UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

Plaintiffs,	**No. ______________**
v.	**DEMAND FOR JURY TRIAL**
Defendants.	**FILED IN CAMERA/UNDER SEAL PURSUANT TO 31 U.S.C. § 3730**

RELATORS' ORIGINAL COMPLAINT

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

UNITED STATES and STATE OF TEXAS *ex rel.* DANIEL W. ELLIOTT, M.D. and LISA A. MINSLOFF, M.D.,

Plaintiffs,

v.

SOUTHEAST TEXAS MEDICAL ASSOCIATES, LLP; STEWARD HEALTH CARE SYSTEM; ONPOINT LAB, L.L.C.; BAPTIST HOSPITALS OF SOUTHEAST TEXAS; MUHAMMAD AZIZ, M.D.; JAMES HOLLY, M.D.; MARY CASTRO, M.D.; VIJAY KUMAR, M.D.; MICHAEL THOMAS, M.D.; SYED ANWAR, M.D.; CAESAR DEIPARINE, M.D.; RONALD PALANG, M.D.; ABSAR QURESHI, M.D.; DEAN HALBERT, M.D.; and WILLIAM GEORGE, M.D.,

Defendants.

No. __________

DEMAND FOR JURY TRIAL

FILED IN CAMERA/UNDER SEAL PURSUANT TO 31 U.S.C. § 3730

RELATORS' ORIGINAL COMPLAINT

1. Daniel Elliott, M.D. ("Dr. Elliott") and Lisa Minsloff, M.D. ("Dr. Minsloff") (together, "Relators") bring this action against Defendants on behalf of the United States of America and the State of Texas through the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3729, *et seq.* ("False Claims Act" or "FCA"), and the Texas Medicaid Fraud Prevention Law, TEX. HUM. RES. CODE ANN. § 36.001, *et seq.*

("TMFPL"). Relators seek to recover all available damages, penalties, and remedies against Defendants for Defendants' violations of federal and state law detailed herein.

INTRODUCTION

2. This is an action under the False Claims Act and the TMFPL to recover damages and civil penalties from Defendants for knowingly submitting, or causing to be submitted, false claims to government health care programs, including, but not limited to, Medicare and the Texas Medicaid program, and for knowingly offering, paying, soliciting, and/or accepting remuneration in exchange for medical referrals in violation of federal and state law, and for making self-referrals for lab services to an entity in which several Defendants own a financial interest in violation of the Stark Law.

3. Relators are practicing physicians who met each other and began dating in their first year of medical school. After medical school, they attended their residency programs in Lubbock, Texas. Toward the end of their respective residency programs, Relators negotiated employment agreements with a medical practice in Beaumont, Texas, named Southeast Texas Medical Associates, sometimes referred to as "SETMA." Relators signed their employment agreements with SETMA in January 2015. A significant portion of SETMA's patients were Medicare and Medicaid patients.

4. Relators married in May 2015 and then completed their respective residency programs. As newly minted doctors eager to use their training to help care for sick people, Relators moved to Dr. Elliott's hometown of Beaumont, Texas, purchased their first home, and prepared to begin their professional careers.

5. Almost immediately, Relators were rocked by a disorienting array of schemes, self-referrals, upcoding, and greed that permeated SETMA, many of its physicians' practices, and some of the health care entities that did business with SETMA.

6. First, in June and July 2015, the Director of Physician Recruitment at Defendant Baptist Hospitals of Southeast Texas ("Baptist Hospital") emailed Relators to explain to them that they needed to execute physician recruiting agreements with the hospital. As explained in further detail below, Relators were not recruited to Beaumont by Baptist Hospital. In fact, Relators had already signed an employment agreement with SETMA, moved to Beaumont, and purchased their first home before Baptist Hospital ever emailed Relators proposed terms for the so-called recruitment.

7. The recruiting agreements were a sham forced upon Relators by SETMA and Baptist Hospital that purported to justify Baptist Hospital paying remuneration to SETMA—a major referral source for the hospital. Notably, these agreements were not for the financial benefit of Relators who had already negotiated and accepted three-year employment agreements with SETMA long before they ever heard of a purported recruiting agreement with Baptist Hospital. Tellingly, the purported recruiting agreements were not fully executed until on or around August 19, 2015, after Relators had already begun working at SETMA.

8. Instead of being bona fide recruiting agreements designed to draw doctors to an underserved area of the country, the agreements were actually intended to benefit SETMA and Baptist Hospital financially. In exchange for the remuneration paid by Baptist Hospital, SETMA's managers encouraged its employee practitioners to make

referrals to Baptist Hospital, including for Medicare and Medicaid patients. The financial relationship between SETMA and Baptist Hospital violated the Stark Law and the Anti-Kickback Statute and did not meet the necessary requirements for a Stark Law exception or an Anti-Kickback Statute safe harbor, therefore making all relevant government-payor claims submitted by Baptist Hospital on referrals from SETMA during this period false under the False Claims Act.

9. Next, Relators discovered that many of the physicians at SETMA had a financial incentive to order and refer laboratory tests. In fact, during their orientation and on-boarding, Relators were told by then Chief Operations Officer Richard "Rick" Bryant that SETMA would monitor the number of drug tests being ordered by Relators because many of the doctors had a financial interest in the lab company that performed the drug testing. Concerned, Dr. Elliott asked whether that was legal. Mr. Bryant explained that it was fine because SETMA supposedly had a sign in the lobby that served as a notice to patients of the apparent conflict of interest.

10. As it turns out, the arrangement is neither fine nor legal; to the contrary, it is brazenly illegal. In fact, as of 2017, the following Defendants are listed as managers or members of Defendant OnPoint Lab, L.L.C. ("OnPoint"):

- Muhammad Aziz, M.D.;
- James Holly, M.D.;
- Syed Anwar, M.D.;
- Caesar Deiparine, M.D.;
- Dean Halbert, M.D.;

- Michael Thomas, M.D.;
- Ronald Palang, M.D.;
- Vijay Kumar, M.D.;
- Mary Castro, M.D.; and
- Absar Qureshi, M.D.

These physicians, along with Dr. William George, M.D. who is not believed to be a member of OnPoint, are collectively referred to herein as "Defendant Physicians."

11. These Defendant Physicians and/or SETMA self-referred patient specimens to a lab company believed to be OnPoint. In fact, Relators recall receiving an email from Defendant Castro—one of the owners of OnPoint—rallying SETMA physicians to order more drug screen tests. SETMA also regularly circulated statistics by email showing the number of drug tests being ordered by each provider. These emails were even sent to pediatricians like Dr. Minsloff.

12. Consistent with Relators' insider account, Medicare payment data published by the Centers for Medicare & Medicaid Services (CMS) reveals an unusually high rate of expensive full-panel drug tests by OnPoint. For example, in 2016 (the only full year in which Relators worked at SETMA), OnPoint billed Medicare for services rendered to a total of 2,554 Medicare beneficiaries. An astonishing 2,545 of those beneficiaries (over 99.6%)—all of whom, of course, were necessarily elderly or disabled in order to qualify for Medicare—received the so-called "22+" drug test, which screens for at least 22 different illicit substances at a cost to taxpayers of over $200 per test.

13. The CMS data also shows that, in the years following OnPoint's founding, several of the Defendant Physicians—including Drs. Holly, Anwar, Aziz, Qureshi, Kumar, and Castro, as well as their SETMA colleague Dr. George—were the highest billers among providers in their respective areas of practice in terms of the number of blood sample draws taken per Medicare beneficiary. For example, in 2016, Dr. Holly ordered over eight blood sample draws for each Medicare beneficiary, more than four times the statewide average among family practice providers. Dr. Holly boasted the second-highest rate of blood draws taken out of more than 1,900 family practice providers in Texas and the sixth-highest rate out of more than 28,000 family practice doctors nationwide, both in the 99.9th percentile.

14. Like Dr. Holly, the other Defendant Physicians and SETMA itself were notable outliers for blood sample draws taken. In the years after OnPoint's founding, Drs. Aziz, Anwar, Qureshi, Kumar, Castro, and George, as well as SETMA itself, consistently ranked among the top 5% or higher in their respective practice areas both in terms of number of blood draws taken and blood draws per beneficiary. For instance, in 2016, Drs. George, Anwar, and Aziz ranked 4th, 9th, and 15th, respectively, out of more than 1,156 internal medicine doctors in Texas for number of blood samples taken, and Dr. Kumar ranked third among all Texas rheumatologists. Likewise, in 2016, SETMA itself ranked third among all Texas clinics in blood draws per beneficiary.

15. SETMA doctors also showed an unusual proclivity to bill Medicare for transporting lab samples. The Medicare code for transporting lab samples allows for tracking and billing by the mile. In 2015, SETMA doctors and SETMA itself occupied

eight of the top nine spots (and nine of the top 14 spots) in Texas in terms of miles billed per beneficiary. In 2016, the same group occupied nine of the top 10 slots in Texas on the same measure, and in 2017, they were seven of the top nine. The SETMA doctors' mileage billing dwarfed the transport miles billed by other providers under this code. For instance, the SETMA doctors that billed this code on average billed more than 300 miles per beneficiary, with Drs. Castro and Qureshi each billing more than 400 miles per beneficiary. In the same years only about 15 providers (most affiliated with SETMA) in all of Texas, a famously large State, charged more than 100 miles per beneficiary for this code. Based on this data, it appears the SETMA doctors were charging Medicare for hundreds of thousands of miles for transporting lab samples. Notably, the OnPoint lab is located in Sugar Land, Texas, more than 100 miles from Beaumont.

16. Next, Relators learned that Defendants Anwar and Aziz—members of SETMA's Executive Management team (and also part owners of OnPoint)—were remotely reviewing charts after other SETMA physicians or personnel prepared those charts. Based on Relators' recollection, these chart reviews were common. On information and belief, these changes likely increased reimbursement to SETMA, either by increasing amounts billed to a provider or increasing per capita payments under managed care programs like TexanPlus by documenting more serious conditions than those documented by the treating physician.

17. After approximately 20 months, Relators ended their employment with SETMA and moved away from Beaumont. SETMA had not turned out to be the patient-focused, care-driven practice they expected. Although they wanted to put their experience

with SETMA behind them and move on with their lives, Relators could not ignore the illegality of Defendants' schemes. Believing it is the right thing to do for patients, taxpayers, and the medical profession, Relators bring this action to stop the health care fraud and abuses they witnessed and to help recover funds that should never have been paid to Defendants.

PARTIES

Plaintiffs

18. Relator Daniel W. Elliott, M.D. is an individual citizen of the United States of America residing in Belton, Texas. Dr. Elliott is a physician specializing in Family Medicine. He has direct, first-hand, and independent knowledge of conduct giving rise to this lawsuit. Dr. Elliott is a former employee of SETMA. During the regular course of his employment, Dr. Elliott had access to information as part of his job duties and responsibilities that supports the claims brought herein.

19. Relator Lisa A. Minsloff, M.D. is an individual citizen of the United States of America residing in Belton, Texas. Dr. Minsloff is a physician specializing in Pediatric Medicine. She has direct, first-hand, and independent knowledge of conduct giving rise to this lawsuit. Dr. Minsloff is a former employee of SETMA. During the regular course of her employment, Dr. Minsloff had access to information as part of her job duties and responsibilities that supports the claims brought herein.

20. The United States of America is a Plaintiff and real party in interest as set forth in the False Claims Act. Relators seek recovery on behalf of the United States for amounts paid by the United States Treasury and the Department of Health and Human

Services as a result of false claims submitted, or caused to be submitted, by Defendants, as well as all applicable enhancements and penalties.

21. The State of Texas is a Plaintiff and real party in interest as set forth under Texas Law. Relators seek recovery on behalf of the State of Texas for amounts paid by Texas Medicaid as a result of false claims submitted, or caused to be submitted, by Defendants, as well as all applicable enhancements and penalties.

Defendants

22. Defendant Southeast Texas Medical Associates, LLP ("SETMA") is a Texas limited liability partnership with a principal office in Beaumont, Texas. The Texas Secretary of State website currently shows no registered agent on file for SETMA. Relators believe SETMA can be served at 2929 Calder, Suite 100, Beaumont, Texas 77702 or through its parent company Steward Health Care System LLC as described below.

23. Defendant Steward Health Care System LLC ("Steward Health") is a Delaware limited liability company headquartered in Dallas, Texas, and doing business in the Eastern District of Texas. In January 2019, SETMA and Steward Health announced that SETMA had become part of Steward Health, which described itself as the "largest private, for profit physician led health care network in the United States."[1] Steward Health can be served through its registered agent C T Corporation, 1999 Bryan Street, Suite 900, Dallas, Texas 75201.

[1] *See* "Southeast Texas Medical Associates Joins Steward Medical Group," https://www.steward.org/news/2019-01-04/southeast-texas-medical-associates-joins-steward-medical-group (last visited April 24, 2020).

24. Defendant OnPoint Lab, L.L.C. ("OnPoint") is a Texas limited liability company transacting business in the Eastern District of Texas. It can be served through its registered agent Chandresh Patel, 1229 Creekway Drive, Suite 103, Sugar Land, Texas 77478.

25. Defendant Baptist Hospitals of Southeast Texas ("Baptist Hospital") is a Texas nonprofit corporation doing business in the Eastern District of Texas. It can be served through its registered agent Corporation Services Company d/b/a CSC-Lawyers Incorporating Service Company, 211 East 7th Street, Suite 620, Austin, Texas 78701.

Defendant Physicians

26. Defendant Muhammad Aziz, M.D. is a resident of Texas who can be served at 2929 Calder, Suite 100, Beaumont, Texas 77702, at his place of abode, or wherever else he may be found.

27. Defendant James Holly, M.D. is a resident of Texas who can be served at 2929 Calder, Suite 100, Beaumont, Texas 77702, at his place of abode, or wherever else he may be found.

28. Defendant Mary Castro, M.D. is a resident of Texas who can be served at 2929 Calder, Suite 100, Beaumont, Texas 77702, at his place of abode, or wherever else she may be found.

29. Defendant Vijay Kumar, M.D. is a resident of Texas who can be served at 2929 Calder, Suite 100, Beaumont, Texas 77702, at his place of abode, or wherever else he may be found.

30. Defendant Michael Thomas, M.D. is a resident of Texas who can be served at 2929 Calder, Suite 100, Beaumont, Texas 77702, at his place of abode, or wherever else he may be found.

31. Defendant Syed Anwar, M.D. is a resident of Texas who can be served at 2929 Calder, Suite 100, Beaumont, Texas 77702, at his place of abode, or wherever else he may be found.

32. Defendant Caesar Deiparine, M.D. is a resident of Texas who can be served at 2929 Calder, Suite 100, Beaumont, Texas 77702, at his place of abode, or wherever else he may be found.

33. Defendant Ronald Palang, M.D. is a resident of Texas who can be served at 2929 Calder, Suite 100, Beaumont, Texas 77702, at his place of abode, or wherever else he may be found.

34. Defendant Absar Qureshi, M.D. is a resident of Texas who can be served at 2929 Calder, Suite 100, Beaumont, Texas 77702, at his place of abode, or wherever else he may be found.

35. Defendant Dean Halbert, M.D. is a resident of Texas who can be served at 2929 Calder, Suite 100, Beaumont, Texas 77702, at his place of abode, or wherever else he may be found.

36. Defendant William George, M.D. is a resident of Texas who can be served at 2929 Calder Street, Suite 100, Beaumont, Texas 77702, at his place of abode, or wherever else he may be found.

RESPONDEAT SUPERIOR AND VICARIOUS LIABILITY

37. Defendant Steward Health owns and controls Defendant SETMA. Steward Health is vicariously liable for the actions and omissions of SETMA. Defendant SETMA is vicariously liable for the actions and omissions of its executives, employees, and agents.

JURISDICTION AND VENUE

38. This Court has subject matter jurisdiction over these claims brought under the False Claims Act, 31 U.S.C. §§ 3279, *et seq*., pursuant to 31 U.S.C. §§ 3730 and 3732, 28 U.S.C. § 1331, and 28 U.S.C. § 1345. This Court has supplemental jurisdiction to entertain the Texas Law causes of action under 28 U.S.C. § 1367(a) and 31 U.S.C. § 3732(b).

39. This Court has personal jurisdiction over Defendants pursuant to 31 U.S.C. § 3732(a) because that section of the False Claims Act authorizes nationwide service of process, implicating the National Contacts Test for personal jurisdiction, and because some or all of Defendants operate, reside, and/or transact business in the Eastern District of Texas.

40. Venue is proper in this district pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1391(b) and 1395(a) because at least some of Defendants transact business in this District.

41. Relators are not aware of any public disclosures of the allegations and transactions contained herein that bar jurisdiction under 31 U.S.C. § 3730.

42. A copy of this Complaint is being served upon the Attorney General for the United States, the United States Attorney's Office for the Eastern District of Texas, and the

Texas Office of the Attorney General. A written disclosure statement setting forth all material evidence and information Relators possess is also being submitted to these offices as required by 31 U.S.C. § 3730(b)(2). *See* Fed. R. Civ. P. 4(d)(4).

43. Relators are the original source of the information forming the basis of this action because they possess direct and independent knowledge of the non-public information upon which the allegations herein are based. *See* 31 U.S.C. § 3730(e)(4)(B). Relators acquired non-public information from approximately September 2014 through March 2017 that is independent from and materially adds to any publicly disclosed information relating to Defendants' violations of the False Claims Act and Texas Law described herein. Relators' first-hand knowledge is derived from, among other things, internal emails, reports, claims submission information, and correspondence, both verbal and written, with some or all of Defendants and other employees or persons.

44. Relators have complied with all conditions precedent to bringing this action.

LEGAL FRAMEWORK

A. The Medicare Program

45. In 1965, Congress enacted The Health Insurance Program for the Aged and Disabled through Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395 *et seq*., ("Medicare"). Medicare is a federal health care program providing benefits to persons who are over the age of 65 and some under that age who are blind or disabled. Medicare is administered by the Centers for Medicare & Medicaid Services (CMS), a federal agency under the Department of Health and Human Services (HHS). Individuals who receive benefits under Medicare are referred to as Medicare "beneficiaries."

46. Medicare is a "Federal health care program," as defined in the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(f).

47. The Medicare Program includes various "Parts," which refer to the type of service or item covered. For purposes of this action, the primary components at issues are Parts A and B. Medicare Part A authorizes payment of federal funds for, among other things, medically necessary inpatient hospital care. Medicare Part B covers, among other things, medically necessary outpatient care, physician services, and diagnostic laboratory services.

48. Medicare reimburses only reasonable and necessary medical products and services furnished to Medicare beneficiaries and excludes from payment services that are not reasonable and necessary. 42 U.S.C. § 1395y(a)(1)(A); 42 C.F.R. § 411.115(k). Providers must provide medical services to Medicare beneficiaries "economically and only when, and to the extent, medically necessary." 42 U.S.C. § 1320c-5(a)(1).

49. Medicare utilizes "Medicare Administrative Contractors," sometimes referred to as "fiscal intermediaries" or "carriers," to administer Medicare in accordance with rules developed by CMS. These contractors are charged with and responsible for accepting Medicare claims, determining coverage, and making payments from the Medicare Trust Fund.

50. CMS contracts out to carriers to review, approve, and pay Medicare claims received from health care providers. Given that it is neither realistic nor feasible for CMS or its contractors to review medical documentation before paying each claim, payment is generally made under Medicare in reliance upon the provider's enrollment obligations as

well as certifications on Medicare claim forms that services in question were "medically indicated and necessary for the health of the patient." In other words, Medicare and Medicaid are "trust-based" systems.

51. Medicare will only reimburse costs for medical services that are necessary for the prevention, diagnosis, or treatment of a specific illness or injury.

52. Certification attestations on Medicare enrollment forms, claim submissions, and Medicare Cost Reports play an important role in ensuring the integrity of the Medicare Program. *See* 42 C.F.R. § 413.24(f)(4)(iv).

53. Medicare enters into agreements with providers to establish their eligibility to participate in Medicare. Providers complete a Medicare Enrollment Application (often called a Form CMS-855A) whereby the providers must certify compliance with certain federal requirements, including specifically the Anti-Kickback Statute and the Stark Law. Among other things, providers agree as follows:

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

Id. All providers participating in Medicare share these obligations, including Defendants.

54. The Medicare Enrollment Application also summarizes the False Claims Act in a separate section explaining the penalties for falsifying information in the application to "gain or maintain enrollment in the Medicare program." *Id.* § 14.

55. As further detailed below, Defendants illegally caused taxpayer funds to be paid from Medicare and Texas Medicaid pursuant to (1) violations of the Anti-Kickback Statute, the Stark Law, and Texas Law and/or (2) as a result of unnecessary, upcoded, and/or unsubstantiated claims.

B. Texas Medicaid Program

56. The Grants to States for Medical Assistance Programs pursuant to Title XIX of the Social Security Act, 42 U.S.C. §§ 1396 *et seq*., administered in the State of Texas as the Texas Medicaid Program ("Texas Medicaid"), is a health care benefit program jointly funded and administered by the State of Texas and the United States. CMS administers Medicaid on the federal level. Medicaid helps pay for reasonable and necessary medical procedures and services provided to individuals who are deemed eligible under state low-income programs.

57. Texas Medicaid is a "Federal health care program," as defined in the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(f), in that it is a State health care program as defined in 42 U.S.C. § 1320a-7(h).

58. The United States funds, on average, fifty to sixty percent of each Texas Medicaid payment made to Medicaid providers. This federal share is known as the Federal Medical Assistance Percentage (FMAP).

59. Compliance with the Anti-Kickback Statute and the Stark Law is a condition precedent for payment for both Medicare and Medicaid.

C. Fraud and Abuse Statutes

60. According to the HHS-Office of the Inspector General ("HHS-OIG"), "[t]he five most important Federal fraud and abuse laws that apply to physicians are the False Claims Act (FCA), the Anti-Kickback Statute (AKS), the Physician Self-Referral Law (Stark law), the Exclusion Authorities, and the Civil Monetary Penalties Law (CMPL)."[2] At least three of these fundamental fraud and abuse laws, as well as Texas Law, are at issue in this action.

(i) The False Claims Act

61. The False Claims Act imposes liability to the United States upon any individual who, or entity that, among other things, "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," 31 U.S.C. § 3729(a)(1)(A); or "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim," § 3729(a)(1)(B); or conspires to commit a violation of the False Claims Act, § 3729(a)(1)(C). Further, Section 3729(a)(1)(G), known as the "reverse false claims" provision, imposes liability upon any person who "knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government." *Id.* § 3729(a)(1)(G).

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[2] HHS-OIG, *A Roadmap for New Physicians, Fraud & Abuse Laws*, https://oig.hhs.gov/compliance/physician-education/01laws.asp (last visited April 24, 2020).

62. "Knowingly" is defined to include actual knowledge, reckless disregard, and deliberate ignorance. *Id.* § 3729(b)(1). The False Claims Act does not require proof of specific intent to defraud in order to establish a violation. *Id.*

63. Pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended, and 28 C.F.R. § 85.5, the applicable per-false-claim penalty under the False Claims Act assessed after January 29, 2018 is a minimum of $11,181 up to a maximum of $22,363.

(ii) The Anti-Kickback Statute

64. The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), is a criminal statute that makes it illegal for individuals or entities to knowingly and willfully solicit or receive "any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind . . . in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(1).

65. The Anti-Kickback Statute also makes it illegal for individuals or entities to knowingly and willfully offer or pay "any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to induce such person . . . to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(2).

66. The Anti-Kickback Statute further prohibits the solicitation, receipt, offer, and payment of any remuneration in exchange for referrals of individuals for services or items reimbursed in whole or in part by a Federal health care program. 42 U.S.C. § 1320a-7b(b). A "Federal health care program" includes any program providing health benefits that is funded directly, in whole or in part, by the United States, including, among others, Medicare, Medicaid, VA health benefits, and TRICARE. *See id.* § 1320a-7b(f).

67. Payments of remuneration to induce patient referrals for services reimbursed with federal health care funds constitute illegal remuneration under the Anti-Kickback Statute. Violation of the Anti-Kickback Statute is a felony punishable by fines and imprisonment. 42 U.S.C. § 1320a-7b(b)(2).

68. The Anti-Kickback Statute arose out of Congress's concern that health care decisions would be inappropriately induced through the payment of remuneration (*i.e.*, things of value), which would undermine the goals of ensuring fair competition for federal funds and providing the highest quality of health care to patients in a market driven by quality of care, not financial incentives. To protect the Medicare and Medicaid programs, among other federal health care programs, Congress enacted a prohibition against the payment of kickbacks in any form. Congress has strengthened the Anti-Kickback Statute on multiple occasions since its enactment to ensure that kickbacks masquerading as legitimate transactions do not evade the statute's reach.

69. As amended by the Patient Protection and Affordable Care Act of 2010 ("ACA"), Pub. L. No. 111-148, § 6402(f), the Anti-Kickback Statute provides that "a claim that includes items or services resulting from a violation of this section constitutes a

false or fraudulent claim for purposes of [the False Claims Act]." 42 U.S.C. § 1320a-7b(g). According to the ACA's legislative history, this amendment to the Anti-Kickback Statute was intended to clarify "that all claims resulting from illegal kickbacks are considered false claims for the purpose of civil actions under the False Claims Act, even when the claims are not submitted directly by the wrongdoers themselves." 155 Cong. Rec. S10854. In other words, compliance with the Anti-Kickback Statute is material to the government's payment decisions.

70. HHS-OIG has promulgated "safe harbor" regulations that identify payment practices that are not subject to the Anti-Kickback Statute because such practices are unlikely to result in fraud or abuse. *See* 42 C.F.R. § 1001.952. Safe harbor protection is afforded only to those arrangements that meet all of the specific conditions set forth in the safe harbor. Defendants' conduct does not enjoy the protection of any safe harbor.

71. The Anti-Kickback Statute safe harbor regulations specify that the safe harbor is not available for physician recruitment arrangements under which remuneration directly or indirectly benefits a third-party entity in a position to make or influence referrals to the hospital. 42 C.F.R. § 1001.952(n). In fact, HHS-OIG has stated that "joint recruitment arrangements" that benefit third-party referral sources in addition to a recruited physician are "subject to a higher degree of scrutiny to ensure that the remuneration is not a disguised payment for past or future referrals."[3]

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[3] HHS-OIG, *Advisory Opinion No. 01-4*, at p. 9 (May 3, 2001), https://oig.hhs.gov/fraud/docs/advisoryopinions/2001/ao01-04.pdf.

72. Compliance with the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), is a condition of payment under federal health care programs, and providers participating in the Medicare and Medicaid programs must agree to comply with the Anti-Kickback Statute and certify such compliance.

(iii) The Stark Law

73. The Stark Law was enacted by Congress to address the overutilization of services by physicians who stood to profit from referring patients to facilities in which they had a financial interest—so-called "self-referrals." The Stark Law, as well as the regulations promulgated thereunder, prohibits physicians who have a "financial relationship" with an entity from making a "referral" to that entity for the furnishing of certain "designated health services" that may be reimbursed by the United States under the Medicare Program. 42 U.S.C. § 1395nn(a)(1); 42 C.F.R. § 411.353(a). An entity may not submit for payment a Medicare claim for services rendered pursuant to a prohibited referral. 42 U.S.C. § 1395nn(a)(1)(B); 42 C.F.R. § 411.353(b).

74. The Stark Law defines "designated health services" to include a variety of services, including clinical laboratory services and inpatient and outpatient hospital services. 42 U.S.C. § 1395nn(h)(6); 42 C.F.R. § 411.351.

75. The Stark Law and its implementing regulations define a "financial relationship" to include, among other things, "a direct or indirect ownership or investment interest" in or "a direct or indirect compensation arrangement" with an entity that provides designated health services. 42 U.S.C. §§ 1395nn(a)(2), (h)(1); 42 C.F.R. § 411.354(a).

76. The Stark Law and its regulations provide that certain enumerated arrangements are excepted from the Stark Law's coverage. *See* 42 U.S.C. §§ 1395nn(b)-(e); 42 C.F.R. § 411.351.

77. Importantly for this action, certain physician recruitment arrangements are excepted from the referral prohibitions under the Stark Law if very specific requirements are met. 42 C.F.R. § 411.357(e). However, where a hospital is providing remuneration to a physician indirectly through another physician practice or directly to a physician who joins a physician practice, there are additional conditions that must be met to satisfy the exception. 42 C.F.R. § 411.357(e)(4). One of those conditions is that the remuneration provided by the hospital cannot take into account the volume or value of any anticipated referrals by the recruited physician or the physician practice or any other physician affiliated with that practice. *Id.* In addition, the arrangement cannot violate the Anti-Kickback Statute. *Id.*

78. As referenced above, arrangements that benefit an existing practice like SETMA are subject to additional scrutiny under the Anti-Kickback Statute.[4] For the reasons detailed herein, SETMA and Baptist Hospital's arrangements violated the Anti-Kickback Statute, took into account the volume or value of past or anticipated future referrals, amounted to sham agreements, and did not satisfy the elements required to meet this Stark Law exception.

79. By law, the United States may not pay a claim for a designated health service referred or provided in violation of the Stark Law. 42 U.S.C. § 1395nn(g)(1).

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[4] *Id.*

Additionally, entities must reimburse any payments that are mistakenly made by the United States. 42 C.F.R. § 411.353(d).

(iv) Texas Law

80. Texas Law also applies to the conduct at issue by Defendants detailed in this action.

81. As defined above, Texas Medicaid Fraud Prevention Law, TEX. HUM. RES. CODE ANN. § 36.001, *et seq*. ("TMFPL"), the Texas Human Resource Code – Medical Assistance Program, TEX. HUM. RES. CODE ANN. § 32.039(b) ("MAP"), and the Texas Patient Solicitation Act, TEX. OCC. CODE ANN. § 102.001, *et seq*, ("TPSA") apply to certain conduct pertaining to the solicitation of patients as well as the submission of claims for reimbursement by Texas Medicaid.

82. The TMFPL, among other things, specifies certain "unlawful acts" in Section 36.002 of the Texas Human Resources Code. These unlawful acts include knowingly making or causing to be made a false statement or misrepresentation of material fact that permits a person to receive an unauthorized or greater benefit or payment under Texas Medicaid, § 36.002(1), and knowingly concealing or failing to disclose information that permits a person to receive an authorized or greater benefit or payment under Texas Medicaid, § 36.002(2).

83. Section 36.101 of the TMFPL authorizes a private right of action for violations of Section 36.002, and Section 36.110 establishes a right to an award to the private plaintiff.

84. TMFPL § 36.002(13) prohibits a person from knowingly engaging in conduct that constitutes a violation under Section 32.039(b) of the Texas Human Resources Code, Chapter 32 – Medical Assistance Program (MAP). MAP § 32.039, entitled "DAMAGES AND PENALTIES," contains a series of enumerated violations, including prohibitions that closely mirror the prohibitions contained in the Anti-Kickback Statute. *See* MAP § 32.039(b)(1-b) – (1-f).

85. However, not all actionable violations require any connection to Texas Medicaid. In particular, MAP § 32.039(b)(1-a) makes it a violation for any person to engage in conduct that violates Section 102.001 of the Texas Occupations Code—the TPSA referenced above.

86. Section 102.001 of the TSPA, entitled "SOLICITING PATIENTS; OFFENSE," provides in relevant part that a "person commits an offense if the person knowingly offers to pay or agrees to accept, directly or indirectly, overtly or covertly any remuneration in cash or in kind to or from another for securing or soliciting a patient or patronage for or from a person licensed, certified, or registered by a state health care regulatory agency." Like the Anti-Kickback Statute, it is a crime to violate the TSPA. Importantly, the TSPA does not tie the unlawful conduct to reimbursement by any federal or state health care programs—penalties under the TMFPL are recoverable for violations of the TSPA regardless of the payor involved.

87. Under Section 36.052 of the TMFPL, a person committing an unlawful act is liable for up to two times the amount of any payment or value provided under Texas Medicaid, interest on the amount of any payment or value provided under Texas

Medicaid, and a civil penalty tied to the False Claims Act. TMFPL § 36.052(1)—(4). The applicable per-unlawful-act penalty under the TMFPL assessed after January 29, 2018 is a minimum of $11,181 up to a maximum of $22,363, per defendant. *Id.* § 36.052(3)(B); 28 C.F.R. § 85.5.

88. Section 36.110 of the TMFPL entitles a private plaintiff to recover up to 30 percent of the proceeds recovered in the action.

DEFENDANTS' UNLAWFUL CONDUCT

89. Relators set forth and detail the unlawful conduct forming the basis of this action by category of conduct and by specifying the identities of Defendants involved in each category of conduct. Relators discovered information and evidence supporting these allegations during their time dealing with and working at SETMA.

A. Sham Recruiting Agreements: Unlawful Inducements, Financial Arrangements, and Referrals (SETMA and Baptist Hospital)

90. Relators, Dr. Daniel Elliott and Dr. Lisa Minsloff, met in medical school in 2008 and later began dating. After medical school, they moved to Lubbock to begin their residency programs.

91. In 2014, in their final year in their respective residency programs, Relators began considering where they wanted to begin their professional careers. Dr. Elliott was raised in Beaumont, Texas and still has friends and family in the area.

92. In or around the summer of 2014, Relators learned about a medical practice named "SETMA" from a relative still living in Beaumont. Relators began discussing potential employment with the then-CEO of SETMA, Defendant James Holly, M.D.

93. By September 2014, Dr. Holly was emailing Relators articles and other website links with information about SETMA. Relators scheduled a date to meet with Dr. Holly at SETMA's primary office in Beaumont on October 18, 2014.

94. Relators interviewed with SETMA and began considering employment with SETMA. Relators emailed Dr. Holly a number of questions in December 2014 about the proposed work obligations and responsibilities. Relators also asked about a potential sign-on bonus from SETMA as well as the name of the hospital at which they would be rounding and admitting patients.

95. On or about December 18, 2014, Dr. Holly responded by email to many of Relators' questions. In answering a question regarding at which hospital Relators would be rounding and admitting patients, Dr. Holly answered, "On call for both but we would prepare [sic] she admit to Baptist."[5] In answering Relators' question of whether there would be a sign-on bonus, Dr. Holly wrote, "$10,000 sign on bonus and moving expenses up to actually [sic] cost of $10,000 each."[6]

96. In early January 2015, Relators continued to ask Dr. Holly questions about the proposed employment. In an email dated January 6, 2015, Dr. Holly explained that SETMA "would like [Dr. Minsloff] to be on staff of only once [sic] hospital." Dr. Holly then wrote that Dr. Minsloff would "be on staff at Baptist."

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[5] It appears the word "prepare" in Dr. Holly's answer was a typo and that Dr. Holly meant to write "prefer." At this time, there were two primary hospitals in Beaumont: Defendant Baptist Hospital and CHRISTUS St. Elizabeth Hospital.

[6] It appears the word "actually" in Dr. Holly's answer was a typo and that Dr. Holly meant to write "actual."

97. Relators decided to accept SETMA's offers of employment. On January 8, 2015, SETMA Chief Operations Officer Richard "Rick" Bryant sent a letter to Relators enclosing employment contracts. The term of employment under each contract was for three years. Mr. Bryant explained that the contracts were identical except for Relators' names. Mr. Bryant directed Relators to sign the contracts and send them back with the dates blank. Mr. Bryant explained that an exact start date could be added later.

98. In or around February 2015, Relators signed the agreements and sent them back to SETMA. Relators then focused on finishing their residencies, planning their wedding, and moving to Beaumont.

99. May of 2015 was a particularly busy month for Relators. They got married on May 23, 2015. In addition, Relators conducted a search for a home in Beaumont to purchase. In late May 2015, they put an offer on a house, which was accepted. Soon after, in June 2015, Relators finished their medical residency programs.

100. In early June 2015, Relators asked Dr. Holly when they could expect their sign-on bonuses. Dr. Elliott explained to Dr. Holly that those bonuses "would definitely help with the home buying process." In a letter on SETMA letterhead dated June 22, 2015, Dr. Holly documented that he, "as CEO of South Texas Medical Associates, LLP," approved the early payment of Relators' bonuses "to expedite the mortgage process, which will allow them to make the move to Beaumont and get settled in their home before they begin their new jobs." Relators had also been looking for a moving company. On June 26, 2015, their moving company confirmed that Relators' belongings would be packed and moved beginning on July 1, 2015.

101. Importantly, all of these events—Relators' employment negotiations, moving plans, home purchase, and sign-on bonus payment—all occurred without involvement or recruitment by Defendant Baptist Hospital. In fact, it was not until June 16, 2015—after Relators had signed employment agreements with SETMA and after Relators' offer on their Beaumont home had been accepted—that Baptist Hospital's Director of Physician Recruitment, Michelle Wiltz, reached out to Relators.

102. In a June 16, 2015, email to Relators, Ms. Wiltz introduced herself as a "Physician Recruiter" with Baptist Hospital in Beaumont who would "be helping with the recruitment." Ms. Wiltz wrote, "Has SETMA informed you of this[?] I hope so! I don't want to catch you off guard! In order to recruit you we need to do a few things[.]"

103. Of course, Relators had already signed three-year employment agreements with SETMA and were only a couple weeks from closing on their new Beaumont home and moving in. Relators do not recall responding to Ms. Wiltz's June 16, 2015, email.

104. Relators closed on their house in early July 2015 and moved in. On July 7, 2015, SETMA's Chief Operations Officer, Richard "Rick" Bryant, emailed Relators to inform them that SETMA had already made preparations for Relators to begin their jobs in August 2015.

105. On July 14, 2015, Ms. Wiltz at Baptist Hospital emailed Mr. Bryant at SETMA. Ms. Wiltz explained that she had "not heard from either doctor and I called again today and left a message! Let me know if you hear from them!"

106. The same day, Mr. Bryant emailed Relators asking them to respond to Ms. Wiltz. Mr. Bryant explained that Ms. Wiltz "represents Baptist and needs to get some

paperwork completed so we can get your bonuses paid to us. I realize Dr[.] Holly provided those in advance." Relators got in touch with Ms. Wiltz as instructed by Mr. Bryant.

107. The next day, July 15, 2015, Ms. Wiltz emailed Relators, attaching so-called "LOIs." These "LOIs" included letters from Ms. Wiltz to Relators, dated June 30, 2015, and addressed to Relators' prior Lubbock, Texas residence. Ms. Wiltz's letter began: "We are very pleased that you are considering establishing a . . . practice in Beaumont, Texas."

108. On July 22, 2015, Ms. Wiltz emailed Relators with proposed recruiting agreements for their review. Ms. Wiltz—Baptist Hospital's Director of Physician Recruitment—had not even met Relators. In fact, her email stated, "I look forward to meeting you!"

109. In late July or early August, relying on instruction from SETMA and Mr. Bryant's email that the "paperwork" had something to do with their sign-on bonuses, Relators signed the recruiting agreements prepared by Baptist Hospital.

110. In reality, SETMA and Baptist Hospital were conspiring to execute sham recruiting agreements that would purport to allow Baptist Hospital to pay substantial amounts of money to SETMA for SETMA's benefit. While the "paperwork" purported to recruit Relators to Beaumont, the agreements actually created an unlawful financial arrangement under which Baptist Hospital would, among other things: (1) repay SETMA the sign-on bonuses that SETMA had already paid to Relators; (2) cover a portion of

Relators' salaries; and (3) pay so-called "incremental expenses" incurred by SETMA by virtue of adding Relators to SETMA's payroll.

111. As in most illegal kickback situations, this arrangement made no business sense unless Baptist Hospital had an expectation of referrals. Indeed, the entire purpose of a physician recruitment exception to the Stark Law and a similar "safe harbor" under the Anti-Kickback Statute is to allow entities like hospitals to recruit physicians to areas that are generally underserved in a particular medical specialty. The agreements that Baptist Hospital asked Relators to sign included a covenant that read:

> Hospital, having determined that it is necessary to provide assistance and incentives in order to recruit Physician to locate a new private medical practice to the Hospital's Service Area for the benefit of the community served by Hospital, agrees as follows . . .

But, as shown above, by the time Baptist Hospital presented Relators with these contracts, Relators had already signed three-year employment agreements approximately six months prior, had moved to Beaumont and purchased a house, and were scheduled to begin practicing in a matter of weeks. Nonetheless, Baptist Hospital was pretending to have recruited Relators and was committing to pay potentially hundreds of thousands of dollars toward Relators' employment with SETMA.

112. Why would Baptist Hospital agree to such a hefty financial commitment when the doctors were already in the community? The answer is always the same with health care fraud: benefitting referral sources to induce referrals. With the benefit of retrospection, Dr. Holly's emails from almost a year before make more sense. He explained that SETMA would prefer that Dr. Minsloff admit patients at Baptist Hospital.

Then, in a January 2015 email, Dr. Holly expressed his intent that Dr. Minsloff would only be on staff at Baptist Hospital.

113. The conspiracy between SETMA and Baptist Hospital is borne out by the fact that SETMA and Baptist Hospital were apparently discussing entering into a financial arrangement before Relators knew anything about it. In her June 16, 2015, email to Relators, Ms. Wiltz asked, "Has SETMA informed you of this[?] I hope so! In order to recruit you we need to do a few things[.]" Yet, Ms. Wiltz, Baptist Hospital, and SETMA were all aware that Baptist Hospital did not recruit Relators. In other words, these purported recruitments were not doctor-focused—they were SETMA-focused.

114. In addition, despite being in touch for over six months and negotiating employment agreements, SETMA and Dr. Holly apparently failed to mention to Relators that they were expected to sign a recruiting agreement with a hospital.

115. The conspiracy between SETMA and Baptist Hospital is further highlighted by how they handled SETMA's obligation to pay Relators' sign-on bonuses. Recall that Dr. Holly confirmed in an email to Relators in December 2014 when SETMA and Relators were negotiating employment that Relators would receive sign-on bonuses of $10,000. SETMA paid those bonuses to Relators, documenting the payments in the following letter:

SOUTHEAST TEXAS MEDICAL ASSOCIATES, LLP
2929 Calder, Suite 100 • Beaumont, Texas 77702 • (409) 833-9797 • (888) 833-0523
www.setma.com

EXECUTIVE MANAGEMENT
James Holly, MD
Chief Executive Officer
Muhammad Aziz, MD
Managing Partner
Syed Anwar, MD
Chief Medical Officer
Richard Bryant, RN, MBA
Chief Operations Officer
Richmond Holly
Chief Information Officer
Jonathon Owens
Clinical Systems Engineer
Margaret Ross, RN, MSN
Director of Operations
Brandon Sheehan, BSN, RN
Inpatient Clinical Coordinator

PARTNERS
Mary Castro, MD
Bobbie Colbert, MD
Caesar Delparine, MD
Dean Halbert, MD
Vijay Kumar, MD
Phuc Nhat Le, MD
Damien Luviano, MD
Vincent Murphy, MD
Ronald Palang, MD
Absar Qureshi, MD
Michael Thomas, MD
Mark Wilson, MD
Memoriam

CLINICAL LOCATIONS
SETMA 1
2929 Calder
Suite 100
Beaumont, Texas 77702
SETMA 2
3570 College
Suite 200
Beaumont, Texas 77701
SETMA West
2010 Dowlen
Beaumont, Texas 77706
SETMA Nederland
2400 Highway 365
Suite 201
Nederland, Texas 77627
SETMA Port Arthur
2501 Jimmy Johnson Blvd
Suite 401
Port Arthur, Texas 77642
SETMA Orange
610 Strickland
Suite 140
Orange, Texas 77630
SETMA Lumberton
1378 LHS Drive
Lumberton, Texas 77657

June 22, 2015

To Whom It May Concern:

I, James L. Holly, as CEO of South Texas Medical Associates, LLP, have approved the early payment of Daniel Elliott and Lisa Minsloff's sign-on bonuses. Daniel and Lisa will begin their employment at the clinic on August 1, 2015. I am sending them a check from my account to expedite the mortgage process, which will allow them to make the move to Beaumont and get settled in their home before they begin their new jobs. Please let me know if you need any additional information regarding this matter.

James L. Holly, MD
CEO
1-409-833-9797
jholly@setma.com

SETMA: Healthcare Where Your Health Is The Only Care!

116. This letter makes clear that Dr. Holly authorized the payment of sign-on bonuses from SETMA to Relators. The letter says nothing about Baptist Hospital or a recruiting agreement. In fact, Relators had not even seen the purported recruiting agreements at the time of the letter.

117. The email from Mr. Bryant at SETMA to Relators the following month made clear that SETMA wanted Baptist Hospital to cover a $20,000 obligation that was previously incurred and paid by SETMA. In an email dated August 19, 2015, Dr. Holly instructed Relators as follows: "[L]et me know when Baptist sends you the checks for your sign-on bonus. I need to replace that money."

118. SETMA also executed an addendum to both of Relators' recruiting agreements. For purported extra expenses incurred as a result of employing Relators, Baptist Hospital agreed to pay SETMA up to $7,500 a month for the first 12 months of Relators' employment, for a total of $90,00. In other words, Baptist Hospital stepped in to cover costs that SETMA had already agreed to incur when SETMA agreed to employ Relators. Baptist Hospital ended up paying SETMA $82,500 out of the maximum $90,000.

119. Baptist Hospital's records also show that it paid SETMA an additional amount of approximately $95,544 to subsidize Relators' salaries during the first year of their employment with SETMA. Again, SETMA already had employment agreements with Relators under which SETMA had incurred these salary obligations. Baptist Hospital stepped in later and agreed to cover some of SETMA's preexisting wage obligations.

120. The chronology of events above establishes that SETMA and Baptist Hospital exploited Relators for their own financial gain. Baptist Hospital did not recruit Relators. Instead, Relators were instructed by their employer—after they had signed

three-year employment agreements with SETMA—to sign "paperwork" with a local hospital that SETMA represented had something to do with Relators' sign-on bonuses.

121. The papered arrangement orchestrated by SETMA and Baptist Hospital was intended to mimic a bona fide situation that enjoys protections under the Anti-Kickback Statute and the Stark Law: one in which physicians are actually recruited to underserved areas by hospitals.

122. Relators later discovered that SETMA was encouraging its doctors to refer patients to Baptist Hospital. In fact, SETMA's management would frequently circulate internal emails showing the "census" numbers of patients admitted at St. Elizabeth Hospital and Baptist Hospital. On February 26, 2017, after receiving one of these emails, Defendant Syed Anwar, M.D. replied, "Why are there so many admits in St. Es? **This is not good for our relationship with [B]aptist[.]**" (emphasis added).

123. At least one purpose of the financial relationship between SETMA and Baptist Hospital was to influence referrals from SETMA to Baptist Hospital. And, as shown in the correspondence above, referrals to Baptist Hospital were tracked and encouraged by SETMA.

124. The arrangement between SETMA and Baptist Hospital violated the Anti-Kickback Statute, the Stark Law, and Texas Law. As a result, all relevant referrals between SETMA and Baptist Hospital and payments from payors are either false under the False Claims Act or violations of Texas Law.

B. Unlawful Inducements, Financial Arrangements, and Referrals; Unnecessary Testing (SETMA, Steward Health, OnPoint, Defendant Physicians)

125. SETMA's relationship with Baptist Hospital was not its only illicit backdoor partnership. Soon after Relators joined SETMA, they learned about another set of troubling financial connections among SETMA, Defendant Physicians, and a diagnostic testing firm believed to be Defendant OnPoint. As Relators came to discover after joining SETMA, Defendant Physicians routinely ordered, and encouraged SETMA's employee providers to order, a high volume of medically unnecessary diagnostic tests, including expensive complex drug screenings. As explained below, these referrals are believed to have included referrals to OnPoint in violation of the Stark Law, the Anti-Kickback Statute, the False Claims Act, and Texas Law.

i. SETMA's Relationship with OnPoint

126. Incorporated in 2014, OnPoint is a limited liability company that operates out of Sugar Land, Texas, on the outskirts of Houston, over 100 miles from SETMA's offices in Beaumont, Texas. OnPoint's website proclaims that the firm is "your solution for all your lab needs" and "the experts when it comes to high [*sic*] complex lab tests such as 59-panel urine toxicology screening and DNA testing."[7] The website explains that the lab provides its drug testing services using "Urine Samples" as well as "[t]hrough other kind [*sic*] of fluids such as blood, saliva and even sweat."[8]

[7] OnPoint Lab, "LABORATORY ABOUT US," at http://onpointlab.com/about-us.html (last visited April 24, 2020).

[8] OnPoint Lab, "LABORATORY SERVICES REQUESTS," at http://onpointlab.com/laboratory-services.html (last visited April 24, 2020).

127. Relators first learned about Defendant Physicians' investment interests in a diagnostic testing firm during their on-boarding at SETMA in or around August 2015. Unprompted, SETMA's Chief Operations Officer, Richard "Rick" Bryant, alerted Relators that SETMA tracked on a weekly basis some information generated by its physicians. In particular, Mr. Bryant said, SETMA would track the number of patient drug screenings ordered by SETMA providers because several SETMA partners had an interest in a diagnostic testing firm. Relators do not recall whether Mr. Bryant divulged the name of the diagnostic testing firm at that time.

128. According to information published by the Texas Secretary of State, the members of OnPoint included or include Defendants Drs. Holly, Aziz, Anwar, Castro, Thomas, Halbert, Kumar, Palang, Qureshi, and Deiparine. According to a search of these public records, OnPoint appears to be the only Texas lab company in which most or all of these defendants have a membership interest. Drs. Holly, Aziz, and Anwar were and/or are managers of OnPoint. Neither OnPoint's nor SETMA's website appears to mention the membership or managerial relationship between OnPoint and Defendant Physicians.

129. Surprised and alarmed by Mr. Bryant's unusual, preemptive warning, Dr. Elliott asked him whether it was legal for SETMA doctors to refer drug tests to a diagnostic testing firm in which SETMA doctors had a financial interest. Mr. Bryant assured Relators that it was legal because there was supposedly a "sign in the lobby" of SETMA's offices that divulged the relationship with the testing firm.

130. Periodic drug screenings may be appropriate for some patients, particularly patients that had been prescribed pharmaceutical drugs that are prone to abuse and

addiction (such as opiates and benzodiazepines). Depending on the particular patient's risk profile and medical history, such patients should be screened periodically throughout the year, with the norm for such patients generally being approximately every three months. Periodic drug testing may also be appropriate for patients with a personal or family history that indicates an elevated risk of drug abuse.

131. Patients can usually be tested using a quick, simple, and inexpensive preliminary screening urinalysis test. Then, if that test reveals cause for concern, the physician may order a more complex test to confirm the presence or amount of drugs (or related metabolites) in the sample. In a typical family or internal medicine practice like Dr. Elliott's and Defendant Physicians' practices (as opposed, for example, to a practice focused on patients with a history of substance abuse), the expansive and expensive complex tests are not routinely ordered for most patients.

132. Some Defendant Physicians strongly encouraged SETMA providers to order expensive full-panel drug test for patients regardless of medical necessity. In fact, these testing numbers were tracked and then sent out to all providers on a weekly basis.

133. Relators recall one particular email exchange towards approximately the end of 2016 that epitomized the pressure placed on SETMA providers to order these tests. In response to one of these emails showing statistics about the number of tests, Dr. Castro urged SETMA providers to order more drug screens for no apparent reason other than to drive up testing numbers and revenue. To the best of Relators' recollection, Dr. Castro wrote something along the lines of, "Come on guys . . . we need to order more drug screens." Dr. Castro's email was sent to all SETMA doctors, including pediatricians like

Dr. Minsloff and family practice providers like Dr. Elliott. Dr. Castro's directive did not refer to any particular patients that needed to be tested; nor did her email suggest that such additional drug screenings were warranted by medical necessity.

134. Defendant Physicians practiced what they preached. For example, Relators recall Dr. Castro's "stats" that were circulated each week via email showing that she had ordered as many as 80-100 complex drug screenings in a single week.

135. Furthermore, rather than the simple, quick, and inexpensive drug tests, some Defendant Physicians and SETMA routinely ordered expensive complex drug screenings for their patients. These drug screenings were several times more expensive than the alternative tests under both private insurance and government payor payment rubrics. And, rather than being completed onsite in the clinic, these complex tests required a sample to be collected and transported to an off-site testing facility.

136. Although Relators cannot specifically recall the name of the lab where the samples were sent for complex drug testing during their employment with SETMA, they do believe that the tests were done through a "send-out" to a diagnostic testing company in the Houston area. This was odd because there were several diagnostic testing firms that provided similar testing services much closer to SETMA's offices in Beaumont.

137. On information and belief, the diagnostic testing firm to which SETMA doctors were encouraged to send samples was OnPoint, the company in which some Defendant Physicians were personally invested.

ii. Unusual Trends in Medicare Payment Data Related to Lab Testing

138. Medicare payment data published by the Centers for Medicare & Medicaid Services (CMS) contains some alarming statistics that corroborate Relators' account, particularly with respect to sample transport costs, blood sampling, and drug testing.

139. In summary, the data shows that SETMA, especially Defendant Physicians, billed Medicare for an unusually high number of miles to transport lab specimens and took an extremely large number of blood samples compared with other practitioners in their respective fields. In addition, OnPoint performed complex drug testing services at an extraordinarily high incidence for the patient populations being tested and apparently performed duplicative drug testing to drive up reimbursement rates.

140. These facts are consistent with and reinforce Relators' allegations that SETMA and Defendant Physicians funneled lab tests, including medically unnecessary lab tests and complex drug tests, to the lab testing company some Defendant Physicians own.

The Healthcare Common Procedure Coding System

141. The Healthcare Common Procedure Coding System (HCPCS) is a collection of codes that represent procedures, supplies, products, and services that may be provided to Medicare beneficiaries and individuals enrolled in private health insurance programs.

142. The HCPCS is divided into two principal subsystems, referred to as Level I and Level II of the HCPCS. Level I of the HCPCS is comprised of Current Procedural Terminology (CPT), a numeric coding system maintained by the American Medical Association. The CPT is a uniform coding system consisting of descriptive terms and identifying codes that are used primarily to identify medical services and procedures

furnished by physicians and other health care professionals. Level I codes are identified using five numeric digits (e.g. 36415).

143. Level II of the HCPCS is a standardized coding system that is used primarily to identify products, supplies, and services not included in the CPT codes, such as ambulance services and durable medical equipment, prosthetics, orthotics, and supplies used outside a physician's office. Level II codes are also referred to as "alpha-numeric codes" because they consist of a single alphabetical letter followed by four numeric digits (e.g. P9603), unlike the five numeric digits for Level I (CPT) codes.

144. Providers use these codes to report services rendered to Medicare beneficiaries and to become eligible for reimbursement.

145. CMS publishes comprehensive data regarding services and procedures provided to Medicare beneficiaries. The data contains summary reports of all submitted Medicare charges organized by national provider identifier (NPI), HCPCS code, provider type, and place of service, among other fields.

Blood Sampling (HCPCS Code 36415)

146. One HCPCS code that reveals suspicious practices among SETMA providers consistent with Relators' allegations is the 36415 code. This code refers to the "[i]nsertion of needle into vein for collection of blood sample." CMS guidance explains that each unit of service of this code is intended to include all collections of venous blood by venipuncture during a single episode of care regardless of the number of times venipuncture is performed to collect the blood specimens.

147. The number of intravenous blood samples is correlated to the number of laboratory tests performed because the blood samples are used primarily for testing.

148. The Medicare payment data from CMS shows that SETMA and Defendant Physicians ordered an unusually high number of intravenous blood samples from their Medicare patients compared to other providers in the same practice area. The tables below show the rankings of SETMA and several Defendant Physicians for blood draws per beneficiary (Code 36415) among all similar practitioners in Texas.

Table 1. Texas Rankings for Blood Draws per Beneficiary (2015-17).

Year	Provider Type	Provider	Rank	# of Providers[9]	Percentile
2015	Clinical Labs	SETMA	3	84	96.43%
2015	Family Practice	Holly	2	2,011	99.90%
2015	Family Practice	Castro	45	2,011	97.76%
2015	Internists	George	2	1,173	99.83%
2015	Internists	Anwar	20	1,173	98.29%
2015	Internists	Qureshi	25	1,173	97.87%
2015	Internists	Aziz	40	1,173	96.59%
2016	Clinical Labs	SETMA	4	80	95.00%
2016	Family Practice	Holly	2	1,918	99.90%
2016	Family Practice	Castro	70	1,918	96.35%
2016	Internists	George	3	1,156	99.74%
2016	Internists	Anwar	28	1,156	97.58%
2016	Internists	Qureshi	9	1,156	99.22%
2016	Internists	Aziz	25	1,156	97.84%
2017	Clinical Labs	SETMA	3	80	96.25%
2017	Family Practice	Holly	4	1,924	99.79%
2017	Family Practice	Castro	86	1,924	95.53%
2017	Internists	George	2	1,112	99.82%
2017	Internists	Anwar	23	1,112	97.93%
2017	Internists	Aziz	14	1,112	98.74%

[9] This column refers to the number of Texas providers in the stated practice area that billed Medicare for intravenous blood draws (Code 36415) during the stated year.

149. As this data reveals, these Defendants ordered intravenous blood draws at an extremely high rate compared with other Texas practitioners in their respective fields. For comparison, during his only full year at SETMA in 2016 while working as a family practice doctor just like Dr. Holly and Dr. Castro out of the very same clinical group in the same city, Relator Dr. Elliott ranked 893 out of 1,918 practitioners (53.44th percentile) in terms of number of intravenous blood draws per Medicare beneficiary.

150. Several Defendants were also notable outliers in terms of the total number of blood draws taken. For example, in 2015, Drs. George, Anwar, and Aziz ranked 2nd, 5th, and 25th, respectively, out of 1,173 Texas internists in terms of total blood draws billed for Medicare beneficiaries. That same year, Dr. Holly ranked 14th among over 2,000 Texas family doctors, and Drs. Castro and Halbert were each in the top 100. Dr. Kumar ranked 2nd out of all Texas rheumatologists on this measure. In 2016, Drs. George, Anwar, and Aziz ranked 4th, 9th, and 15th among 1,156 internists in Texas, while Drs. Qureshi and Palang were in the top 100. Similarly, Drs. Holly, Halbert, and Castro were all in the top 100 among 1,918 Texas family practice doctors, and Dr. Kumar was 3rd among Texas rheumatologists. And in 2017, Drs. Anwar, George, and Aziz were all in the top 15 among 1,112 Texas internists; Drs. Holly, Castro, and Halbert were all in the top 50 among 1,924 Texas family doctors; and Dr. Kumar was 2nd among Texas rheumatologists.

151. Viewing this data in terms of individual patients is similarly illuminating. For example, in 2016, Dr. Holly ordered an incredible 8.18 intravenous blood draws *for each Medicare beneficiary* he treated, assuming these tests were actually performed and

Dr. Holly did not just submit these bills without performing the services. The statewide average among other Texas family practice doctors was just 1.88 blood draws per Medicare beneficiary treated, meaning Dr. Holly ordered more than four times as many intravenous blood draws per patient as the norm in his field.

152. The data also shows that Dr. Holly's blood-draw rate skyrocketed after he obtained an interest in OnPoint. In 2013, the year before OnPoint opened in August 2014, Dr. Holly ranked in the 27th percentile (1,632 out of 2,255 providers) among Texas family practice doctors in terms of the number of blood draws per beneficiary, taking only 1.51 blood draws per beneficiary. In 2014, Dr. Holly ranked in the 36th percentile (1,389 out of 2,195 providers), taking only 1.45 blood draws per beneficiary.

153. In 2015 and 2016, the first two full years of OnPoint's existence, although his field of practice did not change and he continued to work at the same clinics in the Beaumont area, Dr. Holly shot up the charts, becoming one of the most prolific requesters of blood draws among all family practice physicians in the entire country. The unusual inclination of these SETMA doctors to order extraordinarily high numbers of blood tests further corroborates the allegation that SETMA and Defendant Physicians funneled medically-unnecessary lab tests to OnPoint.

Sample Transport Costs (HCPCS Code P9603)

154. Once the blood had been taken from the patients' veins, Defendants could send it to Sugar Land for testing. But first, they had to get it there.

155. One of the Level II HCPCS codes is P9603. This code is intended to apply only for "[t]ravel allowance one way in connection with medically necessary laboratory

specimen collection drawn from home bound or nursing home bound patient." The P9603 code is billed based on "prorated miles actually traveled."

156. According to CMS guidance, the P9603 code is intended to cover the estimated travel costs of collecting a specimen, including the laboratory technician's salary and associated travel expenses. The P9603 code is designed to be used in situations where the average trip to a patient's homes is longer than 20 miles roundtrip.

157. From 2015 through 2017 (*i.e.*, the first year after OnPoint was founded through the last year for which CMS data is currently available), SETMA and Defendant Physicians' use of the P9603 code has been highly unusual.

158. The P9603 code is used nationwide almost exclusively by providers that are designated as Clinical Laboratories, not individual physicians. But individual SETMA doctors (particularly Defendant Physicians) routinely billed for this code.

159. For example, in 2015, only 27 providers that were <u>not</u> listed as Clinical Laboratories billed even a single charge to the P9603 code, out of hundreds of NPIs nationwide that charged this code. Among those 27 providers, eight were SETMA doctors, six of whom are Defendants (Drs. Holly, Anwar, Aziz, Qureshi, Castro, and George). In 2016, eight of the 25 non-Clinical Laboratory providers that charged the P9603 code were SETMA doctors (including the same six Defendant Physicians). And in 2017, the SETMA doctors (including the same Defendants) were six of the 12 non-Clinical Laboratory providers that billed for this code.

160. In addition to the individual doctors' billings, SETMA itself submitted a high volume of charges under this code during each relevant year.

161. The SETMA doctors that billed to this code and SETMA itself also billed for an unusually high number of transport miles per beneficiary. The charts below depict the top 20 billers to the P9603 code out of all NPIs in Texas in 2015, 2016, and 2017 (SETMA doctors are bolded and highlighted in yellow, and the SETMA clinic is bolded and highlighted in red).

Table 2. 2015 Top P9603 Billers Per Beneficiary (All Texas Providers).

Rank	Last Name/Organization Name of the Provider	City of the Provider	Number of Services (Miles)	Number of Medicare Beneficiaries	Services / Beneficiary
1	ROBIN JOHNSON	AUSTIN	24,800	36	688.889
2	**QURESHI**	**BEAUMONT**	**31,043**	**64**	**485.047**
3	**ANWAR**	**BEAUMONT**	**81,851.30**	**196**	**417.609**
4	**AZIZ**	**BEAUMONT**	**44,968**	**113**	**397.947**
5	**GEORGE**	**NEDERLAND**	**127,267**	**333**	**382.183**
6	**CASTRO**	**NEDERLAND**	**24,072**	**63**	**382.095**
7	**SOUTHEAST TEXAS MEDICAL ASSOCIATES**	**BEAUMONT**	**289,244.50**	**948**	**305.110**
8	**DAO**	**LUMBERTON**	**7,023**	**24**	**292.625**
9	**ARCALA**	**NEDERLAND**	**10,444**	**42**	**248.667**
10	LUTKA	CROWLEY	60,198	321	187.533
11	MEDICAL CENTER LABORATORIES II, LTD.	HOUSTON	1,463,512	8,860	165.182
12	LEANNAH INVESTMENT PARTNERS, LTD	LUBBOCK	555,909	3,763	147.730
13	HARDIN	LONGVIEW	77,842	528	147.428
14	**HOLLY**	**BEAUMONT**	**8,414**	**58**	**145.069**
15	ELITE CLINICAL LABORATORY, INC	HOUSTON	22,590	162	139.444
16	COLMED COLLECTION SERVICES, LLC	GRAND PRAIRIE	72,107	543	132.794
17	SOUTH TEXAS CLINICAL LABORATORY LTD	KINGSVILLE	117,077	911	128.515
18	PHYSICIAN LABORATORY SERVICES, LLC	EDINBURG	173,434	1,603	108.193
19	LAB SERVICES INC	MISSION	30,546	311	98.219
20	ADVANCE MEDICAL LAB	MISSION	144,136.90	1,574	91.574

Table 3. 2016 Top P9603 Billers Per Beneficiary (All Texas Providers).

Rank	Last Name/Organization Name of the Provider	City of the Provider	Number of Services (Miles)	Number of Medicare Beneficiaries	Services / Beneficiary
1	ROBIN JOHNSON	AUSTIN	16,679	29	575.138
2	**CASTRO**	**NEDERLAND**	**26,488**	**56**	**473.000**
3	**QURESHI**	**BEAUMONT**	**42,073**	**99**	**424.980**
4	**GEORGE**	**NEDERLAND**	**131,050**	**355**	**369.155**
5	**ANWAR**	**BEAUMONT**	**58,872**	**185**	**318.227**
6	**AZIZ**	**BEAUMONT**	**41,392**	**138**	**299.942**
7	**SOUTHEAST TEXAS MEDICAL ASSOCIATES**	**BEAUMONT**	**239,072**	**891**	**268.319**
8	**DAO**	**LUMBERTON**	**3,869**	**17**	**227.588**
9	**HOLLY**	**BEAUMONT**	**16,025**	**77**	**208.117**
10	**ARCALA**	**NEDERLAND**	**5,757**	**28**	**205.607**
11	ELITE CLINICAL LABORATORY, INC	HOUSTON	16,940	90	188.222
12	LEANNAH INVESTMENT PARTNERS, LTD	LUBBOCK	568,505	3,616	157.219
13	LUTKA	CROWLEY	65,795	470	139.989
14	ADVANCE MEDICAL LAB	MISSION	17,353	145	119.676
15	GAMMA HEALTHCARE, INC	TYLER	1,121,778	11,169	100.437
16	LAB SERVICES INC	MISSION	31,624	325	97.305
17	SOUTH TEXAS CLINICAL LABORATORY LTD	KINGSVILLE	97,623	1,065	91.665
18	NEER DIAGNOSTIC LABORATORY LLC	HOUSTON	24,185.40	268	90.244
19	SML INC.	HOUSTON	18,550	223	83.184
20	ADVANCE MEDICAL LAB	MISSION	147,043.20	1,834	80.176

Table 4. 2017 Top P9603 Billers Per Beneficiary (All Texas Providers).[10]

Rank	Last Name/Organization Name of the Provider	City of the Provider	Number of Services (Miles)	Number of Medicare Beneficiaries	Services / Beneficiary
1	**CASTRO**	**NEDERLAND**	**28,764**	**53**	**542.717**
2	ROBIN JOHNSON	AUSTIN	10,679	21	508.524
3	**AZIZ**	**BEAUMONT**	**66,997**	**160**	**418.731**
4	**GEORGE**	**NEDERLAND**	**120,764**	**313**	**385.827**
5	**SOUTHEAST TEXAS MEDICAL ASSOCIATES**	**BEAUMONT**	**244,116**	**898**	**271.844**
6	**ANWAR**	**BEAUMONT**	**57,129**	**215**	**265.716**
7	**HOLLY**	**BEAUMONT**	**21,183**	**85**	**249.212**
8	LUTKA	CROWLEY	127,891	615	207.953
9	**QURESHI**	**BEAUMONT**	**9,990**	**49**	**203.878**
10	NEER DIAGNOSTIC LABORATORY LLC	HOUSTON	35,688.70	313	114.021
11	LEANNAH INVESTMENT PARTNERS, LTD	LUBBOCK	462,075	4,076	113.365
12	SOUTH TEXAS CLINICAL LABORATORY LTD	KINGSVILLE	107,778	958	112.503
13	GAMMA HEALTHCARE, INC	TYLER	1,229,343	11,682	105.234
14	LAB SERVICES INC	MISSION	22,395	241	92.925
15	SML INC.	HOUSTON	20,645	286	72.185
16	METROSTAT CLINICAL LABORATORY-AUSTIN INC	KYLE	439,782.20	6,101	72.084
17	SCHRYVER MEDICAL SALES AND MARKETING, LLC	CARROLLTON	1,249,712	17,410	71.781
18	ADVANCE MEDICAL LAB	MISSION	111,673.90	1,561	71.540
19	SCHRYVER MEDICAL SALES AND MARKETING, LLC	GARLAND	17,732.40	271	65.433
20	ADVANCE MEDICAL LAB	MISSION	15,629.90	249	62.771

[10] It appears Drs. Dao and Arcala left SETMA in or around 2016 or 2017, although they continued to practice in the Beaumont area. Yet, after disassociating with SETMA, they appear to have ceased billing P9603 altogether.

162. This data is alarming. It reveals that SETMA and these SETMA doctors are extreme outliers when it comes to billing the P9603 code for transporting medical samples. From 2015 through 2017, SETMA doctors consistently dominated the rankings, occupying nearly all of the top ten slots across Texas for charges per beneficiary under this code.

163. Similar to the increase in blood draws Dr. Holly showed after 2013, Dr. Holly's P9603 code billing appears to start only after 2014, coinciding with OnPoint's formation. Shockingly, this data shows Dr. Holly billed zero miles under P9603 in 2013.

164. Further, the data shows that the number of miles billed by SETMA and its doctors per Medicare beneficiary not only exceeded, but dwarfed the per-beneficiary billings of nearly every other provider. The chart below shows the average mileage billed to the P9603 code among the SETMA providers compared with the averages among all Texas providers and all providers nationwide that billed to this code.

Table 5. Average Mileage Per P9603 Beneficiary (2015-17).

Year	Group	Average Miles / Beneficiary	Comparison to U.S. Average
2015	SETMA	339.12 miles	385.6%
2015	All Texas Providers	81.79 miles	93.0%
2015	All U.S. Providers	87.94 miles	--
2016	SETMA	305.85 miles	382.0%
2016	All Texas Providers	63.17 miles	78.9%
2016	All U.S. Providers	80.07 miles	--
2017	SETMA	309.61 miles	377.9%
2017	All Texas Providers	71.45 miles	87.2%
2017	All U.S. Providers	81.92 miles	--

165. Indeed, there were only a few other providers across all of Texas that billed *even half* as many miles per beneficiary as these SETMA doctors did. This is particularly

remarkable in light of the fact that Texas is a vast state with some providers practicing in remote, rural areas that are far removed from major urban centers.

166. Another striking data point concerns the percentage of Medicare beneficiaries that received this code. For instance, in 2015, SETMA sought reimbursement for services rendered to a total of 1,224 Medicare beneficiaries. Among this group of Medicare beneficiaries, SETMA charged the P9603 code for transporting specimens—a code that is supposed to be reserved for homebound and nursing home patients—to 948 unique beneficiaries, or 77.5% of its entire Medicare patient population. Similarly, in 2016, SETMA charged the P9603 code for 891 out of a total 1,194 Medicare patients, or 74.62%.

167. This data shows that SETMA and many of the SETMA doctors, including several Defendant Physicians, apparently billed Medicare to transport specimens to a testing facility far from Beaumont. These anomalies are consistent with the allegation that the SETMA doctors self-referred lab tests to their company, OnPoint, which is located over 100 miles away from Beaumont in Sugar Land.

Drug Testing (HCPCS Codes G0483, G0479, 83992, 80159, 80171, and 80184)

168. The HCPCS contains several different codes related to drug testing. Among them, Code G0483 refers to a "definitive" test for "22 or more drug class(es)," while Code G0479 refers to a "presumptive" test for "any number of drug classes." The primary difference between a definitive and presumptive test is that the presumptive test only indicates the presence of drugs (or associated metabolites) in the sample, but it does

not measure the level of intoxication. The definitive test, on the other hand, can be used to identify specific drugs and drug concentrations (or those of associated metabolites).

169. In addition, there are certain drug-specific tests, including Code 83992 (a definitive test for measuring phencyclidine [PCP] in blood), Code 80159 (a definitive test for measuring the amount of the antipsychotic drug clozapine, which is often used to treat schizophrenia, in plasma or serum), Code 80171 (a definitive test for measuring gabapentin, a nerve pain medication, in blood, serum, or plasma), Code 80183 (a test for measuring the metabolite oxcarbazepine in blood), and Code 80184 (a therapeutic drug assay for identifying the barbiturate phenobarbital in blood).

170. The different types of drug tests carry very different costs. For example, in 2016, the average Medicare payment amount to OnPoint for the individual substance tests (e.g., Codes 83992, 80159, 80171, and 80184) ranged from about $15 to about $24 per test. Meanwhile, the average Medicare payment amount to OnPoint for the presumptive multi-drug screen was about $59. The average payment amount for the definitive "22+" drug test was significantly higher, at about $211 per test.

171. The CMS payment data shows that OnPoint routinely performed the most expensive, definitive 22+ drug test (Code G0483) for Medicare patients. For example, in 2016, OnPoint billed this code for 2,545 unique Medicare beneficiaries out of a total Medicare patient population of just 2,554 patients. In other words, OnPoint performed the most expensive, full-panel drug test for 99.6% of its Medicare patients in 2016. Similarly, in 2017, OnPoint billed the definitive 22+ drug test for 4,407 unique Medicare beneficiaries out of a total of 4,550 Medicare patients (96.9%).

172. Many of these expensive definitive drug tests were not medically justified for this patient population. Indeed, this data is limited to Medicare patients, who are, by definition, elderly or disabled. In 2017, for example, about 58% of OnPoint's Medicare patients were over the age of 65 and more than 20% were over the age of 75.

173. As reported in the CMS Medicare payment data, OnPoint was among the most prolific billers in the country for the costly definitive drug tests. The chart below shows OnPoint's rankings among all providers that billed to the G0483 code in the relevant year both in Texas and across the United States in terms of the number of services billed to Medicare for the definitive tests (G0483).[11]

Table 6. OnPoint Percentile Rankings for G0483 Code Among All Providers.

Year	Service	Texas Percentile *(All Providers)*	U.S. Percentile *(All Providers)*
2016	Definitive Test (G0483)	96.57%	95.42%
2017	Definitive Test (G0483)	98.10%	97.80%

174. Moreover, OnPoint did not just perform this definitive test once per patient. On average, OnPoint performed the test 1.9 times for each Medicare beneficiary in 2016, for a total reimbursement value of approximately $1,019,914 for this code. In 2017, those numbers increased to an average of 2.1 definitive tests per Medicare beneficiary, good for a total reimbursement value of approximately $2,282,897 for this code.

175. The G0483 code was not used in 2015, but OnPoint's 2015 data also shows curious billing practices in that year. For instance, OnPoint billed Medicare for services related to a total of 527 patients in 2015. It billed nearly all of them for a wide variety of

[11] The data is limited to 2016 and 2017 because this code was apparently not used in 2015.

drug tests, typically several times per test for each patient. The chart below depicts some of the specific drug-related tests billed to Medicare by OnPoint in 2015, along with the number of services for each test and the estimated total reimbursement.

Table 7. OnPoint Medicare Drug Testing Billing Summary (2015).

HCPCS Code	HCPCS Description	Number of Unique Beneficiaries	% of Medicare Census[12]	Number of Services	Average Medicare Payment	Est. Total Payment[13]
G6045	Dihydrocodeinone	522	99.1%	587	$27.54	$16,165.98
84311	Chemical Analysis (spectrophotometry)	522	99.1%	1,171	$9.33	$10,925.43
83789	Mass spectrometry	521	98.9%	2,334	$24.09	$56,226.06
82542	Chemical analysis (chromatography)	521	98.9%	2,910	$24.09	$70,101.90
G6058	Drug confirmation, each procedure	521	98.9%	3,314	$17.67	$58,558.38
G6031	Benzodiazepines	521	98.9%	1,172	$24.67	$28,913.24
82491	Chemical Analysis	520	98.7%	589	$24.09	$14,189.01
83992	PCP Drug Level	518	98.3%	1,164	$19.60	$22,814.40
G6056	Opiate(s), drug and metabolites	518	98.3%	2,320	$25.95	$60,204.00
G6046	Dihydromorphinone	518	98.3%	582	$34.28	$19,950.96
G6052	Meprobamate (tranquilizers)	517	98.1%	581	$23.50	$13,653.50
G6044	Cocaine or metabolite	517	98.1%	594	$20.21	$12,004.74
G6053	Methadone	517	98.1%	1,160	$21.78	$25,264.80
G6042	Amphetamine or methamphetamine	514	97.5%	1,153	$20.73	$23,901.69
G6043	Barbiturates	507	96.2%	1,139	$15.27	$17,392.53
TOTAL						$450,266.62

[12] As noted above, OnPoint had a total of 527 Medicare beneficiaries in 2015. This column reflects the share of these patients that reportedly received the relevant services.

[13] The estimated payment field in this table is calculated by multiplying the average Medicare payment amount times the total number of services charged.

176. This data shows that OnPoint tested almost every one of its 527 Medicare patient beneficiaries (by definition, all senior citizens or persons with disabilities) in 2015 for a wide variety of illicit drugs, typically multiple times for each test.

177. In addition to billing for an unjustifiably large number of drug tests for an unjustifiably high percentage of Medicare beneficiaries, OnPoint also conducted a variety of redundant drug tests. For example, in 2016—the same year that OnPoint conducted nearly two definitive tests per patient on 2,545 out of its 2,554 total Medicare patients—it also performed many other drug testing services on, apparently, the same patients. In particular, OnPoint conducted 9,674 clozapine tests on 2,549 Medicare beneficiaries, as well as 9,680 PCP tests on 2,550 Medicare beneficiaries, 4,840 gabapentin tests on 2,549 Medicare beneficiaries, and 4,841 phenobarbital tests on 2,549 beneficiaries. OnPoint also performed 3,962 "presumptive" tests on 2,128 Medicare beneficiaries that year.

178. Put differently, OnPoint performed all of these tests, some of which are redundant of one another, *multiple times on nearly every Medicare patient they had*. The total Medicare payment amount for these drug tests in 2016 alone (not including more than $1 million for the definitive drug tests) was about $919,119.

179. All told, these Defendants have pocketed several million dollars in unlawful reimbursements from Medicare alone, not to mention payments from the Texas Medicaid program and private insurers, through their laboratory operation in Sugar Land.

C. Unlawful and Unsubstantiated Upcoding (SETMA, Steward Health, Muhammad Aziz, M.D., Syed Anwar, M.D.)

180. Relators also were told that Defendants Anwar and Aziz—members of SETMA's Executive Management team—were remotely reviewing charts after other

SETMA physicians or personnel prepared those charts. Based on Relators' recollection, these chart reviews were common. Dr. Elliot recalls seeing almost daily emails as to how Drs. Anwar and Aziz were going to remotely "review" charts.

181. Dr. Elliott recalls a communication discussing the types of changes that would be made, including, for example, changing "depression" to "major depressive disorder." On information and belief, these changes likely increased reimbursement to SETMA, either by increasing amounts billed to a provider or increasing per capita payments under managed care programs like TexanPlus by documenting more serious conditions than those documented by the treating physician.

D. Relators Grow Concerned and Decide to Leave SETMA

182. Relators became increasingly concerned about the conduct described above. Relators were new to the practice of medicine, but they began to suspect SETMA and many of its physicians were engaged in health care fraud. Relators determined that they could no longer be affiliated with SETMA, and they decided to leave.

183. On December 12, 2016, Relators sent letters to Dr. Holly informing SETMA of their decision to resign.

184. Two days later, on December 14, 2016, Dr. Holly emailed Relators copying SETMA's "Executive Management." Dr. Holly explained that Relators had a 36-month obligation to both SETMA and Baptist Hospital. Dr. Holly instructed Relators to discuss their "binding [recruiting agreement] obligation to Baptist" with Baptist Hospital, claiming that "SETMA is not a party to it." This, of course, was not true.

185. In February 2017, Baptist Hospital's attorneys sent demand letters to Relators claiming, among other things, that if they were to "foolishly decide" not to fulfill the recruiting agreements Relators would be sued for potentially hundreds of thousands of dollars. But, the recruiting agreements were shams concocted by SETMA and Baptist Hospital, and Relators would not continue practicing with SETMA. Relators did the right thing under the circumstances: they resigned and left Beaumont.

186. After hoisting an exploitative financial arrangement between SETMA and Baptist Hospital upon Relators, Baptist Hospital, fully aware it had not recruited Relators, took an additional step: it sued Relators in an arbitration and demanded that Relators, among other things, pay to Baptist Hospital all amounts Baptist Hospital had paid to SETMA.

CONCLUSION

187. The above provides a shameful snapshot of how America's health care system becomes corrupted by avarice and cheating. These unlawful acts allowed Defendants to profit handsomely and unjustifiably at the expense of taxpayers and patients. This cascade of improper financial arrangements, self-referrals, and upcoding is more than just illegal—it is pernicious, dishonest, and must be stopped and remedied.

CAUSES OF ACTION

FIRST CLAIM FOR RELIEF

Violations of the False Claims Act: False Claims for Payment
31 U.S.C. § 3729(a)(1)(A)
(All Defendants)

188. Relators reallege and incorporate by reference each of the preceding paragraphs as if fully set forth in this claim for relief.

189. Through the acts and omissions alleged above, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the United States and the State of Texas for payment or approval, within the meaning of 31 U.S.C. § 3729(a)(1)(A).

190. Defendants violated the federal False Claims Act by submitting, or causing to be submitted, claims for reimbursement from federal health care programs, including Medicare and Texas Medicaid, knowing that those claims were ineligible for the payments demanded.

191. False claims submitted, or caused to be submitted, by Defendants included claims resulting from unnecessary services, upcoded charges, and/or claims tainted by Anti-Kickback and Stark Law violations.

192. Each claim submitted as a result of the Defendants' illegal conduct represents a false claim.

193. The United States, unaware of their falsity, paid and may continue to pay claims that would not be paid but for Defendants' unlawful conduct.

194. Defendants' conduct described herein was knowing, as that term is used in the False Claims Act, and material, as that term is defined in *Universal Health Services, Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016).

195. By reason of the false or fraudulent claims, the United States has sustained damages in a substantial amount to be determined at trial, and is entitled to treble damages plus a civil penalty for each false or fraudulent claim.

SECOND CLAIM FOR RELIEF

Violations of the False Claims Act: Use of False Statements
31 U.S.C. § 3729(a)(1)(B)
(All Defendants)

196. Relators reallege and incorporate by reference each of the preceding paragraphs as if fully set forth in this claim for relief.

197. Defendants knowingly used or caused to be made or used false records or statements that were material to false or fraudulent claims for payment submitted to federal health care programs. Those false records or statements used or caused to be used by Defendants include false or upcoded claims as well as false certifications of compliance with the Anti-Kickback Statute and the Stark Law.

198. Defendants' conduct described herein was knowing, as that term is used in the False Claims Act, and material, as that term is defined in *Universal Health Services, Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016).

199. The United States, unaware of the falsity of the records and statements made by, used, or caused to be used by Defendants, approved, paid, and participated in

payments made by federal health care programs for claims that would otherwise not have been approved and paid.

200. By reason of these false records or statements, the United States has sustained damages in a substantial amount to be determined at trial, and is entitled to treble damages plus a civil penalty for each false or fraudulent claim.

THIRD CLAIM FOR RELIEF

Violations of the False Claims Act: Conspiracy to Violate the False Claims Act
31 U.S.C. § 3729(a)(1)(C)
(All Defendants)

201. Relators reallege and incorporate by reference each of the preceding paragraphs as if fully set forth in this claim for relief.

202. Defendants knowingly conspired with each other and/or other individuals and agents to violate 31 U.S.C. §§ 3729(a)(1)(A) and (B) and to defraud the United States by causing federal health care programs to pay for false claims submitted in violation of federal law.

203. By reason of Defendants' conspiracy, the United States has sustained damages in a substantial amount to be determined at trial, and is entitled to treble damages plus a civil penalty for each false or fraudulent claim caused to be submitted.

FOURTH CLAIM FOR RELIEF

Violations of the False Claims Act: Knowing Retention of Overpayments
31 U.S.C. § 3729(a)(1)(G)
(All Defendants)

204. Relators reallege and incorporate by reference each of the preceding paragraphs as if fully set forth in this claim for relief.

205. As set forth herein, Defendants presented numerous claims for payment to the United States through federal health care programs and knowingly retained overpayments in violation of 31 U.S.C. § 3729(a)(1)(G) when Defendants failed to repay the money as required by federal law.

206. For the reasons alleged herein, many of these claims were false within the meaning of the False Claims Act. More specifically, Defendants knowingly and improperly avoided or decreased an obligation to repay money to the United States.

207. By reason of Defendants' conduct, the United States has sustained damages in a substantial amount to be determined at trial, and is entitled to treble damages plus a civil penalty for each false or fraudulent claim caused to be submitted.

FIFTH CLAIM FOR RELIEF

Violations of Texas Law
TEX. HUM. RES. CODE § 36.002(1)
(All Defendants)

208. Relators reallege and incorporate by reference each of the preceding paragraphs as if fully set forth in this claim for relief.

209. The TMFPL, among other things, specifies certain "unlawful acts" in Section 36.002 of the Texas Human Resources Code. These unlawful acts include knowingly making or causing to be made a false statement or misrepresentation of material fact that permits a person to receive an unauthorized or greater benefit or payment under Texas Medicaid.

210. Through the acts and omissions alleged above, Defendants knowingly made, or caused to be made, false statements or misrepresentations of material fact to the

State of Texas that permitted some or all Defendants to receive unauthorized and greater benefits and payments from Texas Medicaid.

211. Defendants violated Texas Law by submitting, or causing to be submitted, claims for reimbursement from Texas Medicaid knowing that those claims were ineligible for the payments demanded.

212. False claims submitted, or caused to be submitted, by Defendants included claims resulting from unnecessary services, upcoded charges, and/or claims tainted by Anti-Kickback and Stark Law violations.

213. Each claim submitted as a result of the Defendants' illegal conduct represents a false statement or misrepresentation of material fact.

214. The State of Texas, unaware of the falsity of the claims and statements made or caused to be made by Defendants, paid and may continue to pay claims that would not be paid but for Defendants' unlawful conduct.

215. By reason of Defendants' unlawful conduct, the State of Texas has sustained damages in a substantial amount to be determined at trial, and is entitled to double damages plus a civil penalty for each unlawful act.

SIXTH CLAIM FOR RELIEF

Violations of Texas Law
TEX. HUM. RES. CODE § 36.002(2)
(All Defendants)

216. Relators reallege and incorporate by reference each of the preceding paragraphs as if fully set forth in this claim for relief.

217. The TMFPL, among other things, specifies certain "unlawful acts" in Section 36.002 of the Texas Human Resources Code. These unlawful acts include knowingly concealing or failing to disclose information that permits a person to receive an unauthorized or greater benefit or payment under Texas Medicaid.

218. Through the acts and omissions alleged above, Defendants knowingly concealed and failed to disclose information to the State of Texas that permitted some or all Defendants to receive unauthorized and greater benefits and payments from Texas Medicaid.

219. False claims submitted, or caused to be submitted, by Defendants included claims resulting from unnecessary services, upcoded charges, and claims tainted by Anti-Kickback and Stark Law violations.

220. Defendants concealed or otherwise failed to disclose to the State of Texas the unnecessary services, upcoded charges, and/or violations of the Anti-Kickback and Stark Law detailed herein.

221. Due to this concealed conduct, the State of Texas paid and may continue to pay claims that would not be paid but for Defendants' unlawful conduct.

222. By reason of Defendants' unlawful conduct, the State of Texas has sustained damages in a substantial amount to be determined at trial, and is entitled to double damages plus a civil penalty for each unlawful act.

SEVENTH CLAIM FOR RELIEF

Violations of Texas Law
TEX. HUM. RES. CODE § 36.002(5)
(All Defendants)

223. Relators reallege and incorporate by reference each of the preceding paragraphs as if fully set forth in this claim for relief.

224. The TMFPL, among other things, specifies certain "unlawful acts" in Section 36.002 of the Texas Human Resources Code. These unlawful acts include knowingly paying, charging, soliciting, accepting, or receiving a gift, money, donation, or other consideration as a condition to the provision of a service or product or the continued provision or service or product if the cost of the service or product is paid for, in whole or in part, under Texas Medicaid.

225. Through the acts and omissions alleged above, Defendants knowingly paid, charged, solicited, accepted, or received a gift, money, donation, or other consideration as a condition to the provision of a service or product or the continued provision or service or product if the cost of the service or product is paid for, in whole or in part, under Texas Medicaid.

226. Due to this unlawful conduct, the State of Texas paid and may continue to pay claims that would not be paid but for Defendants' unlawful conduct.

227. By reason of Defendants' unlawful conduct, the State of Texas has sustained damages in a substantial amount to be determined at trial, and is entitled to double damages plus a civil penalty for each unlawful act.

EIGHTH CLAIM FOR RELIEF

Violations of Texas Law
TEX. HUM. RES. CODE § 36.002(13)
(All Defendants)

228. Relators reallege and incorporate by reference each of the preceding paragraphs as if fully set forth in this claim for relief.

229. The TMFPL, among other things, specifies certain "unlawful acts" in Section 36.002 of the Texas Human Resources Code. These unlawful acts include knowingly engaging in conduct that constitutes a violation under Section 32.039(b) of the Texas Human Resources Code.

230. Through the acts and omissions alleged above, Defendants committed violations of Section 32.039(b) of the Texas Human Resources Code, including violations of Section 32.039(b)(1) and Section 32.039(b)(1-a) through (1-f).

231. Due to this unlawful conduct, the State of Texas paid and may continue to pay claims that would not be paid but for Defendants' unlawful conduct.

232. By reason of Defendants' unlawful conduct, the State of Texas has sustained damages in a substantial amount to be determined at trial, and is entitled to double damages plus a civil penalty for each unlawful act.

233. Additionally, each violation of Section 32.039(b)(1-a) and the Texas Patient Solicitation Act, Texas Occupations Code 102.001, whether or not the unlawful conduct is related to reimbursement by any federal or state health care programs, is subject to penalties under the TMFPL.

PRAYER FOR RELIEF

WHEREFORE, Relators respectfully pray for judgment against Defendants as follows:

a. On Claims for Relief One, Two, Three, and Four (False Claims Act), treble damages and all applicable civil penalties in the maximum amount allowed by law;

b. On Claims for Relief Five, Six, Seven, and Eight (Texas Law), double damages and all applicable civil penalties in the maximum amount allowed by law;

c. All attorney's fees and costs associated with prosecuting this civil action, as provided by law;

d. Interest on all amounts owed to the United States, the State of Texas, and/or Relators; and

e. For all other relief the Court deems just and proper.

JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), Relators demand a jury trial for all claims and issues so triable.

April 29, 2020

Respectfully submitted,

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