UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

UNITED STATES OF AMERICA *ex rel.*
SAMUEL L. ARMFIELD, III, and
PATRICIA ARMFIELD,

Plaintiffs,

vs. **Case No. 8:07-CV-2374-T-27TBM**

JAMES P. GILLS, *et al.*,

Defendants.
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ORDER

BEFORE THE COURT is Defendants' Motion for Summary Judgment (Dkt. 387) on Counts II and III of the Fourth Amended Complaint and Relators' opposition (Dkt. 404). The parties have filed various supplemental memoranda and documentation related to the Motion for Summary Judgment (*see, e.g.,* Dkts. 444, 459, 462, 466).[1] Argument on the motion was heard on October 17, 2012.

Relators' allegations in Counts II and III are particularly troubling. The gravity of Relators' contentions required considerable deliberative study. Relators essentially accuse Defendants of Medicare fraud based on allegedly false claims on which even Relators concede reasonable minds could differ. But for the medical opinions of Sylvia Norton, and the coding and coverage explanations of Barbara Scott and Susan Garrison, summary judgment in favor of Defendants would

[1] Summary judgment in favor of Defendants as to Count I of the Relators' Corrected Second Amended Complaint was previously granted (Dkt. 249) (restated in Count I of the Fourth Amended Complaint). Defendants' motion for summary judgment as to Count IV of the Fourth Amended Complaint was denied. *See* Orders (Dkts. 330, 461).

be granted. However, a resolution of the parties' respective contentions depends, for the most part, on the credibility of the parties' respective experts and whether a reasonable jury could find, if indeed Defendants' Medicare claims were not reimbursable, that they were submitted with knowledge that they were not reimbursable.

While there is certainly some question[2] whether Relators will be able persuade a jury that Defendants knowingly submitted false claims to Medicare as alleged in Counts II and III, for purposes of summary judgment, Defendants have not demonstrated that no reasonable jury could find for Relators on Counts II and III of the Fourth Amended Complaint. More specifically, disputed issues of material fact exist as to whether the claims submitted by Defendants were false and if so, whether Defendants acted knowingly in submitting the claims. Accordingly, Defendants' Motion for Summary Judgment (Dkt. 387) is due to be denied on both Counts.

Introduction

In this *qui tam* action filed under the False Claims Act and the federal anti-kickback statute, Relators' Fourth Amended Complaint asserts claims against Defendants for fraudulent billing of lens rotations disguised as lens repositions (Count II) and fraudulent billing for duplicative evaluation and management services (Count III). *See* Fourth Amended Complaint (Dkt. 362, pp. 20, 35).

[2] The Court is not the trier of fact. Notwithstanding, some observations of the parties' respective contentions are inescapable in evaluating whether a reasonable jury could find in favor of Relators. Defendants present compelling explanations for their conduct from a medical perspective. They offer sound, logical expert opinions and persuasive argument in support of summary judgment. To avoid summary judgment, Relators rely on what they contend are disputed issues of material fact based on inferences drawn form Defendants' patient charts and standard procedures, a comparison of Defendants' Medicare billing practices with various regulatory provisions applicable to Medicare claim submissions, and the opinions of their experts. Essentially, Relators' opposition can be succinctly stated: Reasonable minds could differ on whether Defendants' Medicare claims were knowingly false. Applying summary judgment principles, a jury will have to resolve these contentions.

In their Motion for Summary Judgment, Defendants argue that they cannot be held liable on Counts II and III because the challenged claims were proper and, even if erroneous, were based on objectively reasonable interpretations of ambiguous regulatory provisions precluding a finding that they acted with actual knowledge, deliberate ignorance, or reckless disregard with respect to the falsity of such claims. Relators respond that disputed issues of material fact preclude summary judgment in favor of Defendants.

Factual Background

On March 29, 2005, Dr. James P. Gills performed a "comprehensive" bilateral eye examination on Relator Samuel Armfield, M.D. (Dkt. 412, ¶ 9.14). During the examination, Dr. Armfield underwent tests to assess twelve ophthalmic parameters, including Snellen visual acuity, intraocular pressure, pupillary function, confrontation visual field, extra-ocular muscle integrity, fundus, *etc.* *Id.* at ¶ 9.15. Dr. Gills diagnosed Dr. Armfield with mature cataracts in both eyes. *Id.* at ¶ 9.16. Medicare was billed for this examination under CPT Code 99204[3] with a surgery-decision modifier ("57").[4] *Id.* at ¶ 9.14.

Dr. Gills performed cataract surgery on Dr. Armfield's right eye on April 22, 2005. *Id.* at ¶ 9.17. During the surgery, Dr. Gills implanted a "toric" prosthetic intraocular lens ("**IOL**"). An IOL replaces the function of the natural lens removed during cataract surgery. Conventional IOLs can correct for nearsightedness and farsightedness. In addition, a toric lens can correct for astigmatism. *Id.* at ¶ 9.18.

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[3] Current Procedural Technology ("**CPT**") codes are developed by the American Medical Association ("**AMA**"). CPT Code 99204 refers to an office or other outpatient visit for the evaluation and management of a new patient.

[4] A surgical decision modifier reflects a decision was made during the examination regarding surgery on the same or subsequent day.

Facts Relating to Count II

Five days after his cataract surgery (April 27, 2005), Dr. Armfield complained of blurred vision in his right eye. *Id.* at ¶ 9.19. On April 28, 2005, he was examined by Dr. Gills at the Institute's office. Dr. Gills determined that Dr. Armfield's vision difficulty was caused by a "toric malpositioning" and that the toric lens implanted in Dr. Armfield's right eye required adjustment. A lens repositioning procedure was scheduled for the following day. *Id.* at ¶ 9.20.

On April 29, 2005,[5] Dr. Gills successfully repositioned Dr. Armfield's right eye IOL, rotating the toric lens from the 93° axis to the 63° axis. *Id.* at ¶ 9.22.[6] This procedure was performed in the "minor procedure room" at the Institute. *Id.* at ¶ 9.23. Medicare was billed for the procedure using CPT Code 66825-78RT[7] and ICD-9-CM Code 996.53.[8] *Id.* at ¶ 9.24.

Facts Relating to Count III

During his visit to the Institute on April 28, 2005, Dr. Armfield was also examined in anticipation of cataract surgery on his left eye, which had been scheduled for the following day. *Id.* at ¶ 9.30. In many respects, this examination was similar to that performed by Dr. Gills on both of

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[5] Dr. Armfield returned to the Institute on April 29, 2005 for the lens repositioning procedure and cataract removal surgery in his left eye. *Id.* at ¶ 9.21. He proceeded with the repositioning procedure but opted to cancel the cataract surgery on his left eye. *Id.* at ¶ 9.35.

[6] The repositioning of the toric lens was performed with a needle inserted through the site of the prior incision. *Id.* at ¶¶ 9.26, 9.27.

[7] CPT Code 66825 states: "Repositioning of intraocular lens prosthesis, requiring an incision (separate procedure)." The "78" modifier reflects an "unplanned return to the operating/procedure room, by the same physician or other qualified health care professional following initial procedure for related procedure during the postoperative period."

[8] ICD-9 Code 996.53 refers to a "mechanical complication of prosthetic ocular lens prosthesis."

Dr. Armfield's eyes during the initial comprehensive examination on March 29, 2005. *Compare id.* at ¶ 9.15 with *id.* at ¶ 9.31. For example, during the examination, Dr. Armfield underwent tests that assessed eight ophthalmic parameters. One of the parameters (intraocular pressure), showed increased pressure in both eyes. *Id.* at ¶ 9.31.

Medicare was billed for that portion of the office visit on April 28, 2005 related to the decision for surgery on Dr. Armfield's left eye using CPT Code 99213[9] with modifier "24" (indicating that the service was unrelated to the first cataract surgery) and modifier "57" (indicating that the decision to perform cataract surgery on the second eye was made during the examination). *Id.* at ¶ 9.32. Dr. Gills' standard practice is to perform, and then bill for, a patient exam after the patient has had cataract surgery on one eye and before cataract surgery on the second eye. *Id.* at ¶ 9.33.

Summary Judgment Standard

Summary judgment is proper if, following discovery, the pleadings, depositions, answers to interrogatories, affidavits and admissions on file show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986); Fed. R. Civ. P. 56(c). "An issue of fact is 'material' if, under the applicable substantive law, it might affect the outcome of the case." *Hickson Corp. v. N. Crossarm Co.*, 357 F.3d 1256, 1259-60 (11th Cir. 2004). "An issue of fact is 'genuine' if the record taken as a whole could lead a rational trier of fact to find for the nonmoving party." *Id.* at 1260. All the

[9] CPT Code 99213 relates to the evaluation and management of an established patient, usually involves a physician meeting with the patient and/or family for approximately 15 minutes, and requires at least two of the following three components: (1) An expanded problem focused history; (2) An expanded problem focused examination; (3) Medical Decision making of low complexity.

evidence and factual inferences reasonably drawn from the evidence must be viewed in the light most favorable to the nonmoving party. *Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 157 (1970); *Jackson v. BellSouth Telecomms.*, 372 F.3d 1250, 1280 (11th Cir. 2004).

Once a party properly makes a summary judgment motion by demonstrating the absence of a genuine issue of material fact, the nonmoving party must go beyond the pleadings through the use of affidavits, depositions, answers to interrogatories and admissions on file, and designate specific facts showing that there is a genuine issue for trial. *Celotex*, 477 U.S. at 323-24. The evidence must be significantly probative to support the claims. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). The Court will not weigh the evidence or make findings of fact. *Anderson*, 477 U.S. at 249; *Morrison v. Amway Corp.*, 323 F.3d 920, 924 (11th Cir. 2003). Rather, the Court's role is limited to deciding whether there is sufficient evidence upon which a reasonable jury could find for the non-moving party. *Id.*

Discussion

A claim under Section 3729(a) requires proof of "(1) a false or fraudulent claim; (2) which was presented, or caused to be presented, by the defendant to the United States for payment or approval; (3) with the knowledge that the claim was false." *United States ex rel. Walker v. R&F Props. of Lake County, Inc.*, 433 F.3d 1349, 1355 (11th Cir. 2005). For conduct occurring before May 20, 2009, the FCA generally imposes civil liability on any person who "knowingly presents, or causes to be presented, to an officer or employee of the United States Government ... a false or fraudulent claim for payment or approval," 31 U.S.C. § 3729(a)(1) (2009), or who "knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent

claim paid or approved by the Government," 31 U.S.C. § 3729(a)(2) (2009).[10] In this context, "knowingly" means the person "(1) has actual knowledge of the information [submitted in the claim for payment]; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b).[11]

Claims submitted for payment under the Medicare program may be false "if they claim reimbursement for services or costs that either are not reimbursable or were not rendered as claimed." *Walker*, 433 F.3d at 1356 (citations omitted). "[A] claim may be false even if the services billed were actually provided, if the purported provider did not actually render or supervise the service." *United States v. Mackby*, 261 F.3d 821, 826 (9th Cir. 2001) (citing *Peterson v. Weinberger*, 508 F.2d 45, 52 (5th Cir. 1975).[12]

Count II – Falsity

Relators' claim in Count II has three components: (1) false use of CPT Code 66825 for the lens repositioning procedure because it was not performed in an operating room; (2) false use of CPT Code 66825 for the lens repositioning procedure because the repositioning constitutes a refractive procedure which is not covered by Medicare; and (3) the lens repositioning procedure was not medically necessary.

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[10] The FCA has been amended twice since this case was filed in the Fraud Enforcement and Recovery Act of 2009, Pub. L. No. 111-21, 123 Stat. 1617 and in the Patient Protection and Affordable Care Act of 2010, Pub. L. 111-148, 124 Stat. 119.

[11] In defining "knowingly" to include deliberate ignorance of the truth, Congress attempted "to reach what has become known as the 'ostrich' type situation where an individual has 'buried his head in the sand' and failed to make simple inquiries which would alert him that false claims are being submitted." *United States v. Bourseau*, 531 F.3d 1159, 1168 (9th Cir. 2008) (quoting S. Rep. No. 99-345, at 21 (1986), as reprinted in 1986 U.S.C.C.A.N. 5266, 5286).

[12] The Eleventh Circuit adopted as binding precedent all decisions the former Fifth Circuit made prior to October 1, 1981. *Bonner v. City of Prichard*, 661 F.2d 1206, 1209 (11th Cir. 1981).

A return trip to the operating room

Relators contend that "CPT 66825 requires a return trip to the operating room" and that Defendants' claims were false because the toric lens rotation procedures were performed in Defendants' minor procedure room rather than in an operating room. In this regard, Relators contend that Defendants falsely certified that they complied with Florida regulatory requirements for the repositioning procedure which were prerequisites to receiving payment from Medicare. Specifically, Relators contend Defendants' in-office minor procedure room did not meet the Florida regulatory requirements for Level II surgeries. Defendants counter that the post surgery repositioning procedure performed on Dr. Armfield constituted a Level I surgery with topical anesthesia, their minor procedure room is exclusively used for surgical procedures, and that the minor procedure room met all Florida regulatory requirements for a Level I surgical procedure.

A claim may be legally false under an implied certification theory when a claimant makes no express statement regarding compliance with a statute or regulation, but by submitting a claim for payment, implies that he has complied with preconditions of payment expressly contained in the relevant statute or regulation. *Mikes*, 274 F.3d at 699-700. "Under an implied false certification theory ... the analysis focuses on the underlying contracts, statutes, or regulations themselves to ascertain whether they make compliance a prerequisite to the government's payment." *United States ex rel. Conner v. Salina Reg'l Health Ctr., Inc.*, 543 F.3d 1211, 1218 (10th Cir. 2008) (citation omitted).

Relators' contention that Defendants' use of CPT Code 66825 was false because the rotation procedure was performed in a "minor procedure room" as opposed to an operating room is not persuasive. Although Defendants' expert, Kevin Corcoran, conceded that in order for office surgery

to be reimbursed by Medicare, the surgery must be performed in conformance with state law, *See* Deposition of Kevin Corcoran (Dkt. 404-10, p. 160), Relators have not demonstrated *material* factual disputes with respect to whether Defendants' minor procedure room met the Florida regulatory requirements for a Level I surgery, or that the procedure did not constitute a Level I procedure.

By use of modifier "78" to CPT 66825, Defendants indicated a complication requiring a return trip to the operating room for the related cataract surgery. On this record, Defendants' minor procedure room appears to meet Medicare's definition of operating room "as a place of service specifically equipped and staffed for the sole purpose of performing procedures." Defendants' witnesses confirm, without conflicting evidence, that the minor procedure room is equipped, staffed and used for surgical purposes. *See* Deposition of James Gills (Dkt. 387-24, p. 132)("It's a special room where no exams take place and only minor surgical facilities are present. It has a operating room, it has a surgical keratometry to look at the astigmatism . . . it's just like a minor-surgical-procedure room."). The only issue, therefore, is whether the repositioning procedure constituted a Level I or Level II surgery.

Level I procedures are defined as those where medication is limited, anesthesia is local or topical, and the chances of complications requiring hospitalization are remote. Fla. Admin. Code 64B8-9.009 (3)(a). Level II procedures, on the other hand, involve anesthesia: "peri-operative medication and sedation . . . altering the level of consciousness." Fla. Admin. Code 64B8-9009(4).

It is undisputed that Dr. Armfield's IOL repositioning procedure was performed under "[t]opical and intraocular" anesthesia, that is, "[t]he eye was anesthetized . . ." Indeed, Relators expressly incorporate Dr. Gill's surgical notes in Count II: "Local anesthesia was used." (Dkt. 362,

¶ 70). Defendants have demonstrated that the procedure constituted a Level I surgery and therefore Relators' contention that Defendants' use of CPT Code 66825 with a modifier "78" was false is refuted by the undisputed facts.

Relators' reliance on the medical file of "Patient RB" does not raise an issue of *material* fact in this regard. It is apparent from Patient RB's file that RB returned to the surgery center for a post operative rotation of his lens because the lens was "dislocated," as opposed to "[o]ff axis," like Dr. Armfield's. That likely accounts for the different anesthetic approach and the longer procedure in RB's case. In any event, RB's procedure was not identical to the one performed on Dr. Armfield, as Relators contend, and nothing in RB's patient records demonstrates that Defendants' use of the minor procedure room for Dr. Armfield's post operative lens repositioning rendered their initial certifications impliedly false. Finally, contrary to Relators arguments, no registration is required for offices performing Level 1 surgeries. Fla. Admin. Code 64B-4.003(1)(a); 64B8-9.0091.

Refractive procedures are not covered by Medicare

Arguing that Medicare excludes coverage for all refractive procedures, Relators contend that Defendants' Medicare claims for the post surgical toric lens repositionings were false because the rotations were performed solely as refractive procedures to correct pre-existing astigmatism, rather than as a separate surgical procedure necessitated by a mechanical complication of an IOL implant as contemplated by CPT 66825.

Defendants argue that Dr. Armfield's vision difficulties after cataract surgery were caused by a "toric malpositioning," diagnosed as a "mechanical complication due to ocular lens prosthesis." Defendants contend that their use of CPT 66825 was correct because that code encompasses the "repositioning of intraocular lens," which requires an incision (separate procedure), which they

accomplished by use of a needle to reposition the lens. Further, Defendants contend that even if use of CPT 66825 was erroneous, their use of CPT 66825 was "based on objectively reasonable interpretations of ambiguous regulatory provisions, which precludes any finding of actual knowledge, deliberate ignorance, or reckless disregard of their truth or falsity."

This issue arising from Relators' contention boils down to whether a post surgical toric lens repositioning is merely a refractive astigmatism correction procedure which is not covered by Medicare, as Relators contend, or whether the repositioning was performed to correct a mechanical complication due to a "malpositioned prosthetic device," as Defendants contend.

To a large extent, a resolution of this issue depends on an interpretation of governing regulations, to which the parties offer differing interpretations. Relators point to various regulatory and statutory provisions in support of their contention that refractive procedures are universally not covered by Medicare. For example, Relators contend that 42 U.S.C. § 1395y(a)(7) excludes coverage for "refractive services." Actually, that section excludes coverage for "procedures to determine the refractive state of the eyes." The post surgical lens repositioning at issue certainly is not a procedure to determine the refractive state of the eye. Notwithstanding, Medicare's Benefit Policy Manual, as Relators point out, expressly excludes from coverage "eye refractions by whatever practitioner and for whatever purpose performed" and "[e]xpenses for all refractive procedures . . .".

Relators also rely on the acknowledgments of Dr. Gills and his son in their depositions that the rotation procedure is used to correct preexisting astigmatism after the initial cataract surgery, *See* Deposition of James Gills, Jr., M.D. (Dkt. 404-1, pp. 162-63, 170; Deposition of James Pitzer Gills, III, M.D. (Dkt. 404-2, pp. 121-22, 125-26). and in his deposition, Dr. James Gills seems to agree that

"the rotation of the toric lens . . ." could be described "as 'refractive surgery to correct preexisting astigmatism.'" (Dkt. 404-1, p. 173).

On the other hand, Defendants' expert, Dr. Charles B. Slonim opines: "Just because the procedure to reposition a misaligned IOL will improve the patient's vision does not make it a 'refractive" procedure; it is still a procedure to correct a malpositioned lens." Dr. Slonim explains: " The rotation of an astigmatic-correcting toric intraocular lens (IOL) does not constitute "refractive surgery" or cosmetic surgery or a refractive procedure that Medicare does not reimburse. Instead, this procedure repositions an out-of-position IOL implant." Further, he opines: "An out-of-position IOL is described by diagnosis code ICD-9-CM 996.53: 'Mechanical complication of prosthetic ocular lens prosthesis,'" and the 'procedure to address that condition is described by CPT Code 66825. '" (Dkt. 387- 4, p. 1).

Accordingly, based on Dr. Slonim's opinions, it remains unclear on this record whether post surgical toric lens rotations intended to treat pre-existing astigmatism are universally excluded from coverage by Medicare, as Relators contend, or constitute a covered procedure properly coded by CPT Code 66825. Additionally, disputed facts exist as to whether and/or in what circumstances these rotations were medically necessary or required to correct a mechanical complication following surgery. *See, e.g.*, Deposition of James Gills, Jr., M.D. (Dkt. 404-1), p. 162 ("The medical file we had in all cases justified the patient's needs and desires to have the astigmatism corrected."); Deposition of Sylvia Norton, (Dkt. 385 - 1, p. 7)("The functionality of A-C IOLs is not a covered benefit of Medicare;" pp. 7 - 9).[13]

[13] At a minimum, it is debatable whether a rotation of a toric lens necessitated when the astigmatism correction was not achieved based on the originally calculated lens alignment represents a "mechanical complication" for purposes of diagnosis code ICD-9-CM 996.53 ("Mechanical complication of prosthetic ocular lens prosthesis.").

Defendants argue that Medicare's previous payment of a premium for the insertion of astigmatism correcting IOLs demonstrates that Medicare has never excluded coverage for procedures to correct complications with those devices. In 1999, Medicare enacted a policy whereby it would pay a "flat premium in the amount of $50, over and above the payment allowance already included in the ASC fee for a standard IOL" in an effort to "encourage beneficiary access" to new technology IOLs (including astigmatism-correcting IOLs). *See* 64 Fed. Reg. 32198, 32203 (June 6, 1999).[14] New technology IOLs were defined as those with "specific clinical advantages and superiority over existing IOLs with regard to reduced risk of intraoperative or postoperative complication or trauma, ... reduced induced astigmatism, ... or other comparable clinical advantages." *Id.* at 32206. Medicare indicated that it believed "the fiscal impact of this rule will be negligible" and recognized that new technology IOLs "will substitute for spectacles in some cases, and in others will allow the patient to wear a single vision prescription rather than bifocals." *Id.* at 32205.

While it may be true that for a period of time Medicare paid a premium for the insertion of new technology IOLs, that does not necessarily lead to the conclusion that Medicare intended to cover a second surgical procedure (*i.e.,* toric lens rotations) performed solely to advance the astigmatism correcting function of toric IOLs. Indeed, Medicare will generally not cover the original cataract surgery when performed "solely to improve vision ... [when] [g]lasses or visual aids provide satisfactory functional vision ... ." Local Coverage Determination (LCD) for Cataract Extraction (L29095) (Dkt. 387-19, p. 2).

Moreover, at least with respect to claims submitted after January 2007, there is evidence in the record suggesting that toric lens rotations intended to correct pre-existing astigmatism were not

[14] The new technology IOL status for astigmatism-correcting IOLs expired on May 18, 2005.

covered by Medicare. In 2007, the Centers for Medicare & Medicaid Services provided additional guidance relating to the "payment for insertion of intraocular lenses that replace beneficiaries' natural lenses and correct pre-existing astigmatism following cataract surgery." CMS Ruling 1536-R (Jan. 22, 2007), p. 1. Specifically, CMS concluded:

> [T]he astigmatism-correcting functionality of an IOL does not fall into the benefit category and is not covered. Any additional provider or physician services required to insert or monitor a patient receiving an astigmatism-correcting IOL are also not covered. For example, eye examinations performed to determine the refractive state of the eyes following insertion of such an IOL are non-covered.

Id. at p. 4. That is, Medicare does not pay for "[f]acility or physician services and resources required to insert and ***adjust*** an astigmatism-correcting IOL following cataract surgery that exceed the services and resources furnished for insertion of a conventional IOL." CMS Manual System Pub. 100-04, Transmittal 1228, "Instructions for Implementation of CMS 1536-R" (Apr. 27, 2007) (emphasis added). Similarly,

> There is no Medicare benefit category that allows payment of physician charges for ***subsequent treatments, services,*** and supplies required to examine and monitor a beneficiary following removal of a cataract with insertion of an astigmatism-correcting IOL that exceed the physician charges for services and supplies to examine and monitor a beneficiary following removal of a cataract with insertion of a conventional IOL.

Id. (emphasis added).[15]

[15] As a result, "[p]rior to a procedure to remove a cataractous lens and insert an astigmatism correcting lens, the facility and the physician must inform the beneficiary that Medicare will not make payment for services that are specific to the insertion, ***adjustment, or other subsequent treatments*** related to the astigmatism-correcting functionality of the IOL." *Id.* (emphasis added).

Procedure not medically necessary

Relators contend that the repositioning procedures are not considered medically necessary for Medicare reimbursement purposes because the patients' astigmatism can be corrected with contacts or eyeglasses, pointing out that Medicare only pays claims for benefits that are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A).

Regardless of whether toric lens rotations designed to correct pre-existing astigmatism are *per se* non-reimbursable, the procedure must still be medically necessary to be reimbursable by Medicare. *See* Expert Report of Kevin Corcoran (Dkt. 387-22, p. 3); Supplemental Expert Report of Kevin Corcoran (Dkt. 387-13, p. 4).[16] Whether the toric lens rotations were medically necessary, however, is an issue vigorously contested by the parties and the subject of competing expert opinions. *See, e.g.*, Deposition of Sylvia Norton, M.D. (Dkt. 404-6, pp. 125-26). Specifically, it remains controverted whether, as Relators argue, a lens rotation intended to correct a misaligned axis after cataract surgery performed "for the purpose of refractive error compensation" is a non-covered "eye refraction" procedure which is "considered a substitute or alternative to eye glasses or contact lenses, and is thereby excluded by [42 U.S.C. § 1395y(7)]." *Cf.* Medicare Coverage Issues Manual, Health Care Financing Administration, Department of Health and Human Services, Transmittal 131 (Nov. 22, 2002), § 35-54 ("radial keratotomy and keratoplasty to treat refractive defects are not covered" because they are considered a "substitute or alternative to eye glasses or contact lenses").

[16] While Corcoran suggests that a rotation is reimbursable by Medicare in most circumstances, he notes: "In extraordinary cases requiring an IOL exchange (CPT 66986), Medicare will likely cover the procedure if glasses and contact lenses have failed and no less invasive option exists." *Id.* at 4. Corcoran does not explain, however, why a rotation is reimbursable regardless of whether glasses or contact lenses could remedy the purported "complication."

Considering the facts in a light most favorable to Relators as the non-moving party, genuine issues of material fact preclude summary judgment in favor of Defendants on the medically necessary component of Count II.

Conclusion as to Count II

Since the parties proffer competing expert opinions with regard to the scope and interpretation of the applicable regulatory provisions, including the Ruling and Transmittal, and the medical necessity of a repositioning of the lens for Medicare purposes, the weight to be afforded those opinions will involve a credibility determination inappropriate for summary judgment. Construing the facts and reasonable inferences in the light most favorable to Relators as the non-moving party, disputed issues of material fact preclude summary judgment in favor of Defendants on Count II. However, no material facts are in dispute with respect to Relators' contention that the minor procedure room did not comply with applicable Florida regulations, or that the procedure was not a Level I surgery. Evidence on this contention will not be admitted during trial.

Count III – Falsity

In Count III, Relators contend that Defendants' claims for payment for the office visit after the first cataract surgery to determine the need for cataract surgery on the second eye were false because (1) the surgical decision had already been made prior to the second examination and (2) Defendants did not actually furnish the services required to justify the use of CPT Code 99213. Relators also contend that claims arising from decisions for surgery made by optometrists were false because under Florida law (as incorporated by Medicare), an optometrist is not permitted to make a decision for surgery. *See* Fla. Stat. § 463.014(4); Fla. Admin. Code 64B8-9.007.

Medicare allows for reimbursement for an office visit within the global period of a surgery when the office visit is unrelated to the surgery. *See* Medicare Claims Processing Manual, Ch. 12, § 40.1(B). Modifier 24 is used to indicate that the visit falls within the global surgery period. Id., § 40.2(7). Medicare also allows payment for an office visit during which the decision for surgery is made. *Id.*, § 40.2(4). Modifier 57 is used to indicate that decision. The visit and examination must be medically necessary and actually performed in full. 42 U.S.C. § 1395y(a)(1)(A).

Medicare claims for "evaluation and management" of a patient for purposes of diagnosis or treatment are submitted using CPT Code 99213. Defendants utilized CPT Code 99213 with Modifiers 24 and 57 in submitting Medicare claims for the examination of the patient before cataract surgery on the second eye, indicating that the visit was unrelated to the first surgery and that the decision for surgery on the second eye was made at that time.

Relators contend that the decision to perform surgery on the second eye was made by Defendants during the initial surgical consultation and that Defendants' use of Modifier 57 to indicate that the decision to perform cataract surgery on the patient's second eye was made during the second visit after surgery on the first eye was therefore false. Relators also argue that the second examination was not medically necessary or not performed in full, essentially because the qualifying testing was already performed on the patient during the initial surgical examination.

Relators acknowledge the testimony of Myra Cherchio that the "plan for surgery on the second eye is not *finalized* until after the first cataract surgery is performed." Notwithstanding, Relators maintain that Cherchio's "statements in and of themselves indicate that a decision for surgery on both eyes has been made at the time of the first appointment." Relators rely on representative patient files to support their contentions, arguing that "'reasonable minds' could

disagree as to whether Defendants' use of Modifier 57 on its 99213-24-57 claims was knowingly false."[17]

Relators also point out that Defendants allow optometrists to make the decision to perform surgery on the second eye in approximately 40% of the cases. They proffer that optometrists are not authorized to perform surgery in Florida and that Florida law "places responsibility for diagnosing and treating surgical problems on the licensed doctor of medicine who is to perform the procedure," citing Fla. Adm. Code, 64B8-9.007. Relators argue that Defendants' claims for the decisions for surgery made by optometrists are therefore false as not in compliance with Florida law and accordingly non-reimbursable by Medicare.

Finally, Relators' expert, Sylvia Norton, M.D., in addressing the propriety of submitting claims to Medicare for the examination of a cataract patient after the first eye surgery but before surgery on the second eye, opines that "[a] comprehensive bilateral eye examination which discloses no conditions that would pose a risk of complication during cataract surgery constitutes the medically required grounds for a decision to conduct bilateral cataract with IOL implant surgery . . ." (Dkt. 385 - 1, p. 13). After reviewing Dr. Armfield's charts and finding no "evidence of any issue that would militate against the decision to conduct, after April 22, 2005, cataract with IOL implant surgery on Dr. Armfield's left eye," and noting that it was Defendants' standard practice to conduct a second examination before surgery on the second eye, Dr. Norton concludes that the second examination was "nonsensical," and "[t]here was no medically reasonable or necessary basis that

[17] Two examples relied on by Relators is Defendants' failure to perform one of the cataract surgical qualifying tests, glare testing, during the second visit. Relators point out that this testing was performed during the initial surgical consultation on both eyes, demonstrating, at least in Relators' view, that the decision to perform cataract surgery on the second eye had already been made and that the second examination, performed the day after surgery on the first eye, was not medically necessary, or not fully performed (Dkt. 459, pp. 6 - 8).

would justify Dr. Gills' billing of Medicare for the April 28, 2005 examination of Dr. Armfield's left eye." *Id.* at p. 14. She opines that "the later examination did not result in the decision to conduct surgery on Dr. Armfield's left eye. That decision had been made at least six days before." *Id.*

Defendants dispute Relators' contentions, arguing that "Medicare unambiguously requires a patient assessment before any decision to perform surgery," citing 42 U.S.C. § 1395y. Defendants acknowledge that they "routinely perform another examination to determine whether and how to proceed" (Dkt. 387, p. 13). Relying on the opinions of Dr. Slonim and Kevin Corcoran, Defendants argue that "the final decision to proceed with the second eye surgery, and confirmation that there is medical necessity to operate on the second eye after the first cataract surgery, has long been recognized as a Medicare requirement" (Dkt. 387, p. 13).[18]

Although it may be, as Defendants urge, and Dr. Slonim opines, that good medical practice dictates that the decision to operate on the second eye be made (or reevaluated) after surgery on the first eye, it does not necessarily follow that an examination during which the surgical decision is "finalized" is reimbursable by Medicare. Clearly, Dr. Norton's opinions that the second examination on Dr. Armfield was not medically necessary and therefore not reimbursable demonstrates the existence of disputed issues of material fact. The jury will have to resolve the differing opinions of Drs. Norton and Slonim. At a minimum, therefore, the record contains conflicting evidence as to whether the decision for surgery on the second eye was made at the initial comprehensive

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[18] Dkt. 387- 4, p. 3 (Dr. Slonim): "I believe that it was appropriate for Dr. Gills to have billed Medicare for the exam he performed of Dr. Armfield's left eye in anticipation of cataract surgery on that eye, following Dr. Armfield's first cataract surgery on his right eye . . . Medicare does require, however, that a patient be examined prior to cataract surgery to determine the medical necessity for that surgery"); Dkt. 387 - 13, p. 6 (Kevin Corcoran): "Eye surgeons must examine their patients prior to cataract surgery on a second eye, and this examination may take place very shortly after cataract surgery has been performed on the patient's first eye. In my professional opinion, not only is such an examination required, but it is appropriately billed to Medicare for eligible patients").

examination or the second examination, whether the second examination was medically necessary, and whether submission of a claim for reimbursement using Modifier 57 was false and knowingly submitted.

Moreover, even if the second examination was reimbursable, the examination must have been actually performed in a manner warranting the use of CPT Code 99213. Disputed issues of material fact exists with respect to whether the use of the surgical decision Modifier 57 in connection with examinations performed by optometrists was knowingly false. Finally, as noted earlier, disputed issues of material fact exist with respect to whether Defendants actually performed the services required to justify the use of CPT Code 99213.

In sum, construing the facts and reasonable inferences in the light most favorable to the non-moving party, disputed issues of material fact exist which preclude summary judgment in favor of Defendants on Count III.

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Defendants contend that, because their interpretations of Form 1500 and the CPT Codes were objectively reasonable (even if incorrect), their certifications could not, as a matter of law, have been ***knowingly*** false under the FCA. *See Safeco Ins. Co. of America v. Burr*, 551 U.S. 47, 70 n.20 (2007); *see also United States ex rel. Hixson v. Health Mgmt. Sys., Inc.*, 613 F.3d 1186, 1190 (8th Cir. 2010) ("[A] statement that a defendant makes based on a reasonable interpretation of a statute cannot support a claim under the FCA if there is no authoritative contrary interpretation of that statute. That is because the defendant in such a case could not have acted with the knowledge that the FCA requires before liability can attach.") (citing 31 U.S.C. § 3729(b)(1) and referring also to *Safeco*, 551 U.S. at 70 n.20). Relators respond by arguing that Defendants willfully turned a blind

eye to their Medicare billing and failed to take reasonable steps to ensure that their claims were accurate.

The evidence of record, together with reasonable inferences to be drawn therefrom, could support a jury determination that Defendants acted with deliberate ignorance or reckless disregard. On the other hand, a reasonable jury could conclude that Defendants were merely taking advantage of ambiguous regulations and/or disputed legal questions. *See Hixson*, 613 F.3d at 1190 ("[W]e agree with the Ninth Circuit's holding that a defendant does not act with the requisite deliberate ignorance or reckless disregard by 'tak[ing] advantage of a disputed legal question.'") (quoting *Hagood v. Sonoma County Water Agency*, 81 F.3d 1465, 1478 (9th Cir. 1996) (internal quotation omitted)).

Relators have introduced evidence from which a reasonable jury could infer that Dr. James Gills and Dr. Pit Gills failed to properly supervise the preparation and submission of Medicare claims. *See* Deposition of James Gills, Jr., M.D. (Dkt. 404-1), pp. 196-97, 202; Deposition of James Pitzer Gills, III, M.D. (Dkt. 404-2), pp. 103, 108, 133-34. While these doctors are not required to personally prepare Medicare claims, they must take reasonable steps to ensure that claims submitted on their behalf are accurate. *See United States v. Stevens,*, 605 F.Supp.2d 863, 867 (W.D. Ky. 2008) (citing *U.S. v. Krizek*, 111 F.3d 932, 942 (D.C. Cir. 1997)).

Relators also point to the timing of Defendants' decision to begin charging for astigmatism lenses and correction of astigmatism, including toric lens rotations, as evidence that Defendants acted knowingly. In this regard, the record suggests that prior to 2005, Defendants did not charge for procedures designed to correct astigmatism based on an understanding that astigmatism-correcting procedures were not covered by Medicare. *See* Deposition of James Gills,

Jr., M.D. (Dkt. 404-1), pp. 116-17 ("Q. Were they covered by Medicare or not covered by Medicare? A. They probably were not.").[19] Beginning in or about 2005, in response to "economic problems," Defendants began charging for toric lens rotations designed to correct astigmatism purportedly based on the advice of one or more consultants. *Id.* at pp. 117-18, 162-63, 170.

That Defendants may have submitted the claims on the advice of one or more consultants is not controlling, based on the current record. *See United States v. Lorenzo*, 768 F.Supp. 1127, 1132 (E.D. Pa. 1991) (discounting reliance on advice of healthcare consultant when advice was based on flawed assumption). While good faith reliance on an expert's advice may refute the contention that Defendants acted knowingly, Defendants must demonstrate that they disclosed all material facts to the expert and that they relied in good faith on the expert's advice that the submitted claims were properly reimbursable. *See United States v. Condon,* 132 F.3d 653, 656 (11th Cir. 1998). The record is not entirely clear as to the nature of the advice relied on by Defendants and the timing of that advice. For example, the earliest written advice in the record relating to reimbursement for toric lens rotations is in a letter dated December 7, 2009. *See* Expert Report of Kevin Corcoran (Dkt. 387-22, Attachments). At a minimum, disputed issues of material fact exist as to the timing and nature of the advice Defendants claim to have relied on in submitting the claims.

As Relators have submitted evidence from which a reasonable jury could infer that Defendants submitted claims in deliberate ignorance of whether their certifications were accurate, disputed issues of material fact preclude summary judgment in favor of Defendants. *See, e.g.*,

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[19] This statement, considered in its proper context, was a reference by Dr. Gills to procedures used over the years to correct astigmatism in general, including "astigmatic surgery," and use of lenses and correction of astigmatism," as opposed to IOL rotations specifically. He indicated, however, that "our use of lenses and correction of astigmatism has not changed before or after the charge." (Dkt. 404, pp. 116 - 117).

United States ex rel. Taylor-Vick v. Smith, 513 F.3d 228, 231 (5th Cir. 2008) (noting that cases which turn on the moving party's state of mind are not-well suited for summary judgment); *International Shortstop, Inc. v. Rally's Inc.*, 939 F.2d 1257, 1265 (5th Cir. 1991) (same); *see also Rogers v. Evans*, 792 F.2d 1052, 1059 (11th Cir. 1986) ("Ordinarily, summary judgment should not be granted in cases where motive, intent, subjective feelings, and reactions are to be searched.").[20]

Conclusion

While Defendants make strong arguments in support of summary judgment, the summary judgment standard requires that all reasonable inferences be drawn in a light most favorable to Relators, the non-moving parties. *See Adickes*, 398 U.S. at 157; *Jackson*, 372 F.3d at 1280. Applying this standard, summary judgment is not appropriate on Counts II and III of the Fourth Amended Complaint, for the reasons discussed. Ultimately, it will be for the jury as the trier of fact to determine whether the preponderance of the evidence supports Relators' claims. Accordingly, Defendants' Motion for Summary Judgment (Dkt. 387) is **DENIED** as to Counts II and III of the Fourth Amended Complaint.

DONE AND ORDERED this 30th day of January, 2013.

JAMES D. WHITTEMORE
United States District Judge

Copies to: Counsel of Record

[20] Defendants recently submitted the Amended Declaration of J. Bradley Houser (Dkt. 444) in which he avers that the Medicare carrier processing Defendants' claims, First Coast, has been paying for the "second" examinations for years under the CPT Code used by Defendants. Furthermore, the Declaration sets forth that subsequent to the filing of the pending motion for summary judgment, First Coast began making inquiries with respect to the coding of the "second" examination and after receiving requested documentation, continued to pay for the "second" examinations as coded by Defendants. For the reasons discussed in Relators' Response (Dkt. 459), these facts are not dispositive with respect to whether Defendants knowingly submitted the claims at issue in Count III.