one or all counts of the pending qui tam action 3) move to dismiss the relator’s complaint, either because there is no case, or the case conflicts with significant statutory or policy interests of the United States, 4) settle the pending qui tam action with the defendant prior to the intervention decision, and 5) advise the relator that the DOJ intends to decline intervention, which usually, but not always, results in the dismissal of the qui tam action.\textsuperscript{144}

A relatively new area of FCA activity (non-traditional) are mischarges to the Medicare Part C (MA-PD) prescription drug

\textsuperscript{140} Memorandum from Sally Yates, Deputy Attorney General to Assistant Attorney Generals, all United States Attorneys, et al. (Sept. 9, 2015), 1, 6, https://www.justice.gov/archives/dag/file/769036/download ("These twin aims – of recovering as much money as possible, on the one hand, and of accountability for and deterrence of individual misconduct, on the other – are equally important.") [hereinafter, \textit{Yates Memo}].


\textsuperscript{142} Id.

\textsuperscript{143} Id.

\textsuperscript{144} Id.
program. The United States intervened on a second lawsuit filed under the qui tam provisions of the FCA against United Health Group, the nation’s largest MA-PD organization. “[A]s ever more Medicare and Medicaid beneficiaries move to ‘managed care’ (privately administered) plans, government sleuths will have access to less data.” “This could lead to lower fraud-related recoveries.”

The qui tam provision permits private parties to sue on behalf of the United States for false claims for government funds, and to receive a share of any recovery. The FCA permits the government to intervene in such a lawsuit, as it did here. The “government’s intervention in this matter illustrates the government’s emphasis on combating healthcare fraud.” Individuals can report tips and complaints from all sources about potential fraud, waste, abuse, and mismanagement to the Department of Health and Human Services at 800-HHS-TIPS Hotline.

In addition to anonymous tips, the legislature has responded to the increased dependence on whistleblowers by creating protections against retaliation. Whistleblowers risk losing their position in a company or financial stability by reporting on unlawful activities. If a settlement is not reached or a claim is not litigated,

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145 Rasmussen & Reisinger, supra note 14.
146 MA-PDs are more commonly recognized as Health Maintenance Organizations (HMOs).
147 The Economist, supra note 121.
148 Id.
150 Id.
152 Id. (further supporting and encouraging whistleblowers).
153 National Whistleblower Center, False Claims Act/Qui Tam FAQ, supra note 149 (describing the Whistleblower Protection Provisions in the FCA and other remedies).
154 Id.
whistleblowers need to know that they are protected.\textsuperscript{155} Whistleblowers are typically employees or former employees who are no longer a part of the company.\textsuperscript{156} There is more at stake than just dollars.\textsuperscript{157} By continuing to incentivize and protect whistleblowers, the federal government is preparing itself for success in future litigation.\textsuperscript{158} The legislature has responded by criminalizing certain activity and also protecting the individuals who are attempting to report individuals and organizations who are taking part in such activity.\textsuperscript{159} The next step is how we deal with people who have been identified in participating.

V. INDIVIDUAL PROSECUTIONS ON THE RISE

The DOJ has increased its focus and pursuit of individual prosecutions and personal liability, and this trend should continue.\textsuperscript{160} There is also a “renewed emphasis” on nonmonetary remediation to

\textsuperscript{155} Id. ("any employee...discriminated against because of lawful acts [] in furtherance of an action under the Act is entitled to all relief necessary to make the employee whole").

\textsuperscript{156} Scott Hensley, Pfizer Whistleblower Tells His Bextra Story, NPR (Sept. 3, 2009), 3:30 PM, https://www.npr.org/sections/health-shots/2009/09/pfizer_whistleblower_tells_his.html ("Kopchinski, 45, worked [] until he was fired by the company in 2003. By then he was already talking with lawyers about evidence he had accumulated on the company’s marketing of Bextra").

\textsuperscript{157} Bill Berkrot, Pfizer Whistleblower’s Ordeal Reaps Big Rewards (Sept. 2, 2009, 8:49 PM), https://www.reuters.com/article/us-pfizer-whistleblower/pfizer-whistleblowers-ordeal-reaps-big-rewards-idUSN021592920090903 ("In the Army I was expected to protect people at all costs," Kopchinski said in a statement. "At Pfizer I was expected to increase profits at all costs, even when sales meant endangering lives.").

\textsuperscript{158} Rasmussen & Reisinger, supra note 14 (“Since [the Yates Memo] was issued in September 2015, more individuals have been criminally prosecuted, whether in health care fraud or white-collar crime generally, says Gejae Gobena, a partner at Hogan Lovells and former chief of the DOJ Criminal Division’s health care fraud unit.").

\textsuperscript{159} National Whistleblower Center, False Claims Act/Qui Tam FAQ, supra note 149.

\textsuperscript{160} Yates Memo, supra note 140, at 2. See Rasmussen & Reisinger, supra note 14 (discussing that this shift and rise in individual prosecution is attributed to the Yates Memo).
hold companies publicly liable for the damage they have caused.\textsuperscript{161} Sally Yates, a former Deputy Attorney General and once acting Attorney General, outlined a memo regarding the policy of making corporate executives responsible for wrongdoing on their watch.\textsuperscript{162} By explicitly articulating this mandate, the Justice Department has increasingly prosecuted individuals in both civil and criminal cases, whether in health care fraud or white-collar crime (across the board fraud).\textsuperscript{163} The mandate evaluates individuals and holds them liable for their actions, resulting in fewer individual civil releases.\textsuperscript{164}

The Yates Memo explicitly mandated that “[t]he guidance in this memo will apply to all future investigations of corporate wrongdoing."\textsuperscript{165} First, “to be eligible for any cooperation credit, corporations must provide to the Department all relevant facts about the individuals involved in corporate misconduct.”\textsuperscript{166} This principle establishes a foundational requirement of full cooperation and disclosure. Second, “[b]oth criminal and civil corporate investigations should focus on individuals from the inception of the investigation.”\textsuperscript{167} Yates understood the need for a balanced and holistic approach to targeting fraud. Next, “criminal and civil attorneys handling corporate investigations should be in routine communication with one another.”\textsuperscript{168} In addition, “[a]bsent

\textsuperscript{161} Nonmonetary remediation includes but is not limited to Corporate Integrity Agreements; see Health Care Fraud and Abuse Control Program, The Dep’t of Health and Human Servs. and The Dep’t of Justice, ANNUAL REPORT FOR FY 2007, 14, 17, https://oig.hhs.gov/publications/docs/hcfae/hcfareport2007.pdf; see also Corporate Integrity Agreements, OFFICE OF INSPECTOR GENERAL (2018), https://oig.hhs.gov/compliance/corporate-integrity-agreements/index.asp (“Providers or entities agree to the obligations, and in exchange, OIG agrees not to seek their exclusion from participation in Medicare, Medicaid, or other Federal health care programs”).

\textsuperscript{162} See Yates Memo, supra note 140, at 3 (“If a company seeking cooperation credit \textbf{declines to learn of such facts} or to provide the Department with complete factual information about individual wrongdoers, its cooperation will not be considered a mitigating factor”) (emphasis added).

\textsuperscript{163} Rasmussen & Reisinger, supra note 14.

\textsuperscript{164} Id.

\textsuperscript{165} Id.

\textsuperscript{166} Id.

\textsuperscript{167} Id. note 140, at 3.

\textsuperscript{168} Id. at 4.
extraordinary circumstances, no corporate resolution will provide protection from criminal or civil liability for any individuals.”169 This principle emphasizes the focus on accountability.

Following, the Yates Memo also emphasizes that “[c]orporate cases should not be resolved without a clear plan to resolve related individual cases before the statute of limitations expires and declinations as to individuals in such cases must be memorialized.”170 This is an important procedural step for all attorneys who are attempting to bring civil or criminal law suits in fraud related cases. Finally, “[c]ivil attorneys should consistently focus on individuals as well as the company and evaluate whether to bring suit against an individual based on consideration beyond that individual’s ability to pay.”171 Yates provides clear guidance for the Department and mandates individual prosecution while also emphasizing nonmonetary remediation. She concludes her memo by stating “we believe [these changes] will maximize our ability to deter misconduct and to hold those who engage in it accountable.”172 The focus is not only to punish, but to prevent future unlawful activities and to encourage people to do business the right way.

Prosecution of individuals who have committed health care fraud is crucial to deterring fraudulent activity. The government should continue to pursue unethical individual perpetrators and hold them accountable for professional misconduct and endangerment of the public. The HEAT initiative and partnership between the two departments (Attorney General’s Office and DHHS) “has focused efforts to reduce and prevent Medicare and Medicaid financial fraud through enhanced cooperation.”173 For instance, “Dr. Windsor owned pain management clinics in Georgia and Kentucky that operated under the umbrella of National Pain Care, Inc., including clinics in Lexington, London, Somerset, Hazard, Prestonburg, and Pikeville, Kentucky.”174 He billed for surgical monitoring services that the

169 Id. at 5.
170 Id. at 6.
171 Id.
172 Id. at 7.
174 Id.
clinics did not perform and placed patients at risk. He claimed he monitored the neurological health of patients during surgery when in reality, he assigned an unqualified medical assistant to the work. The U.S. Attorney’s Office recovered a $20 million consent judgment for the government. To pay the judgment to the government, Dr. Winsor was ordered to sell the majority of his properties and assets.

The government should continue pursuing individual prosecutions. Sunita Kumar, “own[ed] one pharmacy herself and operat[ed] a second pharmacy, both located in Brooklyn, New York, [and] conducted a multimillion-dollar scheme to defraud Medicare and Medicaid programs by fraudulently seeking reimbursements for prescription drugs.” Specifically, Kumar’s pharmacies billed and received reimbursements from Medicare and Medicaid for prescriptions that she “did not actually dispense to customers.” This pharmacist even obtained prescriptions from other individuals, “who were willing to forego delivery of the medications.” In exchange, the owner and operator of the pharmacy distributed a “share of the reimbursed proceeds, in the form of kickbacks.”

Sometimes, an individual alone can cause $9 million in damage for fraudulent reimbursements from Medicare and Medicaid. Although Kumar may not have been influenced by a pharmaceutical company to sell more of certain drugs, she was able to design a plan to obtain personal economic gain by defrauding federal health care programs through her own pharmacy.

\[\text{Refereces:} \]

175 Id.
176 Id.
177 Id.
178 Id.
180 Id.
181 Id.
182 Id.
183 Id.
184 Id.
Pharmacies and prescription drugs are in a “fast-growing area of fraud.”\textsuperscript{185} “Elderly patients may receive kickbacks to sell their details to a pharmacist.”\textsuperscript{186} “He will then provide them with drugs they need while billing Medicare for costlier ones.”\textsuperscript{187} “Another scam is to turn a doctor’s clinic into a prescription-writing factory for painkillers (or “pill mill”) and resell them on the street.”\textsuperscript{188} “A clinic in New York was recently charged with fraudulently producing prescriptions for more than 5m oxycodone tablets, which were sold locally for $30-$90 each.”\textsuperscript{189} “New York’s Medicaid sleuths have stepped up spot checks to see if the drugs in the back room square with invoices.”\textsuperscript{190} “But this is a lot of work, so most outlets are never checked.”\textsuperscript{191}

The DOJ reached a settlement with Ralph Cox III, former CEO, in late 2016 for illegal compensation agreements with physicians who agreed to refer patients to Tuomey Healthcare System Inc., not part of Columbia, South Carolina-based Palmetto Health, in violation of the Stark Law.\textsuperscript{192} When the highest officer is being held accountable, other managing directors are put on notice and may be moved to action to ensure compliance in their own organizations. “Very public, very embarrassing” individual prosecutions have the potential to have a deterrent effect on health care fraud if decision makers will be the ones held accountable.\textsuperscript{193}

Although the Yates Memo briefly mentions criminal prosecutions, the violations of the FCA and AKS typically result in large civil settlements and monetary recoveries. However, criminal prosecutions do also occur. “In Texas, after a 2 week trial, a supplier of DME [durable medical equipment] was found guilty of five counts

\textsuperscript{185} The Economist, \textit{The $272 Billion Swindle}, supra note 122.
\textsuperscript{186} \textit{Id.}
\textsuperscript{187} \textit{Id.}
\textsuperscript{188} \textit{Id.}
\textsuperscript{189} \textit{Id.}
\textsuperscript{190} \textit{Id.}
\textsuperscript{191} \textit{Id.}
\textsuperscript{193} Rasmussen & Reisinger, \textit{supra} note 14.
of health care fraud due to the submission of false claims to the Medicare program."\textsuperscript{194} "The jury heard evidence that the supplier hired recruiters to target elderly and disabled Medicare beneficiaries for unnecessary DME such as power wheelchairs."\textsuperscript{195} "Through former employees and the recruiters, the supplier bought and sold false certificates of medical necessity for the items and sought reimbursement in excess of $1.6 million from the Medicare program."\textsuperscript{196} "The court sentenced the supplier to 120 months incarceration and restitution of over $1.6 million."\textsuperscript{197} Criminal prosecutions are important to put frauds and schemers on notice. Individuals who want to take advantage of and exploit seniors and needy communities may have been drawn to an area where they believe they can get away with their criminal activity. The government is not only protecting patients and health care consumers but exposing those who are violating their oath to help and cure society.

Prior to Jeff Sessions being confirmed as the U.S. Attorney General, there was speculation that "[w]ith respect to criminal fraud cases, Sessions has been wary of deferred prosecution agreements."\textsuperscript{198} "In 2010, at a Senate Judiciary Committee confirmation hearing, he expressed concern about a ‘too big to fail’ approach that would allow larger corporations to escape criminal charges."\textsuperscript{199} However, it is clear that the opioid crisis is a top priority for his administration. After a little over a year in office, Attorney General Sessions "announced the creation of a new effort, the [DOJ] Prescription Interdiction & Litigation (PIL) Task Force, to fight the prescription opioid crisis."\textsuperscript{200} In a similar effort to HEAT, but with a

\textsuperscript{194} Health Care Fraud and Abuse Control Program, Annual Report for FY 2007, supra note 161.

\textsuperscript{195} Id.

\textsuperscript{196} Id.

\textsuperscript{197} Id.

\textsuperscript{198} Jeff Overley, LAW360, 5 FCA ISSUES TO WATCH AS TRUMP TAKES POWER (Jan. 6, 2017), https://www.law360.com/articles/845515/5-fca-issues-to-watch-as-trump-takes-power.

\textsuperscript{199} Id.

\textsuperscript{200} Off. of Pub. Affairs, Dep’t of Justice, Attorney General Sessions Announces New Prescription Interdiction & Litigation Task Force (Feb. 27, 2018),
narrower focus, "[t]he PIL Task Force will aggressively deploy and coordinate all available criminal and civil law enforcement tools to reverse the tide of opioid overdoses in the United States, with a particular focus on opioid manufacturers and distributors." The press release concludes by timelining and highlighting the Attorney General’s past year and opioid-related enforcement. Although it is too early to tell how the DOJ under Attorney General Sessions will operate moving forward, it appears it will continue the work of previous administrations with a pointed effort towards attacking the opioid crisis.

VI. MOVING FORWARD

There are different options for change and areas for improvement. Although it is important to prosecute individuals and hold them accountable, some may view individual prosecution as addressing the symptoms rather than the root of the cause. Thus, the government should also prioritize locating actors, whether they are companies or hospitals, who participate in these schemes. The first approach requires broadening the scope of prosecution because this may be more effective than identifying individuals and reacting on a micro level. Fraud is a much larger issue than isolated, greedy individuals if companies encourage their sales representatives to incentivize and influence the actions of health care professionals. It is imperative that agencies such as the DOJ continue to identify companies who incentivize health care and medical service providers, influence clinical judgments, and create negative ripple effects across our nation. Both approaches can be advantageous, but the government cannot exclusively pursue one approach. There must be a balance.

The DOJ Press Releases themselves actually undermine the ability to weed out the kickback schemes. They miss the ability to understand and address the influence and motivation behind certain referrals and how the options appeared.


201 Id.
202 Id.
Criminal convictions will also be utilized in administrative law hearings. State medical boards for physicians and pharmacists will be notified and typically take action against professional licensees.\textsuperscript{204} For those who may not be criminally convicted, it will be important for administrative law judges to have evidence of civil lawsuits and settlements before them. Deputy attorney generals, such as in the Health Quality Enforcement section of the California Department of Justice, bring suits against licensees suspected of not being in compliance with health care regulations and professional responsibilities.\textsuperscript{204}

The federal government will continue to increase FCA civil penalties and criminal penalties.\textsuperscript{205} The Bipartisan Budget Act of 2015\textsuperscript{206} "requires annual re-indexing of FCA penalties for inflation, the minimum per-claim penalty will increase from $10,781 to $10,957 (it jumped from $5,500 to $10,781 last year)."\textsuperscript{207} There was an increase in the maximum per claim penalty as well.\textsuperscript{208}

In the advertising and promotional world, if the promoted product is really that good, it should speak for itself. If the product is not itself a terrible one, the free market should have health care professionals and providers suggest it to their patients, if it is the right choice for them. The health care industry provides many options and in a competitive free market, companies are trying to make themselves known and give themselves every edge available. Although marketers promote products that are ultimately designed to help people, a marketer’s primary responsibility is to sell the product.

\textsuperscript{203} "Health Quality Enforcement Section brings disciplinary actions against state-licensed physicians and other health-related licensees, which involve both administrative and trial court proceedings." State of CA, Dep’t of Justice, \textit{Career Opportunities: Division of Civil Law} (2018), http://ag.ca.gov/careers/descriptions/civillaw.php.

\textsuperscript{204} Id.

\textsuperscript{205} Policy and Medicine, \textit{Department of Justice Increases FCA Civil Penalties, Again} (Feb. 6, 2017), http://www.policymed.com/2017/02/department-of-justice-increases-fca-civil-penalties-again.html.


\textsuperscript{207} Policy and Medicine, \textit{DOJ Increases FCA Civil Penalties}, http://www.policymed.com/2017/02/department-of-justice-increases-fca-civil-penalties-again.html (attributing the sharp increase to a required “annual re-indexing of FCA penalties for inflation”).

\textsuperscript{208} Id.
The issue is complicated because it involves not only the ethical responsibilities of the medical professionals, but also the ethical responsibilities of those promoting the products. The promoters are not subject to the ethical standards of a medical professional. More enforcement may benefit the consumers but may also benefit companies and competitors to have a more even and level arena to promote their products.209

Overall, the increase in health care enforcement has been profitable for the government and society has benefited from the recovery of their taxpayer dollars.210 The government benefits through large recoveries and the consumers and citizens benefit from efficiency and lower costs.211 Every year, the federal government is more efficient and able to recover larger sums to return to federally funded healthcare programs.212 Under Attorney General Jeff Sessions, the DOJ has continued to “aggressively target schemes billing Medicare, Medicaid, and TRICARE (a health insurance program for members and veterans of the armed forces and their families) for medically unnecessary prescription drugs and compounded medications that often were never even purchased and/or distributed to beneficiaries.213 The charges also involve individuals contributing to the opioid epidemic, with a particular focus on medical professionals involved in the unlawful distribution of opioids and other prescription narcotics, a particular focus for the

209 NHCAA, The Challenge of Health Care Fraud, supra note 4 (However, “health care fraud inevitably translates into higher premiums and out-of-pocket expenses for consumers, as well as reduced benefits or coverage”).
210 See DOJ, Fiscal Year 2016, supra note 67.
211 Id. “‘These health care recoveries benefit vulnerable citizens in Medicare and Medicaid and the taxpayers who pay for these programs,’ said Inspector General Daniel R. Levinson of the U.S. Department of Health and Human Services.” Id.
212 DOJ, Fiscal Year 2016, supra note 67. Although not all are health care fraud recoveries, the following fiscal year recoveries come from the DOJ press releases. 2010: $3 billion; 2014: nearly $6 billion; 2015: $3.5 billion; 2016: over $4.7 billion. Id.
Department. According to the CDC, approximately 91 Americans die every day of an opioid related overdose. The departments lists strike forces in different parts of the U.S. and what they’re charging and pursuing.

The opioid crisis is bringing more attention to how medications are being prescribed and the government is seeking to identify the responsible actors in the crisis. Addressing health care fraud may also help address the opioid crisis. Pharmaceutical companies are skirting regulations in order to sell more medications and physicians prescribing medications are incentivized and financially benefiting from overprescribing these medications. Individual and groups of whistleblowers, with the assistance of the federal government, are not only able to hold companies responsible for their unlawful marketing and production, but also the physicians who are overprescribing and financially gaining from misfortune of those in their care. It is typically employees within the company who are the most equipped to report those who are committing fraud but who also have the most at risk.

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214 Id.
215 Id.
216 Id.
217 FORTUNE.COM, supra note 127.
218 Berkrot, supra note 157 (“Under a later Pfizer regime, he was selling the epilepsy drug Neurontin when a previous whistleblower suit was filed against the company over similar illegal promotion tactics that led to stiff penalties and a form of corporate probation”).
219 See DOJ, Shire, supra note 33 (overprescribing medications or products such as bioengineered human skin substitutes in exchange for cash, speaking engagements, lavish dinners, etc.).
220 See Hensley, supra note 156 (“In pursuing a case against Pfizer for fraudulently promoting drugs that eventually led to the largest health fraud settlement in U.S. history, the feds leaned heavily on evidence supplied by a half-dozen whistleblowers”).
221 Id. 156 (Kopchinski describes “practices that bothered him” such as “encouraging doctors to start patients at high doses of Bextra – eight times the approved starting dose in the case of migraine patients” that motivated him to blow the whistle on Pfizer; see also Berkrot, supra note 157 (discussing the hardships for whistleblowers, “despite the potential for huge rewards”) (emphasis added).
As briefly mentioned, technology can play a huge role in labor-intensive work such as “sift[ing] through heaps of records.”222 “Florida’s Agency for Health Care Administration (AHCA) has recovered up to $50m a year solely from hospitals billing for treatment of illegal aliens that is wrongly coded as ‘emergency care.’”223 Today, there is a “central database [that] houses near-real-time information for Medicare.”224 “This helps the 300 workers at the inspector-general’s office who are trained in data analytics to ‘triage’ the tips that flow in.”225 HHS’s Mr. Cantrell states that, “[HHS] receive[s] far more than we can investigate closely”226 However, technology has not been the cure all. “The electronification of patient records can allow ‘cloning,’ in which treatments automatically trigger excessive billing codes by defaulting to set templates.”227

Although relatively recent proposed legislation such as the failed Graham-Cassidy bill aimed to “repeal and replace” the ACA, there have been no mentioned efforts of repealing the *qui tam* provisions enacted to broaden the FCA and its reach.228 The FCA and anti-fraud enforcement is bipartisan, and recovery of taxpayer dollars is beneficial to both sides of the aisle.229 Based on the health care repeal attempts thus far, there does not appear to be a health care repeal coming soon that would endanger the efficacy of the False Claims Act or the ACA whistleblower protections.230

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223 Id.
224 Id.
225 Id.
226 Id.
227 Id. Human intervention is still required.
229 “Trump has made statements that suggest he’s mindful of improper billing and prepared to continue aggressive enforcement. For example, his campaign platform vowed to ‘attack our debt and deficit by vigorously eliminating waste, fraud and abuse in the federal government. While that may be boilerplate language, it at least suggests that Trump isn’t indifferent to improper billing.” Jeff Overley, Law360, 5 FCA Issues to Watch, *supra* note 190.
230 Rachel Roubein, TIMELINE: The GOP’s failed effort to repeal ObamaCare, The Hill, 2017, available at
The existing legislation and government enforcement agencies do not form a perfect system. Relators, who may have been personally involved and culpable, stand to financially benefit from blowing the whistle on companies they are no longer a part of (potential indemnification suits if relator had personal involvement that can be proven). As evidenced in the DOJ press releases, the federal government has been highly successful in obtaining large settlements from companies doing business the wrong way.

In August 2017, the U.S. Attorney’s Office in the District of Minnesota stated that companies allegedly paid kickbacks to physicians in various forms, including travel, entertainment and improper consulting agreements, such as examples of trips included luxury skiing vacations and high-end fishing, golfing, and hunting trips, to induce physicians to use Precision Lens’ and Sightpath Entities’ products and services. There were “payments in excess of fair market value” for consulting agreements related to nonexistent or unrecorded services. These illegal kickbacks to physicians violated the Anti-Kickback Statute and the FCA. “Medicare beneficiaries depend on their physicians to make decisions based on sound medical judgment... our office will take decisive action to address allegations that medical providers are receiving improper financial benefits that could influence medical decision making.”

In fiscal year 2016, the Justice Department recovered over $4.7 billion from FCA cases, which were dominated by health care and mortgage fraud recoveries. In their press release, they stated that this was a “direct result of the high priority the Obama


231 Id.
232 DOJ, Fiscal Year 2016, supra note 67.
234 Id.
235 Id.
236 Id.
237 DOJ, Fiscal Year 2016, supra note 67.
Administration has placed on fighting health care fraud." 238 It appears that Attorney General Jeff Sessions under the Trump Administration may continue this trend. 239 After analyzing Trump’s statements as a presidential candidate, "[e]xperts say … that the Trump administration won’t ease scrutiny of how health care providers and drugmakers bill taxpayers." 240 The largest recovery in 2016 is in relation to the drug and medical device industry. 241 Wyeth and Pfizer Inc. allegedly had false and fraudulent prices on two drugs used to treat acid reflex and failed to report deep discounts available to hospitals, as required by the government to ensure that Medicaid program enjoyed same pricing benefits. 242 In addition, the Novartis Pharmaceuticals Corp case settled allegations that the company gave kickbacks to specialty pharmacies in return for recommending Exjade, an iron chelation drug, and Myfortic, an anti-rejection drug for kidney transplant recipients. 243 Tenet Healthcare Corp settled under allegations that four of its hospitals engaged in schemes to defraud the U.S. by paying kickbacks in return for patient referrals. 244 Finally, Millennium Health gave free items to induce physicians to

238 Id.

239 “Experts say that the upshot of Sessions’ concern could result in the DOJ’s more frequently declining to join FCA cases if the agency can’t complete investigations quickly enough. But that probably wouldn’t prevent the DOJ from eventually intervening once investigations are complete, and it usually wouldn’t prevent whistleblower attorneys from moving ahead with declined cases.” Jeff Overley, Law360, 5 FCA Issues to Watch, supra note 190.

240 Id.

241 DOJ, Fiscal Year 2016, supra note 67.

242 Id.


refer expensive and profitable lab tests, a violation of the Anti-Kickback Statute and Stark Law.\textsuperscript{245}

Although health care fraud costs the United States a lot of money, “[e]fforts to claw back stolen cash are highly cost-effective: in 2011-13 the government’s main fraud-control programme, [sic] run jointly by the Department of Health and Human Services (HHS) and the Department of Justice, recovered $8 for every $1 it spent.”\textsuperscript{246}

There is no perfect solution that will fix the enormous issue that is health care fraud. From pharmaceutical fraud, durable medical equipment fraud, hospital fraud, home health fraud, health maintenance organization (HMO) fraud, kickbacks, and self-referrals, physician, other practitioners, and hospitals have found opportunities to unlawfully profit through federal health care programs.\textsuperscript{247} As with many problems, “[f]raud migrates”\textsuperscript{248} and “[f]raud mutates, too.”\textsuperscript{249} These schemes do not happen overnight. They are developed and learned and evolve. However, the combination of the False Claims Act, the Anti-Kickback State, the Physician Self-Referral Law, and innovative proposals such as data mining and enhancement and streamlining of public records may allow the federal government to be in a more favorable position to successfully combat health care fraud today.


\textsuperscript{246} The Economist, The $272 Billion Swindle, supra note 122.

\textsuperscript{247} Health Care Fraud and Abuse Control Program, Annual Report for FY 2007, supra note 161.

\textsuperscript{248} The Economist, The $272 Billion Swindle, supra note 122.

\textsuperscript{249} Id.