

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

UNITED STATES OF AMERICA and
the State of TENNESSEE, *ex rel.* GARY
ODOM and ROSS LUMPKIN, O.D.,

Plaintiffs,

vs.

SOUTHEAST EYE SPECIALISTS,
PLLC, SOUTHEAST EYE SURGERY
CENTER, LLC, EYE SURGERY
CENTER OF CHATTANOOGA, LLC,
DARYL F. MANN, O.D. and JOHN R.
BIERLY, M.D.

Defendants.

Case No: 3:17-cv-00689

Chief Judge Waverly D. Crenshaw, Jr.

FIRST AMENDED COMPLAINT FOR
VIOLATION OF FEDERAL FALSE CLAIMS
ACT, 31 U.S.C. § 3729, *et seq.* and
TENNESSEE MEDICAID FALSE CLAIMS
ACT, Tenn. Code Ann. § 71-5-181, *et seq.*

JURY TRIAL DEMANDED

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Pursuant to the *qui tam* provisions of the federal False Claims Act, 31 U.S.C. § 3729 *et seq.*, (the “False Claims Act” or the “FCA”) and the analogous provisions of the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181, *et seq.* (“TMFCA”), *qui tam* Plaintiff-Relators Mr. Gary Odom and Dr. Ross Lumpkin (hereinafter “Relators”), on behalf of the United States of America and the State of Tennessee, for this Complaint against Defendants SouthEast Eye Specialists, PLLC., (“SEES”), Southeast Eye Surgery Center, LLC., Eye Surgery Center of Chattanooga, LLC., (collectively “SEES Defendants”), Daryl Mann, O.D. and John Bierly, M.D., allege as follows:

I. INTRODUCTION AND OVERVIEW

1. Betraying the fundamental obligation of physicians – to make medical decisions based solely on the best interests of patients – Defendant SEES and its co-founders, Defendants Dr. Mann and Dr. Bierly, place their own financial interests, and the financial interests of optometrists that steer patients to SEES, over the interests of SEES patients.

2. By giving things of value to optometrists, including a portion of its surgical fees and returning the patient for lucrative primary eye care, payments to upgrade procedures, dinners, golf tournaments, tickets to sporting events, continuing education, and numerous other gifts, SEES fully intends to – and does in fact – induce optometrists to refer patients with cataracts to SEES for surgery, enriching both SEES and the optometrists.

3. SEES patients are unaware that their optometrist’s referral to a SEES surgeon and other recommendations about their course of treatment are driven by their optometrist’s financial arrangements with SEES.

4. This deliberate, ongoing scheme violates the Anti-Kickback Statute (“AKS”) which prohibits providing things of value to induce the recommendation or

referral of patients. The purpose of the AKS is to protect patients from medical judgments being clouded by improper financial considerations and to protect federal healthcare programs from the potential for abuses that increase costs. OIG Compliance Program for Individual and Small Group Physician Practices, 65 Fed. Reg. 59,434, 59,440 (Oct. 5, 2000). Payment for referrals can affect the quality of healthcare “by encouraging physicians to order services and supplies based on profit rather than the patients’ best interests” *Id.*

5. The AKS also serves to prevent unfair competition that “shut[s] out competitors who are unwilling to pay for referrals.” *Id.* SEES’ practices stifle ophthalmology competition in Tennessee. Because SEES offers optometrists lucrative financial inducements for referrals, surgeons that comply with the law lose patients to SEES.

6. SEES’ kickback scheme is simple and extremely lucrative, in part because of the nature of cataract surgery, which is one of the most commonly performed elective surgical procedures in the United States (more than 2,000,000 are performed each year).

7. A cataract is the clouding of the natural lens of the eye. The main symptom is blurry vision; having cataracts has been described as like looking through a foggy window. Cataract surgery replaces the natural, cloudy lens with an artificial lens. Cataract surgery is very straightforward and takes only 5 -10 minutes per eye, which means minute-for-minute cataract surgery reimbursement is estimated to be higher than reimbursement for major operations such as coronary artery bypass, carotid endarterectomy and craniotomy.

8. Only ophthalmologists perform cataract surgery. They are medical doctors who specialize in eye problems and perform eye surgery.

9. Optometrists (or ODs) provide primary eye care including eye exams, vision tests, the prescription of corrective lenses and provide management of many

diseases. Optometrists are not medical doctors and are not licensed or trained to perform most eye surgeries, including cataract surgery. However, optometrists frequently diagnose cataracts and when they do they often refer patients to an ophthalmologist for surgery.

10. Congress has generally forbidden payment for referrals in the health care setting. Referrals to a surgeon should be based on the specific medical needs, preferences and convenience of the patient, and the reputation and skill of the surgeon without the influence of improper remuneration.

11. SEES is a self-described “Referral Center” and has stated that it “has no other option” for patients. It only performs surgery and does not render primary eye care. All of its patients come through referrals and SEES is totally dependent on outside optometrists for virtually all of its business. Although SEES employs some optometrists, they do not have their own patients. Their role is to assist the SEES ophthalmologists, by, for example, performing pre-operative evaluations of patients that are referred to SEES.

12. In order to secure a stream of patients, SEES has implemented a scheme to illegally induce optometrists to refer – or steer – cataract patients to it by providing them a variety of forms of financial remuneration.¹ SEES tracks its payments to optometrists and their referrals to SEES in order to evaluate and maximize its “return on investment”. SEES targets certain referrers and has even taken optometrists off SEES’ mailing list for events when they have not referred patients. There is thus no room for doubt that one purpose of SEES’ scheme is to induce optometrists to refer patients to it.

13. SEES’ kickback scheme has several components. First, SEES plies optometrists with a variety of classic financial inducements, including free continuing

¹ Although most referrals to SEES come from optometrists, other eye care providers occasionally refer to SEES. For ease of reference, discussions in this Complaint of inducements to optometrists who refer to SEES encompass such other referring providers.

education (which optometrists are required by State law to take and would otherwise be an expense of the optometrist), free dinners with open bars, lunches for the optometrists and their staff, golf outings, baseball games, and other events. Some high referrers receive inducements like invitations to be on a SEES “Advisory Board” and attend expensive Advisory Board dinners.

14. Second, SEES provides optometrists with financial inducements through its “co-management” model. Under SEES’ model, co-managed “cataract care” is shared by the surgeon who performs the surgery and receives 80% of the fee, and the patient’s optometrist who performs the post-operative exams and receives 20% of the fee. When done lawfully, co-management is designed exclusively for the health, convenience and preference of the individual patient. By way of example, an elderly patient may need to travel a significant distance to a surgical center for cataract surgery. Since the surgery is always done as an outpatient service, the patient returns home only to travel again the next day for the initial post-operative exam – and then repeat the journey a third time days later. Co-management allows the individual patient to choose to receive surgical follow-up care from their regular optometrist’s office rather than the surgeon if it would be more convenient for the patient and deemed medically appropriate by the operating ophthalmologist.

15. The cornerstone of appropriate co-management is patient health, patient convenience and patient choice. SEES has corrupted this patient care model by using it to serve its own interests and the interests of its referring optometrists. SEES unabashedly admits that it has a blanket co-management model that is designed to drive revenue to the referring optometrists. Under the SEES model, referrers and referees routinely conspire to push the patient to have their surgery performed by SEES and to have it co-managed, which renders patient choice illusory. Without that push, SEES founder and Defendant Mann acknowledged, patients would ask “You’re the surgeon, why aren’t you doing the post-operative care?” As a result of SEES’ practice, the

referring optometrists receive a share of the surgical fee for nearly every patient they refer to SEES and a guarantee that SEES will return the patient to the optometrist for lucrative post-operative primary care, which are substantial financial incentives to refer patients to SEES over other surgeons.

16. Finally, SEES induces referrals by paying optometrists to upsell their cataract patients to upgraded premium lenses. During cataract surgery the natural lens is replaced with an artificial lens. While the artificial lens eliminates the “cloudiness” it does not correct for all vision problems- such as astigmatism and/or the need for reading glasses. An upgraded premium lens can help to correct these conditions to reduce the need for glasses or contact lenses. Because neither Medicare nor TennCare pays for premium lenses, that cost is paid by the patient or private insurer. If the patient elects a premium lens, SEES, pays the optometrist \$150 per lens. As with its other inducements, SEES tracks payments of premium lens commissions to referring optometrists.

17. Defendants Daryl Mann and John Bierly, the co-founders, partial owners and officers of the SEES Defendants devised and oversee this vast pay-for-patients scheme. At all times they have each been directly and personally involved in the management, marketing and implementation of this scheme, and personally benefitted from it, with full knowledge that it violated the Anti-Kickback Statute.

18. As a result of this kickback scheme, since at least 2012, the SEES Defendants, under the direction and control of Defendants Mann and Bierly, knowingly submitted and caused the submission of claims to the Medicare and TennCare programs that were false based on Defendants’ violations of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7(b) (the “AKS”). In doing so, the Defendants violated the FCA, 31 U.S.C. § 3729, *et seq.*, and the TMFCA, Tenn. Code Ann. § 71-5-181, *et seq.*

19. Relators Gary Odom and Ross Lumpkin seek, through this action, to recover damages and civil penalties arising from the false or fraudulent records,

statements and/or claims that Defendants knowingly made or caused to be made which resulted in millions of dollars of reimbursement to SEES by the Medicare and TennCare programs for claims that were ineligible for payment because of Defendants' fraudulent scheme and unlawful conduct.

II. PARTIES

A. Relators

20. Relator Gary Odom has served as Executive Director of the Tennessee Association of Optometric Physicians since 1981. He previously served as an Investigator for Tennessee's Division of Health Regulatory Boards, a Special Investigator for the State Attorney General's Office (Nashville), and as a Representative in the Tennessee House of Representatives.

21. Relator Dr. Ross Lumpkin, O.D., is an optometrist currently practicing in Camden, Tennessee. He is a past president of the Tennessee Association of Optometric Physicians. He received his Doctor of Optometry from the Southern College of Optometry in 2010 and has remained in practice over the past eleven years, first in Nashville and presently in Camden, Tennessee.

22. Relators became aware of the fraud as members of the optometric community. Mr. Odom and Dr. Lumpkin began noticing severe declines in optometrist attendance at state association continuing medical education seminars. Relators learned that around 2010 SEES and other practices had begun promoting many more free seminars and dinners. Through reading promotional materials for these practice-sponsored events, word-of-mouth at professional events, and discussions with other practitioners, Relators became aware that SEES and other practices nationwide used routine co- management to induce optometrist referrals. In 2016, Dr. Lumpkin attended a SEES continuing medical education seminar for the first time. There, he personally heard and recorded SEES representatives promoting co-management as a revenue

opportunity for optometrists. Dr. Lumpkin attended additional SEES seminars and heard and recorded similar SEES promotional pitches.

B. Defendants

1. SouthEast Eye Specialists, PLLC

23. SouthEast Eye Specialists, PLLC (“SEES”) is a medical practice group headquartered at 7268 Jarnigan Road, Suite 200, Chattanooga, TN 37421-3097. SEES maintains it is a referral center and only receives patients through referrals from outside optometrists or medical doctors. SEES was founded in 1999 by Defendants Dr. John Bierly and Dr. Daryl Mann and has operated since then. SEES has surgical centers in Chattanooga, Knoxville and Nashville, as well as other satellite offices throughout Tennessee. The SEES surgical group currently includes 11 M.D.s (ophthalmic surgeons) and 10 O.D.s (optometrists), and performs approximately 12,000 cataract surgeries a year.

24. In 2017 SEES was acquired by Flexpoint Ford, LLC (“Flexpoint Ford”), a private equity firm focused on the healthcare and financial services sectors. Flexpoint Ford announced on February 27, 2017 that it formed a partnership with SouthEast Eye Specialists and its affiliates and now has a “stake” in SEES’ practice. SEES Co-Founder Dr. Daryl Mann explained: “We chose to partner with the Flexpoint Ford team based upon their deep experience in healthcare services and understanding of the importance of our practice’s co-management model.” Iris Dorbian, *Flexpoint Ford Backs SEES and Center for Facial Rejuvenation*. PE Hub Network (Feb. 27, 2017).

2. SEES Affiliated Surgery Centers

25. Defendants Southeast Eye Surgery Center, LLC (“SESC”) and Eye Surgery Center of Chattanooga, LLC (“ESCC”) are licensed health care facilities, that operate SEES’ ambulatory surgical treatment centers in Knoxville, Tennessee and Chattanooga, Tennessee, respectively. SEES performs many of the Medicare/Medicaid funded procedures described below at these surgery centers and these centers receive facility and other ancillary fees for SEES’ surgeries.

26. In Knoxville and Chattanooga, SEES has primarily performed its procedures at SESC's and ESCC's facilities. For each Medicare-funded surgery, these centers received additional facility and other fees (including for example anesthesia), typically exceeding the professional/physician fees.

27. SESC's sole officers prior to 2017 were SEES Co-Founders and current officers Defendants Bierly and Mann. Its registered agent was SEES Co-Founder Dr. John Bierly, at 7268 Jarnigan Road, Suite 200, Chattanooga, TN 37421-3097.

28. ESCC's sole officers prior to 2017 were SEES officers, Defendant Bierly and Dr. Daryl McDaniel. Its registered agent was also SEES Co-Founder Dr. John Bierly, at 7268 Jarnigan Road, Suite 200, Chattanooga, TN 37421-3097.

29. On February 10, 2017, FlexPoint Ford acquired a majority interest in ESCC and SESC. From February 2017 to the present, Defendants Mann and Bierly have been both Vice President of, and manage, ESCC and SESC. Defendants Mann and Bierly also managed the day-to-day operations of SESC and Bierly managed the day-to-day operations of ESCC prior to FlexPoint Ford's acquisition.

30. Defendants SESC and ESCC are not independent of Defendant Southeast Eye Specialists PLLC, and receive the proceeds of the claims generated by the unlawful conduct alleged in this Complaint. Defendant Mann and Defendant Bierly have equity ownership in the surgery centers and Defendant Mann monitors the capacity and demand at the surgery centers and staffs the centers. Defendants SESC, ESCC and SEES are hereafter referred to collectively as the "SEES Defendants."

3. Dr. Darryl F. Mann

31. Defendant Dr. Darryl F. Mann, SEES Co-Founder and optometrist joined with Defendant Bierly and began SEES in Tennessee in 1999. Dr. Mann, along with Dr. Bierly, has been in charge of SEES management functions since its inception and at the time of the allegations in this lawsuit, including all decisions regarding the SEES model,

the use of co-management and payment of remuneration to referring optometrists. Dr. Mann has been President, Vice President and on the Board of Governors of Defendant SEES and Vice President of Defendants SESC and ESCC. Dr. Mann currently manages SESC and ESCC. For purposes of this lawsuit, in all respects concerning Dr. Mann's management and oversight of Defendants SEES, SESC and ESCC, Dr. Mann's scienter and actions are imputed to SEES, SESC and ESCC and their conduct is imputed to him.

4. Dr. John R. Bierly

32. Defendant Dr. John (Jack) R. Bierly, SEES Co-Founder and ophthalmic surgeon joined with Defendant Mann and began SEES in Tennessee in 1999. Dr. Bierly, along with Dr. Mann, has been in charge of SEES' management functions since its inception and at the time of the allegations in this lawsuit, including all decisions regarding the SEES model, the use of co-management and payment of remuneration to referring optometrists. Dr. Bierly has been Secretary, Vice President and on the Board of Governors of SEES and Vice President of SESC and ESCC. After the Flexpoint Ford acquisition, Dr. Bierly had a 100% ownership interest in SEES and currently manages SEES, SESC and ESCC. For purposes of this lawsuit, in all respects concerning Dr. Bierly's management and oversight of SEES, SESC and ESCC, Dr. Bierly's scienter and actions are imputed to SEES, SESC and ESCC and their conduct is imputed to him.

III. JURISDICTION AND VENUE

33. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331, 28 U.S.C. § 1367, and 31 U.S.C. § 3732, the last of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3729 and 3730.

34. Although the issue is no longer jurisdictional, the public disclosure provisions of 31 U.S.C. § 3730(e)(4) do not bar this suit. There has been no statutorily relevant public disclosure of the Complaint's "allegations or transactions". To the extent

there has been a relevant public disclosure, Relators are an original source of the information on which this complaint is based. They voluntarily reported the information to the Government before the filing of the complaint, have information that is independent of any such public disclosure and that information materially adds to any information that the Government may have. The FCA and the Tennessee FCA each provide the government veto power to oppose dismissal of an action based upon public disclosure grounds. 31 U.S.C. § 3730(e)(4)(A); Tenn. Code Ann. § 71-5-183(e)(2)(A). On February 21, 2020, the United States and the State of Tennessee exercised their right to object to dismissal of the Relators' complaint in this case on the basis of the public disclosure bar. *See* Doc. 71.

35. This Court has personal jurisdiction over the Defendants pursuant to 31 U.S.C. § 3732(a) because that section authorizes nationwide service of process and because the Defendants have minimum contacts with the United States. Moreover, the Defendants can be found and transact business in the Middle District of Tennessee.

36. Venue is proper in the Middle District of Tennessee pursuant to 28 U.S.C. §§ 1391(b) and 1395(a) and 31 U.S.C. § 3732(a) because the Defendants can be found in and/or transact or have transacted business in this district. At all times relevant to this Complaint, Defendants regularly conduct substantial business within this district and maintain employees and offices in this district.

IV. APPLICABLE LAW

A. The False Claims Act

37. The FCA was originally enacted during the Civil War. Congress substantially amended the Act in 1986—and, again, in 2009 and 2010—to enhance the ability of the United States to recover losses sustained as a result of fraud against it. The Act was amended after Congress found that fraud in federal programs was pervasive and that the Act, which Congress characterized as the primary tool for combating government

fraud, was in need of modernization. Congress intended that the amendments would create incentives for individuals with knowledge of fraud against the Government to disclose the information without fear of reprisals or government inaction, and to encourage the private bar to commit legal resources to prosecuting fraud on the government's behalf.

38. The FCA provides, in pertinent part, that any person who:

(a)(1)(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(a)(1)(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

* * *

is liable to the United States Government for a civil penalty of not less than \$5,000 and not more than \$10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104-410), plus 3 times the amount of damages which the Government sustains[.]

31 U.S.C. § 3729(a)(1).

39. For purposes of the FCA, a person acts “knowingly” if that person: “(i) has actual knowledge of [the falsity of] the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information.” 31 U.S.C. § 3729(b)(1)(A). The FCA does not require proof that a defendant specifically intended to commit fraud. 31 U.S.C. § 3729(b)(1)(B).

B. Medicare (Part B)

40. Medicare is a federally-funded health insurance program that covers certain medical expenses for persons who are over 65, who are disabled, or who suffer from End Stage Renal Disease.

41. The Medicare Program has four parts: Part A, Part B, Part C and Part D. Medicare Part A, the Basic Plan of Hospital Insurance, covers the cost of inpatient

hospital services and post-hospital nursing facility care. Medicare Part B, the Voluntary Supplemental Insurance Plan, covers the cost of services performed by physicians and certain other health care providers, both inpatient and outpatient, if the services are medically necessary and directly and personally provided by the provider. Medicare Part C covers certain managed care plans, and Medicare Part D provides subsidized prescription drug coverage for Medicare beneficiaries.

42. The Medicare program is administered through the Department of Health and Human Services, Centers for Medicare and Medicaid Services (“CMS”).

43. Medicare coverage is limited to those items and services that are medically reasonable and necessary. 42 U.S.C. § 1395y(a)(1). Health care practitioners and providers are required to ensure that all services are “provided economically and only when, and to the extent, medically necessary.” 42 U.S.C. § 1320c-5(a)(1), (3). Providers who furnish services or items substantially in excess of the needs of their patients may be excluded from participation in federal health care programs altogether. 42 U.S.C. § 1320a-7(b)(6).

44. Medicare Part B is a voluntary subsidized insurance program covering, inter alia, physicians’ services, outpatient hospital care, and laboratory services. Part B’s benefits are paid from the federal Supplemental Medical Insurance Trust Fund, which is financed by individual premiums and general federal tax revenues.

45. Medicare Part B pays for “medical and other health care services” provided by a physician, subject to specific exclusions, *see* 42 C.F.R. § 424.24.

46. In order to enroll as a Medicare provider, optometrists, ophthalmologists, practice groups and surgical centers must complete Form CMS-855B. Form CMS-855B requires applicants to certify that they will “abide by the Medicare laws, regulations and program instructions,” and to certify their understanding that “payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with

such laws regulations, and program instructions (including, but not limited to, the Federal Anti-Kickback statute and the Stark law), and on the supplier's compliance with the applicable conditions of participation in Medicare.”

47. By submitting CMS-855B, optometrists, ophthalmologists, practice groups and surgical centers certify that they are eligible for participation in the Medicare Program, and that they have complied with all applicable regulations and laws governing the program, specifically including, but not limited to, the Anti-Kickback Statute.

48. When submitting claims for payment under Medicare Part B, healthcare providers must certify on CMS Form 1500 their compliance with applicable laws and regulations governing the program, specifically including, but not limited to, the Anti-Kickback Statute.

C. The Medicaid/TennCare Program

49. The Medicaid Program, enacted under title XIX of the Social Security Act of 1965, 42 U.S.C. § 1396, *et seq.*, provides funding for medical and health-related services for certain individuals and families with low incomes and virtually no financial resources. Those eligible for Medicaid include pregnant women, children, and persons who are blind or suffer from other disabilities and who cannot afford the cost of healthcare. 42 U.S.C. § 1396d. The Medicaid program is a joint federal-state program. 42 U.S.C. § 1396b. If a state elects to participate in the program, the costs of Medicaid are shared between the state and the federal government. 42 U.S.C. § 1396a(a)(2). In order to receive federal funding, a participating state must comply with requirements imposed by the Social Security Act and regulations promulgated thereunder.

50. The State of Tennessee participates in the Medicaid program pursuant to Tenn. Code Ann. §§ 71-5-101 to 75-5-199. The federal government, through CMS, provides approximately 65% of the funds used by the Tennessee Medicaid program to provide medical assistance to persons enrolled in the Medicaid program.

51. In return for receipt of federal subsidies, the State of Tennessee is required to administer its Medicaid programs in conformity with a state plan that satisfies the requirements of the Social Security Act and accompanying regulations. 42 U.S.C. §§ 1396--1396v; Tenn. Code Ann. § 71-5-102. In Tennessee, the Department of Finance & Administration (F&A) administers the state Medicaid program through the Division of TennCare. Tenn. Code Ann. § 71-5-104. TennCare operates as a special demonstration project authorized by the Secretary of the Department of Health and Human Services under the waiver authority conferred by 42 U.S.C. § 1315. F&A supervises TennCare's administration of medical assistance for eligible recipients. Tenn. Code Ann. §§ 71-5-105 to 71-5-107. F&A is authorized to promulgate rules and regulations to carry out the purposes of TennCare. Tenn. Code Ann. §§ 71-5-124 to 71-5-134.

52. Physicians and laboratories receiving reimbursement from Medicaid must make express and/or implied certifications in their state Medicaid provider enrollment forms that they will comply with all federal and state laws applicable to Medicaid.

53. Tennessee has enacted regulations prohibiting kickbacks in connection with State Medicaid services. Pursuant to these regulations, Tennessee has made compliance with federal anti-kickback statutes and rules a prerequisite to receiving or retaining reimbursement payments from state-funded health care programs. *See* Tenn. Code Ann. § 71-5-118; Tenn. Comp. R. & Regs. 1200-13-18-.07(g).

D. The Anti-Kickback Statute

1. The Anti-Kickback Statute Prohibits Financial Incentives to Induce Referrals

54. The federal health care Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) (“AKS”) prohibits any person or entity from knowingly and willfully offering, making or accepting payments or remuneration of any kind, directly or indirectly, to induce or reward any person for referring, recommending or arranging for the purchase of any item for which payment may be made under a federally-funded health care program.

55. The AKS arose out of Congressional concern that financial inducements can influence health care decisions and result in goods and services being more expensive, medically unnecessary, and harmful to patients. To protect the integrity of federal health care programs, Congress prohibited the payment of kickbacks in any form, regardless of whether the kickback actually gives rise to overutilization or unnecessary care.

56. “Willfully” under the AKS requires that the defendant intended to violate the law, but a person “need not have actual knowledge of the AKS or specific intent to commit a violation of the AKS. 42 U.S.C. § 1320a-7b(h).

57. “Remuneration” under the AKS means “anything of value in any form or manner whatsoever”. *See, e.g.*, 56 Fed. Reg. 35,952, 35,958 (1991).

58. Courts have interpreted the AKS to apply to any arrangement where *one* purpose of the remuneration was to induce the referral of goods or services.

59. An opportunity to earn a fee may be sufficient to constitute an inducement, even if payments were reasonable for the services provided.

60. As a matter of law, compliance with the AKS is material to the government’s decision to pay claims to healthcare providers. Congress explicitly provided that claims for payment submitted in violation of the AKS “constitute [] . . . false or fraudulent claim[s] for purposes of [the FCA].” 42 U.S.C. § 1320a-7b(g).

61. In addition, as demonstrated in multiple ways, compliance with the AKS is material to government payment because it is at the heart of healthcare providers’ bargain with the government and is not minor and insubstantial.

62. Compliance with the AKS is a precondition to both participation as a health care provider in and payment under Medicaid, Medicare, CHAMPUS/TRICARE, CHAMPVA, Federal Employee Health Benefit Program, and other federal health care programs.

63. In order to receive payment, optometrists, ophthalmologists, and other providers who participate in federal health care programs must certify explicitly, in a provider agreement or on claim forms, that they have complied with the applicable federal rules and regulations, including specifically the AKS.

64. For example, to establish eligibility and seek reimbursement from the Medicare Program, hospitals and other providers enter into Provider Agreements with CMS. As part of that agreement, the provider must sign the following certificate:

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

65. Moreover, the United States routinely enforces the AKS both criminally and civilly, obtaining convictions and recovering damages for the submission of kickback-tainted claims.

66. Any party convicted under the AKS must be excluded from federal health care programs (*i.e.*, not allowed to bill for services rendered) for a term of at least five years. 42 U.S.C. § 1320a-7(a)(1). Even without a conviction, if the Secretary of the Department of Health and Human Services (“HHS”) finds administratively that a provider has violated the statute, the Secretary may exclude that provider from the federal health care programs for a discretionary period (in which event the Secretary must direct the relevant State agency to exclude that provider from the State health program), 42 U.S.C. § 1320a-7(b)(7), and may consider imposing administrative sanctions of \$50,000 per kickback violation. 42 U.S.C. § 1320a-7a(a)(7).

2. No Safe Harbors Cover SEES’ Arrangements with Optometrists

67. The AKS provides certain “safe harbors” for conduct that would otherwise be prohibited. 42 U.S.C. § 1320a-7b(b)(3). Congress directed HHS to adopt additional

safe harbors. Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93, § 14 (1987). Safe harbors provide those who comply in good faith with safe harbor requirements that they are not subject to prosecution under the AKS. Payment practices that do not fully comply with a safe harbor may be still be lawful, but only if no purpose of the payment practice is to induce referrals of Federal health care program business. 64 Fed. Reg. 63,518, 63,519 (Nov. 19, 1999).

68. HHS has promulgated certain safe harbor regulations, including for certain referral arrangements for specialty services. 42 C.F.R. § 1001.952(s). The safe harbor for specialty services provides that remuneration within the meaning of the AKS does not include an exchange of value among individuals and entities where one party agrees to refer a patient to the other for the provision of a specialty service in return for an agreement to refer the patient back *provided*, among things, that the parties “***receive no payment from each other for the referral and do not share or split a global fee from any Federal health care program in connection with the referred patient.***” *Id.*

69. When developing the safe harbor for certain specialty service referral arrangements, HHS-OIG specifically declined to extend that safe harbor to situations with a split global fee or bundled payment, citing potential abuse as the reason and stating:

Summary of Final Rule: Because of the potential for abuse when the referring physician and the specialty physician receiving the referral split a global payment from a Federal health care program, we are revising the regulation ***specifically to exclude remuneration received in such circumstances*** from the safe harbor.

Id. at 63,548 (emphasis added).

70. Moreover, based in part upon comments about the exact referral situation at issue here, OIG specifically cited concerns with potentially abusive ophthalmologist-optometrist agreements for Medicare funded cataract surgeries. For cataract surgery, providers bill for the surgical portion of the care using CMS modifier code -54 and bill

for the post-operative care using CMS modifier code -55. HHS-OIG noted that it received numerous comments on potentially abusive co-management relationships between optometrists and ophthalmologists, concluding that “the serious issues raised by the ophthalmologists about ***apparently routine or blanket agreements to split global Medicare fees with referring optometrists*** (as well as other information that has come to our attention from industry and Government sources) has caused us to modify the scope of this safe harbor.” *Id.* (emphasis added). It stated that it thus:

revised the safe harbor regulation to preclude protection for arrangements between parties that share or split a global or bundled payment from a Federal Health Care program for the referred patient. Thus, for example, ***the safe harbor does not protect referral arrangements where the parties bill Medicare using the 54/55 modifiers to indicate an 80 percent-20 percent split of the surgical fee for cataract surgery.***”

Id. (emphasis added).

71. When one commenter questioned whether the AKS applies to specialty referral arrangements where there is no kickback or other consideration for the referral, HHS explained that “the opportunity to generate a fee may constitute the requisite remuneration under the statute, even if no payment or rebate is made for a referral. *Id.* In fact, it then explicitly referred back to the type of fee splitting situation at issue here and stated:

For instance, the opportunity to split a global surgical fee, as in the hypothetical described in the previous comment, is an example of a circumstance in which ***an opportunity to generate a fee is something of value to a referring party*** apart from any payment for the referral. Giving a person an opportunity to earn money may well be an inducement to that person to channel potential Medicare patients toward a particular recipient.

Id. at 63,549 (citing *United States v. Bay State Ambulance and Hospital Rental Service, Inc.*, 874 F.2d 20, 29 (1st Cir. 1989)) (emphasis added).

72. In the absence of a safe harbor, whether a global fee splitting agreement violates the AKS is evaluated on a “case-by-case analysis of all of the facts and circumstances...” *Id.*

V. FACTUAL BACKGROUND

73. A cataract is a clouding of the human ocular lens, impairing vision. Cataract surgery involves the removal of the natural lens and replacing it with an artificial lens, also known as an intraocular lens (IOL). By age 80, 50% of Americans have experienced cataracts or have had cataract surgery.

74. Traditional cataract surgery includes the insertion of a “traditional IOL.” This procedure removes the cloudy lens, but the new artificial lens does correct all vision issues. Individuals with traditional IOLs may still require vision correction (*i.e.* bifocal glasses or contact lenses). Medicare covers cataract surgery as a global surgical procedure, which means that Medicare pays one global fee for the pre-operative care, the surgery, and the post-operative care for 90 days following the surgery.

75. A patient may also elect to receive a “premium IOL” that corrects refractive vision problems, and reduces an individual’s dependence on glasses or contact lenses after surgery. Medicare does not pay for additional fees associated with a “premium IOL”: these must be covered out of pocket by the patient or by private insurance. A Medicare patient receiving a “premium IOL” therefore has surgery and care paid for by Medicare, and is responsible for any additional vision correction fees.

76. Medicare and Medicaid allow billing for co-management of a patient between an optometrist/OD and ophthalmologist/surgeon under certain circumstances. CMS sets the global surgical fee split for cataract surgery, with the ophthalmologist providing surgery collecting 80% of the global fee, using billing modifier -54, and the provider performing post-operative care collecting 20%, using billing modifier -55.

77. Like all arrangements involving referrals for federally-funded health care services, however, arrangements between referring optometrists and ophthalmologists, including co-management arrangements, must comply with the AKS.

VI. ALLEGATIONS

78. The SEES Defendants have implemented a scheme, developed and directed by Defendants Mann and Bierly, to provide kickbacks to optometrists for the purpose of inducing, receiving, and maintaining referrals of patients to SEES, including patients covered by federal health insurance programs. That scheme violates the AKS and the claims for payment submitted by the SEES Defendants violate the FCA and the TMFCA.

A. SEES' Scheme to Provide Financial Benefits to Optometrists to Induce Referrals Violates the Anti-Kickback Statute

79. SEES' business is founded on providing financial benefits to optometrists who refer patients to SEES. In 1999 Defendants Mann and Bierly co-founded SEES and implemented a scheme to secure business from optometrists by providing them numerous types of remuneration to line their pockets and enhance their practices and thereby induce their referrals, upon which SEES depends.

80. As demonstrated below, SEES carried out its scheme by providing kickbacks to optometrists in several ways, including blanket co-management agreements (with fee splitting, promising primary eye care billing, and cutting checks for premium lenses); as well other remuneration such as free continuing education, dinners, golf tournaments, events and gifts, all to induce referrals. And SEES ruthlessly tracked the referrals and payments in order to target high referrers with more payments and to evaluate its return on its investment in individual optometrists.

1. SEES' Co-Management Practice Is an Unlawful Inducement

81. Splitting of surgical fees is appropriate and payable by CMS under certain circumstances. Where a global fee split is based on the needs of an individual patient without consideration of the financial interests of the healthcare providers the practice does not violate the AKS. Those circumstances do not exist here, where SEES has transformed co-management from a patient care tool into a primary marketing tool to induce referrals.

82. SEES' own internal documents, as well as presentations to optometrists regarding co-management, acknowledge the rules for lawful co-management and highlight that it must not be routine or automatic, it must be the patient's choice, and that the decision must be in the best interests of the patient with no financial considerations. SEES' practices violate these basic principles, and their co-management model, which is for the purpose of inducing referrals, violates the AKS.

- a. SEES has blanket co-management agreements with referring optometrists and does not decide co-management on a patient-by-patient basis

83. SEES' co-management model is premised on the fact that the patient will be referred to SEES and the optometrist will see the patient post-operatively and share in the fee. This decision is not made on a case-by-case patient basis. SEES' own marketing brochure presumes post-ops are "with Referring Optometrist":



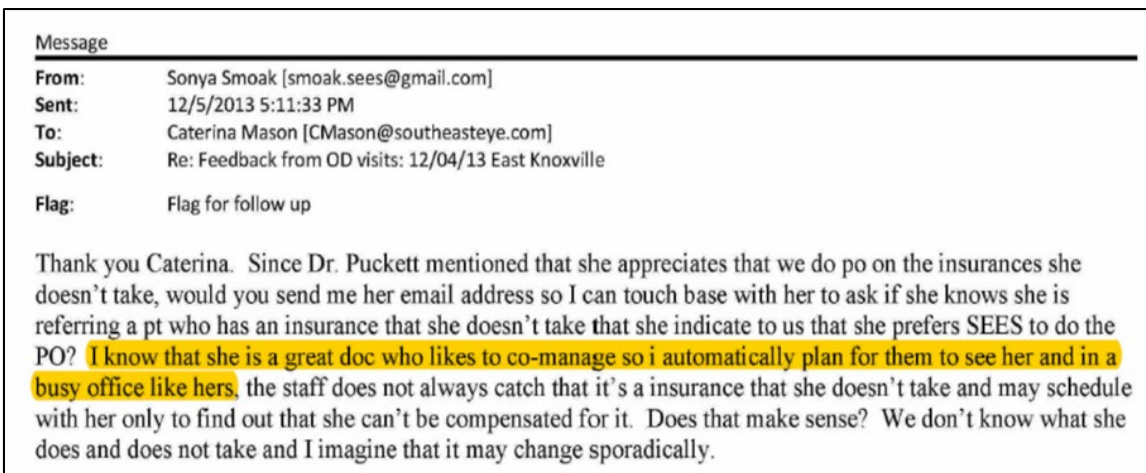
84. In the December 6, 2016 SEES seminar in Nashville, SEES ophthalmic surgeon Dr. William Goodman, presenting on behalf of SEES, stated that patients are “the ultimate decider,” but **should arrive from a referring optometrist “with the notion that co-management has already been set in place.”** Dr. Goodman noted that because patients expected co-management coming into surgery, in his experience only one or two SEES patients opt-out of co-management every five months or so.

85. This vividly illustrates that SEES’ co-management of patient care is essentially a fait accompli, rather than an individualized determination based on the needs of a patient. The decision is not made on a case-by-case basis for each patient at SEES

and instead is made routinely on an optometrist-by-optometrist basis for the financial benefit of the referring optometrists and SEES.

86. SEES admits that its protocol is to return patients to the optometrist for post-operative (“PO” or “po”) care whenever possible and pursuant to a post-operative preference sheet (“PO preference sheet”) that SEES maintains by optometrist, and which states how each would routinely request all of their patients for post-operative exams be handled. SEES updates referring optometrists’ preferences such as when SEES was told “Dr. Billingsley now prefers for us to send her patients back for all 3 PO’s. Can you please update your PO preference sheet to reflect this?”

87. Many optometrists co-manage all of their patients with SEES except when insurance does not cover the co-management. The primary motivation is financial and the decision is automatic and routine. SEES emails acknowledge that SEES automatically plans for certain optometrists to co-manage except when they do not accept that patient’s insurance:



88. Even taking into account insurance that will not compensate for fee splitting, meaning that the referring optometrists does not see the patient post operatively for those patients, SEES admittedly still co-manages more than 70% of its cataract patients.

89. Medicare has paid SEES for 56,746 cataract surgeries and certain related procedures since 2012. Approximately 45,986 of those procedures were co-managed. In financial terms, Medicare paid SEES approximately \$20,423,955, almost 80% of which or \$15,879,883 was for co-managed patients. This does **not** include Medicare payments to SESC and ESCC, the ambulatory surgery center defendants, for the facility fees and anesthesia, which is even more lucrative. The number and percentage of co-managed procedures is astounding.

90. The ability to bill for these post-op exams is a lucrative inducement. Optometrists complain when their patients are not sent back for PO exams, with their associated fees, and SEES marketers note these complaints in spreadsheets and emails, and remind surgery schedulers to check the optometrists' preferences.

91. While SEES marketers' notes from visits with optometrists about their experiences with SEES sometimes mention being pleased with good surgical outcomes, the notes make clear that referring ODs are happy they get their patients back for post-operative care. For example, in 2012 one OD told a SEES marketer that "she likes that we allow them to do the POs". Another note in 2015 regarding an OD stated that she "hasn't had any more issues with us doing the PO's. Dr Puckett said she refers to us because we don't keep patients". And another stated that one OD "appreciates being able to do the 1-day PO, because Dr. Lindsey did not allow the O.D.'s to do this." In 2016 a note about another OD reported that "he is very glad that SEES has a presence in Nashville. He did not always get the patients back for PO care when he sent patients to Dr. Loden".

92. The goal of getting money to optometrists through this model was specifically marketed to optometrists and discussed often by SEES, including by Defendants Mann and Bierly, as well as by other SEES principals and marketers.

93. For example, at the June 20, 2016 SEES CE seminar in Nashville when introducing the SEES' model to optometrists, Dr. Mann emphasized that "for the most

part, **our real goal is to keep as much patient revenue in your practice as we can.**

Dr. Mann further offered training to any optometrists who were not doing post-operative care on patients and would like to, noting that **“again, we want this patient to get as much services in your office as possible.”** Dr. Bierly stated in this same seminar that “the ophthalmologists we hire are to doing that [co-management],” and suggested that **referring optometrists would be pleased with how SEES could “help you grow your practices.”**

94. These relationships are key to SEES’ model and success. As Mann promised in a 2017 letter written to high volume referring OD Walter Choate, thanking him for being instrumental in bringing SEES to Nashville, **the goal is working with “referring doctors to capture as much patient services revenue as possible,”** and that SEES is “at the mercy of optometrists, that it is “authentically committed to the co-management model.”

95. And a SEES marketer, in pitching potential referring ODs stated that **SEES can serve optometrists through “how we co-manage and invest in their practice.”**

96. Even when recently transitioning SEES’ ownership, in part, to an investment company, SEES reiterated its primary commitment to optometrists. At its November 29, 2017 Advisory Board meeting, Defendant Mann announced SEES’ partnership with Flexpoint Ford and expressed that the “business model will continue to stay the same—referral based **only serving our Optometric community.**” He said he would “hold true” to what SEES knows works: “business model that adds value and **pushes revenue into our primary care optometry practices.**”

b. SEES’ co-management is not the patient’s choice

97. Patient choice should be paramount to the decision of where and by whom a patient receives treatment. SEES’ scheme deprives patients of choice by directing

patients to SEES' surgeons and having them returned to the referring physician for post-operative care, regardless of the patient's preference for either.

98. Although patients sign consent forms prior to surgery, SEES does not actually provide a meaningful patient choice, which is foundational in order for co-management to be legitimate.

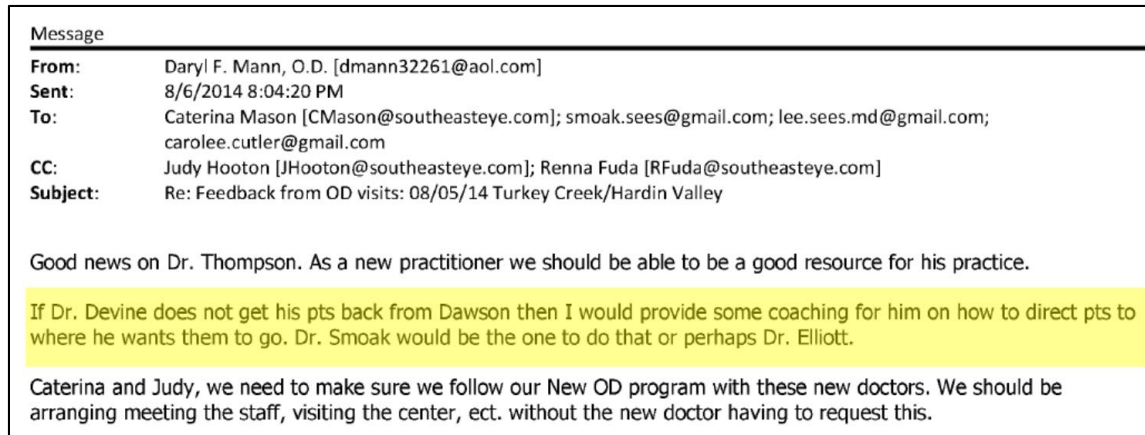
99. In fact, SEES suggests that it is the optometrists' choice, not the patients', and carefully advises optometrists on how to always gain consent—by telling the patient that they will be seeing the referring optometrist back for the post-operative care.

100. In the June, 2016 SEES Nashville seminar, Dr. Mann emphasized that referred patients **“should come in already expecting (co-management).”** Because co-management requires patient consent, Dr. Mann noted it was critical for optometrists to **“let your patient know that cause of insurance that you accept et cetera, that ‘I’ll be seeing you back for the post-operative care.’ They should come in already expecting that, otherwise, they may say ‘Well, why am I going back to - I only saw that doctor one time, why am I going back to them? You’re the surgeon, why aren’t you doing the post-operative care?’”**

101. While sometimes careful to acknowledge that it is ultimately the patients' choice, Mann makes very clear that the optometrist should steer the patient back to the optometrist.

102. Dr. Mann was not shy about his view that the choice about co-management should be the optometrists'. When a SEES marketer described to Dr. Mann and others that one physician refers patients to non-SEES surgeons if the patient requests (but complains that he won't get his patients back) Dr. Mann stated in an email that SEES

should “provide some coaching” for an OD on “how to direct patients to where he wants them to go”:



103. Although geographic distance of the patient from the surgeon can be a legitimate reason to use co-management for the convenience of the patient, SEES’ co-management is not justified on that basis. It may make sense on a case-by-case basis for an optometrist to co-manage care when a patient, who had surgery in a city far from her home, would otherwise have to drive a far distance back to the surgeon’s office for post-operative care. That is not what is happening here.

104. SEES induces optometrists to refer to SEES even though local options are available and regardless of patient choice—pushing their co-management model and support of optometry. For example, marketing notes summarize one OD’s appreciation of co-management and what SEES can do for the optometrist, even though “the patient requests to go somewhere closer”:

Wayne Connell: wayne.connell@gmail.com (Tapp Optical-Knoxville) I met with Sharon (office manager) to discuss SEES services, locations, and doctors. I met with Dr. Connell to discuss SEES. Dr. Connell said he likes our doctors and how we co-manage patients with the O.D's. He also appreciates how we support optometry. Dr. Connell said he only refers to SEES. He said it's easier to refer patients to our Morristown office when he's working in Morristown than it is to our west Knoxville office. He said he still refers patients to us even when the patient requests to go somewhere closer. He appreciates getting his patients back. He said in the past when he has referred patients elsewhere (Baptist Eye Surgeons), often times his patient would come back a year later saying they bought eye glasses from where he had referred them, and also was seeing them for primary eye care. For now Dr. Connell is at Tapp Optical twice a week and in Morristown 3 days per week. Dr.

105. An email to Defendants Mann and Bierly explained that another OD refers to SEES because when he referred a patient to Dr. Seal whose office is across the street, he didn't get that patient back. A marketer's notes reflect that even though this OD's office is across the street from Dr. Seal's he will refer to SEES:

Message

From: Caterina Mason [CMason@southeasteye.com]
Sent: 7/30/2014 1:54:16 AM
To: dmann32261@aol.com; lee.sees.md@gmail.com; Zachary McCarty [ZMcCarty@southeasteye.com]; johnrbierly@comcast.net; raylv7@gmail.com; Phillips.Leslie08@yahoo.com; justdovit@mindspring.com; Edward_petersen@hotmail.com
CC: Judy Hooton [JHooton@southeasteye.com]; Trish Cole [TCole@southeasteye.com]; Cindy Privett [CPrivett@southeasteye.com]
Subject: Feedback from O.D. visits: 07/29/14 Downtown Chattanooga

Ken Perkins

I met with Dr. Perkins to discuss SEES. Dr. Perkins said even though his clinic location is across from Dr. Seal's office, he still refers to us. He said he referred one cataract patient to Dr. Seal because this patient's sister had her cataracts done by Dr. Seal. Dr. Perkins said he didn't get this patient back, and Dr. Seal scheduled for this patient to follow up with her annually. Dr. Perkins also mentioned Dr. Seal has an OCT, but he won't refer to her for testing because he's worried he won't get these patients back either. He said he's happy with our services, and will continue to refer to us. We discussed SEES doctors, upcoming CE's, and the masquerade ball. I thanked him for his support.

106. Conversely, SEES routinely co-manages patients with doctors who are less than one mile from their office, where there is no argument that it is more convenient for the patient to see their referring optometrists instead of returning to SEES for post-

operative care. One such OD is Mark Kapperman—who is on SEES Advisory Board—and is less than a mile from SEES' Chattanooga office.

107. SEES cannot clinically justify co-management for the majority of patients that they co-manage in urban centers of Chattanooga, Knoxville and Nashville based on geography. Referring optometrists for patients in these cities are not likely to be significantly closer to the patient than the SEES surgical center.

- c. SEES' co-management is not done in the best interest of the patients and can and has affected patient care

(1) Optometrists, not the patients, are SEES' client

108. SEES focuses primarily on its relationship with the referring optometrist as paramount and astonishingly has emphasized numerous times that its client is the optometrist, not the patient.

109. For example, Dr. Mann stated in his June 2016 CE seminar for optometrists that SEES is “very good at trying to build your relationship with your patient... **our clients are you all.**”

110. At an Advisory Board dinner in August of 2017, James Pereyra, the then-new CEO of SEES, transparently stated “our direct customer is the patient, but **our true customer is our referring doctors.**” The minutes of that meeting note that “Dr. Bierly mentioned this is a conversation he has previously had with Dr. Mann”.

111. SEES' approach was not lost on optometrists. One optometrist commented to a SEES marketer in 2017 that “he is concerned that SEES is not putting the patient first because they are more concerned with money.”

(2) SEES puts healthcare providers' interests over patient interests

112. A primary purpose of the AKS is to ensure that medical judgment and patient care is not based on the financial interests of healthcare providers rather than the interests of patients. While cataract surgery may often be necessary for patients referred to SEES, the routine nature of co-management and the financial relationship between the

optometrists and SEES affects the independence of the medical opinions as well as aspects critical to patient care.

113. First and foremost, SEES promises optometrists that they will agree with the optometrist's diagnosis. SEES does this because it values its financial relationship with the referring optometrist more than the needs of the individual patient.

114. During the SEES June, 2016 Nashville seminar, Defendant Mann emphasized to his audience of optometrists that **SEES will never “throw [optometrists] under the bus,” even if a diagnosis is missed.** Specifically citing an example of cataract patients with glaucoma—who can be at higher risk for post-operative complications—Dr. Mann emphasized that SEES optometrists “will not say much about [the glaucoma] . . . it's your patient . . . we're not going to take over that care if you don't want us to. **We'll agree with your diagnosis.**”

115. In 2012 a SEES OD noticed an issue with a patient referred by one of SEES' high referrers (Dr. Jerry Winston) and brought it to Mann's attention to seek advice. She noted that this patient, in addition to 4 or 5 other patients, had advanced glaucoma but it was not diagnosed by Dr. Winston. She told Mann that she told Dr. Winston about it and said that she would “never throw him under the bus”. She added that this optometrist “is missing some pretty significant disease.”

116. SEES' practices interfere with patient care in other ways as well. On information and belief, SEES bars its surgeons from any patient contact that is not directly related to the patients' surgery: the surgeons do not examine patients prior to the surgical procedure. SEES' own brochure on the process explains that the evaluation appointment is with the OD from SEES and the patient first meets the surgeon immediately before the procedure. This is not necessarily in the best interests of the patient nor in line with professional norms.

117. When SEES first began in Knoxville, Dr. Elliott raised a question at the Advisory Board dinner in 2010 about how to respond to his patients' questions regarding why he was referring a patient to another optometrist (meaning that the surgeon was not doing the evaluation at SEES). Dr. Mann responded that it was a good question and he didn't have all of the answers, but essentially that a surgeon could be available for emergencies.

118. Additionally, Dr. Goodman, a SEES ophthalmologist told another ophthalmologist after he joined SEES in September, 2018 that he was now operating on patients he had never met. Specifically, in response to a phone call from a local ophthalmologist about a particular patient, he said that before he started at SEES he may have taken out one 20/20 cataract a year but now he takes out 20/20 cataracts every day **"on patients he has never met."** "I'm just shaking my head". He said "It is a system. It is a whole different way of practicing ophthalmology."

119. Finally, post-operative exams are scheduled for the convenience of the doctors, not the patients and are even missed or arranged so that SEES provides a free exam to the patient the same day of surgery rather than the next day without regard to the patient's needs. For example, SEES longtime marketer and Practice Development Coordinator, Judy Hooten, explained to an OD how they can maneuver the schedule so that the OD can bill for the entire 90-day post-op period regardless of his schedule:

Message

From: Judy Hooton [JHooton@southeasteye.com]
Sent: 2/9/2015 2:40:35 PM
To: Matt Bohrman [mcbohrman@gmail.com]
CC: Trish Cole [TCole@southeasteye.com]
Subject: RE: Cat Sx Scheduling Q

I just wanted to let you know that we should schedule the patient's appointment even if you do not have the insurance. If this happens again, please let me know.

Regarding the pre-op appointment, we would see the patient for a cataract evaluation and perform any special testing at this time. If the patient needs surgery, we would schedule this and the post op appointment after the cataract evaluation. The PO appointment is normally scheduled 1 day and 1 week following the surgery; however, we sometimes do a same day PO if the referring doctors cannot see the patient the day after surgery. If we do a same day PO, then the referring doctor normally sees the patient at day 3 or 4 and then 1 week following the first PO visit. Even when the patient goes back to see the referring doctor at day 3 or 4, they will still be able to bill for the full 90 days of PO care This will give us a lot of flexibility when scheduling the patient back to see you since you are only there on Tuesday, Friday and Saturday. I am copying Trish on this email so she will know that you want to do the PO care.

Judy Hooton
 SouthEast Eye Specialists
 jhooton@southeasteye.com
 Phone: (423) 508-7337 ext. 204
 Fax: (423) 508-7338
 Cell: (423) 667-5647

120. Another SEES marketer corresponded with an OD explaining that SEES leaves the post-operative preference up to each individual doctor:

Message

From: Caterina Mason [CMason@southeasteye.com]
Sent: 9/29/2016 1:30:23 AM
To: docopt92@yahoo.com
Subject: SouthEast Eye Specialists post-ops

Hi Dr. Billingsley,

Sorry I missed you today. Thank you for your recent cataract referrals. We appreciate the opportunity to work with you and your patients!

Your office staff said you typically do the 1-week & 1-month PO's, and that we currently have a few patients scheduled back with you for their 1-day PO. Please let me know if you prefer for us to do the same day or 1-day PO for you, and then send them back to you for the other PO's.

We leave the PO preference up to each individual doctor, so whatever you prefer works for us.

Also, I would like to bring in breakfast or lunch the next time I'm in Maryville. I would love to have around 15 minutes to spend with you and your staff if possible. I'll call your office the next time I will be in your area to see if we can schedule something.

Please let me know if I can be of assistance in any way.

Take Care,

Caterina Mason
 Professional Relations Consultant
 SouthEast Eye Specialists
 cmason@southeasteye.com
 (865) 221-1121 cell

- d. SEES guarantees optometrists the opportunity to bill for future primary care by promising to send patients back for primary care and to not compete

121. An integral part of SEES kickback scheme is SEES' promise to send the optometrists' patients back to them and to not compete for glasses and other primary eye care services. "Always sending the patient back" guarantees the referring optometrists the opportunity to bill for expensive primary eye care, which is part of SEES scheme to get surgery referrals.

122. The Safe Harbor regulations expressly provide a safe harbor for agreements to send patients who need specialist services back upon completion of those services only **when there is no split of the global fee**. 64 Fed. Reg. at 63548.

123. Both the regulations and case law establish that "an opportunity to generate a fee is something of value to a referring party." *See United States v. Bay State Ambulance and Hospital Rental Service, Inc.*, 874 F2d 20, 29 (1st Cir. 1989); 64 Fed. Reg. at 63,549.

124. SEES routine co-management guarantees that the patient will return to the referring optometrist for all primary eye care services. In addition to post-operative care, surgical patients typically return for follow up examinations 6-12 months after surgery, and for yearly exams. At this time, the majority of cataract patients will also require glasses or other optical services. Medicare covers the costs of one pair of eyeglasses after cataract surgery.

125. As SEES recognizes, this primary eye care is lucrative and important to optometrists. It is marketed by SEES as one of the most important benefits it provides to the optometrists.

126. As a marketer for SEES explicitly put in his call notes as a selling point to optometrists, **"We want you to know we will not do that, never compete w you."**

127. Another marketer explained that she "would remind these doctors about our co-management concept (that they always get their patients back from SEES) and

that we don't offer the same services like some of the other ophthalmologists might (*i.e.* primary eye care and optical)."

128. As early as 2012, notes from SEES' marketers comment that OD Dr. Fitzgerald appreciates this and: **"wants to support SEES because we support ODs. He's also pleased he doesn't have to worry about losing patients with SEES, like he has in the past with other doctors."**

129. Defendant Bierly admitted the value of the primary care appointments for glasses stating **"there may be just about as much money in the post op spectacles"** in discussing a patient who already has a surgeon lined up for cataract surgery and suggesting he be sent back to him for glasses.

130. SEES Center Director Dr. Robin Brady in a December 6, 2016 SEES seminar reiterated "we don't provide any primary care, we don't try to compete with you in that way." He explained that SEES will even accept patients that get referred to SEES for primary care, accept the patient even though SEES knows it will not provide the primary care, and then send the patients to SEES referring partners for the primary care. As he advertised it to the optometrists "we try to convert any M.D. patients referred in back to the optometric community, so that we can kind of backfill your practice with patients." He explained that if SEES can't "convert" an M.D. patient by phone, they will accept the patient from the primary care doctor, then let patient know "up front" no primary routine care is provided by SEES, then "turn around then try to get them in [an optometrists'] office."

131. In order to induce referrals, SEES guarantees that it will funnel patients back to the optometrist after a surgery to secure the optometrist's opportunity to maintain these lines of revenue themselves.

2. SEES Pays Optometrists to Upgrade Patients to Premium Lenses and a More Expensive Procedure

132. SEES also pays optometrists for an additional approximately 10% in fees where the patient elects to have vision-correcting cataract surgery (as opposed to traditional cataract surgery). The Tennessee Fee payment schedule for cataract surgery is approximately \$600. SEES offers two vision correcting “premium IOL” options: one adds \$1,695 of patient funded fees per eye (with \$150 per eye as the optometrists’ co-management fee), and another which adds \$2,995 of patient funded fees per eye (with \$300 per eye as the optometrists’ co-management fee).

133. For referring to SEES a Medicare patient who elects a “premium IOL”, the co-managing optometrist would therefore receive approximately \$100 from Medicare for their share of the global fee, and either \$150 or \$300 directly from SEES for the lens upgrade, for a total of up to approximately \$400 per eye. As HHS-OIG observed when adopting a safe-harbor for referrals to specialty practices, no payment may be made from the specialty practice to the referring provider. 64 Fed. Reg. at 63,547-48; 42 C.F.R. § 1001.952(s)(3).

134. Significantly, the patients do not know that the referring optometrists are being paid \$150 or \$300 when they select upgraded lenses because SEES pays that money directly to the optometrists.

135. SEES advertises in seminars that it will collect out-of-pocket fees for vision correcting “premium IOLs,” and deliver monthly checks to referring optometrists for their share.

136. SEES has detailed excel spreadsheets of the premium co-management fees/refunds given to the ODs, which are extensive. One such spreadsheet shows more than \$600,000 of payments/refunds made to referring optometrists for premium lenses through 2017.

137. SEES acknowledges the benefits of cutting checks and even discussed having executive directors and Defendant Mann personally deliver the checks to guarantee face time with those high referring optometrists. Russell McBryde noted that **“no optometrist is going to say they can’t see someone who has a check for them.”**

From: Russell McBryde
Sent: Thursday, September 7, 2017 9:49 AM
To: Bruce Short <BShort@southeasteye.com>
Cc: Daryl Mann <DMann@southeasteye.com>; James Pereyra <JPereyra@southeasteye.com>; Erica Scales <EScales@southeasteye.com>; Kevin Clemons <KClemons@southeasteye.com>; Julie Campbell <JCampbell@southeasteye.com>
Subject: Re: Distribution of Co management fees - An easy way for the ED to visit the refering practices

Genius! I love the idea. It's a great way to continue to establish the working relationship between our EDs and the referral network. No optometrist is going to say they can't see someone who has a check for them. Julie, Kevin and Erica, can you guys jump on a quick 10 minute call today to discuss the messaging and how to route your visits? I'm available anytime today between 12pm-4pm. You guys let me know what time works best and I'll send out an invite for the call. Bruce, I'll call you directly to discuss logistics on obtaining the checks.

3. SEES Provides Free Continuing Education, Dinners, Golf Tournaments and Other Remuneration to Optometrists

138. In addition to SEES’ co-management practices, and commissions for upselling, all of which fly in the face of AKS regulations and subvert patient choice, SEES also provides classic kickbacks to optometrists including free continuing education events, dinners, golf tournaments, baseball games and other events in order to induce referrals.

139. SEES explained to its investor Flexpoint Ford that SEES’ continuing education seminars, visits to the largest referral sources, provision of golf tournaments, and other events and activities are “business development activities geared towards referring optometrists”. As demonstrated below, SEES provided an array of other financial benefits to induce optometrist referrals.

a. SEES provides referring optometrists with free continuing education events with food and drink

140. SEES frequently provides referring optometrists with free continuing medical education courses (“CEs”) and dinners to induce referrals. SEES provided these free events in Knoxville and Chattanooga for years and later expanded to other areas, including Nashville in 2016.

141. SEES’ continuing medical education courses target potential referring optometrists. The subject matter covered by the courses provides optometrists training on various topics including post-operative cataract and glaucoma surgery care. The seminars also offer optometrists training on Medicare coding related to co-management. Biographies for speakers at a number of seminars emphasize experience with co-management models.

142. SEES advertises these seminars to optometrists through email, social media, and direct mail campaigns. SEES representatives also visit the offices of potential referring optometrists personally to invite the optometrists to these events. During their “visits” with the targeted highest referrers, SEES marketers encourage the optometrists to attend and note such interactions in their spreadsheets. It is at these visits and the continuing education events that SEES marketers build relationships with referring optometrists and tout SEES co-management business model and what they can do for optometrists.

143. In these free seminars, in addition to providing valuable continuing education credits, SEES representatives repeatedly tout their routine co-management as a revenue opportunity for referring optometrists as discussed above. SEES also used the seminars to encourage optometrists to direct patients into expecting co-management prior to surgery. SEES designed CEs to target cataract co-management because it is SEES’ most financially profitable service line.

144. Continuing medical education courses are valuable remuneration because they are a requirement of continued professional certification for optometrists, and seminars typically cost \$25-\$50 per credit. SEES offers 2-credit or more seminars, along with dinners, and open bars per event, all of which is free to participants. The value of these events can exceed \$100 per event.

145. At some point SEES became concerned about the risk presented by these free events (in part because of an optometrist's email suggesting a kickback/compliance concern).

146. Suddenly, in 2017, SEES tried to hide the scheme by charging a "nominal" amount, and set up a foundation to ostensibly sponsor the CEs, but nothing else changed.

147. As the Director of Clinic Operations informed an inquiring OD, "cost is not the issue. If it was, we'd definitely have to charge more. **I can explain the reason via a phone call as Dr. Mann wishes us not to publish the reason in print.**"

148. And Ms. Hooton told Relator Lumpkin at a SEES CE event on March 30, 2017 "we set it at \$10 per credit... a very nominal fee. In fact, it costs me probably more to administer it ... it's not worth it for us, but it's just what it is... just trying to keep everybody out of trouble; regulatory issue... we wanted to make sure we weren't doing an Anti-Kickback issue."

149. However, a nominal \$5 or \$10 fee admittedly did not come close to covering the costs, is much less than other industry CEs and below fair market value, and did not solve the AKS problem. Hooten's analysis highlights that SEES was aware that they were providing something of value to the optometrists.

b. SEES hosts annual golf tournaments for certain referring optometrists

150. SEES has been hosting golf tournaments for its referring doctors in Chattanooga since 1999. Each tournament typically has between 25-30 players. In 2013

they began hosting tournaments in Knoxville and in 2014, SEES added a spring golf tournament in Knoxville as well. These free events are outings for referring optometrists, occasionally their spouse who works with the OD, and SEES physicians and admittedly is a way to “build relationships between referring and our [SEES] providers.”

151. There was a specific push to first invite the highest referrers/supporters. As Defendant Mann stated in 2014 about the Knoxville tournament, “If we need to ‘invite only’ then we will base it on referring doctors first.” Another email discussing the invite list suggested “strong supporters” of SEES and to check the new patient referral report “to see who the other supporters are.”

152. Referrals were the primary consideration for attendance as was also evidenced by a decision to include one last minute OD, Dr. Fitzgerald, in the golf outing. Specifically, when this optometrist with a high handicap, and whose form had been lost, was inquiring about playing last minute, Defendant Mann asked Hooten if that optometrist refers SEES patients. A referral report was run and after learning that Dr. Fitzgerald had referred “37 total patients to us this year” and has “really picked up in Sevierville this year” he was added to the list.

153. According to SEES’ internal documents, the “average cost of tourney is \$7,200-\$7,700.” With an average 25-30 players that would be at least \$240 per person per event—with no money being charged to or paid by any of the referring optometrists attending the event. In 2013 when first beginning the Knoxville golf tournament, Defendant Mann suggested that they not skimp on this event. In discussing which country club to choose for hosting the event and the cost he said, “My recommendation is to try to make this a golfing experience that exceeds the quality of the average tournament we all get invited to play in. I think the additional \$500 to \$1500 cost will be well worth it for your inaugural event.”

c. SEES provided dinners and other events and gifts to referring optometrists

154. SEES also provided referring optometrists with free expensive food and drinks in several ways.

155. High referring optometrists were placed on “Advisory Boards” that met over SEES expensed dinners. The purpose of these dinners was to have high referring optometrists gather with SEES management to involve them in SEES’ business practices and maintain their referrals. These dinners were held at expensive restaurants such as Ruth’s Chris, Bistro by the Tracks, St. John’s Restaurant, and Del Friscos with a budget of \$1,500 for each dinner.

156. Certain high level referrers were also invited to “round tables” or an informal continuing education format held at a restaurant. For example, attendees were chosen from a list of highest volume referring doctors on premium lenses, at Defendant Mann’s and Defendant Bierly’s request as evidenced by an email in 2017 requesting “a list of higher volume referring doctors that co-manage on a lot of our premium lenses” for the Roundtable. Moreover, Hooten specifically targeted “doctors that we co-manage frequently with on special lenses” for small roundtable CEs.

157. Free items and events were not just provided directly to SEES referring optometrists. SEES also invited their families and staff to an annual baseball game and picnic and provided lunches for high referrers and their staff in order to induce referrals from the optometrists. SEES maintains spreadsheets of notes to target certain high referring ODs with action items that include lunches for OD and staff.

158. SEES provided referring optometrists with additional gifts including pens, umbrellas, tumblers, golf shirts, chocolates and other holiday gifts to induce referrals. SEES maintained marketing notes made after each visit where many of these gifts were provided. The notes would often state what was provided, that the OD appreciated the gifts, and list other SEES support.

159. SEES also provided door prizes for various SEES events, including expensive items such as an Apple TV, camera, Bose Bluetooth speakers and Bose Bluetooth headphones.

d. SEES' events, dinners and gifts were not de minimus

160. While some individual gifts SEES provided to referring optometrists might standing alone have been permissible as *de minimus*, the combined remuneration provided to an individual referring optometrist certainly was not *de minimus*. SEES kept records of the amounts spent on events and even had yearly budgets that provided how much each division (Chattanooga, Knoxville and West—Nashville) expected to spend on such “client relations”.

161. SEES maintains documents that show the budgeted and actual costs yearly. For example, one spreadsheet showed that expenses for client relations in 2014 were over \$71,000, which included, among other things, parties, events, gifts, flowers, CEs, and Advisory Board Dinners:

Client Relations									
Gifts & Flowers (specific to Division)	\$1,400	\$721	\$110	\$642			\$1,473	(\$73)	
iBoost Gift	\$2,500	\$1,620	\$360	\$534			\$2,515	(\$15)	
Parties & Events									
Ballgame & Picnic (Chatt & West)	\$3,700	\$4,947	\$1,094				\$6,041	(\$2,341)	
Golf Tournament (Chatt & West)	\$5,000	\$4,546	\$535	\$1,491			\$6,571	(\$1,571)	
Golf Tournament (Knox)	\$5,000			\$4,201			\$4,201	\$799	
30 Year Celebration (all Div)	\$12,000	\$12,210	\$2,722	\$2,464	\$679	\$2,084	\$20,159	(\$8,159)	
Total Parties & Events:	\$25,700						\$36,972	(\$11,272)	
Advisory Board Meetings (Chatt)	\$3,000	\$2,311	\$517	\$132	\$35	\$106	\$3,101	(\$101)	
Advisory Board Meetings (Knox)	\$3,000			\$2,479			\$2,479	\$521	
CME Courses:									
Chattanooga	\$16,000	\$13,130					\$13,130		
Less exhibitor fees - Chatt	(\$9,500)	(\$4,750)					(\$4,750)		
West	\$1,000		\$2,691				\$2,691		
Knoxville	\$15,200			\$16,477			\$16,477		
Less exhibitor fees - Knox	(\$8,000)			(\$5,650)			(\$5,650)		
Total CME Courses:	\$14,700						\$21,898	(\$7,198)	
Meals & Entertainment	\$8,500	\$1,564	\$78	\$1,866			\$3,508	\$4,992	
Total Client Relations	\$58,800						\$71,946	(\$13,146)	
Total Marketing Expense	\$92,770						\$103,209	(\$10,439)	

4. SEES Consistently Tracked All Referrals and Payments in Order to Target the Most Valuable Optometrists and Evaluate Its Return on Investment

162. From SEES' inception in 1999, it has closely monitored and tracked all referrals from optometrists. The spreadsheets it utilizes include tabs for cataract surgeries monthly and annually and include the "Run rate" "% Change" and "3-year average" for each referring doctor.

163. SEES maintains reports called, for example, "Pt Count by Referring Provider by Visit Type" and maintains a list entitled "Cataract Surgery Referrals-All Divisions". Some of these lists include multiple years (2014, 2015, and 2016), and percentage changes from each year.

164. SEES also maintains lists and spreadsheets tracking the highest referring optometrists, for example, entitled, "Top Super Targets", "Top Referring Doctors" and "Top 10 NC Referring ODs YTD". The spreadsheet's columns detail efforts to court each individual optometrist, including lunches and support for the optometrists and their staff, and issues of concern to each physician, including obstacles to referring patients to SEES.

165. While tracking referrals alone is not prohibited, paying money and other remuneration to optometrists to induce those referrals and targeting optometrists to receive remuneration based upon those referrals, as discussed below, is. That is exactly what the Defendants did. SEES tracked the return on investment of its events and noted that "the only questionable event in terms of ROI was the baseball game." SEES also tracked the "collections" attributed to referring optometrists.

166. SEES tracked the referrals of the optometrists who attended its CEs and after the 2016 CEs in Nashville decided that those who were noted unlikely to refer patients were to be removed from future CE lists.

167. Specifically, in March of 2017 after the Nashville co-management CE seminars, SEES created an action item list directing the generation of a “list cross referencing CE attendance against referrals”.

Continuing Education			
• March 30 th (third CE)/ Next CE target is Mid May	Judy		James to get commitment from Goodman
• Generate a list cross referencing CE attendance against referrals	Judy	Done	See attached list
SouthEast Eye Specialists 03/19/2017			

168. SEES created lists of each OD, which CE in 2016 in Nashville they attended, and notes about their referral patterns (excerpt of part of the chart below; highlights in original).

A	B	C	D	E	F
First Name	Last Name	Attended CE on 6/20/16	Attended CE on 9/27/16	MTOPS Sponsorship on 12/6/16	Comments
Brad	Altman		X		Started referring 9/16, on Advisory Board
Corinne	Bacher, OD			X	No referrals. Clarksville - Eyecare Plus
Alan	Ballard, OD			X	No referrals. Brentwood, would refer to SEES if closer
Chris	Bates, OD		X		Referred 1 pt in 10/16
James	Blanks, OD			X	No referrals. Works for Ophthalmologist in Tullahoma
Megan	Blemker, OD	X		X	No referrals. Unsure where working. Last location listed is closed.
Donald	Blocker, OD		X		Started referring to SEES 1/17 (Portland Satellite)
Kenneth	Browner, OD		X		Started referring to SEES 11/16
David	Brown, OD	X			No referrals. Franklin (Christopher Optical)
Walter	Choate, OD	X		X	Started referring 7/16, on Advisory Board
Elena	Collier, OD	X			Started referring 2/17. Antioch & Nashville - Walmart
Garry	Collins, OD	X			No referrals. Brentwood - Collins Eye Center
Sarah	Connolly, OD			X	No referrals. Wang Vision Center
Sachie	Craig, OD			X	No referrals. Works for Eye Health Partners
Trula	Davis, OD	X			No referrals. Franklin, would refer to SEES if closer
Hank	DeHaven, OD	X			Started referring 7/16. Refers a lot.
Leslie	DeHaven, OD	X			No referrals. Maternity Leave

169. Demonstrating that one purpose of the free CEs is to induce referrals, SEES highlighted ODs who had zero referrals and whom SEES believed would never refer patients because they worked for an ophthalmology practice and noted to “remove them from the mailing list”.

85						
86	Has referred patients to SEES					
87	Works for an ophthalmology practice				Remove from mailing list	
88	Would refer to SEES if in South Nashville					
89						
90						

B. In Violation of the FCA and TMFCA Defendants Knowingly Submitted and Caused to be Submitted, False Claims for Cataract and Other Eye Surgeries for Which Unlawful Kickbacks Were Paid

170. The optometrists involved in the conduct discussed above and in the tracking sheets SEES maintained and referenced were paid kickbacks through co-management and other remuneration which resulted in false claims being submitted to Medicare and TennCare in violation of the False Claims Act.

1. Defendants Submitted False Claims for Payment

171. One purpose of SEES' practices is clearly to induce referrals, as is evident from SEES' efforts to target referring optometrists with gifts and revenue opportunities, its efforts tracking the return on its investment and statements made by SEES' Directors and upper level management in sponsored seminars.

172. Defendants Mann and Bierly were involved in the creation and marketing of the scheme and know that routine co-management agreements and payment of other remuneration to induce referrals violate the AKS.

173. Each claim submitted in violation of the AKS is a false claim within the meaning of the False Claims Act. 42 U.S.C. § 1320a-7b(g).

174. The following are representative example optometrists paid by SEES to induce their referrals, and many refer most—and in some instances nearly all—of their patients to SEES.

Name	Practice Name	Location
Kenneth Nix	Sequatchie Valley Eye Care	Dunlap, TN
Thomas Foster	Foster Family Eye Care	Sweetwater, TN
Mark Kapperman	Kapperman White & McGarvey Eyecare	Chattanooga, TN
Jerry Richt	The Bradley Eye Care Center	Cleveland, TN
William Frye	Horner Rausch Optical	Tullahoma, TN
Barry Winston	Winston Eye and Vision Center	Knoxville, TN
Steven Elliott	Volunteer Eyecare	Clinton, TN
Wayne D. Connell	Volunteer Eyecare	Knoxville, TN
James Lett	Thompson & Lett Eye Care	Chattanooga, TN
Walter Choate	Choate Eye Associates	Goodlettsville, TN

175. Specifically, each of these optometrists received at least the following inducements from SEES:

176. Kenneth Nix, an OD practicing outside Chattanooga, was a member of the SEES Chattanooga Advisory Board and attended many SEES dinners and events. He also attended more than 20 SEES CEs. SEES gave Dr. Nix many gifts such as a tumbler, iboost gift card, umbrella and holiday gifts (even delivering one to his home when he was on sick leave). Dr. Nix was a “Top Referring Doctor in 2014” with more than 120 referrals. In September of 2017 SEES listed him on the “top super targets” list and it was noted that due to the sale of his practice and health issues his referrals may decline, but they should watch his associate’s referrals. He was noted to “frequently co-manage” premium lenses and SEES provided him with checks for premium lens patients, including, for example in 2017, checks in the amounts of \$4,950. Dr. Nix was also the highest SEES referrer for cataract surgeries billed and paid for by TennCare.

177. Thomas Foster, an OD in practice with his wife near Knoxville, was a member of the SEES Knoxville Advisory Board and attended many SEES dinners and

events. In 2013 Dr. Foster was noted by SEES to be in the top 20% for referral of new patients and cataract surgeries, and in 2014 he was on SEES' top referring doctor list with more than 120 referrals. Notes from SEES marketers in 2013 reflect that Foster "still refers all of his cataracts to us" and in 2015 noted that they "refer everything our way". In September of 2017 he was on SEES "top super targets" list which contained the action item of "lunch for doctors and staff". He and his wife were contacted, based upon referrals, before the "official" invitations went out for the 2014 golf tournament. He attended SEES golf tournaments, more than 20 SEES' CEs and SEES gave Dr. Foster numerous gifts such as an umbrella, Keurig, and portable chargers. SEES also provided Foster with checks for premium lens patients, including for example in 2017 checks in the amounts of \$3,150.

178. Mark Kapperman, a Chattanooga OD in practice with Troy White—less than a mile away from SEES' Chattanooga office—was a member of the SEES Chattanooga Advisory Board and attended many SEES dinners and events. He attended golf outings, ballgames and picnics and SEES provided many lunches and gifts. Dr. Kapperman was a "Top Referring Doctor in 2014" with more than 120 referrals. In September of 2017 he was on SEES "top super targets" list which contained the action item of "lunch for doctors and staff". SEES also provided Kapperman with checks for premium lens patients, including, for example in 2017, checks in the amounts of \$7,650.

179. Jerry Richt, a Chattanooga OD, was a member of the SEES Chattanooga Advisory Board and attended many SEES dinners and events. He attended more than 20 CEs, golf tournaments, and other events. Dr. Richt was one of eight high referrers to be invited to a "roundtable" in Cleveland TN and was on a list of ODs that co-manage premium lenses. Dr. Richt was given many holiday and other gifts. He was a "Top Referring Doctor in 2014" with more than 120 referrals. Notes from SEES marketers' visits state in 2013 that he "said he refers all of his cataracts to SEES" and reiterated that again in 2016, when questioned by the marketer about why his referrals were down.

SEES also provided Richt with checks for premium lens patients, including, for example in 2017, checks in the amounts of \$3,450.

180. William Frye, an OD practicing outside Nashville, attended many SEES dinners and events, including golf tournaments, SEES ballgames and picnics, and more than 40 SEES CEs, including a dinner roundtable for “a small group of hand selected Optometric Physicians” to discuss clinical practices and how SEES operates. SEES also provided him with other gifts and lunches. In 2014, he was on the list of top referring doctors with more than 100 referrals and in 2017 was listed as a top referrer. SEES also provided Frye with checks for premium lens patients, including, for example in 2017, checks in the amounts of \$1,800.

181. Barry Winston, a Knoxville OD in practice with his brother and son, Jerry and Sam, was a member of the SEES Knoxville Advisory Board and attended many SEES dinners and events. SEES also provided Dr. Winston with other gifts and lunches. In 2013 he told a SEES marketer that he “appreciates what we do for them” and in 2015 marketers noted that he “refers all patients to us.” In 2013, Dr. Winston was listed in the top 50% of cataract surgery referrals. In 2014 he was listed as a high priority and was on the top referring doctors list with more than 80 referrals. In 2016 he was on the “Top 10 NC Referring list” and in 2017 was on the “Top Super Target list” for 2017. He attended more than 20 CE events and golf tournaments, and received other gifts. SEES also provided Winston with checks for premium lens patients, including, for example in 2017, checks in the amounts of \$6,900.

182. Stephen Elliott and Wayne Connell, Knoxville ODs practicing together, attended many SEES CEs and events. SEES also provided them with gifts, breakfast and lunches. Dr. Elliott was on the Knoxville SEES Advisory Board, and marketing notes from 2013 stated that he will refer everything to SEES and “doesn’t let his patients dictate where they go.” That same year Dr. Elliott was listed by SEES to be in the top 30% for referral of new patients and cataract surgeries, and in 2014 was a “Top Referring

Doctor” with more than 120 referrals. In June of 2018 he reiterated to SEES marketers that he refers all patients to SEES. SEES provided Dr. Elliott with various gifts and SEES also provided him with checks for premium lens patients, including, for example in 2017, checks in the amounts of \$1,950. His partner Dr. Connell also told a SEES marketer that “he refers all of his cataracts to SEES” and that he appreciates us sending his patients back for the PO’s”. SEES marketers’ notes also noted that he “likes that SEES is optometry friendly, and he will continue to refer patients to us.” In 2014 Dr. Connell was listed as a “strong supporter” for an invite list to the SEES golf tournaments which he regularly attended. SEES also provided Connell with gifts and checks for premium lens patients, including, for example in 2017, checks in the amounts of \$450.

183. James Lett, a Chattanooga OD, was a member of the SEES Chattanooga Advisory Board and attended many SEES dinners and events. He attended more than 20 CEs, golf tournaments, and other events. SEES also provided him with many holiday and other gifts. Notes from SEES marketers’ visits state in 2013 that he “will continue to refer all of his patients to SEES” and in 2014 “he said he refers all of his patients to us”. Marketers’ notes show that in 2015 and 2017 his referrals remained constant and consistent. SEES also provided Lett with checks for premium lens patients including, for example in 2017, checks in the amounts of \$1,500 for premium lens patients.

184. Walter Choate, a Nashville OD, supported SEES and was instrumental in bringing it to Nashville. He was on the SEES Nashville Advisory Board and attended many dinners and other events paid for by SEES. In September of 2017, SEES stated that Dr. Choate “is our top referring OD” with 78 referrals YTD. He attended many CEs including 2 of the 3 CEs in Nashville in 2016 and a roundtable at Oak Steakhouse; lunches were brought to his office; and marketing notes reflect his number of referrals and document the gifts provided to him. SEES also provided Choate with checks for premium lens patients, including, for example in 2017, checks in the amounts of \$4,200.

185. The following are specific examples of claims for procedures submitted and/or caused to be submitted by SEES Defendants and Defendants Mann and Bierly to Medicare—and paid by Medicare—that resulted from referrals by the optometrists listed above.

Bene	Referring Optometrist Lase Name	Procedure Code²	Date of Service	Surgery Payment to SEES	ASC Payment to Defendant ESCC	ASC Payment to Defendant SESC	Payment to OD
J.D.	Nix	66984	10/23/12	\$447.11	\$723.10		\$111.78
H.L.	Nix	66984	4/27/18	\$384.84	\$722.51		\$92.38
V.S.	Foster	66984	7/13/15	\$380.77	\$704.39		\$95.20
H.L.	Foster	66982	12/10/20	\$457.49	\$750.42		\$114.20
P.C.	Kapperman	66984	6/4/13	\$383.98	\$710.96		\$95.99
D.H.	Kapperman	66982	1/9/19	\$480.13	\$567.13		\$121.45
H.H.	Richt	66984	5/5/14	\$387.88	\$718.32		
D.J.	Richt	66984	7/8/16	\$372.01	\$719.93		
E.L.	Frye	66984	8/22/17	\$373.89	\$714.62		\$91.60
C.M.	Frye	66984	9/4/18	\$384.84	\$722.51		\$114.09
K.H.	Winston	66982	4/27/15	\$471.54		\$817.55	\$91.43
D.M.	Winston	66884	0/1/17	\$381.51		\$843.61	\$91.60
V.G.	Elliott	66984	12/2/13	\$383.98		\$853.28	\$95.99
N.M.	Elliott	66984	7/31/19	\$385.21		\$840.89	\$97.33

² Cataract surgeries are billed using Current Procedural Terminology (CPT) codes. The procedures included in these sample claims are cataract surgeries and YAG laser capsulotomy codes: CPT 66984 (Removal of cataract with insertion of lens, simple), CPT 66982 (Removal of cataract with insertion of lens, complex), and CPT 66821 (Removal of recurring cataract in lens capsule using laser).

J.P.	Connell	66984	8/24/16	\$372.01		\$855.22	\$94.89
J.K.	Connell	66984	1/23/19	\$385.21		\$840.89	\$95.95
B.S.	Lett	66984	8/17/17	\$381.51	\$714.62		\$88.86
V.A.	Lett	66821	9/14/20	\$188.62	\$189.80		\$40.00
V.D.	Choate	66984	8/8/16	\$372.01			\$91.14
J.A.	Choate	66821	3/2/18	\$196.76			\$47.72

186. The following are specific examples of claims for procedures submitted and/or caused to be submitted by SEES Defendants and Defendants Mann and Bierly to TennCare—and paid by TennCare—that resulted from referrals by the optometrists listed above:

Bene	Referring Optometrist	Procedure Code	Dates of Service	Reimbursement SEES
J.H.	Kenneth Nix	66984	5/8/18	\$424.66
M.L.	Kenneth Nix	66984	6/20/19	\$417.08
P.G.	William Frye	66984	10/31/12	\$417.08
B.H.	William Frye	66984	3/10/21	\$424.66
P.J.	Wayne Connell	66984	8/19/15	\$417.08

187. The Defendants submitted and caused the submission of claims for payment for the surgeries tainted by SEES payment of kickbacks to referring optometrists, including but not limited to the above representative examples. Through their illegal conduct, Defendants have submitted thousands of false or fraudulent claims to Medicare, Medicare Advantage providers and other government health care programs.

188. In 2015 and 2016, Medicare and Blue Cross Blue Shield of Tennessee collectively represented —55% of SEES’ reimbursement.

189. Defendants’ claims for payment for surgeries that are tainted by kickbacks have resulted in tens of millions of dollars billed to Medicare and TennCare.

190. SEES most common co-management procedures are cataracts, but they also routinely co-managed other Medicare funded procedures, including YAG capsulotomy for IOL related vision improvement, and Selective Laser Trabeculoplasty for glaucoma treatment. In the December 6th seminar, Dr. Robin Brady emphasized to his audience of optometrists that “every surgery that we provide is co-manageable, to a point that CMS allows a co-management code.”

191. Not only does SEES collect substantial and improper professional fees from the Government, but its affiliated surgical centers, Defendants Southeast Eye Surgery Center and Eye Surgery Center of Chattanooga—whose officers are the same as SEES officers and/or co-founders—also collect fees tainted by kickbacks.

192. Each surgical procedure performed at these surgical centers results in facility, anesthesia and other ancillary fees that likely exceed all professional fees combined.

193. Defendants have also submitted and caused the submission of false records and statements material to false or fraudulent claims including by falsely certifying compliance with the AKS.

2. Defendants Acted Willfully and Knowingly

194. Through its schemes of providing remuneration through co-management and other inducements including CEs, dinners, and other events, Defendants acted both “willfully” within the meaning of the AKS and “knowingly” within the meaning of the FCA and TMFCA. They each had actual knowledge that their conduct violated the AKS, but even if they did not they acted in deliberate ignorance, or with reckless disregard, of

the fact that they were submitting false claims to Medicare and Medicaid as alleged here and that they were making false records or statements material to false claims to get paid.

195. As demonstrated above, SEES, Mann and Bierly each had actual knowledge that they were paying kickbacks to optometrists for the purpose of securing referrals and that the claims for payment tainted by those violations were therefore false or fraudulent claims under the FCA, but at a minimum they acted in deliberate ignorance, or reckless disregard, of whether the claims were false or fraudulent.

196. First, co-management and its appropriateness has been the subject of much guidance and information that SEES itself has acknowledged; yet SEES has ignored that guidance. Second, providing things of value, whether commissions for recommending more expensive procedures, or free events and meals to induce referrals, are classic kickbacks that the industry and all physicians know violate the AKS. *See, e.g.,* <https://oig.hhs.gov/compliance/physician-education/01laws.asp> (explaining Anti-Kickback Statute prohibition on receiving anything of value to induce or reward referrals).

197. Defendants were aware of and repeatedly warned of the illegality of their practices.

a. SEES knew its co-management model violated the AKS

198. As described above, no AKS safe harbor applies to co-management arrangements between ophthalmologists and referring optometrists. Indeed, when the safe harbor for specialty arrangements was considered, HHS expressly rejected a safe harbor for such co-management arrangements. Thus, where such an arrangement is used to induce referrals, as SEES routine co-management practice clearly was, it violates the AKS. In combination with the other extensive remuneration to the same optometrists, SEES conduct plainly violated the AKS.

199. Even if SEES had any doubt, it was warned away from its conduct in numerous ways. For example, the American Academy of Ophthalmology is the largest

professional association of ophthalmologists. The AAO has released a number of position papers/guidance documents on ophthalmologist-optometrist co-management agreements, cautioning against routine co-management.

200. A joint position paper, issued with the American Society of Cataract and Refractive Surgery, emphasized that co-management was to be “an exceptional, rather than a routine, occurrence.” American Academy of Ophthalmology et. al., Joint Position Paper: Ophthalmic Postoperative Care. (2000). It also stated that “co-management must not be done as a matter of routine policy” and if it “is done on a routine basis for predominately financial reasons, it represents unethical behavior and may be illegal.”

201. While the American Optometric Association did not adopt the “exceptional, rather than routine” language, it nevertheless emphasized in its paper issued in 2000 that co-management of post-operative care should be “determined on a case-by-case basis and **not prearranged.**” American Optometric Association, Optometric Postoperative Care, (Apr. 27, 2000).

202. In 2015, the AAO noted that a criteria of appropriate co-management that “must be met” included that there was “no agreement between the operating ophthalmologist and a referring non-operating practitioner to automatically send patients back to the non-operating practitioner.” American Academy of Ophthalmology et. al., Ophthalmic Postoperative Care: A Joint Position Paper of the American Academy of Ophthalmology and the American Society of Cataract and Refractive Surgery (June 2015).

203. In 2016, the AAO again emphasized that “routine co-management or transfer of care referral arrangements are not appropriate. Instead, co-management and transfer of care arrangements should be conducted pursuant to written patient-specific protocols where each of the following criteria are met, [such as having] no agreement or understanding between the operating ophthalmologist and a referring non-operating practitioner to automatically send patients back to the non-operating practitioner.”

American Academy of Ophthalmology et. al., Comprehensive Guidelines for the Co-Management of Ophthalmic Postoperative Care. (Sept. 7, 2016).

204. The industry understanding that routine cataract co-management agreements were prohibited was widespread and extensively disseminated by professional societies (to which Mann and Bierly belonged), professional journals, articles, professional guidelines and regulations, such that anyone engaged in these agreements, including each of the Defendants, would have actual knowledge that such arrangements could violate the AKS.

205. SEES itself acknowledged that routine co-management is improper. Indeed, its own presentation to optometrists, for which Defendant Mann was listed as a presenter, and expressly acknowledges that co-management cannot be routine:

<p>AAO/ASCRS CM Position Paper, cont'd</p> <ul style="list-style-type: none">• Surgeon inform patient of financial obligations and reimbursement• Transfer occurs when clinically appropriate and in patient's best interest• Surgeon confirms co-manager is legally entitled and trained...• Not be done as a matter of routine policy	<p>AAO/ASCRS Comanagement Position Paper closing paragraph</p> <ul style="list-style-type: none">• Surgeon has ultimate responsibility for the pre-op assessment and post-op care• Decision to co-manage be in patient's best interest and not financial considerations• If done on a routine basis for financial reasons... unethical behavior and may be illegal
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206. In this same presentation they also acknowledge that it is illegal to induce referrals.

207. SEES also created a presentation on "Cataract Co-management" which makes clear their understanding that agreements to send patients back must not be automatic and must comply with the AKS:


Co-management Guidelines

- ▶ Non-operating doctor is willing to accept the care of the patient
- ▶ State law permits the non-operating doctor to provide postoperative care
- ▶ There is no agreement between the ophthalmologist and the optometrist to automatically send patients back to the optometrist
- ▶ The arrangement complies with all applicable federal and state laws including the federal anti-kickback and Stark laws

In that same presentation, they note:



Financial Considerations



Economic considerations should never influence the decision to co-manage or the timing of the transfer of care.

208. Moreover, Dr. Mann understood that establishing a blanket schedule for post-op appointments should not be put in writing, as he advised SEES' manager of surgery scheduling in a 2017 email (regarding the plan that had been agreed to be based upon Dr. Kapperman's blanket preferences):

Message

From: Daryl Mann [dmann32261@aol.com]
on behalf of Daryl Mann <dmann32261@aol.com> [dmann32261@aol.com]
Sent: 1/9/2017 2:56:51 PM
To: Trish Cole [TCole@southeasteye.com]
Subject: Re: Post op appointments

I do not think we should put this in writing.

Daryl F. Mann, OD
SouthEast Eye Specialists, PLLC
Suite 200 Jarnigan Medical Center
7268 Jarnigan Road
Chattanooga, TN 37421
O: 423-508-7337
C: 423-280-7337

209. SEES' CEO also flagged as potentially unlawful the checks that SEES pays for premium upgrades. When a suggestion was made by an employee to use these checks and the amount SEES has paid as a marketing tool and/or cross reference with referral activity from the doctors they cut checks for, Mr. Pereyra said "actually we need to be cautious--that this could run afoul of the Stark law".

Message

From: James Pereyra [/O=FIRST ORGANIZATION/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=96E9ECBB2E52498297AB27274F79136D-JAMES]
Sent: 5/12/2017 3:08:55 PM
To: Bruce Short [BShort@southeasteye.com]
Subject: RE: Co Management Payments April 2017

Actually, we need to be cautious here, lots of ways to get tripped up with the Stark laws.

From: Bruce Short
Sent: Friday, May 12, 2017 4:25 AM
To: James Pereyra <JPereyra@southeasteye.com>
Subject: RE: Co Management Payments April 2017

Is there anyway we can use this factoid in sales??? We paid 26k ..people like to follow...maybe a thank you note from you to the top referral payments or an in person meeting with all your spare time
Thank you, John. This is an excellent report. In the future (not in the short-term) we may want to cross reference this report with the referral activity from the doctors that we cut checks for. Not a priority item, but someday it will be nice.

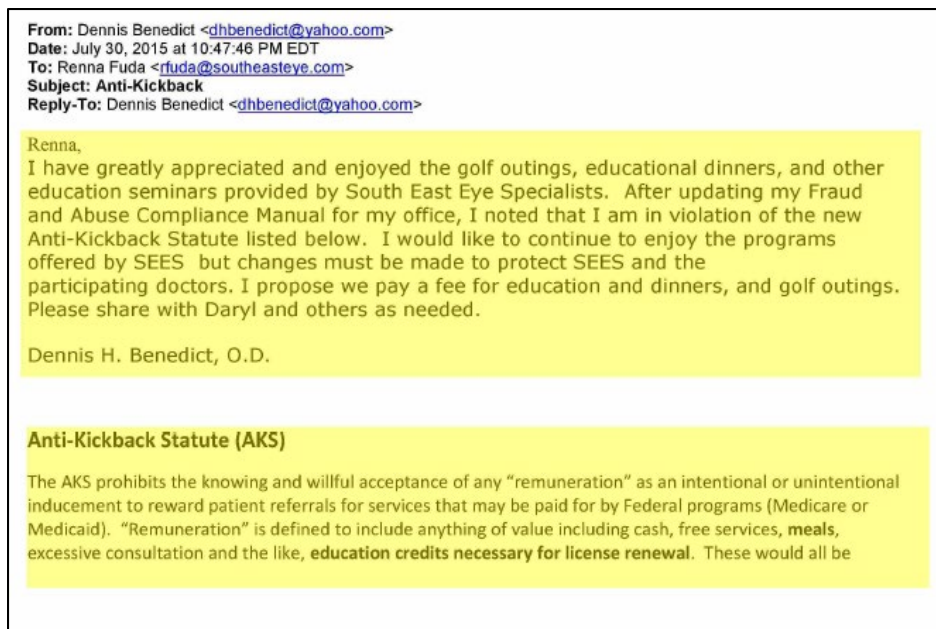
James

b. SEES knew its other payments to optometrists violated the AKS

210. SEES was also well aware that free events and other goods that it provided to referring optometrists could violate the AKS. Ample guidance available to physicians instructs that providing such items to induce referrals violates the law, and cases enforcing the AKS have received wide publicity.

211. Optometrists also called to SEES attention the kickback problems. In 2015, Dr. Dennis Benedict emailed SEES with this belief that the CEs, golf outings and other gifts from SEES violated the kickback laws, specifically quoting the section of the law and stating that CE credits and meals were inappropriate.

212. Dr. Benedict proposed that SEES charge a fee for CEs, golf outings and dinners in order to avoid kickback violations:



213. That email was forwarded to Defendant Mann and discussed with Defendant Bierly and others at SEES.

214. Dr. Benedict sent a second email a month later which Zach McCarty forwarded to Dr. Mann stating that the doctor is “still at it”.

215. SEES then decided to set up a foundation for the CEs, charge a nominal amount for the CE that didn’t cover the costs and still was not standard for the industry.

216. Although following the warnings, SEES made some cosmetic changes, it did not change its practice of providing dinner events for their CEs. For example, in Nashville in September of 2017, SEES held a CE event at the Gaylord costing more than \$100 per person (more than \$6,000 for 50 attendees), and included passed hors d’oeuvres, a \$60 per person buffet and alcohol/open bar.

217. Finally, Hooten, SEES head marketer and Practice Development Coordinator for many years (and during the time period for the conduct at issue), was well aware of AKS rules and also stated that she knows the co-management rules and signed up for an outside compliance program on the topic.

VII. CAUSES OF ACTION

Count I **False Claims Act** **31 U.S.C. §3729(a)(1)(A)** **(All Defendants)**

218. Relators reallege and incorporate by reference the allegations contained in paragraphs 1 through 217 above as though fully set forth herein.

219. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. § 3729, *et seq.*, as amended.

220. By and through the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the United States Government for payment or approval.

221. The Government, unaware of the falsity of claims made or caused to be made by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal conduct.

222. By reason of Defendants' acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

223. Additionally, the United States is entitled to the maximum penalty of up to \$11,000 for each and every violation alleged herein occurring prior to November 2, 2015, and as adjusted for inflation thereafter. 28 C.F.R. § 85.5.

Count II
False Claims Act
31 U.S.C. § 3729(a)(1)(B)
(All Defendants)

224. Relators reallege and incorporate by reference the allegations contained in paragraphs 1 through 217 above as though fully set forth herein.

225. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. § 3729, *et seq.*, as amended.

226. By and through the acts described above, Defendants knowingly made, used, and caused to be made or used, false records or statements material to false or fraudulent claims.

227. The Government, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal conduct.

228. By reason of Defendants' acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

229. Additionally, the United States is entitled to the maximum penalty of up to \$11,000 for each and every violation alleged herein occurring prior to November 2, 2015, and as adjusted for inflation thereafter. 28 C.F.R. § 85.5.

Count III
Tennessee Medicaid False Claims Act
Tenn. Code Ann. § 71-5-182(a)(1)(A)
(All Defendants)

230. Relators reallege and incorporate by reference the allegations contained in paragraphs 1 through 217 above as though fully set forth herein.

231. This is a claim for treble damages and penalties under the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181, *et seq.*

232. By and through the acts above, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the Tennessee State Government for payment or approval under the Medicaid program.

233. The Tennessee State Government, unaware of the falsity of the claims that Defendants made or caused to be made, paid and continues to pay the claims that would not be paid but for Defendants' illegal conduct.

234. Defendants have damaged, and continue to damage, the State of Tennessee in a substantial amount to be determined at trial.

235. Additionally, the Tennessee State Government is entitled to the maximum penalties pursuant to the Tennessee Medicaid False Claims Act for each and every violation alleged herein.

Count IV
Tennessee Medicaid False Claims Act
Tenn. Code Ann. § 71-5-182(a)(1)(B)
(All Defendants)

236. Relators reallege incorporate by reference the allegations contained in paragraphs 1 through 217 above as though fully set forth herein.

237. This is a claim for treble damages and penalties under the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181, *et seq.*

238. By and through the acts above, Defendants knowingly made, used, or caused to be made or used false records and statements material to a false or fraudulent claim under the Medicaid program.

239. The Tennessee State Government, unaware of the falsity of the records, statements, and claims that Defendants made or caused to be made, paid and continues to pay the claims that would not be paid but for Defendants' illegal conduct.

240. Defendants have damaged, and continue to damage, the State of Tennessee in a substantial amount to be determined at trial.

241. Additionally, the Tennessee State Government is entitled to the maximum penalties pursuant to the Tennessee Medicaid False Claims Act for each and every violation alleged herein.

PRAYER

WHEREFORE, *qui tam* Relators pray for judgment against the Defendants as follows:

1. That Defendants cease and desist from violating 31 U.S.C. § 3729, *et seq.* and Tenn. Code Ann. § 71-5-181, *et seq.*;
2. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the United States and the State of Tennessee have sustained because of Defendants' actions, plus a civil penalty of not less than \$5,500 and not more than \$11,000 for each violation of 31 U.S.C. § 3729 occurring prior to November 2, 2015, and as adjusted for inflation thereafter. 28 C.F.R. § 85.5 and the maximum penalties under the Tennessee Medicaid False Claims Act, Tenn. Code. Ann. § 71-5-182(a);
3. That Relators be awarded the maximum amount allowed pursuant to § 3730(d) of the False Claims Act and the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-183(d);
4. That Relators be awarded all costs of this action, including attorneys' fees and expenses; and
5. That Relators recover such other relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, *qui tam* Relators Gary Odom and Ross Lumpkin hereby demand a trial by jury.

Dated: May 6, 2021

Respectfully submitted,

/s/ Amy L. Easton
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