

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

UNITED STATES OF
AMERICA ex rel. LIESA KYER

Plaintiff-Relator

v.

CASE NO. 2:20-cv-00732

THOMAS HEALTH SYSTEM, INC.,
HERBERT J. THOMAS MEMORIAL
HOSPITAL ASSOCIATION (d/b/a/
THOMAS MEMORIAL HOSPITAL),
CHARLESTON HOSPITAL, INC. (d/b/a
ST. FRANCIS HOSPITAL),
THS PHYSICIANS PARTNERS, INC.,
and BRIAN ULERY

Defendants.

RELATOR'S RESPONSE TO DEFENDANTS' BRIEF ADDRESSING *LOPER*
***BRIGHT'S* EFFECT ON RELATOR'S CLAIMS**

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INTRODUCTION

In February 1989, harkening back to Congress’ prohibition of kickbacks in healthcare ten years earlier, California Representative Stark introduced H.R. 939, the Ethics in Patient Referrals Act, to close a loophole on the prohibition of “the payment of ‘any remuneration, directly or indirectly, overtly or covertly’ in return for patient referrals,” where referral schemes were disguised as legitimate business arrangements. 135 Cong. Rec. 2035 (1989). Such arrangements were designed to “lock-in referrals by creating a *web* of financial relationships binding the referring physicians to the provider.” *Id.* (emphasis added). And, because “half-way measures” would only allow providers to exploit new loopholes, the Ethics in Patient Referrals Act created a “bright line rule” prohibiting “[p]roviders of Medicare services...from accepting referrals from physicians” with whom they have a compensation arrangement. *Id.* For “transactions that pose little risk of abuse,” exceptions were provided. *Id.*

This bright line rule persists thirty-five years later, and the Supreme Court’s decision in *Loper Bright Enters. v. Raimondo* does not blur or dampen that line. 144 S. Ct. 2244, 2273 (2024). Relator alleges that the compensation arrangements between the Thomas Health defendants and certain physicians crossed the line prior to *Loper Bright*, and they are still over the line after *Loper Bright*. The Defendants dispute that any violation exists, and urge the Court to dismiss based on their anticipated defense based on exceptions. But that is not the question before the Court now. Instead, this matter is before the Court on a motion to dismiss, and the Court must take all well-pleaded allegations as true and ascertain whether the complaint plausibly alleges violations of the False Claims Act, where the underlying conduct is alleged to have violated both the Stark Law and the Anti-Kickback Statute.

Whether Defendants' compensation arrangements "pose little risk of abuse" and meet every requirement of a Stark exception is not a question before the Court, because that is fact-dependent and it is Defendants' burden—not Relator's—to prove. It is not something the Court need or should resolve in its *Twombly* analysis.¹ See *Republican Party v. Martin*, 980 F.2d 943, 952 (4th Cir. 1992) ("A motion to dismiss under Rule 12(b)(6) tests the sufficiency of a complaint; importantly, it does not resolve contests surrounding the facts, the merits of a claim, or the applicability of defenses") (emphasis added). This is so whether the exception upon which Defendants may rely is statutory or regulatory—the burden of proof is theirs, and their opportunity to try to make that showing is not now, but after discovery. In short, it remains, as it always has been, Defendants' burden to prove any exception applies to their alleged fraudulent conduct to avoid liability. E.g., *United States ex rel. Drakeford v. Tuomey*, 792 F.3d 364, 374 (4th Cir. 2015). *Loper Bright* does not change the burden on Defendants under *Tuomey*, nor, under *Martin*, that the applicability *vel non* of an affirmative defense is not decided on a motion to dismiss.

Defendants' analysis regarding *Loper Bright* is sparse, but it appears, at base, that the parties agree that the Court's ability to assess the plausibility of Relator's allegations survives post-*Loper Bright*. In their opening brief, Defendants argue that the Court need not look beyond the Stark Law statutory language to make a determination about Defendants' motion to dismiss. If the Court were to read *Loper Bright* to suggest it cannot look to the duly authorized regulations promulgated through notice and comment by the agency vested by Congress with the power to provide exceptions (which would include necessarily related definitions),² then, yes, the Court

¹ *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 572 (2007).

² As set forth in Relator's opening brief, *Loper Bright* only applies when an agency's action is challenged (a situation not present here) and when, in the initial instance, the statute has been found to be ambiguous, requiring the assessing court to engage in the traditional practice of statutory interpretation. ECF 67, PageID # 587, 590-592.

could indeed look only to the statute to determine that the First Amended Complaint (“FAC”) states a claim with Rule 9(b) particularity, and the case can proceed to discovery.

When looking to the statute, Defendants concede that the best reading of a statute aligns with a statute’s meaning at the time it was enacted. ECF 66 at PageID # 575. Here, the best reading supports Relator’s allegations. From its inception, the Stark Law was created to prohibit referrals for designated health services from physicians to hospitals with whom they have any financial relationship, and the statute itself clearly expresses that prohibition: If a physician has a financial relationship with an entity like the Thomas Health Defendants, then (1) “the physician may not make a referral to the entity for the furnishing of designated health services for which payment otherwise may be made” and (2) “the entity may not present or cause to be presented [an affected] claim to any individual, third-party payor, or other entity for designated health services furnished pursuant to” such prohibited referral. 42 U.S.C. 1395nn(a). Congress defined a “financial relationship” to include a “compensation arrangement” (42 U.S.C. 1395nn(a)(2)); a “compensation arrangement” to be *any* arrangement involving *any* remuneration between a physician and an entity (42 U.S.C. § 1395nn(h)(1)) (emphasis added); and remuneration to include “any remuneration, *directly or indirectly*, overtly or covertly, in cash or in kind.” *Id.* (emphases added).

Relator’s allegations fall squarely within these unambiguous *per se* prohibitions. Relator plausibly alleges the existence of a prohibited financial relationship under the Stark Law by identifying non-expected arrangements involving remuneration, provided directly and indirectly, between physicians and entity defendants.³ On a motion to dismiss, then, the question is whether

³ But, as discussed at length in Relator’s opening brief and further herein, the Court certainly may consider and apply the regulations, and nothing about *Loper Bright* prevents that.

the complaint plausibly alleges the elements of the False Claims Act, including that false claims were submitted. As set forth in Relator's opposition to Defendants' motion to dismiss, Relator's FAC satisfies the *Twombly* and Rule 9(b) standards. See *Edwards v. City of Goldsboro*, 178 F.3d 231, 244 (4th Cir. 1999) (courts must "draw[] all reasonable factual inferences from those facts in the plaintiff's favor.") How and if Defendants choose to satisfy their burden of proving that the financial relationships that Relator has plausibly alleged do not offend the Stark Law because they satisfy an exception is an argument for another day.

At bottom, Defendants do not identify any basis to disregard the unambiguous language of the Stark Law or to read out the regulations authorized by Congress. The Court requested the parties submit briefing on whether certain definitions found in the Stark regulations "are consistent with congressional authorization and the statute." ECF 63 at PageID # 563. As detailed in Relator's opening brief, they are, as Defendants seem to agree with their citation to *Washington Hospital*. 795 F.2d 139, 143 (D.C. Cir. 1986). There is simply nothing inconsistent with the regulatory definitions of compensation arrangements as "direct" or "indirect," when the statute defines a prohibited compensation arrangement as "any," and Congress intended the Stark Law to close a loophole on a "web" of such arrangements. Contrary to Defendants' implications, *Loper Bright* did not, in overruling *Chevron*, eviscerate all regulations, let alone Stark regulations. But, rather than engage deeply with the *Loper Bright* questions posed by the Court, Defendants instead chose to spend the bulk of their brief relitigating their motion to dismiss. In doing so, they mischaracterize the Stark Law, how exceptions to the Stark Law apply to the facts at hand, and whose burden it is to prove that an exception applies. Here, Relator responds to Defendants' miscasting of *Loper Bright* and sets forth the correct Stark Law elements, standards, and application.

As laid out in Relator's opposition to Defendants' Motion to Dismiss, and further supported in her supplemental brief regarding *Loper Bright*, the FAC provides sufficient basis for the Court to deny Defendants' motion.

I. Defendants' Analysis of *Loper Bright* is Inaccurate in Key Respects

Defendants misstate the holding in *Loper Bright* and wrongly assert that *Loper Bright* means courts "cannot defer to [an] agency's interpretation of [a] statute, as previously allowed under *Chevron*." ECF No. 66 at PageID # 571, citing *Loper Bright*, 144 S. Ct. at 2273. *Loper Bright* means no such thing. Rather, under *Loper Bright*, courts assessing a challenged agency action are no longer *required* to defer to an agency's permissible interpretation of an ambiguous statute *simply because the statute is ambiguous*. 144 S. Ct. at 2263, 2273 (overruling *Chevron* because the mandatory *Chevron* deference could not be squared with the APA).

Loper Bright took away the *Chevron*-era handcuffs, where courts were *required* to defer to an agency's interpretation of an ambiguous statute if that agency's interpretation was permissible. But *Loper Bright* does not impose new handcuffs such that courts may no longer consider—even, when appropriate, defer to—the authority of the Executive Branch. On the contrary, courts simply may no longer mechanically do so. *Loper Bright* does not require a court to *disagree* with an agency's interpretation of a statute, and the same considered deference set forth in *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944), remains after *Loper-Bright*. Indeed, an agency's interpretation, although no longer binding on a court, may still be especially informative. 144 S. Ct. at 2267. *Loper Bright* instructs courts to give those interpretations "due respect," while exercising their "independent judgment" to seek out the best meaning of a statute. *Id.* at 2257. While the Court stated that "under the APA [courts] may not defer to an agency interpretation of the law simply because a statute is ambiguous," it did not hold that any court was required to reach

a different interpretation than that of an agency. *Id.* at 2273. Moreover, the court held that “[c]areful attention to the judgment of the Executive Branch may help inform” whether an agency has acted within its statutory authority. *Id.* Incredibly, notwithstanding that *Loper Bright* cites to it, Defendants do not cite to *Skidmore*, let alone any of its progeny, but instead, in direct contravention of the opinion itself, suggest to this Court that *Loper Bright* means the Court cannot defer to an agency’s judgment as part of its own statutory interpretation process.

In assessing the Stark Law, *Loper Bright* now requires courts to exercise deference to agency interpretation as described in *Skidmore*—a standard not addressed by Defendants. In *Skidmore*, the Court explained that agency interpretations and opinions “constitute a body of experience and informed judgment to which courts and litigants may properly resort for guidance.” 323 U.S. at 140. Thus, to the extent the Court needs to look to agency interpretation of the Stark Law to resolve any statutory ambiguity, *Skidmore* applies, and there can be no argument (and certainly Defendants have made none) that HHS acted outside its authority in promulgating regulations or that the agency failed to engage in reasoned decision-making.⁴ To the contrary, to the extent the regulatory definitions and exceptions noted by the Court reflect HHS’s interpretation of the Stark Law, that decision-making was consistent with its expertise and the Stark Law itself.

Defendants attempt to have their cake and eat it too, arguing that the court need only look at the statutory exceptions, but then claiming the fundamental prohibition of a financial relationship in the statute itself is unworkable because it would lead to absurd results. ECF 66 at

⁴ As discussed in Relator’s Supplemental Briefing, to the extent the Court is concerned with ambiguity with the noted regulations, *Kisor v. Wilkie*, instructs deference to the agency’s reasonable interpretation. 588 U.S. 558, 563, 575 (2019). *See* ECF No. 67 # 592-593. *See also United States v. Boler*, 115 F.4th 316, n.4 (4th Cir. 2024) (finding that “*Loper Bright* dealt specifically with ambiguities in statutory directives” and applying *Kisor* to address agency interpretation of sentencing guidelines).

PageID # 575-576. This ignores that this is precisely the framework set forth by Congress’ “bright line rule” prohibiting referrals from physicians to entities with which they have a financial relationship, because anything short of that would lead to providers simply exploiting another set of loopholes. Congress chose to enact exceptions, discussed below, to the bright line rule in recognition that some relationships did not pose a risk of program or patient abuse. And this framework certainly has worked to effectuate the statute’s purpose. *See e.g. United States ex rel. Reilly v. North Broward Hospital District, et al.* (S.D. Fla. 2015) (\$69.6 million settlement resulting from Stark Law and FCA violations); *United States ex rel. Drakeford v. Toumey* (D.S.C. 2015) (\$237 judgment against defendant for Stark Law and FCA violations); *United States ex rel. Baklid-Kunz v. Halifax Hospital Medical Center, et al.*, (M.D. Fla. 2014) (\$85 million settlement resulting from Stark Law and FCA violations); *United States ex rel. Bookwalter v. UPMC* (W.D. PA 2012) (\$38 million settlement in 2024 resulting from Stark and FCA violations); FAC at ¶¶ 274-275.

Loper Bright requires that courts respect the statutory delegation of authority to an agency. 144 S. Ct. at 2273. “When the best reading of a statute is that it delegates discretionary authority to an agency, the role of the reviewing court under the APA is, as always, to independently interpret the statute and effectuate the will of Congress subject to constitutional limits...and ensur[e] the agency has engaged in ‘reasoned decision-making’ within those boundaries.” *Id.* at 2263. “[W]here the legislative delegation to an agency on a particular question is implicit rather than explicit, a court may not substitute its own construction of a statutory provision embodying a reasonable interpretation of it made by the administrator of an agency.” *Newport News Shipbuilding and Dry Dock Co. v. Garrett*, 6 F.3d 1547, 1557 (Fed. Cir. 1994) (citations omitted).

HHS's regulations referenced in the FAC are well-within the agency's delegated authority and there is nothing, whether in caselaw, the text of either the statute or the regulations, the history of either, or the plain reading of either, to suggest, let alone conclude, that the at-issue definitions found in the regulations are not the function of reasoned decision-making by the agency and well within the bounds of the Stark Law. *See* ECF 67 at PageID #590-596.

II. Defendants Mischaracterize the FAC and the Stark Law and Regulations

A. It is Defendants' Burden to Prove a Stark Law Exception

The Stark Law narrowly specifies several exceptions to the bright line prohibition of compensation arrangements under Stark Law, including physician services provided by physicians within the same practice group, in-office ancillary services, bona-fide employment relationships, and prepaid plans, among others. *See e.g.*, 42 U.S.C. §§ 1395nn(b)(1)-(3), (e)(2), (h)(1)(C). The statute then specifically, and unambiguously, delegates the authority to HHS to determine other permissible exceptions under 42 U.S.C. § 1395nn(b)(4) and requires those exceptions to be specified by regulation through notice and comment rule making. There appears to be no dispute on this point.⁵

There is, however, a potential dispute about the role exceptions play here, where Defendants have challenged the plausibility of the FAC. Fortunately, this dispute was long ago resolved by the Fourth Circuit in its *United States ex rel. Drakeford v. Tuomey* decision, where it

⁵ Defendants repeatedly intone that the FAC is unclear, but the FAC is actually quite pellucid, and it is Defendants who have chosen to muddy the waters. For example, at the same time that they appear to assert in their briefing that their compensation arrangements qualify for the three statutory exceptions (a premature argument with no evidentiary support) and the Court need only look to those *statutory* exceptions, they also appear to rely on *regulatory* exceptions (e.g., the indirect compensation exception), appearing to cherry-pick the regulations they think survive *Loper Bright*, again wrongly signaling to the Court that *Loper Bright* effected an evisceration of regulations writ large.

held “[t]he applicability of an exception is an affirmative defense as to which Defendants, not Relator, have the burden of proof.” 792 F.3d 364, 374 (4th Cir. 2015). This is binding case law on the matter at hand, yet Defendants ignore it for this holding in their motion to dismiss and do not cite it at all in the rehashing contained in their *Loper Bright* brief.⁶ Instead, there, Defendants double down on their invitation to this Court to ignore that authority as they obfuscate the burden-shifting required to prove the existence of an applicable exception under the Stark Law, improperly and bizarrely asserting it is Relator who must “qualify for these exceptions.” ECF No. 66 at PageID # 573. This is as wrong now as it was in Defendants’ motion to dismiss. Indeed, Defendants’ motion, like its opening brief regarding *Loper Bright*, focused not on whether the FAC plausibly alleged the elements of Stark, AKS, and False Claims Act claims but instead on things that are relevant only to affirmative defenses for which Defendants, not Relator, have the burden of proof.

The Fourth Circuit is not alone in holding defendants to their burden; courts across the country agree that the burden to prove the applicability of an exception to a prohibited financial relationship is the defendant’s to bear. *See, e.g., United States ex rel. Bookwalter v. UPMC*, 946 F.3d 162, 169 (3d Cir. 2019) (“In litigation, these exceptions are affirmative defenses. So once a plaintiff proves a prima facie violation of the Stark Act, the burden shifts to the defendant to prove that an exception applies.”); *United States ex rel. Kosenske v. Carlisle HMA, Inc.*, 554 F.3d 88, 95 (3d Cir. 2009) (“Once the plaintiff or the government has established proof of each element of a violation under the [Stark] Act, the burden shifts to the defendant to establish that the conduct was protected by an exception.”); *United States v. Vernon*, 723 F.3d 1234, 1270-71 (11th Cir. 2013) (same); *United States v. Robinson*, 505 Fed. Appx. 385, 387 (5th Cir. 2013) (per curiam)(same);

⁶ In their response brief, Defendants persist in ignoring this binding case law and instead erroneously assert the Fourth Circuit disagrees that the “Stark Law’s statutory exceptions are affirmative defenses.” ECF 69, PageID # 608.

United States v. Solinger, 457 F. Supp. 2d 743, 756-57, 756 n. 11 (W.D. Ky. 2006) (same); *United States v. Sutter Health*, No. 14-cv-04100-KAW, 2024 U.S. Dist. LEXIS 160915, at *13 (N.D. Cal. Sep. 6, 2024) (same); *United States ex rel. Byrd v. Acadia Healthcare Co.*, No. 18-312-JWD-EWD, 2022 U.S. Dist. LEXIS 52275, at *75 (M.D. La. Mar. 23, 2022)(same); *United States ex rel. Fischer v. Community Health Network, Inc.*, No. 1:14-cv-01215-RLY-DLP, 2021 U.S. Dist. LEXIS 271155, at *14-15 (S.D. Ind. Oct. 20, 2021) (same); *Shahbadian v. Trihealth, Inc.*, No. 1:18-cv-790, 2019 U.S. Dist. LEXIS 174180 at *9 (S.D. Ohio Oct. 8, 2019) (same); *see also United States v. Rogan*, No. 02 C 3310, 2006 U.S. Dist. LEXIS 103309 at *55 (N.D. Ill. Oct. 2, 2006), *aff'd*, 517 F.3d 449 (7th Cir. 2008) (same) (also recognizing a relator need not prove, as an element of their case, that a defendant's conduct does not fit within as exception.).

“Indeed, ‘a motion to dismiss filed under Federal Rule of Civil Procedure 12(b)(6) ... generally cannot reach the merits of an affirmative defense...’” *Shuff v. Bank of Am., N.A.*, No. 5:20-cv-00184, 2021 U.S. Dist. LEXIS 11299, at *10 (S.D. W. Va. Jan. 21, 2021) (citing *Goodman v. Praxair, Inc.*, 494 F.3d 458, 464 (4th Cir. 2007)). In “rare circumstances,” a court may circumvent this rule “where facts sufficient to rule on an affirmative defense are alleged in the complaint.” *Id.* Such rare circumstances are not present here, particularly when the FAC alleges Defendants do not satisfy any exception, which must be taken as true at this stage. *See, e.g.* FAC at ¶¶ 97, 210, 233, 257, p. 73, 266, p. 75. The FAC contains no allegations that suggest, let alone prove, Defendants meet any exception, whether the exception resides in the Stark Law or Stark regulations. In fact, the opposite is true. The FAC specifically alleges that Defendants do *not* meet a Stark Law exception. *See, e.g.* FAC at ¶ 97 (Defendants’ “arrangements do not comply with an exception under the Stark Law”), ¶ 210 (the “remuneration does not qualify for any statutory exception”), ¶ 233 (“Defendants did not take steps to ensure that their compensation arrangements

complied with an exception to the Stark Law”), ¶ 257, p. 73 (Defendants “violated the requirements of the Stark Statute and the elements of the Stark exceptions, including the requirements that compensation must be at fair market value and that arrangements must be commercially reasonable in the absence of referrals”), ¶ 266, p. 75 (“Defendants had direct and indirect financial relationships with the referring physicians which did not meet an exception under the Stark Statute”).

In short, whether, as Defendants claim, “the cumbersome statute provides Defendants the protections and permissions that defeat Relator’s claim” is an assertion Defendants can attempt to prove at summary judgment or trial and has no place on a motion to dismiss. *See, e.g., United States v. Millennium Radiology, Inc.*, No. 1:11cv825, 2014 U.S. Dist. LEXIS 138549, *14 n. 2 (S.D. Ohio Sept. 30, 2014) (safe harbor determination “should be made at the summary judgment stage, or even at trial, and not on a motion to dismiss”).

B. The FAC Plausibly Alleges Violations of Stark, the AKS, and the False Claims Act

1. Defendants Ignore that Relator’s Specific Allegations Meet the Prima Facie Elements of the Violations at Issue

In addition to mischaracterizing the law, Defendants mischaracterize the FAC. For example, Defendants assert that Relator “relied” on an exception for bona fide employment relationships. Not so. First, the FAC does not *rely* on *any* exceptions, although, as noted above, it clearly contains facts that plausibly allege that Defendants will be unable to prove that their arrangements qualify for any exception. While the FAC does provide the language of that exception, it, as noted above, alleges that Defendants’ arrangements do not satisfy it.

By way of another example, Defendants’ brief and their motion focus on the concept of fair market value, arguing that the FAC fails to show that Defendants’ compensation arrangements

were not above fair market value and erroneously asserting in their discussion about the Stark Law that “Relator relies on the existence of a compensation arrangement between Defendants that includes compensation that is ‘above fair market value.’” ECF No. 66 at PageID # 573, citing “Dkt. 52 ¶245.” Again, not so. First, paragraph 245 of the FAC does not relate to the Stark Law at all. In total, the allegation is: “The compensation funded by Thomas Health Hospitals by these cash transfers was commercially unreasonable and above fair market value. This compensation was based on manipulated wRVU payments for services furnished by non-physician providers, but credited to the referring physicians.” This allegation supports Relator’s Anti-Kickback Statute claims, not, as Defendants mischaracterize to the Court, her Stark Law claims. *See* ECF 52 at PageID #402 (“VI. DEFENDANTS’ VIOLATIONS OF THE AKS. A. Defendants Paid Remuneration to THSPP and THSPP Physicians. ¶ 236. The remuneration offered and paid by the Thomas Hospital to THSPP and THSPP physicians (under the direction of defendant Ulery), as described in Section V, not only created financial relationships under the Stark law, but also constitutes illegal remuneration under the AKS.”) One form of remuneration offered to induce referrals alleged in the FAC is the cash transfers made by Thomas Health hospitals to the THSPP physicians. *Id.* at ¶ 237. FAC paragraphs 237-244 set out detailed allegations regarding this impermissible remuneration. FAC paragraph 245 (the paragraph cited by Defendants as though it were a Stark-related allegation) through paragraph 251 contain detailed allegations regarding a second form of impermissible remuneration to induce referrals under the AKS: commercially unreasonable and above fair market value compensation.

Second, even had they not cited a paragraph relating to the AKS for support for their Stark-based arguments, it is simply not true that Relator “relies” on there being above fair market value compensation. As is clear from the statutes themselves, fair market value is not an element of any

of the statutes at issue here—not Stark, not AKS, and not the FCA. To the extent fair market value is relevant, it is because *Defendants* must prove (among other things) that compensation does *not* exceed fair market value, and that it does *not* take into account the volume or value of referrals, in order to satisfy a Stark Law exception, which, again, is an affirmative defense as to which *Defendants* have the burden of proof. The same is true for AKS safe harbors. *E.g.*, *United States v. Berkeley Heartlab, Inc.*, 225 F. Supp. 3d 487, 511 (D. S.C. 2016) (under the AKS “safe harbors are affirmative defenses, and the defendant carries the burden of proof at trial”) (citations omitted). But although it is squarely Defendants’ burden to prove that they satisfy every element of an exception, the FAC nonetheless plausibly alleges that Defendants cannot satisfy any Stark exception or AKS safe harbor. For example, as to fair market value, which is one of many elements that Defendants would need to prove to satisfy Stark exceptions (whether statutory or regulatory), the FAC alleges that comparative data supports a finding that the at-issue compensation was above fair market value. Comparing compensation to industry benchmarks is the prototypical way of evaluating fair market value, and courts routinely hold that allegations like those in the FAC are sufficient to plausibly allege that compensation is above fair market value. *See, e.g.*, *U.S. ex rel. Schubert v. All Children’s Health Sys.*, No. 8:11-cv-01685-T-27EAJ, 2013 U.S. Dist. LEXIS 163075 *32-35 (M.D. Fla. Nov. 15, 2013) (allegations that physician salaries exceeding the 75th percentile in published salary survey were above fair market value held sufficient to satisfy Rule 9(b)). Relator anticipates that discovery will bear the allegations out, of course, and Defendants’ attempt to flip pleading standards on their head and their unsupported and premature assertions that they can avail themselves of the protections of either statute are entirely misplaced.

Moreover, it is difficult to take seriously Defendants’ assertion that the FAC’s “lack of specificity” makes it difficult to know what violations are at issue. ECF No. 66 at PageID # 573.

Defendants know precisely what violations are alleged in the FAC and indeed described the FAC in their motion to dismiss as alleging “that Defendants engaged in payment schemes that run afoul of the Stark Law and Anti-Kickback Statute.” ECF 57, at PageID # 476. Contrary to the picture Defendants unsuccessfully attempt to paint with a nod to “*See generally* Dkt. 52” in their brief, the FAC unambiguously states Defendants violated the Stark Law and then goes on to expatiate how they did so. FAC at ¶¶ 93-122; 123-235.

Nonetheless, again conflating burdens of proof with pleading standards, Defendants argue that the FAC does not “allege the existence of a compensation arrangement prohibited by the Stark Law,” and posit that the FAC doesn’t state a claim because wRVU compensation arrangements are allowed under the Stark Law. ECF 66 at PageID # 573-574. The thrust of Defendants’ argument are three conclusory sentences, without any supportive citation. *Id.* at PageID # 578. Defendants cite to the Court’s Order requesting supplemental briefing on *Loper Bright* to support their first flawed argument (that the bona fide employment exception has been deemed to permit wRVU compensation as described in the FAC), and then provide no support for their remaining assertions (that Congress and CMS essentially blessed the schemes alleged in the FAC). These conclusory statements flip the burdens, are inaccurate, and do not render the allegations in the FAC implausible.

As discussed at length *supra*, an exception to an otherwise prohibited financial relationship is Defendants’ burden to prove. One would search the Stark Law in vain for any sign that “wRVU compensation” does not constitute “remuneration” for purposes of establishing a compensation arrangement.

Furthermore, it is factually false to claim that CMS allows “wRVU compensation” under “any compensation arrangement.” ECF. 66 at PageID # 578. In truth, CMS has never issued a

blanket approval of wRVU-based compensation arrangements and certainly not arrangements like the ones alleged in the FAC, where, *inter alia*, it is alleged that the physicians were given wRVU credit (and thus received compensation) for services they did not “personally perform,” but that were performed by non-physician practitioners. Far from allowing such arrangements, the government has engaged in enforcement actions, to include False Claims Act cases, to curtail them. *See, e.g., supra* at page 7 (citing, *e.g., Bookwalter v. UPMC* (W.D. PA 2012) (2024 \$38 million settlement)).⁷

2. Direct and Indirect Compensation Relationships are Within the Four Corners of the Stark Statute

The Stark Law defines “a compensation arrangement” as “any arrangement involving any remuneration between a physician” and an entity such as Defendants. 42 U.S.C. § 1395nn(h)(1)(A). Defendants argue that the concepts of “direct” or “indirect” compensation arrangements are not a logical reading of the statute. ECF 66, at PageID # 575. But that position flatly ignores both the plain language of the statute and clear, unchallenged congressional intent. As discussed above, Congress intended to combat a “web” of financial relationships posing a risk of program or patient abuse by broadly defining “financial relationship” to include “any” “compensation arrangement,” and a compensation arrangement as any arrangement involving any remuneration (*i.e.*, “any remuneration, directly or indirectly, overtly or covertly, in cash or in kind”) between a physician and an entity. 42 U.S.C. § 1395nn(h)(1). Thus, according to the statute,

⁷ To the extent Defendants intend to avail themselves of the protections of a Stark exception related to wRVU-based compensation, the special rule set out at 42 C.F.R. § 411.354(d)(2) may apply to determine whether Defendants have satisfied their burden of showing compliance, as many exceptions include a requirement that compensation not be determined in a manner that takes into account the volume or value of referrals, but the rule only applies to “unit-based” compensation that is paid to a physician for items or services “actually provided” by the physician himself. *See* 85 Fed. Reg. 77492, 77540-77541 (rule applies to compensation “for [physician’s] personally performed services”).

a financial relationship exists where there is *any* arrangement involving *any* remuneration, provided *directly or indirectly*, between a physician and an entity. 42 U.S.C. § 1395nn(a)(2); 1395nn(h)(1)(A). Notwithstanding Defendants’ assertion, the only logical conclusion is that a reasonable interpretation of “any arrangement” within a web of financial relationships is one that could be either direct or indirect.

The FAC alleges both. As to direct compensation arrangements, the FAC sets forth particularized allegations supporting that the physicians and Defendants had a direct compensation arrangement (i.e., per the statutory definition, an arrangement involving remuneration provided *directly* between a physician and an entity) because, e.g., the various entities within the Thomas Health System functioned as a single entity, and the physician employment contracts with Defendant THSPP “specify that the *Thomas Health Hospitals* desire to provide employment to the physician. ECF 60 at PageID #512, discussing same and referencing FAC at ¶¶ 95-122. Not only do Defendants not address these allegations in their motion to dismiss, far from arguing that the FAC fails to plausibly allege the existence of a direct compensation arrangement, Defendants agree that it does: “The *Amended Complaint* fundamentally establishes a direct compensation arrangement....” ECF 57 at PageID # 486.

But the FAC also (in the alternative) supports with particularized detail how the Court could find that the compensation arrangement was indirect (i.e., per the unambiguous statutory definition, an arrangement involving remuneration provided *indirectly* between a physician and an entity). Citing the regulatory definition, the FAC describes the “unbroken chain” of entities with financial relationships between them (i.e., the physicians are (at least nominally) employed by THSPP, which is owned by Thomas Health, which owns the hospitals). It alleges that the aggregate compensation paid to the physicians varies with the volume or value of their referrals to the

hospitals because each time they perform a procedure at the hospitals (i) they make a referral to the hospital for the associated facility component, and (ii) their compensation increases because they receive wRVU credit. FAC at ¶¶ 94, 128-130. Thus, the physician’s aggregate compensation “rises or falls as the volume or value of his referrals rise and fall.” *Id.* at ¶ 129. See also *Tuomey*, 792 F.3d at 379 (“In sum, the more procedures the physicians performed at the hospital, the more facility fees [the hospital] collected, and the more compensation the physicians received in the form of increased base salaries and productivity bonuses.”). Finally, the FAC alleges that Thomas Health Hospitals had knowledge of the physicians’ compensation arrangements and gives specific examples of alleged false claims that were submitted to government payors by each hospital for services furnished pursuant to referrals from the physicians. *See e.g.*, FAC at ¶¶ 2-5, 11-15, 93-122, 125-128, 148-149, 164, 167-235, Appendices A-C; *see Bookwalter*, 946 F.3d at 170-71 (describing elements of an indirect compensation arrangement).

CONCLUSION

The Court need not look beyond the contours of the statute in order to deny Defendants’ Motion to Dismiss, but it clearly permissibly may. HHS’s regulatory definitions noted by the Court are consistent with the Stark Law and with the agency’s authority. As to exceptions, some are statutory, and some are regulatory (promulgated because Congress empowered HHS to do so) but all are Defendants’ burden to prove. Nothing in *Loper Bright* suggests a contrary conclusion. Relator’s FAC alleges, with particularity (including specific exemplary false claims), that Defendants submitted false claims resulting from referrals from physicians with whom they had a financial relationship, and no exception, either statutory or regulatory, applies. As such, denial of Defendants’ motion is appropriate.

For all of the foregoing reasons and those contained in Relator's opposition to Defendants' motion (ECF 60), the Court should deny Defendants' Motion to Dismiss in its entirety.

Respectfully submitted,

/s/ Letitia Neese Chafin

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CERTIFICATE OF SERVICE

I hereby certify that a true and accurate copy of the foregoing will be served via the Court's electronic filing system and served on all counsel of record on this 18th day of October 2024.

/s/ Letitia Neese Chafin
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