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Recent Court Actions Provide Insight into Future of Healthcare Fraud and Abuse Laws

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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*[1] False Claims Act (FCA) and Stark Law case to brief the court on the implications of *Loper Bright Enterprises v. Raimondo*[2] on the interpretation of the Stark Law in the case at hand.[3] That same month, a federal judge in the Middle District of Florida dismissed a *qui tam* lawsuit on a novel theory that the FCA's whistleblower provisions are unconstitutional.[4] This article discusses these cases and their potential impact on federal fraud and abuse laws.

1 *Qui tam* suits are discussed below.

2 Loper Bright Enterprises v. Raimondo, 144 S. Ct. 2244 (2024).

3 United States ex rel. Kyer v. Thomas Health System, Inc., Case No. 2:20-cv-00732 (S.D. W. Va. September 12, 2024), Order, ECF Doc. 63, available at https://www.wvsd.uscourts.gov/sites/wvsd/files/opinions/2-20-cv-732.pdf.

4 United States ex rel. Zafirov v. Florida Medical Associates, LLC, Case No. 8:19-cv-01236-KKM-SPF (M.D. Fla. Sept. 30, 2024), Order, available at: https://storage.courtlistener.com/recap/gov.uscourts.flmd.364103/gov.uscourts.flmd.364103.346.0.pdf.

Background

Healthcare valuation's *raison d'être* stems from the federal healthcare fraud and abuse laws, including the Anti-Kickback Statute, Stark Law, and FCA. 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).[5] DHS include, but are not limited to, the following:

- Inpatient and outpatient hospital services
- Radiology and certain other imaging services
- Radiation therapy services and supplies
- Certain therapy services, such as physical therapy
- Durable medical equipment
- Outpatient prescription drugs[6]

Under the Stark Law, financial relationships include ownership interests through equity, debt, or other means, as well as compensation arrangements between physicians and entities involving any remuneration, directly or indirectly, in cash or in kind.[7]

On its face, the Stark Law may prohibit legitimate business arrangements. However, the law contains many exceptions, which describe ownership interests, compensation arrangements, and forms of remuneration to which the Stark Law does not apply.[8] An arrangement must fully fall within one of the exceptions in order to be shielded from enforcement of the Stark Law.[9] Notably, "the Stark Law statutory framework is relatively skeletal and its application to many common situations is ambiguous."[10] 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.[11]

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 the Medicare and Medicaid programs.[12] Violation of the Stark Law can also trigger a violation of the FCA, which prohibits any person from knowingly submitting, or causing to be submitted, false claims to the government.[13] FCA violators are liable for treble damages (i.e., "three times the government damages") as well as a monetary penalty linked to inflation.[14] 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.[15] Private citizens who pursue successful *qui tam* actions are entitled to a portion of the government's recovery.[16] Notably, Congress boosted the incentives for whistleblowers in 1986, significantly increasing the number of *qui tam* suits brought each year.[17] Both of the lawsuits discussed in this article were originally filed under the FCA's *qui tam* provisions, 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."[18] 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 the interpretation was reasonable.[19] However, the June 2024 ruling in *Loper Bright* shifted the authority to interpret statutes and regulations to the courts, and placed significantly more scrutiny on executive agencies, such as

5 Jennifer O'Sullivan, Cong. Rsch. Serv, RL32494, Medicare: Physician Self-Referral ("Stark I and II"), July 27, 2004, available at: http://www.policyarchive.org/handle/10207/bitstreams/2137.pdf; Limitation on Certain Physician Referrals, 42 U.S.C. § 1395nn.
6 Limitation on Certain Physician Referrals, 42 U.S.C. § 1395nn(a)(1)(B); Definitions, 42 C.F.R. § 411.351.
7 Limitation on Certain Physician Referrals, 42 U.S.C. § 1395nn.
8 Ibid.
9 "Comparison of the Anti-Kickback Statute and Stark Law," Health Care Fraud Prevention and Enforcement Action Team (HEAT), Office of Inspector General (OIG), U.S. Department of Health & Human Services, accessed December 23, 2024, https://oig.hhs.gov/documents/provider-compliance-training/939/StarkandAKSChartHandout508.pdf.
10 Charles B. Oppenheim et al., "The Future of the Stark Law is Clouded by Uncertainty," Hooper Lundy Bookman, September 19, 2024, https://hooperlundy.com/the-future-of-the-stark-law-is-clouded-by-uncertainty/.
11 Ibid.
12 Limitation on Certain Physician referrals, 42 U.S.C. § 1395nn(g).
13 "The False Claims Act," U.S. Department of Justice, updated February 23, 2024, https://www.justice.gov/civil/false-claims-act.
14 Ibid.
15 Ibid.
16 Ibid.
17 Office of Public Affairs, U.S. Department of Justice, "False Claims Act Settlements and Judgments Exceed $2.68 Billion in Fiscal Year 2023," Press Release, February 22, 2024, https://www.justice.gov/opa/pr/false-claims-act-settlements-and-judgments-exceed-268-billion-fiscal-year-2023.
18 Loper Bright Enterprises, et al. v. Raimondo, 144 S. Ct. 2244 (2024), https://scholar.google.com/scholar_case?case=6039670076559479890&q=loper+bright&hl=en&as_sdt=4,60,376; Amy Howe, "Supreme Court Strikes Down Chevron, Curtailing Power of Federal Agencies," *SCOTUSblog*, June 28, 2024, https://www.scotusblog.com/2024/06/supreme-court-strikes-down-chevron-curtailing-power-of-federal-agencies/.
19 Ibid.

*Post-*Loper Bright*, the likelihood of agency regulations being overturned by courts will increase, and these decisions will incentivize litigants to challenge undesirable agency regulations through the legal system.*

the Department of Health and Human Services (HHS), and their ability to implement omnibus laws passed by Congress.[20] In its decision, the Supreme Court stated that courts must determine a statute's "best reading"—that is, the "statute's meaning 'at the time of enactment' and … 'the reading the court would have reached if no agency were involved.'"[21]

Post-*Loper Bright*, the likelihood of agency regulations being overturned by courts will increase, and these decisions will incentivize litigants to challenge undesirable agency regulations through the legal system.[22] For example, as noted above, the healthcare industry is heavily regulated by fraud and abuse laws. HHS and its agencies have historically interpreted these statutes through the regular issuance of updated or revised regulations and guidance (e.g., Special Fraud Alerts and Advisory Opinions). The healthcare valuation terms, fair market value (FMV), general market value (GMV), and commercial reasonableness (CR) were updated, clarified, and—in the case of CR—formally defined by the Centers for Medicare & Medicaid Services (CMS) in its 2020 revisions to the Stark Law. In its commentary, CMS indicated its belief that Congress intended for FMV/GMV remuneration methodology to be consistent with "the concepts and principles of the valuation community,"[23] not unilaterally dictated by government regulators. Post-decision, the interpretation of FMV, GMV, and CR will likely be left to the courts, which will necessarily look to the healthcare valuation community—both as a practical matter and in accordance with congressional intent—for guidance on these terms and methodology.[24]

Kyer

The question of when and how the *Loper Bright* decision will affect courts' interpretation of fraud and abuse laws was first addressed by parties in *United States ex rel. Kyer v. Thomas Health System, Inc.* ("*Kyer*"). This 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.[25] After the Department of Justice (DOJ) declined to 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 the pleadings were filed prior to the *Loper Bright* decision.[26] 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.[27] 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."[28] 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."[29]

20 Kaye Pestaina, Michelle Long, and Justin Lo, "Supreme Court Decision Limiting the Authority of Federal Agencies Could Have Far-Reaching Impacts for Health Policy," 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/.
21 *Kyer*, Defendant's Brief Addressing *Loper Bright's* Effect on the Stark Law and Relator's Claims (October 4, 2024), 3.
22 Michelle Long, Justin Lo, and Kaye Pestaina, "SCOTUS Case Could Weaken the Impact of Regulation on Key Patient and Consumer Protections," Kaiser Family Foundation, April 9, 2024, https://www.kff.org/private-insurance/issue-brief/upcoming-scotus-case-could-weaken-impact-regulation-key-patient-consumer-protections/.
23 Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations, 85 Fed. Reg. 77553 (December 2, 2020).
24 "What the Supreme Court's '*Chevron* Deference' Ruling Could Mean for Health Care Law," Baker Donelson, June 25, 2024, https://www.bakerdonelson.com/what-the-supreme-courts-chevron-deference-ruling-could-mean-for-health-care-law.
25 *Kyer*, First Amended Complaint and Demand for Jury Trial.
26 Samantha Groden and Christopher Janney, "Stark Law Comes Under *Loper Bright* Spotlight," Dentons on Call (blog), September 19, 2024, https://www.dentonshealthlaw.com/stark-law-comes-under-loper-bright-spotlight/#5a9b983a-463c-4698-82d7-00f2d6a97af9-link.
27 *Kyer*, Order (September 12, 2024).
28 Ibid., 1, 7–8.
29 Ibid., 2.

In response to the judge's order, each party argued that the relator's Stark Law claim can be decided without deferring to an agency interpretation of the law, although for different reasons. The relator argued that the amended complaint does not challenge an agency action, so *Loper Bright* would not be implicated at this stage. Further, the relator asserted 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.[30] The defendants, on the other hand, argued that "[t]his Court can determine—from the Stark Law itself—that relator has not stated a claim upon which relief may be granted."[31] Ultimately, the court dismissed the case, relying only on the Stark Law (and not its underpinning regulations).

Zafirov

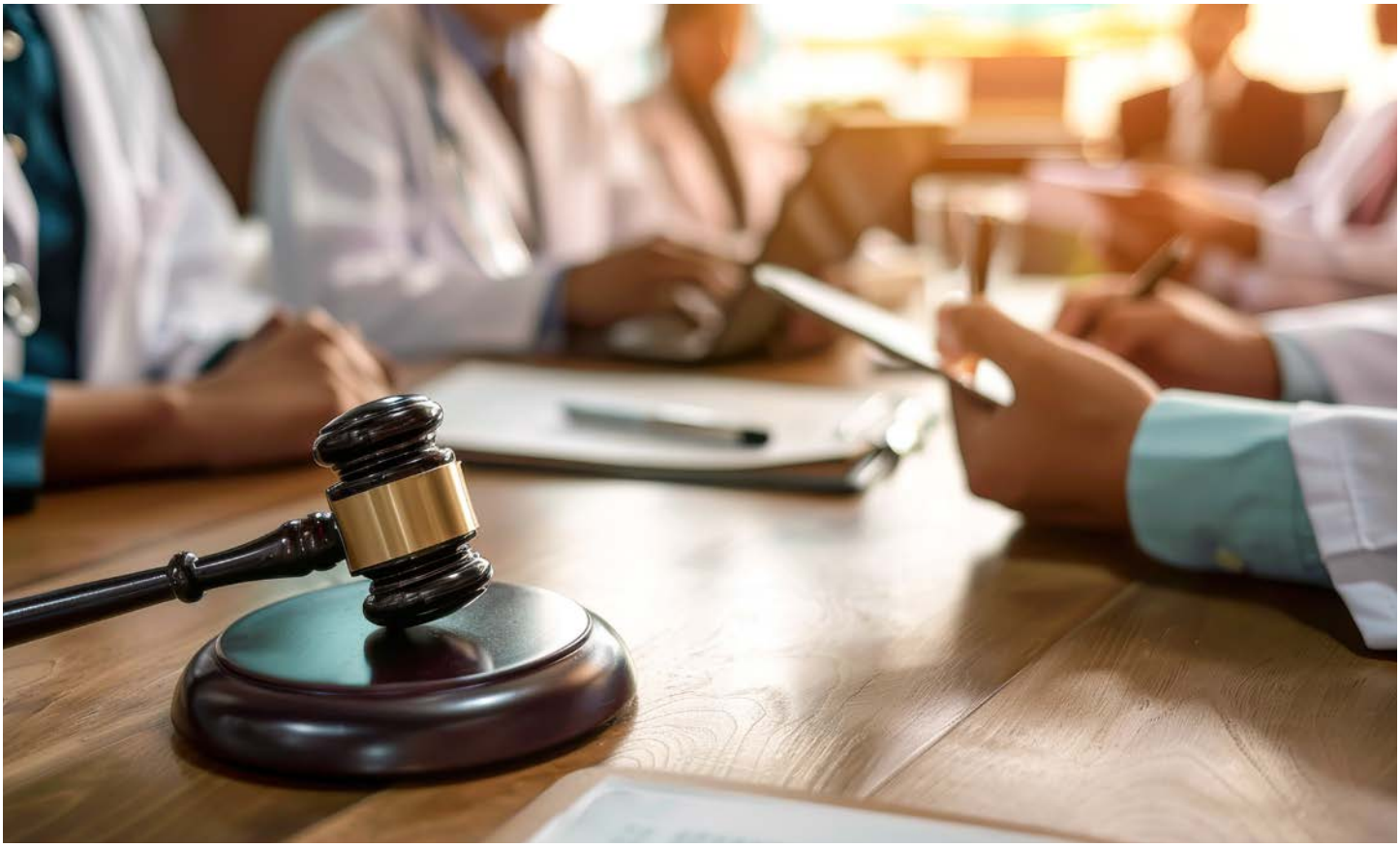
Meanwhile, on September 30, 2024, a judge in the Middle District of Florida dismissed an FCA whistleblower case. In *United States ex rel. Zafirov v. Florida Medical Associates, LLC*, a former physician of the defendant medical practice alleged that the defendants had misrepresented patient diagnoses 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.[32] In their 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."[33] The judge agreed, reasoning that relators are Officers of the United States (as defined

30 *Kyer*, Relator's Supplemental Briefing Regarding *Loper Bright*, Pursuant to ECF 63 (October 4, 2024), 8.

31 *Kyer*, Defendant's Brief Addressing *Loper Bright's* Effect on the Stark Law and Relator's Claims (October 4, 2024), 11.

32 "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, accessed December 23, 2024, https://www.bloomberglaw.com/external/document/XEITU4AO000000/litigation-overview-motion-for-judgment-on-the-pleadings.

33 "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/.



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.[34] While this is the first federal court decision finding the FCA's *qui tam* provisions unconstitutional,[35] 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."[36] Second, the arguments utilized in the defendants' motion and the court's decision echo a U.S. Supreme Court dissent issued in 2023. In *United States ex rel. Polansky v. Executive Health Resources, Inc.*, Justice Thomas questioned the constitutionality of the FCA's *qui tam* provisions: "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."[37] 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 the judge in *Zafirov* who, notably, clerked for Justice Thomas.[38] In fact, *Zafirov* breaks from a number of other federal circuits.[39] It is expected that the decision will be appealed to the Eleventh Circuit.

34 *Zafirov*, Order, 16–17, 30.

35 "Foley Secures Precedent-Setting Victory."

36 *Zafirov*, Order, 45–47.

37 United States ex rel. Polansky v. Executive Health Resources, Inc., 143 S. Ct. 1720 (2023), available at https://scholar.google.com/scholar_case?case=12915004371170259376&q=polansky&hl=en&as_sdt=4,60.

38 Jonathan A. Porter, host, *False Claims Act Insights*, podcast, episode 11, "Are the FCA's *Qui Tam* Provisions Unconstitutional? One Federal Judge Says 'Yes,'" featuring 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.

39 See, e.g., Riley v. St. Luke's Episcopal Hospital, 252 F.3d 749, 758 (5th Cir. 2001); United States ex rel. Lagatta v. Reditus Laboratories, LLC, Case No. 1:22-CV-01203, 2024 WL 4351862 (C.D. Ill. September 30, 2024); United States ex rel. Wallace v. Exactech, Inc., 703 F. Supp. 3d 1356 (N.D. Ala. 2023); United States ex rel. Miller v. ManPow, LLC, Case No. 2:21-cv-05418-VAP-ADSx, 2023 WL 8290402, at *1 (C.D. Cal. August 30, 2023); United States ex rel. Thomas v. Care, Case No. CV-22-00512-PHX-JAT, 2023 WL 7413669, at *4 (D. Ariz. November 9, 2023); United States ex rel. CLJ, LLC v. Halickman, Case No. 20-cv-80645, 2024 WL 3332055, at *21 n. 5 (S.D. Fla. June 14, 2024); United States ex rel. Butler v. Shikara, 2024 WL 4354807 at *10–13 (S.D. Fla. September 6, 2024).

The impact of Loper Bright *on Stark and other complex federal healthcare laws reliant on agency regulation is yet unknown. But the judge in* Kyer *rightly predicted that "[i]nevitably,* Loper Bright *will begin to ripple through the Stark Regulations. The only question for the courts is when and how."*

Implications for Fraud and Abuse Laws

By themselves, either of these cases are groundbreaking, representing a significant potential change in the interpretation, and adjudication, of fraud and abuse laws. Taken together, however, they could be harbingers of paradigm shifts in federal fraud and abuse enforcement. Over 75 percent of all FCA cases are brought by relators and, in approximately 10 percent of those cases, the government declines to intervene.[40] If the Supreme Court ultimately rules that the FCA's *qui tam* provisions are unconstitutional, those cases will likely never be adjudicated; while the federal government could potentially choose to pursue 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 the judge in *Kyer* rightly predicted that "[i]nevitably, *Loper Bright* will begin to ripple through the Stark Regulations. The only question for courts is when and how."[41] 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. VE

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40 "Fraud Statistics—Overview, October 1, 1986–September 30, 2023," Civil Division, U.S. Department of Justice, https://www.justice.gov/opa/media/1339306/dl?inline.
41 *Kyer*, Order, 8.