False Claims Act & CARES Act

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False Claims Act

- "False Claims Act serves as the government's **primary civil tool to address false claims for federal funds** or property involving a multitude of other government operations and functions…"
- "Of the more than $3 billion in settlements and judgments recovered by the Department of Justice [in 2019], $2.6 billion relates to matters that involved the healthcare industry, including drug and medical device manufacturers, managed care providers, hospitals, pharmacies, hospice organizations, laboratories and physicians….
- Of the $3 billion in settlements and judgments in 2019, over $2. 1.billion arise from lawsuits filed under the qui tam provisions of the FCA.
  - https://www.justice.gov/opa/pr/justice-department-recovers-over-3-billion-false-claims-act-cases-fiscal-year-2019

"The False Claims Act (FCA) is America's first whistleblower law and one of the strongest whistleblower laws in the United States."

https://www.whistleblowers.org/protect-the-false-claims-act/

31 U.S.C. §§ 3729 – 3733

False Claims Act Violations

- Prohibits:
  - Presenting false claims for approval
  - Making a false statement material to a false claim
  - Conspiracy to do the same
  - Failing to return government funds
  - False receipts
  - Making a false claim material to an obligation to pay money to the government
- Damages/Penalties:
  - Civil Penalty : Not less than $5,000 and not more than $10,000 (as adjusted by 28 USC §2461) (currently $11,181 and not more than $22,363) https://www.justice.gov/civil/false-claims-act
  - Plus 3 times the amount of damages which the Government sustains;
  - Plus Attorneys Fees
- Other Features:
  - Prohibits retaliation
  - Excludes tax claims
  - Whistleblowers who participated in fraud can bring claim unless convicted for that conduct, but recovery could be reduced to $0.

31 USC § 3729

Qui Tam Provision ("private attorneys general")

- Qui Tam is short for ***"qui tam pro domino rege quam pro se ipso in hac parte sequitur»,*** meaning "who as well for the king as for himself sues in this matter."
- **(b) Actions by private persons.--(1)** A person may bring a civil action for a violation of section 3729 for the person and for the United States Government. The action shall be brought in the name of the Government. The action may be dismissed only if the court and the Attorney General give written consent to the dismissal and their reasons for consenting.

31 U.S.C.A. § 3730

- Typical Qui Tam Plaintiffs
  - Current or former employees
  - Competitors
  - Customers/patients
  - Anyone with personal knowledge and specific information

Qui Tam Proceedings

- Filed under Seal
  - Served on Government
  - Government Investigation
- DOJ Intervention

  Before the expiration of the 60-day period or any extensions obtained under paragraph (3), the Government shall--

  (A) proceed with the action, in which case the action shall be conducted by the Government; or

  (B) notify the court that it declines to take over the action, in which case the person bringing the action shall have the right to conduct the action.

- d) **AWARD TO QUI TAM PLAINTIFF**

(1) If the Government proceeds with an action brought by a person under subsection (b), such person shall, subject to the second sentence of this paragraph, **receive at least 15 percent but not more than 25 percent of the proceeds of the action or settlement** of the claim, depending upon the extent to which the person substantially contributed to the prosecution……. plus reasonable attorneys' fees and costs.

(2) If the Government **does not proceed** with an action under this section, the person bringing the action or settling the claim shall receive an amount which the court decides is reasonable . . . . **The amount 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**. Such person shall also receive an amount for reasonable expenses which the court finds to have been necessarily incurred, plus reasonable attorneys' fees and costs.

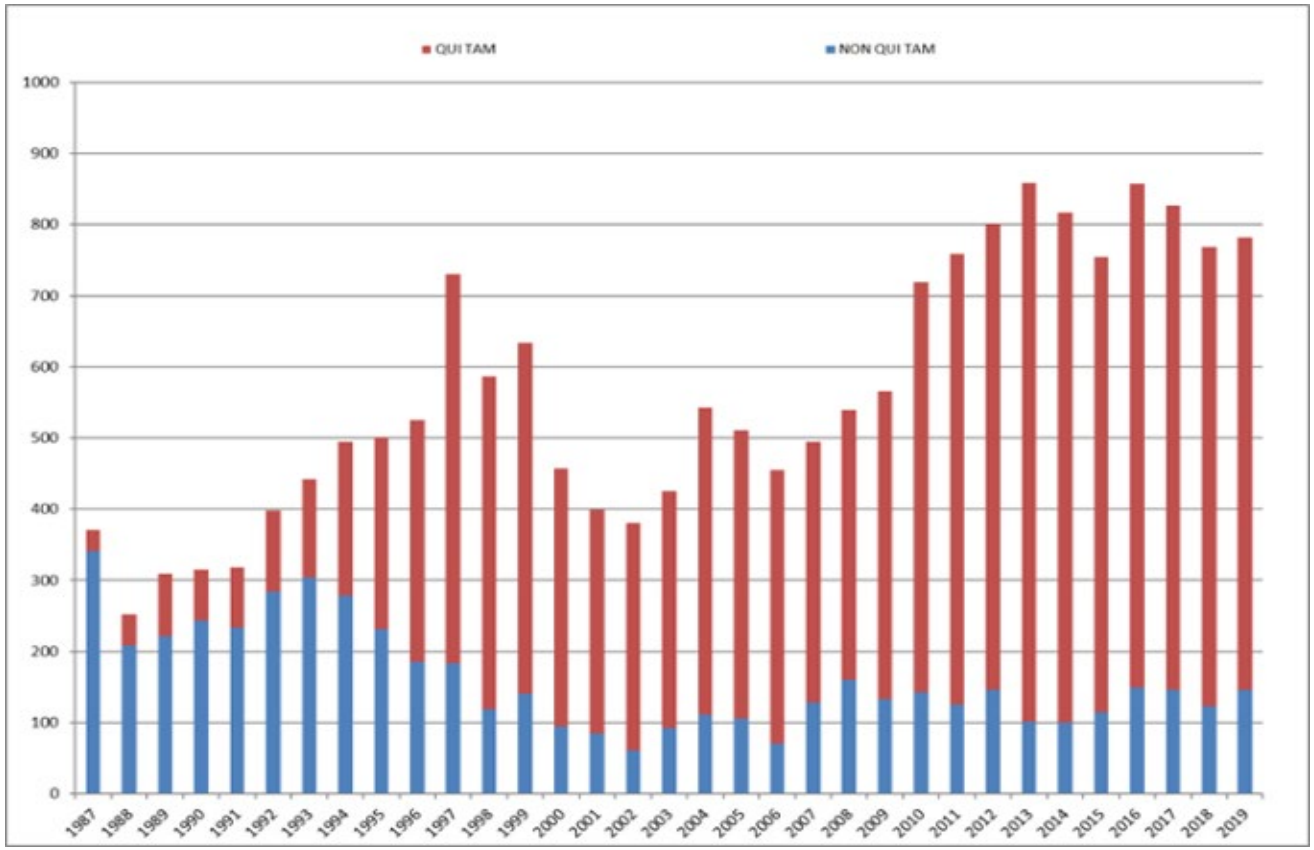
31 U.S.C.A. § 3730 (4)

- Average Time Period for Intervention Decision (painfully Quick vs. Painfully Slow)
- Significance of Intervention (non-intervention)

Government Intervention Decision In FCA Cases

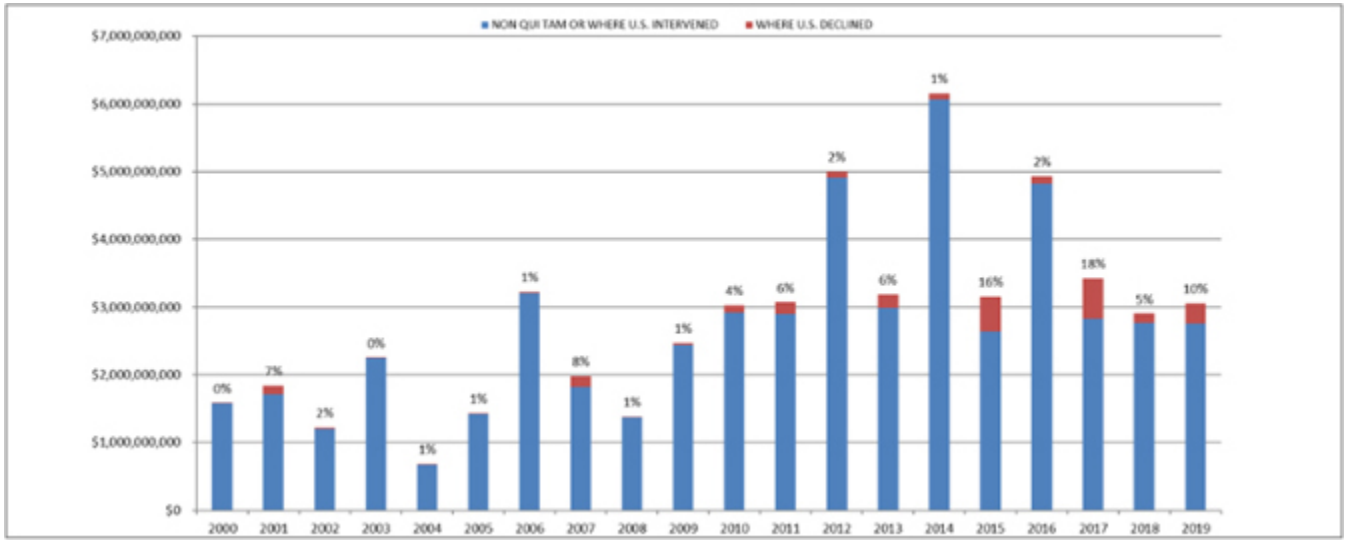
- Critical to Outcome of FCA Case. In 2019:
  - $1.9 billion, or 63% of total 2019 recoveries, in qui tam cases where the government intervened
  - $844 million, or 28%, in cases brought by the government
  - $293 million, 10%, in cases where DOJ declined to intervene in a qui tam (higher than previous years)
  - 85% of 2019 recoveries came from health care sector ($2.6 billion)
- Factors in Government's Intervention Decision
  - As part of the decision process, the views of the investigative agency are solicited and considered, and a detailed memorandum discussing the relevant facts and law is prepared.
  - This memorandum usually includes a discussion of efforts to advise the named defendant of the nature of the potential claims against it, any response provided by the defendant, and settlement efforts undertaken prior to intervention
    - https://www.justice.gov/sites/default/files/usao-edpa/legacy/2012/06/13/InternetWhistleblower%20update.pdf
- Who Decides?

Qui Tam v. Non-Qui Tam Recovery 1987-2019



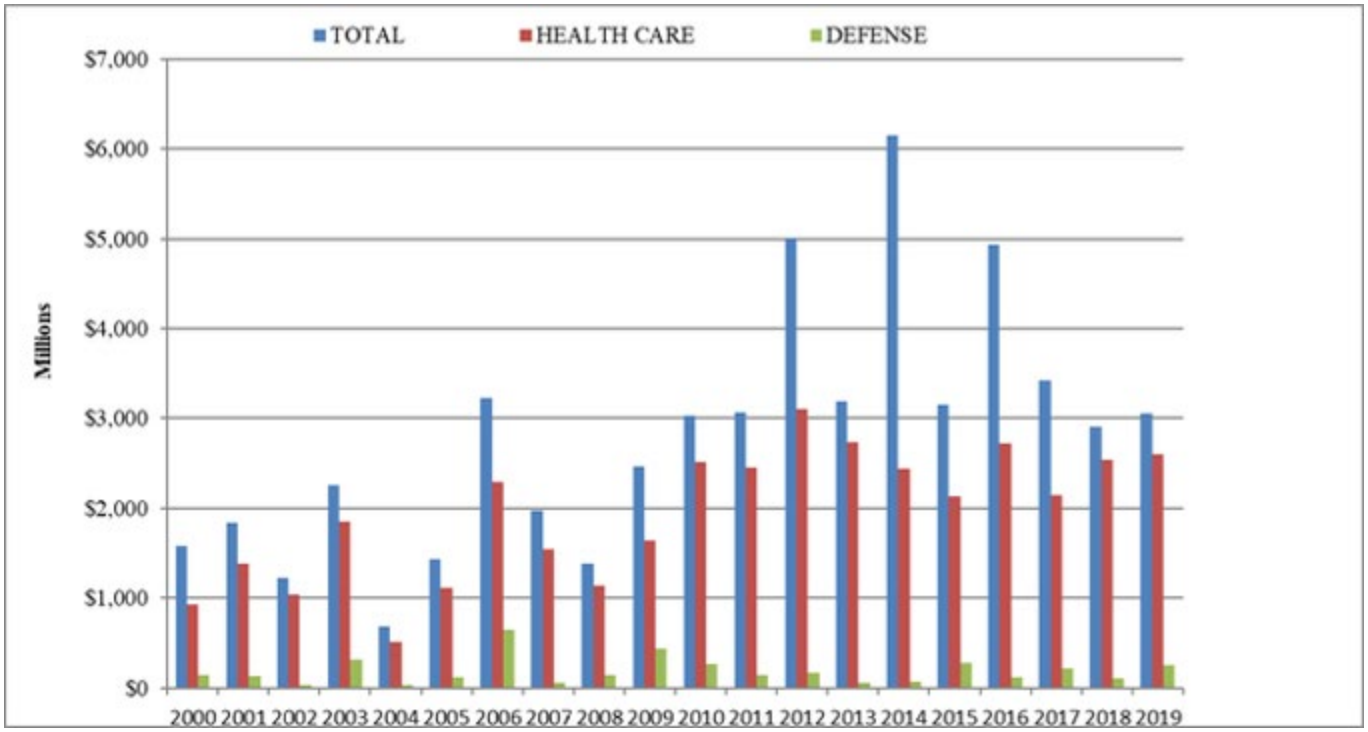
Source: https://www.gibsondunn.com/2019-year-end-false-claims-act-update/

Qui Tam Intervention v. No Intervention 2000-2019



Source: https://www.gibsondunn.com/2019-year-end-false-claims-act-update/

Distribution of Recovery by Sector 2000-2019



Source: https://www.gibsondunn.com/2019-year-end-false-claims-act-update/

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Current FCA Enforcement Trends

- In 2019:
  - 782 new FCA matters docketed
  - 146 (19%) initiated by the government
  - 636 (81%) initiated by *qui tam* whistleblowers
  - Whistleblowers initiated 713 of the 804 suits in 2014
  - DOJ intervenes 20% of the time—accounts for disproportionate amount of recoveries.
  - 10% of recoveries came from declined cases (significant increase from previous years)
  - First FCA settlement premised on cybersecurity vulnerabilities related to flaws in the security surveillance system sold to multiple states and the federal government
  - $162 million in settlements premised on a hybrid antitrust-FCA theory for anticompetitive conduct
  - Heightened focus on opioids crisis

NEBRASKA HEALTH CARE FRAUD TASK FORCE

- FBI
- U. S. Department of Health and Human Services, Office of Inspector General
- Nebraska Attorney General's Office, Medicaid Fraud and Patient Abuse Unit
- Nebraska Dept. of Health & Human Services - Medicaid & Long Term Care Program Integrity
- Drug Enforcement Administration
- U. S. Dept. of Defense, Defense Criminal Investigative Service
- U. S. Food and Drug Administration
- Internal Revenue Service
- NE Department of Insurance – Fraud Prevention Division
- Social Security Administration
- U.S. Postal Service
- Veterans Administration
- Blue Cross Blue Shield Nebraska

NEBRASKA ATTORNEY GENERAL'S OFFICE
MEDICAID FRAUD AND PATIENT ABUSE UNIT

- The Nebraska MFPAU investigates and prosecutes Medicaid provider fraud and patient abuse and neglect.
- Medicaid providers are those doctors, dentists, hospitals, nursing homes, pharmacies, chiropractors, home health workers, medical equipment providers, and other persons and entities who are paid by the Medicaid program for the services they provide.
- The MFPAU also reviews and can act on complaints of abuse and neglect of patients at health care facilities that receive Medicaid payments. This includes both physical abuse or neglect and financial exploitation of a patient.

Avoiding FCA Liability: Proactive Steps

- Effective Compliance Program
- Regulatory Guidance
- Investigate Regulatory Complaints, Hotline Calls, Payor Feedback (i.e., claims denials)
- Consider Self-Disclosure

Mitigating FCA Liability

1) "Guidelines for Taking Disclosure, Cooperation, and Remediation in to Account in FCA Matters." (May 2019)

Identifies factors that will be considered and the credit that will be provided by DOJ when entities or individuals voluntarily self-disclose misconduct that could serve as the basis for FCA liability and/or administrative remedies, take other steps to cooperate with FCA investigations and settlements, or take adequate and effective remedial measures.

https://www.justice.gov/jm/jm-4-4000-commercial-litigation#4-4.112

2) HHS OIG Provider Self-Disclosure Protocol

"Providers who wish to voluntarily disclose self-discovered evidence of potential fraud to OIG may do so under the Provider Self-Disclosure Protocol (SDP). Self-disclosure gives providers the opportunity to avoid the costs and disruptions associated with a Government-directed investigation and civil or administrative litigation.

https://oig.hhs.gov/compliance/self-disclosure-info/protocol.asp

Recent Cases: Reverse False Claim, Overpayment, Obligation

- HHS Overpayments: 42 U.S.C. 1320a-7k(d)

"Any funds that a person receives or retains … to which the person, after applicable reconciliation, is not entitled."

An overpayment must be reported and returned "by the later of … 60 days after the date on which the overpayment was identified ,,, or the date any corresponding cost report is due, if applicable."

Any overpayment retained by a person after the deadline for reporting and returning the overpayment … is an obligation as defined in the False Claims Act.

- Reverse FCA Provision – 31 U.S.C. 3729(a)(1)(G)

  "Obligation" – an established duty from … the retention of an overpayment. 31 U.S.C. 3729(b)(3)
- Medicare Program; Reporting and Returning of Overpayments, 42 C.F.R. Parts 401.305 (81 Fed. Reg. 7654 (Feb. 12, 2016)
- *United HealthCare Insurance Company v. Azar*, 330 F.Supp.3d 173 (D.D.C. 2018)
- *U. S. ex rel. Olson v. Fairview Health Services of MN,* 831 F.3d 1063 (8th Cir. 2016)

Without fraud, punitive damages would seem an unreasonable levy against individuals guilty only of "knowingly" receiving an overpayment from the government fisc.

If there is no allegation of fraudulent conduct under the False Claims Act, there can be no reverse liability under section 3729(a)(1)(G).

Need to plead the who, what, when, where, and how of defendant's concealment of its obligation to return the overpayment.

Must demonstrate the provider knew it had an "obligation" to pay back the payment it received.

Overpayment Rule

- *Sturgeon v. Pharmerica Corp.*, 438 F. Supp. 3d 246, 280 (E.D. Pa. 2020)
  - The Patient Protection and Affordable Care Act then defined "overpayment" as "any funds that a person receives or retains under subchapter XVIII [Medicare] or XIX [Medicaid] of this chapter to which the person, after applicable reconciliation, is not entitled under such subchapter." The ACA also clarified that a "repayment retained by a person after the deadline for reporting and returning the overpayment" is an "obligation" for False Claims Act purposes
- *United States ex rel. Ormsby v. Sutter Health*, No. 15-CV-01062-LB, 2020 WL 1590521, at *29 (N.D. Cal. Mar. 16, 2020)
  - Any overpayment retained for more than 60 days becomes an "obligation" for purposes of the reverse-FCA provision. 42 U.S.C. § 1320a-7k(d)(3).

Recent Cases: False Certification

- *Universal Health Servs., Inc. v. United States*, 136 S. Ct. 1989, 1999, 195 L. Ed. 2d 348 (2016)
  - We first hold that the implied false certification theory can, at least in some circumstances, provide a basis for liability. By punishing defendants who submit "false or fraudulent claims," the False Claims Act encompasses claims that make fraudulent misrepresentations, which include certain misleading omissions. When, as here, a defendant makes representations in submitting a claim but omits its violations of statutory, regulatory, or contractual requirements, those omissions can be a basis for liability if they render the defendant's representations misleading with respect to the goods or services provided.
  - The second question presented is whether, as Universal Health urges, a defendant should face False Claims Act liability only if it fails to disclose the violation of a contractual, statutory, or regulatory provision that the Government expressly designated a condition of payment. We conclude that the Act does not impose this limit on liability. But we also conclude that not every undisclosed violation of an express condition of payment automatically triggers liability. Whether a provision is labeled a condition of payment is relevant to but not dispositive of the materiality inquiry.

Recent Cases: Objective Falsehood

- *United States v. AseraCare, Inc.*, 938 F.3d 1278, 1297 (11th Cir. 2019)
  - when a hospice provider submits a claim that certifies that a patient is terminally ill "based on the physician's or medical director's clinical judgment regarding the normal course of the individual's illness," 42 U.S.C. § 1395f(7), 42 C.F.R. § 418.22(b), the claim cannot be "false"—and thus cannot trigger FCA liability—if the underlying clinical judgment does not reflect an objective falsehood.
  - in order to properly state a claim under the FCA in the context of hospice reimbursement, a plaintiff alleging that a patient was falsely certified for hospice care must identify facts and circumstances surrounding the patient's certification that are inconsistent with the proper exercise of a physician's clinical judgment. Where no such facts or circumstances are shown, the FCA claim fails as a matter of law.
- Circuit Split: *United States v. Care Alternatives*, 952 F.3d 89 (3d Cir. 2020):
  - We depart from this framing of FCA falsity. As previously articulated, limiting falsity to factual falsity is inconsistent with our case law, which reads FCA falsity more broadly as legal falsity, encompassing circumstances where a claim for reimbursement is non-compliant with requirements under the statute and regulations.
  - The Eleventh Circuit also determined that clinical judgments cannot be untrue. AseraCare III, 938 F.3d at 1297. ("[A] reasonable difference of opinion among physicians reviewing medical documentation ex post is not sufficient on its own to suggest that those judgments ... are false under the FCA."). We again disagree.

Recent Cases: CARES Act & Nursing Homes

- COVID Impact on Seniors:
  - According to the CDC, 8 of 10 COVID-19 deaths were Adults over 65
- Elder Justice Initiative (DOJ)
- State "Immunity" in Some States

https://www.kutakrock.com/newspublications/publications/2020/06/states-implement-covid-19-legal-protections

Recent Cases: Retaliation

- *Sherman v. Berkadia Commercial Mortg. LLC*, 956 F.3d 526 (8th Cir. 2020):
  - The statute also contains an anti-retaliation provision, which prohibits an employer from terminating or otherwise retaliating against an employee for "lawful acts done by the employee ... in furtherance of [a civil action for false claims] or other efforts to stop 1 or more violations of this subchapter." 31 U.S.C. § 3730(h)(1).
  - In order to qualify as protected activity under the FCA's anti-retaliation provision, the employee's conduct: (1) "must have been in furtherance of an FCA action," and (2) "must be aimed at matters which are calculated, or reasonably could lead, to a viable FCA action, meaning the employee in good faith believes, and ... a reasonable employee in the same or similar circumstances might believe, that the employer is possibly committing fraud against the government."
- *United States ex rel. Strubbe v. Crawford Cty. Mem'l Hosp.*, 915 F.3d 1158, 1168 (8th Cir. 2020):
  - This court will apply the McDonnell Douglas framework to FCA retaliation claims
  - A temporal connection between the protected conduct and adverse action may be sufficient to establish a prima facie case where the proximity is "very close."
  - FCA enforcement must be ***sole*** cause of conduct alleged to be retaliatory

Anti-retaliation Provisions (31 U.S.C. § 3730)

(h) Relief from retaliatory actions.

(1) In general. Any employee, contractor, or agent shall be entitled to all relief necessary to make that employee, contractor, or agent whole, if that employee, contractor, or agent is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment because of lawful acts done by the employee, contractor, agent or associated others in furtherance of an action under this section or other efforts to stop 1 or more violations of this subchapter.

(2) Reinstatement with the same seniority status

- Two times the amount of back pay,
- Interest on the back pay, and
- Compensation for any special damages sustained as a result of the discrimination, including litigation costs and reasonable attorneys' fees.

Recent Cases: Sub-Regulatory Guidance

- *Azar v. Allina Health Services*, 139 S. Ct. 1804 (2019)
  - U.S. Supreme Court holds that must undertake notice-and-comment rulemaking under Medicare Act before it changed a substantive legal standard (formula for calculating disproportionate share hospital payments)
  - A change to a substantive legal standard requires notice and comment rulemaking under the Administrative Procedure Act – undermines enforcement based on agencies sub-regulatory "guidance".
- DHHS October 31, 2019 Memo regarding Allina:
  - Where the Department of Health and Human Services ("HHS" or "the Department") or the Centers for Medicare & Medicaid Services ("CMS") issued guidance that, under Allina, should have been promulgated through notice-and-comment rulemaking, **the Department's ability to bring enforcement actions predicated on violations of those payment policies is restricted**. If the Center for Medicare intends for a particular guidance document to be used in enforcement actions, then the guidance must comply with Allina.
    - https://www.alston.com/files/docs/20191031-CMS-Memo-re-Medicare-Payment-Rules.pdf

Recent Cases: Anti-Kickback Statute

- *U.S. ex rel. Benaissa v. Trinity Health*, 963 F.3d 733, 738 (8th Cir. 2020)
  - Dr. Benaissa argues that these allegations give rise to a plausible inference that Trinity paid these five physicians for referrals in violation of the Stark and Anti-Kickback laws. See 42 U.S.C. §§ 1395nn(a)(1); 1320a-7b(b)(1). And he contends that, because the government will not pay claims that are tainted by violations of these statutes, see 42 U.S.C. §§ 1320a-7b(g); 1395nn(a)(1)(B) and (g)(1), every claim submitted by these physicians constitutes a false or fraudulent claim in violation of 31 U.S.C. § 3729(a)(1)(A).
  - The FCA imposes liability on any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A). "The FCA is not concerned with regulatory noncompliance. Rather, it serves a more specific function, protecting the federal fisc by imposing severe penalties on those whose false or fraudulent claims cause the government to pay money." United States ex rel. Dunn v. N. Mem'l Health Care, 739 F.3d 417, 419 (8th Cir. 2014) (citation omitted). "Accordingly, the FCA generally attaches liability, not to the underlying fraudulent activity, but to the claim for payment." Id.

Recent Cases: Anti-Kickback Statute

- *United States v. Jain*, 93 F.3d 436, 438 (8th Cir. 1996)
  - Psychologist Swaran Kumar Jain and his corporation, the Center for Mental Health Services, Inc., appeal their convictions for violating the mail fraud and Medicare anti-kickback statutes by receiving payments from a psychiatric hospital for referring patients to that hospital.
  - In the Medicare anti-kickback statute, the word "willfully" modifies a series of prohibited acts. Both the plain language of that statute, and respect for the traditional principle that ignorance of the law is no defense, suggest that a heightened *mens rea* standard should only require proof that **Dr. Jain knew that his conduct was wrongful, rather than proof that he knew it violated "a known legal duty**." Therefore, the district court's definition of "willfully" correctly construed the 1980 amendment to § 1320a-7b.

CONCLUSIONS

- **FCA LIABILITY A SIGNIFICANT RISK FOR HEALTH CARE PROVIDERS**
- **COVID-RELATED FUNDING IS A DOUBLE-EDGED TOOL – BE ATTENTIVE TO THE FINE PRINT**
- **UTILIZE AVAILABLE TOOLS TO PROACTIVELY AVOID OR MITIGATE FCA LIABILITY**
- **HAVE A NICE DAY –BE CAREFUL OUT THERE!**

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(1) The views expressed are the speaker's own. They are not the official position of the Department of Justice.