

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

UNITED STATES OF AMERICA EX REL. LIESA KYER,

Plaintiff,

v.

CIVIL ACTION NO. 2:20-cv-00732

THOMAS HEALTH SYSTEM, INC., et al.,

Defendants.

ORDER

Pending before the court is Defendants' Motion to Dismiss the Plaintiff's First Amended Complaint, filed by Defendants Charleston Hospital, Inc., Herbert J. Thomas Memorial Hospital Association, THS Physicians Partners, Inc., Thomas Health System, Inc., and Brian Ulery ("Defendants"). [ECF No. 56]. Plaintiff Relator Liesa Kyer ("Relator") responded, [ECF No. 60], and Defendants timely replied, [ECF No. 61].

This *qui tam* action is brought by a private citizen—not the Government—to enforce a law primarily defined and redesigned by an agency—not Congress. Relator's claim properly comes under the False Claims Act, and Relator alleges that the claims submitted by Defendants were false under the Stark Law. Over the last 30 years, the Stark Law has grown complex, nuanced, and reliant on agency regulation to define key terms and safe harbors. Relator's claims and Defendants' arguments for dismissal rely heavily on Stark Law regulations.

In the past, I could simply defer to an agency’s interpretation of a statute without too much handwringing over the province of the court versus the expertise of an agency. No longer. In June 2024, the Supreme Court decided *Loper Bright Enterprises v. Raimondo* and reaffirmed that it is “emphatically” my duty to say what the law is. 144 S. Ct. 2244 (2024).

Now, I do not know how *Loper Bright* will affect Relator’s Stark Law claim. I do know, however, that my obligation under *Loper Bright* is different: I must ensure that the Stark regulatory scheme is consistent with the power given by Congress and the statute as it was signed into law. Such is *Loper Bright*’s instruction.

What concerns me is this: I cannot determine if Relator has stated a claim without first determining the contours of the statute. Deeper still, the statute is fleshed out in the regulations. *Loper Bright* mandates that I carefully consider the regulations—without blindly deferring to any agency interpretation. Here, the Stark Regulations build the foundation of Relator’s Stark-based claim. Therefore, for the following reasons the parties are **ORDERED** to file supplemental briefing on the effect, if any, of *Loper Bright*.

I. Procedural Background

On November 9, 2020, Relator Liesa Kyer, who worked as a nurse at Thomas Memorial Hospital for several years, initiated this lawsuit on behalf of the United States of America against Defendants under the *qui tam* provisions of the False Claims Act, 31 U.S.C. §§ 3729–33 (“FCA”), for alleged violations of the FCA, the Stark Law, 42 U.S.C. § 1395nn, and the Anti-Kickback Statute, 42 U.S.C. §§ 1320a-7a(a)(7)

and 1320a-7b(b) (“AKS”). [ECF No. 2, ¶¶ 1, 5]. The United States received several extensions of time to consider whether it would elect to intervene and take over prosecution of this case. [ECF Nos. 7, 11, 14, 17, 21]. Ultimately, the United States notified the court on July 3, 2023, that it would not be intervening at that time. [ECF No. 22, at 2].¹ Defendants filed a Motion to Dismiss the original Complaint on January 5, 2024. [ECF No. 36]. That motion was denied as moot, [ECF No. 53], after Relator filed the operative First Amended Complaint on March 1, 2024, [ECF No. 52], within the amendment period allowed under the Scheduling Order, [ECF No. 50].

In her First Amended Complaint, Relator brings four causes of action under the FCA: (1) presentment of false claims to the United States for payment or approval, in violation of 31 U.S.C. § 3729(a)(1)(A); (2) using false statements material to the payment of false or fraudulent claims, in violation of 31 U.S.C. § 3729(a)(1)(B); (3) conspiracy between Defendants to commit a violation of the FCA, in violation of 31 U.S.C. § 3729(a)(1)(C); and (4) making, using, or causing 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 concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the Government, in violation of 31 U.S.C. § 3729(a)(1)(G). [ECF No. 52, ¶¶ 276–302].

Defendants filed the Motion to Dismiss on April 16, 2024, arguing that the Amended Complaint should be dismissed on two grounds. [ECF No. 56]. First, Relator

¹ Once the Government gets involved in a *qui tam* action at any point, it “may move to dismiss an FCA action.” *United States, ex rel. Polansky v. Executive Health Resources, Inc.*, 599 U.S. 419, 438 (2023).

failed to file the amendment under seal pursuant to 31 U.S.C. § 3730(b)(2), thereby mandating automatic dismissal. [ECF No. 57, at 2]. Second, Relator failed to state a claim upon which relief may be granted under Rule 12(b)(6), in part because her FCA allegations were not pleaded with the level of particularity required by Federal Rule of Civil Procedure 9(b). [ECF No. 57, at 4]. Relator responded in opposition on May 21, 2024, [ECF No. 60], and Defendants replied on June 4, 2024. [ECF No. 61].

II. Legal Standards

a. Stark Law and Regulations

Broadly, the Stark Law prohibits physicians and entities in financial relationships from improperly benefiting from referrals (often termed “self-referrals”). Looking only at the text, the Stark Law states that

if a physician (or an immediate family member of such physician) has a financial relationship with an entity specified in paragraph (2), then--

(A) the physician may not make a referral to the entity for the furnishing of designated health services for which payment otherwise may be made under this subchapter, and

(B) the entity may not present or cause to be presented a claim under this subchapter or bill to any individual, third party payor, or other entity for designated health services furnished pursuant to a referral prohibited under subparagraph (A).

42 U.S.C. § 1395nn(a). The statute goes on to define “financial relationship” as “an ownership or investment interest in the entity” or “a compensation arrangement” between the physician and the entity. 42 U.S.C. §§ 1395nn(a)(2)(A)–(B). Section (h) further defines “a compensation arrangement” as “any arrangement involving any remuneration between a physician . . . and an entity other than an arrangement involving only remuneration described in subparagraph (C).” 42 U.S.C. §

1395nn(h)(1)(A). Lastly, “remuneration” is defined in three different ways, one being

(iii) A payment made by an insurer or a self-insured plan to a physician to satisfy a claim, submitted on a fee for service basis, for the furnishing of health services by that physician to an individual who is covered by a policy with the insurer or by the self-insured plan, if-

(I) the health services are not furnished, and the payment is not made, pursuant to a contract or other arrangement between the insurer or the plan and the physician,

(II) the payment is made to the physician on behalf of the covered individual and would otherwise be made directly to such individual,

(III) the amount of the payment is set in advance, does not exceed fair market value, and is not determined in a manner that takes into account directly or indirectly the volume or value of any referrals, and

(IV) the payment meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

42 U.S.C. §§ 1395nn (h)(1)(C)(iii)(I)–(IV).

From there, the Stark Regulations take over. Rulemaking has reshaped the Stark Law for the last thirty years.² Relative to the pending case, the Stark Regulations find an “indirect compensation arrangement” when three conditions are met. 42 C.F.R. §§ 411.354(c)(2)(i)–(iii). Generally, they are (1) an unbroken chain of persons and/or entities with a financial relationship with each other, (2) a referring physician receives “aggregate compensation” from a financially related entity that “varies with the volume or value of referrals,” and (3) the entity furnishing designated health services “has actual knowledge of, or acts in reckless disregard or deliberate

² A non-exhaustive list of the “more significant” rulemakings is summarized by the Centers for Medicare & Medicaid Services (CMS) in the latest final rule. Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations, 85 Fed. Reg. 77,492 (Dec. 2, 2020) (codified at 42 C.F.R. pt. 411) (chronologizing the first 1992 proposed rulemaking through the most recent final rules, effective on January 1, 2022).

ignorance of” the aggregate compensation scheme. *Id.* Complicated further, the Stark Regulations provide special rules and exceptions to indirect compensation agreements. *Id.* at 411.354(c)(4). Exceptions in § 411.355 and § 411.357(p) redefine certain indirect compensation arrangements to take them outside the Stark Law.

In total, a Stark Law claim necessarily requires reliance on the regulations—complex, nuanced, and potentially beyond Congress’s intent. My obligation under *Loper Bright* compels me to carefully consider the statute-regulation relationship.

b. *Loper Bright*

For 40 years, federal courts were instructed to defer—in varying ways—to agency interpretation of statutory language. *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), overruled by *Loper Bright Enterprises v. Raimondo*, 144 S. Ct. 2244 (2024). On June 28, 2024, The Supreme Court overruled *Chevron* and held *Loper Bright* in its place. The Court, abolishing the two-step *Chevron* deference analysis, reaffirmed that “[i]t is emphatically the province and duty of the judicial department to say what the law is.” *Id.* at 2257 (quoting *Marbury v. Madison*, 1 Cranch 137, 177, 2 L.Ed. 60 (1803)).

The Administrative Procedure Act, “a check upon administrators whose zeal might otherwise have carried them to excesses not contemplated in legislation creating their offices,” could not be reconciled with *Chevron* for multiple reasons. *Id.* at 2261 (quoting *U.S. v. Morton Salt Co.*, 338 U.S. 632, 644 (1950)). First, the “best” reading of a statute is the one the court—not the agency—concludes is best “after applying all relevant interpretive tools.” *Id.* at 2266. Second, courts have the expert

competence necessary to resolve statutory ambiguities. *Id.* Agencies do not. *Id.* Lastly, courts are expected to handle technical statutory questions. *Id.* at 2267. In every case, the parties are “steeped in the subject matter,” and the courts do not answer questions blindly. *Id.*

Of course, the Executive Branch’s expertise and interpretation may be informative, especially “to the extent it rests on *factual* premises within [the agency’s] expertise.” *Id.* (quoting *Bureau of Alcohol, Tobacco and Firearms v. FLRA*, 464 U.S. 89, 98, n.8 (1983) (emphasis added)). Nevertheless, courts may not abandon their responsibility to interpret the law. *Id.* at 2273. “[C]ourts need not and under the APA may not defer to an agency interpretation of the law simply because a statute is ambiguous.” *Id.*

III. Discussion

In the time since Defendants’ Motion became ripe, the United States Supreme Court decided *Loper Bright*. No party supplemented its Motion to Dismiss argument to discuss *Loper Bright*’s impact on Relator’s claim, however, I am concerned that I must carefully consider this newest precedent.

Over time the Stark Law (and accompanying regulations) has evolved into a labyrinth of multipart compliance requirements where the exception-to-the-exception-to-the-exception is the norm. Steven D. Wales, *The Stark Law: Boon or Boondoggle? An Analysis of the Prohibition on Physician Self-Referrals*, 27 *Law & Psychol. Rev.* 1, 22–23 (2003) (collecting critical descriptions of the Stark Law, which can just as easily be used to describe the Stark Regulations today). Perhaps, under

Chevron, federal courts could wade through Stark Law claims by deferring and defaulting to an agency’s interpretation. *United States ex rel. Drakeford v. Tuomey Healthcare System, Inc.*, 675 F.3d 394, 407 (4th Cir. 2012) (determining what constitutes a “referral” under Stark Regulations); *Council for Urological Interests v. Burwell*, 790 F.3d 212, 219–24 (D.C. Cir. 2015) (interpreting regulations of physician-entity equipment leases and the definition of “entit[ies] furnishing designated health services”); *United States v. Solinger*, 457 F.Supp.2d 743, 756–57 (W.D. Ky. 2006) (interpreting a regulation establishing a Stark exception).

That deference is no longer required; indeed, that deference is no longer acceptable. *Loper Bright Enterprises*, 144 S. Ct. at 2273. Inevitably, *Loper Bright* will begin to ripple through the Stark Regulations. The only question for courts is when and how. Because I have seen very little research on this intersection of law, the parties should welcome the opportunity to lay out *Loper Bright* versus Stark for the first time.

As mentioned, commentary on *Loper Bright’s* impact is sparse: one federal court and two speculative online blog posts. Scholarship and cases across the country have only begun to address *Loper Bright’s* impact on federal healthcare regulation. *United States ex rel. Sheldon v. Forest Laboratories, LLC*, No. ELH-14-2535, 2024 WL 3555116 at *33 (D. Md. July 23, 2024) (slip copy) (inviting the parties to submit supplemental briefing on *Loper Bright’s* impact on the court’s interpretation of the Medicaid Rebate Statute in a False Claims Act claim); Anna Akers Hornsby, et al., *The Overturn of Chevron: A New Design for Healthcare Law*, Eye on Enforcement

(Jul. 15, 2024), <https://www.eyeeonenforcement.com/2024/07/the-overturn-of-chevron-a-new-design-for-healthcare-law> (“ . . . *Loper* may give a defendant that has not complied with guidance the opportunity to argue to a court that the guidance is inconsistent with a statute or otherwise outside of an agency’s statutory authority.”); Pascal Naples, et al., *Post-Chevron Health Care Regulations: What May Be in Store for Stark Law Litigation*, JD Supra (Jul. 24, 2024), <https://www.jdsupra.com/legalnews/post-chevron-health-care-regulations-1965853> (“the court could disagree with . . . any definition contained within a regulation promulgated by CMS pursuant to the Stark Law.”).

The problem is that I cannot determine if Relator has stated a claim upon which relief can be granted if I do not know what the Stark Law requires. Here, the Stark Regulations provide the definitional foundation of Relator’s Stark Law claim. 42 C.F.R. § 411.354(a) (providing that financial relationships may be “direct or indirect compensation arrangements”); 42 C.F.R. § 411.354(c)(1) (defining a “direct compensation arrangement”); 42 C.F.R. § 411.354(c)(2) (defining an “indirect compensation arrangement”); 42 C.F.R. § 411.354(c)(4) (exceptions to indirect compensation arrangements). The question before the court is whether those definitions are consistent with congressional authorization and the statute.

Without regulations, the Stark Law is certainly shorter: When a physician and an entity have a “financial relationship,” (1) the physician may not make referrals to the entity “for the furnishing of designated health services for which payment otherwise may be made” and (2) an entity may not present a claim to a third-party

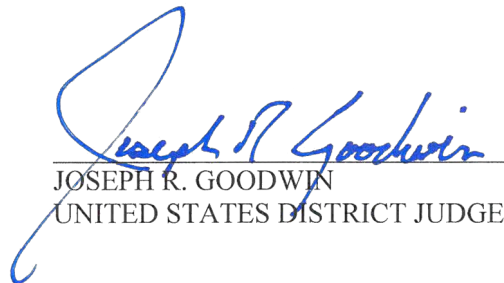
payor “furnished pursuant to” a prohibited referral. 42 U.S.C. § 1395nn(a). *Loper Bright* mandates a careful, considerate examination.

Because the parties have not had an opportunity to address *Loper Bright*'s impact on the pending claim, if any, I **ORDER** both the Plaintiff and Defendants to file simultaneous briefs on the issue by October 4, 2024. Both Plaintiff and Defendants shall file responses to the opposing party's brief by October 18, 2024.

The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

The court further **DIRECTS** the Clerk to post a copy of this published order on the court's website, www.wvwd.uscourts.gov.

ENTER: September 12, 2024


JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE