UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

UNITED STATES OF AMERICA, *ex rel.* LYNDA PINTO,	§	
Plaintiffs,	§	18-cv-2674
v.	§	
	§	Judge Ewing Werlein, Jr.
RICK NASSENSTEIN,	§	
Defendant.	§	Jury Demanded

UNITED STATES OF AMERICA'S COMPLAINT IN PARTIAL INTERVENTION

I. PRELIMINARY STATEMENT

1. The United States of America, on behalf of the United States Department of Health and Human Services (HHS) and its component agency, the Centers for Medicare and Medicaid Services (CMS), having partially intervened in this action, brings claims against Defendant Richard "Rick" Nassenstein (Nassenstein) to recover treble damages and civil penalties under the False Claims Act (FCA), 31 U.S.C. § 3729 *et seq*. arising from violations of the Physician Self-Referral Law, 42 U.S.C. § 1395nn (commonly referred to as the "Stark Law"). The United States also seeks to recover damages and restitution under common law and equitable theories of unjust enrichment and payment by mistake.

2. The Stark Law prohibits a medical diagnostic services provider like Cardiac Imaging, Inc. (CII) from billing Medicare for designated health services referred by a physician with whom the provider has a financial relationship, including a compensation arrangement, which does not meet any statutory or regulatory exception. Congress enacted the Stark Law to protect Medicare patients from physicians' financial arrangements impacting their medical decision-making, and to protect the Medicare program from physicians' financial relationships leading to unnecessary overutilization of services or increased costs. Any claim submitted to Medicare in violation of the Stark Law is materially false within the meaning of the FCA.

3. Defendant Rick Nassenstein is formerly the President, Chief Financial Officer (CFO), and one-third owner of CII.

4. CII is an Illinois-based medical services company that provides cardiac

positron emission tomography (PET) scans to, among others, Medicare beneficiaries.

5. Cardiac PET scans are noninvasive diagnostic procedures that help physicians detect and diagnose cardiac disease. As described in greater detail below, these procedures are designated health services under the Stark Law. The procedures incorporate a cardiovascular stress test component that, pursuant to Medicare regulations, requires direct supervision by a physician.[1]

6. As detailed below, beginning by at least 2017, Defendant Rick Nassenstein knowingly caused CII to enter into financial relationships with physicians that referred patients to CII for cardiac PET scans, paying the referring physicians illegal compensation in violation of the Stark Law; knowingly presented or caused to be presented materially false or fraudulent claims to the Medicare program; and knowingly made, used, and caused to be made or used false records or statements material to false or fraudulent claims in violation of the FCA.[2]

7. The scheme revolved around an illegal fee that CII paid to every physician that referred patients to CII for mobile cardiac PET scans. Since 2014, CII has operated a mobile cardiac PET scanning business pursuant to which CII performed cardiac PET scans for the physicians' patients onboard converted semi-trailer trucks that CII transported to the physicians' practices. CII contractually required these physicians to refer exclusively

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[1] For clarity, except as relevant, this Complaint refers to the entire procedure, including the cardiovascular stress test component, as a "cardiac PET scan."

[2] CII and its current owner, Sam Kancherlapalli, previously settled related claims arising from the conduct described herein.

to CII for mobile PET scans. As part of its arrangement with referring physicians, CII paid physicians a fee of at least $500 per hour, ostensibly as compensation for the physicians to supervise the PET scans for the physicians' patients.

8. Under the Stark Law, a compensation arrangement between a provider like CII and a referring physician is illegal if the compensation exceeds fair market value for the services actually provided in exchange.

9. CII's fee failed to meet this fair market value requirement.

10. CII's fee grossly exceeded fair market value for the supervision referring physicians actually provided. As Nassenstein knew, physicians supervising CII's cardiac PET scans were not required to be present for or involved in overseeing the scans and did not have to interrupt their ordinary practice of medicine. Instead, what CII required and what physicians actually did was remain available in the event of an emergency—akin to an "on-call" arrangement common in medicine.

11. Despite knowing the minimal burden supervising CII's scans imposed on physicians, as President, Nassenstein personally led successive efforts to cover up the excessiveness of CII's fee. In particular, Nassenstein procured and caused CII to rely upon a sham fair market value opinion from a third-party consultant.

12. As Nassenstein knew, the consultant's opinion was premised on the false understanding, based on information Nassenstein gave it, that supervising physicians were required to remain on CII's truck and oversee each scan, even though Nassenstein knew that was not the case. Relying on this false premise, the consultant concluded that fair market value for supervision was equivalent to what cardiologists were paid when they

were not supervising, plus the operational costs they incurred during the hours CII spent scanning their patients. By basing CII's fee on full-time salary and operational costs when physicians weren't fully—or even minimally—occupied supervising the scans, Nassenstein caused CII to effectively pay physicians for services they were not providing, or to vastly overpay for the limited services the physicians did provide.

13. Because supervising CII's scans amounted to an on-call arrangement, and industry standard is to value such arrangements at ten to fifteen percent of clinical compensation, the fair market value for physician supervision of CII's scans was closer to the $30-75 per hour range.

14. Nassenstein thus knowingly caused CII to pay a supervision fee that exceeded fair market value by at least $425 per hour (a factor of six). A typical scanning day was around eight hours. In just one scan day for one physician, then, CII would pay $8,000 for physician supervision, when fair market value for that supervision was closer to $240 to $600 for the day. This inflated payment to physicians was directly attributable to Nassenstein's knowingly incorrect justification for the payment based on his knowingly unsound analysis of the physician's time and duties.

15. Nassenstein used this fundamentally flawed, deceptive, and self-serving fair market value analysis to help recruit new doctors to refer patients to CII for cardiac PET scans. He also quashed or ignored concerns raised by at least one other executive at CII, the company's then-Chief Operating Officer, that the fees CII paid referring physicians exceeded fair market value.

16. Further, Nassenstein was responsible for negotiating and signing the

agreements with referring physicians under which CII paid this illegal fee, and he signed and submitted numerous Medicare enrollment forms certifying falsely that CII complied with the Stark Law and the FCA.

17. Between 2017 and June 2023, CII paid over $40 million in these illegal fees to physicians that referred cardiac PET scans to CII, and the company submitted over 75,000 false claims to Medicare for designated health services that CII furnished pursuant to prohibited referrals in violation of the Stark Law. Nassenstein knowingly made or caused to be made these false claims and made, used, or caused to be made or used, false statements material to those false and fraudulent claims.

18. Between 2017 and June 2023, because of Nassenstein's fraudulent conduct in violation of the FCA and the Stark Law, Medicare paid at least tens of millions of dollars in false claims, which the United States now seeks to recover, in addition to FCA damages and penalties, all in amounts to be determined at trial.

19. As President and part-owner of CII, and as alleged below, Nassenstein knew that the fee CII paid referring physicians was required to comply with the Stark Law and that, if it did not, CII's claims would violate the FCA; he knew that compliance required the fee to be fair market value; he knew that the physician supervision CII required and which was actually provided posed *de minimis* burdens or costs for physicians; and he nevertheless was instrumental in setting the amount of this excessive fee and perpetuating the cover-up through which CII continued to pay $500 per hour or more to referring physicians. Further, Nassenstein drafted, signed, and implemented the agreements under which CII paid the illegal fees and signed the Medicare enrollment forms certifying that

CII complied with the Stark Law.

20. The claims against Nassenstein relate back to the original filing date of Relator's Complaint pursuant to 31 U.S.C. § 3731(c).

II. JURISDICTION AND VENUE

21. This Court has subject matter jurisdiction over this action pursuant to 31 U.S.C. §§ 3730(a) & 3732(a) and 28 U.S.C. §§ 1331 & 1345, and supplemental jurisdiction over the common law and equitable causes of action under 28 U.S.C. § 1367(a).

22. This Court may exercise personal jurisdiction over Defendant pursuant to 31 U.S.C. §§ 3732(a) & (b), because, as detailed below, Nassenstein conducted business in the Southern District of Texas.

23. Venue lies in the Southern District of Texas pursuant to 31 U.S.C. § 3732, 28 U.S.C. §§ 1391(b)-(c), and 28 U.S.C. § 1395 because Nassenstein transacted business in the Southern District of Texas.

III. THE PARTIES

24. Plaintiff the United States of America (the United States or the "Government") brings this action on behalf of HHS and CMS, which administers the Health Insurance Program for the Aged and Disabled established by Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395 *et seq.* ("Medicare" or the "Medicare Program").

25. Relator Lynda Pinto (Relator) is a resident of Illinois. From 2013 to 2015, Relator was employed by CII as a billing manager.

26. Defendant Rick Nassenstein is a resident of Florida. Between 2014 and 2017, Nassenstein served as CII's CFO. Beginning in 2017, Nassenstein became President of CII

and acquired a thirty-three percent ownership stake in the company. In 2020, he was terminated or relinquished his position as President and sold his shares in CII to the company's present owner, Sam Kancherlapalli. Thereafter, and continuing through the present, Nassenstein remained on CII's payroll, but did not have a formal title or job duties

IV. THE LAW

A. The False Claims Act

27. The FCA makes it unlawful for any person to submit, or cause the submission of, false or fraudulent claims for payment to the Government. *See* 31 U.S.C. §§ 3729, *et seq*. Under the FCA, any person who "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," 31 U.S.C. § 3729(a)(1)(B), is liable to the United States for treble damages and penalties.

28. The FCA defines "knowingly" to include actual knowledge of information, reckless disregard of the truth or falsity of the information, or deliberate ignorance of the truth or falsity of the information. 31 U.S.C. § 3729(b)(1). No proof of specific intent to defraud is required to show that a person acted knowingly under the FCA. *Id.*

29. Under the FCA, the term "claim" means any request or demand for money, whether under a contract or otherwise, presented to an officer, employee, or agent of the United States. 31 U.S.C. § 3729(b)(2)(A)(i). A "claim" is also a request or demand for money made to a contractor or other recipient if (a) the money is to be spent or used on the United States' behalf or to advance a Government program or interest and (b) if the United

States provides, has provided, or will reimburse such contractor or other recipient for any portion of the money requested or demanded. 31 U.S.C. § 3729(b)(2)(A)(ii).

30. The FCA defines "material" to mean "having a natural tendency to influence, or be capable of influencing, the payment or receipt of property." 31 U.S.C. § 3729(b)(4).

31. Claims for reimbursement to Medicare in violation of the Stark Law (as described below) are ineligible for payment and are materially false claims under the FCA.

32. Violations of the FCA subject the defendant to mandatory civil penalties per FCA violation, plus three times the amount of damages that the United States sustains as a result of the defendant's actions. 31 U.S.C. § 3729(a).

B. The Stark Law

33. Enacted as amendments to the Social Security Act, the Stark Law prohibits a physician from referring "designated health services" (DHS), as defined in 42 U.S.C. § 1395nn(h)(6) and 42 C.F.R. § 411.351, to hospitals and other entities that furnish DHS with which the physician has a direct or indirect financial relationship (as defined in the statute and regulations) that does not satisfy the requirements of an applicable exception. 42 U.S.C. § 1395nn(a)(1); 42 C.F.R. § 411.353(a). The Stark Law also prohibits the hospital or other entity from submitting claims to Medicare for designated health services furnished pursuant to a prohibited referral and prohibits Medicare from paying such claims. 42 U.S.C. § 1395nn(a)(1); 42 C.F.R. § 411.353(b)-(c).

34. "Designated health services" include certain imaging services, including cardiac PET scans. *See* 42 U.S.C. § 1395nn(h)(6); *see also* 42 C.F.R. § 411.351 (referencing the list of items and services that are designated health services found at

https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/List_of_Codes).

35. "Financial relationships" include "compensation arrangements" involving the payment of remuneration. 42 U.S.C. § 1395nn(h)(1)(A) and (h)(1)(B); 42 C.F.R. § 411.354(a).

36. "Compensation arrangement" is defined as "any arrangement involving remuneration, direct or indirect, between a physician (or a member of a physician's immediate family) and an entity." 42 U.S.C. § 1395nn(h)(1)(A); 42 C.F.R. § 411.354(c).

37. The Stark Law provides that, unless an exception under 42 U.S.C. § 1395nn applies and its requirements are satisfied, if a physician "has a financial relationship with an entity . . . then (A) the physician may not make a referral to the entity for the furnishing of designated health services for which payment otherwise may be made" by Medicare and "(B) the entity may not present or cause to be presented a claim [to Medicare] or bill to any individual, third party payor, or other entity for designated health services furnished pursuant to a referral prohibited under [the Stark Law]." 42 U.S.C. § 1395nn(a)(1).

38. Statutory exceptions exist for compensation arrangements in which an entity furnishing DHS compensates a referring physician for specific services the physician provides to the entity. 42 U.S.C. § 1395(e)(3); 42 C.F.R. § 411.357(d) & 411.357(l). At all relevant times, these exceptions required, *inter alia*, that the compensation the physician receives not exceed fair market value for the services provided. 42 U.S.C. § 1395(e)(3); 42 C.F.R. § 411.357(d) & 411.357(l).

39. "Fair market value" is defined as "[t]he value in an arm's-length transaction, consistent with the general market value of the subject transaction." 42 C.F.R. § 411.351.

40. With respect to compensation for services, "general market value" means "the compensation that would be paid at the time the parties enter into the service arrangement as the result of bona fide bargaining between well-informed parties that are not otherwise in a position to generate business for each other." 42 C.F.R. § 411.351. In other words, general market value (and thus fair market value) cannot be determined by reference to other compensation arrangements between entities and physicians that refer DHS to those entities. *See id*.

41. The Stark Law is a strict liability statute.

42. The Stark Law explicitly states that Medicare may not pay for any designated health services referred in violation of the statute. 42 U.S.C. § 1395nn(g)(1).

43. In addition, the regulations interpreting the Stark Law expressly require that any entity collecting payment for designated health services "performed pursuant to a prohibited referral must refund all collected amounts on a timely basis." 42 C.F.R. § 411.353(d).

44. Any claim submitted to Medicare in violation of the Stark Law is false within the meaning of the FCA.

C. The Medicare Program

a. *Relevant Background*

45. In 1965, Congress enacted Title XVIII of the Social Security Act, known as the Medicare Program or Medicare, to pay for the costs of certain health care services. *See* 42 U.S.C. §§ 1395, *et seq*. HHS, through CMS, is responsible for administering and supervising the Medicare Program. The Secretary of HHS, acting through CMS, has overall

responsibility for Medicare, and has broad authority to "prescribe such regulations as may be necessary" for its implementation. 42 U.S.C. § 1395hh(a)(1).

46. Entitlement to Medicare is based on age, disability, or affliction with end-stage renal disease. *See* 42 U.S.C. §§ 426, 426-1.

47. Individuals who are insured under Medicare are referred to as Medicare "beneficiaries."

48. The Medicare Program is comprised of four parts: A, B, C, and D. Health care services and payment under Part B of the Medicare Program are relevant to the allegations in this Complaint. Medicare Part B is a federally subsidized, voluntary insurance program that covers a percentage of the fee schedule amount (typically 80 percent) for outpatient services, including services provided to Medicare beneficiaries by diagnostic testing facilities. 42 U.S.C. §§ 1395k, 1395l; 42 C.F.R. § 410.152.

49. CMS relies on Medicare Administrative Contractors, commonly called "MACs," to serve as the primary operational contacts with health care providers enrolled in Medicare Part B. The MACs are responsible for processing and paying claims on behalf of Medicare, as well as performing certain administrative functions at the regional level. 42 U.S.C. § 1395u; *see* 42 C.F.R. § 421.5(b).

50. Between 2014 and 2023, CII operated in several states comprising territory covered by multiple MACs. At all relevant times, Novitas Solutions, Inc., Noridian Healthcare Solutions, First Coast Service Options, Inc., National Government Services, Inc., and Palmetto GBA served as the MACs for CII. As MACs, these entities were responsible for processing and paying the claims submitted by CII, depending on the state

in which CII furnished PET scan services.

b. *Medicare Coverage of Diagnostic Testing*

51. Medicare Part B only covers services that are reasonable and necessary for the diagnosis or treatment of an illness. *See* 42 U.S.C. § 1395y(a)(1)(A); 42 C.F.R. § 411.15(k)(1).

52. Through the MACs, Medicare Part B pays for diagnostic procedures furnished by independent diagnostic testing facilities (IDTFs), including mobile cardiac PET scanning units like those operated by CII. 42 C.F.R. § 410.33(a)(1), 410.33(b).

53. An IDTF is a facility that is separate and independent of a hospital or a physician's office where patients go to obtain certain imaging and diagnostic tests that are ordered by the patients' physicians. For example, when a doctor orders that a patient obtain a cardiac PET scan, the patient can obtain that service from a hospital, a doctor's office that has the necessary equipment, or from an IDTF. An IDTF may be at a fixed location, or, as in the case of CII, a mobile unit. 42 C.F.R. § 410.33(a)(1). Regulations governing IDTFs apply even when an IDTF furnishes the diagnostic tests in a physician's office. *Id*.

54. All diagnostic tests payable under the physician fee schedule, including those provided by IDTFs, must be furnished under the appropriate level of supervision by a physician, unless a specified exception applies. 42 C.F.R. § 410.32(b)(1). "Services furnished without the required level of supervision are not reasonable and necessary" within the meaning of the statute and are thus not covered by Medicare. *See* 42 U.S.C. § 1395y(a)(1)(A); 42 C.F.R. § 411.15(k)(1).

55. Medicare regulations provide for three different "levels" of supervision

applicable to diagnostic testing by IDTFs:

> (i) General supervision means the procedure is furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the procedure. . ..
>
> (ii) Direct supervision in the office setting means the physician (or other supervising practitioner) must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure," but need not "be present in the room when the procedure is performed. . .."
>
> (iii) Personal supervision means a physician must be in attendance in the room during the performance of the procedure.
>
> 42 U.S.C. 410.32(b)(3).

56. Medicare provides that, with limited exceptions, all diagnostic tests must be performed under at least the general supervision of a physician, while other tests require direct or personal supervision. 42 C.F.R. § 410.32(b)(3). "In the case of a procedure requiring the direct or personal supervision of a physician . . . the IDTF's supervising physician must personally furnish this level of supervision whether the procedure is performed in the IDTF or, in the case of mobile services, at the remote location." 42 C.F.R. § 410.33(b)(2).

57. Pursuant to the Medicare Physician Fee Schedule (MPFS) published by CMS, cardiovascular stress tests—which, as explained below, comprise one part of the cardiac PET scans furnished by CII—require direct supervision by a physician board certified in internal medicine, cardiology, or nuclear medicine.

c. *Medicare Enrollment Forms and Certifications*

58. Medicare regulations require providers and suppliers, including IDTFs, to certify that they meet, and will continue to meet, the requirements of the Medicare statute and regulations. 42 C.F.R. § 424.516(a)(1).

59. To be eligible to participate in and submit claims to Medicare Part B and obtain reimbursement, providers, suppliers, and other entities must enroll in the Medicare program. IDTFs do so using Medicare Enrollment Applications, Form CMS-855B ("Form 855B"), which they submit to the relevant MAC. IDTFs must also resubmit Form CMS-855 to change information, including when they add new supervising physicians, or to reactivate, revalidate, and/or terminate Medicare enrollment.

60. Section 15 ("Certification Statement") on Form 855B requires the enrolling IDTF to make a series of certifications, including that claims the enrolling entity submits will comply with the Stark Law, and that the entity will not knowingly submit false claims and will not submit claims with recklessness or deliberate ignorance as to their falsity:

> **A. Additional Requirements for Medicare Enrollment**
> These are additional requirements that the supplier must meet and maintain in order to bill the Medicare program. Read these requirements carefully. By signing, the supplier is attesting to having read the requirements and understanding them.
>
> By his/her signature(s), the authorized official(s) named below and the delegated official(s) named in Section 16 agree to adhere to the following requirements stated in this Certification Statement:
>
> . . .
>
> 3. I agree to abide by the Medicare laws, regulations and program instructions that apply to this supplier. The Medicare laws, regulations, and program instructions are available through the Medicare contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier's compliance with all applicable conditions of participation in Medicare.
>
> . . .

6. I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and I will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity.

61. Each time an IDTF submits Form 855B, two of its authorized officials must sign the certification statement in Section 16, "attesting to having read the requirements [set forth in Section 15] and understanding them."

62. Form 855B also includes a section entitled "Penalties for falsifying information on this application," which explains the penalties for furnishing false information "to gain or maintain enrollment in the Medicare program." Among these is a provision notifying enrolling IDTFs and signing individuals that

> The Civil False Claims Act, 31 U.S.C. Section 3729, imposes civil liability, in part, on any person who, with actual knowledge, deliberate ignorance or reckless disregard of truth or falsity (a) presents or causes to be presented to the United States Government or its contractor or agent a false or fraudulent claim for payment or approval; (b) uses or causes to be used a false record or statement material either to a false or fraudulent claim or to an obligation to pay the Government; (c) conceals or improperly avoids or decreases an obligation to pay or transmit money or property to the Government; or (d) conspires to violate any provision of the False Claims Act.

63. During the enrollment process, the MAC will provide the enrollee with a unique National Provider Identifier or "NPI" number. The enrollee will then use the NPI number to identify all claims submitted to the MAC for Medicare reimbursement. At all times relevant to this Complaint, CII's NPI was 1770830606.

64. To obtain Medicare reimbursement for outpatient items or services, providers and suppliers, including IDTFs like CII, submit a claim form known as the Form CMS-1500 ("CMS 1500") or its electronic equivalent, known as an 837P. Among the

information the provider or supplier includes on a CMS 1500 or through the 837P format are certain five-digit codes, including Current Procedural Terminology Codes ("CPT codes") and Healthcare Common Procedure Coding System ("HCPCS") Level II codes, that identify the services rendered and for which reimbursement is sought, and the NPI of the "rendering provider" and the "referring provider or other source." Put simply, these codes designate the medical services provided in a standardized format and provide for the reimbursement amount for the medical service that was provided to the Medicare beneficiary.

65. During all time periods relevant to this Complaint, federal regulations designated and continue to designate CPT and HCPCS codes as the standard codes to be used for billing physician services and other health care services to Medicare. 45 C.F.R. § 162.1002(b)(1), (c)(1).

66. When submitting claims to Medicare, providers certify on the CMS 1500, among other things, that (a) the services rendered are medically indicated and necessary for the health of the Medicare beneficiary; (b) the information on the claim form is "true, accurate, and complete"; and (c) the provider understands that "payment and satisfaction of this claim will be from Federal and State funds, and that any false claims, statements, or documents, or concealment of material fact, may be prosecuted under applicable Federal and State laws." *See* CMS 1500, Ctrs. For Medicare & Medicaid Servs., https://www.cms.gov/medicare/cms-forms/cms-forms/downloads/cms1500.pdf (last visited January 10, 2024). Providers further certify that their claims comply "with all applicable Medicare . . . laws, regulations, and program instructions for payment including

but not limited to the Federal anti-kickback statute and Physician Self-Referral law (commonly known as the Stark Law).” *See id.* CMS 1500 also requires providers to acknowledge that: “Any person who knowingly files a statement of claim containing any misrepresentation or any false, incomplete or misleading information may be guilty of a criminal act punishable under law and may be subject to civil penalties.” *See id.*

67. Similarly, when enrolling to submit claims electronically, providers certify that they will submit claims that are “accurate, complete, and truthful.” Electronic Data Interchange (EDI) Enrollment Form, Ctrs. For Medicare & Medicaid Servs., https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS10164B.pdf (last visited January 10, 2024).

68. Under Medicare, a provider of medical services has a duty to familiarize itself with the statutes, regulations, and guidelines regarding coverage for the Medicare services it provides. *Heckler v. Cmty. Health Servs. of Crawford Ctny., Inc.,* 467 U.S. 51, 64 (1984).

69. Generally, once a medical provider submits a CMS 1500, or the electronic equivalent, to the Medicare program, Medicare claims are paid directly to the provider, in reliance on the foregoing certifications, without any review by the Medicare program or MAC of supporting documentation, including medical records.

70. Because it is not feasible for the Medicare program or the MACs to review medical records corresponding to each of the millions of claims for payment it receives from providers, the program relies on providers to comply with Medicare requirements and to submit truthful and accurate certifications and claims. Moreover, beyond the submitting

entities' representations, there is no reasonable means for CMS or the MACs to determine or know, from the face of a CMS 1500, whether the underlying claim arose from a prohibited financial relationship in violation of the Stark Law.

71. During the time periods identified in this Complaint, CII, under Nassenstein's leadership and direction, billed Medicare under Part B for the medical services for cardiac PET scans and made these required statements when it updated its enrollment and billed its claims.

V. FACTUAL ALLEGATIONS

A. Background

1. Cardiac PET Scans

72. Positron emission tomography (PET) myocardial perfusion imaging, or cardiac PET scans, are noninvasive nuclear imaging tests used to help detect and diagnose heart disease. The procedure involves injecting patients with small amounts of a safe radioactive substance called a "tracer"—often Rubidium-82—that can be detected by a PET scanning device. The machine then generates an image that shows how and how well blood flows through the heart.

73. Cardiac PET scans typically incorporate a cardiovascular stress test, in which the heart is "stressed," usually (in the mobile cardiac PET scan context) using medicine such as Lexiscan/regadenoson (pharmacologic stress). Comparing images taken before and after the stress test component enables physicians to see how the heart functions under stress as compared to a pre-stressed baseline.

74. Furnishing cardiac PET scans requires not only the necessary technicians,

staffing, licensing, drugs, supplies, equipment, and expertise, but also access to large, expensive PET scanners that are usually only found in hospital settings. Outpatient physicians, normally cardiologists or other internists, typically refer their patients to get cardiac PET scans from these hospitals. However, in recent years, several companies have begun providing cardiac PET scans on a mobile basis, outside of the hospital setting.

2. Cardiac Imaging, Inc.

75. CII is one such company. CII is an Illinois-based medical services company that, since 2014 and continuing through the present, has furnished cardiac PET scans, including cardiovascular stress tests, to Medicare beneficiaries (and others) on a mobile basis.[3]

76. CII was founded sometime between 2010 and 2013 by Sam Kancherlapalli, now a resident of Florida, who is presently the CEO and owner of the company.

77. CII owns and operates large semi-trailer trucks that it converted and equipped with PET scanning systems and the other equipment and supplies necessary to furnish cardiac PET scans on a mobile basis (the "mobile scanning units"). These mobile scanning units can be moved to an outpatient practice that has contracted with CII for a designated scanning day, set up in a parking lot, scan patients on site, and then be moved to another site to scan patients at a different practice the next day.

78. These mobile scanning units are essentially self-contained, in all recent cases

[3] CII has a separate line of business providing cardiac PET scanning services on a non-mobile (*i.e.*, fixed-site) basis. CII's fixed-site PET scanning business is not at issue in this case.

running off their own power and typically using mobile hotspots for internet access.

79. CII operates or has operated its mobile PET scanning in Texas, Louisiana, Arizona, Florida, Nevada, New York, Oklahoma, Arkansas, California, New Jersey, Pennsylvania, Alabama, and New Mexico.

80. CII has enrolled with Medicare as an IDTF.

81. CII submits claims to Medicare seeking payment for cardiac PET scans it furnishes to Medicare beneficiaries using Form 1500 and/or 837P.

82. In submitting claims for payment during the relevant time period, CII billed Medicare using the following codes: HCPCS Code A9555 for the Rubidium-82 (radiopharmaceutical tracer); HCPCS Code J2785 for the Lexiscan/regadenoson (pharmacologic stress drug); CPT Code 78491 or 78492 for the cardiac PET scan(s); and CPT Code 93017 for the cardiovascular stress test.

83. CPT Codes 78491 and 78492 are DHS and require general supervision by a physician throughout the procedure.

84. CPT Code 93017 requires direct supervision by a physician throughout the procedure.

85. Between 2017 and June 2023, CII submitted over 75,000 claims for DHS using codes 78491 or 78492 to Medicare.

3. Rick Nassenstein

86. Nassenstein is a Certified Public Accountant with a Bachelor of Science degree in accounting.

87. In 2004, Nassenstein began work for American Diagnostic Medicine (ADM),

a company owned in part by Kancherlapalli. Nassenstein eventually became CFO of ADM until its closure after bankruptcy in 2015. Even before the end of his tenure at ADM, however, Nassenstein provided work and services for other companies owned by Kancherlapalli, including CII.

88. Nassenstein thereafter became CFO of CII in 2015, until Kancherlapalli made him President and granted him one-third ownership in the company by 2017.

89. As CFO, Nassenstein was primarily responsible for managing CII's finances and accounting practices and supervised the staff of CII's corporate office.

90. Nassenstein served as President of CII until around February 2020, when he stepped down or was terminated, and sold his shares back to Kancherlapalli.

91. As President, Nassenstein was responsible for and managed CII's executive team, including its new CFO, Chief Operating Officer (COO), and Vice President of Sales. He frequently joined sales calls, helped address concerns and close deals with new referring physicians, managed the operations team, negotiated and signed agreements with new physicians' practices, signed Medicare enrollment forms (*i.e.*, Form 855B) and otherwise managed nearly all aspects of CII's mobile cardiac PET scan business.

92. While President, Nassenstein received an annual salary of $500,000.00 and total distributions amounting to $2,370,185.66. When he ultimately sold his shares back to Kancherlapalli in 2020 he received $1,891,127.00 and Kancherlapalli owes him a further $891,127.00 in connection with the sale.

93. Although Nassenstein is no longer President of CII and is not responsible for its daily operations, since stepping down as President in early 2020 and through at least

June 2023, Nassenstein continued to receive an annual salary of $100,000.00 from CII.

B. Nassenstein Knowingly Caused CII to Pay Excessive "Supervision Fees" to Referring Physicians that Violated the Stark Law and Caused False Claims and Statements in Violation of the FCA

94. As alleged below, Nassenstein was central to the illegal scheme to pay excessive compensation to referring physicians: Nassenstein oversaw the drafting and implementation of agreements pursuant to which CII paid remuneration to physicians that referred DHS to CII and signed them on CII's behalf; he was instrumental in concealing that CII's payments to referring physicians unlawfully exceeded fair market value; and he signed and submitted Medicare Enrollment Forms certifying that CII's mobile cardiac PET scan business would comply with the Stark Law and the FCA.

95. Nassenstein took these actions despite knowing that CII's payments were subject to the Stark Law and could not legally exceed fair market value, that the payments did in fact exceed fair market value, and that claims CII submitted to the Medicare Program in violation of the Stark Law violated the FCA as well.

96. Nassenstein also knew that CII billed Medicare for DHS referred by physicians to whom CII paid the excessive fees.

97. Nassenstein thus knowingly caused CII to submit claims to the Medicare Program that violated the Stark Law and the FCA.

1. Nassenstein Knowingly Caused CII to Enter into Compensation Arrangements with Physicians who Referred Designated Health Services to CII

98. As Nassenstein knew, CII furnished cardiac PET scans exclusively pursuant to agreements, called Medical Supervision Agreements (MSAs), that CII entered into with

outpatient cardiologists and other physicians who referred patients to CII for cardiac PET scans.

99. Nassenstein knew that CII entered into MSAs with every physician who referred cardiac PET scans to CII (either directly with the referring physician or with the referring physician's practice).

100. These MSAs governed the terms under which CII furnished cardiac PET scans to referring physicians' patients. The MSAs also provided for CII to pay remuneration directly to referring physicians for the stated purpose of compensating the physicians for specific services related to supervising CII's cardiac PET scans, including cardiovascular stress tests.

101. Nassenstein knew that CII paid remuneration to referring physicians under the MSAs.

102. The MSAs thus constituted "compensation arrangements" and formed the basis for "financial arrangements" as those terms are defined under the Stark Law. 42 U.S.C. § 1395nn(h)(1)(A) and (h)(1)(B); 42 C.F.R. § 411.354(a).

103. Except as noted below (pertaining to annual maximum fees CII paid referring physicians), the MSAs were essentially standardized agreements that contained the same substantive terms and were based off a template that Nassenstein helped draft and implement and which he, as President, typically signed on behalf of CII.

104. Under the MSA, CII was responsible for all essential aspects of furnishing the cardiac PET scans. CII provided all the necessary drugs, equipment, supplies, personnel, accreditations, and licensures, including for radiopharmaceuticals used in the

procedure. CII employees also performed all aspects of the procedure, including patient intake, administering the radiopharmaceutical and cardiovascular stress test drugs, and operating the scanner and all other equipment.

105. For example, the MSA CII entered into with Dr. Baxter Montgomery/Montgomery Heart and Wellness which Nassenstein and the practice signed on October 14, 2017, provides:

> 4. <u>CII's Responsibilities.</u>
>
> CII shall:
>
> a. be responsible for all equipment maintenance and repairs and transportation as required for the duration of this Agreement for the equipment listed hereafter: PET scanner with Invia 4DM cardiac PET software, housed in a medical trailer, radiopharmaceutical infusion system, and all hot lab equipment and accessories;
>
> b. be responsible for obtaining and maintaining all required accreditations and certifications for technologists, nurses and paramedics;
>
> c. employ nuclear medicine technologists that are registered with the State of Arizona and trained to inject radioactive isotopes to patients;
>
> d. employ nurse(s) or paramedic (s) certified with (ACLS) training to inject stress agent (Lexiscan) to patients and monitor patient vitals (aminophylline may be used to attenuate severe and/or persistent adverse reactions);
>
> e. provide Rubidium (Rb-82) radiopharmaceutical injections, Lexiscan pharmacological stress agent including all IV and EKG supplies, and all sterile supplies;
>
> f. comply with all State and Federal regulations in accordance with its Radiation safety protocols; and

> g. obtain ACR (American College of Radiology) accreditation at its own cost and maintain all ACR standards to provide high quality care. Group agrees to cooperate with CH in order to assist CII in obtaining any required accreditations and/or certifications.
>
> . . .
>
> 6. Radioactive Materials License.
>
> During the term of this Agreement. CII shall be responsible for obtaining a RAML (Radioactive Material License) and the payment of all renewal fees, all necessary physicist services, all record keeping and QA needed to maintain a RAML.

106. The other MSAs contain identical or substantially identical language.

107. CII also hired its own physicians to read and interpret the scans should referring physicians want to outsource that function, as was often the case.

108. Except for referring physicians who chose to interpret scans themselves, and who in those situations billed Medicare for interpreting the scans, CII also handled all of the billing for all of the cardiac PET scans it furnished.

109. In short, the MSAs provided for a "turnkey" service in which physicians who referred patients to CII for cardiac PET scans did not need to hire any specialized staff; obtain any special licenses or accreditations; or purchase, maintain, and learn to use any additional equipment or supplies. They merely signed the agreements and began scheduling scanning days and referring patients to CII.

110. Under the MSAs, referring physicians did not pay CII anything in exchange for the services CII provided.

111. Instead, CII was compensated by Medicare and other health insurance plans

when it submitted claims for payment for the cardiac PET scans referred by physicians with whom it had entered into MSAs.

112. Although referring physicians did not pay CII anything for their services, under the MSAs, CII paid referring physicians $500 per hour that CII furnished cardiac PET scans for the physicians' patients, ostensibly for the physicians to supervise those scans.

113. Witnesses offered sworn testimony that some physicians negotiated for and were paid fees even higher than $500 per hour and as high as $750 per hour for supervision of these tests.

114. The MSAs set a limit on the total annual fees CII paid referring physicians. These annual fees were determined by multiplying $500 per hour by the total volume of referrals the parties anticipated the practice would make. Because these annual fees were specific to each practice's anticipated referrals, this was the only substantive way the MSAs were different from one another.

115. For example, the MSA CII entered into with Coastal Cardiology Associates, PLLC in Corpus Christi, Texas and which Nassenstein and the practice each signed on August 23, 2019, stated that "CII agrees to pay [the referring physician] $500 per hour up to a maximum annual fee of $180,000.00 per year (the "Maximum"). It is anticipated that [the referring physician] will not provide more than an average of 30 hours per month or 360 hours every 12 months during the Term hereof . . ."

116. The MSA CII entered into with Pedro Diaz Santana, M.D. in Laredo, Texas and which Santana signed on September 27, 2017 and Nassenstein signed on October 14,

2017, stated that "CII agrees to pay [the referring physician] $500 per hour up to a maximum annual fee of $90,000.00 per year (the "Maximum"). It is anticipated that [the referring physician] will not provide more than an average of 15 hours per month or 180 hours every 12 months during the Term hereof . . ."

117. The MSA CII entered into with Donald C. Roa, M.D. in Harlingen, Texas and which Roa signed on September 26, 2017 and Nassenstein signed on October 14, 2017 stated that "CII agrees to pay [the referring physician] $500 per hour up to a maximum annual fee of $210,000.00 per year (the "Maximum"). It is anticipated that [the referring physician] will not provide more than an average of 35 hours per month or 420 hours every 12 months during the Term hereof . . ."

118. The other MSAs contain identical or substantially identical language, varying only based upon the estimated number of hours of scanning CII expected that referrals by the practice would generate.

119. Some annual fees reflected in the MSAs exceeded $300,000.00.

120. All told, from 2017 to June 2023, CII paid over $40 million in fees to referring physicians pursuant to MSAs.

121. In exchange for these $500 per hour fees, the MSAs required one principal responsibility from the referring physicians: supervision over the cardiac PET scans, including the cardiac stress tests.

122. For example, the MSA CII entered into with Baxter Montgomery/Montgomery Heart and Wellness in Houston, Texas, which Nassenstein and the practice signed on October 14, 2017, provides:

> 1. Description of Service.
>
> CII owns and operates a mobile imaging facility ("the Unit") which is enrolled in Medicare/Medicaid as an Independent Diagnostic Testing Facility (IDTF) where Cardiac PET examinations are performed. CII desires to enter into an agreement with [the referring physician, defined elsewhere as the "Group"] whereby Group will provide certain supervisory services for the Unit. Group employs or contracts with licensed physician(s) who are qualified to perform and interpret cardiac positron emission tomography examinations ("Cardiac PET Exams") performed by CII. **CII desires to contract with Group for the service of providing general and direct supervisory services for CII's Unit and its patients**.

(Emphasis added).

123. The other MSAs contain identical or substantially identical language.

124. The MSAs required referring physicians to provide either general supervision or direct supervision, as appropriate, during and for the cardiac PET scans CII furnished to their referred patients.

125. The MSAs enumerates a list of responsibilities that CII supposedly required of referring physicians as part of supervision, including providing "quality review and quality improvement activities when appropriate and as may be necessary," "responsib[ility] for the direct and ongoing oversight of the quality of the testing performed at the [mobile scanning] Unit," "responsib[ility] for the proper calibration of equipment used to perform Cardiac PET Exams at the [mobile scanning] Unit;" "responsib[ility] for the qualifications of the [mobile scanning] Unit's non-physician personnel who use the equipment to furnish Cardiac PET Exams," "oversee[ing] the injection of radiopharmaceuticals and pharmacological stress agents and assist in any reactions to these

injections appropriately as mandated by State law . . .”

126. As alleged below, in practice, whether providing general or direct supervision, referring physicians supervising cardiac PET scans rarely or never actually performed or participated in most of these enumerated responsibilities.

127. The referring physicians’ non-supervision responsibilities under these agreements involved limited ancillary administrative services, such as providing CII with patient billing information and assisting with patient scheduling, and, under the Amended MSA, certain “Complementary Services”: “utilities, a fax machine, restrooms, common areas, wireless internet access at the Unit location, and parking.”

128. However, by 2017 when Nassenstein implemented the MSA, referring providers did not actually provide any use of their utilities, fax machines, or internet in connection with CII’s mobile cardiac PET scans.

129. Under the MSAs, CII had the unilateral right to terminate the agreement with 30 days’ notice.

130. The MSAs also contained exclusivity provisions barring referring physicians from referring patients to other providers of mobile cardiac PET scans, both during the term of the agreement and for a year afterward.

131. Further, in a section entitled “Regulatory Compliance,” each of the MSAs also provided that:

> The parties represent and warrant that they and their employees and/or agents (as applicable) are familiar with the requirements imposed by federal and state law applicable to this Agreement and that, in the performance of this Agreement, they will fully comply with these and all other applicable statutes, rules and

regulations with respect thereto. It is the intention of the parties to comply at all times under this Agreement, as may be applicable, with the Physician Self-Referral ("Stark") Law, 42 U.S.C. §§ 1395, et seq.; Medicare and Medicaid Anti-Fraud and Abuse Statutes, 42 U.S.C. §1320a-7b(b) ("Anti-Kickback Statute"); and all applicable laws and regulations in the jurisdiction where the services are provided hereunder.

132. The other MSAs contain identical or substantially identical language.

133. As President, Nassenstein was responsible for and oversaw the drafting and implementation of the template MSA, and Nassenstein signed MSAs on CII's behalf.

134. Examples of MSAs that Nassenstein signed on behalf of CII include the following, and many more:

Date Signed by CII	Referring Physician/Contracting Practice	CII Signatory
Oct. 14, 2017	Xavier Heart Institute	Rick Nassenstein, President
Oct. 14, 2017	Montgomery Heart and Wellness	Rick Nassenstein, President
Oct. 23, 2017	Round Rock Cardiology	Rick Nassenstein, President
Feb. 13, 2018	Advanced Cardiovascular Specialists, LLP	Rick Nassenstein, President
Mar. 29, 2018	Cardiology Associates Imaging LLC	Rick Nassenstein, President
May 1, 2018	Heart & Rhythm Institute of South Texas, P.A.	Rick Nassenstein, President
June 11, 2018	Jamil N. Bitar, MD	Rick Nassenstein, President
June 20, 2018	Thomas Parisi MD	Rick Nassenstein, President
June 28, 2018	St. Peter's Health Partners Medical Associates, P.C.	Rick Nassenstein, President
July 10, 2018	Advanced Heart	Rick Nassenstein, President
July 11, 2018	Encompass Care	Rick Nassenstein, President
April 15, 2019	Texan Cardiovascular Institute	Rick Nassenstein, President

135. As one of the individuals responsible for drafting and implementing the MSA, as a frequent signatory to the MSAs CII entered into with practices, and as President, Nassenstein was familiar with and understood the contents of the agreements CII executed

with referring providers, including the provisions detailing referring physicians' responsibilities in supervising cardiac PET scans, setting the rate of payment for physician supervision, and affirming familiarity with "the requirements imposed by federal and state law applicable" to the agreements, including the Stark Law.

136. Nassenstein also knew that some of the physicians solicited to become CII referring physicians had concerns that CII's remuneration under the MSAs violated the Stark Law, and he personally assisted his sales team address these concerns, including by sharing legal opinion letters with the concerned physicians and by instructing his team to explain that the remuneration was fair market value for physician supervision when he had deceived a third party consultant into deeply flawed fair market value opinions.

2. Nassenstein Knew that CII's Payments to Referring Physicians were Subject to the Stark Law and were Barred from Exceeding Fair Market Value

137. In addition to signing the MSAs, certifying his understanding of and compliance with the Stark Law and other applicable law, Nassenstein frequently signed Form 855B Medicare enrollment forms.

138. IDTFs are required to submit a signed Form 855B each time they modify their enrollment, including by adding a new supervising physician.

139. As a result, each time CII signed a new physician client to refer patients and supervise scans, the company would submit a Form 855B.

140. As President, Nassenstein signed the forms as one of CII's authorized officials, certifying, among other things, that CII's claims complied with applicable law, including the Stark Law, and that the company would "not submit claims with deliberate

ignorance or reckless disregard of their truth or falsity."

141. For example, on June 15, 2018, Nassenstein signed the Form 855B CII submitted to Medicare when enrolling Dr. Lee Davis as a supervising physician. This Form 855B, like the others Nassenstein signed, agrees to abide by the Medicare laws, regulations, and program instructions and acknowledges that Medicare's payment of claims is conditioned on compliance with the Stark Law:

> 3. I agree to abide by the Medicare laws, regulations and program instructions that apply to this supplier. The Medicare laws, regulations, and program instructions are available through the Medicare contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier's compliance with all applicable conditions of participation in Medicare.

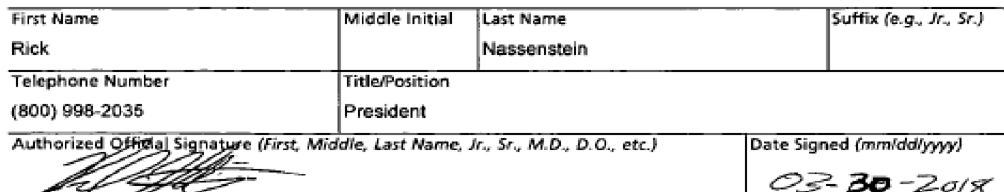
142. Further, this Form 855B, like the others Nassenstein signed, certifies that Nassenstein read the form; that his signature bound CII to "the laws, regulations, and program instructions of the Medicare program"; and "that the information contained [in the Form 855B] is true, correct, and complete":

C. 2ND Authorized Official Signature

I have read the contents of this application. My signature legally and financially binds this supplier to the laws, regulations, and program instructions of the Medicare program. By my signature, I certify that the information contained herein is true, correct, and complete and I authorize the Medicare fee-for-service contractor to verify this information. If I become aware that any information in this application is not true, correct, or complete, I agree to notify the Medicare fee-for-service contractor of this fact in accordance with the time frames established in 42 CFR § 424.516.

If you are changing, adding, or deleting information, check the applicable box, furnish the effective date, and complete the appropriate fields in this section.

CHECK ONE	☐ CHANGE	☒ ADD	☐ DELETE
DATE *(mm/dd/yyyy)*		03/30/2018	



Authorized Official's Information and Signature

First Name	Middle Initial	Last Name	Suffix *(e.g., Jr., Sr.)*
Rick		Nassenstein	

Telephone Number	Title/Position
(800) 998-2035	President

Authorized Official Signature *(First, Middle, Last Name, Jr., Sr., M.D., D.O., etc.)*	Date Signed *(mm/dd/yyyy)*
[signature]	03-30-2018

All signatures must be original and signed in ink (blue ink preferred). Applications with signatures deemed not original will not be processed. Stamped, faxed or copied signatures will not be accepted.

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143. Between 2017 and 2020, Nassenstein signed numerous other Medicare enrollment forms for new referring providers, each of which included the same certification language, and pursuant to which CII billed Medicare tens of millions of dollars.

144. Further, Nassenstein was informed by at least one set of attorneys for CII that to comply with the Stark Law, CII's remuneration to referring physicians could not exceed fair market value.

145. For example, on September 21, 2017, attorneys with the law firm of Robbins, Salomon, and Patt, Ltd. (RSP) in Illinois informed Nassenstein by letter that

> the Stark personal services exception generally requires that a physician's services contract be set out in writing, be signed by the parties, be at least 1 year in duration, and set forth all of the services to be covered by the arrangement and the compensation (**<u>not to exceed fair market value</u>**) to be paid over the term"

(emphasis added).

146. CII furnished this letter to potential referring physician clients to try to assuage the physicians' fears that the arrangement was unlawful.

147. Notably, the lawyers who provided this opinion did not opine on whether the fee was actually fair market value, and the letter explicitly states that the lawyers relied on representations by CII that "[t]he amount of compensation to the [referring physicians] constitutes fair market value for the services performed."

148. The letter from RSP to Nassenstein also states as follows:

> **<u>RSP strongly believes it is in CII's best interests—and strongly urges CII—to formally request an advisory opinion from OIG [HHS Office of Inspector General] regarding whether the MSA could (i) potentially generate</u>**

> **prohibited remuneration under the AKS and/or Stark** or (ii) constitute grounds for the imposition of sanctions and penalties under Sections 1128(b)(7) or 1128(a)(7) of the Social Security Act. In the event an advisory opinion is sought, RSP expects OIG will specifically address the safeguards put in place in the MSA and whether these safeguards render the risk for prohibited remuneration under the AKS and/or Stark sufficiently low such that the MSA would not be subject to sanctions or penalties in connection with the AKS and/or Stark.
>
> (emphasis added).

149. Neither Nassenstein nor CII sought any such advisory opinion.

150. Nassenstein also prevented other CII employees and executives from speaking to the company's lawyers about CII's payments to referring physicians, including CII's COO who raised and tried to address concerns relating to the fee, including concerns that the fee exceeded fair market value.

151. Nassenstein also knew that some potential referring physicians told CII that they could not agree to work with the company unless they knew that the CII's compensation for supervision was fair market value.

152. For example, on September 26, 2018, a representative of Slocum Dickenson Medical Group in Oneida, New York, emailed CII's sales team, saying, "Our attorney is doing a more in-depth review of the contract and he was wondering if he could speak to Cardiac Imaging's attorney? He is looking at them from a FMV [fair market value] and Stark perspective." The email thread was forwarded to Nassenstein, who told the salespeople that he would "have attorney [sic] send full version" of the legal opinion letter to the practice.

153. In one communication with a consultant who provided a fair market value

opinion for the company (described below), Nassenstein wrote: "Just checking on timing to update. We have a couple anxious doctors ready to sign and want to hold off until we know our pricing in is FMV [fair market value] range [sic]."

3. Nassenstein Knew that the Fees CII Paid Referring Physicians Grossly Exceeded Fair Market Value

a. *Nassenstein Knew that Physician Supervision for CII's Cardiac PET Scans Required Minimal Time, Involvement, or Costs*

154. Whether providing general supervision or direct supervision for CII pursuant to an MSA, referring physicians were not required to, and did not, substantially interrupt their ordinary practice of medicine while concurrently supervising CII's cardiac PET scans.

155. As Nassenstein knew, CII did not require physicians, while supervising, to be present for, observe, oversee, or have any involvement in the cardiac PET scans; to visit or board its mobile scanning units; or to clear or limit their usual schedule of patients while supervising scans—and supervising physicians typically did not. This was the case whether physicians were providing direct supervision or general supervision.

156. Further, despite the terms of the MSA, CII did not require supervising physicians to calibrate CII's scanning equipment, monitor the qualifications of CII's on-site personnel, or "oversee the injection of radiopharmaceuticals and pharmacological stress agents"—and supervising physicians did not.

157. As Nassenstein knew, while providing supervision pursuant to MSAs, referring physicians would usually concurrently see other patients, perform other tasks, and run their practices as usual.

158. Nassenstein knew that whether referring providers were providing direct

supervision or general supervision, all that CII required was they were available in case of an emergency, such as a patient having an adverse reaction to the stressing medication—something that was exceedingly rare.

159. Nassenstein provided sworn testimony as follows:

> Q. Cardiac Imaging didn't require [supervising physicians] to be on the trailer?
>
> A. They were not, correct.
>
> . . .
>
> Q. Were they required to come onto the truck for any part of the procedure?
>
> A. I don't remember them having that requirement.
>
> Q. Okay. So based on your recollection physicians could supervise the scans, start to finish, from inside their offices while the scans were happening on the truck out front?
>
> A. I believe they could.
>
> . . .
>
> Q. Okay. As far as you know could doctors see other patients while they were supervising?
>
> A. As far as I know they could.
>
> Q. And they could bill for those visits?
>
> A. They could do whatever they wanted to do with that. They just -- our requirement was for them to be available and accessible to be on our trailer at a moment's notice or have the walkie-talkie communicate with them. That was our requirements. What they did with their time other than that, that would be their responsibility.

160. As Nassenstein also knew, the mobile scanning units were essentially self-contained, and did not require the use of the supervising physician's practice's personnel,

utilities, internet access, or substantial other resources.

161. For example, Nassenstein testified that the only utility the mobile scanning units could conceivably use from the practices would be electricity, but that except for several instances early in CII's business and before the MSA went into effect in 2017, he was not aware of any instances in which the mobile scanning units used practices' electric power.

162. Similarly, he testified that by 2016, the mobile scanning units used wi-fi hotspot devices, rather than practices' wi-fi, for internet access.

163. Nassenstein knew that to the extent CII's mobile scanning units made use of physicians' offices on scanning days, it was typically at most the use of their parking lots (for CII's truck) and limited use of the practices' waiting rooms (for patients waiting for their CII appointment) and restrooms (for CII staff and patients).

164. Nassenstein was accordingly aware that the $500 supervision payment did not compensate referring physicians for the services other than supervision described in the MSA.

b. *Nassenstein Knew that CII's Fee Did Not Reflect the Limited Commitment of Time, Attention, and Costs Required of Supervising Physicians*

165. Beginning in or around 2013, Kancherlapalli first set CII's fee at $500 per hour based on his second-hand understanding of what another provider of mobile cardiac PET scans paid its referring physicians who supervised the scans.

166. At some time prior to Nassenstein becoming President in 2017, Nassenstein, together with another CII employee, conducted internet research that he and CII

purportedly used to justify the $500 fee that Kancherlapalli was using at CII's inception.

167. Nassenstein's research was limited to researching the average annual salary and operating costs for full-time outpatient clinical cardiologists.

168. Nassenstein did not research the market value of physicians' time or costs for supervising cardiac PET scans or for supervising any procedure that did not require the physicians' personal presence or involvement, nor did he research or inquire into how industry experts evaluate such arrangements—*e.g.*, using "on-call" rates.

169. Nassenstein thus did not actually research the market value of the services CII's referring physicians provided pursuant to the MSA and which CII paid them for.

170. After Nassenstein became President, he spearheaded an effort on CII's behalf to procure a fair market value report from a third-party fair market value consultant called the Carnahan Group (Carnahan) that could be cited to justify paying $500 per hour as fair market value for physician supervision of CII's mobile cardiac PET scans.

171. Nassenstein was the sole CII representative involved in assisting Carnahan with their report and was the Carnahan analysts' sole source of material (including the MSA) and information about the details and duties involved with being a CII physician supervision.

172. Nassenstein exchanged emails with Carnahan's analysts and held several phone calls with them purportedly explaining CII's business model and what physician supervision under the MSA entailed.

173. Carnahan ultimately produced a fair market value report and opinion concluding that $500 per hour did not exceed fair market value for physician supervision

of CII's PET scans.

174. Like Nassenstein's prior attempt to justify CII's fees, Carnahan's analysts arrived at this conclusion by adding together (a) the effective hourly rate of compensation for a full-time cardiologist and (b) the hourly operating costs for an outpatient cardiology practice.

175. Carnahan's analysts took this approach because they believed, based on the information they received from Nassenstein and from the descriptions of supervising physicians' duties in the MSA, that supervising CII's cardiac PET scans required physicians' presence onboard CII's trucks, thereby preventing the physicians from running their practices. Because Carnahan believed based on this misinformation from Nassenstein that supervision would fully occupy the physicians' time and attention while scans were taking place, they concluded that a fair market value for that time would be equivalent to what physicians would have earned had they been able to continue seeing patients and running their practices as usual—in essence, the economic value of what Carnahan believed were physicians' opportunity costs while supervising.

176. The report itself reflects the erroneous belief that CII required physicians to supervise cardiac PET scans from onboard the mobile scanning units. The report states that, as Carnahan's analysts understood it, supervising physicians had to be "present in the facility and to be able to immediately furnish assistance and direction through the performance of the procedure."

177. Two of the Carnahan analysts who produced the consultant's fair market value report and opinion testified that they understood the "in the facility" requirement to

mean that the supervising physicians were required to be onboard CII's mobile scanning unit.

178. Both analysts further testified that if Carnahan had understood that physicians were not onboard the mobile scanning units and, as was in fact the case, could see other patients and were being paid for their mere availability, Carnahan would have applied an "on-call" methodology to arrive at the fair market value for supervision of CII's scans.

179. On-call arrangements typically have a fair market value of approximately ten to fifteen percent of full-time salary.

180. Carnahan's report also reflects that its fair market value conclusion incorporated costs it believed cardiology practices would incur pursuant to the MSA, including utilities, fax machines and internet access.

181. Nassenstein specifically directed Carnahan to include those costs, even though he knew practices did not actually incur them.

182. Carnahan's analysis and opinion that $500 per hour was fair market value were thus premised on the erroneous beliefs, based on information and material from its contact at CII, Nassenstein, that supervising CII's cardiac PET scans fully occupied physicians' time and substantial practice resources.

183. Carnahan sent Nassenstein its final fair market value report and opinion on February 15, 2017.

184. Nassenstein testified that he does not recall receiving Carnahan's report, but that his typical practice would **not** have been to "read the report from start to finish."

Instead, he would only have "read the numbers"—*i.e.*, the baseline fair market value conclusion that justified what CII was already paying referring physicians.

185. If Nassenstein had in fact read the report, he would have seen that Carnahan's description of the services physicians provided in exchange for the $500 per hour fee did not reflect what he knew physicians actually did while supervising.

186. Nassenstein thus either actually knew (if he read the report) or was deliberately ignorant or reckless (if he failed to read it) to the fact that, just like his prior internet research, Carnahan's analysis failed to evaluate the value of the supervision services physicians actually provided in exchange for the $500 per hour fees.

187. On May 9, 2023, Carnahan sent CII a letter clarifying the basis for its prior reports and fair market value opinions. Carnahan wrote:

> The FMV [Fair Market Value] hourly rate ranges contained in the reports signed and issued by Carnahan are premised upon the simultaneous presence of those two essential factors: First, that the independent contractor Supervising Cardiologist is physically present inside of the mobile testing facility, and, second, that the independent contractor Supervising Cardiologist is actually and fully engaged in the clinical activity of supervising the diagnostic testing of the patient. . . . **If the Supervising Cardiologist was not physically present inside of the mobile testing facility, a different calculation of the FMV hourly rate would have been called for based upon an "on call" rate.**

(Emphasis added).

188. Carnahan's letter concluded by effectively retracting its prior opinions:

> Carnahan's opinions contained in the final reports that were issued to CII by Carnahan concerning the FMV of operating costs for which a Supervising Cardiologist may be compensated are based upon the business model in which the

> Supervising Physician's facilities are made available for exclusive use by CII staff and patients who are present for CII administered diagnostic procedures, and further that the facilities are not otherwise available for use by the Supervising Cardiologist or his or her associates for income generating purposes. . . . **To the extent that CII has cited, or attempted to rely upon, Carnahan's previously issued reports or communications in a manner inconsistent with the above paragraphs, such reliance was and continues to be misplaced and not authorized by Carnahan**.

(Emphasis added).

189. Further, on at least one occasion, when CII's then-COO raised concerns to Nassenstein via email regarding the structure and payment of CII's remuneration to referring physicians, Nassenstein pulled her aside, told her not to send emails anymore, that he "didn't like the culture" of sending emails, and that she ought to convey her concerns by "picking up the phone and speaking." The COO testified that she "knew that was code for stop putting stuff in emails."

4. Nassenstein Knowingly Caused CII to Submit Claims to the Medicare Program for Cardiac PET Scans Referred by Physicians that CII Paid the Illegal Fees and Made, Used, and Caused False Statements to Medicare that the Claims Complied with the Stark Law

190. As alleged above, Nassenstein worked to conceal that CII's remuneration to referring physicians exceeded fair market value and, working with CII's sales team, he worked to assuage potential referring physicians' valid concerns that CII's remuneration violated the Stark Law using misleading information.

191. Nassenstein knew that CII only performed cardiac PET scans for patients referred by physicians with whom CII had entered into MSAs and to whom CII paid remuneration for supervising cardiac PET scans, and he knew that CII submitted claims

for payment to Medicare for these cardiac PET scans.

192. From 2017 through June 2023, all of the claims CII submitted to Medicare for CPT Codes 78491 and/or 78492, which are DHS, were referred by physicians that CII paid illegal $500 per hour or more fees pursuant to MSAs in violation of the Stark Law.

193. By way of illustration, CII submitted a claim to Medicare for a cardiac PET scan for each of the following patients referred to CII by a physician whom CII also paid the illegal fee:

Date of Claim	Patient	DHS Billed	Referring Physician	Estimated payment for claim	Provider
09/21/2017	1	78492	P.D.S.	$2,722.75	CII
01/13/2018	2	78492	D.R.	$2,663.67	CII
02/20/2018	3	78492	O.G.G	$2,728.10	CII
06/08/2019	4	78492	R.G	$2,733.48	CII
03/11/2020	5	78492	K.S.	$2,738.81	CII

194. In fact, as alleged above, by signing a false Form 855B each time CII signed a new referring physician, thereby enabling CII to maintain enrollment in the Medicare Program, Nassenstein made it possible for CII to bill Medicare for these scans.

195. By way of illustration, Nassenstein signed the following Forms 855B, each of which added a supervising physician who referred DHS that CII improperly billed to Medicare, and to whom Nassenstein knowingly caused CII to pay illegal fees:

Date Nassenstein Signed	Supervising Physician Added
03/21/2017	G.B
11/07/2017	W.C.
01/01/2018	S.C.
03/30/2018	L.D.
12/17/2018	M.W.

196. By knowingly creating and procuring unsound and self-serving fair market value analyses, aiding CII's sales team in recruiting referring physicians, including those who raised concerns over whether CII's remuneration violated the Stark Law, signing MSAs that falsely claimed compliance with the Stark Law and FCA, and signing false Form 855Bs, Nassenstein knowingly caused each of CII's claims for DHS and each of its certifications that the claims it submitted complied with the Stark Law, on CMS 1500s and on its Form 855Bs, to be false.

VI. CONCLUSION

197. Nassenstein personally profited off the Medicare program by causing CII to pay attractive "supervision fees" to referring physicians that he knew grossly exceeded fair market value and causing CII to bill Medicare for the services they referred and to misrepresent that the claims were legal and payable. He collected a salary from CII throughout the illegal billings and even after he stopped performing meaningful work. In addition, the more referrals CII received, and the more CII could bill Medicare, the higher the company's profits and the greater Nassenstein's distributions and the greater the value of his share in the company's ownership. Nassenstein engaged in this illegal scheme despite full knowledge that paying referring physicians above-fair market value remuneration violated the Stark Law and would cause false claims to Medicare, violating the FCA. He knew the law; he knew that there was a lawful way to run CII's mobile cardiac PET scan business; and he nevertheless took successive steps to cause CII to continue paying the illegal fee, billing Medicare, and making false representations about it. And as

a direct result of his illegal conduct, Nassenstein received millions of dollars of taxpayer funds that he should never have received.

FIRST CAUSE OF ACTION
Violations of the False Claims Act:
Submitting or Causing the Submission of False Claims for Payment
31 U.S.C. § 3729(a)(1)(A)

198. The United States realleges and incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

199. The United States seeks relief against Defendant Nassenstein for his violations of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A).

200. By virtue of the acts described above, Defendant knowingly presented or caused to be presented materially false or fraudulent claims for payment or approval to Medicare in violation of 31 U.S.C. § 3729(a)(1)(A); that is, Defendant knowingly made or presented, or caused to be made or presented, to the Medicare Program claims for payment for services performed at CII referred by physicians with whom CII had prohibited financial relationships in violation of the Stark Law.

201. Payment of the false and fraudulent claims was a reasonable and foreseeable consequence of Defendant's conduct.

202. By reason of its payment of these tens of thousands of false or fraudulent claims, the United States has sustained damages in a substantial amount to be determined at trial. The United States is also entitled to treble damages plus a civil penalty for each false or fraudulent claim.

SECOND CAUSE OF ACTION
Violations of the False Claims Act:
Making or Using False Records or Statements
31 U.S.C. § 3729(a)(1)(B) (formerly § 3729(a)(2))

203. The United States realleges and incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

204. The United States seeks relief against Defendant for his violations of the False Claims Act, 31 U.S.C. § 3729(a)(1)(B).

205. Defendant made, used, and caused to be made or used false records or statements, including false Medicare enrollment forms and false certifications made and caused to be made by CII when submitting the false claims for payment, which were material to the United States' payment of the false or fraudulent claims at issue in this case.

206. Payment of the false or fraudulent claims was a reasonable and foreseeable consequence of Defendant's statements and actions.

207. The false records and statements made and caused to be made by Defendant were material to the United States' payment of the false claims.

208. Defendant made and used such false records or statements with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

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

THIRD CAUSE OF ACTION
Unjust Enrichment

210. The United States realleges and incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

211. The United States paid CII for false claims and based on false statements submitted to the Medicare program in violation of the Stark Law based on the conduct of Defendant. Defendant voluntarily received and has retained funds from CII. By directly or indirectly obtaining government funds to which he was not entitled, and which it would be inequitable for him to retain, Defendant was unjustly enriched, and is liable to account for and pay such amounts, or the proceeds therefrom, the amount of which is to be determined at trial, to the United States.

FOURTH CAUSE OF ACTION
Payment by Mistake

212. The United States realleges and incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

213. By reason of the foregoing, the United States made payments to CII (directly or indirectly), in reliance on the erroneous and material belief that the payments were for services that complied with the Stark Law and not unpayable because of CII’s remuneration to referring physicians in violation of the Stark Law. Nassenstein participated in and benefitted from the transactions whereby the United States made these payments. Consequently, the United States is entitled to recover the amount of the payments in an amount to be determined at trial.

RELIEF REQUESTED

WHEREFORE, the United States respectfully requests judgment against Defendant as follows:

a. On Causes of Action One and Two (False Claims Act), treble damages and civil penalties in the maximum amount allowed by law;

b. On Causes of Action Three and Four (common law), damages to the extent allowed by law;

c. All costs associated with prosecuting this civil action, as provided by law;

d. Interest on all amounts owed to the United States; and

e. All other relief the Court deems just and proper.

JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38, the United States requests a trial by Jury.

Respectfully submitted,

BRIAN M. BOYNTON
PRINCIPAL DEPUTY ASSISTANT
ATTORNEY GENERAL

ALAMDAR S. HAMDANI
UNITED STATES ATTORNEY

By: */s/ Samuel R. Lehman*
JAMIE ANN YAVELBERG
SARA MCLEAN
SAMUEL R. LEHMAN
JAKE M. SHIELDS
Attorneys, Civil Division
U.S. Department of Justice
175 N St. NE
Washington, DC 20002
Telephone: (202) 307-2151
Facsimile: (202) 514-0280
Email: Samuel.R.Lehman@usdoj.gov

By: */s/ Melissa M. Green*
MELISSA M. GREEN
Assistant United States Attorney
Attorney-in-Charge
Texas Bar No. 24097419
Southern District of Texas Bar No. 2982744
1000 Louisiana, Suite 2300
Houston, Texas 77002
Telephone: (713) 567-9519
Facsimile: (713) 718-3303
Email: Melissa.Green@usdoj.gov

COUNSEL FOR THE UNITED STATES
OF AMERICA

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing Government's Complaint in Partial Intervention were served through the Court's CM/ECF notice of electronic filing and by e-mail on February 1, 2024, to:

Charles Siegel and Caitlyn Silhan
Waters & Kraus, LLP
3141 Hood Street, Suite 200
Dallas, Texas 75219
Email: siegel@waterskraus.com
Email: csilhan@waterskraus.com

David Marchand
MARCHAND LAW, LLP
8117 Preston Rd., Suite 300
Dallas, Texas 75225
Email: dave@mrlaw.com

Attorneys for Plaintiff/Relator

/s/ Melissa M. Green
MELISSA M. GREEN
Assistant United States Attorney