UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

– – – – – – – – – – – – – – – – – – – X

UNITED STATES OF AMERICA
ex rel. JOHN PEPE M.D., and RICHARD SHERMAN M.D.,

Plaintiffs,

- against -

FRESENIUS VASCULAR CARE, INC. d/b/a AZURA VASCULAR CARE

Defendant.

– – – – – – – – – – – – – – – – – – – X

Civil Action No.
14-CV-3505

(Komitee, J.)
(Tiscione, M.J.)

COMPLAINT-IN-INTERVENTION OF THE UNITED STATES OF AMERICA AND DEMAND FOR JURY TRIAL

BREON PEACE
United States Attorney
Eastern District of New York
271 Cadman Plaza East
Brooklyn, New York 11201

Of Counsel:

Jolie Apicella
Anjna Kapoor
Assistant U.S. Attorneys

Mary Ellen Buntin
Special Assistant U.S. Attorney

TABLE OF CONTENTS

The United States of America, by its attorney, Breon Peace, United States Attorney for the Eastern District of New York, having filed a notice of intervention pursuant to 31 U.S.C. §3730(b)(4), alleges for its Complaint-in-Intervention as follows:

NATURE OF THE ACTION

1. This is a civil fraud action brought by the United States of America (the "United States" or the "Government") against Fresenius Vascular Care, Inc. d/b/a Azura Vascular Care ("FVC" or "Defendant") under the False Claims Act, 31 U.S.C. § 3729, *et seq.*, and at common law, to recover damages sustained by, and penalties owed to, the United States as the result of the Defendant having submitted false claims to the Government.

SUMMARY OF CLAIMS

2. From about January 1, 2012 through at least June 30, 2018, Defendant owned, operated or otherwise controlled nine outpatient surgery facilities in Brooklyn, Queens, Staten Island, Long, Island, Manhattan, the Bronx, and Westchester (collectively, the "FVACs"). During this period, Defendant performed vascular interventions—namely, fistulagrams and angioplasties—on End Stage Renal Disease ("ESRD")[1] patients.

3. These unwarranted, routinely performed, potentially harmful interventions failed to meet Medicare's "reasonable and necessary" requirement pursuant to 42 U.S.C. § 1395y(a)(1).

4. Defendant knowingly submitted false claims for payment for these interventions to federal and state health care programs, including Medicare, Medicaid, TRICARE, and the Federal Employees Health Benefits Program ("FEHBP").

---

[1] End Stage Renal Disease is also known as End Stage Kidney Disease.

5. ESRD is a medical condition in which the patient's kidneys cease functioning on a permanent basis, thereby leading to the need for a regular course of hemodialysis dialysis treatment ("dialysis") or a kidney transplant to maintain life.

6. ESRD patients—many of whom are elderly, disadvantaged members of minority groups—are particularly vulnerable. These patients are admitted more frequently to intensive care units and have higher mortality risks than the general population. Many ESRD patients have multiple co-morbidities.

7. To help treat ESRD, patients undergo dialysis, which is the process of removing toxins, fluids, and salts from the blood of ESRD patients by artificial means. During dialysis, a dialysis machine is connected to the patient, which, in turn, filters waste products from the blood and restores the blood's normal constituents. Blood is taken from the patient by use of a "fistula," cleaned through an artificial filter, and returned to the patient's body.

8. Even with early dialysis, an estimated 20–50 percent of ESRD patients die within two years of diagnosis of ESRD.

9. Most dialysis treatments in the United States are performed in outpatient dialysis clinics.[2] In accordance with Medicare regulations, an interdisciplinary team is required to monitor vascular access to ensure that dialysis is working,[3] and reimbursement for monitoring services is included in a composite rate paid to the dialysis clinic.

10. Per Medicare's assignment of responsibility for vascular access monitoring to the dialysis clinic,[4] the dialysis clinic team conducts the dialysis and observes the patient undergoing

---

[2] The Centers for Medicare & Medicaid Services refers to a dialysis clinic as the "ESRD facility."
[3] *See* Medicare Claims Processing Manual, Chapter 8, Section 180iii; 42 CFR § 494.80; 42 CFR § 494.90(a)(5).
[4] *See* "Conditions for Coverage for End Stage Renal Disease Facilities," 42 CFR Parts 405 *et al*.

dialysis approximately three times per week, for four hours per day. The dialysis clinic team is thus in a unique position to determine whether there are problems with vascular access.

11. The interdisciplinary team is responsible for making timely referrals when necessary to achieve and sustain vascular access. 42 CFR § 494.90(a)(5).[5] If a potential obstruction is flagged at dialysis, the patient's nephrologist, or the attending dialysis nephrologist, may refer the patient to a vascular access center, such as one of the nine FVACs at issue in this case, for an interventional procedure.

12. Here, the FVACs routinely performed medically unnecessary, non-referred vascular interventions—fistulagrams and angioplasties—on ESRD patients. A fistulagram involves the penetration of a patient's skin and blood vessels with a needle, the insertion of a catheter into those blood vessels, the injection of dye into the catheter, and the X-ray imaging of those vessels to visualize blood flow through a fistula ("fistulagram") or blood vessel ("angiogram"). A percutaneous transluminal angioplasty ("angioplasty") also involves the insertion of a catheter into a patient's blood vessel. In an angioplasty, the wire contains a balloon that is inflated to stretch out and expand a narrowed vessel to restore the blood flow.

13. A fistulagram is only medically necessary when the ESRD patient has certain diagnostically specific and appropriate indications.

14. An angioplasty is only medically necessary when there is documentation supporting the presence of residual, hemodynamically significant stenosis.

---

[5] This regulation states: "The interdisciplinary team must provide vascular access monitoring and appropriate, timely referrals to achieve and sustain vascular access. The hemodialysis patient must be evaluated for the appropriate vascular access type, taking into consideration co-morbid conditions, other risk factors, and whether the patient is a potential candidate for arteriovenous fistula placement. The patient's vascular access must be monitored to prevent access failure, including monitoring of arteriovenous grafts and fistulae for symptoms of stenosis."

15. Defendant's fraudulent scheme—the CTE Scheme—worked as follows:

- After an initial referral to an FVAC from a patient's treating nephrologist or dialysis clinic, the FVACs routinely scheduled follow-up appointments or so-called "clinically timed evaluations" ("CTEs") without a further referral from a medical official.

- Prior to a CTE appointment, FVACs did not request any information concerning a patient's recent dialysis treatment from that patient's treating nephrologist or the dialysis clinic that was administering dialysis. In many cases, the records documenting administration of dialysis at the patient's clinic in the days before a CTE demonstrated with quantifiable, objective measures that the patient was dialyzed without any issues.

- Nonetheless, the FVACs brought patients in for a CTE, during which patients received a precursory physical exam. Significantly, the FVAC then recorded a pretextual indication to justify subjecting the patient to a fistulagram, which was followed by an angioplasty, for which the FVAC exaggerated the amount of vascular narrowing or stenosis.

- To ensure robust revenues, Defendant essentially enrolled ESRD patients into a course of CTEs. Upon discharge, the FVACs would schedule additional "follow-up" visits. Critically, the FVACs planned to perform vascular interventions at each CTE. Indeed, FVACs frequently gave patients written instructions that included not only the date of the next CTE but directions not to eat or drink for four hours prior to the appointment time, thus assuming that surgery would be necessary. The potentially harmful fistulagrams and angioplasties—which should not be presumptively considered routine—became routine for these ESRD patients.

16. The nine FVACs at issue performed thousands of angioplasties on ESRD patients that were not medically necessary, in furtherance of Defendant's CTE Scheme. FVC had full knowledge that the procedures were not necessary. As early as 2011, the Chief Medical Officer and two other employees of FVC's corporate parent, Fresenius Medical Care Holdings, conducted a study involving 54,000 Medicare beneficiaries that showed that "preventative" or "elective" angioplasties did not benefit ESRD patients. Indeed, if anything, the procedures were associated with decreased, rather than increased, vascular access.

17. Defendant nonetheless took advantage of patients to promote its own financial gain. This conduct came at a cost to patients.

18. Defendant knew that it was subjecting patients to uncomfortable, time-consuming interventions that were unjustified by clinical and other information amassed by patients' treating physicians and dialysis clinics. Further, Defendant knew that these interventions also exposed patients to grave risks, including, but not limited to, over-sedation, infection, rupture of blood vessels, internal or external bleeding, and new or recurrent stenoses that could warrant yet more invasive procedures—thereby setting the stage for cyclical dependency on interventions.

19. Defendant's CTE Scheme also cost taxpayers, whose hard-earned dollars fund the nation's federal health care programs that paid FVC for the procedures it performed.

PARTIES

20. Plaintiff is the United States of America, which brings this complaint-in-intervention on behalf of the Office of the Inspector General of the Department of Health and Human Services and the Centers for Medicare & Medicaid Services ("CMS"), which administers the Medicare and Medicaid programs. The United States filed its notice of partial intervention in this action on April 18, 2022.

21. Relators, board-certified nephrologists Dr. John Pepe and Dr. Richard Sherman, filed their initial complaint in this action on June 3, 2014, and amended the complaint on December 6, 2016, October 24, 2017, and on August 8, 2020, respectively.

22. Defendant FVC is headquartered at 1200 West Swedesford Road, Building 3, Suite 120, Berwyn, Pennsylvania, 19312. It was formed by and is a wholly owned business unit of Fresenius Medical Care Holdings, Inc. ("FMC"), a limited partnership organized under the laws of New York corporation and does business as "Fresenius Medical Care North America."

23. FVC is one of the largest clinic networks for interventional radiology in North America. At all relevant times, FVC transacted business in the Eastern District of New York.

24. Its corporate leadership oversaw the operations of three regions that covered geographical portions of the United States. The North, South, and Western Regions were each governed by their own regional leadership. The nine New York FVACs are part of the North Region.

25. FVC formed a Medical Advisory Board ("MAB"), led by its Chief Medical Officer ("CMO") and ostensibly charged with reviewing and analyzing clinical quality. According to internal FVC documents, the MAB was necessary "to ensure the delivery of the highest level of patient care" and "to be used extensively, with structure, to assist in the development of best practice standards, clinical and governance policies and recommendations for operation of FVC Centers, particularly in areas that are the subject of significant new medical literature." MAB members were chosen jointly by the FVC Chief Medical Officer and its President. The members were physicians who were serving or who had recently served as the medical director at an FVAC.

26. FMC is and was a wholly owned subsidiary of German company Fresenius Medical Care Ag & Co. KGaA ("Fresenius AG"). FMC holds itself out as the world's largest provider of dialysis products and services. Fresenius AG substantially grew the Fresenius Vascular Care business unit with the acquisition in 2011 of American Access Care Holdings for $385 million. The press release announcing the acquisition stated: "Fresenius said that acquiring AAC will enable it to achieve critical mass in its vascular access business." According to FMC's annual reports and SEC filings, in 2012-2018, between 31-34 percent of the company's total revenue was attributable to reimbursements by U.S. federal healthcare benefit programs, including Medicare and Medicaid. The American Access Care Holdings ("AAC") clinic network was comprised of

28 freestanding outpatient centers providing vascular access treatment to dialysis patients in New York and elsewhere in the U.S, including the nine FVAC centers at issue in this case. Following the acquisition, AAC clinics were absorbed operationally into the FVC chain. FVC has since added at least 15 additional vascular access clinics.

27. As of June 20, 2017, FVC has done business as Azura Vascular Care. The press release announcing this "strategic rebranding" stated that its vascular care centers "are supported by the resources of their experienced management team and their parent company, healthcare leader Fresenius Medical Care North America." The press release further stated that, "[W]e are one integrated organization, operating daily with a common purpose."

28. According to its website, FVC presently operates 66 FVACs in approximately 25 states (and Puerto Rico) throughout the United States. FVC owned, operated, and otherwise controlled nine FVACs at the following locations in New York State:

- American Access Care of Bellmore (now "American Access Care Nassau County"), 250 Pettit Avenue, Suite 2, Bellmore, NY 11710;
- American Access Care Brooklyn, 577 Prospect Avenue Lower Level, Brooklyn, NY 11215;
- American Access Care of New York (now "American Access Care Manhattan"), 403 E. 91st Street, Floor 2, New York, NY 10128;
- American Access Care Queens, 176-60 Union Turnpike #130, Suite 130, Flushing, NY 11366;
- American Access Care Suffolk County, 32 Central Avenue, Hauppauge, NY 11788;
- American Access Care Bronx, 1200 Waters Place N. Lobby, Suite M 115, Bronx, NY 10461;
- Saqib Chaudhry, MD – Flushing, 176-60 Union Turnpike Utopia Center, Suite 145, Flushing, NY 11366;
- Saqib Chaudhry, MD – Roslyn, 1044 Northern Boulevard, Suite 302, Roslyn, NY 11676 (no longer operating); and

- Verrazano Vascular Associates at Access Care Physicians, 2025 Richmond Avenue, Suite 1LL, Staten Island, NY 10314.

JURISDICTION AND VENUE

29. This Court has jurisdiction over the claim in this action pursuant to 31 U.S.C. § 3730(a) and 28 U.S.C §§ 1331 and 1345.

30. Venue lies in this District pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1391(b) and 1391(c) because at least one of the Defendant's FVACs is located or transacts business within this District and because a substantial part of the false or fraudulent acts set out in 31 U.S.C. § 3729 occurred in this District.

STATUTORY AND REGULATORY BACKGROUND

I. THE FALSE CLAIMS ACT

31. The False Claims Act, 31 U.S.C. § 3729, *et seq.* ("FCA"), reflects Congress's objective to "enhance the Government's ability to recover losses as a result of fraud against the Government." S. Rep. No. 99-345, at 1 (1986), *available at* 1986 U.S.C.C.A.N. 5266. As relevant here, the FCA establishes civil penalties and treble damages liability to the United States for an individual or entity that:

> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or]
>
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; or …
>
> (G) 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 or improperly avoids or decreases an obligation to pay or transmit money to the Government.

31 U.S.C. § 3729(a)(1)(A)-(B), (G).

32. "Knowing," within the meaning of the FCA, is defined to include reckless disregard and deliberate indifference to the truth or falsity of the information. *Id.* § 3729(b)(1).

33. Submitting a payment request to Medicare for medical procedures that do not comply with applicable coverage standards constitutes a false claim actionable under section 3729(a)(1)(A) of the FCA. Creating medical records for medical procedures that make it appear that they comply with coverage standards and form the basis of a payment request to Medicare constitutes the creation of false record or statement material to a false claim actionable under section 3729(a)(1)(B) of the FCA.

34. The Patient Protection and Affordable Care Act ("PPACA"), Pub. L. No. 111-148, 124 Stat. 119, 755, Title VI, Subtitle E, § 6402(a) (Mar. 23, 2010), requires, *inter alia,* that any person who has received a Medicare or Medicaid overpayment must "report and return the overpayment to the [HHS] Secretary [or] the State …, as appropriate," within "60 days after the date on which the overpayment was identified." 42 U.S.C. § 1320a-7k(d)(1),(2). The PPACA further provides that "any overpayment retained by a person after [this] deadline … is an obligation" under 31 U.S.C. § 3729(a)(1)(G). *See* 42 U.S.C. § 1320a-7k(d)(3).

35. Under the FCA, the Government is entitled to recover three times the amount of each claim and, for each claim, a civil penalty of not less than $5,500 and not more than $11,000 for each violation occurring before and including November 2, 2015, and of not less than $12,537 and up to $25,076 per violation for violations occurring after November 2, 2015. *See* 28 C.F.R. § 85.5; 87 Fed. Reg. 89 (May 9, 2022).

II. FEDERAL HEALTHCARE PROGRAMS

36. Defendant submitted or caused claims to be submitted for payment to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395lll ("Medicare"); the

Medicaid Program, 42 U.S.C. §§ 1396-1396w-5 ("Medicaid"); the TRICARE Program, 10 U.S.C. §§ 1071-1110b ("TRICARE"); and the FEHBP, 5 U.S.C. §§ 8901-8914. Some of these claims were for patients who were dual-eligible for two programs. All these claims included patients who were either insured by Medicare or Medicaid.

A. The Medicare Program

37. Pursuant to Title XVIII of the Social Security Act, 42 U.S.C. § 1395, *et seq.*, the federal Medicare Program was established in 1965 to provide health insurance for elderly and disabled persons.

38. Medicare coverage was extended to include treatment for individuals with ESRD in 1972 and was further extended when an age requirement for ESRD coverage was removed in 1978. This legislative amendment was prompted by the increasing number of patients receiving kidney dialysis and the substantial cost of this life-saving procedure. *See* Pub. L. No. 92-603, § 2991, 86 Stat. 1329, 1463-64 (1972) (codified at 42 U.S.C. § 1395c).

39. Medicare does not offer coverage for "[e]xaminations performed for a purpose other than treatment or diagnosis of a specific illness, symptoms, complaint, or injury," with limited specified exceptions not applicable here. 42 C.F.R. § 411.15(a)(l).

40. Medicare does not cover "expenses incurred for items or services— . . . (B) in the case of items and services . . . , which are *not reasonable and necessary for the prevention of illness*." 42 U.S.C. § 1395y(a)(1) (emphasis added).

41. It is the obligation of every health care provider seeking payment under Medicare to assure that services it provides, "(1) will be provided economically and only when, and to the extent, medically necessary; (2) will be of a quality which meets professionally recognized standards of health care; and (3) will be supported by evidence of medical necessity and quality in

such form and fashion and at such time as may reasonably be required by a reviewing quality improvement organization in the exercise of its duties and responsibilities." 42 U.S.C. § 1320c-5(a).

42. "All diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary." 42 C.F.R. § 410.32.

43. Medicare considers a procedure such as a fistulagram or angioplasty performed on an ESRD patient "reasonable and necessary" if the procedure is:

- Safe and effective;
- Not experimental or investigational . . . ; and
- Appropriate, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is:
- Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member
- Furnished in a setting appropriate to the patient's medical needs and condition;
- Ordered and furnished by qualified personnel;
- One that meets, but does not exceed, the patient's medical need; and
- At least as beneficial as an existing and available medically appropriate alternative.

CMS, Medicare Program Integrity Manual § 13.5.1; *see also id.* § 13.3 (incorporating § 13.5.1's definition of reasonable and necessary for individual claim determinations).

44. In submitting a Medicare claim for payment, a healthcare provider certifies compliance with 42 U.S.C. § 1395y(a)(1), including § 1395y(a)(1)(B).

B. The Medicaid, TRICARE, and Federal Employee Health Benefits Program

45. Medicaid is a joint federal-state program that provides health care benefits for the poor and disabled. Medicaid is funded by both federal and state dollars. The federal portion of each state's Medicaid payment, known as the Federal Medical Assistance Percentage ("FMAP") is based on the state's per capita income compared to the national average. *See* 42 U.S.C. § 1396d(b). During the relevant time periods, and to date, the FMAP is 50 percent for New York.

46. Medicaid programs provide ESRD coverage to eligible individuals for the first 90 days of a patient's treatment, which is not covered by Medicare. Medicare coverage for individuals with ESRD typically begins 90 days after the initiation of dialysis treatment. For those ESRD patients that are eligible for Medicaid, the New York Medicaid program pays Medicare copayments and/or deductibles for ESRD services. [6]

47. Like Medicare, Medicaid will not pay for treatments that are not medically necessary or appropriate. *See, e.g.*, 18 N.Y.C.R.R. §§ 500.1(b); 515.2(b)(1)(i)(c). [7]

---

[6] Medicare Coverage of Kidney Dialysis & Kidney Transplant Services, U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services, 9 (Dec. 2021), https://www.medicare.gov/media/4416; Data Book: Beneficiaries Dually Eligible for Medicare and Medicaid, Medicare Payment Advisory Commission and the Medicaid and CHIP Payment and Access Commission, 11 (Feb. 2022), https://www.macpac.gov/wp-content/uploads/2022/02/Beneficiaries-Dually-Eligible-for-Medicare-and-Medicaid-February-2022.pdf; DIALYSIS PATIENTS CITIZENS, https://www.dialysispatients.org/policy-issues/ promote-financial-security/medicaid/ (last visited July 6, 2022).

[7] Providers billing New York Medicaid must first complete and sign a Medicaid enrollment application which contains the following attestation:

> ALL STATEMENTS, DATA AND INFORMATION TRANSMITTED ARE TRUE, ACCURATE AND COMPLETE TO THE BEST OF MY KNOWLEDGE; NO MATERIAL FACT HAS BEEN OMITTED; I UNDERSTAND THAT PAYMENT AND SATISFACTION OF THIS CLAIM WILL BE FROM FEDERAL, STATE AND LOCAL PUBLIC FUNDS AND THAT I MAY BE FINED AND/OR PROSECUTED UNDER APPLICABLE FEDERAL AND STATE LAWS FOR ANY VIOLATION OF THE TERMS OF THIS CERTIFICATION, INCLUDING BUT NOT LIMITED TO FALSE CLAIMS, STATEMENTS OR DOCUMENTS, OR CONCEALMENT OF A MATERIAL FACT.

48. TRICARE is a government-funded health care program for active and retired members of the American uniformed services and their families. TRICARE covers dialysis and ESRD-related services for its members. For members who are primarily covered by Medicare, TRICARE will pay the Medicare deductible and patient cost share. *See* 10 U.S.C. §§ 1071-1110.

49. TRICARE uses standards applicable to Medicare for the scope of its coverage and will not reimburse for medically unnecessary procedures. *See* 10 U.S.C. § 1079(j)(2); 32 C.F.R. § 199.4(a)(1)(i).

50. The Federal Employees Health Benefits Program ("FEHBP") is a federally funded insurance program established by Congress in 1959, pursuant to the Federal Employees Health Benefits Act. 5 U.S.C. § 8901, *et seq*. The Program is for federal employees, retirees, and their spouses and unmarried children under the age of 26. 5 C.F.R § 890.302.

51. The Office of Personnel Management ("OPM") administers the Program and contracts with various health insurance carriers ("Carriers") to provide services to FEHBP members. 5 U.S.C. §§ 8902, 8909(a). Benefits provided to FEHBP members include dialysis and ESRD-related services.

52. Monies for the FEHBP are maintained by the United States Treasury in the Employees Health Benefits Fund (the "Fund"), which OPM administers. 5 U.S.C. § 8909(a). The Fund—which the United States Treasury holds and invests—is the source of all relevant payments to the Carriers for services rendered to FEHBP members. 5 U.S.C. § 8909.

53. Federal agencies and their employees contribute to the Fund through health insurance premiums, referred to as contributions. 5 U.S.C. § 8906. Federal employees' portions of the contribution are withheld from each paycheck, then forwarded to the Fund by the employing agency, along with the agency's share of the premium. 5 U.S.C. § 8906(d), (e). The Treasury

holds and invests the Treasury Fund balances. 5 U.S.C. § 8909. Proceeds from the Fund are used to pay Carriers for covered claims paid on behalf of FEHBP members.

54. Carriers do not have any right to monies from the Treasury for reimbursement of benefits unless and until they incur legitimate costs for actual covered services rendered to the members and submit claims to the Government for the payment for those services. 5 U.S.C. 8902; Federal Acquisition Regulation, 48 C.F.R. 31.201-6. FEHBP benefits are payable only for services necessary to prevent, diagnose, or treat an illness, disease, injury, or condition. 5 U.S.C. 8902(d) and 8902(j).

55. References in this Complaint in Intervention to the "federally funded healthcare programs" or "Government programs" include these Medicare, Medicaid, TRICARE, and FEHBP.

C. Medicare Coverage for ESRD Patients[8]

56. Medicare Part B[9] medical insurance covers the cost of certain legitimately provided outpatient ESRD treatments, such as dialysis. It also covers certain vascular interventions, including fistulagrams and angioplasties, when they are reasonable and medically necessary.

57. In its regulations, CMS delineates divisions of care for ESRD treatments.

D. The Dialysis Clinic Is Responsible for Monitoring Vascular Access

58. An ESRD patient's dialysis clinic "interdisciplinary team" is charged with responsibility for monitoring the patient's fistula and overall vascular access:

> The interdisciplinary team must provide vascular access monitoring and appropriate, timely referrals to achieve and sustain vascular access. The hemodialysis patient must be evaluated for the appropriate vascular access type, taking into consideration co-morbid conditions, other risk factors, and whether the patient is a potential candidate for arteriovenous fistula placement. The patient's

---

[8] The other federal healthcare programs at issue provide insurance coverage for ESRD patients in the same manner as the primary payor, Medicare. These programs work in coordination with Medicare benefits to cover ESRD-related services. *See generally, e.g.* 42 CFR §§ 411.160 – 411.165.

[9] The outpatient ESRD treatments at issue are all covered by Part B.

> vascular access must be monitored to prevent access failure, including monitoring of arteriovenous grafts and fistulae for symptoms of stenosis.

See 42 CFR § 494.90(a)(5); *see also* 42 CFR § 494.80; Medicare Claims Processing Manual, Chapter 8, § 180iii.

59. "Procedures associated with monitoring access involve taking venous pressure, aspirating thrombus, observing elevated recirculation time, reduced urea reduction ratios, or collapsed shunt, etc." *See* Medicare Claims Processing Manual, Chapter 8, § 180iii.

60. Medicare provides examples of conditions detected during vascular access monitoring that support a finding of "medical necessity" for vascular studies such as fistulagrams:

- Elevated dynamic venous pressure >200mg HG when measured during dialysis with the blood pump set on a 200cc/min.,
- Access recirculation of 12 percent or greater,
- An otherwise unexplained urea reduction ratio <60 percent, and
- An access with a palpable "water hammer" pulse on examination (which implies venous outflow obstruction).

Medicare Benefit Policy Manual, Ch. 11 (End Stage Renal Disease), § 40.H.

61. The interdisciplinary team is also responsible for making referrals for diagnostic tests such as fistulagrams. *See* 42 CFR § 494.90(a)(5).

62. Medicare reimburses a dialysis clinic for the services it provides to an ERSD patient at a "composite" rate. *See* Medicare Claims Processing Manual, Chapter 8, § 180iii.

63. Outpatient procedures necessary to repair a patient's vascular access, including fistulagrams and angioplasties, are performed at centers such as FVACs. The costs of these procedures are paid under Part B on a fee-for-service basis. *See generally* 42 U.S.C. § 1395rr(a); 42 C.F.R. § 414.314(b); Claims Manual 100-04, ch. 8, § 140(B).

64. Medicare's assignment of responsibility for vascular access monitoring to the dialysis clinic, as embodied in Medicare Final Rule "Conditions for Coverage for End Stage Renal

Disease Facilities," 42 CFR Parts 405, *et al*., makes sense: the team observes the patient and uses his fistula to access his blood system approximately three times per week, for four hours per day. The team is actually using the fistula while observing and recording critical clinical information about the functionality of the fistula and the dialysis process. Indeed, the interdisciplinary team "must develop and implement a written, individualized plan of care for each ESRD patient" with numerous components including, for instance, a protocol for managing the patient's volume status and a goal of achieving a hemodialysis Kt/V [10] of at least 1.2. 42 CFR § 494.90(a)(1).

E. Medicare Guidance Gives Notice to ESRD Providers as to How Binding Statutes and Legislative Rules are Applied

65. Medicare has issued extensive guidance concerning how it applies the Medicare Act, and regulations and rules promulgated under the Act. This guidance extends to vascular access procedures and whether such procedures are reasonable and necessary.

66. As a provider of services to Medicare beneficiaries, Defendant was aware of this guidance. [11]

67. Deciding what is "reasonable and necessary" under § 1395y(a)(1)(B) is delegated in the first instance to the Secretary of Health and Human Services ("HHS"), and HHS may decide whether not to pay for certain types of treatments by promulgating national coverage

---

[10] Kt/V is a measurement of the efficacy of a hemodialysis session. It identifies the effective removal of a specific solute (clearance - K) resulting from a given treatment (characterized by time - t) in a given patient (with a specific volume of distribution - V for the solute considered).

[11] Providers billing Medicare must first complete and sign a Medicare Enrollment Application (Form CMS 8550). This agreement provides:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to me or to [my medical practice]. The Medicare laws, regulations, and program instructions are available through the fee-for-service 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 … and on the supplier's compliance with all applicable conditions of participation in Medicare.

determinations. In addition, HHS contracts with Medicare Part B carriers to provide coverage for out-of-hospital medical services, and these carriers issue guidelines for providers, such as Medical Policy Articles and Local Coverage Determinations.

68. National Government Services Inc. ("NGS"), the Medicare Part B carrier that covers New York, published a Medical Policy Article relating to vascular surgery procedures for ESRD patients on March 1, 2012, which was in effect, with minor revisions, through December 31, 2016. *See* National Government Services Inc., Medical Policy Article A51630, Dialysis Access Maintenance (the "MPA"). [12]

69. This guidance indicated that fistulagrams and angioplasties are medically necessary if and when they are "intended to restore and/or maintain functional patency of the access." Specifically, clinical findings were required to indicate that the functionality of the fistula had been impaired:

> When diagnostic non-invasive vascular studies are performed to evaluate an AV access [fistula] on a routine basis in the absence of signs and symptoms the services are considered monitoring and are not separately covered by Medicare.
>
> In the absence of clinical findings suggesting the need to re-establish appropriate flow in a dialysis fistula, it is seldom reasonable and necessary to perform diagnostic angiography [fistulagrams] … as part of the decision to treat (*i.e.*, CPT codes 75710, 75820, 93990).
>
> *****
>
> Claims will not be paid if documentation in the medical record (e.g., procedure report) does not verify that the services described by the submitted CPT codes were provided and/or were not medically necessary.

---

[12] From June 1, 2010, until March 1, 2012, NGS had in place a Local Coverage Determination, effective in New York, regarding vascular surgery procedures for ESRD patients. *See* National Government Services, Inc., Local Coverage Determination L30737, Dialysis Access Maintenance (the "LCD"). The LCD contained nearly identical coverage rules and principles as the later MPA regarding the use of fistulagrams and angioplasties for dialysis access in ESRD patients. *See also* Local Coverage Article, Dialysis Access Maintenance – Medical Policy Article (A52839), effective from 10/1/2015 to present; Local Coverage Article (A51630), effective 3/1/2012 through 9/30/2015 (same).

> Medicare does not pay for services that are screening in nature or that are not providing clinically relevant information. *Id*.

70. The MPA further informed providers such as FVC that, to seek payment for performing a fistulagram or angioplasty on an ESRD patient, the patient should have previously undergone a clinical examination that produced diagnostically specific and appropriate clinical findings demonstrating a need for therapies to re-establish physiologically appropriate flow in the dialysis fistula, and that such findings be documented in patients' medical records. *Id*. These clinical findings could include "elevated venous pressure in the AV dialysis access," "prolonged bleeding following needle removal," or "abnormal physical findings, specifically pulsatile graft/fistula or loss of thrill," meaning blood vessels that upon manual or aural (using a stethoscope) examination suggest abnormal blood flow.

71. Both the MPA and a Local Coverage Determination ("LCD"), noted that fistulagrams performed for monitoring purposes are not covered under Medicare Part B.[13]

72. With respect to angioplasties, the MPA noted that even in the presence of qualifying symptoms demonstrating a need for therapy generally, such procedures are "not necessary for all poorly functioning AV dialysis accesses." MPA A52839. Angioplasties are considered "reasonable and necessary" only "if there is documentation supporting the presence of residual, hemodynamically significant stenosis, generally >/50 percent of the vessel diameter." The MPA further noted provided that "[t]here must be clear documentation of the site and extent of any hemodynamically significant stenosis." It reiterated that "[a]ngioplasty of vessels not documented

[13] *See* L27355 at VI ("If the service is done for monitoring purposes, it is not covered under Part B. No separate payment for noninvasive vascular studies for monitoring the access site of an ESRD patient, whether coded as the access site or peripheral site, is permitted to any entity.").

to be stenosed significantly by angiography or ultrasound will be considered not medically necessary." *Id*.

73. With respect to fistulagrams, the MPA noted that that "[a] referral must be on record for *each* non-invasive study performed. A referral for one type of study does not qualify as a referral for all tests." (Emphasis added.) Specifically, such procedures that are "done for monitoring purposes" or "routine screening tests" are not covered by Medicare. [14]

74. Other guidance made the obvious point that it is the responsibility of the provider to ensure the medical necessity of procedures and documentation of such in the medical record. [15]

FACTS

75. From January 1, 2012 through at least June 30, 2018, the nine New York area FVACS performed thousands of fistulagrams and angioplasties on ESRD who were beneficiaries of Medicare, Medicaid, FEHBP and TRICARE.

76. Defendant submitted, or otherwise caused to be submitted, claims for reimbursement, to the federally funded healthcare programs for performing these procedures.

I. PROPER CARE AND TREATMENT OF ESRD PATIENTS

77. Most individuals with ESRD require and receive dialysis at outpatient dialysis clinics, where medical procedures and devices are used to replicate the blood cleaning functions performed by healthy kidneys. ESRD patients typically undergo dialysis treatments three times a week for an indefinite period. Each treatment can last three to five hours, including the dialysis

[14] The "Limitations" section of the MPA reiterated that "Medicare does not pay for services that are screening in nature or that are not providing clinically relevant information." *Id*.

[15] Local Coverage Determination ("LCD") for Non-Invasive Vascular Studies (L27355) at V., effective 11/15/2008, revised 1/1/2012 (emphasis added), superseded on 10/1/2015 by L33627 (same) 10/1/2015 (rev'd 1/1/2017) to present).

itself as well as a series of standard monitoring tests to confirm that the dialysis is working effectively. The patient will typically be seen by a nurse, under the supervision of a nephrologist.

78. ESRD patients' vascular systems need to function well to receive dialysis treatment.

79. To gain access to a patient's vascular system to perform dialysis, there must be a point of entry to connect the dialysis machines to the patient with a sufficient blood flow rate. A common solution is to surgically create a "fistula," which is an artificial connection of a major vein and artery that is close enough to the skin's surface to permit access for dialysis.

80. When a patient undergoes dialysis treatment, the dialysis clinic is responsible for performing a series of standard monitoring, surveillance, and if medically indicated, diagnostic procedures to determine whether the dialysis is functioning effectively or whether the patient has a condition that is impairing its proper functioning. This standard protocol includes:

(a) Monitoring: At least monthly, qualified medical individuals should perform physical evaluations of the patient to detect dysfunction of the fistula or other vascular access site.

(b) Surveillance: Evaluations of intra-access blood flow, static vascular dialysis pressure, recirculation, and other measures that suggest dialysis dysfunction.

(c) Diagnosis: Specialized testing that is prompted by an abnormality or medical indication undertaken to diagnose the cause of a vascular access dysfunction. Only persistent abnormalities in any of the monitoring or surveillance parameters (a single isolated abnormal value) should prompt a referral for access imaging.

See Kidney Disease Outcomes Quality Initiative, 2006 Updates, Clinical Practice Guidelines ("KDOQI Guidelines"), Guideline 4.[16] The KDOQI Guidelines' professional standard of medical

[16] The National Kidney Foundation's Kidney Disease Outcomes Quality Initiative provides evidence-based guidelines for hemodialysis vascular access. Since the last update in 2006, the guidelines were updated in 2019. *See* Lo CE, Huber TS, Lee T, *et al*; KDOQI Vascular Access Guideline Work Group. KDOQI clinical practice guideline for

necessity for fistulagram requires dialysis clinic data (the clinical and surveillance parameters above) and a physical examination.

81. When the results of monitoring tests show problems at the point where the dialysis machine connects to a patient's vascular system ("the vascular access site") that are preventing dialysis from effectively cleaning a patient's blood, the treating physician or clinic may refer that patient to a vascular access center, such as an FVAC, to diagnose the cause and, if appropriate, perform a procedure to enable dialysis to function properly.

82. Procedures such as fistulagrams and angioplasties can present significant risks to the patient including infection, sepsis, allergic reaction, rupture of blood vessels, and internal or external bleeding.[17]

II. DEFENDANT'S CTE SCHEME CHURNED PATIENTS IN A CYCLE OF UNREASONABLE AND MEDICALLY UNNECESSARY INTERVENTIONS

A. The CTE Cycle Began with an Initial Visit and, Typically, a Fistulagram

83. Defendant's Scheme started with an initial patient visit to an FVAC for a fistulagram.[18]

84. Upon arrival at an FVAC, staff and doctors would put patients "on the table." In practice, this meant to perform procedures on them and bill for the most expensive procedures. Putting these patients "on the table" at the FVACs worked as follows:

- An interventionalist would ostensibly evaluate the patient for a fistulagram.[19]

---

vascular access: 2019 update. Am. J Kidney Dis. 2020; Vol. 75 (Iss. 4) (Sup 2): S1-S164., April 2020 ("2019 KDOQI Guidelines").

[17] In addition, exposure to the iodine-containing dye used in radiological procedures could have an adverse impact on any residual kidney function. Residual kidney function is one of the most important predictors of a patient's survival. Accordingly, it is recommended that this contrast dye be used judiciously and in the smallest volumes in ESRD patients to preserve residual kidney function. *See* 2019 KDOQI Guideline 15.

[18] As used here, fistulagrams includes angiograms on peripheral arteries and veins (those in patients' arms or legs).

[19] FMC's Corporate Compliance Department expected that if an interventionalist did not believe a fistula was necessary, they would communicate this to the patient's referring dialysis clinic or nephrologist. In practice, the

- Patients received pain medication, such as fentanyl, and a sedative.

- In the procedure room, an interventionalist would most often perform a fistulagram with the assistance of a radiology tech. A nurse or the radiology tech would place a blood pressure cuff on the patient's arm, a clip on their finger to monitor oxygen, and stickers with wires on their legs and arms to check the patient's heart rate.

- A nurse or tech would draw up medication and the interventionalist (or an anesthesiologist if local anesthesia is used) would inject it into the patient.

- Sometimes the area of the procedure would be cleaned, shaved and covered with surgical drapes from the shoulders to feet.

- The interventionalist would then insert small catheters into the patient's fistula and possibly may inject blood thinners.

- The radiology techs or the interventionalist would then take X-rays.

- After the narrowing or blockage was purportedly identified, an interventionalist would perform an angioplasty to address the blockage. For patients that have a stenosis (narrowing) that is "hemodynamically significant" (generally, a reduction in blood flow through the fistula that is below the dialysis machine's requirement for adequate treatment) in their fistula or surrounding blood vessels, an angioplasty may be a proper procedure to expand the narrowed vessel so that sufficient blood flow for dialysis can be restored.

- The interventionalist would typically read and interpret the images himself, determining the percentage of stenosis.[20] Sometimes others in the room questioned this reading or interpretation. The stenosis percentage should have been, but was not always, documented in the records.

- To perform the angioplasty, the interventionalist would insert a tube (catheter) into the patient's skin with a small balloon at one end into a blood vessel. The catheter would be guided through the patient's blood vessel until it reaches the area of narrowing, at which point the balloon would be inflated to widen the vessel.

---

interventionalists almost always performed a fistulagram at the initially referred appointment. Rarely, would a patient leave without a fistulagram. The dialysis clinic and nephrologist were rarely, if ever, consulted, at any point.

[20] Patient records do not always contain clear photos of the degree of stenosis before the intervention. In some instances, the images are missing altogether. In others, the images are not clear enough to view the degree of stenosis.

- After the procedure, assuming there were no adverse events, the patient would be taken from the operating room to another room, where they were offered juice and a sandwich. They might stay in the recovery area for up to two hours while waiting for the bleeding to stop. If there was an emergent event, a patient may require an ambulance to a hospital for urgent care.

- Upon discharge, the FVAC gave the patient a sheet with a "follow-up" appointment date and instructions not to eat or drink before the pre-scheduled appointment. The FVAC might also arrange the patient's transportation to and from the FVAC facility.

- The FVAC typically completed a procedure report on every patient. The report detailed the procedure performed and the purported clinical indication, or reason, for the procedure. The purported clinical indication that the FVAC interventionalist determined required a procedure would suggest a problem with access.

B. The Cycle Continued with Non-Referred, Clinically Unsupported CTEs and Procedures

85. In accordance with Defendant's policy and practice, an FVAC would schedule CTEs without further referral from the patient's treating physician or patient's dialysis clinic. These CTEs would take place at regularly timed intervals, approximately every three months. Notably, the patient had already been monitored and evaluated by the dialysis clinic, and federal healthcare programs had already paid for these services.

86. CTEs were scheduled at FVACs without regard to clinical findings and other information that was available from, among other sources, the clinics that administered patient dialysis.

87. In fact, patients had been scheduled for a procedure, not an evaluation. The FVAC staff knew with near certainty before the patient arrived that the FVAC would perform a procedure on the patient.

88. At the CTE appointment, after a perfunctory physical examination in which a physician would look at and touch the patient's vascular access site, FVAC interventionalists

performed fistulagrams as a matter of routine even where the patient presented without a clinical justification or indications of difficulty with dialysis.

89. The FVACs would then routinely perform fistulagrams and angioplasties, separately billing federal healthcare programs for what were risky and often unnecessary procedures.

90. The FVAC often instructed the patient to come back for a follow-up appointment "before a small problem becomes a big problem."

91. If a patient did not heed the instructions to return, they often would receive a phone call from staff at the FVAC to schedule them for a follow-up appointment.

C. Defendant Ignored Clinical Evidence from Dialysis Clinics and Created Pretextual Reasons to Justify Interventions

92. Patient dialysis clinic records contained a wealth of information obtained during dialysis. During dialysis, clinic doctors and staff were uniquely positioned to observe the patient, how the patient tolerated dialysis, and whether dialysis worked.

93. For example, a treating nephrologist's or dialysis clinic's referral for a fistulagram considers a myriad of factors including clearance rates, re-circulation of blood, abnormalities in blood flow rates, Kt/V, and arterial or venous pressure.

94. CMS, the component of the Department of Health and Human Services that administers the Medicare Program, implemented a Quality Incentive Program designed to encourage high quality and cost-effective healthcare services for ESRD patients. As part of this effort, CMS identified as a clinical measure of adequate dialysis that patients have a Kt/V equal to or greater than 1.2. *See* 78 Fed. Reg. 72191 (Dec. 2, 2013).

95. FMC, FVC's parent corporation, acknowledged the importance of the Kt/V metric by using it as a reference point to demonstrate the quality of dialysis administered at its own

dialysis clinics. *See* FMC 2014 Annual Medical Quality Report at p. 18 (describing CMS clinical measure and noting that 94.5 percent of its own dialysis patients maintained Kt/V rates equal to or greater than 1.2 in 2013). Even though FVC would have had access to the records for FMC's dialysis clinics and could have requested the information from non-FMC dialysis clinics, FVC never considered whether a patient exhibited diminished Kt/V before pre-emptively performing a fistulagram.

96. Procedure notes from these follow-up CTE appointments at FVACs contain scant mention of any fistula malfunction.

97. Rather than consider clinical information obtained during dialysis, Defendant performed pretextual physical exams to justify interventions.

98. For example, the FVACs did not consider the patient's actual blood flow before performing a fistulagram. FVC knew that "[c]linical practice guidelines recommend that the preferred method of surveillance for arteriovenous fistula (AVF) is the measurement of AVF blood flow."

99. Instead, FVC routinely relied on the purported presence of a "soft" indicator of impaired vascular access.

100. As indicated in the "Physical Exam" column in Exhibit 1, attached to and incorporated in this Complaint-in-Intervention, over 72 percent of the procedure entries provide "pulsatility" as the justification for an intervention (column H). This finding squares with the medical review, which revealed that FVC claimed pulsatility at similarly suspect large percentages and proceeded to perform a fistulagram on that basis. Objective indications for performing the procedure are absent.

101. Notably, in over 79 percent of these clinical evaluations, an angioplasty was performed (Ex. 1 column I) during a CTE appointment. As FVC's employees knew and acknowledged, clinical signs of access dysfunction monitored and recorded by the dialysis clinic include "difficult cannulation,"[21] prolonged bleeding, swollen extremity, neck and chest wall collaterals, emergence of aneurysms [and] poor clearances via Kt/V or URR (urea reduction ratio).

102. Rather than considering actual malfunction or flow rates before performing a fistulagram at a CTE appointment, the FVAC most often noted only "pulsatility," which is a vibratory sensation felt when the FVAC provider placed their hand on the patient's skin.

103. Pulsatility is a non-quantitative, subjective visual assessment. Defendant conveniently seldom, if ever, corroborated the pulsatility sensation it recorded with the results of other monitoring tests before concluding that the patient's ability to receive dialysis has been impaired and intervening with a surgical procedure.

104. In justifying fistulagrams based on pulsatility or other subjective observations like poor or decreased thrill (the motion of blood flowing through the fistula), FVACs routinely ignored objective factors like clinical measures of blood flow.

D. Defendant Falsified Patient Records to Justify Interventions

1. Defendant falsely indicated that physicians had referred patients for CTEs.

105. Claims that Defendant submitted for payment of procedures performed during CTEs almost uniformly misrepresented that a patient's doctor—usually the treating nephrologist—had referred the patient for the procedure.

---

[21] Cannulation is the act of establishing a "canal" between an arterialized vein (the fistula) and the system of blood lines that allow blood to be circulated between the patient and the dialysis machine.

106. Similarly, Defendant often falsified patient records to indicate that a patient's treating or attending nephrologist referred the patient for each follow-up appointment and multiple procedures over many months.

107. Defendant's records, including procedure reports, also falsely indicated that patients had symptoms of the type that would justify a referral from their treating nephrologist or dialysis center. However, corresponding medical records from the patients' dialysis clinics often showed that patients were not referred and had no relevant symptoms prior to the date of service at the FVAC. The patients' treating nephrologists were usually excluded from the decision to call the patient back to the FVAC.

108. Fistulagrams performed without any clinical indication of necessity should not be performed, can cause patient harm, and are not covered by federal healthcare programs. Medicare requires a referral from the treating physician to substantiate the fact that while performing the monitoring function, signs and symptoms of impaired dialysis function were observed.

2. Defendant created false medical records to indicate significant stenosis.

109. Additionally, the radiologic images taken at the FVAC prior to the procedure do not show the degree of blockage in the patient's vein as recorded in the corresponding procedure report.

110. After performing the medically unnecessary fistulagrams at a CTE, an FVAC interventionalist would regularly perform an angioplasty where the patient information and records did not support "the presence of residual, hemodynamically significant stenosis."

111. FVAC interventionists often recorded inflated the percentage of stenosis within the vessel, justifying the reason for performing the angioplasty.

112. In the FVACs, Defendant billed for angioplasties on over 84 percent of the dates of service in which fistulagrams were performed. Based on a review of these claims to date, at least 55 percent of these angioplasties were not supported by documentation, representing a 50 percent or greater narrowing and were therefore medically unnecessary.

3. Defendant submitted and was paid for these false claims.

113. Defendant billed the federal healthcare programs and received payment (at an average rate of as much as $6,438.74 per procedure) for procedures, which were medically unnecessary and therefore not covered procedures. *See* Exhibit 2, attached to and incorporated in this Complaint-in-Intervention (providing average reimbursement rates for Current Procedural Terminology codes).[22]

114. Defendant submitted claims for payment to the federal healthcare programs and was paid by these payors, for medical procedures that did not comply with the applicable standards for medical necessity.

115. The Government would not have paid Defendant for any such procedures, such as those described above, if it had known that 1) the patient did not exhibit diagnostically specific and appropriate indications and 2) the patient documentation revealed that they were not reasonable and necessary.

III. DEFENDANT KNOWINGLY SUBMITTED FALSE CLAIMS IN FUTHERANCE OF THE CTE SCHEME

A. Defendant Knew That "Elective" Interventions on ESRD Patients Were Unnecessary and Harmful Prior to Ramping Up the CTE Business Plan

[22] The Current Procedural Terminology ("CPT") codes offer doctors and health care professionals a uniform language for coding medical services and procedures to streamline reporting, increase accuracy and efficiency. CPT codes are also used for administrative management purposes such as claims processing and developing guidelines for medical care review.

116. In 2011, three physicians from FMC's Clinical Research Division, among others, published a study addressing the effectiveness and proper role of fistulagrams and angioplasties in treating dialysis patients. One of the authors included FMC's Chief Medical Officer.

117. This study, published in the Clinical Journal of the American Society of Nephrology ("the 2011 CJASN Article"),[23] stated:

- A review of over 54,000 Medicare beneficiaries from 2004-2007, primarily sourced from FMC dialysis clinics, found no difference in vascular access survival between those who received "preventative" or "elective" angioplasties and those that did not.

- The only patients who benefitted from these angioplasties were those with relatively new fistulas (< three months old), had low blood flow rates or low Kt/V clinical measures.

- In contrast, all other patient groups saw preventative angioplasties associated with *decreased* access survival—a conclusion consistent with the fact that interventional procedures themselves cause damage to blood vessels and create new stenoses.

- Preventative angioplasties were also associated with the risk (>1%) of certain "serious adverse events," which rate did not include the further incidence of harm to residual kidney function caused by contrast dye.

118. This study also acknowledged that the decision of whether, and when, a dialysis patient should receive an access intervention was in the discretion of the attending physician at the clinic providing the dialysis treatment. Indeed, this was the course of action by FVC's parent, FMC, which operated dialysis clinics. After a confirmatory reading indicated problems with a patient's blood flow rate, FMC's practice was that "Further referral for intervention was then at the discretion of the attending physician [meaning the nephrologist]."

---

[23] Chan, *et al*., "Access Survival amongst Hemodialysis Patients Referred for Preventive Angiography and Percutaneous Transluminal Angioplasty," Clin. J. Am. Soc. Nephrol. (Nov. 2011).

119. The study concluded, "Overall, the results of this study suggest that angiography PTA[24] provides limited access survival benefits in the ESRD population as a whole."

120. The article was widely distributed among FVC executives, including FVC's President, Chief Medical Officer, and the MAB. The FVC Chief Medical Officer's reaction was that "it goes to show you how 40,000 patients can give you the wrong answer."

B. Despite the 2011 Study, FVC Promoted the Use of CTEs

121. FVC looked for ways to legitimize follow-up fistulagram procedures when it was really geared to drive up revenue.

122. A 2012 internal memo signed by FVC's President regarding "Follow-Up Fistulagram Procedures" described the practice of 15 FVAC physicians who perform "prophylactic, or follow up, Fistulagram procedures (with possible Angioplasty) at any point between one to three months post an Angioplasty procedure." Notably, the memo recognized that this follow-up practice would "increase procedure count." While acknowledging that "the presence of a stenosis in the absence of a functional abnormality is not an indication for an intervention," it set forth a plan to justify the procedures. Through this memo, FVC established a so-called "Clinical Quality Team" tasked with performing medical chart audits of follow-up procedures to "ensure quality outcomes are above standard across all access centers." This team was tasked to ensure that if an angioplasty was performed, "the stenosis is documented at 55 percent of higher."

123. In 2013, FVC's Chief Medical Officer drafted a "CTE White Paper," which promoted and purported to justify the CTE Scheme.

---

[24] Percutaneous transluminal angioplasty.

124. The White Paper, which was reviewed by multiple subcommittees of FVC's MAB, advocated for a "CTE model" consisting of fixed surveillance and intervention to treat "clinically silent stenosis."

125. The paper conceded, "Critics of CTE believe it results in too frequent interventions." The MAB Quality Subcommittee recommended that the White Paper de-emphasize "negative points" to highlight that "clinical exams, not fistulagrams, are the primary reason for patients coming through the door."

126. The White Paper criticized the professional standards expressed in the KDOQI Guidelines as out of date. The White Paper emphasized how important it is to have someone perform a physical exam who has the skill to do it properly, that is, an FVAC interventionalist. The White Paper downplayed the importance of checking access flow, even though FVC had previously acknowledged blood flow is a critical metric in judging fistula functionality.

127. The White Paper concluded, "[t]he Medical Advisory Board firmly stands on the belief that aggressive clinical monitoring with serial physical exams and interventions as clinically warranted, offers the best access care available … the CTE offers the highest level of care by individualizing treatment regimens."

128. The FVC Chief Medical Officer presented the White Paper at a 2013 Symposium of FVAC Medical Directors, ignoring the KDOQI guidelines and claiming that there are "no standards" for "frequency of intervention."

129. However, the Chief Medical Officer acknowledged that the 2011 CJASN Article, which concluded "that angiography-PTA provides limited access survival benefits in the ESRD population as a whole" presented an "internal challenge."

130. Later that year, at an FVC MAB Meeting, FVC worked to integrate the CTE business plan in all its centers. The focus of "all of our research energy … in the next 3 to 5 years" is to "show what we are doing is appropriate, timely, benefits the patient, prolongs life of access and improves morbidity and mortality."

131. Despite attempts to promote CTEs as favorable to the patient, FVC never developed significant evidence that this is so.

132. FVC continued to distribute the White Paper internally, though FVC never published it.

133. FVC's Chief Medical Officer, who was also an FVAC interventionalist, widely advocated for CTEs at symposiums attended by FVAC Medical Directors.

134. By 2015, FVC's MAB created the Research Subcommittee comprising of FVC executives and physicians, which identified as "the most important area[] FVC wanted to develop studies to support.… 1. Support reasons for repeat visits to FVC centers and preemptive treatments (CTE)[.]"

135. Next, FVC found a way to advocate for CTEs without the supportive research it hoped to develop. FVC created and distributed copies of a "marketing card" to FVACs throughout the country that its "marketing team" deemed to be targets for increasing revenue through CTEs. These target FVACs included all the FVAC locations in New York. FVC also provided the marketing card to FMC dialysis centers.

136. The marketing card advocated for "Preemptive Interventions" as "routine maintenance that includes surveillance, monitoring and when needed, repair of subclinical stenosis." The marketing card claimed that this routine maintenance would extend access longevity and improve the quality of patients' lives.

137. For support, it cited a medical article by renal doctor Nicola Tessitore and others that FVC believed lent support to the CTE Scheme of interventions at regularly timed intervals.

138. However, FVC mischaracterized the study, which concerned only patients with measurably diminished rate of flow.

C. Defendant Aggressively Implemented the CTE Scheme

139. Defendant took steps to ensure the success of the CTE Scheme. These efforts included training, setting goals, incentivizing staff and physicians with rewards, outreach to dialysis clinics, and closely tracking CTEs.

1. Defendant set goals and provided incentives.

140. Behind the veneer of concern with quality outcomes, FVC was focused on increasing volume or "growth" of patients and procedures. FVAC and FVC Regional Directors communicated monthly about targets for volumes of procedures performed.

141. By 2015, FVC acquired a majority interest in nearly 40 FVACs nationwide. As it continued to grow, FVC used recruiters to find nurses interventionalists to work in FVACs. New hires were told about the CTE plan of scheduling follow-up appointments at a three-month interval "default."

142. Some practicing interventionalists reported having never heard of the concept of calling back patients for interventions on a regular schedule until working at a FVAC. But they soon learned from FVC corporate, the FVAC Manager, the Regional Director, and the Regional VP that the CTE plan was FVC's practice. These supervisors might complain to an interventionalist if they learned he sent a patient home without performing a procedure. Some interventionalists who disagreed with the CTE plan left the FVAC or told to quit because "maybe this is not for you."

143. FVC based its physicians' compensation in part by the volume of its billings for procedures. Given these incentives, it is unsurprising that data analytics programs using Medicare data identify several FVAC interventionalists as outliers for their billing of angioplasties.

144. At certain FVACs, interventionalists were offered a "productivity bonus," which was based on total amount of procedures performed after 1000 procedures per year. In verbal discussions, interventionalists were sometimes required to defend a low number of procedures up the hiring chain: first to their FVAC manager, then to FVC's marketing team, up to the regional managers, division vice-presidents and finally to the FVC corporate level.

145. FVC's Chief Medical Officer instructed interventionalists to review their "PPD," which stood for procedures per day. Interventionalists were given summaries of their PPD stats in comparison to other FVACs.

146. FVC's marketing team were assigned a particular geographic region of FVACs in which to market and promote the CTE model. All three of FVC's Regional Marketing Teams were supervised by FVC's Vice President of Sales.

147. Marketing Regional Directors assigned a geographic area of FVACs to oversee received a salary plus annual bonus based on performance. FVC set performance metrics based on whether the FVACs in the region met financial revenue and profit revenue goals.

148. The Brooklyn FVAC, where FVC's Chief Medical Officer was the Medical Director, set targets for number of ESRD procedures, including fistulagrams and angioplasties, quotas for "renal cases" and congratulated the office team when those numbers were met and exceeded.

149. Each FVAC had baseline "goal" numbers of medical procedures in total monthly. In staff meetings at the Brooklyn and Staten Island FVACs, managers presented those target

volume numbers. Managers wrote these targets on the white boards in the staff lounges. Front desk employees and nurses received financial awards for meeting target goals. FVAC physicians were aware of these minimum procedure thresholds.

150. In 2014, a Senior Director of Sales & Marketing working from Staten Island, announced a contest to three regions comprising the "North Region." The goal was to hit 400 procedures in 3rd quarter of 2014. The Sales Director encouraged the team to use the "1 minute assessment" video to show dialysis staff in the clinics how quickly they can decide if referral is warranted and to use Tessitore article. The Director instructed, "[t]ell them they are doing an assessment when they cannulate." The Director sent the contest announcement to top executives at FVC.

151. Sales employees participated in other contests held by FVC to incentivize these employees with bonus increases tied to growing new patient referrals.

152. For example, the "Fall Follow Up Contest," held during the 4th quarter of 2015, was an FVC competition among its sales representatives. Participating employees were compared and ranked on performance details. The main metric used was the number of new patients each employee brought to FVC. The sales representatives assigned to New York were among one of four locations that won the contest. All winners received an extra 20 percent in bonus. FVC executives signed off on over $350,000 worth of bonuses.

153. FMC was aware of these bonuses and of the contest.

154. Volume of patients and procedures were metrics used to award FVC managers. FVC created a bonus scorecard for its western FVAC locations. Procedures per day were valued at 25 points, making it the weightiest factor comprising the total score used to determine bonuses.

155. To increase profitability, FVC created a flyer for a competition called the "Summer Sizzle" that promised financial rewards for staff working at FVACs with the greatest per day increase in the number of procedures from May through July 2015. FVACs were to "compete" against each other for the greatest procedure increase. Rewards were to be offered to the top three FVACs in the nation and the top FVAC in every region. "Winners" of this competition were to receive a $100 gift card and 10 percent increase in their quarterly bonuses.

156. In a conference call on May 21, 2015, to address "concerns" about this competition, FMC's Head of Compliance acknowledged that, "we shouldn't be performing or billing for non-medically necessary procedures."

2. FVC conducted formal CTE training for staff and made outreach to nephrology practices for ESRD patient referrals.

157. The implementation of the CTE Scheme was an institutional effort. To advance this CTE Scheme, FVC deployed its marketing and sales team to bring in new patients.

158. In 2013, a Sales Director set up a training in which FVC's Chief Medical Officer would present on Clinically Timed Evaluations to FVC sales representatives.

159. In 2014, FVC provided a final version of the White Paper to its sales representatives to encourage the reps to buy into the CTE plan.

160. Sales representatives engaged in outreach to dialysis clinics and nephrology practices, recorded their business development connections and received promotions and monetary bonuses for volume of new patients.

161. However, some nephrologists were skeptical of CTEs and believed the FVACs were over-performing procedures on their patients. In some instances, these treating nephrologists told their patients not to attend additional follow-up appointments and stopped referring patients

to the FVAC. In others, the patients were worried about access failure and thrombosis, as they had learned from the FVAC, and continued to receive treatments from the FVAC.

3. Defendant closely tracked and analyzed follow-up procedures.

162. Despite some concerns from FMC Compliance, Defendant continued to closely track and analyze the number of follow-up procedures in each of its FVAC locations.

163. FVC compared average procedures per patient throughout its FVACs, marked total procedures and follow-up procedures by year and by FVAC location.

164. FVC analyzed its data identifying the dates and locations of CTE visits on the patient level. Attached as Exhibit 1 is a chart of procedures created from FVC's electronic medical records data at the request of its Vice President of Operations in May 2016. The chart tracked 42,643 "clinical evaluations" as the recorded indication for procedures performed at FVACs nationwide from 2011 through 2016 (column G).

D. Defendant was aware that similar conduct was considered to violate the FCA.

165. In recent years, the United States investigated and settled actions with vascular interventionalists for violations of the FCA arising from subjecting dialysis patients to unnecessary fistulagrams and angioplasties.

166. By the time FVC acquired the American Access Care facilities in 2011, it was aware of investigations of AAC in Florida, Connecticut and Rhode Island by the Department of Justice and HHS-OIG for similar allegations as alleged in this Complaint. This information was formally disclosed in the July 19, 2011 merger and purchase agreement between American Access Care and its subsidiaries and FVC.

167. In May 2015, DOJ announced that it had settled a FCA case against a vascular access company in New York City, Mattoo & Bhat Medical Associates, P.C., whose trade name

was AV Care. The press release stated, "As a regular practice, AV Care routinely scheduled patients for fistulagrams and angioplasties as many as three months in advance, and [its] surgeons … performed these fistulagrams as a matter of routine even if the patient presented without a clinical reason." Further, the press release noted, "angioplasties were performed when the patient information and records did not support the presence of a restriction in the blood vessel of over 50 percent."

168. On May 19, 2015, FVC's North Regional Vice President and Director of Human Resources became aware of this settlement and questioned how aspects of the government's Complaint in Intervention might reflect on their incentive programs (*i.e.*, offering gift cards to FVAC staff for reaching "goal" numbers of specific medical procedures in a month). They were also concerned with whether FVC could be similarly seen as encouraging the performance of unnecessary medical procedures. On the same day, the North Regional Vice President brought this issue to attention of FVC's Vice President of Operations.

169. In July 2015, the DOJ announced that it had settled a FCA case, filed on July 26, 2011, in the Southern District of Florida against American Access Care for billing Medicare for unnecessary angioplasties performed on dialysis patients at its Miami facility prior to being acquired by FVC in 2011. The press release noted that "Patients at the facility were routinely brought back for follow-up visits that were not justified by the patients' condition." FVC knew it could face similar problems. Soon after the announcement of settlement, an FVAC interventionalist emailed the FVC Vice President of Operations a link to Press Release, stating: "we should discuss…"

170. In September 2015, DOJ announced that it had settled two additional FCA cases against AAC facilities, prior to being acquired by FVC, one in Rhode Island and the second in

Connecticut for, among other conduct, submitting claims to Medicare and Medicaid for procedures performed during dialysis patient follow-up visits which were not medically necessary, prior to being acquired by Fresenius.

171. FVC, by and through their legal counsel, reviewed these Settlement Agreements and became aware of DOJ's enforcement of CMS' requirements that to bill for a medically necessary angioplasty, the documentation must support "hemodynamically significant stenosis."

172. Despite this knowledge, there is no evidence that Defendant conducted a review of its claims. Instead kept (and continues to retain) the funds it improperly received because of its false claims.

IV. EXAMPLES OF SPECIFIC INSTANCES IN WHICH FVACS PERFORMED UNNECESSARY PROCEDURES

173. The following cases studies are representative of the many thousands of instances in which FVACs performed medically unnecessary fistulagrams and angioplasties on ESRD patients. These studies examples are representative and not intended to be comprehensive.

174. For additional detail from the files of the below patients, attached as Exhibit 3, attached to and incorporated in this Complaint-in-Intervention, is a chart detailing the dates of follow-up appointments, the purported justifications in the medical records for performing the procedures, and the recorded amount of stenosis that was unsupported by radiological the images.

A. Patient "A"

175. Patient A is a 68 year-old with ESRD who receives dialysis treatments. After an initial referral to an FVAC, Patient A underwent at least 22 procedures at 11 separate dates of service from May 2012 and April 2016, at the FVAC in Flushing, Queens. At each visit in this four-year period, Patient A underwent at least a fistulagram and an angioplasty.

176. The FVAC documented the indication for returning for each follow-up as "clinical evaluation." The recorded justification for proceeding with interventions in the FVAC procedure reports was "vascular access issues."

177. To justify proceeding with a fistulagram at Patient A's appointments in 2014 and 2015, the FVAC's procedural records indicated that a physical exam revealed "pulsatility" in the fistula. This visual assessment was not corroborated by the results of any other test.

178. To justify proceeding with an angioplasty, Patient A's records always recorded stenoses of over 50 percent. But when compared to the percentage of stenosis observable from the pre-procedure radiological images, the FVAC's records contain numerous instances of inflated percentages of stenosis. FVAC interventionalists performed angioplasties on Patient A where the patient information and records did not support "the presence of residual, hemodynamically significant stenosis, generally [greater than or equal to] 50 percent of the vessel diameter."

179. Eight of the 11 angioplasties performed on Patient A from this period were medically unnecessary.

180. At the end of each visit, Patient A received discharge instructions to return for a follow up appointment.

181. Defendant was aware that Patient A continuously and repeatedly returned to the FVAC in Queens for CTE appointments. *See* Ex. 1 at rows 3007-3008.

B. Patient "B"

182. Patient B is a 41-year-old with ESRD who receives dialysis treatments. After an initial referral to an FVAC from a dialysis center, Patient B visited an FVAC in the Bronx on 29 separate dates from December 2012 through May 2018.

183. At each of the 29 appointments, Patient B underwent at least 58 procedures consisting of fistulagrams and angioplasties. The FVAC recorded the indication for returning for these follow-up appointments as "clinical evaluation."

184. To justify proceeding with an angioplasty, Patient A's records always record stenoses of over 50 percent. But when compared to the percentage of stenosis observable from the pre-procedure radiologic images, the FVAC's records contain numerous instances of inflated percentages of stenosis. FVAC interventionalists performed angioplasties on Patient A where the patient information and records did not support "the presence of residual, hemodynamically significant stenosis, generally [greater than or equal to] 50 percent of the vessel diameter."

185. Twenty-seven of the 29 angioplasties performed on Patient A from this period could not be plausibly supported by the medical documentation and were therefore medically unnecessary.

186. After each appointment, Patient B received instructions to return in at time intervals. Following those instructions, Patient B returned on the follow-up date.

187. Of the 29 dates of service, Patient B's records indicate only three legitimate referrals . In six years, Patient B's dialysis contain only four indications of issues with dialysis, which were predominately prolonged bleeding issues. While this patient's dialysis records largely indicate the fistula appeared to be functioning, the FVAC's procedure reports indicate vascular access issues.

188. Defendant was aware that Patient B continuously and repeatedly returned to the FVAC in Bronx for CTE appointments FVAC in the Bronx. *See* Ex. 1 at rows 14038-14039.

C. Patient "C"

189. Patient C is a 58 year-old with ESRD who has received dialysis treatment for fourteen years. After a legitimate referral to the Bronx FVAC, Patient C underwent fistulagrams followed by angioplasties on 15 separate visits from July 2012 through February 2018.

190. At 12 of the 15 appointments, interventionalists noted either clinical evaluation or pulsatility to justify the need for a fistulagram.

191. To justify proceeding with an angioplasty, Patient C's records always record stenoses of over at least 65 percent. But when compared to the percentage of stenosis observable from the pre-procedure radiologic images, the FVAC's records contain numerous instances of inflated percentages of stenosis.

192. In total for this period, after a fistulagram, FVAC interventionalists performed 15 medically unnecessary angioplasties on Patient C.

193. Patient C's dialysis records from this period contains only one referral to an FVAC. Patient C's dialysis facility did not record any other indication of fistula impairment.

194. While Patient C's dialysis records otherwise indicate the fistula appeared to be functioning, the FVAC procedure reports indicate vascular access issues.

195. After each intervention at the FVAC, Patient C received discharge instructions to return for a follow-up appointment.

196. Defendant was aware that Patient C continuously and repeatedly returned to the FVAC in Bronx for CTE appointments. *See* Ex. 1 at rows 25350-25353.

D. Patient "D"

197. Patient D had ESRD and died at age 74 in November 2014. After an initial referral from a dialysis facility, Patient D underwent at least nine medically unnecessary angioplasties on 12 separate visits to the Brooklyn FVAC from February 2012 through October 2014.

198. To justify proceeding with an angioplasty, Patient D's records always contain stenoses of over at least 65 percent to support "the presence of residual, hemodynamically significant stenosis." But when compared to the percentage of stenosis observable from the pre-procedure radiologic images, the FVAC's records contain numerous instances of inflated percentages of stenosis.

199. In total for this period, after a fistulagram, FVAC interventionalists, including FVC's former Chief Medical Officer, performed 9 medically unnecessary angioplasties on Patient D.

200. After each appointment, Patient D received discharge instructions to return notwithstanding that Patient D's dialysis facility in the four days prior to the procedures did not record any indication of fistula impairment. While Patient D's fistula appeared to be functioning according to dialysis records, the FVAC procedure reports indicated vascular access issues.

201. Defendant was aware that Patient D continuously and repeatedly returned to the FVAC in Brooklyn for CTE appointments. *See* Ex. 1 at rows 34553-34556.

E. Patient "E"

202. Patient E had ESRD and died at age 70 in July 2018. Following one legitimate referral from a dialysis center, Patient E returned to the Bronx FVAC on 26 separate dates from January 2012 through June 2018.

203. At each of the 26 appointments, Patient E underwent a fistulagram and an angioplasty.

204. To justify proceeding with an angioplasty, Patient E's records always record stenoses of over at least 60 percent to support "the presence of residual, hemodynamically significant stenosis." But when compared to the percentage of stenosis observable from the pre-procedure radiologic images, the FVAC's records contain numerous instances of inflated percentages of stenosis.

205. In total for this period, after a fistulagram, FVAC interventionalists, including FVC's former Chief Medical Officer, performed 17 medically unnecessary angioplasties on Patient E.

206. In fact, the radiological images from these 17 procedures reveal that none of Patient E's veins exhibited hemodynamically significant stenosis of anywhere near 50 percent of the vessel diameter. Certain FVAC reports falsely indicated that Patient E's veins showed 70 percent stenosis where no stenosis at all is observable from the images.

207. After each appointment, Patient E received instructions to return. Following those instructions, Patient E visited the FVAC for the pre-scheduled follow-up appointments even though there was only one initial referral from the dialysis center.

208. Apart from one instance of bleeding during dialysis, Patient E's dialysis records from this entire period do not contain any notes indicating issues with dialysis or vascular flow. While Patient E's dialysis records indicate the fistula appeared to be functioning prior to each intervention, the FVAC procedure reports indicate numerous vascular access issues.

209. Defendant was aware that Patient E continuously and repeatedly returned to the FVAC in the Bronx for CTE appointments. *See* Ex. 1 at rows 5707-5710.

F. Patient "F"

210. Patient F is a 60-year-old with ESRD. Patient F underwent fistulagrams and angioplasties at the Manhattan FVAC on 14 separate days from March 2012 through October 2016.

211. At each of the 14 appointments, Patient F underwent a fistulagram and an angioplasty.

212. To justify proceeding with an angioplasty, Patient F's records always contained stenoses of over at least 70 percent to support "the presence of residual, hemodynamically significant stenosis." But when compared to the percentage of stenosis observable from the pre-procedure radiologic images, the FVAC's records contain numerous instances of inflated percentages of stenosis.

213. In total for this period, after a fistulagram, FVAC interventionalists performed at least nine medically unnecessary angioplasties on Patient F. Actually, none of Patient F's veins exhibited hemodynamically significant stenosis of anywhere near 50 percent of the vessel diameter.

214. Patient F received directions to return for a follow-up appointment, not to eat or drink anything for 6-8 hours prior to the pre-scheduled appointment and to make transportation arrangements to return home.

215. Following those instructions, Patient F visited the FVAC on each follow-up date even though there were no referrals made from the dialysis center. Patient F's dialysis records from this period indicate a well-functioning fistula while the FVAC procedure reports state vascular access issues. Defendant was aware or should have been aware that Patient F continuously and repeatedly returned to the FVAC in Manhattan for CTE appointments.

G. Patient "G"

216. Patient G is an 80 year-old with ESRD. Patient G underwent fistulagrams and angioplasties at the Brooklyn FVAC on 21 separate days from January 2012 to April 2018.

217. Twenty of the 21 FVAC's procedure reports for Patient G provide only subjective findings, namely pulsatility. For example, on June 11, 2014, Patient G returned for a "clinical evaluation" visit. At the physical exam, the FVAC recorded only a "pulsatility" finding to justify the fistulagram. The FVAC interventionalist then performed an angioplasty on Patient G.

218. Three months later, on September 10, 2014, Patient G returned for a "clinical evaluation" visit. At the physical exam, the interventionalist found only "pulsatility" to perform the fistulagram. The FVAC interventionalist then performed an angioplasty on Patient G.

219. In another "clinical evaluation" appointment on March 11, 2015, finding again "pulsatility" to justify the need for a fistulagram, the FVAC interventionalist then performed another angioplasty on Patient G.

220. Three months later, on June 10, 2015, Patient G went to another "clinical evaluation" at which a physical exam again revealed "pulsatility" and the FVAC interventionalist performed a fistulagram and angioplasty.

221. On October 7, 2015, at another "clinical evaluation" visit, the FVAC providers noted "pulsatility," and performed a fistulagram followed by an angioplasty on Patient G.

222. At each of the 21 appointments, Patient G underwent a fistulagram and an angioplasty.

223. To justify proceeding with an angioplasty, Patient G's records always record stenoses of over at least 60 percent to support "the presence of residual, hemodynamically significant stenosis." But when compared to the percentage of stenosis observable from the pre-

procedure radiologic images, the FVAC's records contain numerous instances of inflated percentages of stenosis. In fact, none of Patient G's veins exhibited hemodynamically significant stenosis of anywhere near 50 percent of the vessel diameter.

224. In total for this period, after a fistulagram, FVAC interventionalists, including FVC's former Vice President of Operations, performed at least 15 medically unnecessary angioplasties on Patient G.

225. After each appointment, Patient G received instructions to return at a regularly timed interval, not to eat or drink anything prior to the appointment and make transportation arrangements. Following those instructions, Patient G visited the FVAC on each follow-up date.

226. The dialysis center did not make any referrals of Patient G to the FVAC. Patient G's dialysis records from this period indicated the fistula appeared to be functioning, but the FVAC's procedure reports indicated vascular access issues.

227. Defendant was aware that Patient G continuously and repeatedly returned to the FVAC in Brooklyn for CTE appointments. *See* Ex. 1 at rows 24939-24943.

H. Patient "H"

228. Patient H had ESRD and died at age 69. Patient H was initially referred by a dialysis center to the Brooklyn and Staten Island FVACs. FVAC interventionalists performed fistulagrams and angioplasties on Patient H at 15 separate visits from February 2012 through July 2016.

229. At each of the 15 appointments, Patient H underwent a fistulagram and an angioplasty.

230. To justify proceeding with an angioplasty, Patient H's records always contained stenoses of over at least 60 percent to support "the presence of residual, hemodynamically

significant stenosis." But when compared to the percentage of stenosis observable from the pre-procedure radiologic images, the FVAC's records contain numerous instances of inflated percentages of stenosis. In fact, none of Patient H's veins exhibited hemodynamically significant stenosis of anywhere near 50 percent of the vessel diameter. At least 13 FVAC procedure reports falsely indicate Patient H's veins showed 70 percent stenosis where no stenosis at all is observable from the images.

231. In total for this period, after a fistulagram, FVAC interventionalists, including FVC's former Vice President of Operations, performed at least 14 medically unnecessary angioplasties on Patient G.

232. After each FVAC appointment, Patient H received instructions to return for a follow up appointment.

233. Patient H's dialysis records from this time did not indicate any issues with dialysis or vascular flow.

234. Patient H's dialysis records contained no referrals to an FVAC.

235. While this patient's dialysis records uniformly indicate completed dialysis with a fistula that is functioning well, the FVAC's report stated this patient experienced vascular access issues.

236. Defendant was aware that Patient H continuously and repeatedly returned to the FVAC in Brooklyn and Staten Island for CTE appointments. *See* Ex. 1 at row 32073.

I. Patient "I"

237. Patient I is a 74-year-old with ESRD. After an initial legitimate referral, Patient I returned for 10 separate follow-up appointments to the Brooklyn FVAC from April 2013 through April 2018.

238. Six of the FVAC's procedure reports provided only the subjective finding of increased pulsatility to justify the fistulagrams performed on Patient I.

239. For example, on July 24, 2014, Patient I returned for a "clinical evaluation" visit. At the physical exam, the interventionalist recorded "pulsatility" to justify performing a fistulagram and an angioplasty on Patient I.

240. Three months later, on October 21, 2014, at another "clinical examination," the physical exam revealed pulsatility again. The FVAC interventionalist proceeded to perform a fistulagram and an angioplasty on Patient I.

241. At a "clinical examination" on October 1, 2015, pulsatility was recorded as observed in Patient I's records to justify a fistulagram on Patient I.

242. At a "clinical evaluation" on March 8, 2016, pulsatility was recorded as observed in the Patient I's records. The FVAC interventionalist again performed a fistulagram on Patient I.

243. At nine of the ten visits, an FVAC interventionalist performed angioplasties where Patient I's information and records did not support "the presence of residual, hemodynamically significant stenosis, generally [greater than or equal to] 50 percent of the vessel diameter." Despite FVAC's procedure reports falsely indicating the existence of stenosis greater than 60 percent, the images from the procedures show that none of these veins exhibited hemodynamically significant stenosis of anywhere near 50 percent of the vessel diameter.

244. After each appointment, Patient I was scheduled to return at a regularly timed interval.

245. Patient I's dialysis records from this period do not contain any referrals to an FVAC. Patient I's dialysis records uniformly show completed dialysis with a well-functioning fistula but the FVAC's report states this patient experienced vascular access issues.

246. Defendant was aware that Patient I continuously and repeatedly returned to the FVAC in Brooklyn for CTE appointments. *See* Ex. 1 at row 32073.

J. Patient "J"

247. Patient J had ESRD and died at age 59. Before Patient J's death in October 2014, Patient J returned for seven separate follow-up appointments to the Queens FVAC from January 2012 through May 2014.

248. Only one of these interventions was found to be supported by the medical documentation while the other six were found to be medically unnecessary. At these visits, an FVAC interventionalist performed angioplasties where the patient information and records did not support the presence of residual, hemodynamically significant stenosis.

249. Six of seven image studies in the patient file significantly overstated the amount of stenosis present when compared to the stenosis observable from the images. Despite the FVAC's procedure reports falsely indicating the existence of stenosis greater than 70 percent in all cases, the images from the procedures show that none of these veins exhibited hemodynamically significant stenosis of anywhere near 50 percent of the vessel diameter.

250. After each appointment, Patient J was scheduled to return for a follow up appointment at a defined interval time.

251. Patient J's dialysis records from this time do not contain any referrals to an FVAC.

252. While Patient J's dialysis records uniformly show completed dialysis with a functioning fistula, the FVAC report states this patient experienced vascular access issues.

253. In total for this period, after a fistulagram, FVAC interventionalists, performed at least six medically unnecessary angioplasties on Patient J.

K. Summary

254. In sum, for the FVACs located in New York from about January 1, 2012 through June 30, 2018, at least 1,288 out of a total of 2,303 angioplasty procedures among 60 patients (55.92 percent) were medically unnecessary. These findings do not represent the entirety of the false claims at issue in this action but are based on a statistically valid random sample review of medical files drawn from larger universe. The specific fraudulent practices described in this Complaint-in-Intervention are not limited to the particular patients or Defendant FVACs detailed above. Exhibit 3, attached to and incorporated in this Complaint-in-Intervention, is a chart of the particular claims at issue for all dates of service the Government contends were false claims. The Exhibits attached are fully incorporated into this Complaint, and the statements, descriptions, data, and other facts described in those Exhibits are alleged as if fully set forth in the body of the Complaint.

CLAIMS FOR RELIEF

COUNT ONE
(Violation of 31 U.S.C. § 3729(a)(1)(A))

255. The United States incorporates by reference all paragraphs of this complaint set out above as if fully set forth.

256. Defendant presented, or caused to be presented, false or fraudulent claims for payment or approval to the United States.

257. Such acts were made or done knowingly, as defined in 31 U.S.C.§ 3729(a)(1).

COUNT TWO
(Violation of 31 U.S.C. § 3729(a)(1)(B))

258. The United States incorporates by reference all paragraphs of this complaint set out above as if fully set forth.

259. Defendant made, used, or caused to be made or used, false records or statements material to false or fraudulent claims submitted to the United States.

260. Such acts were made or done knowingly, as defined in 31 U.S.C.§ 3729(a)(1).

COUNT THREE
(Violation of 31 U.S.C. § 3729(a)(1)(G))

261. The United States incorporates by reference all paragraphs of this complaint set out above as if fully set forth.

262. Defendant made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease obligations to pay or transmit money to the United States.

263. Such acts were made or done knowingly, as defined in 31 U.S.C. § 3729(a)(1).

COUNT FOUR
(Unjust Enrichment)

264. The United States incorporates by reference all paragraphs of this complaint- set out above, as if fully set forth.

265. As a consequence of the acts and events set forth above, Defendant was unjustly enriched at the expense of the United States by receiving and retaining money from the United States to which Defendant was not entitled – money which, under the circumstances, should be returned to the United States in equity and good conscience.

266. The United States is entitled to recover all money by which Defendant has been unjustly enriched as a result of Defendant's submission of the false claims, in an amount to be determined at trial.

COUNT FIVE
(Payment Under Mistake of Fact)

The United States incorporates by reference all paragraphs of this complaint set out above, as if fully set forth.

267. As a direct result of Defendant's submission of the false claims, Medicare and the federal healthcare programs paid Defendant for claims submitted as provided in Exhibit 2. Medicare and the federal healthcare programs were unaware at the time of the falsity of Defendant's claims, and acting in reasonable reliance on the validity of these claims, did make payments for these claims to Defendant.

268. The United States' payments to Defendant for the claims in Exhibit 2 were made under the mistaken and erroneous belief that the claims were medically necessary when in fact they were not. These mistaken federal payments flowed to Defendant, which benefitted from them.

269. As a result of these mistaken federal payments flowing to Defendant, the United States has been damaged, and is entitled to recover those damages from Defendant in an amount to be determined at trial.

PRAYER FOR RELIEF

WHEREFORE, the United States requests that judgment be entered in its favor and against Defendant as follows:

(a) treble the United States' damages, in an amount to be determined at trial, plus an $11,000 penalty for each violation occurring before and including November 2, 2015 and not less than $12,537 and up to $25,076 per violation for violations occurring after November 2, 2015 to for each claim submitted in violation of 31 U.S.C. § 3729(a)(1)(A);

(b) treble the United States' damages, in an amount to be determined at trial, plus an $11,000 penalty for each violation occurring before and including November 2, 2015 and not less than $12,537 and up to $25,076 per violation for violations

occurring after November 2, 2015 to for each claim submitted in violation of 31 U.S.C. § 3729(a)(1)(B);

(c) treble the United States' damages, in an amount to be determined at trial, plus an $11,000 penalty for each violation occurring before and including November 2, 2015 and not less than $12,537 and up to $25,076 per violation for violations occurring after November 2, 2015 to for each claim submitted in violation of 31 U.S.C. § 3729(a)(1)(C);

(d) an award of costs pursuant to 31 U.S.C. § 3729(a)(3); and

(e) such further relief as is proper.

DEMAND FOR JURY TRIAL

The United States demands a jury trial for all issues so triable.

Dated: Brooklyn, New York
July 12, 2022

BREON PEACE
United States Attorney
Eastern District of New York

By: */s/ Jolie Apicella*
JOLIE APICELLA
ANJNA KAPOOR
Assistant United States Attorneys

MARY ELLEN BUNTIN
Special Assistant United States Attorney

271 Cadman Plaza East
Brooklyn, NY 11201
Tel.: (718) 254-6528
Email: jolie.apicella@usdoj.gov

Counsel for the United States