IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF KANSAS

UNITED STATES ex rel. MONA SABET EDALATI, et al.,

Plaintiffs,

v.

Case No. 2:17-cv-02395-HLT

PARAMJEET SABHARWAL, et al.,

Defendants.

MEMORANDUM AND ORDER

This is a case arising primarily out of the False Claims Act ("FCA"), 31 U.S.C. §§ 3729-3733. Plaintiffs Mona Sabet Edalati and her husband Dr. David Edalati initiated this lawsuit on behalf of the United States¹ alleging in part that Defendants submitted false claims for payment to Medicare. They also allege Defendants breached an employment contract and initiated a malicious prosecution in state court. Defendants assert various counterclaims for breach of contract and unjust enrichment.

Plaintiffs move for partial summary judgment on two of their FCA claims, specifically Counts 3 and 5. Doc. 144. Count 3 alleges that certain Defendants knowingly presented false or fraudulent claims by using improper place-of-service codes to seek higher reimbursement rates from Medicare. Count 5 alleges that they conspired to do the same. The Court finds that there is no genuine dispute of fact on the issue of whether Defendants qualified for provider-based status, which means the place-of-service codes were false. But there remains a question of fact as to

The False Claims Act allows private individuals to sue on the United States's behalf. See 31 U.S.C. § 3730(b). The United States may intervene but often does not. U.S. ex rel. Thomas v. Black & Veatch Special Projects Corp., 820 F.3d 1162, 1167 n.3 (10th Cir. 2016). When the United States declines to intervene, the private plaintiff, or relator, may continue the case in the name of the United States. Id.; see also 31 U.S.C. § 3730(b)(1), (c)(3). The United States has declined intervention in this case. Doc. 11.

whether Defendants acted knowingly as that term is defined in the FCA. Plaintiffs are also not entitled to summary judgment on the conspiracy claim. Accordingly, the Court grants summary judgment on Counts 3 and 5 on the issue of whether the claims were false but denies it as to all other arguments for these claims.

I. BACKGROUND²

Dr. Paramjeet Sabharwal and Dr. Wanda Kaniewski are licensed bariatric surgeons. They are husband and wife. SOF 1. Minimally Invasive Surgical Hospital ("MISH") is a Kansas corporation that operates a for-profit hospital at 11217 Lakeview Avenue in Lenexa, Kansas. SOF 2. MISH is a hospital that performs surgeries, radiology, and laboratory services. SOF 75. From 2013 through 2015, MISH's tax returns showed that Dr. Sabharwal and Dr. Kaniewski were each 50% shareholders in MISH. SOF 16. From 2016 through 2018, Dr. Sabharwal was shown to own 100% of all shares of MISH. *Id.* ³

MISH is licensed by the state to operate a medical facility designated as a hospital. SOF 54. As a hospital located in Kansas, it is required to be licensed by the Kansas Department of Health and Environment. SOF 76. Centers for Medicare & Medicaid Services ("CMS") also verifies hospitals seeking enrollment under Medicare Part A, and MISH has been verified by CMS and its contractors as a hospital. SOF 100. Between 2011-2020, MISH also met Medicare requirements of being a participating provider and was eligible to establish provider-based departments. SOF. 102.

Kansas Institute of Medicine, Inc., and Kansas Institute of Medicine LLC ("KIM Inc." and "KIM LLC" respectively, collectively the "KIM entities") were formed in 2013. SOF 3-4.

The following facts are undisputed or are construed in favor of Defendants as the non-moving parties.

Defendants contend that the tax returns wrongfully suggested an ownership stake by Dr. Kaniewski. To the extent that is true, it does not affect the issues in this order.

Dr. Sabharwal and Dr. Kaniewski were each 50% shareholders in KIM Inc. from 2018-2018. SOF 17.

Dr. Sabharwal's purpose in creating KIM LLC was so KIM Inc. could employ physicians. SOF 10. The KIM entities were also created to keep the billing for physician professional services separate from the billing for hospital charges, such as facility fees, medical supplies, and diagnostic tests. SOF 72. KIM Inc. and KIM LLC are intended to be one and the same. SOF 10. The KIM entities own and operate clinics throughout the Kansas City metropolitan area. SOF 8. All these clinics are operated under the name "Kansas Institute of Medicine." SOF 9. One of these is a physician clinic at 11227 Lakeview Avenue in Lenexa, Kansas ("Lakeview Clinic"). SOF 8. Lakeview Clinic is a physician clinic where patients are treated in an office setting for a broad range of specialties, including cardiology, internal medicine, pain management, and primary care. SOF 75.

Until May 2021, MISH and Lakeview Clinic operated in the same building, but they had separate leases, addresses, entrances, signage, lobbies, and reception areas. SOF 18.4 However, Lakeview Clinic was part of MISH's campus, and there was common internal access between the MISH and KIM sides of the building. SOF 80. Medical records for patients treated at KIM clinics were accessible to nurses at MISH. SOF 94. And certain MISH departments, like the laboratory and infusion clinic, were located at 11227 Lakeview Avenue, the address of Lakeview Clinic. SOF 101. Patients at Lakeview Clinic could be referred for services at MISH. SOF 95. The KIM entities' income and expenses were included on MISH's CMS cost reports, and MISH provided no-interest loans to the KIM entities as needed for day-to-day operations. SOF 96. MISH provides office support for the KIM clinics, including billing, human resources, bookkeeping, payroll, and

⁴ Both MISH and Lakeview Clinic moved to a new location in May 2021. SOF 19.

accounting functions. SOF 86. But the KIM entities separately employ certain personnel, such as physicians, medical assistants, and front office staff. SOF 87. As CEO of both MISH and the KIM entities, Dr. Sabharwal exercises administrative and financial control over both MISH and Lakeview Clinic. SOF 83.

MISH and Lakeview Clinic have separate business licenses. SOF 56, 78. MISH and the KIM entities have separate bank accounts, file separate tax returns, file separately with the Kansas Secretary of State, and have separate accounts receivable. SOF 65. MISH's name was on the door to the hospital, while the door of Lakeview Clinic said "Kansas Institute of Medicine." SOF 67. Bills sent to patients who were seen at Lakeview Clinic were on "Kansas Institute of Medicine" letterhead and did not reference MISH. SOF 68. MISH's state license does not include reference to "Kansas Institute of Medicine" or include Lakeview Clinic's address. SOF 55.

MISH has never owned either the KIM entities or Lakeview Clinic. SOF 11. In annual reports filed with the State of Kansas and signed by Dr. Sabharwal under penalty of perjury, MISH certified that it did not hold more than 50% equity ownership in any other business entity in Kansas. SOF 12. MISH's tax returns also averred that MISH did not directly own 20% or more stock in any corporation or capital in any partnership. SOF 15.

Dr. David Edalati was hired in October 2013 to practice medicine at Lakeview Clinic. SOF 5. He had two separate employment contracts: one executed in October 2013, and one executed in March 2015. *Id.* The first contract said it was between Dr. Edalati and MISH, but he was actually always employed and paid by KIM Inc. SOF 6. Dr. Sabharwal fired Dr. Edalati on behalf of the KIM entities in February 2016. SOF 7.

To receive payment from Medicare for Medicare patients, an institutional health care provider must complete an enrollment application and agree to adhere to a set of eligibility requirements. SOF 28. That applications requires a provider attest to the following:

I agree to abide by the Medicare laws, regulations and program instructions that apply to this provider. The Medicare laws, regulations, and program instructions are available through the Medicare contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark Law), and on the provider's compliance with all applicable conditions of participation in Medicare.

Id. Providers also attest that they will not present false or fraudulent claims for payment by Medicare. SOF 29. Because they accept Medicare, CMS rules and regulations are applicable to the clinics run by the KIM entities and MISH. SOF 30.

Place of service ("POS") codes are used to indicate the setting in which a medical service is provided. SOF 31. They designate the actual place where the service was provided and determine whether payment is at a "facility" or "non-facility" rate. *Id.* Payment rates differ depending on whether the physician services were provided in a hospital setting versus somewhere else. SOF 33. The POS code affects Medicare reimbursement. *See* SOF 34. In a hospital setting, reimbursement rates are higher because Medicare takes into account higher overhead expenses, while payment for the same procedure in an office setting will be less because there is less overhead expense. *Id.* Use of the correct POS code ensures that Medicare provides correct reimbursement for the overhead portion of services provided. SOF 33.

If a patient receives face-to-face care in an office setting, the POS code is 11.SOF 32. If the encounter is in an inpatient hospital setting, the proper POS code is 21. *Id.* An encounter at an outpatient hospital setting is POS code 22. *Id.* Professional services provided in a physician's

office within a hospital or on a hospital's campus must be coded as 11 unless the physician space is a provider-based department of the hospital. SOF 35.

The CMS-1500 form ("Form 1500") is the standardized billing form used for professional services. SOF 36. When a Medicare patient is seen at Lakeview Clinic, the physician generates a "superbill" that reflects the office visit and billing codes for the services provided. SOF 37. MISH personnel would then generate a Form 1500 reflecting the services described in the superbill and submit that claim to Medicare electronically. SOF 38. Medicare paid claims for Lakeview Clinic into a KIM Inc. bank account, while MISH's claims were paid into a MISH bank account. SOF 42. MISH had a Medical Records Committee that reviewed every hospital patient chart to ensure the proper paperwork was completed and included. SOF 64. But the review of Lakeview Clinic charts was "more random." *Id*.

The Form 1500 was filled out solely based on the information in the superbill, except for the POS code. SOF 39. A POS code 11 would mean the services were provided at Lakeview Clinic, but MISH billing personnel would submit the Form 1500 with a POS code 22, indicating that the services occurred in a hospital outpatient setting. *Id*. This is the procedure billing personnel were instructed to use by supervisors. *Id*.

Beginning in 2013, Dr. Sabharwal decided to start seeking facility fees for all Medicare patient visits at Lakeview Clinic. SOF 45. From that point, the Form 1500s for patient claims from Lakeview Clinic contained a POS code 22. *Id.* MISH separately sought a facility fee for each patient visit. *Id.* Dr. Sabharwal did not consult any legal expert or other consultant before deciding that MISH would seek facility fees from Medicare for patient visits occurring at Lakeview Clinic, and MISH has never had a legal compliance department. SOF 46, 51. But Dr. Sabharwal thought the rules were very clear. SOF 46. He personally reviewed 42 C.F.R. § 413.65 for the requirements

for provider-based status as to Lakeview Clinic. SOF 47. He believed Lakeview Clinic met the requirements for provider-based status. *Id.* Defendants never submitted an "attestation" pursuant to 42 C.F.R. § 413.65(b) seeking determination as to whether Lakeview Clinic qualified for provider-based status, although they were not required to do so before they began billing as provider-based. SOF 48-49, 104. Dr. Sabharwal was aware that the total reimbursement paid by Medicare for physician services in a provider-based setting plus a facility fee would exceed the amount paid for the same services in a standalone clinic. SOF 50.

Plaintiffs have identified 1,383 claims for services provided by Dr. Edalati at Lakeview Clinic that MISH personnel submitted with POS code 22. SOF 69. The claims were paid by Medicare. *Id.* Plaintiffs allege the damages for these 1,383 claims is the difference between what Medicare paid and what would have been paid had POS code 11 been used and no facility fee charged, totaling \$106,526. SOF 70-71. Dr. Sabharwal has filed an affidavit stating he believed the POS codes for the 1,383 claims at issue were correct when submitted and still believes they were correct. SOF 108.

MISH has a several step process for a physician to obtain clinical privileges at MISH, and renewal must occur every two years. SOF 57, 59. A physician without clinical privilege cannot see patients at MISH. SOF 58. Dr. Edalati never sought or received admitting or clinical privileges at MISH. SOF 60. Another physician, Dr. Shadrach Smith, was employed with the KIM entities and saw patients at the Lakeview Clinic beginning July 7, 2015. SOF 62. But Medicare records show that claims for Dr. Smith used POS code 22 before he obtained privileges at MISH on November 27, 2015. *Id.*; SOF 63.

II. STANDARD

Summary judgment is appropriate if there is "no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The moving party bears the initial burden of establishing the absence of a genuine issue of fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). The burden then shifts to the nonmovant to demonstrate that genuine issues remain for trial. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586-87 (1986). In applying this standard, courts view the facts and any reasonable inferences in a light most favorable to the non-moving party. *Henderson v. Inter-Chem Coal Co.*, 41 F.3d 567, 569 (10th Cir. 1994). "An issue of material fact is genuine if a reasonable jury could return a verdict for the nonmoving party." *Id.* (internal quotation and citation omitted).

III. ANALYSIS

"The False Claims Act (FCA) imposes liability on anyone who 'knowingly' submits a 'false' claim to the Government." *United States ex rel. Schutte v. SuperValu Inc.*, 143 S. Ct. 1391, 1395 (2023). As relevant here, the "two essential elements of an FCA violation are (1) the falsity of the claim and (2) the defendant's knowledge of the claim's falsity." *Id.* at 1398; *see also* 31 U.S.C. § 3729(a)(1)(A) (imposing civil liability for any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval"). The FCA also penalizes conspiring to violate any of the statute's substantive provisions. *See* 31 U.S.C. § 3729(a)(1)(C).

There are additional elements of an FCA claim: "To show a false claim, [a plaintiff] must establish (1) a false statement or fraudulent course of conduct; (2) made with the requisite scienter; (3) that is material; and (4) that results in a claim to the Government or conceals, decreases, or avoids an obligation to pay the Government." *United States ex rel. Janssen v. Lawrence Mem'l Hosp.*, 949 F.3d 533, 539 (10th Cir. 2020). There doesn't seem to be any dispute that claims were submitted to Medicare. Materiality is defined under the FCA as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4); see also Universal Health Servs., Inc. v. United States, 579 U.S. 176, 192-195 (2016) (discussing the FCA's materiality requirement). It is undisputed that the POS code impacts reimbursement rates. SOF 32-34. For purposes of the motion for summary judgment on Counts 3 and 5, the parties focus on the falsity and scienter elements, so the Court does likewise.

A. Count 3 – Submission of False Claims Under 31 U.S.C. § 3729(a)(1)(A) and (B)

Count 3 encompasses various allegations. *See* Doc. 139 at 18 (alleging improper office visit codes and improper POS codes). Plaintiffs only move as to the POS codes. Doc. 144 at 2. And, even more specifically, Plaintiffs only move for summary judgment on a subset of the POS claims. *Id.* Plaintiffs seek summary judgment on the question of liability and damages for 1,383 POS claims arising out of office visits performed by Dr. Edalati at Lakeview Clinic, which were subsequently billed as though they were performed in a hospital setting, i.e. at MISH. *Id.*⁶

1. Falsity

Plaintiffs' theory of liability at issue in the summary-judgment motion is that Defendants knowingly submitted claims to Medicare for payment for professional services, along with claims for facility fees, as though the services were provided in the outpatient hospital setting (i.e. at MISH) rather than in an office setting (i.e. at Lakeview Clinic). Doc. 145 at 21. Here, the parties generally agree that POS codes classify the setting where services were provided. SOF 31. Services provided in an office setting are usually billed using POS code 11, while encounters in a hospital outpatient setting are billed using POS code 22. SOF 32. It is undisputed that services provided in an office space must be coded using POS code 11 unless the space is a provider-based department of the hospital, in which case it can be billed using POS code 22. See SOF 35. Beginning in 2013, claims for services provided at Lakeview Clinic were submitted using POS code 22, indicating they were provided in a hospital outpatient setting. SOF 39, 45. This was decided based on Dr.

Plaintiffs have apparently identified 10,526 other claims that they contend have false POS codes. Doc. 139 at 26. But they do not seek summary judgment on those claims. Doc. 144 at 2. Plaintiffs also cite both 31 U.S.C. § 3729(a)(1)(A), which prohibits the knowing presentment of a false or fraudulent claim, and 31 U.S.C. § 3729(a)(1)(B), which prohibits knowingly making or using a false record material to a false claim. *See* Doc. 139 at 26. The briefing doesn't distinguish between these two provisions, and the allegations at issue seem to focus on conduct prohibited by § 3729(a)(1)(A), the presentment of false or fraudulent claims. Accordingly, the Court analyzes the motion under that provision and does not reach the merits of any claim asserted under § 3729(a)(1)(B).

Sabharwal's determination that the Lakeview Clinic met the requirements for provider-based status under 42 C.F.R. § 413.65. SOF 47. Thus, whether the claims for services at Lakeview Clinic were correctly or falsely billed using POS code 22 turns on whether Lakeview Clinic met the standard for provider-based status under 42 C.F.R. § 413.65. The Court thus considers the requirements for provider-based status.

Highly summarized, Medicare reimburses services provided in a hospital setting at a higher rate than those provided in an office setting, in part to account for the higher overhead expenses of a hospital. *See* SOF 34. Where a hospital, for example, operates subordinate facilities, Medicare allows certain subordinate facilities to be classified as "provider based" and bill at the higher rate typically paid to hospitals. *See Adventist Healthcare, Inc. v. Sebelius*, 2010 WL 3038917, at *2 (D. Md. 2010). This has led to an increase in facilities claiming provider-based status and led to the passage of regulations setting forth requirements for claiming such status. *Id.* That regulation is 42 C.F.R. § 413.65.⁷

The regulation states that it "applies to all facilities for which provider-based status is sought." 42 C.F.R. § 413.65(a)(1)(i). It include several definitions. Relevant here are the definitions for "main provider," "provider-based entity," and "provider-based status":

Main provider means a provider that either creates, or acquires ownership of, another entity to deliver additional health care services under its name, ownership, and financial and administrative control.

Provider-based entity means a provider of health care services . . . that is either created by, or acquired by, a main provider for the purpose of furnishing health care services of a different type from those of the main provider under the ownership and administrative

Plaintiffs cite to the version of 42 C.F.R. § 413.65 that was in effect from July 16, 2012, through September 30, 2017, because that is the time period that the 1,383 claims at issue in the motion were apparently submitted. Doc. 145 at 2 n.1. Defendants do not dispute this. Although neither side suggests there are material differences in the versions, the Court will likewise rely on the version that was in effect from 2012 through 2017, and all citations are to that version.

and financial control of the main provider, in accordance with the provisions of this section. A provider-based entity comprises both the specific physical facility that serves as the site of services of a type for which payment could be claimed under the Medicare or Medicaid program, and the personnel and equipment needed to deliver the services at that facility. A provider-based entity may, by itself, be qualified to participate in Medicare as a provider under § 489.2 of this chapter, and the Medicare conditions of participation do apply to a provider-based entity as an independent entity.

Provider-based status means the relationship between a main provider and a provider-based entity or a department of a provider, remote location of a hospital, or satellite facility, that complies with the provisions of this section.

Id. § 413.65(a)(2).

There are certain requirements that must be met for an entity, regardless of type or location, to be considered provider-based. "A facility or organization is not entitled to be treated as provider-based simply because it or the main provider believe it is provider-based." *Id.* § 413.65(b)(1). The regulation goes on to state:

Any facility or organization for which provider-based status is sought, whether located on or off the campus of a potential main provider, <u>must meet all of the following requirements</u> to be determined by CMS to have provider-based status:

- (1) Licensure. The department of the provider, the remote location of a hospital, or the satellite facility and the main provider are operated under the same license, except in areas where the State requires a separate license for the department of the provider, the remote location of a hospital, or the satellite facility, or in States where State law does not permit licensure of the provider and the prospective department of the provider, the remote location of a hospital, or the satellite facility under a single license. . . .
- (2) Clinical services. The clinical services of the facility or organization seeking provider-based status and the main provider are integrated as evidenced by the following:
 - (i) Professional staff of the facility or organization have clinical privileges at the main provider.

- (ii) The main provider maintains the same monitoring and oversight of the facility or organization as it does for any other department of the provider.
- (iii) The medical director of the facility or organization seeking provider-based status maintains a reporting relationship with the chief medical officer or other similar official of the main provider that has the same frequency, intensity, and level of accountability that exists in the relationship between the medical director of a department of the main provider and the chief medical officer or other similar official of the main provider, and is under the same type of supervision and accountability as any other director, medical or otherwise, of the main provider.
- (iv) Medical staff committees or other professional committees at the main provider are responsible for medical activities in the facility or organization, including quality assurance, utilization review, and the coordination and integration of services, to the extent practicable, between the facility or organization seeking provider-based status and the main provider.
- (v) Medical records for patients treated in the facility or organization are integrated into a unified retrieval system (or cross reference) of the main provider.
- (vi) Inpatient and outpatient services of the facility or organization and the main provider are integrated, and patients treated at the facility or organization who require further care have full access to all services of the main provider and are referred where appropriate to the corresponding inpatient or outpatient department or service of the main provider.
- (3) Financial integration. The financial operations of the facility or organization are fully integrated within the financial system of the main provider, as evidenced by shared income and expenses between the main provider and the facility or organization. The costs of a facility or organization that is a hospital department are reported in a cost center of the provider, costs of a provider-based facility or organization other than a hospital department are reported in the appropriate cost center or cost centers of the main provider, and the financial status of any provider-based facility or organization is incorporated and readily identified in the main provider's trial balance.

- (4) Public awareness. The facility or organization seeking status as a department of a provider . . . is held out to the public and other payers as part of the main provider. When patients enter the provider-based facility or organization, they are aware that they are entering the main provider and are billed accordingly.
- (5) Obligations of hospital outpatient departments and hospital-based entities. In the case of a hospital outpatient department or a hospital-based entity, the facility or organization must fulfill the obligations of hospital outpatient departments and hospital-based entities described in paragraph (g) of this section.

Id. § 413.65(d) (emphasis added).⁸ The regulation also includes a voluntary process for seeking a determination from Medicare of whether provider-based status is met. *Id.* § 413.65(b).⁹

Plaintiffs argue that the claims at issue—1,383 claims for patient visits at Lakeview Clinic that were submitted using POS code 22 instead of POS code 11—were false because Lakeview Clinic did not qualify for provider-based status under 42 C.F.R. § 413.65. Doc. 145 at 25-26. Their argument is two-fold.

First, they contend that neither Lakeview Clinic nor MISH meet the definitions in 42 C.F.R. § 413.65(a)(2) for provider-based entity or main provider, respectively. A provider-based entity is one that is "created by, or acquired by," a main provider and operated under the ownership of the main provider. And conversely, a main provider is one who creates or acquires ownership of the subordinate entity and operates it under its name and ownership. 42 C.F.R. § 413.65(a)(2). Plaintiffs contend neither of these definitions is met because MISH did not own Lakeview Clinic or operate it under its name.

The regulation contains additional requirements that must be met for off-campus facilities or organizations, 42 C.F.R. § 413.65(e), facilities or organizations operated as joint ventures, *id.* § 413.65(f), and for hospital outpatient departments and hospital-based entities, *id.* § 413.65(g). Of these, only the requirements for hospital outpatient departments and hospital-based entities would seem to apply. But Plaintiffs do not discuss these requirements and the Court will therefore assume for purposes of this motion that Lakeview Clinic met these requirements to the extent they apply.

⁹ This process apparently used to be mandatory. See Doc. 145 at 24-25.

Second, Plaintiffs argue that the undisputed facts show that Lakeview Clinic did not meet several of the mandatory criteria under 42 C.F.R. § 413.65(d). Specifically, Lakeview Clinic did not operate under the same license as MISH, *see id.* § 413.65(d)(1), professional staff at Lakeview Clinic did not necessarily have clinical privileges at MISH, *see id.* § 413.65(d)(2)(i), MISH did not exercise the same monitoring and oversight of Lakeview Clinic as it did for MISH departments, *see id.* § 413.65(d)(2)(ii), Lakeview Clinic's finances were not fully integrated with MISH's financial operations, *see id.* § 413.65(d)(3), and Lakeview Clinic was not held out to the public as part of MISH, *see id.* § 413.65(d)(4).

Nearly all the facts relied on by Plaintiffs in support of these arguments are undisputed. See SOF 8-16, 18, 21, 54-60, 62-68. More specifically, it is undisputed that Lakeview Clinic is owned by the KIM entities, not MISH, and neither Lakeview Clinic nor the KIM entities have ever been owned by MISH. Further, Lakeview Clinic operated under the name Kansas Institute of Medicine, not MISH. MISH's name was on the door to the hospital entrance, while the name on the door to Lakeview Clinic said "Kansas Institute of Medicine." Lakeview Clinic and MISH operate in the same building but have different addresses, leases, entrances, signage, lobbies, and reception areas. MISH and Lakeview Clinic had separate bank accounts and filed separate tax returns and business filings. Neither the Kansas Institute of Medicine nor Lakeview Clinic is included on MISH's hospital license, and MISH and Lakeview Clinic have separate business licenses. Dr. Edalati has never had admitting or clinical privileges at MISH. MISH's Medical Records Committee only provided "random" review of Lakeview Clinic's patient charts compared to the review of MISH charts. And patients seen at Lakeview Clinic received bills on "Kansas Institute of Medicine" letterhead without any reference to MISH. See generally id.

Defendants initially respond to Plaintiffs' 42 C.F.R. § 413.65(a)(2) arguments by asserting that MISH was the "main provider" for Lakeview Clinic and that Lakeview Clinic was created by MISH and was a provider-based entity. Doc. 171 at 20. But these are conclusions of law, not proper statements of fact.

Defendants' remaining arguments address the interpretation of 42 C.F.R. § 413.65. First, in response to Plaintiffs' contention that the definitions of "main provider" and "provider-based entity" in the regulation contemplate ownership by a main provider of the subordinate entity, Defendants argue that the regulation doesn't define "ownership" and should be interpreted to extend to common ownership. Defendants contend that, if read that way, the definitions would be satisfied here because Dr. Sabharwal is a common owner of both MISH and the KIM entities (and by extension, Lakeview Clinic).

But that is contrary to common rules of statutory interpretation, which first and foremost look to the plain language. See Robinson v. Shell Oil Co., 519 U.S. 337, 340 (1997). The regulation states that a "main provider" is one that "either creates, or acquires ownership of, another entity" and operates that entity "under its name, ownership, and financial and administrative control." 42 C.F.R. § 413.65(a)(2). Similarly, a "provider-based entity" is one that "is either created by, or acquired by, a main provider" and furnishes care "under the ownership" of the main provider. Id. To suggest this language also includes situations where there is no direct ownership relationship but rather a common owner over both the main provider and provider-based entity stretches the language beyond its unambiguous meaning. Defendants also suggest that another regulation does include a specific reference to "common ownership," see 42 C.F.R. § 413.17(b)(2), and that phrase should be essentially imported into § 413.65. But, as Plaintiffs note, the inclusion of particular language in some regulations and its omission in others suggests that the omission in the latter is

intentional. Stated differently, the difference between these regulations suggests an intentional decision to omit common ownership in the definitions for main provider and provider-based entity in 42 C.F.R. § 413.65. *See Elwell v. Oklahoma ex rel. Bd. of Regents of Univ. of Oklahoma*, 693 F.3d 1303, 1309 (10th Cir. 2012) (noting that where Congress includes particular language "in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion" (internal quotation and citation omitted)).

Defendants then turn to Plaintiffs' 42 C.F.R. § 413.65(d) arguments. Defendants argue that MISH and Lakeview Clinic meet all the requirements of 42 C.F.R. § 413.65(d). The Court disagrees based on the facts and arguments in this case.

On the licensing factor (requiring the main provider and provider-based entity to operate under the same license), Defendants argue that Lakeview Clinic did not operate under MISH's license because Lakeview Clinic was not required to be licensed under Kansas law. While there is an exception "where the State requires a separate license," that is not exactly the same thing as simply not being licensed because there is no state requirement. Moreover, to the extent Defendants contend that Kansas law did not permit Lakeview Clinic to be licensed on MISH's license, the only authority cited for this is Dr. Sabharwal's conclusory affidavit, which is not sufficient to create a genuine issue of fact on this issue. The affidavit doesn't even say that Kansas law prohibited Lakeview Clinic from being included on MISH's license, only that Lakeview Clinic could not be licensed as a hospital. *See* Doc. 172-1 at 3.

Regarding clinical privileges, it is uncontroverted that "Dr. Edalati never sought nor was he ever granted admitting or clinical privileges at MISH." SOF 60. Another doctor who worked for Lakeview Clinic also did not have clinical privileges at MISH for a short period of time. SOF

62. Defendants nevertheless argue that Medicare Conditions of Participation recognize a physician's privilege to "send a patient" for outpatient services even where the physician does not have formal privileges, and that such informal "privileges" were sufficient to comply with 42 C.F.R. § 413.65(d)(2)(i). But again, this seems at odds with the plain language of the statute that professional staff of the provider-based entity "have clinical privileges at the main provider." And again, it is undisputed that at least some professional staff at Lakeview Clinic did not have "clinical privileges" at MISH. SOF 60, 62. To the extent Defendants rely on their expert for the conclusion that the statutory language should be extended to such informal privileges to "send" patients, that is an improper legal conclusion, and it cannot be read in harmony with the plain language of the regulation.¹⁰

The parties additionally discuss some of the other factors in 42 C.F.R. § 413.65(d). These include the requirement that the main provider maintain the same level of monitoring and oversight of the provider-based entity as it does its own internal departments, *see* 42 C.F.R. § 413.65(d)(2)(ii), the financial integration of the entities, *see id.* § 413.65(d)(3), and public awareness of the relationship between the entities, *see id.* § 413.65(d)(4). The Court does not consider whether there is a genuine issue of fact on these points¹¹ because the regulation requires

Plaintiffs have moved to exclude certain opinions of Defendants' expert Valerie Rinkle. Doc. 140. The Court addresses that motion in a separate order. But it is worth noting that Rinkle acknowledged that the "informal" privilege "to send" a patient would likely exist for almost every doctor in good standing with Medicare. Doc. 141 at 9; see also Doc. 143-1 at 29. To the extent that is true, this would seem to render the "clinical privilege" requirement in 42 C.F.R. § 413.65(d) a nullity and would undercut the purpose of the regulation—to ensure a relationship between a main provider and a provider-based entity. See Robinson, 519 U.S. at 341 (noting that statutory language should be considered in "the specific context in which that language is used, and the broader context of the statute as a whole"). Plaintiffs also note that Rinkle's opinion is only that the Lakeview Clinic "substantially meets" the requirements in 42 C.F.R. § 413.65, and she testified that one of the ways they were "close but not quite there" was because Dr. Edalati did not have admitting privileges at MISH. See Doc. 143-1 at 33. Thus, to the extent Defendants rely on Rinkle's testimony regarding the clinical-privileges requirement, it does not support their cause.

On the regulatory requirement that the main provider provide the same monitoring and oversight of the provider-based entity as it does for its own internal departments, see 42 C.F.R. § 413.65(d)(2)(ii), Plaintiffs argue that MISH's Medical Records Committee did not review the charts from Lakeview Clinic in the same way it reviewed MISH's charts, and that Dr. Sabharwal—not MISH—administratively and financially controlled both MISH and

that a facility meet <u>all</u> the requirements of 42 C.F.R. § 413.65(d) to be eligible for provider-based status. As discussed above, there is no genuine dispute of fact that Lakeview Clinic failed to meet least some of the criteria. Accordingly, no reasonable jury could find that Lakeview Clinic satisfied the requirements for provider-based status. Plaintiffs are therefore entitled to summary judgment on the question of whether the 1,383 claims at issue were "false" for purposes of this motion.¹²

2. Scienter

The FCA's scienter element—the knowing submission of false claims—means that a person "(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1). There need not be a specific intent to defraud. *Id.* The focus is "primarily on what [those submitting the claims] thought and believed," *Schutte*, 143 S. Ct. at 1400, and whether they had knowledge that the claim was false, *United States ex rel. Coffman v. City of Leavenworth, Kan.*, 770 F. App'x 417, 420 (10th Cir. 2019).

Plaintiffs argue that scienter is established because Dr. Sabharwal made the decision himself that Lakeview Clinic met the standards for provider-based status without seeking legal

Lakeview Clinic, as opposed to MISH overseeing Lakeview Clinic. Defendants point to other facts showing that Dr. Kaniewski, as the chief medical officer of MSIH, did oversee Lakeview Clinic's physicians. *See* SOF 91. As to public awareness, Defendants assert that there were signs "inside and outside" the clinic and online stating that MISH owned Lakeview Clinic, and that if the public asked who owned Lakeview Clinic, they were told that MISH owned it. *See* SOF 98. Plaintiffs dispute when this signage was posted, and whether it was sufficient to meet the requirement of 42 C.F.R. § 413.65(d)(4). But an obvious problem with Defendants' position is that, even if there was signage stating that MISH owned Lakeview Clinic and patients were told that MISH owned Lakeview Clinic, it is undisputed that MISH did <u>not</u> own Lakeview Clinic.

Defendants rely heavily on the fact that Plaintiffs, as the moving party, also bear the burden of proof at trial. They are correct that, as part of their FCA claims, Plaintiffs have the burden of establishing falsity. But that doesn't preclude summary judgment. As the movants, Plaintiffs had the burden of coming forward with sufficient facts from which a jury could find that the claims at issue were false, i.e. that Lakeview Clinic did not meet the requirements for provider-based status. They did that by pointing to facts showing that the requirements of 42 C.F.R. § 413.65 were not met. It then became Defendants' burden to point to facts from which a jury could find otherwise. But as discussed above, as to at least some of the regulatory factors, Defendants have failed to do so. Much of Defendants' argument is premised on erroneous statutory interpretation, which is a question of law. The Court has rejected those arguments, and there's nothing left for a jury to decide on this issue. Plaintiffs are therefore entitled to summary judgment on the issue of falsity.

counsel or consultation with industry experts. Doc. 145 at 36. And he did so even though the regulation specifically states that provider-based status is not established based on the belief of the main provider that the clinic is provider based, *id.* (citing 42 C.F.R. § 413.65(b)(1)), and while failing to take advantage of the voluntary attestation process, *id.* (citing 42 C.F.R. § 413.65(b)(3)). They contend Dr. Sabharwal could not have reviewed the regulation and "rationally concluded that the Lakeview Clinic <u>fully</u> met <u>all</u> the requirements for provider-based status." *Id.* at 36-37 (emphasis in original).

In their motion, they rely primarily on *United States v. Cooperative Grain & Supply Co.*, 476 F.2d 47 (8th Cir. 1973). The issue in *Cooperative Grain* was whether a specific intent to defraud was required by the FCA or whether "the defendants' 'clumsiness' or 'carelessness and foolishness in the extreme' constitute conduct that the court can deem to create sufficient knowledge or awareness under the False Claims Act to be civilly actionable." *Id.* at 55-56. The court rejected the notion that any specific intent was required, *id.* at 59, and instead focused on knowledge, which could still encompass negligent misrepresentation, *id.* at 59-60. The court concluded that "extreme carelessness in this case amounted to 'knowing." *Id.* at 60.

But as Plaintiffs acknowledge, *Cooperative Grain* predates the current version of the FCA, which now specifically states that "knowingly" can encompass not just actual knowledge, but also deliberate ignorance, or reckless disregard. And the Supreme Court has outlined what those terms mean. *Schutte*, 143 S. Ct. at 1400. "Actual knowledge" looks to whether a person was aware of information. *Id.* "[D]eliberate ignorance' encompasses defendants who are aware of a substantial risk that their statements are false, but intentionally avoid taking steps to confirm the statement's

Other courts have detailed the history of the FCA following *Cooperative Grain*, stating that the changes to the FCA were meant to clarify the law in keeping with *Cooperative Grain*'s interpretation. *United States v. United Techs. Corp., Sikorsky Aircraft Div.*, 51 F. Supp. 2d 167, 198-99 (D. Conn. 1999). In other words, the FCA's scienter element now encompasses the holding of *Cooperative Grain*.

truth or falsity." *Id.* "And, third, the term 'reckless disregard' similarly captures defendants who are conscious of a substantial and unjustifiable risk that their claims are false, but submit the claims anyway." *Id.* at 1400-01.

Here, the Court agrees that there are facts from which a jury could find that Defendants, or at least Dr. Sabharwal, 14 acted with the requisite scienter. There are facts that he reviewed the regulation, was aware of underlying facts that did not satisfy all regulatory requirements (for example, that MISH did not own Lakeview Clinic), failed to seek any clarification or authoritative guidance on the significance of those facts, and proceeded with billing as though Lakeview Clinic met the criteria for provider-based status. But for purposes of summary judgment, it is also undisputed that Dr. Sabharwal contends he subjectively believed that the standards for providerbased status were met and that the claims were properly submitted. Why he thought this is not entirely clear from the current record, and this issue will likely be tested at trial. But because the focus of the scienter inquiry is "primarily on what [those submitting the claims] thought and believed," id. at 1400, on this current record, scienter cannot be decided on summary judgment. See United States ex rel. Streck v. Takeda Pharms. Am., Inc., 2022 WL 595308, at *13 (N.D. III. 2022) ("While the duty Lilly holds is clear, what Lilly did and the intent with which Lilly did them is hotly contested The Court finds that there are insufficient undisputed facts on which the Court can make a summary judgment determination and reserves this question for the jury.").

In their reply, Plaintiffs suggest that "reckless disregard" under the FCA should be interpreted using only an objective standard. Doc. 179 at 27-28. But the Supreme Court has since

Dr. Sabharwal, Dr. Kaniewski, MISH, and the KIM entities are all named as defendants. But Dr. Kaniewski is not named as to Counts 3 or 5 and thus is not at issue in this motion. Dr. Sabharwal, MISH, and the KIM entities are named in those counts, but neither side distinguishes among their conduct or the basis for liability for each. Given the number of parties and claims in this case, the Court strongly encourages the parties to consider this in advance of trial so that the jury can be properly instructed and the verdict form properly prepared.

rejected such an interpretation: "The FCA's scienter element refers to respondents' knowledge and subjective beliefs—not to what an objectively reasonable person may have known or believed." *Schutte*, 143 S. Ct. at 1399.

The issue in *Schutte* was somewhat the inverse of the facts in this case—an ambiguous regulation but a subjective belief by the defendants that the claims were false in *Schutte* versus a relatively unambiguous regulation in this case and a defendant who contends he subjectively believed the claims were proper. The Supreme Court found that scienter was established if the defendant subjectively believed the claims were false, even if some other person could have objectively found them to be accurate. *Id.* at 1404. But in detailing the scienter requirements of the FCA, the Supreme Court specifically left open the question of whether recklessness could be judged from a purely objective standard in certain cases:

In some civil contexts, a defendant may be called "reckless" for acting in the face of an unjustifiably high risk of illegality that was so obvious that it should have been known, even if the defendant was not actually conscious of that risk. *See* [Farmer v. Brennan, 511 U.S. 825, 836-37 (1994)]. We need not consider how (or whether) that objective form of "recklessness" relates to the FCA today

Schutte, 143 S. Ct. at 1401 n.5 (emphasis added). Based on this, the Court cannot find that Plaintiffs are entitled to summary judgment on Count 3 on the question of whether Defendants knowingly submitted false claims as to the 1,383 claims. That issue will be left for the jury.¹⁵

B. Count 5 – Conspiracy Under 31 U.S.C. § 3729(a)(1)(C)

In Count 5, Plaintiffs move for summary judgment on their conspiracy claim under the FCA as to the 1,383 claims at issue in Count 3. As noted, the FCA penalizes anyone who "conspires to commit a violation" of the FCA. See 31 U.S.C. § 3729(a)(1)(C). The elements of an

The parties dispute whether Plaintiffs have established damages for purposes of summary judgment. Because the Court finds that questions of fact on the issue of scienter remain for trial, and it is Plaintiffs who have moved for summary judgment, the Court does not reach the issue of damages.

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FCA conspiracy claim are an agreement to get false claims paid and an overt act taken toward that

purpose. U.S. ex rel. Conner v. Salina Reg'l Health Ctr., Inc., 459 F. Supp. 2d 1081, 1091 (D. Kan.

2006).

Plaintiffs' analysis on this claim is brief. They state only that MISH submitted false claims

at Dr. Sabharwal's direction, that the KIM entities allowed this to happen, and that the KIM entities

accepted payments from Medicare. Doc. 145 at 37. But these facts do not establish the elements

of an FCA conspiracy. In particular, that MISH personnel or the KIM entities acted at the direction

of Dr. Sabharwal does not evidence an agreement to submit false claims. Plaintiffs are therefore

not entitled to summary judgment on their conspiracy claim. Further, the Court has denied

summary judgment on the underlying FCA claim because factual questions remain for a jury to

decide. Thus, at the very least, it would be premature to reach the conspiracy claim. See Connor,

459 F. Supp. 2d at 1091 ("Because Conner's FCA claims fail to state a claim, there can be no

conspiracy.").

IV. CONCLUSION

THE COURT THEREFORE ORDERS that Plaintiffs'/Relators' Motion for Partial

Summary Judgment on Counts III and V of the First Amended Complaint (Doc. 144) is

GRANTED IN PART AND DENIED IN PART. The motion is granted on the question of the

falsity of the 1,383 POS claims at issue in the motion. The motion is denied on the question of

whether those claims were knowingly false, and on the conspiracy claim. Defendants' liability and

any damages will be decided by a jury.

IT IS SO ORDERED.

Dated: August 18, 2023

/s/ Holly L. Teeter

HOLLY L. TEETER

UNITED STATES DISTRICT JUDGE

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