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TO IMPROVE PATIENT ACCESS TO HIGH-QUALITY HEALTHCARE OUTCOMES AT LOWER COSTS, THE FEDERAL HEALTH FRAUD LAWS NEED TO BE CHANGED AND SIMPLIFIED

Part 3 of a 3-part Special Series

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FALSE CLAIMS ACT

The FCA is a statute that imposes liability on parties for certain acts of knowingly submitting false claims for reimbursement to the government.[1] The FCA applies not only to health fraud law issues, but also to any other false claim submitted to the U.S. government.[2] The law was first passed into law in 1863.[3] It was passed over concern of civil war troop suppliers submitting false claims to the Union Army.[4] The law has been amended multiple times throughout history, in major part to bring the penalties in line with the current value of the dollar.[5]

The FCA begins with:

> (1) In general.--Subject to paragraph (2), any person who—
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> (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), (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, is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104–410 [1]), plus 3 times the amount of damages which the Government sustains because of the act of that person.[6]

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[1] *False Claims Act*, 31 U.S.C. §§ 3729–3733 (West 2010).
[2] David S. Mitchell, Jr., *An Introduction to the False Claims Act*, Ark. Law., Summer 2016, at 26 (2016).
[3] *The False Claims Act: A Primer*, U.S. Department of Justice (Apr. 22, 2011), https://www.justice.gov/sites/default/files/civil/legacy/2011/04/22/C-FRAUDS_FCA_Primer.pdf.
[4] *The False Claims Act: A Primer*, U.S. Department of Justice (Apr. 22, 2011), https://www.justice.gov/sites/default/files/civil/legacy/2011/04/22/C-FRAUDS_FCA_Primer.pdf.
[5] *The False Claims Act: A Primer*, U.S. Department of Justice (Apr. 22, 2011), https://www.justice.gov/sites/default/files/civil/legacy/2011/04/22/C-FRAUDS_FCA_Primer.pdf.
[6] *False Claims Act*, 31 U.S.C. §§ 3729–3733, 3729(a)(1) (West 2010).

The government does not have to prove specific intent to prevail on a claim under the FCA.[7]

In a nutshell, the FCA exists to protect taxpayers from fraudulent claims made to the government.[8] FCA claims are substantial: in 2016, the U.S. Department of Justice issued a press release stating that in fiscal year 2016, it recovered $4.7 billion from FCA cases.[9] The Department further noted it was their third highest recovery under the FCA in history.[10] Because the FCA covers areas of law outside of the context of the health fraud laws, it is important to note the Department's recovery in 2016 for healthcare-related FCA cases, amounted to $2.5 billion.[11] From 2009-2016, the Department has recovered $19.3 billion in FCA healthcare cases.[12]

The FCA also encourages the bringing of *qui tam* cases by private entities that may result in payouts from the government (of recovered monies) for the bringing of successful claims against violators of the FCA.[13] *Qui tam* actions allow private parties (hereafter, "relators") to bring actions against FCA alleged violators on behalf of the government, and the government may take over the case; but if it does not elect to do so, the relator may be entitled to 15-25% of the recovery from the violator.[14]

Qui tam actions are brought pursuant to 31 U.S.C. section 3730(b).[15] Specifically, they are brought by relators in the name of the government for violations under 31 U.S.C. section 3729.[16] The Attorney General can give "written consent to the dismissal of the action and their reasons for consenting" or the court cannot otherwise dismiss the action.[17] The complaint and initial disclosures are filed behind closed doors, *in camera*, and are sealed for a minimum of 60 days.[18] In this time frame, the Department of Justice may choose to intervene in the matter and take over as lead counsel of the case.[19] The government can request multiple extensions of time should it feel the need to do so while it is investigating whether or not to intervene in the underlying action.[20]

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[7] Deborah Gordon, *Esquire, Healthcare Finance: A Primer*, American Health Lawyers Association, p. 22 (2008).
[8] *The False Claims Act: A Primer*, U.S. Department of Justice (Apr. 22, 2011), https://www.justice.gov/sites/default/files/civil/legacy/2011/04/22/C-FRAUDS_FCA_Primer.pdf.
[9] *Justice Department Recovers Over $4.7 Billion From False Claims Act Cases in Fiscal Year 2016*, The United States Department of Justice (Dec. 14, 2016), https://www.justice.gov/opa/pr/justice-department-recovers-over-47-billion-false-claims-act-cases-fiscal-year-2016.
[10] *Justice Department Recovers Over $4.7 Billion From False Claims Act Cases in Fiscal Year 2016*, The United States Department of Justice (Dec. 14, 2016), https://www.justice.gov/opa/pr/justice-department-recovers-over-47-billion-false-claims-act-cases-fiscal-year-2016.
[11] *Justice Department Recovers Over $4.7 Billion From False Claims Act Cases in Fiscal Year 2016*, The United States Department of Justice (Dec. 14, 2016), https://www.justice.gov/opa/pr/justice-department-recovers-over-47-billion-false-claims-act-cases-fiscal-year-2016.
[12] *Justice Department Recovers Over $4.7 Billion From False Claims Act Cases in Fiscal Year 2016*, The United States Department of Justice (Dec. 14, 2016), https://www.justice.gov/opa/pr/justice-department-recovers-over-47-billion-false-claims-act-cases-fiscal-year-2016.
[13] David S. Mitchell, Jr., *An Introduction to the False Claims Act*, Ark. Law., Summer 2016, at 26 (2016).
[14] David S. Mitchell, Jr., *An Introduction to the False Claims Act*, Ark. Law., Summer 2016, at 26 (2016).
[15] *False Claims Act*, 31 U.S.C. §§ 3729–3733, 3730(b) (West 2010).
[16] *False Claims Act*, 31 U.S.C. §§ 3729–3733, 3730(b)(1) (West 2010).
[17] *False Claims Act*, 31 U.S.C. §§ 3729–3733, 3730(b)(1) (West 2010).
[18] *False Claims Act*, 31 U.S.C. §§ 3729–3733, 3730(b)(2) (West 2010).
[19] *False Claims Act*, 31 U.S.C. §§ 3729–3733, 3730(b)(2) (West 2010).
[20] *False Claims Act*, 31 U.S.C. §§ 3729–3733, 3730(b)(3) (West 2010).

If the government chooses not to intervene, it may allow the case to proceed by the relator.[21] The government's right to intervene is exclusive.[22] The government also has the authority to settle the underling matter with the principal burden of having a court hearing with the relator, another hearing to take place *in camera*.[23] The court may also place limitations on the relator, for reasons such as harassment, to limit the following: the "number of witnesses the person may call;"[24] "the length of testimony of such witness;"[25] "the person's cross-examination of witnesses;"[26] or "the participation by the person in the litigation" otherwise.[27] The government may also request courtesy copies of court filings as the relator pursues the claim.[28] The government may also request limits on the underlying matter should it determine that allowing the case to proceed without limits may interfere with a parallel investigation going on within the same nexus of facts or involving the same, potentially bad actors.[29]

If the government does indeed exercise its right to intervene, then the relator can "receive at least 15 percent but not more than 25 percent of the proceeds of the action or settlement of the claim."[30] This award is dependent in part on the level of contribution in bringing the matter on the part of the relator.[31] If the government declines to intervene, then the relator can receive an "amount that shall be 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," including reimbursement of expenses incurred, "plus reasonable attorneys' fees and costs," all to "be awarded against the defendant."[32] The statute also provides for protections for the defendant should the court find "that the claim of the person bringing the action was clearly frivolous, clearly vexatious, or brought primarily for purposes of harassment."[33] The statute also provides protection for taxpayers in the form of the government not being liable for expenses,[34] for defendants who are not found liable in the form of "fees and expenses,"[35] and for whistleblowers in the form of retaliation relief.[36]

The FCA continues in 31 U.S.C. section 3731 to explain the procedure in a false claim.[37] 31 U.S.C. section 3732 conveys judicial jurisdiction to any federal court district where any one or more of the defendant/defendants may reside.[38] A state action may also be brought within a federal court.[39]

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[21] *False Claims Act*, 31 U.S.C. §§ 3729–3733, 3730(b)(4)(B) (West 2010).
[22] *False Claims Act*, 31 U.S.C. §§ 3729–3733, 3730(b)(5) (West 2010).
[23] *False Claims Act*, 31 U.S.C. §§ 3729–3733, 3730(c)(2)(B) (West 2010).
[24] *False Claims Act*, 31 U.S.C. §§ 3729–3733, 3730(c)(2)(C)(i) (West 2010).
[25] *False Claims Act*, 31 U.S.C. §§ 3729–3733, 3730(c)(2)(C)(ii) (West 2010).
[26] *False Claims Act*, 31 U.S.C. §§ 3729–3733, 3730(c)(2)(C)(iii) (West 2010).
[27] *False Claims Act*, 31 U.S.C. §§ 3729–3733, 3730(c)(2)(C)(iv) (West 2010).
[28] *False Claims Act*, 31 U.S.C. §§ 3729–3733, 3730(c)(3) (West 2010).
[29] *False Claims Act*, 31 U.S.C. §§ 3729–3733, 3730(c)(4) (West 2010).
[30] *False Claims Act*, 31 U.S.C. §§ 3729–3733, 3730(d)(1) (West 2010).
[31] *False Claims Act*, 31 U.S.C. §§ 3729–3733, 3730(d)(1) (West 2010).
[32] *False Claims Act*, 31 U.S.C. §§ 3729–3733, 3730(d)(2) (West 2010).
[33] *False Claims Act*, 31 U.S.C. §§ 3729–3733, 3730(d)(4) (West 2010).
[34] *False Claims Act*, 31 U.S.C. §§ 3729–3733, 3730(f) (West 2010).
[35] *False Claims Act*, 31 U.S.C. §§ 3729–3733, 3730(g) (West 2010).
[36] *False Claims Act*, 31 U.S.C. §§ 3729–3733, 3730(h) (West 2010).
[37] *False Claims Act*, 31 U.S.C. §§ 3729–3733, 3731 (West 2010).
[38] *False Claims Act*, 31 U.S.C. §§ 3729–3733, 3732(a) (West 2010).
[39] *False Claims Act*, 31 U.S.C. §§ 3729–3733, 3731(b) (West 2010).

31 U.S.C. section 3733 lays out the process by which an investigation under the FCA is to proceed.[40]

Prior to even filing a claim against a person for potential violation of the FCA, if the Attorney General has reason to believe that any person may be in the possession, custody, or control of any documentary material or information relevant to a false claims law investigation, may, before commencing a civil proceeding issue in writing and cause to be served upon such person, a civil investigative demand requiring such person

(A) to produce such documentary material for inspection and copying,
(B) to answer in writing written interrogatories with respect to such documentary material or information,
(C) to give oral testimony concerning such documentary material or information, or
(D) to furnish any combination of such material, answers, or testimony.[41]

III. ARGUMENT

There are many policies in place and advocacy groups calling for the evaluation of our federal health fraud laws, as discussed below, in pursuit of the "Triple Aim" to reduce healthcare costs, improve access to care, and improve quality of healthcare outcomes.[42] One example, The Cybersecurity Act of 2015, signed into law as a part of a consolidated appropriations act, called for industry participation in conjunction with public health officials to "convene a task force" to "(1) plan a single system for the federal government to share intelligence regarding cybersecurity threats to the health care industry, and (2) recommend protections for networked medical devices and electronic health records."[43] The urgency requiring passage of the law in large part was based upon the reality that healthcare administration infrastructures by federal payors under the Medicare, Medicaid, and State Children's Health Insurance Program (hereafter, "S-CHIP") depend in large part upon the healthcare information contained by private sector entities.[44] The so-named, Health Care Industry and Cybersecurity Task Force (hereafter, the "Task Force") issued its report in June of 2017.[45] In its report, the Task Force made multiple recommendations that could and should become a part of the changes that are desperately needed to modernize our health fraud laws. The U.S. healthcare system is overly costly, continues to provide limited access to patients for care along with inadequate healthcare outcomes, and changes to the federal health fraud laws will help alleviate this problem by freeing up providers to coordinate on electronic medical records and focus on improved patient healthcare outcomes.

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[40] *False Claims Act*, 31 U.S.C. §§ 3729–3733, 3733 (West 2010).
[41] *False Claims Act*, 31 U.S.C. §§ 3729–3733, 3733 (West 2010).
[42] Mac McCarthy, *ACA and the Triple Aim: Musings of a Health Care Actuary*, Benefits Quarterly: Health Care Reform "Lookback", First Quarter 2015, http://www.ifebp.org/inforequest/ifebp/0166490.pdf.
[43] Consolidated Appropriations Act, 2016, Pub. L. No. 114-113, (129 Stat) 2242 (Dec. 18, 2015).
[44] Jamil N. Jaffer, *Carrots and Sticks in Cyberspace: Addressing Key Issues in the Cybersecurity Information Sharing Act of 2015*, 67 S.C.L. Rev. 585, 586 (2016).
[45] *Report of Improving Cybersecurity in the Health Care Industry*, Health Care Industry Cybersecurity Task Force (Jun. 2017), https://www.phe.gov/Preparedness/planning/CyberTF/Documents/report2017.pdf

Lower Healthcare Costs

Currently, healthcare costs are so high, in part, because of the expense of litigation and the cost to ensure regulatory compliance under the health fraud laws; and the problem is only getting worse as the healthcare system shifts to a value-based payment model.[46] To avoid potential liability under the health fraud laws, healthcare providers are required to find safe harbors, at least under AKS and Stark, that will cover any sort of value-based agreement with other providers.[47] Healthcare costs are exploding under the health fraud laws, in significant part because Medicare and Medicaid annual expenditures as of 2015 are $3.2 trillion, representing 17.8 percent of the national GDP. [48] Couple that with the increased cost of complying with the health fraud laws' requirements, which is estimated to add an additional 10 percent to federal health program spending.[49] Moreover, the health fraud laws, as written, can turn otherwise unwitting payment-billers into criminals.[50]

One example that resulted in a settlement,[51] Carousel Pediatrics, was demanded by the government to repay $22 million in alleged Medicaid over-billing charges and penalties, that upon closer look was only on the hook for $3.75 million.[52] Assuming the worst of Carousel Pediatrics, that dollar amount is 5.9 times the amount that was actually over-billed. It is further not comforting to know that Medicare, by itself, "has a backlog of nearly half a million appeals."[53] Providers become less

[46] Deborah Gersh, Timothy McCrystal, and Jennifer Romig, *Compliance and the Transition to Value-based Care*, Law360 (May 31, 2017), https://www.law360.com/articles/927987/compliance-and-the-transition-to-value-based-care.

[47] Deborah Gersh, Timothy McCrystal, and Jennifer Romig, *Compliance and the Transition to Value-based Care*, Law360 (May 31, 2017), https://www.law360.com/articles/927987/compliance-and-the-transition-to-value-based-care.

[48] *NHE Fact Sheet*, Centers for Medicare and Medicaid Services (Jun. 14, 2017), https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nhe-fact-sheet.html.

[49] Salma S. Safiedine, Rachel Rambo, Jihad Komis, *Staying Legal in an Ever-Changing and Complex Health Care Industry: A Look into Health Care Fraud and the Importance of Compliance Programming*, White Collar Crime Committee Newsletter, American Bar Association Criminal Justice Section's White Collar Crime Committee (Winter/Spring 2015 edition), https://www.americanbar.org/content/dam/aba/publications/criminaljustice/wcc_newsletter_healthcare.authcheckdam.pdf.

[50] Salma S. Safiedine, Rachel Rambo, Jihad Komis, *Staying Legal in an Ever-Changing and Complex Health Care Industry: A Look into Health Care Fraud and the Importance of Compliance Programming*, White Collar Crime Committee Newsletter, American Bar Association Criminal Justice Section's White Collar Crime Committee (Winter/Spring 2015 edition), https://www.americanbar.org/content/dam/aba/publications/criminaljustice/wcc_newsletter_healthcare.authcheckdam.pdf.

[51] Alexa Ura, *State, Carousel Pediatrics Settle Medicaid Fraud Case*, The Texas Tribune (Mar. 17, 2014), https://www.texastribune.org/2014/03/17/carousel-pediatric-settles-medicaid-fraud-investga/.

[52] *How Complex are Health Regulations? The 140,000-code Question*, The Economist (May 31, 2014), https://www.economist.com/news/united-states/21603077-if-rules-were-simpler-defrauding-medicare-would-be-harder-140000-code-question.

[53] *How Complex are Health Regulations? The 140,000-code Question*, The Economist (May 31, 2014), https://www.economist.com/news/united-states/21603077-if-rules-were-simpler-defrauding-medicare-would-be-harder-140000-code-question.

inclined to take on patients with government health benefits, further reducing access to care, as discussed below.[54]

Another cost problem the Health Care Industry and Cybersecurity Task Force proposed to solve in its Task Force Report is the issue of the incredible costs associated with electronic health records.[55] The report also describes a way that providers can work together and therefore reduce costs: through legalizing and incentivizing the collaboration between health care providers with respect to electronic health records.[56] T here is an inherent desire of larger health care organizations to seek to avoid potential liability issues from smaller providers and suppliers down the healthcare supply chain.[57] The 2015 Cybersecurity Act itself incentivizes such collaboration between private entities to shield them from liability.[58] It also allows for information sharing to take place between the federal government and private entities.[59] Currently, such a donation or subsidy would put the providers/suppliers at risk for liability under the AKS and/or Stark.[60]

The problem is further exacerbated by the fact that strict liability is the standard employed by regulatory bodies under the health fraud laws.[61] The AKS further does not require actual intent to defraud the government through the inducement of referrals, making AKS cases easier for the government to prove.[62] Coupled with the aggressiveness that the U.S. Department of Justice employs in pursuing investigations under the federal health fraud laws, and the increasing ability of a Department of Health and Human Services, Office of Inspector General to levy substantial civil monetary penalties, healthcare providers are understandably cautious.[63] *Qui tam* actions under the FFCA are further monetarily incentivizing whistleblowers to come forth and blow their

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[54] *How Complex are Health Regulations? The 140,000-code Question*, The Economist (May 31, 2014), https://www.economist.com/news/united-states/21603077-if-rules-were-simpler-defrauding-medicare-would-be-harder-140000-code-question.

[55] *Report of Improving Cybersecurity in the Health Care Industry*, Health Care Industry Cybersecurity Task Force, p. 27 (Jun. 2017), https://www.phe.gov/Preparedness/planning/CyberTF/Documents/report2017.pdf.

[56] *Report of Improving Cybersecurity in the Health Care Industry*, Health Care Industry Cybersecurity Task Force, p. 27 (Jun. 2017), https://www.phe.gov/Preparedness/planning/CyberTF/Documents/report2017.pdf.

[57] *Report of Improving Cybersecurity in the Health Care Industry*, Health Care Industry Cybersecurity Task Force, p. 27 (Jun. 2017), https://www.phe.gov/Preparedness/planning/CyberTF/Documents/report2017.pdf.

[58] Jamil N. Jaffer, *Carrots and Sticks in Cyberspace: Addressing Key Issues in the Cybersecurity Information Sharing Act of 2015*, 67 S.C.L. Rev. 585, 589 (2016).

[59] Jamil N. Jaffer, *Carrots and Sticks in Cyberspace: Addressing Key Issues in the Cybersecurity Information Sharing Act of 2015*, 67 S.C.L. Rev. 585, 591 (2016).

[60] *Report of Improving Cybersecurity in the Health Care Industry*, Health Care Industry Cybersecurity Task Force, p. 27 (Jun. 2017), https://www.phe.gov/Preparedness/planning/CyberTF/Documents/report2017.pdf.

[61] *Report of Improving Cybersecurity in the Health Care Industry*, Health Care Industry Cybersecurity Task Force, p. 27 (Jun. 2017), https://www.phe.gov/Preparedness/planning/CyberTF/Documents/report2017.pdf.

[62] Emre N. Ilter, Thomas A. Ryan, *Emerging Litigation Threats for Physician Relationships in a Post-ACA World*, Health Law Litigation, 19368380, Winter2015, Vol. 12, Issue 1.

[63] Emre N. Ilter, Thomas A. Ryan, *Emerging Litigation Threats for Physician Relationships in a Post-ACA World*, Health Law Litigation, 19368380, Winter2015, Vol. 12, Issue 1 (*citing to, Press Release, U.S Dep't of Justice, Justice Department Recovers $3.8 Billion from False Claims Act Cases in Fiscal Year 2013* (Dec. 20, 2013)).

whistles.[64,65] Additionally, a "reverse false claim" is a risk providers need to be mindful of as they are required to return any overpayment from the government within 60 days.[66]

Another proposal to reduce costs through an information technology (hereafter, "IT") program known as the "Meaningful Use Program" has been proposed to the current administration by the American Hospital Association (hereafter, "AHA").[67] Specifically, the AHA is asking that Stage 3 of the program be cancelled, as it requires hospitals to "shoulder the expense of upgrading electronic health records solely for regulatory reasons."[68] The AHA is calling for a new rule arguing it would reduce costs by billions a year.[69] The AHA also raised concerns relating to the flexibility of the government in using its enforcement discretion to waive penalties against healthcare providers.[70]

Improve Patient Access To Care

Currently, patient access to healthcare is stymied, in part, because of the overly-burdensome health fraud laws and the hesitation created by the laws in healthcare providers' practices to over-prescribe.[71] For example, the American Hospital Association recently did a case study to assess how patient access to care is affected by the shift from a fee-for-service-based system of reimbursement to a value-based system of reimbursement.[72] Their case, a patient identified as "Wayne," was a "75-year-old male with congestive heart failure (CHF), diabetes, coronary artery disease (CAD) and chronic obstructive pulmonary disease (COPD)."[73] The study noted that "Wayne" was not atypical according to standards set out by the Centers for Disease Control and Prevention.[74] The study showed that "Wayne" was receiving limited access to needed healthcare because of the drive toward value-based reimbursement because of incompatible Electronic Health

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[64] Ayla Ellison, *Stark Law: The 27-Year-Old Act Killing Healthcare Reform Before It Can Begin?*, Becker's Hospital Review (Sep. 7, 2016), http://www.beckershospitalreview.com/legal-regulatory-issues/stark-law-the-27-year-old-act-killing-healthcare-reform-before-it-can-begin.html.

[65] Emre N. Ilter, Thomas A. Ryan, *Emerging Litigation Threats for Physician Relationships in a Post-ACA World*, Health Law Litigation, 19368380, Winter2015, Vol. 12, Issue 1.

[66] Emre N. Ilter, Thomas A. Ryan, *Emerging Litigation Threats for Physician Relationships in a Post-ACA World*, Health Law Litigation, 19368380, Winter2015, Vol. 12, Issue 1 (*citing to, Press Release, U.S Dep't of Justice, Justice Department Recovers $3.8 Billion from False Claims Act Cases in Fiscal Year 2013* (Dec. 20, 2013)).

[67] Virgil Dickson, *AHA's Wish List to Trump Included Killing Stage 3 of Meaningful Use*, Modern Healthcare (Dec. 1, 2016), http://www.modernhealthcare.com/article/20161201/NEWS/161209995.

[68] Virgil Dickson, *AHA's Wish List to Trump Included Killing Stage 3 of Meaningful Use*, Modern Healthcare (Dec. 1, 2016), http://www.modernhealthcare.com/article/20161201/NEWS/161209995.

[69] Virgil Dickson, *AHA's Wish List to Trump Included Killing Stage 3 of Meaningful Use*, Modern Healthcare (Dec. 1, 2016), http://www.modernhealthcare.com/article/20161201/NEWS/161209995.

[70] Virgil Dickson, *AHA's Wish List to Trump Included Killing Stage 3 of Meaningful Use*, Modern Healthcare (Dec. 1, 2016), http://www.modernhealthcare.com/article/20161201/NEWS/161209995.

[71] *See, e.g., Legal (Fraud and Abuse) Barriers to Care Transformation and How to Address Them: Wayne's World*, American Hospital Association (Feb. 28, 2017), http://www.aha.org/content/16/barrierstocare-full.pdf.

[72] *Legal (Fraud and Abuse) Barriers to Care Transformation and How to Address Them: Wayne's World*, American Hospital Assotiation (Feb. 28, 2017), p. 2, http://www.aha.org/content/16/barrierstocare-full.pdf.

[73] *Legal (Fraud and Abuse) Barriers to Care Transformation and How to Address Them: Wayne's World*, American Hospital Assotiation (Feb. 28, 2017), p. 11, http://www.aha.org/content/16/barrierstocare-full.pdf.

[74] *Legal (Fraud and Abuse) Barriers to Care Transformation and How to Address Them: Wayne's World*, American Hospital Assotiation (Feb. 28, 2017), p. 11, http://www.aha.org/content/16/barrierstocare-full.pdf.

Records ("EHRs").[75] The "barriers" encountered by "Wayne" included incompatible EHRs and also that his healthcare providers could not make necessary referrals out of fear of a charge of an inappropriate payment by government payors under the health fraud laws.[76] "Wayne's" healthcare providers were also not able to provide him with necessary support after he was discharged.[77] Providers were not able to fully coordinate "Wayne's" healthcare under the new value-based system.[78] A recent report done by the Agency Healthcare Research and Quality shows a trend that even post-Affordable Care Act, healthcare access is still hampered by disparities in how healthcare access is indeed accessible to minority groups and the poor.[79]

Part of the difficulty in pursuing the goal of higher patient access is that physician relationships with each other and other healthcare providers and suppliers are heavily regulated under the federal health fraud laws.[80] There are business model "attacks" brought upon providers from patients, competitors, and others.[81] Moreover, the Stark law rules, in particular, on self-referral may punish technical violators of the law despite strong efforts to maintain regulatory compliance.[82] There is current debate on the Stark law going on in the House of Representatives because of a revived bill in the House on physician-owned hospitals versus non-physician-owned hospitals.[83]

The 2018 Physician Fee Schedule released in July of 2017 aims to improve patient access by allowing mental health providers to recover fees from providing telemedicine.[84] Multiple bills were introduced in Congress to expand coverage to more patients under Medicaid, in addition to making it easier for certain providers to make notes in a patient's electronic health records.[85] Additionally, there is a push for an outright repeal of the Stark law that is being advocated by executives of large healthcare systems.[86]

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[75] *Legal (Fraud and Abuse) Barriers to Care Transformation and How to Address Them: Wayne's World*, American Hospital Assotiation (Feb. 28, 2017), p. 11, http://www.aha.org/content/16/barrierstocare-full.pdf.
[76] *Legal (Fraud and Abuse) Barriers to Care Transformation and How to Address Them: Wayne's World*, American Hospital Assotiation (Feb. 28, 2017), p. 13, http://www.aha.org/content/16/barrierstocare-full.pdf.
[77] *Legal (Fraud and Abuse) Barriers to Care Transformation and How to Address Them: Wayne's World*, American Hospital Assotiation (Feb. 28, 2017), p. 13, http://www.aha.org/content/16/barrierstocare-full.pdf.
[78] *Legal (Fraud and Abuse) Barriers to Care Transformation and How to Address Them: Wayne's World*, American Hospital Assotiation (Feb. 28, 2017), p. 13, http://www.aha.org/content/16/barrierstocare-full.pdf.
[79] *2016 National Healthcare Quality and Disparities Report*, Agency for Healthcare Research and Quality (Jul. 2017), https://www.ahrq.gov/research/findings/nhqrdr/nhqdr16/index.html.
[80] Emre N. Ilter, Thomas A. Ryan, *Emerging Litigation Threats for Physician Relationships in a Post-ACA World*, Health Law Litigation, 19368380, Winter2015, Vol. 12, Issue 1.
[81] Emre N. Ilter, Thomas A. Ryan, *Emerging Litigation Threats for Physician Relationships in a Post-ACA World*, Health Law Litigation, 19368380, Winter2015, Vol. 12, Issue 1.
[82] Adrienne Dresevic, Clinton Mikel, *Final CY 2016 Stark Law Changes – Welcomed Revisions to Stark*, Health Lawyer, 07363443, Dec2015, Vol. 28, Issue 2.
[83] Jeff Lagasse, *Physician-Owned Hospitals Debate Revived by House Bill*, Healthcare Finance (Mar 2, 2017), http://www.healthcarefinancenews.com/news/physician-owned-hospitals-debate-revived-house-bill-some-say-they-offer-higher-quality-care.
[84] Hall Render Killian Heath & Lyman PC, *Hall Render's This Week in Washington - July 14, 2017*, Lexology, http://www.lexology.com/library/detail.aspx?g=5a0692a3-db8f-450f-9c5e-0b45d40bcd7f.
[85] Hall Render Killian Heath & Lyman PC, *Hall Render's This Week in Washington - July 14, 2017*, Lexology, http://www.lexology.com/library/detail.aspx?g=5a0692a3-db8f-450f-9c5e-0b45d40bcd7f.
[86] Virgil Dickson, *Health Systems Urge Senate to Revamp or Repeal Stark Law*, Modern Healthcare (Jul. 12, 2016), http://www.modernhealthcare.com/article/20160712/NEWS/160719972.

INCREASED HEALTHCARE QUALITY OUTCOMES

Currently, healthcare quality, although improving system-wide, should further be improved because it still has plenty of room to improve.[87] A joint report was issued recently by the American Medical Association's Joint Council on Medical Service and The Council on Science and Public Health to the Chair of the of its Reference Committee calling for even higher levels of use of preventative medicine, for example.[88] The report also calls for more cost-sharing between providers noting that post-ACA, per-person deductibles under employer-sponsored insurance plans, "grew 20 percent to $3,703 in 2017."[89] Healthcare fraud laws have a "trickle-down effect" and "[it] has real and serious consequences on the quality of care" according to a separate white paper report because they cause providers to hesitate in prescribing treatments and care and have potentially, deadly results.[90]

Moreover, current Medicare rules provide for bonuses to hospital groups with lower quality healthcare systems but that have lower costs.[91] This is in large part because the new value-based reimbursement system rewards cheaper healthcare providers with what amounted to $1 billion in bonus payments in 2015 to 231 hospitals.[92] CMS has committed to reviewing this bonus system in the near future.[93]

The 2016 Physician Fee Schedule Final Rule makes it easier for providers to improve access to care in addition to improving quality of patient care outcomes by allowing providers with have additional certainties and invoke fewer uncertainties by allowing CMS to focus more on serious fraud and abuse matters.[94] Large health care providers are on the hook for multiple billions of dollars due to whistleblower actions, and that money and time should be redirected to increasing

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[87] *2016 National Healthcare Quality and Disparities Report*, Agency for Healthcare Research and Quality (Jul. 2017), https://www.ahrq.gov/research/findings/nhqrdr/nhqdr16/index.html.

[88] Peter S. Lund, MD and S. Bobby Mukkamala, *Joint Report of the Council on Medical Service and the Council on Science and Public Health, CMS/CSAPH Joint Report A-17*, American Medical Association, pg. 1 (2017), https://www.ama-assn.org/sites/default/files/media-browser/public/about-ama/councils/Council%20Reports/council-on-medical-service/cms-csaph-joint-report-a17.pdf.

[89] Peter S. Lund, MD and S. Bobby Mukkamala, *Joint Report of the Council on Medical Service and the Council on Science and Public Health, CMS/CSAPH Joint Report A-17*, American Medical Association, pg. 1 (2017), https://www.ama-assn.org/sites/default/files/media-browser/public/about-ama/councils/Council%20Reports/council-on-medical-service/cms-csaph-joint-report-a17.pdf.

[90] *The Real Cost of Health Care Fraud – and New Ways to Fight It: Stopping the Flow of Health Care Fraud with Technology, Data and Analytics*, LexisNexis, p. 2 (Jan. 2014), https://www.lexisnexis.com/risk/downloads/whitepaper/The-Real-Cost-Health-Care-Fraud.pdf.

[91] Jordan Rau, Kaiser Health News, *Medicare Pays Bonuses to 231 Hospitals With Lower Quality Because of Cheaper Costs*, U.S. News & World Report (May 3, 2016), https://www.usnews.com/news/articles/2016-05-03/medicare-pays-bonuses-to-231-hospitals-with-lower-quality-because-of-cheaper-costs.

[92] Jordan Rau, Kaiser Health News, *Medicare Pays Bonuses to 231 Hospitals With Lower Quality Because of Cheaper Costs*, U.S. News & World Report (May 3, 2016), https://www.usnews.com/news/articles/2016-05-03/medicare-pays-bonuses-to-231-hospitals-with-lower-quality-because-of-cheaper-costs.

[93] Jordan Rau, Kaiser Health News, *Medicare Pays Bonuses to 231 Hospitals With Lower Quality Because of Cheaper Costs*, U.S. News & World Report (May 3, 2016), https://www.usnews.com/news/articles/2016-05-03/medicare-pays-bonuses-to-231-hospitals-with-lower-quality-because-of-cheaper-costs.

[94] Hall Render Killian Heath & Lyman PC, *Hall Render's This Week in Washington - July 14, 2017*, Lexology, http://www.lexology.com/library/detail.aspx?g=5a0692a3-db8f-450f-9c5e-0b45d40bcd7f.

quality healthcare outcomes for patients.[95] Concern over legal penalties under the FFCA, in particular, drives providers to be overly-cautious and to conduct additional diagnostics and treatments out of concerns of potential liability.[96]

That is not to say there are not bad actors, there are; and they deserve to pay up.[97] *Qui tam* actions make that possible as whistleblowers can share in the proceeds if the government payor recovers a/the defendant/defendants.[98]

IV. POLICY RECOMMENDATIONS

An amendment to the AKS and Stark to allow larger healthcare providers to coordinate on cybersecurity and to provide to smaller healthcare providers cybersecurity software through donation or subsidization is recommended by the above-discussed Health Care Industry Cybersecurity Task Force.[99] The Task Force included two action items to implement under the recommendation: (1) to have Congress more closely examine the potential impact of AKS and Stark as related to cybersecurity, and (2) to further establish tasks forces to make recommendations to improve cybersecurity.[100] This recommendation should be accepted as a cost-saving mechanism. The IT recommendation from the AHA on cancelling Stage 3 of the Meaningful Use Program should also be accepted as it will lower costs and reduce bureaucratic redundancy.

The bills introduced in Congress to expand Medicaid coverage and to make it easier for providers to make notes on patients' electronic healthcare records should be supported and passed into legislation to increase patient access, although outright repeal of the entire Stark Law would be disastrous and should be disfavored on balance with a more nuance modernization of the law. Additionally, increasing patient access to telemedicine should be supported so rural healthcare recipients can have access to high quality healthcare services and mental healthcare access can be increased.

Moreover, *qui tam* actions should be allowed under the FFCA, but courts need to be more careful about the concerns and interests of patients in having high quality healthcare incomes. This is

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[95] Mark W. Pearlstein, Laura McLane, *False Claims Act Overreach in Healthcare: Patients Lose*, Washington Examiner (Jul. 21, 2017), http://www.washingtonexaminer.com/false-claims-act-overreach-in-healthcare-patients-lose/article/2623712.

[96] Mark W. Pearlstein, Laura McLane, *False Claims Act Overreach in Healthcare: Patients Lose*, Washington Examiner (Jul. 21, 2017), http://www.washingtonexaminer.com/false-claims-act-overreach-in-healthcare-patients-lose/article/2623712.

[97] Daniel E. Wenner, *United States: Heartache for Cardiac-Monitoring Companies Caught Cheating*, Day Pitney LLP (Jul. 12, 2017), http://www.mondaq.com/unitedstates/x/609882/Healthcare/Heartache+for+CardiacMonitoring+Companies+Caught+Cheating.

[98] Daniel E. Wenner, *United States: Heartache for Cardiac-Monitoring Companies Caught Cheating*, Day Pitney LLP (Jul. 12, 2017), http://www.mondaq.com/unitedstates/x/609882/Healthcare/Heartache+for+CardiacMonitoring+Companies+Caught+Cheating.

[99] *Report of Improving Cybersecurity in the Health Care Industry*, Health Care Industry Cybersecurity Task Force, p. 27 (Jun. 2017), https://www.phe.gov/Preparedness/planning/CyberTF/Documents/report2017.pdf.

[100] *Report of Improving Cybersecurity in the Health Care Industry*, Health Care Industry Cybersecurity Task Force, p. 27 (Jun. 2017), https://www.phe.gov/Preparedness/planning/CyberTF/Documents/report2017.pdf.

critical as the U.S. healthcare system shift from a fee-for-service payment system to a value-based outcome system.

V. CONCLUSION

The U.S. healthcare system is overly costly, continues to provide limited access to patients for care along with inadequate healthcare outcomes, and changes to the federal health fraud laws will help alleviate this problem by freeing up providers to coordinate on electronic medical records and focus on improved patient healthcare outcomes. The health fraud laws are numerous and voluminous, and the case law following the statutes and regulations is massive. This contributes to confusion, increased healthcare costs, lower attention to high quality patient care, and highly expensive regulatory compliance complexes. When it comes to healthcare and the interests of public health, these health fraud laws need to be simplified and take into greater account the Affordable Care Act's Triple Aim to lower costs of, higher access to, and better quality in our healthcare system overall.

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