



Recent Court Actions Provide Insight into Future of Fraud & Abuse Laws

Two recent court actions may serve as harbingers for the future of healthcare fraud and abuse laws. In September 2024, a federal judge in the Southern District of West Virginia ordered parties in a *qui tam* False Claims Act and Stark Law case to brief the court on the implications of *Loper Bright Enterprises v. Raimondo* on the interpretation of the Stark Law to the case at hand.¹ That same month, a federal judge in the Middle District of Florida dismissed a *qui tam* lawsuit on a novel theory that the False Claims Act's whistleblower provisions are unconstitutional. This Health Capital Topics article discusses these cases and the potential impact on federal fraud and abuse laws.

The Stark Law prohibits physicians from referring Medicare patients to entities (such as hospitals) with which the physicians or their family members have a direct or indirect financial relationship for the provision of designated health services (DHS).² DHS include, but are not limited to, the following:

- (1) Inpatient and outpatient hospital services;
- (2) Radiology and certain other imaging services;
- (3) Radiation therapy services and supplies;
- (4) Certain therapy services, such as physical therapy;
- (5) Durable medical equipment; and,
- (6) Outpatient prescription drugs.³

Under the Stark Law, financial relationships include ownership interests through equity, debt, other means, and ownership interests in entities also have an ownership interest in the entity that provides DHS.⁴ Additionally, financial relationships include compensation arrangements, which are defined as arrangements between physicians and entities involving any remuneration, directly or indirectly, in cash or in kind.⁵

On its face, the Stark Law may prohibit legitimate business arrangements. However, the law contains a large number of exceptions, which describe ownership interests, compensation arrangements, and forms of remuneration to which the Stark Law does not apply.⁶ An arrangement must fully fall within one of the exceptions in order to be shielded from enforcement of the Stark Law.⁷ Notably, "the Stark Law statutory framework is relatively skeletal and its application to many common situations is ambiguous."⁸ Therefore, parties must rely on the "extensive, complex" regulations that have been developed over the past three decades to provide guidance and clarify those ambiguities.⁹

Civil penalties under the Stark Law include overpayment or refund obligations, a potential civil monetary penalty of \$15,000 for each service, plus treble damages, and exclusion from Medicare and Medicaid programs.¹⁰ Further, violation of the Stark Law can also trigger a violation of the False Claims Act (FCA), which prohibits any person from knowingly submitting, or causing to submit, false claims to the government.¹¹ FCA violators are liable for treble damages (i.e., "three times the government damages"), as well as a monetary penalty linked to inflation.¹² Not only does the FCA give the U.S. government the ability to pursue fraud, it also enables private citizens to file suit on behalf of the federal government through what is known as a "*qui tam*," "*whistleblower*," or "*relator*" suit.¹³ Notably, Congress increased incentives for whistleblowers in 1986, significantly increasing the number of *qui tam* suits brought each year.¹⁴ Both of the lawsuits noted above were originally filed under the *qui tam* provisions of the FCA, but in both cases, the government ultimately decided not to intervene.

On June 28, 2024, the U.S. Supreme Court issued a seismic decision explicitly overruling the "*Chevron* doctrine."¹⁵ Under this doctrine, more commonly referred to as *Chevron* deference, courts were mandated to defer to a federal agency's interpretation of an ambiguous federal statute as long as it was reasonable.¹⁶ However, the June 2024 ruling in *Loper Bright Enterprises v. Raimondo* (*Loper Bright*) has shifted the authority to interpret statutes and regulations to the courts, and placed significantly more scrutiny on executive agencies such as the Department of Health and Human Services (HHS) and their ability to implement omnibus laws passed by Congress.¹⁷ In its decision, the Court stated that courts must determine a statute's "best reading," i.e., the "statute's meaning 'at the time of enactment' and... 'the reading the court would have reached if no agency were involved.'"¹⁸

The question of when and how the *Loper Bright* decision will affect courts' interpretation of fraud and abuse laws will first be answered by parties in *United States ex rel. Kyer v. Thomas Health System, Inc. (Kyer)*. An FCA case brought in the Southern District of West Virginia by a former nurse for the defendant health system broadly alleges that various direct and indirect physician compensation arrangements violated the Stark Law and Anti-Kickback Statute, giving rise to FCA liability.¹⁹ After the Department of Justice (DOJ) declined to

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intervene for the time being (but reserved its “right to intervene for cause at a later time”), the relator filed her amended complaint and the defendants filed a motion to dismiss the case – all of which pleadings were filed prior to the *Loper Bright* decision.²⁰ On September 12, 2024, the federal district judge ordered the parties to brief the effect of *Loper Bright*, if any, on the relator’s Stark Law claim, as both the amended complaint and the motion to dismiss “rely heavily” on Stark regulations.²¹ The judge noted that “the Stark Law has grown complex, nuanced, and reliant on agency regulation to define key terms and safe harbors,” and “under *Chevron*, federal courts could wade through Stark Law claims by deferring and defaulting to an agency’s interpretation.”²² However, *Loper Bright* has made such deference unacceptable. In order to assess the relator’s claims and rule on the motion to dismiss, the court must determine “the contours of the [Stark] statute... without blindly deferring to any agency interpretation.”²³

In response to the judge’s order, both parties argued similarly – that the relator’s Stark Law claim can be decided without deferring to an agency interpretation of the law – but for different reasons. The relator argues that the amended complaint does not challenge an agency action, so *Loper Bright* would not be implicated at this stage. Further, the relator asserts that the amended complaint sufficiently alleges that the defendants had a compensation arrangement involving remuneration with physicians, the exact action policed by the plain language of the Stark Law statute.²⁴ On the other hand, the defendants argue that “[t]his Court can determine – from the Stark Law itself – that relator has not stated a claim upon which relief may be granted.”²⁵

Meanwhile, on September 30, 2024 a judge in the Middle District of Florida dismissed an FCA whistleblower case. In *United States ex rel. Zafirov v. Florida Medical Associates, LLC*, a former physician of the defendant medical practice alleged that the defendant had misrepresented patient diagnoses to Medicare in seeking reimbursement (i.e., they filed false claims). Notably, the DOJ declined to intervene in the case. Subsequently, the defendants moved for a judgment on the pleadings.²⁶ In its motion, the defendants argued in part that the FCA’s “*qui tam* provisions empower relators to act as officers of the United States without being duly appointed, violating the Appointments Clause of Article II of the U.S. Constitution.”²⁷ The judge agreed, reasoning that relators are Officers of the United States (as defined by the constitution and the Supreme Court) because they “possess[] civil enforcement authority on behalf of the United States... and the position mirrors the role of a bank receiver or special prosecutor in its duration and non-personal nature.” Because the relators are Officers

occupying a continuing position established by law, they are consequently subject to the constitution’s Appointments Clause.²⁸ While this is the first federal court decision finding the FCA *qui tam* provisions unconstitutional,²⁹ it is not a wholly novel concept or argument. First, although the FCA was enacted over 160 years ago during the Civil War, “the widespread use of the FCA *qui tam* provision appears to be of relatively modern vintage.”³⁰ Second, the arguments utilized in the defendants’ motion and the court’s decision echo a U.S. Supreme Court dissent issued in 2023. In *US ex rel. Polansky v. Executive Health Resources Inc.*, Justice Thomas questioned the constitutionality of the FCA’s *qui tam* provision: “There are substantial arguments that the *qui tam* device is inconsistent with Article II and that private relators may not represent the interests of the United States in litigation.”³¹ Justices Kavanaugh and Barrett concurred, indicating that at least three Supreme Court justices may be open to visiting the circuit split that now exists as a result of the ruling of Judge Kathryn Kimball Mizelle who, notably, clerked for Justice Thomas.³² In fact, Judge Mizelle’s decision breaks from a number of other federal circuits.³³ It is expected that the decision will be appealed to the Eleventh Circuit.

By themselves, either of these cases are groundbreaking news, representing a significant potential change in the interpretation, and adjudication, of fraud and abuse laws. Taken together, however, these cases could be the harbingers of paradigm shifts in federal fraud and abuse enforcement. Over 75% of all FCA cases are brought by relators, and in approximately 10% of those cases, the government declines to intervene.³⁴ If the Supreme Court ultimately ruled the FCA’s *qui tam* provision to be unconstitutional, those cases would likely never be adjudicated; while the federal government could potentially choose to stay on those cases in which it might otherwise have declined to intervene, resource constraints render that option improbable. The impact of *Loper Bright* on Stark and other complex federal healthcare laws reliant on agency regulation is yet unknown. But Judge Joseph Goodwin of the Southern District of West Virginia rightly forecasts that “[i]nvariably, *Loper Bright* will begin to ripple through the Stark Regulations. The only question for courts is when and how.”³⁵ Certainly, the burden placed on the government if every case involving the Stark Law must rest upon a complete *de novo* consideration of the regulations implicated in the case could force the DOJ to reduce its workload. In other words, depending on the ultimate outcome of these cases, these potential trends could ultimately result in reduced regulatory enforcement.

- 1 United States of America ex rel. Liesa Kyer, v. Thomas Health System, Inc., et al., Case No. 2:20-cv-00732, Order (S.D. W.Va. September 12, 2024) ECF Doc. 63, available at: <https://www.wvsc.uscourts.gov/sites/wvsc/files/opinions/2-20-cv-732.pdf> (Accessed 10/9/24).
- 2 “CRS Report for Congress: Medicare: Physician Self-Referral (“Stark I and II”)” By Jennifer O’Sullivan, Congressional Research Service, The Library of Congress, July 27, 2004, available at: <http://www.policyarchive.org/handle/10207/bitstreams/2137.pdf> (Accessed 6/13/24); “Limitation on certain physician referrals” 42 USC § 1395nn.
- 3 42 USC § 1395nn(a)(1)(B); “Definitions” 42 CFR § 411.351.
- 4 42 USC § 1395nn(a)(2).
- 5 42 USC § 1395nn(h)(1).
- 6 42 USC § 1395nn.
- 7 “Comparison of the Anti-Kickback Statute and Stark Law” Health Care Fraud Prevention and Enforcement Action Team (HEAT) Office of Inspector General (OIG), <https://oig.hhs.gov/documents/provider-compliance-training/939/StarkandAKSChartHandout508.pdf> (Accessed 6/13/24).
- 8 “The Future of the Stark Law is Clouded by Uncertainty” By Charles B. Oppenheim, et al., Hooper Lundy Bookman, September 19, 2024, <https://hooperlundy.com/the-future-of-the-stark-law-is-clouded-by-uncertainty/> (Accessed 10/14/24).
- 9 *Ibid.*
- 10 42 USC § 1395nn(g).
- 11 “The False Claims Act” U.S. Department of Justice, February 2, 2022, <https://www.justice.gov/civil/false-claims-act> (Accessed 1/3/24).
- 12 *Ibid.*
- 13 *Ibid.*
- 14 “False Claims Act Settlements and Judgments Exceed \$2.68 Billion in Fiscal Year 2023” Office of Public Affairs, U.S. Department of Justice, Press Release, February 22, 2024, <https://www.justice.gov/opa/pr/false-claims-act-settlements-and-judgments-exceed-268-billion-fiscal-year-2023> (Accessed 10/15/24).
- 15 “Loper Bright Enterprises, et al. v. Raimondo, Secretary of Commerce, et al.” Supreme Court of the United States, June 28, 2024, https://www.supremecourt.gov/opinions/23pdf/22-451_7m58.pdf (Accessed 7/12/24); “Supreme Court strikes down Chevron, curtailing power of federal agencies” By Amy Howe, SCOTUSblog, June 28, 2024, <https://www.scotusblog.com/2024/06/supreme-court-strikes-down-chevron-curtailling-power-of-federal-agencies/> (Accessed 7/12/24).
- 16 “Supreme Court strikes down Chevron, curtailing power of federal agencies” By Amy Howe, SCOTUSblog, June 28, 2024, <https://www.scotusblog.com/2024/06/supreme-court-strikes-down-chevron-curtailling-power-of-federal-agencies/> (Accessed 7/12/24).
- 17 “Supreme Court Decision Limiting the Authority of Federal Agencies Could Have Far-Reaching Impacts for Health Policy” By Kaye Pestaina, Michelle Long, and Justin Lo, Kaiser Family Foundation, July 1, 2024, <https://www.kff.org/private-insurance/issue-brief/supreme-court-decision-limiting-the-authority-of-federal-agencies-could-have-far-reaching-impacts-for-health-policy/> (Accessed 7/12/24).
- 18 “US ex rel. Kyer v. Thomas Health System, Inc. et al.” No. 2:20-cv-00732, Defendant’s Brief Addressing *Loper Bright’s* Effect on the Stark Law and Relator’s Claims (S.D.W.Va. Mar. 12, 2024), p. 3 (citing “Loper Bright Enterprises, et al. v. Raimondo, Secretary of Commerce, et al.” 144 S.Ct. 2244, 2266 (Jun. 28, 2024)).
- 19 “US ex rel. Kyer v. Thomas Health System, Inc. et al.” No. 2:20-cv-00732, First Amended Complaint and Demand for Jury Trial (S.D.W.Va. Mar. 12, 2024).
- 20 “Stark Law Comes under Loper Bright Spotlight” By Samantha Groden and Christopher Janney, Dentons on Call, September 19, 2024, <https://www.dentonshealthlaw.com/stark-law-comes-under-loper-bright-spotlight/#5a9b983a-463c-4698-82d7-00f2d6a97af9-link> (Accessed 10/14/24).
- 21 No. 2:20-cv-00732, Order (S.D.W.Va. Sept. 12, 2024).
- 22 *Ibid.*, p. 1, 7-8.
- 23 *Ibid.*, p. 2.
- 24 *Ibid.*, p. 8.
- 25 *Ibid.*, p. 11.
- 26 “A motion for judgment on the pleadings... is designed to dispose of cases before trial where the material facts are not in dispute and a judgment on the merits can be rendered by looking to the substance of the pleadings and any judicially noticed facts... This motion is similar to a motion to dismiss for failure to state a claim, but it is filed after the pleadings are closed.” “Litigation, Overview - Motion for Judgment on the Pleadings” Bloomberg Law, <https://www.bloomberglaw.com/external/document/XEITU4AO000000/litigation-overview-motion-for-judgment-on-the-pleadings> (Accessed 10/15/24).
- 27 “Foley Secures Precedent-Setting Victory in Constitutional Challenge to the False Claims Act’s Qui Tam Provisions” Foley & Lardner LLP, October 3, 2024, <https://www.foley.com/news/2024/10/foley-secures-precedent-setting-victory-in-constitutional-challenge-to-the-false-claims-acts-qui-tam-provisions/> (Accessed 10/14/24).
- 28 “US ex rel. Zafirov v. Florida Medical Associates, LLC, et al.” Case No. 8:19-cv-01236-KKM-SPF, Order (M.D. Fla. Sept. 30, 2024), available at: <https://storage.courtlistener.com/recap/gov.uscourts.flmd.364103/gov.uscourts.flmd.364103.346.0.pdf> (Accessed 10/14/24), p. 16-17, 30.
- 29 Foley & Lardner LLP, October 3, 2024.
- 30 Case No. 8:19-cv-01236-KKM-SPF, Order (M.D. Fla. Sept. 30, 2024), p. 45-47.
- 31 “US ex rel. Polansky v. Executive Health Resources Inc.” Case No. 21-1052, Slip Opinion (S.Ct. Jun. 16, 2023), available at: https://www.supremecourt.gov/opinions/22pdf/21-1052_fd9g.pdf (Accessed 10/14/24).
- 32 “False Claims Act Insights - Are the FCA’s Qui Tam Provisions Unconstitutional? One Federal Judge Says ‘Yes’” Podcast by Jonathan A. Porter, Jody L. Rudman and Lorinda G. Holloway, Husch Blackwell, October 9, 2024, <https://www.huschblackwell.com/newsandinsights/false-claims-act-insights-are-the-fcas-qui-tam-provisions-unconstitutional-one-federal-judge-says-yes> (Accessed 10/14/24).
- 33 *See, e.g.*, “Riley v. St. Luke’s Episcopal Hospital” 252 F.3d 749, 758 (5th Cir. 2001); “US ex rel. Lagatta v. Reditus Laboratories, LLC” Case No. 1:22-CV-01203, 2024 WL 4351862 (C.D. Ill. Sept. 30, 2024); “US ex rel. Wallace v. Exactech, Inc.” 703 F. Supp. 3d 1356 (N.D. Ala. 2023); “US ex rel. Miller v. ManPow, LLC” Case No. 2:21-cv-05418-VAP-ADSx, 2023 WL 8290402, at *1 (C.D. Cal. Aug. 30, 2023); “US ex rel. Thomas v. Care” Case No. CV-22-00512-PHX-JAT, 2023 WL 7413669, at *4 (D. Ariz. Nov. 9, 2023); “US ex rel. CLJ, LLC v. Halickman” Case No. 20-cv-80645, 2024 WL 3332055, at *21 n. 5 (S.D. Fla. Jun. 14, 2024); “US ex rel. Butler v. Shikara” 2024 WL 4354807, at *10-13 (S.D. Fla. Sept. 6, 2024).
- 34 “FRAUD STATISTICS – OVERVIEW: October 1, 1986 - September 30, 2023: Civil Division, U.S. Department of Justice” available at: <https://www.justice.gov/opa/media/1339306/dl?inline> (Accessed 10/15/24).
- 35 No. 2:20-cv-00732, Order (S.D.W.Va. Sept. 12, 2024), p. 8.



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Todd A. Zigrang, MBA, MHA, FACHE, CVA, ASA, ABV, is the President of **HEALTH CAPITAL CONSULTANTS (HCC)**, where he focuses on the areas of valuation and financial analysis for hospitals, physician practices, and other healthcare enterprises. Mr. Zigrang has over 28 years of experience providing valuation, financial, transaction and strategic advisory services nationwide in over 2,000 transactions and joint ventures. Mr. Zigrang is also considered an expert in the field of healthcare compensation for physicians, executives and other professionals.



Mr. Zigrang is the co-author of *"The Adviser's Guide to Healthcare - 2nd Edition"* [AICPA - 2015], numerous chapters in legal treatises and anthologies, and peer-reviewed and industry articles such as: *The Guide to Valuing Physician Compensation and Healthcare Service Arrangements* (BVR/AHLA); *The Accountant's Business Manual* (AICPA); *Valuing Professional Practices and Licenses* (Aspen Publishers); *Valuation Strategies*; *Business Appraisal Practice*; and, *NACVA QuickRead*. Additionally, Mr. Zigrang has served as faculty before professional and trade associations such as the American Society of Appraisers (ASA); the National Association of Certified Valuators and Analysts (NACVA); the American Health Lawyers Association (AHLA); the American Bar Association (ABA); the Association of International Certified Professional Accountants (AICPA); the Physician Hospitals of America (PHA); the Institute of Business Appraisers (IBA); the Healthcare Financial Management Association (HFMA); and, the CPA Leadership Institute.

Mr. Zigrang holds a Master of Science in Health Administration (MHA) and a Master of Business Administration (MBA) from the University of Missouri at Columbia. He is a Fellow of the American College of Healthcare Executives (FACHE) and holds the Certified Valuation Analyst (CVA) designation from NACVA. Mr. Zigrang also holds the Accredited Senior Appraiser (ASA) designation from the American Society of Appraisers, where he has served as President of the St. Louis Chapter. He is also a member of the America Association of Provider Compensation Professionals (AAPCP), AHLA, AICPA, NACVA, NSCHBC, and, the Society of OMS Administrators (SOMSA).



Jessica L. Bailey-Wheaton, Esq., is Senior Vice President and General Counsel of HCC. Her work focuses on the areas of Certificate of Need (CON) preparation and consulting, as well as project management and consulting services related to the impact of both federal and state regulations on healthcare transactions. In that role, Ms. Bailey-Wheaton provides research services necessary to support certified opinions of value related to the Fair Market Value and Commercial Reasonableness of transactions related to healthcare enterprises, assets, and services.



Additionally, Ms. Bailey-Wheaton heads HCC's CON and regulatory consulting service line. In this role, she prepares CON applications, including providing services such as: health planning; researching, developing, documenting, and reporting the market utilization demand and "need" for the proposed services in the subject market service area(s); researching and assisting legal counsel in meeting regulatory requirements relating to licensing and CON application development; and, providing any requested support services required in litigation challenging rules or decisions promulgated by a state agency. Ms. Bailey-Wheaton has also been engaged by both state government agencies and CON applicants to conduct an independent review of one or more CON applications and provide opinions on a variety of areas related to healthcare planning. She has been certified as an expert in healthcare planning in the State of Alabama.

Ms. Bailey-Wheaton is the co-author of numerous peer-reviewed and industry articles in publications such as: *The Health Lawyer* (American Bar Association); *Physician Leadership Journal* (American Association for Physician Leadership); *The Journal of Vascular Surgery*; *St. Louis Metropolitan Medicine*; *Chicago Medicine*; *The Value Examiner* (NACVA); and *QuickRead* (NACVA). She has previously presented before the American Bar Association (ABA), the American Health Law Association (AHLA), the National Association of Certified Valuators & Analysts (NACVA), the National Society of Certified Healthcare Business Consultants (NSCHBC), and the American College of Surgeons (ACS).



Janvi R. Shah, MBA, MSF, CVA, serves as Senior Financial Analyst of HCC. Mrs. Shah holds a M.S. in Finance from Washington University Saint Louis and the Certified Valuation Analyst (CVA) designation from NACVA. She develops fair market value and commercial reasonableness opinions related to healthcare enterprises, assets, and services. In addition she prepares, reviews and analyzes forecasted and pro forma financial statements to determine the most probable future net economic benefit related to healthcare enterprises, assets, and services and applies utilization demand and reimbursement trends to project professional medical revenue streams and ancillary services and technical component (ASTC) revenue streams.



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