Graziosi v. Accretive Health, Inc. et al Doc. 306

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

UNITED STATES OF AMERICA, ex rel. CHERRY GRAZIOSI,	)	
Relator,	)	Case No. 13-cv-1194
v.	)	Judge Robert M. Dow, Jr.
R1 RCM, INC. f/k/a Accretive Health, Inc.,	)	
Defendant.	)	

MEMORANDUM OPINION AND ORDER

Relator Cherry Graziosi ("Relator" or "Graziosi") brings suit under the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3729 *et seq.* ("FCA") against Defendant R1 RCM, Inc., formerly known as Accretive Health, Inc. ("Defendant" or "R1"). Relator alleges in the governing Third Amended Complaint [184] that R1 has violated 31 U.S.C. § 3729(a)(2) and (a)(1)(B) by causing its hospital clients to submit legally false claims for "inpatient" hospital services to Medicare and Medicaid (Count II), and that R1 has acted in conspiracy with its hospital clients to commit these violations (Count III).[1] Before the Court are Relator's motion for partial summary judgment [261] and R1's motion for summary judgment [265]. For the following reasons, both motions [261] and [265] are denied. Counsel are directed to file a joint status report no later than December 15, 2020.

[1] All other Defendants have been dismissed from the case. See [100], [114], [294].

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I. Background

The following facts are taken from the parties' Local Rule 56.1 statements and supporting exhibits. See [261-1]-[261-12], [267]-[269], [272], [279], [284], [285], [287], [288], [296], [298]. These facts are undisputed except where a dispute is noted. The Court has jurisdiction over this FCA action pursuant to 28 U.S.C. §§ 1331.

A. The Parties

Relator is an individual who, between January 2010 and October 2013, worked as a "Service Associate" in the Emergency Department of MedStar Washington Hospital Center ("WHC") in Washington, D.C. Defendant R1, formerly known as Accretive Health, Inc. ("Accretive"), is a Delaware corporation with corporate headquarters in Chicago, Illinois. This case involves R1's Physician Advisory Solutions ("PAS") program and recommendations that R1 made to WHC and other hospitals to convert the admission status of patients from "outpatient" or "observation" to "inpatient," allegedly for the purpose of collecting additional revenue from Medicare and Medicaid.

B. Medicare Patient Classifications

Medicare is a federal program that provides health benefits to the aged and disabled. See 42 U.S.C. §§ 1395 *et seq*. Medicare Part A provides coverage for inpatient hospital services. See 42 U.S.C. §§ 1395c–1395i-5. Medicare Part B provides coverage for outpatient hospital services, including hospital patients placed in "observation" status. See 42 U.S.C. §§ 1395j–1395w-6. The Medicare Act defines "service" as "medical care or services and items, such as medical diagnosis and treatment, drugs and biologicals, supplies, appliances, and equipment, medical social services, and use of hospital, CAH, or SNF facilities." 42 C.F.R. § 400.202.

When a Medicare beneficiary is at the hospital and in need of medical or surgical care, a physician or other qualified practitioner must decide whether to admit the beneficiary for inpatient care or treat him or her as an outpatient. The decision of whether a physician assigns a patient an "inpatient" or an "outpatient" status is commonly referred to in the industry as a "level-of-care" or "admission status" determination. [267] at 3.

According to R1, Medicare's distinction between "inpatient" and "outpatient" affects the amount of payment and level of coverage under the inpatient and outpatient prospective payment systems, and not the type of care ultimately required or received. See [267] at 3. "Observation services are commonly ordered for patients who present to the emergency department and who then require a significant period of treatment or monitoring in order to make a decision concerning their admission or discharge." *Id.* at 4. Relator, while agreeing that the inpatient/outpatient distinction affects the amount of payment and level of coverage, denies that the "type of care" between the two classifications is identical. [279] at 4. Relator points out that several R1 officers have testified that Medicare regards "inpatient" as a reimbursable set of services, distinct from all "outpatient" services. See *id*. at 4-5. Relator also contends that Medicare rules defining "inpatient services" require a physician's expectation that the patient will receive in-hospital services for a longer period of time than "outpatients." *Id.* at 5. Relator further emphasizes that inpatient hospital services are compensated through a different payment system and diagnostic-related criteria (Medicare Part A), rather than the fee-for-service compensation system that applies to other hospital services (Medicare Part B). *Id*.

Relator and R1 agree that, in general, Medicare reimburses a hospital a greater amount if the hospital seeks reimbursement for the services provided on an inpatient basis rather than on an outpatient basis. The classification of patients affects the revenue hospitals receive and has

significant financial implications for Medicare beneficiaries, including whether the Medicare beneficiary ultimately will be billed for the services provided during their hospital stay, and whether Medicare will reimburse the patient for skilled nursing facility services after hospital discharge. Once a Medicare beneficiary is discharged from the hospital, the hospital cannot change the beneficiary's status to outpatient and submit an outpatient claim.

In order to determine whether hospital inpatient claims have been appropriately classified as inpatient, the federal Center for Medicare and Medicaid Services ("CMS") partners with various Medicare claims review contractors, such as Medicare Administrative Contractors, Recovery Audit Contractors, and Comprehensive Error Rate Testing contractors, who perform patient admission classification status reviews. When Medicare's claims review contractors reach a conclusion that inpatient care was not reasonable and necessary under 42 U.S.C. § 1395y(a)(1)(A), they deny the hospital inpatient claim for payment.

It is disputed whether there was "clarity" during the 2012-2013 period concerning when a Medicare beneficiary is appropriately admitted to the hospital as an inpatient. During this period, CMS "observed a trend of 'increases in the length of time for which patients receive observation services' and noted that 'hospitals appear to be responding to the financial risk of admitting Medicare beneficiaries for inpatient stays that may later be denied upon contractor review, by electing to treat beneficiaries as outpatients receiving observation services, often for longer periods of time, rather than admit them.'" [267] at 8 (quoting 77 Fed. Reg. 45156–57 (July 30, 2012)). The increasing number of denials also resulted in a large backlog of appeals of Medicare denials. As a result, in 2012 "CMS solicited public comments on '[p]otential policy changes [it] could make to improve clarity and consensus among providers, Medicare, and other stakeholders regarding … when a Medicare beneficiary is appropriately admitted to the hospital as an inpatient

and the cost to hospitals associated with making this decision.'" *Id*. at 9 (quoting 77 Fed. Reg. 45155 (July 30, 2012)).

In August 2013, CMS adopted a "Two Midnight Rule," which created a presumption that a patient qualifies as an inpatient if the physician expects the hospitalization to span two midnights. See [267] at 24-25. The rule requires the application of complex and nuanced medical judgment and also provides for a changing list of exceptions to the rule. The physician's expectation of a hospital stay must be based on complex medical factors such as patient history, comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event. These factors must be documented in the patient's medical record. A patient's length of stay is not determinative of the correct status, even under the Two Midnight Rule. CMS released updates to the rule on October 30, 2015, permitting greater flexibility for exceptions and allowing payments for inpatient admissions on a case-by-case basis based on the judgment of the admitting physician.

Medicare guidelines provide that the admission status decision must be made by a physician exercising his or her "complex medical judgment." [267] at 11. R1 asserts, but Relator disputes, that physicians "are not typically trained on the Medicare rules and regulations regarding admission status during medical school and often lack sufficient time to analyze and apply these rules and regulations to each and every admission classification status decision." *Id*. According to Relator, R1 physicians dispute among themselves whether working hospital physicians understand and apply the relevant federal definitions. For instance, Dr. Steve Andrews testified that physicians in a working hospital typically would be able to understand how Medicare defines inpatient status. See [279-3] at 5.

C. Utilization Review and R1's PAS Program

R1 contends that, in recognition of the pressing patient care responsibilities faced by many treating physicians, CMS has encouraged hospitals to "utilize all the tools necessary" to ensure appropriate initial admission decisions, including through increased use of resources such as "case management and utilization review staff," who are non-treating individuals. [267] at 11. Case management and utilization review staffs often include doctors and nurses who have not personally evaluated the patient. *Id.* Relator does not dispute this but emphasizes that CMS's references to "staff" means persons and entities that are accountable to and supervised by hospital employers, or otherwise subject to CMS supervision. See [279] at 10-11.

According to R1, utilization review and case management staff often make use of commercially available criteria such as the InterQual Level of Care Criteria ("InterQual") or the Milliman Care Guidelines ("Milliman") as a check to help improve the accuracy of treating physicians' initial admission classification status decisions. [267] at 12. R1 asserts, and Plaintiff disputes, that it is also common for hospitals to retain third party vendors such as R1 to assist them by providing recommendations as to whether patients should be classified as inpatient or outpatient for reimbursement and coverage purposes. R1 provides a declaration from Dr. Ronald Hirsch, Rl's Vice President for Regulations and Education, that at least six (unidentified) firms provide utilization review services similar to those offered by R1. R1 maintains, but Relator disputes, that "CMS is aware of the common industry practice of utilizing physician advisors to assist with assigning the proper admission classification status." [267] at 14. For instance, CMS authorizes hospitals to use Quality Improvement Organizations ("QIOs"). QIOs are private consulting firms contracting with CMS to provide hospitals with concurrent and retrospective reviews of various quality and utilization issues, including patient admission classification status. See [267] at 14.

This case involves R1's PAS program, which was designed "to "help [hospitals] comply with applicable CMS policies regarding the use of observation and inpatient admission classification status." [267] at 16. According to R1, the purpose of the PAS program is "to improve the accuracy of hospital-clients' initial admission classification decisions prior to billing, thereby reducing the risk of Medicare audits and denials." *Id.* at 16-17. It is not disputed that R1's protocols require its physician advisors to consider the adequacy of the physician's documentation, the severity of the patient's signs and symptoms, the risks for adverse outcomes, and the intensity of services already rendered, ordered, or anticipated by the treating physician, as required by Medicare guidelines, in making any admission status recommendation. However, Relator asserts, the physician advisors' "consideration is necessarily based entirely on the reviewers' scrutiny of what hospital physicians elect to record (and to record in legible writing) on initial patient records, and do[es] not include medical judgments about how long the relevant patient needs medically to remain in the hospital under treatment." [279] at 14.

R1 physician advisors do not provide any opinion or recommendation regarding the treating physician's plan of care, length of stay, or diagnosis of the patient. It was never a purpose of Rl's "recommendations" to contribute to any improvement in, or to affect in any way, the quality or content of health care services delivered to any patient. R1's recommendations were never intended to be medical opinions about how any patient should be treated, or how long any patient should remain in the hospital. R1's operations reports to hospitals contain standard disclaimer language stating: "Client understands and agrees that Accretive is making recommendations as to appropriate billing and documentation only and does not provide any medical or clinical advice or consultation as to patient care. All decisions and activities with respect to quality and utilization

review, documentation, billing and coding and/or medical treatment remain the sole responsibility of Client, its employees, contractors and medical staff members." [267] at 17.

D. R1's PAS Contracts

Since 2008, R1 has entered into contracts to provide admission status reviews and recommendations, as well as associated services, to over 500 client hospitals. Relator attaches 20 of these contracts as Exhibits 1 through 20 to her motion for partial summary judgment. R1's PAS contracts typically provide that, in exchange for a per-review fee, an R1 physician advisor will review a patient's medical record and provide an admission status classification recommendation within a certain amount of time ("concurrent review"). R1's recommendations are a real-time consultation regarding whether the documentation in a patient's medical record supports an inpatient admission classification status under Medicare guidelines. R1's PAS contracts contain pricing terms reflecting a fixed per-review fee that does not change based on the nature of R1's recommendations. That is, the per-review fee is the same regardless of whether R1 recommends that the patient's admission status be classified as inpatient or as observation/outpatient. R1's standard written presentation marketing its PAS service asked for $185 per case R1 reviewed. See [278] at 9 & n.5.

R1's PAS contracts offer "status assurance," meaning that if a client submits a Medicare claim for reimbursement to CMS with an admission status that matches the recommendation provided by an R1 physician advisor, and that claim is later denied, R1 will "research, defend and appeal these cases through rebuttal, reconsideration and redetermination at no additional charge." [267] at 18.

E. Marketing

In materials marketing the PAS program to prospective hospital clients in 2011, R1 represented that, based on historical data aggregated across R1's PAS program, R1 "recommends and defends upgrades of 30-40% of all observation cases reviewed" and "recommended 25- 45% of [cases initially classified as observation] should have been [i]npatient status." [285] at 10. An "upgrade" was what R1 called a recommendation to "convert" from a lower-paying outpatient claim to a higher-paying "inpatient" claim. [279] at 29. The dollar figures represented in R1's standard written solicitations were generated by the "analytical" staff at R1, "based on the information, the data, that had been collected and reported to hospital clients about the results of Accretive's (R1's) recommendations." [296] at 15. When R1 represented in its solicitations that it "recommends and defends upgrades of 30 to 40 percent of all observation cases reviewed," that "was a(n) accurate composite of all cases sent by all clients at the time." *Id.*

R1's marketing materials also contained what R1 calls a " hypothetical illustration of the potential revenue impact of improving the accuracy of admission classification status decisions: '10 upgrades per month yields $600k per year additional revenue, using Inpatient/Observation delta of $5,000.'" [285] at 11. Relator interprets this as a representation to prospective hospital clients that any single "upgrade" of a patient's billing status from a lower-paying "observation" claim to a higher-paying "inpatient" claim would bring the hospital (on average) an additional $5,000 in revenue from insurance payments. *Id.* at 10-11. R1 explains that "[t]he $5,000 delta was an industry-accepted figure from publicly available information, and it represented the difference between the average inpatient diagnostic-related group ("DRG") payment and the average payment for 24 hours of observation treatment." *Id.* at 11.

R1's marketing materials also contained a document projecting the "financial impact" to a hospital of hiring Rl to be a monetary "return on investment" ranging monthly from a low of "5.7 to 1" to a high of "8.7 to 1," projecting the "revenue increase" to a hospital to be "$527,524" over a six-month period of using Rl's recommendations. [285] at 12. R1 characterizes this as "a compilation of historical data across the PAS program and highly generalized, industry accepted average differentials between certain inpatient reimbursements and outpatient reimbursements," which "did not reflect the actual revenue billed for and collected by any PAS client," since "R1 did not systematically collect billing data from its hospital clients." *Id*. R1 disputes Relator's "imputed purpose behind including this illustration and Relator's implication that prospective clients were guaranteed this return." [288] at 11.

In addition to its standard marketing presentations, Rl also authored marketing proposals aimed at specific prospective hospital clients, in which Rl specified monetary amounts of "reimbursement lift, " "payment lift, " "lift impact on ... payments," "return on investment, " "revenue increase, " and "net revenue impact from recommendation" estimated or projected to result from the hospital implementing Rl's billing recommendations. [285] at 12. Nonetheless, R1 asserts that the sole purpose of its recommendations is to help hospital clients comply with applicable payor policies concerning the use of observation and inpatient admission classification status. *Id*. R1 emphasizes that its marketing materials have never contained promises or assurances regarding future monetary returns for clients. *Id.* at 10.

Relator asserts—and R1 disputes—that R1 officers and principals knew that it was wrong for any "concurrent review" company to solicit potential hospital clients with any representation to the effect that hiring that company to make reviews and recommendations about billing would likely result in an overall increase in revenue to the hospital from payments from Medicare,

Medicaid, or other insurers. [285] at 14. R1 disputes that its officers and principals knew or should have known they were doing anything wrong, because "Relator's proffered evidence simply demonstrates that R1's current and former employees—who uniformly believe they are performing a compliance function—also believe that it would therefore be improper to make specific financial promises to clients or guarantee any specific volume of inpatient recommendations." *Id*. at 15.

F. "Upgrades" to Inpatient Status

Relator does not assert or provide evidence that, in any particular case, R1's physician reviewer incorrectly classified an admission as inpatient rather than outpatient or observation. Instead, Relator's theory is that, in order to cause its hospital clients to increase their receipts from claims to insurers, Rl had to often "recommend" to its hospital clients that they bill insurers for a (higher-paying) "inpatient admission" even though the hospitals' physicians (who had examined, and prepared a plan of care for each patient) had earlier determined that each patient was only in medical need of a (lower-paying) "observation" (or other "outpatient") service. [279] at 29. R1 disputes that it "often" recommended inpatient admissions. R1 further disputes the implication that it had any benchmark or financial goal it was trying to obtain for its clients through the concurrent review program. R1 cites testimony from its employees that there was no benchmark and contends that recommendation trends varied significantly by client. See [285] at 9.

G. Training of Hospital Physicians and Staff

Relator also posits that, to enable hospitals to take advantage of the financial benefits of its "upgrades," R1 trained and pressured treating physicians to accept R1's recommendations without question, overriding their required professional judgment on the proper classification of their patients. R1 denies this and emphasizes that it remains the responsibility of the attending

physician to ultimately decide the appropriate status of the patient. Relator agrees that Medicare and Medicaid regulations require attending physicians to be responsible for such decisions but contends that R1's practices took this control away from them. See [285] at 16-17.

More particularly, R1's contracts make on-site education available to a client's hospital physicians, utilization review staff, and case managers. According to R1, its client education is designed to educate hospitals' physicians on evolving Medicare rules and regulations, so that the physicians can make more accurate admission status decisions on their own. R1's education sessions also serve to maintain the client relationship by educating relevant parties about R1's compliance purpose and how R1's expertise can help physicians make accurate and compliant admission status classifications.

Relator asserts, and R1 disputes, that "[n]umerous Rl officers conducted hundreds of meetings of medical staff members at Rl's client hospitals in order to convince them not to second-guess, but to accept and to sign orders implementing R1's 'billing recommendations.'" [296] at 16. R1 emphasizes that its quarterly education sessions were optional, and many hospitals did not participate. According to Relator, several standard arguments were presented to physicians at the training sessions. First, R1 told hospital physicians that the only purpose of its recommendations was for billing, see [279] at 41, and that the physicians did not need to reconsider their own medical judgments. Dr. Hirsh explained that "hospital physicians really needed to understand ... that they were not being intruded into and they were not being second-guessed about any medical decisions or judgments," since "the only purpose of the recommendations was to provide ... a recommendation about how the ... patient should be billed and not to change the physicians' views or opinions about what the treatment should be." *Id.* at 43. Similarly, R1 Vice President Dr. Weinberg agreed that "if the hospital physician properly understands the intent of the Accretive

(R1) recommendation, there's simply no professional reason to change the hospital physician's mind about any clinical judgment." [279-5] at 7. R1 does not dispute that this is Dr. Weinberg's testimony, but clarifies that R1 "provides recommendations regarding whether the documentation in the medical record appropriately supports a classification status of inpatient or outpatient based on applicable rules and regulations." [296] at 18; see also [279] at 42-43.

Second, according to Relator, R1 told treating physicians that its reviewers were better qualified to make the right classification determination. "R1 agrees that as part of explaining the PAS program to hospital staff, R1 personnel discussed the in-depth specialized training that it provided to all of its physician advisors." [296] at 19. Dr. Hazel Manzano, R1's former Vice President and Medical Director, admitted that this "was communicated to the clinical staffs of these client hospitals … in order to give them an additional reason to consider implementing the Accretive [] recommendations." [279-1] at 31.

Third, R1 officers emphasized the risks physicians faced if they failed to comply with Medicare rules. Dr. Hirsch acknowledged that, in order to get hospital physicians' attention, he and other R1 officers would inform them that they could be violating Medicare law if they decided not to implement R1's recommendations. When asked why he stressed that the classifications were a matter of federal law and that R1's advisors were experts, he responded, "[b]ecause most prefer not to go to prison," [279-2] at 13, "[a]nd they had to follow the laws or they would risk going to prison," *id*. at 14. R1 asserts that Dr. Hirsch's testimony, "[i]n context, … demonstrates that physician education sessions were intended to help physicians understand the importance of compliant billing and to improve documentation in the medical record." [296] at 21.

Fourth, Rl officers told hospital medical staffs about how, given the federal "reimbursement system for hospitals" and "comparing inpatients to outpatients," there were

"financial impacts" on their hospitals from implementing Rl's billing recommendations. [296] at 22.

R1 provides analytics to its clients through monthly Operations Reports. The Operations Reports contain data regarding case submission and recommendation trends, as well as figures that R1 characterizes as "generalized approximations of the financial impacts a facility may expect to see if it were to follow all of R1's recommendations." [267] at 23. Relator, by contrast, characterizes these figures as "actual financial results achieved (or presumed to have been achieved)." [279] at 20. According to R1, "[t]he Operations Reports produced in discovery demonstrate that R1 regularly recommended cases originally classified as inpatient to instead be classified as observation status." [267] at 23. Relator points out that R1 is referring to only some data in some reports and disputes R1's summary. See [279] at 19-20. The reports included numerous dollar figures stating for each month what R1 termed the "Financial Implications of Concurrent Reviews, " the "Gross Direct Quantifiable Value" of R1's recommendations, the "Net Direct Quantifiable Value" of R1's recommendations, and the "Total Impact" in dollars of R1's recommendations. [285] at 13. R1 maintains that "[t]he quantifiable value figures represented highly generalized estimates that may have been available to hospital clients if they were to implement all of R1's recommendations." *Id*. at 14.

H. Sample Data

The parties have not yet completed fact discovery on damages or expert discovery on liability and damages. Instead, they agreed to suspend the issue of whether R1 is required to produce all of its relevant per-patient data until after the Court decides the motions for summary judgment. Thus far, R1 has produced per-patient concurrent review data for a "sample set of fourteen hospitals." [266] at 16-17. (R1 does not discuss how it chose this sample or whether it

is representative of the results it obtained for all of its hospital clients.) Out of this sample, the majority of the cases sent to R1 for review by the hospitals were initially classified as inpatient. [267] at 20. In some cases in the sample, R1 recommended aggregate status change "conversions" to hospitals that would have resulted in decreased revenues to facilities and net savings to government payors if the recommendations were followed. See *id*.

The per-patient data produced thus far also shows that MWHC billed in accordance with R1 recommendations to change the status of Medicare patients from observation to inpatient approximately 75.9% of the time, and billed in accordance with R1 recommendations to change the status of Medicaid patients from observation to inpatient approximately 88.6% of the time.

II. Legal Standard

Summary judgment is proper where "the movant shows that 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). "A party asserting that a fact cannot be or is genuinely disputed must support the assertion by … citing to particular parts of materials in the record" or "showing that the materials cited do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible evidence to support the fact." Fed. R. Civ. P. 56(c)(1). A genuine issue of material fact exists if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). The party seeking summary judgment has the burden of establishing the lack of any genuine issue of material fact. See *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). The Court "must construe all facts and draw all reasonable inferences in the light most favorable to the nonmoving party." *Majors v. Gen. Elec. Co.*, 714 F.3d 527, 532-33 (7th Cir. 2013) (citation omitted). Where, as here, the parties have filed cross-motions for summary judgment, "'we view all facts and inferences in the light most

favorable to the nonmoving party on each motion.'" *Lalowski v. City of Des Plaines*, 789 F.3d 784, 787 (7th Cir. 2015) (quoting *Wis. Alumni Research Found. v. Xenon Pharm., Inc*., 591 F.3d 876, 882 (7th Cir. 2010)).

To avoid summary judgment, the nonmoving party must go beyond the pleadings and "set forth specific facts showing that there is a genuine issue for trial." *Liberty Lobby*, 477 U.S. at 250. Summary judgment is proper if the nonmoving party "fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Ellis v. CCA of Tennessee LLC*, 650 F.3d 640, 646 (7th Cir. 2011) (quoting *Celotex*, 477 U.S. at 322). The non-moving party "must do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). In other words, the "mere existence of a scintilla of evidence in support of the [non-movant's] position will be insufficient; there must be evidence on which the jury could reasonably find for the [non-movant]." *Liberty Lobby*, 477 U.S. at 252.

III. Analysis

Relator brings this case under the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3729 *et seq*. ("FCA"). To state a claim under the FCA, Relator must show that R1 "knowingly present[ed], or cause[d] to be presented, a false or fraudulent claim for payment or approval," 31 U.S.C. § 3729(a)(1)(A), or "knowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to a false or fraudulent claim," *id.* § 3729(a)(1)(B); see also *United States v. Walgreen Co*., 417 F. Supp. 3d 1068, 1084 (N.D. Ill. 2019).

Relator alleges that R1 caused legally false claims for "inpatient" hospital services to be submitted by R1's hospital clients to Medicare and Medicaid. These claims consist of claims for "inpatient" hospital services for patients (1) originally classified by hospital physicians as only in

medical need of "observation" (or other "outpatient") services, (2) who R1 then classified as "inpatient" for the purpose of its billing recommendations, and (3) for whom R1's hospital clients then submitted a claim for "inpatient" services to Medicare or Medicaid. Relator asserts that this subset of claims is "legally false" because they violate two separate legal conditions that are placed on any hospital's entitlement to be paid for Medicare or Medicaid claims: (1) compliance with the Anti-Kickback Act, 42 U.S.C. § 1320a-7b(b); and (2) federal regulations and other sources of authority requiring that the treating hospital physician maintain control over any decision to "admit inpatient." See [278] at 7.

In her motion for partial summary judgment [261], Relator focuses on the portion of her FCA claim that is premised on underlying violations of the Anti-Kickback Act, 42 U.S.C. § 1320a-7b(b) ("AKA"). Relator argues that the subset of claims identified above violate 42 U.S.C. § 1320a-7b(b)(1)(B), which provides in relevant part:

> (1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind--
> …
> (B) in return for … arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony …

"[A] claim that includes items or services resulting from a violation of [the AKA] constitutes a false or fraudulent claim for purposes of" the FCA. 42 U.S.C. § 1320a-7b(g); see also *Stop Illinois Health Care Fraud, LLC v. Sayeed*, 957 F.3d 743, 749 (7th Cir. 2020).

Relator argues that R1's solicitations of and receipts from fees-for-recommendations contracts with hospitals and hospitals systems, including in the twenty contracts attached to her Local Rule 56.1 statement, violated Section 1320a-7b(b)(1)(B) as a matter of law and therefore

claims resulting from those violations also violate the FCA. In particular, Relator seeks summary judgment on three issues and an order concluding that:

1. R1's solicitations of and receipts from fees-for-recommendations contracts with hospitals and hospital systems (including the twenty contracts attached to Relator's Local Rule 56.1 statement) violated 42 U.S.C. § 1320a-7b(b)(1)(B), a provision of the AKA, as a matter of law.

2. Each claim submitted to Medicare or Medicaid by an R1 client hospital for payment for "inpatient" hospital services, which resulted from a violation of the AKA, constitutes a "false claim" as a matter of law for purposes of the FCA.

3. R1 agreed and conspired with the hospital and hospital systems with which it had the twenty contracts to knowingly cause to be presented to Medicare or Medicaid claims for "inpatient" hospital services that as a matter of law were false claims in violation of 31 U.S.C. § 3729(a)(1)(C).

In its motion for summary judgment [265], R1 argues that neither the AKA nor federal regulations requiring physician control over patient admission decisions prohibit hospitals from paying external consultants like R1 to provide compliant patient admission status recommendations.

For the reasons explained below, both parties' motions for summary judgment are denied. At a minimum, there are material factual disputes and multiple inferences that could be drawn from the record concerning whether (1) R1 was paid remuneration in return for recommending "upgrades" to inpatient status; (2) if so, whether R1 acted knowingly and willfully; and (3) whether R1 conspired with its hospital clients to commit FCA violations.

A. Industry Practice

Before examining the statutory language of the FCA and AKA, the Court considers R1's overarching argument that if Relator's theory of liability were accepted, it would "criminalize a widely accepted and relied upon compliance service that benefits hospitals, patients, and the government." [266] at 29. Relator, of course, disputes R1's conclusion that its business practices

are widely accepted. The Court agrees that R1's attempt to show that the Government has somehow endorsed or approved of its business practices is underwhelming and insufficient to entitle R1 to summary judgment.

As an initial matter, R1 does not contend that its business practices fall under any "safe harbor" provision or exception to the AKA, which is the typical way in which an exception to the AKA is carved out for business practices that otherwise technically may run afoul of the statute. Cf. *United States v. George*, 171 F. Supp. 3d 810, 818 (N.D. Ill. 2016) (explaining that once the Government has demonstrated proof of each element of AKA violation, the "burden shirts to the defendant to establish that his conduct was protected by a safe harbor or exception); see also 42 U.S.C. § 1320a-7b(b)(3)(A) through (K); 42 C.F.R. § 1001.952. Nor does R1 point to an advisory opinion by a regulatory body indicating that R1's business model would not subject it to prosecution for AKA violations.[2] R1 argues that it nonetheless would be inappropriate as a matter of law to conclude that it has violated the AKA or FCA, because CMS has suggested that it approves of the use of outside physician advisors like R1's to review patient admission classifications.

R1 relies first and primarily on a few lines from a CMS notice of proposed rulemaking from 2012. See [267] at 33, Ex. 1. R1 repeatedly quotes this notice for the proposition that "CMS

[2] Compare for instance, OIG Advisory Opinion No. 00-1, 2000 WL 35747411 (Mar. 16, 2000), in which the HHS Office of Inspector General opined that a consulting firm's contractual payment arrangements for the performance of auditing services to identify hospital undercharges and overcharges associated with private payors would not be subject to sanctions for violating the AKA. *Id.* at *1. The OIG concluded that the arrangement posed "a limited risk of fraud or abuse under the anti-kickback statute" because (1) the company seeking the opinion "has certified that the Arrangement does not involve Federal health care program business, directly or indirectly"; (2) "the principal activity under the Arrangement is a one-time, wholly retrospective billing audit," and "[s]uch audits raise few questions under the anti-kickback statute because where items or services have been entirely ordered, provided, and claimed prior to the audit, there is little risk that the audit will involve an improper referral under the anti-kickback statute"; and (3) "the prospective portions of the Arrangement … are limited in nature and present few, if any, opportunities for spillover effects on Federal health care program." *Id.* at *3.

has encouraged hospitals to 'utilize all of the tools necessary' to ensure appropriate initial admission classification decisions, including through increased use of nonphysician resources such as 'case management and utilization review staff'"—which R1 apparently interprets to include itself. [266] at 13-14; see also *id.* at 23. Considered in context, however, the notice appears to have little relevance to the legal issues in this case. It recognizes the difficulty that some hospitals were having in determining whether patients should be admitted as inpatients and seeks input on how these difficulties could be alleviated. The notice discussed a number of options, including developing "more specific clinical criteria for admission and payment," "requiring prior authorization for payment of an admission," or "aligning payment rates more closely with the resources expended by a hospital when providing outpatient care versus inpatient care of short duration," which "might reduce payment disparities and influence financial incentives and disincentives to admit." [267] at 37 (quoting 77 Fed. Reg. 45157 (July 30, 2012)).

CMS concludes: "Finally, we are asking commenters to consider the responsibility of hospitals to utilize all of the tools necessary to make appropriate initial admission decisions. We believe this is important because some hospitals have indicated that simply having case management and utilization review staff available to assist in decisionmaking outside of regular business hours may improve the accuracy of admission decisions." *Id.* Read in context, it is apparent that CMS's use of the term "case management and utilization review staff" is referring to *hospital* staff. See [267] at 36 ("Hospitals have indicated that often they do not have the necessary staff (for example, utilization review staff or case managers) on hand after normal business hours to confirm the physician's decision to admit the beneficiary. Thus, for a short stay, the hospital may be unable to review and change a beneficiary's patient status from inpatient to outpatient prior to discharge …."). R1 points to nothing in the notice that expressly or implicitly

sanctions the hiring of an outside consultant to provide recommendations on patient classifications—either as a blanket proposition or on the specific record here (which, as explained below, includes at least some evidence that could be interpreted as R1 touting the PAS program's ability to increase the revenues a hospital collects from Medicare).

R1 also compares its "external physician advisors" to QIOs, which are "private consulting firms contracting with CMS to provide hospitals with concurrent and retrospective reviews of various quality and utilization issues, including patient admission classification status." [267] at 14. As R1 recognizes, QIOs contract with *CMS*, not the hospitals whose classifications are under review; its loyalties are completely different than those of an independent company hired by a hospital with the hopes (encouraged by R1) of obtaining a revenue "boost." QIOs have no incentive to inflate patient classifications to collect additional compensation from the Government.

R1 further maintains that "[e]xternal physician advisors are also sometimes offered or suggested as a corrective action to be taken by hospitals audited by the Government." [267] at 15. The Court has reviewed the supporting materials provided by R1, which consist of three Medicare compliance reviews performed by the Office of Inspector General for billing in the 2010-2014 time period, as well as exhibits including the hospitals' responses to the audits. See [267], Exs. 41-43. All three hospitals had been found to have overbilled Medicare. The references to "external physician advisers" are contained in the hospitals' response letters; two hospitals stated that they would use such advisers, see [267], Exs. 41 & 41, and one blamed an incorrect classification decision on an external physician adviser, *id.*, Ex. 43. No detail is provided about the advisers, their services, or their business models. While the letters suggest that CMS is aware of the existence of companies similar to R1, there is nothing in the exhibits indicating that the Government has recommended or sanctioned the use of external physician advisers to review

patients' admission status, either generally or under a fee arrangement and other facts comparable to those in this case.

Apart from these sources, R1 relies primarily on a declaration from Dr. Hirsh, its Vice President of Regulations and Education for the PAS business. Dr. Hirsh states in his declaration that, "[b]ased on my experience as the Medical Director, Case Management at Advocate Sherman Hospital and in my current role at R1, it is my understanding that it is a common industry practice for hospitals to retain third party firms such as R1 to assist them by providing recommendations as to whether patients should be classified as inpatient or outpatient for billing purposes." [267] at 58. Dr. Hirsh opines that he "believe[s] CMS is well aware of the common industry practice of utilizing external physician advisors to improve the accuracy of admission classification decisions," because he regularly participates in CMS's "Open Door Forums" and conference, where he introduces himself and his role at R1. *Id.* at 58-59. Dr. Hirsh continues that "R1 is one of at least six firms of its kind that provides utilization review services to hospitals." *Id.* at 60. "Based on conversations with case managers and hospital physicians at conferences and during educational sessions, it is [Dr. Hirsh's] understanding that R1's recommendations as to admission classification status tend to be more conservative (*i.e.*, more frequently recommending that patients are classified at a lower status) than those of its competitors." *Id.*

Relator challenges Dr. Hirsh's testimony on several grounds. First, she points out that the parties agreed in their Joint Report on Discovery and Dispositive Motions Schedules that "[n]o party will be permitted to introduce testimony or opinions of an expert witness as a basis to alter or supplement the evidence offered in support of or in opposition to any motion for summary judgment." [250] at 2. The Court agrees with Relator that at least parts of Dr. Hirsh's declaration go beyond his personal knowledge into the province of expert testimony—in particular, his

speculation concerning what is "common industry practice" and the industry practices of which CMS is "aware."

Dr. Hirsh has not been offered or qualified as an expert witness, so he must be evaluated as a lay witness. For lay witnesses like Dr. Hirsh, "[t]estimony about matters outside their personal knowledge is not admissible, and if not admissible at trial neither is it admissible in an affidavit used to support or resist the grant of summary judgment." *Visser v. Packer Engineering Assocs., Inc.*, 924 F.2d 655, 659 (7th Cir. 1991); see also Fed. R. Civ. P. 56(c)(4) (affidavits "must be made on personal knowledge, set out facts that would be admissible in evidence, and show that the affiant or declarant is competent to testify on the matters stated"). "It is true that 'personal knowledge' includes inferences—all knowledge is inferential—and therefore opinions." *Visser*, 924 F.2d at 659. "But the inferences and opinions must be grounded in observation or other first-hand personal experience" and "must not be flights of fancy, speculations, hunches, intuitions, or rumors about matters remote from that experience." *Id.*; see also *Outley v. City of Chicago*, 354 F. Supp. 3d 847, 866 (N.D. Ill. 2019); *Uncommon, LLC v. Spigen, Inc.*, 305 F. Supp. 3d 825, 852 (N.D. Ill. 2018).

Dr. Hirsh's inferences concerning "common industry practice" and "what CMS knew" appear to be based on little more than speculation. Dr. Hirsh claims that there are at least six other companies providing "utilization review services to hospitals," but does identify these companies, nor compare their operations to R1's other than claiming that R1's recommendations are somehow more "conservative." In short, nothing in Dr. Hirsh's declaration convinces the Court that CMS has endorsed R1's business model so heartily that it would be improper as a matter of law to find R1 liable for an AKA violation or, in turn, a violation of the FCA.

B. "Recommending … any … service"

The next issue raised by the parties' motions is whether recommending that a patient (whose treating physician previously determined that outpatient/observation status was appropriate) should be admitted as an inpatient constitutes recommending a "service" in exchange for remuneration as prohibited by the AKA. The Medicare Act defines "service" as "medical care or services and items, such as medical diagnosis and treatment, drugs and biologicals, supplies, appliances, and equipment, medical social services, and use of hospital, CAH, or SNF facilities." 42 C.F.R. § 400.202.

R1 maintains that its recommendations on admission status do not constitute recommendations for ordering services because "R1 does not provide recommendations as to medical care or any of the other services listed" in the Medicare Act. [285] at 1-2. Instead, R1 "provides recommendations regarding whether the documentation in the medical record appropriately supports a classification status of inpatient or outpatient based on applicable rules and regulations." *Id*. Put another way, "classifying patients as observation or inpatient relates to payment and coverage, not to patient care." [266] at 29. According to R1, this is "not the type of recommendations that the [AKA] forbids." *Id*.

Neither party provides any case law interpreting the relevant statutory language in a similar factual context. Looking at the plain language of the statute, however, the Court is not convinced that R1 is entitled to summary judgment based on its argument that its physician advisers do not recommend the ordering of a "service" to its hospital clients when they recommend "upgrading" an outpatient to an inpatient admission. Several of R1's physicians testified that inpatient and outpatient services fall into distinct buckets of "services" for purposes of Medicare. See [279-1] at 27 (Dr. Weinberg admitting that Medicare defines inpatient services as distinct from outpatient

services and pays for them differently); [279-1] at 26 (Dr. Hirsh stating "Medicare says that any service provided to an inpatient is an inpatient service and services provided to outpatients are outpatient services"); [279-1] at 43 (Dr. Manzano acknowledging he is aware that Medicare treats inpatient services as a distinct set of medical services from outpatient services). When Medicare is billed for any services provided on an inpatient basis, the provider is seeking compensation for "medical care or services," 42 C.F.R. § 400.202—regardless of whether that same care or service might have been labeled something else for purposes of billing. Put another way, there is nothing in the statutory language that limits application of the AKA to recommendations that result in the patient *actually receiving different care* than he or she would have received if the recommendation had not been given. Nor has R1 identified any case law suggesting that this is a relevant distinction for purposes of applying the AKA. Even if it were, there is a material dispute concerning whether a patient classified as inpatient receives identical care to an outpatient. For instance, Dr. Manzano admitted that "inpatient" hospital case is presumed to be "more aggressive than outpatient care." [278] at 11; see also *id.* n.14. This makes sense, as Medicare pays on average $5,000 more for inpatient services than it does for outpatient services.

As noted above, R1 claims that its PAS service does not run afoul of the AKA because it does not result in the overutilization of services or supplies. But the opposite inference could also be drawn from the summary judgment record. The AKA "was enacted to 'protect the Medicare and Medicaid programs from increased costs and abusive practices resulting from provider decisions that are based on self-interest rather than cost, quality of care or necessity of services.'" *United States v. Patel*, 778 F.3d 607, 612 (7th Cir. 2015) (quoting Health Res. & Serv. Admin., Program Assistance Letter 1995–10, Guidance on the Federal Anti–Kickback Law, available at http://bphc.hrsa. gov/policiesregulations/policies/pal199510.html (last visited February 2, 2015));

see also *United States ex rel. Young v. Suburban Homes Physicians*, 2017 WL 6625940, at *4 (N.D. Ill. Dec. 28, 2017) (explaining that the "congressional purpose animating" the AKA is "to protect patients and the Medicare program from increased costs and abusive practices resulting from provider decisions clouded by improper financial considerations" (internal quotations marks and citation omitted)). R1 essentially admits that, from the perspective of Medicare, "upgrading" a patient to inpatient status results in "increased costs"—an average of $5,000 per patient. See [285] at 10-11. This is in the hospital client's self-interest, and in turn R1's self-interest, because it makes the PAS program more attractive to clients. But it is not based on concerns about quality of care or necessity of services. R1 admits—and indeed repeatedly emphasizes—that the classification of a patient does not affect the "quality of care" or the services provided by the treating physician or hospital staff.

B. "Remuneration in return for"

The Court now examines whether the per-review fees charged by R1 constitute "remuneration in return" for recommending that R1's hospital clients admit as inpatients individuals who were already classified as outpatient/observation by their treating physicians. As a preliminary matter, the parties dispute what the term "in return for" means, as used in 42 U.S.C. § 1320a-7b(b)(1)(B). This term is not defined in the statute. See *Jones-McNamara v. Holzer Health Systems*, 630 Fed. Appx. 394, 400 (6th Cir. 2015). R1, relying on the Sixth Circuit's opinion in *Jones-McNamara*, argues that "[t]he phrase 'in return for' has been treated as a necessary corollary of 'inducement,' meaning a defendant cannot be found liable for receiving remuneration 'in return for' that which has not been 'induced.'" [266] at 24; see also *Jones-McNamara*, 630 F. App'x at 401 (explaining that the meaning of the term "induced" also "sheds light on the meaning of the phrase 'in return for,' which applies to the recipient of remuneration,

implying that the recipient must be duly induced or 'move[d]'"). According to R1, courts (at least those in other circuits) have "interpreted 'to induce' within the [AKA] as meaning the 'intent to exercise influence over the reason or judgment of another in an effort to cause the referral of program-related business.'" [266] at 25 (quoting *Hanlester Network v. Shalala*, 51 F.3d 1390, 1398 (9th Cir. 1995); citing *United States ex rel. Osheroff v. Tenet Healthcare Corp*., 2012 WL 2871264, at *8 (S.D. Fla. July 12, 2012)). Of course, this case does not involve referrals, so R1 maintains that Relator must prove that "R1 agreed to allow its reason or judgment as to whether a patient was properly classified as inpatient or observation to be corrupted by the per-review fee it received regardless of the content of the recommendation." *Id*.

It is not clear from the parties' briefs or the Court's research whether the Seventh Circuit would interpret "in return for," as used in 42 U.S.C. § 1320a-7b(b)(1)(B), to include an "inducement" requirement framed in the manner urged by R1. Assuming it would, the Court must consider the out-of-circuit case law cited by R1 in conjunction with the body of Seventh Circuit case law recognizing that "'nothing in the [AKA] implies that only the primary motivation of remuneration is to be considered in assessing' the conduct at issue." *United States v. Nagelvoort*, 856 F.3d 1117, 1130 (7th Cir. 2017) (quoting *United States v. Borrasi*, 639 F.3d 774, 782 (7th Cir. 2011)). Instead, if "part of the payment compensated" activities prohibited by the AKA (in that case referrals or future referrals), "that portion of the payment" violates the AKA. *Id*.; see also *Borrasi*, 639 F.3d at 781 (rejecting AKA defendant's argument to "adopt a 'primary motivation' doctrine, under which the trier of fact would determine the defendants' intent in any given case and find them not guilty if the primary motivation behind the remuneration was to compensate for bona fide services provided"); *United States v. Moshiri*, 858 F.3d 1077, 1082 (7th Cir. 2017) (evidence was sufficient to show that defendant, a physician, knowingly and willfully violated

AKA where he received check from hospital knowing he was being paid at least in part for patient referrals rather than the duties outlined in his contract as director of hospital program and that he was aware of AKA's prohibitions); cf. *United States v. Rogan*, 517 F.3d 449, 453 (7th Cir. 2008) (holding that a hospital administrator who had been found to have violated the FCA based on filing over 1800 Medicare and Medicaid reimbursement claim forms that omitted material information—namely, that illegal referrals had occurred and kickbacks were paid in violation of the Stark Amendment to the Medicare Act, 42 U.S.C. § 1395nn, and the AKA, 42 U.S.C. § 1320a–7b—could be required to repay to government the entire amount the hospital received on those claims, regardless of whether patients for whom claims were submitted received some, or even all, of the medical care reflected in the claim forms). Further, "[a] facially legitimate exchange may constitute unlawful remuneration if the surrounding circumstances support the inference that the exchange was intended as an illicit inducement." *United States ex rel. Young v. Suburban Homes Physicians*, 2017 WL 6625940, at *3 (N.D. Ill. Dec. 28, 2017).

In evaluating the parties' motions, the Court accepts that at least part of the purpose of R1's PAS program was to help its hospital clients comply with Medicare rules for classifying patients. The Court also recognizes that Relator does not intend to offer proof that any recommendation was medically (or otherwise factually) inaccurate. See [278] at 23. And the Court keeps in mind that the parties have agreed to defer fact discovery on damages and expert discovery until after the Court rules on summary judgment. With all this in mind, the Court concludes there is sufficient evidence in the record—which may be bolstered or weakened based on further discovery—from which a reasonable juror could conclude that another motivation for all of the cases in which patients were "upgraded" to inpatient status was boosting the amount that R1's hospital clients could collect from Medicare—around $5,000 per case. It is easy to see how a representation that

R1 had recommended and defended "upgrades" in 30-40% of all observation cases, even with a disclaimer that R1 couldn't promise any particular results, could encourage—and could be interpreted as trying to encourage—hospital clients to pay R1's per review fees in exchange for recommending converting admissions to inpatient.

Assuming as a general proposition there is a valid role for outside physician advisors to play in reviewing the patient classification decisions made by hospitals' treating physicians, there are nonetheless several decisions that R1 made in implementing the PAS program that support an inference that both R1 and its hospital clients were motivated by the goal of increasing payments from Medicare, rather than achieving compliance with Medicare regulations. First, R1 allowed its hospital patients to choose to send it only cases in which the treating physician ordered outpatient/observation care. The only potential result of the PAS program implemented in this manner would be an increase in reimbursement to the hospital, since R1 would not be looking at any cases originally classified as inpatient. R1 emphasizes that, in a sample set of fourteen hospitals, a majority of the cases sent to R1 for review were initially classified as inpatient, and in some cases, R1 recommended aggregate status change "conversions" that would have resulted in decreased revenue if the recommendations were followed. However, R1 does not discuss how the sample was selected or whether it is representative of the results it obtained for all of its hospital clients. Relator cannot provide this information, because the parties agreed to defer fact discovery on damages and all expert discovery until the Court rules on summary judgment. Many unanswered questions remain. How many hospitals chose to send R1 cases in which their treating physicians recommended inpatient admission? How often were those decisions overturned, and how did the financial impact of such decisions compare to the financial impact of "upgrades"? Such statistical data may strengthen or weaken the parties' positions.

Second, R1 acknowledges that the treating physician must ultimately be responsible for making the patient classification decisions. [267] at 2-3; [285] at 17 (citing 42 C.F.R. § 412.3(b)). Yet there is evidence in the record that would support a reasonable inference that R1 trained treating physicians and medical staff in a manner designed to cause them to defer to R1's judgment without question, despite their initial determinations that inpatient admission was unnecessary: First, R1 emphasized that its recommendations were for billing purposes only and affect the hospital's revenue, so there was no reason for the physician to change his or her clinical judgment to accept R1's recommendations. Second, R1 told treating physicians and medical staff that R1's physician reviewers were better qualified to make classifications determinations than hospital physicians or staff. Third, Dr. Hirsh testified that he told hospital physicians and staff that they would be breaking federal law and risked going to jail if they made incorrect classification decisions—a warning that understandably got their attention. One permissible inference from these facts is that R1 was seeking not to train hospital physicians and staff about how to make the correct classifications themselves, but rather to ensure that they accepted R1's recommendations without resistance—which was necessary in order for the hospital clients to realize the "revenue boost" that (historically and on an aggregate basis) R1 was able to obtain for other hospitals.

Third, the language R1 chose to use in its marketing materials and reports to hospital clients bolsters the emphasis on a profit motive: R1 spoke in terms of hospitals' "return on investment"—*i.e.*, the amount they could expect to collect in increased revenue, as compared to the amount they spent on R1's physician advisers. R1 used terms like "upgrade" and "lift," implying a judgment that it is better for a patient to be admitted as an inpatient, because inpatient services are more highly compensated by Medicare. R1's own choice of language undermines its claim that the sole purpose of its PAS program was compliance, and that any effect on its hospital clients' revenue

was by happenstance. These facts, taken together and considered along with the record as a whole, convince the Court that a jury should be allowed to determine whether the per-review fees charged by R1 in the subset of cases identified by Relator constitute "remuneration in return" for recommending that R1's hospital clients "upgrade" patients to inpatient status.[3]

C. "knowing and willful"

The Court now turns to whether there are any material factual disputes concerning whether R1's alleged violations of the AKA were "knowing and willful." To establish a knowing and willful violation of the AKA, "the Government must prove that Defendant intended to engage in conduct that he knew was wrongful, though it need not prove that he was aware of the specific statutory provisions that he is alleged to have violated." *Patel*, 17 F. Supp. 3d at 824; see also *United States ex rel. Suarez v. AbbVie Inc.*, 2019 WL 4749967, at *13 (N.D. Ill. Sept. 30, 2019). "The Seventh Circuit has suggested that one way to give content to 'willfully' is to require that 'a defendant know that his conduct was in some way unlawful.'" *United States v. Williams*, 218 F. Supp. 3d 730, 736 (N.D. Ill. 2016) (quoting *United States v. Wheeler*, 540 F.3d 683, 690 (7th Cir. 2008)).

Here, the record could be interpreted either way by a reasonable factfinder. From R1's perspective, it is one of a number of companies that offers physician advisory services reviewing inpatients vs. outpatient classifications to ensure compliance with Medicare regulations. R1

[3] R1 has brought to the Court's attention a case that was filed against one of its competitors in the Eastern District of Pennsylvania, *Polansky v. Executive Health Resources, Inc.*, No. 12-cv-4239, concerning similar business practices. See [267] at 639, Ex. 65. The relator in that case did not bring any AKA-based claims—according to R1, because the relator "apparently recogniz[ed] the lack of legal foundation for the theory." [266] at 30. However, R1 cites to nothing in the record of that case suggesting that anyone ever considered the viability of an AKA claim. The Court will not presume based on silence that anyone determined such a claim lacked merit. More generally, while R1 faults Relator for failing to identify any AKA or FCA cases involving similar facts that survived summary judgment, R1 does no better in identifying any remotely on-point case law supporting its position.

openly marketed this program to potential hospital clients, suggesting that R1 in no way believed that anything it was doing was wrongful.

But other facts point to the opposite conclusion. R1 admits that the treating physician is responsible for determining a patient's admission status. Yet, in training hospital physicians about its PAS program, R1 used a number of tactics that, viewing the record in the light most favorable to Relator, encouraged and were intended to encourage treating physicians to adopt R1's recommendations without question and without consideration of the factors required by Medicare regulations. R1 claims that "[i]f a hospital wanted to implement aggressive inpatient admission policies for the purpose of making additional revenue, it makes little sense to pay R1 a per-review fee in furtherance of a goal that the hospital could accomplish on its own." [266] at 32. But R1 does not explain how a hospital would convince its treating physicians to participate in such a scheme. Even if a hospital could, there is obvious utility in hiring a third party like R1 to come up with a justification for inpatient admission, worded in the way Medicare expects, and convince the hospital's doctors to change their initial determination that inpatient admission was not necessary. The potential return on the $185 per-case "investment" in R1's PAS service is huge: an average of $5,000 in additional compensation from Medicare for each case in which the hospital follows R1's recommendation to admit inpatient. See [278] at 9 & n.5; [285] at 11.

Relator also contends that it would be "wholly illogical" to conclude that R1 engaged in a scheme to "upgrade" patients "without regard to medical necessity," since "R1's contracts with its hospital clients provide that R1 will defend the first two levels of appeals at no additional cost if a hospital client follows R1's inpatient recommendation and that inpatient admission status is later denied as not medically necessary by Medicare." [266] at 33. However, the Court cannot even begin to assess this argument without information concerning how often Medicare denies an

inpatient admission as not medically necessary and how often Relator's hospital clients choose to appeal Medicare's decisions.

Finally, in assessing the evidence of R1's state of mind, the Court finds it noteworthy that multiple R1 executives acknowledged in their depositions that it would be improper to promise hospitals that their revenues would increase if they used R1's service—which is precisely what R1 is alleged to have done here, though by implication rather than express promise. For instance, Dr. Hirsh testified he would not want to participate in soliciting a potential new hospital client by representing that it would "make your hospital more money by getting your hospital more inpatient claims" because "the return on investment from our company is compliance. … There is not guaranteed financial return." [279-2] at 16-17. Dr. Pamela Ann Mulshine testified: "It's wrong to say that we can give you more inpatients. What we can do is look at your cases, see if it justifies inpatient or not." [279-4] at 23-26. And Dr. Weinberg also agreed that it would be wrong to state in a sales pitch that "we will increase your revenue by showing you how to get more inpatients billed." [279-5] at 18-19. The witnesses' care in distinguishing between their PAS program and quite similar, but purportedly improper, programs could be viewed as implying that R1 knew there was a risk the PAS program might also run afoul of the AKA or be improper in some way, yet accepted payments from its hospital clients anyway.

D. First Amendment

In response to Relator's motion for partial summary judgment—but not in its own motion for summary judgment, see [295] at 17 n.8—R1 argues that "Relator's flawed interpretation" of the AKA, "as applied to R1, abridges R1's and its physician advisors' freedom of speech, in violation of the First Amendment," and entitles Relator to summary judgment. [283] at 34. According to R1, Relator "seeks to impose liability on R1 for the recommendations that R1's

physician advisors provide to their hospital clients and for the representations R1 made in marketing the PAS program to prospective hospital clients." *Id*. at 33. Relator contends that this is a content-based regulation of speech, which is subject to strict scrutiny, under which it is "Relator's burden to show that there is a compelling government interest in imposing AKS liability on R1 for its truthful and compliant admission status recommendations." *Id*. at 35.

The Court is not inclined to consider a grant of summary judgment to R1 based on an argument raised for the first time in its response brief. But even if everything R1 says about First Amendment law were correct—a matter the Court need not and does not address—R1 would not be entitled to summary judgment due to material factual disputes.

"It is well settled that First Amendment rights are not immunized from regulation when they are used as an integral part of conduct which violates a valid statute." *California Motor Transport Co. v. Trucking Unlimited*, 404 U.S. 508, 514 (1972). Thus, "it has never been deemed an abridgement of freedom of speech or press to make a course of conduct illegal merely because the conduct was in part initiated, evidenced, or carried out by means of language, either spoken, written, or printed." *Giboney v. Empire Storage & Ice Co*., 336 U.S. 490, 502 (1949). As the Supreme Court has cautioned, "[s]uch an expansive interpretation of the constitutional guaranties of speech and press would make it practically impossible ever to enforce … many … agreements and conspiracies deemed injurious to society." *Id*.

In this case, there are disputed questions of material fact concerning whether the R1 physician advisors' recommendations to upgrade cases to inpatient admission, as provided to hospitals in the context of the PAS program, were "Medicare-compliant." [283] at 36. If a factfinder were to conclude that the recommendations were provided in return for remuneration, they may not be "Medicare-compliant" because they violate the AKA. Likewise, the

recommendations may not be "Medicare-compliant" if they were intended to override the medical judgment of the treating physician, whom Medicare regulations require make patient admission decisions. These issues cannot be resolved at summary judgment.

E. Conspiracy

Most of the parties' arguments in support of summary judgment on Relator's conspiracy claim rehash points the Court has already addressed. First, R1 asserts that because Relator cannot prove an underlying FCA violation, her conspiracy claims also fail. Since there are material questions of fact that preclude summary judgment on the FCA claim, neither party is entitled to summary judgment on the conspiracy claim, either.

Second, R1 argues that Relator's alleged "fees-for-recommendations" scheme does not support a conspiracy claim under the FCA because Relator's theories all rely on underlying violations of "other substantive laws," such as the AKS and Medicare regulations. [266] at 50. R1 cites *United States ex rel. Lisitza v. Par Pharmaceutical Companies, Inc.*, 276 F. Supp. 3d 779, 808 (N.D. Ill. 2017), for the proposition that "[i]f the conspiracy … is not to violate the FCA, but to engage in a course of conduct that violates some other substantive laws such as Medicaid laws and regulations, it falls outside the FCA's conspiracy provision." [266] at 50. However, *Lisitza* did not involved an alleged underlying AKA violation. And R1 ignores that, pursuant to a 2010 amendment, the FCA now expressly provides that "a claim that includes items or services resulting from a violation of [the AKA] constitutes a false or fraudulent claim for purposes of" the FCA. 42 U.S.C. § 1320a-7b(g); see also *Health Care Fraud, LLC*, 957 F.3d at 749; *United States ex rel. Grenadyor v. Ukranian Village Pharmacy, Inc.*, 895 F. Supp. 2d 872, 881 (N.D. Ill. 2012); *United States ex rel. Kester v. Novartis Pharmaceuticals Corp*., 43 F. Supp. 3d 332, 363 (S.D.N.Y. 2014);

United States ex rel. Kroening v. Forest Pharmaceuticals, Inc., 155 F. Supp. 3d 882, 887 (E.D. Wis. 2016).

Third, R1 claims that there is no evidence of any agreement to defraud the government but rather, "[g]iven R1's agreement to pay for appellate costs, R1 has a financial incentive to make compliant recommendations based on CMS guidance, not to erroneously 'upgrade' patients to inpatient." [266] at 51. One reasonably inference to be drawn from the facts is that the $185.00 per-review fee that R1 received for each case it reviewed provided a financial incentive to "upgrade" admission recommendations. It is true, as R1 points out, that it charges the same fee regardless of its recommendation. But given its hospital clients' interest in their financial bottom line, it is not an unreasonable inference that they would stop using R1's services if they provided no financial upside. In sum, neither side is entitled to summary judgment on the conspiracy claim.

IV. Conclusion

For the foregoing reasons, Relator's motion for partial summary judgment [261] and R1's motion for summary judgment [265] are both denied. Counsel are directed to file a joint status report no later than December 15, 2020.

Dated: November 30, 2020

Robert M. Dow, Jr.
United States District Judge