UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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UNITED STATES OF AMERICA, THE STATE OF NEW YORK, THE STATE OF NEW JERSEY, THE STATE OF CALIFORNIA, THE STATE OF COLORADO, THE STATE OF CONNECTICUT, THE STATE OF FLORIDA, THE STATE OF GEORGIA, THE STATE OF ILLINOIS, THE STATE OF INDIANA, THE STATE OF LOUISIANA, THE STATE OF MARYLAND, THE STATE OF MASSACHUSETTS, THE STATE OF MICHIGAN, THE STATE OF NEVADA, THE STATE OF NORTH CAROLINA, THE STATE OF RHODE ISLAND, THE STATE OF TENNESSEE, THE STATE OF TEXAS, THE COMMONWEALTH OF VIRGINIA, *ex rel.* JOHN PEPE, M.D., and RICHARD SHERMAN, M.D.,

Plaintiffs,

v.

FRESENIUS MEDICAL CARE HOLDINGS, INC., FRESENIUS VASCULAR CARE, INC., and GREGG MILLER,

Defendants.

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THE STATES of GEORGIA, NEW JERSEY, and NEW YORK, *ex rel.* JOHN PEPE, M.D., and RICHARD SHERMAN, M.D.,

Plaintiffs,

v.

FRESENIUS VASCULAR CARE, INC. d/b/a AZURA VASCULAR CARE, AMERICAN ACCESS CARE PHYSICIAN, PLLC, ACCESS CARE PHYSICIANS OF NJ, LLC, NEW JERSEY INTERVENTIONAL ASSOCIATES, LLC, SNAPFINGER VASCULAR ACCESS CENTER, LLC, FRESENIUS VASCULAR CARE AUGUSTA, LLC, AMERICAN ACCESS CARE OF ATLANTA, LLC, and GREGG MILLER, M.D.,

Defendants.

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Civil Action No.
14-CV-3505

(DeArcy Hall, J.)
(Tiscione, M.J.)

**INTERVENING STATES' CONSOLIDATED COMPLAINT-IN-INTERVENTION**

JURY TRIAL DEMANDED

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## COMPLAINT-IN-INTERVENTION OF GEORGIA, NEW JERSEY, AND NEW YORK

The States of Georgia, New Jersey, and New York (collectively, the "Intervening States") allege as follows for their Complaint-in-Intervention against Defendants Fresenius Vascular Care, Inc. d/b/a Azura Vascular Care ("FVC"); American Access Care Physician, PLLC ("AACP PLLC"); Access Care Physicians of NJ, LLC ("ACP NJ"); New Jersey Interventional Associates, LLC ("NJIA"); Snapfinger Vascular Access Center, LLC ("Snapfinger"); Fresenius Vascular Care Augusta, LLC ("FVAC Augusta"); American Access Care of Atlanta, LLC ("AAC Atlanta"); and Gregg Miller, M.D. ("Miller") (collectively "Defendants").

## PRELIMINARY STATEMENT

1. The Intervening States bring this action to recover treble damages and civil penalties under their respective false claims acts, and other monetary relief pursuant to other state statutes and the common law against Defendants, who owned, operated, and/or otherwise controlled a network of outpatient vascular care and ambulatory surgery centers in the Intervening States (collectively, these "Fresenius Vascular Access Centers" are referred to as the "FVACs").

2. Defendants used the FVACs to perform medically unnecessary vascular interventions—namely fistulagrams and angioplasties—on patients with End Stage Renal Disease ("ESRD"), which were justified by falsifying patient records and referrals. Driven by their bottom line, Defendants subjected these patients to unnecessary and potentially dangerous procedures every three to four months, for years.

3. In so doing, from January 1, 2012 through at least June 30, 2018, Defendants submitted and/or caused to be submitted false claims for payment to Medicare and the Intervening States' Medicaid Programs for the unwarranted procedures.

**A. End Stage Renal Disease**

4. ESRD is a medical condition in which a patient's kidneys cease functioning on a permanent basis. As a result, an ESRD patient needs a regular course of hemodialysis treatment ("dialysis") or a kidney transplant to survive. Dialysis is a treatment that removes waste—toxins and salts—and excess fluid from the blood of an ESRD patient by artificial means since the kidneys are no longer able to perform this vital function.

5. ESRD patients are particularly vulnerable; they often include the elderly and disadvantaged members of minority groups. These patients often have multiple comorbidities and experience more frequent admissions to intensive care units, as well as higher mortality risks than the general population.

6. An estimated 20 to 50 percent of ESRD patients die within two years of this diagnosis, even if they obtain early intervention and treatment.

7. In order to receive dialysis, the ESRD patient must undergo a surgical procedure to create a vascular access, essentially a surgically created vein, to allow the dialysis machine to access the bloodstream. This vascular access is commonly referred to as a "fistula" when it involves an artificial joining of a patient's vein and artery; fistulas are generally created in the patient's arm. The fistula causes extra pressure and extra blood to flow into the vein, thereby making it grow larger and stronger. This larger vein provides easy, reliable access to blood vessels. Without a fistula, the vein cannot withstand the repeated needle insertions necessary for dialysis.

8. During dialysis, a machine connects to the patient to perform the kidney functions. Specifically, a needle is placed in the fistula to remove blood from the patient, which is then cleaned in an artificial filter, and finally returned to the patient's body through a different needle

in the fistula. The dialysis machine also monitors the patient's blood pressure in order to adjust how fast the blood flows in and out of their body during the treatment.

9. In the United States, outpatient dialysis clinics perform most dialysis treatments. In accordance with Medicare regulations, an interdisciplinary team must monitor a patient's fistula to ensure that the dialysis procedure works properly. The composite rate paid to the dialysis clinic includes reimbursement for monitoring services.

10. Patients most commonly undergo dialysis approximately three times per week, for four hours per session. As a result, the interdisciplinary team sits in a unique, and ideal, position to monitor the patient's vascular access.

11. The interdisciplinary team has responsibility for making timely referrals when necessary to achieve and sustain vascular access. 42 C.F.R. § 494.90(a)(5).[1] If the interdisciplinary team flags a potential obstruction during dialysis, the patient's nephrologist, or the attending dialysis nephrologist, may refer the patient to a vascular access center, such as one of the FVACs at issue in this case, for an interventional procedure, such as a fistulagram or angioplasty to maintain the patient's fistula for dialysis.

12. 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").

[1] 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."

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

13. 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. An angioplasty is only medically necessary when there is documentation supporting the presence of residual, hemodynamically significant narrowing or stenosis in the patient's vessel.

**B. Defendants' Scheme**

14. The FVACs routinely performed medically unnecessary, non-referred vascular interventions—fistulagrams and angioplasties—on ESRD patients.

15. Defendants' fraudulent scheme—the "CTE Scheme"—worked as follows:

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

- Prior to a CTE appointment, the 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 and false indication to justify subjecting the patient to a fistulagram, which was routinely followed by an angioplasty, for which the FVAC falsified the amount of vascular narrowing or stenosis by exaggerating the stenosis level.

- To ensure robust revenues, Defendants essentially enrolled ESRD patients into a course of CTEs. At the conclusion of each CTE, the FVACs would schedule additional "follow-up" visits. Critically, the FVACs planned to perform vascular interventions at each CTE. Indeed, the 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. In furtherance of Defendants' CTE Scheme, the FVACs at issue performed thousands of medically unnecessary fistulagrams and/or angioplasties on ESRD patients. Defendant FVC had full knowledge that the procedures were not necessary and indeed could be harmful. As early as 2011, the Chief Medical Officer and two other employees of FVC's corporate parent, Fresenius Medical Care Holdings, Inc., conducted a study involving 54,000 Medicare beneficiaries receiving dialysis that showed that "preventative" or "elective" angioplasties did not benefit ESRD patients. Indeed, patients who received elective procedures—like the medically unnecessary ones Defendants performed here—had a *higher access failure rate* than patients who did not receive elective procedures.

17. Defendants nonetheless took advantage of patients to promote their own financial gain; this conduct came at a cost to patients.

18. Defendants intentionally subjected patients to uncomfortable, time-consuming, medically unnecessary interventions as indicated by clinical and other information amassed by patients' treating physicians and dialysis clinics. Moreover, Defendants knew that these interventions also exposed patients to grave risks, including, but not limited to, over-sedation, infection, ruptured blood vessels, internal or external bleeding, and new or recurrent stenoses that might warrant even more invasive procedures—thereby setting the stage for cyclical dependency on interventions.

19. Defendants' CTE Scheme also cost taxpayers, whose hard-earned dollars fund the nation's federal health care programs that paid Defendants for these medically unnecessary, fraudulent procedures.

## JURISDICTION AND VENUE

20. On June 3, 2014, John Pepe, M.D. and Richard Sherman, M.D. ("Relators") filed an initial complaint on behalf of themselves, the United States, and the State of New York alleging

violations of the Federal False Claims Act ("Federal FCA") and New York False Claims Acts ("NY FCA"). On February 6, 2015, Relators filed their First Amended Complaint, which again included claims on behalf of themselves, the United States, and the State of New York. On December 7, 2016, Relators filed their Second Amended Complaint, which added claims on behalf of the State of New Jersey pursuant to the New Jersey False Claims Act ("NJ FCA"). On October 24, 2017, Relators filed their Third Amended Complaint, which added claims on behalf of seventeen additional states, pursuant to their respective state false claims acts. On August 8, 2020, Relators filed their Fourth Amended Complaint, which again included claims on behalf of the same nineteen states.

21. On August 11, 2022, the Intervening States filed a Notice of Election to Intervene pursuant to the Georgia False Medicaid Claims Act ("GA FMCA"), NJ FCA, and NY FCA.

22. This Court has subject matter jurisdiction to entertain the original action filed by Relators under 28 U.S.C. §§ 1331 and 1345, and pursuant to 31 U.S.C. § 3732(b) because the action arises from the same transaction or occurrence as an action brought under 31 U.S.C. § 3730 ("FCA"). Additionally, this Court has supplemental jurisdiction over the subject matter of the claims brought by the Intervening States pursuant to 28 U.S.C. § 1367.

23. 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 Defendants' FVACs is located in 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.

## PARTIES

**Plaintiffs**

24. Plaintiff the State of Georgia ("Georgia") was at all times relevant to this action a sovereign state of the United States of America.

25. Plaintiff the State of New Jersey ("New Jersey") was at all times relevant to this action a sovereign state of the United States of America.

26. Plaintiff the State of New York ("New York") was at all times relevant to this action a sovereign state of the United States of America.

27. Relators Dr. John Pepe and Dr. Richard Sherman are board-certified nephrologists. Dr. Pepe resides in New York, and Dr. Sherman resides in New Jersey.

**Defendant Fresenius Vascular Care, Inc. d/b/a Azura Vascular Care**

28. Defendant FVC, a wholly owned business unit of Fresenius Medical Care Holdings, Inc. ("FMC"), a New York corporation that does business as Fresenius Medical Care North America, is headquartered at 1200 West Swedesford Road, Building 3, Suite 120, Berwyn, Pennsylvania 19312. FVC is "a risk-sharing strategic partner" and "not exclusively a management company." 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.

29. FVC provided administrative and support services to the FVACs and paid for all costs and expenses associated with the operation of the FVACs. Defendants AACP PLLC, ACP NJ, NJIA, Snapfinger, FVAC Augusta, and AAC Atlanta reimbursed FVC for these costs from monies received from Federal Healthcare Programs, including Medicare and Medicaid.

30. FVC presently operates 66 FVACs in approximately 25 states (and Puerto Rico) throughout the United States.

31. At all relevant times, FVC owned, operated, and/or otherwise controlled FVACs at the following locations in Georgia:

- Atlanta Access Care (now "Azura Vascular Care Atlanta"), 250 East Ponce De Leon Avenue, Suite 100, Decatur, GA 30030;
- Augusta Vascular Center, 630 13th Street, Suite 250, Augusta, GA 30901;

- Augusta Vascular Center West, 3623 J. Dewey Gray Circle, Suite 100, Augusta, GA 30909; and

- Defendant Snapfinger (now "Azura Vascular Care Snapfinger"), 5246 Snapfinger Park Drive, Decatur, GA 30035.

32. At all relevant times, FVC owned, operated, and/or otherwise controlled FVACs at the following locations in New Jersey:

- Defendant ACP NJ, previously located at 2401 Morris Avenue, Suite West 112, Union, NJ 07083, and presently located at 1050 Galloping Hill Road, Suite 101, Union, NJ 07083;

- American Access Care of New Jersey (now "Azura Surgery Center Cherry Hill"), 207 South Kings Highway, Suite 2, Cherry Hill, NJ 08034;

- Image Guided Surgery & Aesthetics, previously located at 2401 Morris Avenue, Suite West 111, Union, NJ 07083, and presently located at 1050 Galloping Hill Road, Suite 102, Union, NJ 07083; and

- Verona Veins at Access Care Physicians (now "Azura Vascular Care Woodland Park"), 1225 McBride Avenue, Suite 116-117, Woodland Park, NJ 07424.

33. At all relevant times, FVC owned, operated, and/or otherwise controlled FVACs at the following locations in New York:

- 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, also located at American Access Care Brooklyn, 1915 Ocean Avenue, Brooklyn, NY 11230;

- American Access Care of New York (now "American Access Care Manhattan"), 403 East 91st Street, Floor 2, New York, NY 10128;

- American Access Care Queens, 176-60 Union Turnpike, 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 11576;
- Verrazano Vascular Associates at Access Care Physicians, 2025 Richmond Avenue, Suite 1LL, Staten Island, NY 10314; and
- American Access Care of Westchester, 15 North Broadway, White Plains, NY 10601.

**Defendant Gregg Miller, M.D.**

34. Defendant Miller is a member of FVC's "Senior Leadership" and resides in New York. He has been FVC's Vice President of Operations since at least October 2015, prior to which he held the position of FVC's Chief Medical Officer. Miller, an interventional nephrologist, practiced at an FVAC in New York. During the relevant period, he performed fistulagrams and angioplasties on ESRD patients. According to Miller's corporate website biography, "[a]s a researcher and trainer of physicians he revolutionized the way dialysis patients receive care for their vascular access. With more than nine specialty publications, he has delivered his message both nationally and internationally, impacting tens of thousands of dialysis patients." Miller transacted business in the Eastern District of New York.

**AACP PLLC, ACP NJ, NJIA, Snapfinger, FVAC Augusta, AAC Atlanta**

35. Defendant AACP PLLC is a physician-owned New York professional limited liability company. At all relevant times, it employed interventionalists who performed the vascular access services at the FVACs located in New York. AACP PLLC submitted claims to Medicare and Medicaid for these services. Miller serves as the President of AACP PLLC, and at all relevant times, he had an ownership interest in AACP PLLC.

36. Defendant ACP NJ, a New Jersey limited liability company, operates as a multi-specialty business group with one or more individual providers who specialize in different practice areas. Dr. Miller serves as the Authorized Official responsible for the operations of ACP NJ.

37. Defendant NJIA, a New Jersey limited liability company, operates as a clinic/center with a focus on ambulatory surgical services. Dr. Miller is listed as the Owner of NJIA.

38. Defendants ACP NJ and NJIA employed interventionalists who performed vascular access services at the FVACs located in New Jersey. Defendants ACP NJ and NJIA submitted claims for those vascular access services to Medicare and Medicaid.

39. Defendant Snapfinger is a Georgia limited liability company that is wholly owned by Defendant FVC.

40. Defendant FVAC Augusta is a Delaware limited liability company that is majority owned by Defendant FVC and minority owned by Vascular Radiology Associates II.

41. Defendant AAC Atlanta is a Delaware limited liability company that is majority owned by American Access Care, LLC and minority owned by physician Kevin Sullivan. American Access Care, LLC is a subsidiary of Defendant FVC.

42. Defendants Snapfinger, FVAC Augusta, and AAC Atlanta employed interventionalists who performed vascular access services at the FVACs located in Georgia. Defendants Snapfinger, FVAC Augusta, and AAC Atlanta submitted claims for those vascular access services to Medicare and Medicaid.

43. Defendants AACP PLLC, ACP NJ, NJIA, Snapfinger, FVAC Augusta, and AAC Atlanta (collectively, the "Enrolled Entities") are enrolled as providers with Medicare and Medicaid.

44. FVC and Miller control the Enrolled Entities directly, by virtue of direct ownership, and indirectly, through management agreements whereby FVC and Miller perform virtually all services for the Enrolled Entities.

45. The Enrolled Entities knowingly submitted false claims to Medicare and Medicaid at the direction of FVC and Miller.

## STATUTORY AND REGULATORY BACKGROUND

### I. STATE FALSE CLAIMS ACTS

46. Each of the Intervening States has its own state false claims act that imposes liability for, among other things, (1) knowingly submitting, or causing to be submitted, false or fraudulent claims to the State's Medicaid Program; (2) knowingly making, using, or causing to be made or used, false records or statements material to false or fraudulent claims made to the State's Medicaid Program; and (3) knowingly making, using, or causing to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the State's Medicaid Program or knowingly or improperly avoiding or decreasing an obligation to pay or transmit money to the State's Medicaid Program. *See* O.C.G.A. § 49-4-168, *et seq.*; N.J.S.A. 2A:32C-1, *et seq.*; N.Y. State Fin. Law § 187, *et seq.*

47. Knowing and knowingly, within the meaning of the Intervening States' false claims acts, are defined to include reckless disregard or deliberate indifference to the truth or falsity of the information. *See* O.C.G.A. § 49-4-168(2); N.J.S.A. 2A:32C-2; N.Y. State Fin. Law § 188(3)(a).

48. Under the Intervening States' false claims acts, each Intervening State is entitled to recover three times the amount of all damages, plus civil penalties. *See* O.C.G.A. § 49-4-168.1; N.J.S.A. 2A:32C-3; N.Y. State Fin. Law § 189(1).

## II. MEDICARE AND MEDICAID

49. Defendants 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, and the Medicaid Program, 42 U.S.C. §§ 1396-1396w-5. Some of these claims were for patients who were beneficiaries of both Medicare and Medicaid (these individuals are referred to as "dual-eligible beneficiaries").

### A. The Medicare Program

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

51. Medicare coverage was extended to include treatment for individuals with ESRD in 1972. Medicare expanded its coverage for ESRD in 1978 when an age requirement was removed. This legislative amendment was prompted by the increasing number of patients receiving 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).

52. 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).

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

54. 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).

55. "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.

56. 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).

57. 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 Program

58. The Medicaid Program is authorized by Title XIX of the Social Security Act and Title 42 of the Code of Federal Regulations. Medicaid is a joint federal-state program that provides health care benefits for certain groups including the poor and disabled. Medicaid is funded by both federal and state dollars.

59. The federal portion of each state's Medicaid payments, known as the Federal Medical Assistance Percentage ("FMAP"), is based on a state's per capita income compared to the national average. 42 U.S.C. § 1396d(b). During the relevant time periods, and to date, the FMAP for Georgia has ranged from 65.6% to 73.5%, and the FMAP for New Jersey and New York has ranged from 50% to 56.2%.[2]

60. Like Medicare, Medicaid will not pay for treatments that are not medically necessary or appropriate. *See* Georgia Department of Community Health, Division of Medicaid, Part I Policies and Procedures for Medicaid/Peachcare for Kids § 405(D) (October 1, 2022); N.J.A.C. 10:49-5.1(a)(1); 18 N.Y.C.R.R. §§ 500.1(b); 515.2(b)(1)(i)(c).

C. Medicare and Medicaid Coverage for ESRD Patients

61. Medicare coverage for individuals with ESRD typically begins 90 days after the initiation of dialysis treatment. Thus, Medicaid provides coverage for medically necessary ESRD care to eligible individuals for the first 90 days of a patient's treatment, after which Medicare becomes the primary payor. For those ESRD patients that are eligible for both Medicare and

[2] These FMAP figures include the 6.2% increase available to states in 2020–2022 by the Families First Coronavirus Response Act, Pub. L. No. 116–127 § 6008, 134 Stat. 177, 208 (2020).

Medicaid, Medicaid pays Medicare copayments and/or deductibles for medically necessary ESRD services.[3]

62. Medicaid pays the full cost of medically necessary care, including ESRD treatments such as dialysis and associated vascular procedures like fistulagrams and angioplasties, for Medicaid patients who are not able to obtain primary coverage under Medicare.

63. For patients who receive Medicare benefits, Medicare Part B 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. The outpatient ESRD treatments at issue are all covered by Part B for patients who receive Medicare benefits.

64. If a service is medically unnecessary under Medicare regulations, Medicaid will also consider it medically unnecessary and will not pay ancillary costs (such as copays) for that service.

[3] 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 26, 2023).

## III. DIALYSIS CARE UNDER MEDICARE AND MEDICAID

### A. The Intervening States' Medicaid Programs Require Medicaid Providers, Including Defendants, to Comply with Federal and State Laws and Regulations

65. Defendants signed and submitted provider applications and/or agreements with each of the Intervening States' Medicaid Programs.[4] These documents include express agreement to comply with applicable federal and state laws, rules, and regulations.

66. In addition, Defendants agreed to comply with policy manuals issued by each of the Intervening States' Medicaid Programs, as required by federal regulation. *See* 42 C.F.R. § 431.18.

#### *i. Georgia Medicaid Regulations and Provider Agreements*

67. As mentioned, federal Medicaid regulations require state Medicaid agencies to issue policy manuals to furnish Medicaid providers with the policies and procedures needed to receive reimbursement for covered services they provide to eligible state Medicaid recipients. 42 C.F.R. § 431.18. Accordingly, Georgia regulations authorize and require the state's Medicaid agency, the Georgia Department of Community Health ("DCH"), to "publish the terms and conditions for receipt of medical assistance in Policies and Procedures Manuals for each of the categories of services authorized under the State Plan." Ga. Comp. R. & Regs. R. 350-1-.02(3). These manuals are disseminated to providers enrolled in the applicable category of service, and amendments thereto are effective "as specified by the Department at the time of dissemination."

[4] Defendants also signed 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.

*Id.* Further, DCH maintains current and past versions of the Georgia Medicaid Policies and Procedures Manuals online for providers to view at https://www.mmis.georgia.gov.

68. All providers enrolled in Georgia Medicaid are subject to DCH's Part I Policies and Procedures for Medicaid/PeachCare for Kids manual ("Part I manual"). *See* DCH Part I Policies and Procedures for Medicaid/PeachCare for Kids, at "Preface" (Apr 1 2015) (the Part I manual "[a]long with the statement of participation, any applicable letter of agreement, and program specific manual encompasses the terms and conditions for doing business as a Medicaid Provider in Georgia").

69. The Part I manual emphasizes the importance Georgia places on compliance and spells out the specific conditions it places on providers submitting claims. For example, under the Part I manual, each enrolled provider must:

> Comply with all State and Federal laws and regulations related to furnishing Medicaid/PeachCare for Kids services. *Id*. at R. 106(B), p. 35.
>
> Neither bill the Division [Georgia Department of Community Health, Division of Medicaid] for any services not performed or delivered in accordance with all applicable policies, nor submit false or inaccurate information to the Division relating to provider…claims…." *Id.* at R. 106(J), p. 36.
>
> Bill the Division for only those covered services that are medically necessary[5] and within accepted professional standards of practice. *Id. at* R. 106(K), p. 36.

[5] The Part I manual defines medically necessary to mean "medical services or equipment based upon generally accepted medical practices in light of conditions at the time of treatment which is (a) appropriate and consistent with the diagnosis of the treating physician and the omission of which could adversely affect the eligible member's medical condition, (b) compatible with the standards of acceptable medical practice in the United States, (c) provided in a safe, appropriate and cost effective setting given the nature of the diagnosis and the severity of the symptoms, (d) not provided solely for the convenience of the member or the convenience of the health care provider or hospital, (e) not primarily custodial care unless custodial care is a covered service or benefit under the member's evidence of coverage, and (f) there must be no other effective and more conservative or substantially less costly treatment, service and setting available." *Id.* at Definitions, p. 12.

70. As enrolled providers in Georgia Medicaid, Defendants Snapfinger, AAC Atlanta, and FVAC Augusta were subject to the conditions set out in the DCH Part I manual at all times relevant to the Complaint.

71. All Georgia Medicaid providers wishing to submit claims electronically rather than on paper must complete an Electronic Funds Transfer Agreement. Defendants Snapfinger, AAC Atlanta, and FVAC Augusta submitted these documents as part of their enrollment and revalidation of enrollment in Georgia Medicaid, on October 24, 2012 (Snapfinger), February 2, 2009 (AAC Atlanta), and March 22, 2012 (FVAC Augusta). In so doing, these Defendants agreed to the following requirements:

> Legal Compliance. Provider shall abide by all federal and state laws governing the Medicaid program.
> ...
> Provider further acknowledges and agrees that only Payees who have agreed in writing to: 1) comply with all Department policies regarding the payment of medical assistance; and 2) be subject to the recoupment policies outlined in the Provider's Statement of Participation as set forth in the Power of Attorney for Electronic Claims Submission, shall be deemed acceptable Payees.
> …
> Provider understands that payment will be from federal and state funds and that any falsification, or concealment of a material fact, may be prosecuted under federal and state laws.

Georgia Department of Community Health Electronic Funds Transfer Agreement.

72. Defendant Miller is also aware of the requirements that providers must follow for participation in and reimbursement from Georgia Medicaid. Indeed, Dr. Miller signed and accepted "Verification of Policy Manuals" statements as the "Authorized Official" on behalf of Defendants Snapfinger and AAC Atlanta, certifying that:

> [T]he Department's policies and procedures manuals outline the terms and conditions for receipt of medical assistance and participation in the Georgia Medicaid/PeachCare for Kids program. I understand and acknowledge that my staff, agents, credentialing personnel, contractors, subcontractors, and I are required to comply with the policies and procedures outlined in Part I, Policies and

> Procedures for Medicaid/PeachCare for Kids and the applicable Part II and/or Part III policy manuals…I further understand that failure to abide by the Department's policies and procedures will result in adverse actions including, but not limited to, the suspension and/or termination from the Medicaid program.

73. DCH has also partially delegated administration to Care Management Organizations ("CMOs"), which administer health plans and process and pay Medicaid claims to their contracted providers. To enroll as a provider with a CMO, at all times relevant to the Complaint, a provider was required to first enroll with DCH as a Medicaid provider, certify compliance with the Part I manual, and verify access to and understanding of all applicable Medicaid manuals and policies.

74. Because it is not feasible for the Georgia Medicaid Program or its CMO contractors to review medical records corresponding to each of the claims for payment they receive from providers, the program relies on providers to comply with Georgia Medicaid requirements and relies on providers to submit truthful and accurate certifications and claims.

75. Generally, once a provider submits a claim to the Georgia Medicaid Program, the reimbursement for the claim is paid directly to the provider, in reliance on the foregoing certifications, without any review of supporting documentation, including medical records.

76. Georgia regulations governing the licensure of ESRD facilities make clear that dialysis clinics "shall coordinate services for each patient through an interdisciplinary treatment team approach." Ga. Comp. R. & Regs. R. 111-8-22-.12(1).

77. Defendants violated the terms of their Georgia Medicaid provider applications, the Georgia Medicaid Part I manual, and the applicable Georgia regulations by engaging in the misconduct described in this Complaint.

*ii. New Jersey Medicaid Regulations and Provider Agreements*

78. Federal regulations require each state to designate a single State agency responsible for the Medicaid Program. The agency must create and implement a "plan for medical assistance" that is consistent with Title XIX and with the regulations of the Secretary of Health and Human Services. The Division of Medical Assistance & Health Services, commonly referred to as "DMAHS" under the Department of Human Services, is designated in accordance with 42 C.F.R. 412.30, as the single State agency for the administration of the New Jersey Medicaid Program. Under the authority of N.J.S.A. 30:4D-1 *et seq.*, as amended and supplemented, N.J.S.A. 30:4D-5, and pursuant to N.J.S.A. 30L4D-4, 30:4I-1 *et seq*. and 30:4J-1 *et seq.*, DMAHS is authorized to administer the Medicaid Program as well as other special programs.

79. The Medicaid Fiscal Agent and DMAHS maintain New Jersey Medicaid and NJ FamilyCare provider manuals. Each is designed for use by a specific type of provider that provides services to Medicaid and/or NJ FamilyCare beneficiaries. Each manual is written in accordance with federal and state laws, rules, and regulations, with the intent to ensure that such laws, rules, and regulations are uniformly applied. *See* N.J.A.C. 10:49-1.4(a).

80. Each provider manual consists of two chapters, broken down into subchapters. The first chapter is referred to as N.J.A.C. 10:49, Administration Manual, and outlines the general administrative policies of the New Jersey Medicaid Program and other special programs, including NJ FamilyCare. The second chapter of each manual specifies the rules and regulations relevant to the specific provider-type and the services provided. Following the second chapter of the manuals is the Fiscal Agent Billing Supplement ("FABS").

81. The FABS includes prior authorization forms and instructions; information for the proper completion and submission of claim forms; the procedure to follow when claims are rejected and returned to the provider by the Fiscal Agent during the adjudication process; third

party liability verification procedure for submitting crossover claims, and examples of timely submission of claims; electronic media claims ("EMC") submission; Remittance Advice Statements; procedures for Electronic Funds Transfer ("EFT"); adjustments for overpayment of claims, and adjustments by Medicare; procedure to follow when a claim is paid in error (voids); procedures for inquiries about claims; procedure for ordering forms; information about provider services; and item-by-item instructions for completing the claim form and other forms. *See* N.J.A.C. 10:49-7.1 (b). If there is any conflict between the FABS and the pertinent laws or rules governing the Medicaid Program or the charity care program, the laws and rules of the Medicaid Program and the charity care program, as appropriate take precedence.

82. As defined in N.J.A.C. 10:6-1.2, an [A]mbulatory surgical center means any distinct entity that: operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization; has an agreement with the Centers for Medicare & Medicaid Services ("CMS") as a Medicare participating provider for ambulatory surgical services; is licensed, if required, by the New Jersey State Department of Health, or is similarly licensed by a comparable agency of the state in which the facility is located; and meets the enrollment requirements of the New Jersey Medicaid/NJ FamilyCare programs as indicated in the Administration chapter at N.J.A.C. 10:49-3.2 and N.J.A.C. 10:66-1.3.

83. Pursuant to N.J.A.C. 10:52-2.1(a), an Ambulatory Surgical Center ("ASC") shall be any distinct entity that operates for the purpose of providing surgical services to patients not requiring hospitalization, which has an agreement with CMS to participate in the Medicare program and meets the specific conditions for coverage set forth in federal regulations in 42 C.F.R. Part 416.

84. Covered services provided by an ASC are outlined in N.J.A.C. 10:66-5.1, which states:

(a) Medicaid and NJ FamilyCare fee-for-service covered procedures in an ASC are those surgical and medical procedures that appear at 42 C.F.R. 416.166, the federal regulations governing ASC services.

(b) Medicaid-covered and NJ FamilyCare fee-for-service covered surgical procedures include, but are not limited to, those procedures that:

1. Are commonly performed at a hospital, but may be safely performed at an ASC;

i. Are not commonly or safely performed in a physician's office;

2. Require a dedicated operating room or suite and require a postoperative recovery room or short-term, meaning not overnight, convalescent room;

3. Do not generally exceed a total of 90 minutes operating time and four hours recovery or convalescent time; and

4. Are not emergent or life threatening in nature, for example:

i. Do not generally result in extensive blood loss;

ii. Do not require major or prolonged invasion of body cavities; or

iii. Do not directly involve major blood vessels.

85. Pursuant to N.J.A.C. 10:66-1.1(b), [M]edically necessary services provided in an independent clinic setting shall be in compliance with all applicable state and federal Medicaid and NJ FamilyCare fee-for-service laws, and all applicable policies, rules, and regulations as specified in the appropriate provider services manual of the New Jersey Medicaid and NJ FamilyCare fee-for-service programs. Services provided in an out-of-State independent clinic

setting shall be in compliance with all applicable laws, rules, and regulations of the State in which the facility is located.

86. As defined in N.J.A.C. 10:66-1.1(c), [I]ndependent clinic services are preventive, diagnostic, therapeutic, rehabilitative, or palliative services that are provided by a facility (freestanding) that is not part of a hospital but is organized and operated to provide medical care to outpatients, including such services provided outside the clinic by clinic personnel to any Medicaid or NJ FamilyCare fee-for-service beneficiary who does not reside in a permanent dwelling or does not have a fixed home or mailing address. Clinic services do not include services provided by hospitals to outpatients.

87. Each independent clinic, including each satellite, shall be individually approved by the New Jersey Medicaid and NJ FamilyCare fee-for-service programs and enrolled with the Division's fiscal agent, for approved service(s). If a clinic wishes to add a service(s), approval from the New Jersey Medicaid and NJ FamilyCare fee-for-service programs shall be obtained before reimbursement for the service(s) may be claimed. See N.J.A.C. 10:66-1.3.

88. In addition to the requirements set forth at 42 C.F.R. 416.47, medical records in an ASC shall include, but not be limited to:

1. Patient identification;

2. Significant medical history and results of physical examination;

3. Pre-operative diagnostic studies (entered before surgery), if performed;

4. Findings and techniques of the operation, including a pathologist's report on all tissues removed during surgery, except those exempted by the governing body;

5. Any allergies and abnormal drug reactions;

6. Entries related to anesthesia administration;

7. Documentation of properly executed informed consent; and

8. Discharge diagnosis.

*See* N.J.A.C. 10:66-5.4.

89. Providers that participate in the New Jersey Medicaid Program shall complete a Provider Application and sign a Provider Agreement or a specialized agreement, and submit such other information or documentation, including, but not limited to, social security number and date of birth, as the program may require, depending on the nature of the services provided.

90. All program providers, except institutional, pharmaceutical, and transportation providers, shall be required to certify that the services billed on any claim were rendered by or under his or her supervision (as defined and permitted by program regulations); and all providers shall certify that the information furnished on the claim is true, accurate and complete. N.J.A.C. 10:49-9.8(a). All claims for covered services must be personally signed by the provider (for example, hospital, home health agency, independent clinic) unless the provider is approved for EMC submission by the Fiscal Agent. The provider must apply to the Fiscal Agent for EMC approval and sign an electronic billing certificate. N.J.A.C. 10:49-9.8.1.

91. Providers shall agree to the following:

1. To keep such records as are necessary to disclose fully the extent of services provided, and as required by N.J.S.A. 30:4D-12(d), to retain individual patient records for a minimum period of five years from the date the service was rendered;

2. To furnish information for such services as the program may request;

3. That where such records do not document the extent of services billed, payment adjustments shall be necessary;

4. That the services billed on any claim and the amount charged therefore, are in accordance with the requirements of the New Jersey Medicaid and NJ FamilyCare programs;

> 5. That no part of the net amount payable under any claim has been paid, except that all available third-party liability has been exhausted, in accordance with program requirements; and
>
> 6. That payment of such amount, after exhaustion of third-party liability will be accepted as payment in full without additional charge to the Medicaid or NJ Family Care beneficiary or to others on his behalf.

*See* N.J.A.C. 10:49-9.8(b).

92. As enrolled providers in New Jersey Medicaid, Defendants ACP, NJIA, and the three FVACs operating in the state had an obligation to comply with all New Jersey Administrative Code provisions delineated herein at all times relevant to the Complaint.

93. As enumerated above, all New Jersey Medicaid providers that wish to submit claims electronically, rather than on paper, must apply to the Fiscal Agent for EMC approval and sign an electronic billing certificate. ACP (Little Falls), ACP (Union) and ACP d/b/a Azura Surgery Center (Cherry Hill) initially enrolled on November 1, 2017, January 22, 2020, and January 1, 2017, respectively. Each facility recertified, effective July 11, 2023. By renewing their applications for certification, each entity agreed to the requirements outlined in ¶¶ 90 and 92, above.

94. Defendant Miller serves as the Authorized Official for the operations of ACP NJ and he is listed as the owner of NJIA. As the signatory of the provider and reimbursement agreements that controlled ACP NJ and NJIA's participation in the New Jersey Medicaid Program, Dr. Miller was keenly aware of his obligation to comply with both federal and State regulations controlling New Jersey Medicaid.

95. Pursuant to N.J.A.C. 10:49-21.1, managed care organizations can participate in New Jersey's Medicaid Program. The Medicaid/NJ FamilyCare Managed Care Program is a program under which Health Maintenance Organizations (HMOs) contract with the Department

of Human Services to provide health care services to Medicaid beneficiaries. Requirements governing HMO providers and services are codified at N.J.A.C. 10:49-74.

96. Because it is not feasible for the New Jersey Medicaid Program or its HMO contractors to review medical records corresponding to each of the claims for payment received from the providers, the Medicaid Program relies on providers to comply with the requirements outlined in the provider and reimbursement agreements, as well as to submit truthful and accurate certifications for the claims.

97. Defendants violated the terms of their New Jersey provider applications and the applicable New Jersey policy manual by engaging in the misconduct described in this Complaint.

*iii. New York Law, Medicaid Regulations, and Medicaid Provider Agreements*

98. From 2012 to the present, Miller, on behalf of AACP, has annually executed the New York Medicaid provider billing certification, which states in relevant part:

> I (or the entity) have furnished or caused to be furnished the care, services, and supplies itemized and done so in accordance with applicable federal and state laws and regulations; I have read the eMedNY Provider Manual and all revisions thereto; all claims are made in full compliance with the pertinent provisions of the Manual and revisions; all claims for care, services and supplies provided at the order of another professional have to the best of my knowledge been ordered by that professional in bona fide compliance with the procedures set forth in the manual and revisions. *All care, services and supplies for which claim is made are medically necessary for the treatment of the named recipient . . . .*

(Emphasis added.)

99. The relevant eMedNY Provider Manual, with which Defendants expressly agreed to comply in their New York Medicaid provider agreements, states:

> A hospital or diagnostic and treatment center may perform an ordered ambulatory service only when the treatment, test or procedure has been ordered in writing and is the result of a referral made by a licensed physician, nurse practitioner, dentist, podiatrist, physician's assistant, or mid-wife.

New York State Medicaid Program, Physician Policy Guidelines at 37. The services provided must be "performed . . . upon [a] written order of a qualified physician, nurse practitioner, physician's assistant, dentist or podiatrist to test, diagnose or treat a [Medicaid] enrollee." *Id.* at 45. This guideline applies to "[d]iagnostic radiology services" such as fistulagrams. *Id.*

100. New York regulations incorporate by reference federal regulations found in 42 C.F.R. Part 494. *See* 10 NYCRR § 751.1.

101. New York Medicaid also requires providers to follow the applicable standard of care for their field of practice. For dialysis treatments the standard of care is found in the Kidney Disease Outcomes Quality Initiative ("KDOQI"), 2006 updates, including for related vascular procedures such as fistulagrams and angioplasties.

102. In addition, 18 NYCRR § 504.3(e) requires New York Medicaid providers to agree to "submit claims for payment only for services . . . which were medically necessary."

103. 18 NYCRR § 504.3(f) requires New York Medicaid providers to agree to "submit claims . . . in the manner specified by the [New York State Department of Health ("NY DOH")] in conformance with the standards and procedures for claims submission."

104. As relevant here, 18 NYCRR § 515.2(a) defines as unacceptable practices "conduct which is contrary to:

> (1) the official rules and regulations of the [NY DOH];
>
> . . .
>
> (3) the official rules and regulations of the [New York] Departments of Health, Education and Mental Hygiene, including the latter department's offices and divisions, relating to standards for medical care and services under the [Medicaid] program; or
>
> (4) the regulations of the Federal Department of Health and Human Services promulgated under title XIX of the Federal Social Security Act.

105. In addition to the above, 18 NYCRR § 515.2(b) defines as unacceptable practices the following:

> (1) False claims. (i) Submitting, or causing to be submitted, a claim or claims for:
>
> (a) unfurnished medical care, services or supplies;
>
> (b) an amount in excess of established rates or fees;
>
> (c) medical care, services or supplies provided at a frequency or in an amount not medically necessary; or
>
> (d) amounts substantially in excess of the customary charges or costs to the general public.
>
> (ii) Inducing, or seeking to induce, any person to submit a false claim under this subdivision.
>
> (2) False statements. (i) Making, or causing to be made any false, fictitious or fraudulent statement or misrepresentation of material fact in claiming a medical assistance payment, or for use in determining the right to payment.
>
> (ii) Inducing or seeking to induce the making of any false, fictitious or fraudulent statement or a misrepresentation of material fact.
>
> (3) Failure to disclose. Having knowledge of any event affecting the right to payment of any person and concealing or failing to disclose the event with the intention that a payment be made when not authorized or in a greater amount than due.
>
> . . .
>
> (11) Excessive services. Furnishing or ordering medical care, services or supplies that are substantially in excess of the client's needs.
>
> (12) Failure to meet recognized standards. Furnishing medical care, services or supplies that fail to meet professionally recognized standards for health care or which are beyond the scope of the person's professional qualifications or licensure.

106. Further, 18 NYCRR §§ 515.5(d) and (e) state that New York Medicaid providers, whether reimbursed on a cost-related or fee-for-service basis, may not claim costs or submit claims for services credited to or furnished by any person "in violation of any condition of participation in the [New York State Medicaid] program."

107. Under the regulations listed above, claims submitted to Medicaid for medically unnecessary services, or services that failed to meet professional standards, are in violation of a material condition of payment of the New York State Medicaid Program.

108. The New York False Claims Act provides, in pertinent part, that any person who

> (a) knowingly presents, or causes to be presented a false or fraudulent claim for payment or approval;
>
> (b) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
>
> . . .
>
> (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 state or a local government; or
>
> (h) knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the state or a local government, or conspires to do the same;
>
> shall be liable to the state or a local government, as applicable, for a civil penalty of not less than six thousand dollars and not more than twelve thousand dollars, as adjusted to be equal to the civil penalty allowed under the federal False Claims Act, 31 U.S.C. sec. 3729, *et seq*., as amended, as adjusted for inflation by the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended (28 U.S.C. 2461 note; Pub. L. No. 101-410), plus three times the amount of all damages, including consequential damages, which the state or local government sustains because of the act of that person.

N.Y. State Fin. Law § 189.

109. Under the New York False Claims Act, "knowing and knowingly"

> (a) means that a person, with respect to information:
>
> (i) has actual knowledge of the information;
>
> (ii) acts in deliberate ignorance of the truth or falsity of the information; or
>
> (iii) acts in reckless disregard of the truth or falsity of the information; and
>
> (b) require no proof of specific intent to defraud, provided, however that acts occurring by mistake or as a result of mere negligence are not covered by this article.

N.Y. State Fin. Law § 188(3).

110. In addition, the New York False Claims Act defines a "claim" to mean

> (a) . . . any request or demand, whether under a contract or otherwise, for money or property that
>
> > (i) is presented to an officer, employee or agent of the state or a local government; or
> >
> > (ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the state or a local government's behalf or to advance a state or local government program or interest, and if the state or local government (A) provides or has provided any portion of the money or property requested or demanded; or (B) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded;
>
> (b) does not include requests or demands for money or property that the state or a local government has already paid to an individual as compensation for government employment or as an income subsidy with no restrictions on that individual's use of the money or property.

N.Y. State Fin. Law § 188(1).

111. New York Social Services Law § 145-b(1)(a) provides in pertinent part as follows:

> It shall be unlawful for any person, firm or corporation knowingly by means of a false statement or representation, or by deliberate concealment of any material fact, or other fraudulent scheme or device, on behalf of himself or others, to attempt to obtain or to obtain payment from public funds for services or supplies furnished or purportedly furnished pursuant to this chapter.

112. Under New York Social Services Law § 145-b,

> "statement or representation" includes, but is not limited to: a claim for payment made to the state, a political subdivision of the state, or an entity performing services under contract to the state or a political subdivision of the state; an acknowledgment, certification, claim, ratification or report of data which serves as the basis for a claim or a rate of payment, financial information whether in a cost report or otherwise, health care services available or rendered, and the qualifications of a person that is or has rendered health care services.

N.Y. Soc. Serv. Law § 145-b(1)(b).

113. New York Executive Law § 63(12) provides, in relevant part, as follows:

> Whenever any person shall engage in repeated fraudulent or illegal acts or otherwise demonstrate persistent fraud or illegality in the carrying on, conducting or transaction of business, the attorney general may apply . . . for an order enjoining the continuance of such business activity or of any fraudulent or illegal acts, [and] directing restitution and damages . . . .

114. New York Executive Law § 63-c(1) provides, in relevant part, as follows:

> Where any money, funds, credits, or other property, held or owned by the state, or held or owned officially or otherwise for or in behalf of a governmental or other public interest, . . . has heretofore been . . . without right obtained, received, converted, or disposed of, an action to recover the same, or to recover damages or other compensation for so obtaining, receiving, paying, converting, or disposing of the same, or both, may be maintained by the state in any court of the state, or before any court or tribunal of the United States, or of any other state, or of any territory of the United States, or of any foreign country, having jurisdiction thereof.

115. By engaging in the conduct described in this Complaint, Defendants violated the terms of their billing certification, and applicable laws, regulations, and provider manuals.

B. The Dialysis Clinic Is Responsible for Vascular Access

116. Federal regulations charge the dialysis clinic's "interdisciplinary team" with responsibility for monitoring each ESRD 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 vascular access must be monitored to prevent access failure, including monitoring of arteriovenous grafts and fistulae for symptoms of stenosis.

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

117. Medicare's assignment of responsibility for vascular access monitoring to the dialysis clinic makes sense: the dialysis clinic observes the patient and uses his fistula to access his blood system approximately three times per week, for four hours per day. The dialysis clinic

actually uses the fistula while observing and recording critical clinical information about the functionality of the fistula and the dialysis process.

118. Federal regulations also expressly require the dialysis clinic's interdisciplinary team to achieve and sustain adequate dialysis. *See* 42 C.F.R. § 494.90(a)(1). This is expressed as the clearance of urea through hemodialysis of 1.2 Kt/V or greater. *Id.* Kt/V is a key measurement of the effectiveness of dialysis treatment at removing urea from blood. K is the dialyzer clearance of urea, t is time under dialysis, and V is the volume of distribution of urea.

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

120. 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.

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

122. 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.

123. New Jersey and New York also reimburse for dialysis services at a composite rate. *See* 10 NYCRR §§ 86-4.37, 86-4.38.

124. Georgia reimburses for dialysis services at a Treatment Rate. *See* Georgia Department of Community Health, Division of Medicaid, Part II Policies and Procedures for Dialysis Services § 903.1 (October 1, 2022).

125. 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 Medicare Part B on a fee-for-service basis for Medicare-eligible patients. *See generally* 42 U.S.C. § 1395rr(a); 42 C.F.R. § 414.314(b); Claims Manual 100-04, ch. 8, § 140(B).

126. For claims paid to Defendants where Medicaid was the primary payor, the Intervening States' Medicaid Programs paid some claims on a fee-for-service ("FFS") basis and other claims through Medicaid CMOs in Georgia and through Medicaid managed care organizations ("MCOs") in New Jersey and New York. Fee-for-service payments are payments where a State Medicaid Program pays a provider directly for a service according to the State's Medicaid fee schedule. CMOs and MCOs contract with a State Medicaid Program to deliver health care services to Medicaid recipients in exchange for a set monthly payment per enrolled member (called a "capitation" payment). Payments to healthcare providers through CMOs and MCOs are made when the CMO or MCO pays a provider for a service out of the Medicaid recipient's capitation payment, according to a fee agreement between the CMO or MCO and the provider. In both cases, the Intervening States' Medicaid Programs pay Defendants claims.

127. All services provided by Defendants to Medicaid recipients, whether paid on a FFS basis or through a CMO or MCO, must comply with the relevant State's Medicaid regulations, including those listed above, in order to be eligible for reimbursement.

## IV. CARE AND TREATMENT OF ESRD PATIENTS

128. 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, often for several years. Each treatment can last three to five hours, including the dialysis 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.

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

130. 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. The fistula is usually created in the patient's arm or leg.

131. Each patient's fistula must be regularly monitored to confirm that it permits successful dialysis.

132. 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 (not a single isolated abnormal value) should prompt a referral for access imaging.

*See* KDOQI Guidelines, Guideline 4.

133. The KDOQI Guidelines' professional standard of medical necessity for a fistulagram requires dialysis clinic data (the clinical and surveillance parameters above) and a physical examination.

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

135. 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.

136. 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).

137. Similarly, federal regulations require dialysis clinic interdisciplinary teams to provide care to sustain adequate dialysis of at least 1.2 Kt/V. 42 C.F.R. § 494.90(a)(1).

138. 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 the 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).

139. When the results of monitoring tests show problems at the vascular access site (where the dialysis machine connects to a patient's vascular system) 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.

140. An angioplasty may be medically necessary for patients who have a stenosis, or narrowing, that is "hemodynamically significant" in their fistula or surrounding blood vessels, to expand the narrowed vessel so that sufficient blood flow for dialysis can be restored. Generally, a stenosis is hemodynamically significant when it causes a reduction in blood flow through the fistula that is below the dialysis machine's requirement for adequate treatment.

141. As described in greater detail below, fistulagrams and angioplasties are invasive surgical procedures that generally require a patient to be sedated and/or to go under anesthesia, after which the provider inserts catheters into the patient's fistula, takes x-rays, and, if the provider performs an angioplasty, inserts wires and a balloon into the fistula. *See infra* ¶ 146.

142. 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. 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 possible in ESRD patients to preserve residual kidney function. *See* 2019 KDOQI Guideline 15.

# FACTS

## I. DEFENDANTS' CTE SCHEME

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

143. Most patients' first contact with Defendants was when their dialysis provider referred them to one of the FVACS for an evaluation and possible treatment of a problem identified during dialysis.

144. At the conclusion of that properly referred visit, Defendants' CTE Scheme began when they scheduled a clinically timed follow-up evaluation approximately three months later.

145. The CTE Scheme involved repeated medically unnecessary procedures performed on these patients quarterly, often for years at a time.

146. Upon arrival at an FVAC for a CTE appointment, staff and doctors would put patients "on the table." In practice, this meant to perform procedures on them and bill for fistulagrams and angioplasties. Putting these patients "on the table" at the FVACs worked as follows:

- An interventionalist would ostensibly evaluate the patient for a fistulagram.[6]
- 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 technician. A nurse or the radiology technician would place a blood pressure cuff on the patient's arm, a pulse oximeter on their finger to monitor oxygen in the patient's red blood cells, and electrodes (stickers with wires connected to an ECG machine) on their legs and arms to check the patient's heart rate.
- A nurse or technician would draw up medication and the interventionalist (or an anesthesiologist if local anesthesia is used) would inject it into the patient.

[6] FMC's Corporate Compliance Department documents state that if an interventionalist did not believe a fistulagram was necessary, they would communicate this to the patient's referring dialysis clinic or nephrologist. In practice, the interventionalists almost always performed a fistulagram at the initial referred appointment. Rarely would a patient leave without a fistulagram. The dialysis clinic and nephrologist were rarely, if ever, consulted.

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

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

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

- The interventionalist would typically read and interpret the images himself, determining the percentage of stenosis.[7] Sometimes others in the room questioned this reading or interpretation. The stenosis percentage should have been, but was not always, documented in the records.

- After the narrowing or blockage was purportedly identified, an interventionalist would perform an angioplasty to address the blockage. As stated above, *see supra* ¶ 140, angioplasties are only medically necessary where stenosis is hemodynamically significant, which means that stenosis prevents the dialysis machine from providing adequate treatment.

- To perform the angioplasty, the interventionalist would insert a catheter with a small balloon at one end through the patient's skin and into a blood vessel. After guiding the catheter through the patient's blood vessel until it reached the area of narrowing, the interventionalist would inflate the balloon to widen the vessel.

- After the procedure, the patient would be taken from the operating room to a recovery room for up to two hours while waiting for the post-procedure bleeding to stop. Some patients suffered adverse reactions and were transported by ambulance to a hospital for emergency treatment.

- Upon discharge, the FVAC gave the patient a sheet with a "follow-up" appointment date, usually three months later, and instructions not to eat or drink before the next pre-scheduled appointment. The FVAC sometimes arranged the patient's transportation to and from the FVAC facility for the next appointment.

- 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 the vascular access.

[7] 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.

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

147. In accordance with Defendants' policy and practice, FVACs scheduled CTEs without further referral from the patient's treating physician or patient's dialysis clinic.

148. Because each FVAC scheduled the next visit at the end of the patient's current visit, the CTE appointment was scheduled before the patient returned to their nephrologist. Thus, defendants knew, when they made each follow-up appointment, that no new referral could have been made by the patient's nephrologist.

149. Defendants scheduled CTEs approximately every three months. Notably, during the intervening three months, the patient had already been monitored and evaluated by the dialysis clinic, and Medicare and Medicaid had already paid for these services.

150. 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.

151. 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.

152. FVACs instructed patients not to eat or drink before the next visit, even though that visit was usually three months in the future. FVACs obviously could not know three months in advance whether a patient's fistula would have problems functioning. This provides further evidence that patients were virtually guaranteed to have a procedure performed on each visit regardless of necessity.

153. 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.

154. The FVACs would then routinely perform fistulagrams and angioplasties, billing Medicare and Medicaid for these risky and often unnecessary procedures.

155. The FVAC often misleadingly instructed the patient to come back for a follow-up appointment "before a small problem becomes a big problem." Some FVACs falsely advised patients that they could potentially lose the ability to receive dialysis if the patients did not undergo these medically unnecessary procedures. These false warnings abused patients' trust.

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

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

157. Defendants' CTEs were medically unnecessary, and fraudulent, because they lacked valid referrals. Under Medicare and Medicaid rules, the patients subjected to CTEs should not have had a follow-up appointment scheduled without a new referral from their treating nephrologists.

158. A second, independent, reason why these visits were medically unnecessary and fraudulent is that FVACs ignored clinical evidence from patients' dialysis clinics that showed no problems with their fistulas.

159. Even though Defendants would have had access to the records for FMC's dialysis clinics and could have requested the information from non-FMC dialysis clinics that purportedly referred each patient to the FVAC for each appointment, Defendants never considered whether a patient exhibited diminished Kt/V, or any other clinical sign of problems with blood flow, before pre-emptively performing a fistulagram.

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

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

162. 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."

163. However, FVC failed to consider the patients' actual blood flow before performing a fistulagram.

164. Instead, FVC routinely relied on the purported presence of a "soft" indicator, pulsatility, to determine that the patients' vascular access was impaired.

165. Pulsatility is a non-quantitative, subjective assessment. Essentially, pulsatility is the vibratory sensation felt when a provider placed their hand on a patient's skin. Every access point will have a pulse. A physical exam could reveal any abnormal pulsatility, but only if the provider is familiar with the patient's baseline pulsatility.

166. In other words, pulsatility cannot be evaluated in a vacuum, but must be compared to the patient's regular pulsatility levels—precisely the information in dialysis center records that Defendants ignored.

167. Defendants seldom, if ever, corroborated the pulsatility sensation with the dialysis clinic's physical exam, or the results of monitoring before concluding that a patient's ability to receive dialysis had been impaired and intervening with a surgical procedure. Indeed, rather than considering actual malfunction or flow rates before performing a fistulagram at a CTE appointment, the FVAC most often noted only "pulsatility," after placing a hand on the patient's skin.

168. As confirmed by CTE data requested by Miller for 2011 to 2016, the basis for over 72 percent of 42,643 "clinical evaluations" procedures was "pulsatility" or other subjective indicators. See Exhibit 1[8] (columns G and H), attached to the Federal Amended Complaint-in-Intervention and incorporated by reference in this Complaint-in-Intervention.

169. There is little, if any, evidence that Defendants considered other clinical signs that they knew and acknowledged as indicators of access dysfunction. These signs, which would have been monitored and recorded by the dialysis clinics, included difficult cannulation,[9] prolonged bleeding, swollen extremity, neck and chest wall collaterals, emergence of aneurysms, and poor clearances via Kt/V or URR (urea reduction ratio).

170. 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.

171. A review of the FVAC records for the entire period at issue in this case reveals that pulsatility or other non-objective indicators, were the predominant bases for the performance of fistulagrams by the FVACs. Objective indicators for performing the procedure were largely absent.

172. Notably, in over 79 percent of the clinical evaluations that Defendants' FVACs performed between 2011 and 2016 across the United States, an angioplasty was performed (Exhibit 1, column I) during a CTE appointment.

[8] References to "Exhibit 1" are to Exhibit 1 of the Federal Amended Complaint-in-Intervention, docket nos. 63-1, 63-2, and 63-3. In the interests of judicial economy, the Intervening States incorporate by reference the federal Exhibit 1.

[9] 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.

## II. DEFENDANTS FALSIFIED RECORDS AND PERFORMED MEDICALLY UNNECESSARY PROCEDURES

### A. Defendants Falsified Records to Justify Interventions

#### *i. Referrals*

173. Claims that Defendants 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.

174. Similarly, Defendants 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.

175. Defendants' 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. In fact, the FVAC regularly excluded the patients' treating nephrologists from the decision to have the patient return to the FVAC.

176. Procedures performed without any clinical indication of necessity should not be performed, can cause patient harm, and are not covered by Medicare or Medicaid. Both Medicaid and Medicare require 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.

*ii. Soft Indicators of Impaired Vascular Access*

177. A second, independent reason why Defendants' claims are false is that Defendants falsely claimed that soft indicators of impaired vascular access—primarily pulsatility—indicated impaired vascular access.

178. The rate at which FVAC providers identify pulsatility is much greater than the rate at which a physician would ordinarily expect to observe such symptoms.

179. Patients' dialysis records indicate that these findings were false: In many cases, patients had gone to dialysis only one day prior, yet their dialysis records do not record pulsatility or any other vascular access issue, which strongly indicates that the FVACs subjected patients to these unnecessary procedures under false pretenses.

*iii. Stenosis*

180. A third, independent reason why Defendants' claims are false is that the radiologic images taken at the FVACs prior to the procedures do not show the degree of blockage in the patient's vein as recorded in the corresponding procedure report.

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

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

B. Defendants Performed and Billed for Medically Unnecessary Procedures

183. In addition to submitting claims that were false because of the falsified referrals and falsified stenosis levels, Defendants' claims for fistulagrams and angioplasties are also false because they are medically unnecessary.

184. Fistulagrams are only medically necessary if a dialysis patient experiences problems with dialysis as indicated by several factors such as clearance rates, Kt/V, and arterial/venous pressure.

185. Defendants instead relied almost exclusively on pulsatility and other subjective indicators to justify fistulagrams and ignored the myriad indicators—including the primary records from dialysis clinics—that the patients were not having problems with their dialysis treatments.

186. As a result, Defendants performed medically unnecessary fistulagrams.

187. Further, angioplasties are only medically necessary where hemodynamically significant stenosis is present in a patient's fistula.

188. Instead of accurately evaluating and recording stenosis levels, Defendants falsely inflated stenosis levels on a regular basis.

189. Because Defendants' patients did not have the required level of hemodynamically significant stenosis that would justify an angioplasty, Defendants' angioplasties were medically unnecessary.

## III. DEFENDANTS KNOWINGLY SUBMITTED FALSE CLAIMS

### A. FMC, FVC, and FVC Executives, Including Miller, Control and Operate FVACs as an "Integrated Organization"

190. FMC is and was a wholly owned subsidiary of German company Fresenius Medical Care AG & Co. KGaA ("Fresenius AG") and holds itself out as the world's largest provider of dialysis products and related services such as the procedures at issue in this case.

191. Fresenius AG substantially grew the FVC business unit with the acquisition in 2011 of American Access Care Holdings ("AAC") 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 and 34 percent of the company's total revenue was attributable to reimbursements by U.S. federal healthcare benefit programs, including Medicare and Medicaid.

192. The AAC clinic network was comprised of 28 freestanding outpatient centers providing vascular access treatment to dialysis patients in Georgia, New Jersey, and New York, including the 18 FVACs 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 nationally.

193. FVC's corporate leadership oversaw the operations of three regions that covered geographical portions of the United States: The North, South, and Western Regions. The New Jersey and New York FVACs are part of the North Region. The Georgia FVACs are part of the South Region.

194. 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."

195. FVC formed a Medical Advisory Board ("MAB"), led by its then Chief Medical Officer, Defendant Miller. 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 [FVACs], particularly in areas that are the subject of significant new medical literature." Miller and FVC's President jointly selected the MAB members, which included physicians serving or who had recently served as the Medical Director at an FVAC. The

Medical Directors oversaw all operations of their respective FVACs. Medical Directors and FVAC medical staff members reported to Miller as Chief Medical Officer.

196. The MAB had six subcommittees whose members included FVC's president, Defendant Miller and other FVC leadership, and certain FVAC interventionalists. These subcommittees included: Quality, Peer Review, Research, Physician Training and Education, and PAD (peripheral artery disease).

B. Defendants Knew that Elective Interventions Were Unnecessary and Harmful as Early as 2011

197. 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 FMC physicians was FMC's Chief Medical Officer.

198. This study, published in the Clinical Journal of the American Society of Nephrology ("the 2011 CJASN Article"),[10] 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 "preventive" or "elective" angioplasties and those who did not.
- The only patients who benefitted from these preventative or elective angioplasties were those who had (1) relatively new fistulas (less than three months old), (2) low blood flow rates, or (3) 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 (greater than 1%) of certain "serious adverse events," in addition to further harm to residual kidney function caused by contrast dye.

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

199. This study also acknowledges 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 "[f]urther referral for intervention was then at the discretion of the attending physician [meaning the nephrologist]."

200. The study concluded, "Overall, the results of this study suggest that [fistulagrams and angioplasties] provide[] limited access survival benefits in the ESRD population as a whole."

201. The article was widely distributed among FVC executives, including FVC's President, Defendant Gregg Miller, and other MAB members. Miller's reaction in an email was that "it goes to show you how 40,000 patients can give you the wrong answer."

C. Defendants Promoted the CTE Scheme Despite this Evidence

202. Defendants looked for ways to legitimize CTEs to reap financial gains, notwithstanding the evidence, including from FMC's own study, that follow-up procedures were not necessary and could indeed be harmful.

*i. FVC established quality standards of care which it did not enforce*

203. A 2012 internal memo signed by FVC's President regarding "Follow-Up Fistulagram Procedures" described the practice of 15 FVAC physicians who performed "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."

204. While the memo acknowledged 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.

205. 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."

206. The Clinical Quality Team was further tasked with ensuring that "the stenosis is documented at 55 percent or higher."

207. Defendants did not enforce this performance standard and therefore did not adhere to this justification for CTEs.

208. Ultimately, Defendants looked for other ways to rationalize CTEs in order to maximize their profits at the expense of their patients' well-being.

*ii. Defendants' White Paper*

209. In 2013, Miller and other MAB members drafted a "CTE White Paper" (the "White Paper"), which promoted and purported to justify the CTE Scheme.

210. Multiple subcommittees of FVC's MAB reviewed the White Paper, which advocated for a "CTE model" consisting of fixed surveillance and intervention to treat "clinically silent stenosis."

211. The White Paper posited that monitoring and surveillance done by dialysis clinics was not sufficiently effective in assessing vascular access and concluded that subjective findings based on physical exams by interventionalists would be more useful.

212. The White Paper conceded that "[c]ritics of CTE believe it results in too frequent interventions."

213. The MAB Quality Subcommittee recommended that the paper de-emphasize "negative points" to highlight that "clinical exams, not fistulagrams, are the primary reason for patients coming through the door."

214. The White Paper criticized the professional standards expressed in the KDOQI Guidelines as out of date.

215. 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.

216. The White Paper stated, "[f]urthermore, the choice to intervene is not based on one single data point. Rather, it is a conglomerate of factors comprising clinical signs, surveillance methods, patient specificity, and CTE's."

217. 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."

218. Ultimately the White Paper purported to set a new standard for treating ESRD patients—one that disregarded established standards and marginalized the importance of critical information obtained by dialysis clinics, in favor of examinations that would be made by FVAC interventionalists.

219. Making matters worse, Defendants did not even implement or live up to the watered down, purported standard of care outlined in the White Paper.

220. Although the White Paper stressed that a CTE must consist of a "detailed access history," important patient information obtained by dialysis clinics was not considered at all during CTEs. This included the dialysis clinics' observations concerning access flow and venous pressure to evaluate dialysis efficacy in accordance with the KDOQI Guidelines. *See* KDOQI Guideline 4.2.

221. Similarly, far from considering a "conglomerate of factors," Defendants disregarded dialysis clinic monitoring that determined whether the following clinical signs of access dysfunction existed:

- Difficult cannulation;
- Prolonged bleeding;
- Swollen extremity;
- Neck and chest wall collaterals;
- Emergence of aneurysms; and/or
- Poor clearances via Kt/V or URR (urea reduction ration).

222. In addition, Defendants disregarded dialysis clinic surveillance, which could indicate the presence of dysfunction using the following methods:

- Duplex Doppler Ultrasound;
- Ultrasound Dilution;
- Urea Dilution;
- Crit Line III (optidilution by ultrafiltration);
- Differential Conductivity;
- In-Line Dialysance; and/or
- Trending of direct or indirect statis pressures.

223. Notably, although the Defendants disregarded the monitoring and surveillance performed by the dialysis clinics, they did not perform these functions themselves.

224. Instead, Defendants justified access procedures with subjective findings obtained only upon physical examination. *See* Exhibit 1 (column H).

225. The White Paper, as implemented, was categorically contrary to, and subverted, the mandate of care for ESRD patients by an interdisciplinary team. *See* 42 C.F.R. § 494.90(a)(5).

226. The White Paper served Defendants' financial interests by purporting to justify the CTE Scheme. Thus, the White Paper was designed to provide cover to allow Defendants to perform unreasonable and unnecessary vascular access procedures that disregarded Medicare and Medicaid reimbursement requirements. *See* 42 U.S.C. § 1395y(a)(1)(A); 42 U.S.C. § 1320c-5(a) (requiring Medicare providers must ensure their services are provided "economically and only when, and to the extent, medically necessary"); *see also* Georgia Department of Community Health, Division of Medicaid, Part I Policies and Procedures for Medicaid/Peachcare for Kids § 405(D) (October 1, 2022); N.J.A.C. 10:49-5.1(a)(1); 18 N.Y.C.R.R. §§ 500.1(b); 515.2(b)(1)(i)(c).

227. Presentations prepared by Miller in 2013 show that he and FVC knew that the White Paper was incomplete because it was not supported by clinical trials.

228. Miller also knew the 2011 CJASN Article presented an "internal challenge" to the White Paper because the article concluded "that angiography-PTA provides limited access survival benefits in the ESRD population as a whole."

229. Defendants nonetheless promoted and implemented the White Paper.

230. Miller 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."

231. 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."

232. An FMC consultant who attended the MAB meeting informed FMC's Chief Medical Officer and Defendant Miller, that he had conducted an informal survey of doctors about

surveillance: "Two said they did not always understand the reason for their patients to return to FVC."

233. In response to this feedback, Miller asked the FMC consultant, "Do you think the concept of clinically timed evaluations helps to explain the return visits, or do you think this is [sic] will be interpreted as BS?" The FMC consultant replied, "I really like the idea of CTE."

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

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

*iii. Defendants Attempted to Justify CTEs in Other Misleading Ways*

236. Miller widely advocated for CTEs at symposiums attended by FVAC Medical Directors and others.

237. In 2013, a member of FVC's MAB analyzed 97,354 patient visits at 36 FVACs, to test his "hypothesis" about whether referred patient visits or CTEs showed higher rates of stenosis greater than 50%. The data showed that CTE visits had a higher rate of such stenosis than referred visits, which the MAB member called "surprising." The MAB member intended to publish a paper with this finding to "prove[] the value of th[e CTE] approach."

238. An internal presentation also from 2013 admits that "[n]o prospective randomized studies exist in the literature" and stated that answering the question, "Does access intervention prolong the life of an access" was a "[u]nique opportunity for [a] large scale prospective collaborative stud[y]." The presentation states that FVC "can change the way the world delivers care to ESRD patients!"

239. By 2015, however, studies still did not support the CTE model. The FVC MAB created the Research Subcommittee composed of FVC executives and physicians, including

Miller, 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)[.]"

240. Defendants thus knew that they did not have evidence to support their CTE Scheme, yet they continued to perform medically unnecessary procedures at clinically timed visits. Instead of working with a partner on a "collaborative stud[y]," Defendants forged ahead alone, using an unproven medical intervention—CTEs—on a vulnerable population without the strict oversight that is legally required for human subjects research.

241. By continuing to schedule CTEs and perform procedures on ESRD patients at these visits despite lacking scientific evidence that CTEs were medically effective, Defendants effectively experimented on vulnerable ESRD patients to test their unproven "hypothesis" that their CTEs were effective—in the face of clinical evidence that they were not.

242. Defendants regularly conducted invasive procedures on vulnerable patients by implementing their clinically unsupported but financially lucrative plan to subject patients to CTEs—without telling the patients that the CTEs were not supported by scientific literature and without the patients' consent to enroll in what was essentially a clinical trial—in the hopes that analysis of the CTE patients' outcomes would justify their decision to perform medically unnecessary procedures.

243. 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 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.

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

245. Because FVC had not developed its own studies, the marketing card only cited an article by renal doctor, Nicola Tessitore, in support of CTEs.

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

247. Miller later urged that another Tessitore article be disseminated "to all of our reps."

248. But the second Tessitore article involved sophisticated diagnosis of stenosis greater than 50% through both physical examination and ultrasound evaluation of flow rates and venous pressure during the patient's dialysis session. In contrast, as discussed above, the FVACs relied solely on a physical evaluation of pulsatility in nearly three-quarters of patient visits.

249. Despite these significant differences, and the fact that the applicable kidney guidelines from KDOQI recommended against routine procedures absent hemodynamically significant stenosis, FVC created a Tessitore article worksheet for its sales representatives to pressure providers to refer more patients. The sheet provided scripts and solutions for handling two specific objections from nephrologists: (1) "I am not sure your follow ups are really benefitting the patients, or your doctor does too many follow ups" and (2) "Why would I send a patient to you that is not having a problem?"

D. Defendants Aggressively Pressured FVACs to Implement the CTE Scheme

250. Defendants took steps to ensure that they would profit from the CTE Scheme. These efforts included training physicians to routinely use CTEs, setting targets for numbers of procedures performed at each FVAC, incentivizing staff and physicians with rewards, closely

tracking CTEs, and using sales and marketing representatives to increase referrals from dialysis clinics.

*i. Defendants Set Goals and Provided Incentives*

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

252. By 2015, FVC had acquired a majority interest in nearly 40 FVACs nationwide.

253. As it continued to grow, FVC used recruiters to find nurses and interventionalists to work in the FVACs.

254. As Chief Medical Officer, Miller played a critical role in the hiring of FVAC physicians.

255. New hires were told about the CTE Scheme of scheduling follow-up appointments at a three-month interval "default."

256. FVC preferred that its physician new hires be "business minded."

257. Once a patient entered an FVAC, FVC wanted that patient to receive a procedure. Indeed, when evaluating a new acquisition vascular access center, FVC wanted to know the percentage of patients "sent home without a fistulagram."

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

259. Miller pressured FVAC physicians to perform more interventions. Miller told one physician who questioned whether procedures were clinically necessary, in sum or substance, "How can you expect to make money if you are sending 80% of the patients home."

260. FVAC physicians felt pressure to always find at least 50 percent stenosis regardless of actual necessity when a patient was on the operating table.

261. FVAC physicians received instructions to take some liberty with their evaluation decisions. One physician recalled hearing, "If it is 30% or 50%, no one is going to argue with you."

262. Frustrated with the pressure to perform CTEs and with Miller's threats to monitor his work, one FVAC physician told Miller to look at the patient images himself: "You're telling me to treat something, and I don't see anything to treat."

263. Defendants even provided FVAC physicians with a written template procedure note with a prewritten finding for a purported physical examination designed to justify their surgical interventions and prewritten stenosis levels between 50% and 80%. The template was designed for physicians to fill in the name of the appropriate vein or artery, but it includes prewritten findings of pulsatility and thrill, and states that either a fistulagram or thrombectomy is indicated. The template is thus further evidence that Defendants intended for the FVAC physicians to perform procedures on their vulnerable ESRD patients at virtually every CTE appointment.

264. FVC based its physicians' compensation in part on the volume of their billings for procedures. Given these incentives, it is not surprising that data analytics programs using Medicare data identify several FVAC interventionalists as outliers for their billing of angioplasties.

265. At certain FVACs, interventionalists received offers of a "productivity bonus," based on the total number 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.

266. Miller instructed interventionalists to review their "procedures per day" ("PPD"). Interventionalists were given summaries of their PPD statistics in comparison to other FVACs.

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

268. 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.

269. The Brooklyn FVAC, where Miller served as the Medical Director, set targets for the number of ESRD procedures, including fistulagrams and angioplasties, quotas for "renal cases," and congratulated the office team when those numbers were met and exceeded.

270. In fact, each FVAC had monthly baseline "goal" numbers of medical procedures. 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 which were sometimes referred to as "budgets."

271. FVACs in Georgia and New Jersey similarly had "budget[ed]" numbers of procedures per day, including fistulagrams and angioplasties, which Defendants tracked.

272. FVC internally circulated monthly "Performance Scorecards," which reflected the procedures per day performed by all FVACs within one Region. These "scorecards" tracked the supply cost per procedure and the compensation per procedure.

273. FVAC physicians often claimed that these goals were excessive and difficult to meet. For example, one such physician practicing in the Staten Island FVC told FVC's corporate leadership, "[n]ot sure where those ESRD numbers came from … but if we don't have any FMC centers feeding us or getting referrals from Brooklyn and Bayonne, sorry to say, those numbers after April are unattainable … even if we captured every dialysis patient on the island … doing 1834 ESRD procedures is unrealistic."

274. Yet, FVC continued to pressure the FVACs to meet financial expectations.

275. Notably, Miller congratulated the Brooklyn FVAC when it met its procedure goals and admonished the facility when it fell short.

276. The performance goals were also monitored by FVC.

277. FVC's "Joint Venture Reporting Analyst" prepared financial packages that budgeted for the performance of a specific number of procedures and tracked revenues.

278. These financial packages showed that procedures increased throughout the period at issue. For instance, at all relevant times in the New York FVACs, angioplasties comprised around or over 50 percent of interventions, and the largest percentage of procedures overall. Angioplasties also comprised around or over 50 percent of interventions for FVACs in New Jersey and Georgia.

279. Defendants became concerned when a particular FVAC's financials missed the marks set by FVC. For example, Miller wrote FVC corporate in 2015 that "Manhattan financials are a disaster. This is a perfect storm of decreased thrombectomy, decreased stents and 24% medicaid. We absolutely need to do a deep dive on all expenses. We need to improve all physician efficiencies and find new sources of revenue generation."

280. In 2014, a Senior Director of Sales & Marketing for FVC, working from Staten Island, announced a contest involving the North, South, and East Regions. The goal was to hit 400 procedures in the 3rd quarter of 2014. The Sales Director encouraged the team to use the "1 minute assessment" video created by Miller to show dialysis staff in the clinics how quickly they can decide if a referral is warranted. The Sales Director instructed FVC sales representatives to encourage referrals even where patients did not meet the KDOQI guidelines for referral, even though those guidelines provide the standard of care for ESRD patients. The Sales Director sent the contest announcement to top executives at FVC.

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

282. 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 and those assigned to Defendant Snapfinger were among the contest winners. All winners received an extra 20% in bonuses. FVC executives signed off on over $350,000 worth of bonuses.

283. Contemporaneous emails show that FMC had knowledge of the contest and of these bonuses.

284. Volume of patients and procedures were metrics used to reward 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 in the total score used to determine bonuses.

285. 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 would receive a $100 gift card and a 10% increase in their quarterly bonuses.

286. During 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."

*ii. FVC Conducted Formal CTE Training and Made Outreach to Nephrology Practices for ESRD Patient Referrals*

287. To advance the CTE Scheme, FVC trained FVAC physicians and staff, and deployed its marketing and sales team to bring in new patients.

288. FVC organized training for new FVAC physicians. Physicians from "high Volume new acquisitions" only required one to two weeks of training.

289. FVC required that new Medical Directors in FVACs be trained for two weeks. FVC's goal was to "[t]each medical director[s] how to be more efficient and cut the costs." This training was for those whose centers were "not making the profits as expected" and those "below their expected numbers."

290. Medical Directors' training included meeting the FVC marketer and learning about FVC human resources and finances.

291. Medical Directors were trained on the FVC philosophy: "simply increase revenue and decrease expense."

292. In 2013, a Sales Director set up a training in which Miller would present on CTEs to FVC sales representatives.

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

294. 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.

295. 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.

296. In others, the patients were worried about access failure and thrombosis, which their FVACs falsely told them were risks of not continuing CTEs, and continued to receive treatments from the FVAC.

297. In fact, at least one FVAC located in Georgia provided patients with false informed consent forms. The forms provided by this FVAC state that there were no "generally recognized and accepted practical alternatives" to the CTE procedures, and that if the patient "choose[s] not to have the above procedure, [their] prognosis (future medical condition) is: Inability to properly dialyze."

298. In other words, Defendants told patients that stopping CTEs or refusing medically unnecessary procedures would result in dialysis failure.

299. These statements in the FVAC consent form are false: most ESRD patients in the United States do not undergo CTEs and are able to continue dialysis.

300. Defendants were thus performing medically unnecessary procedures on some patients on the basis of sham informed consent.

301. By June 2015, FVC was pitching more nephrology practices to join its chain. FVC boasted that it added value by "increas[ing] procedure volumes" and "revenue per procedure." FVC promised that if the practice joined FVC, it could expect increases in procedures and revenues per procedure. Such an increase would be driven by performing 50% more angioplasties over a five-year period.

*iii. Defendants Closely Tracked and Analyzed Follow-Up Procedures*

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

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

304. FVC analyzed its data identifying the dates and locations of CTE visits. *See* Exhibit 1. The chart tracked 42,643 "clinical evaluations" as the recorded indication for procedures performed at FVACs nationwide from 2011 through 2016. *Id.* at column G.

E. Defendants Knew that Similar Conduct Was Considered to Violate the FCA

305. 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.

306. By the time FVC acquired the American Access Care facilities in 2011, it had knowledge of investigations of AAC in Florida, Connecticut, and Rhode Island by the Department of Justice ("DOJ") and the Department of Health and Human Services for similar allegations as alleged in this Complaint-in-Intervention. This information was formally disclosed in the July 19, 2011, merger and purchase agreement between American Access Care and its subsidiaries and FVC.

307. 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."

308. 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 Miller's attention.

309. In July 2015, 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 this settlement, an FVAC interventionalist emailed Miller a link to Press Release, stating: "we should discuss . . . ."

310. In September 2015, DOJ announced that it had settled two additional FCA cases against AAC facilities, prior to those facilities being acquired by FVC, one in Rhode Island and the second in Connecticut for, among other conduct, submitting claims to Medicare and Medicaid for medically unnecessary procedures performed during dialysis patient follow-up visits.

311. 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."

312. Despite this knowledge, there is no evidence that Defendants conducted a review of their claims. Instead, Defendants kept (and continue to retain) the funds they improperly received because of their false claims.

## IV. DEFENDANTS SUBMITTED FALSE CLAIMS, AND/OR CAUSED FALSE CLAIMS TO BE SUBMITTED, TO GEORGIA, NEW JERSEY, AND NEW YORK

313. During the period January 1, 2012 through June 30, 2018, Defendants submitted or caused to be submitted false claims to Georgia, New Jersey, and New York for reimbursement for fistulagrams, angioplasties, and other procedures that were not reasonable or medically necessary as required by Medicare and Medicaid.

314. Defendants received payments from Medicare and Medicaid for these claims.

315. Medicare and Medicaid would not have paid the claims submitted by Defendants had they known that the procedures were neither reasonable nor medically necessary.

316. Defendants knew that they were submitting claims for services that were neither reasonable nor medically necessary as required by Medicare and Medicaid.

317. Defendants were on notice, by statute, regulation, and guidance that their claims were false.

318. The knowledge and responsibility for the submission of the claims started at the top, with FVC's executive officers, and with the MAB, which was supposed to ensure quality of care and compliance with the law but did just the opposite.

319. Defendants controlled the FVACs' coding and billing process. The FVACs used FVC's billing and coding employees. FVC's billing and coding departments were grouped under its "Revenue Cycle" division, described by FVC as "the process of converting patient visits into codes, charges, claims, which ultimately turn into payments and Accounts Receivable."

320. FVC executives, including Miller, were included in both FVAC-specific and FVC-wide discussions regarding billing and coding issues, including those concerning the requirement for hemodynamically significant stenosis before performing angioplasties. For example, in a November 9, 2015, email, FVC's Vice President of Revenue Cycle wrote to Miller, FVC's General Manager, and FVC's Vice President and CFO, stating: ". . . coding review below. Error rate of 13% with significant impact (negative) to revenue per procedure. Will need language to protect us in the event of audit . . . ." Attached to this email was a coding review for a FVAC facility that noted, among numerous other billing issues, instances in which "no documented hemodynamically significant stenosis identified in the report to justify angioplasty intervention" and "multiple angioplasties billed when only one angioplasty is reportable."

321. FVAC physicians were educated by FVC on its medical documentation, dictation guidelines, and coding policies. Training was conducted in person and documented as part of the physician onboarding process in a 466-page Physician Clinical Orientation Manual. Physician education continued throughout employment and included educational PowerPoints, created by FVC's Coding Manager, as well as the templates for patient dictations that were shared between the FVC Coding Manager, FVC Regional Directors, FVAC interventionalists, and Miller.

322. After a patient encounter concluded, an FVAC interventionalist created a record through a dictation and documented therein what procedures were performed and any indicators of alleged medical necessity. After a review of the dictation transcription and the associated medical records for the encounter, the FVC Coding Manager and FVC Coders sought and received clarifications and amendments to patient reports and dictations to maximize billing potential and note omitted medical necessity.

323. The Enrolled Entities then submitted the claims for payment to Medicare and Medicaid.

324. High level FVC executives, including Miller, were aware of the specifics of the claims process.

## V. EXAMPLES OF SPECIFIC INSTANCES OF FVACS PERFORMING UNNECESSARY PROCEDURES

325. The following case studies for the period of January 1, 2012 through June 30, 2018, are representative of the many thousands of instances in which Georgia, New Jersey, and New York FVACs performed medically unnecessary fistulagrams and angioplasties on ESRD patients. These case studies are examples and are not intended to be comprehensive.

### A. Examples of Georgia FVACs Performing Unnecessary Procedures

#### *i. Patient K*

326. Patient K is a 69-year-old with ESRD who receives dialysis treatments. After an initial referral, Patient K was subjected to numerous medically unnecessary fistulagrams and angioplasties at an Augusta, Georgia FVAC from December 2016 through at least April 2018. Georgia Medicaid paid for these visits and the procedures performed by Defendants at these visits. The below paragraphs include specific examples of just some of the false claims that Defendants submitted and caused to be submitted to Georgia Medicaid for Patient K.

327. Patient K was first seen at the FVAC on November 29, 2016 and again a few days later on December 1, 2016 pursuant to a referral from Patient K's treating nephrologist to address a clotted access in Patient K's fistula. In both instances, the referral forms submitted by Patient K's nephrologist indicated that the desired procedure was "declot."

328. Following these procedures to address Patient K's clotted access, the FVAC scheduled Patient K for a follow-up appointment for December 15, 2016.

329. Patient K was seen at the FVAC on December 15, 2016. Although there was no referral in the FVAC's files for this visit, the FVAC interventionalist performed a fistulagram. To justify the fistulagram, the FVAC's files noted an indication of "decreased bruit and/or thrill" which – like pulsatility – is a "soft" indicator of impaired vascular access. At this visit, the FVAC presented Patient K with an informed consent form, which stated that there were no "generally recognized and accepted practical alternatives" to the CTE procedures, and that if Patient K "cho[se] not to have the above procedure, [Patient K's] prognosis (future medical condition) is: Inability to properly dialyze." FVAC Augusta billed this procedure to Georgia Medicaid on December 21, 2016. The Internal Claim Number (ICN)[11] assigned to the FVAC's claim was *0150, and Georgia Medicaid subsequently reimbursed FVAC Augusta $533.54.

330. On March 7, 2017, Patient K returned to the FVAC. As before, the FVAC's medical records did not contain a referral. Further, Patient K had successfully received dialysis the day before this visit. The FVAC's records nonetheless included an indication of "decreased bruit and/or thrill," and the FVAC interventionalist performed a fistulagram and an angioplasty. At this visit, the FVAC presented Patient K with the same informed consent form warning that declining

[11] All ICNs have been redacted. The State of Georgia will produce them upon request pursuant to the Stipulated Protective Order approved and entered as an Order of the Court on July 10, 2023. Dkt. No. 100.

the CTE procedures would likely result in the "[i]nability to properly dialyze." FVAC Augusta billed this procedure to Georgia Medicaid on May 4, 2017. The ICN assigned to the FVAC's claim was *3820, and Georgia Medicaid subsequently reimbursed FVAC Augusta $1,055.04. Upon discharge, the FVAC scheduled a follow-up appointment for approximately four months later, on July 11, 2017.

331. Patient K was seen at the FVAC on July 18, 2017. Once again, there was no referral in the FVAC's files for this visit, and Patient K had successfully received dialysis the day before this visit. Here also the FVAC interventionalist performed a fistulagram and an angioplasty (and stent placement), and the FVAC's records included an indication of "decreased bruit and/or thrill" to justify the fistulagram. Patient K was again presented with the same informed consent form warning that declining the CTE procedures would likely result in the "[i]nability to properly dialyze." FVAC Augusta billed this procedure to Georgia Medicaid on July 21, 2017. The ICN assigned to the FVAC's claim was *8504, and Georgia Medicaid subsequently reimbursed FVAC Augusta $4,811.05. Upon discharge, the FVAC scheduled a follow-up appointment for approximately three months later.

332. Patient K was seen at the FVAC on March 29, 2018, again without a referral, and received a fistulagram and angioplasty. Patient K had successfully received dialysis the day before this visit, yet the FVAC's files included an indication of "decreased bruit and/or thrill." The FVAC once more presented Patient K with the informed consent form warning that declining the CTE procedures would likely result in the "[i]nability to properly dialyze." FVAC Augusta billed this procedure to Georgia Medicaid on May 15, 2018. The ICN assigned to the FVAC's claim was *8727, and Georgia Medicaid subsequently reimbursed FVAC Augusta $1,046.54. Upon discharge, the FVAC scheduled a follow-up appointment for three months later, on June 28, 2018.

333. Throughout the time period of Patient K's visits to the FVAC, she was under consistent monitoring by her treating nephrologist and dialysis team, which would identify any access issues that impaired dialysis administration and would make referrals to an FVAC for specific issues as appropriate. Indeed, Patient K's treating nephrologist and dialysis team referred her to an FVAC for specific issues that impaired dialysis administration on April 11, 2017, October 3, 2017, and April 18, 2018. These referrals, which typically specified the exact issue (such as "clotted access") and the desired procedure (such as "Declot"), demonstrate that Patient K was being monitored by her treating nephrologist and dialysis team, and thus accordingly there was no reason for the FVAC to schedule Patient K for "follow-up" appointments and to perform medically unnecessary fistulagrams and angioplasties when Patient K was successfully receiving dialysis.

334. Patient K was subsequently scheduled for sixteen appointments at an Augusta FVAC from April 2018 through February 2020, many of which included medically unnecessary "clinically timed" fistulagrams and angioplasties.

*ii. Patient L*

335. Patient L had ESRD and received dialysis treatments prior to passing away in 2020 at the age of 79. Patient L was subjected to numerous medically unnecessary fistulagrams and angioplasties at an Augusta, Georgia FVAC from July 2017 through at least February 2018. As a dual-eligible beneficiary, Patient L received coverage for ESRD services from both Medicare and Medicaid. The below paragraphs include specific examples of just some of the false claims that Defendants submitted and caused to be submitted to Georgia Medicaid for Patient L.

336. Patient L was seen at the FVAC on July 20, 2017. Although there was no referral in the FVAC's files for this visit, the FVAC interventionalist performed a fistulagram and an angioplasty on Patient L. At this visit, the FVAC presented Patient L with an informed consent form, which stated that there were no "generally recognized and accepted practical alternatives"

to the CTE procedures, and that if Patient L "cho[se] not to have the above procedure, [Patient L's] prognosis (future medical condition) is: Inability to properly dialyze." FVAC Augusta billed this procedure to Georgia Medicaid on August 8, 2017. The ICN number assigned to the FVAC's claim was *4044, and Georgia Medicaid subsequently reimbursed FVAC Augusta $436.51. Upon discharge, the FVAC scheduled a follow-up appointment for August 31, 2017.

337. On August 31, 2017, Patient L returned to the FVAC despite there being no referral in the FVAC's files for this visit. The FVAC interventionalist performed a fistulagram and an angioplasty. At this visit, the FVAC presented Patient L with the same informed consent form warning Patient L that declining the CTE procedures would likely result in the "[i]nability to properly dialyze." FVAC Augusta billed this procedure to Georgia Medicaid on September 20, 2017. The ICN number assigned to the FVAC's claim was *8074, and Georgia Medicaid subsequently reimbursed FVAC Augusta $93.01. Upon discharge, the FVAC scheduled a follow-up appointment for two months later.

338. Patient L was seen at the FVAC on January 4, 2018, again without a referral. The FVAC interventionalist performed a fistulagram and angioplasty, and the FVAC's medical records noted an indication of "decreased bruit/thrill" to justify the fistulagram. Here as well, Patient L was presented with the informed consent form warning that declining the CTE procedures would likely result in the "[i]nability to properly dialyze." FVAC Augusta billed the fistulagram and angioplasty procedures to Georgia Medicaid on January 30, 2018. The ICN assigned to the FVAC's claim was *9439, and Georgia Medicaid subsequently reimbursed FVAC Augusta $137.88. Upon discharge, the FVAC scheduled a follow-up appointment for February 1, 2018.

339. Patient L returned to the FVAC on February 15, 2018, and once again received a fistulagram, even though the FVAC's files lacked a referral. As before, the FVAC justified the

procedure via an indication of "decreased bruit and/or thrill." And as before, the FVAC presented Patient L with the same informed consent form warning that declining the CTE procedures would likely result in the "[i]nability to properly dialyze." FVAC Augusta billed the fistulagram to Georgia Medicaid on March 7, 2018. The ICN assigned to the FVAC's claim was *9961, and Georgia Medicaid subsequently reimbursed the FVAC Augusta $51.72. Upon discharge, the FVAC scheduled a follow-up appointment for three months later.

340. Throughout the time the FVAC was scheduling repeat appointments for Patient L, the functionality of her fistula was being monitored by her treating nephrologist and dialysis team, which would identify any access issues that impaired dialysis administration and would make referrals to the FVAC for specific issues as appropriate. Indeed, Patient L's treating nephrologist and dialysis team did refer her to an FVAC for specific issues that impaired dialysis administration on at least October 31, 2017 and November 21, 2017. These referrals, which typically specified the exact issue (such as "pain in arm and swelling"), demonstrate that Patient L was being monitored by her treating nephrologist and dialysis team, and that accordingly there was no reason for the FVAC to schedule Patient L for "follow-up" appointments and to perform medically unnecessary fistulagrams and angioplasties when Patient L was successfully receiving dialysis.

B. Examples of New Jersey FVACs Performing Unnecessary Procedures

*i. Patient M*

341. Patient M lived with ESRD and received dialysis treatments prior to passing away in March 2020, at the age of 85. Patient M endured at least three medically unnecessary fistulagrams and angioplasties at FVC centers, Verona Veins at Access Care Physicians and Azura Surgery Center, between August 2012 and May 2018. FVC billed these unnecessary fistulagrams and angioplasties to Medicare and New Jersey Medicaid and received reimbursement for the procedures.

342. Patient M visited FVC on August 31, 2012, and January 25, 2013, to address trouble with cannulation. Following the January 25, 2013, procedure, FVC scheduled Patient M for a follow-up appointment in six months. On August 21, 2013, Patient M returned to FVC where medical records indicate that the reason for the visit involved a timed "clinical evaluation." However, a review of the file did not evidence a referral for this visit. FVC performed a fistulagram and an angioplasty and billed these procedures to New Jersey Medicaid in the amount of $316.61. New Jersey Medicaid paid FVC $316.61. Upon discharge, FVC scheduled Patient M for a follow-up appointment on February 24, 2014.

343. On August 28, 2015, Patient M had an appointment at FVC, where the medical records note the reason for the visit as a timed "clinical evaluation." A file review did not locate a referral for this visit. However, file notes from a May 15, 2015, visit indicated that Patient M should return for a visit in three months. FVC performed a fistulagram and an angioplasty and billed these procedures to New Jersey Medicaid in the amount of $800.00, respectively. FVC received payment from New Jersey Medicaid of $64.24. Upon discharge, FVC scheduled Patient M for a follow-up appointment on November 25, 2015.

344. On March 23, 2016, Patient M was seen at FVC and the medical records again note the reason for the visit as a timed "clinical evaluation." However, the discharge sheet from Patient M's prior visit on December 2, 2015, directed the patient to return for a follow-up appointment on March 2, 2016. A review of FVC's file did not locate a referral for this visit. FVC performed a fistulagram and an angioplasty and billed these procedures to New Jersey Medicaid in the amount of $406.00. FVC received payment from New Jersey Medicaid of $32.58. Upon discharge, FVC scheduled a follow-up appointment for July 6, 2016.

345. Throughout the times FVC continued to schedule Patient M for repeat visits, the treating nephrologist and dialysis team provided referrals to FVC for a specific issue, namely an aneurysm, that impaired the administration of dialysis on August 13, 2014, May 27, 2015, and November 2, 2016. These referrals typically identified the reason for the referral, e.g. swollen extremity and the desired procedure, e.g. fistulagram, which demonstrates that Patient M's treating nephrologist and dialysis were indeed monitoring the functionality of the fistula.

346. During the same period, FVC saw Patient M on numerous occasions without a referral at intervals which strongly suggest unnecessary clinically timed evaluations, including on February 24, 2014, November 19, 2014*, March 18, 2015*, December 2, 2015, July 6, 2016*, February 18, 2017*, June 14, 2017*, September 20, 2017, January 10, 2018 and May 16, 2018. The * visits all purportedly sought to address an aneurysm.

*ii. Patient N*

347. Patient N endured at least 9 timed unnecessary fistulagrams and angioplasties from at least March 2013 to June 2018. FVC billed and received payment for these unnecessary procedures from Medicare and New Jersey Medicaid.

348. FVC saw Patient N for visits on March 11, 2013, May 27, 2014 and September 30, 2014, to address poor blood flow and venous pressure issues. On March 10, 2015, FVC's medical records indicate the reason for Patient N's visit as a timed "clinical evaluation." FVC's file did not include a referral for this visit. The discharge sheet for Patient N's November 1, 2014, visit indicates a follow-up appointment for March 10, 2015. FVC performed a fistulagram and an angioplasty and billed Medicare for $7,173.00, which resulted in reimbursement of $1834.71. Upon discharge, FVC scheduled a follow-up appointment for July 9, 2105.

349. On July 9, 2015, Patient N returned to FVC for the scheduled appointment. FVC's medical records note the reason for this visit as a timed "clinical evaluation." Again, Patient N's

file did not include a referral for the visit. FVC performed a fistulagram and an angioplasty and billed these procedures to both Medicare and New Jersey Medicaid in the amounts of $7,173.00 and $2,465.00, which resulted in reimbursements of $1,843.97 and $98.88 from the two programs. Upon discharge, FVC scheduled Patient N for a follow-up appointment on November 5, 2015.

350. Patient N returned to FVC on November 6, 2015, where the records reflect a reason for the visit as a timed "clinical evaluation." FVC's records did not include a referral for the visit. FVC performed a fistulagram and an angioplasty, billing Medicare and New Jersey Medicaid $7173.00 and $7,073.00, and received reimbursements of $1,842.91 and $468.75. Upon discharge, FVC scheduled Patient N for a follow-up appointment on March 17, 2016.

351. FVC actually saw Patient N on July 19, 2016, with a stated reason for this visit as "clinical evaluation." FVC's records did not include a referral for this visit. The discharge sheet for Patient N's March 15, 2016, visit noted a follow-up appointment scheduled for July 19, 2016. FVC performed a fistulagram and an angioplasty, and billed these procedures to Medicare and New Jersey Medicaid in the amount of $7,188.00 and $7,088.00, and received $1,839.79 and $467.82 reimbursement from the two programs. Upon discharge, FVC scheduled Patient N for a follow up appointment on November 8, 2016.

352. Patient N returned to FVC on November 8, 2016, as scheduled. FVC's medical records note the reason for this visit as a timed "clinical evaluation." FVC's files did not contain a referral for this visit. Despite the absence of a referral, FVC performed a fistulagram and an angioplasty and billed these procedures to Medicare and New Jersey Medicaid at rates of $7,188.00 and $7,088.00. FVC received reimbursements from the programs of $1,838.75 and $467.82. Upon discharge, FVC scheduled Patient N for a follow-up appointment on February 28, 2017. Patient N attended the February 28, 2017, appointment with FVC's records noting the reason

for the appointment as a timed "clinical evaluation." FVC's files did not contain a referral for this visit. Again, FVC performed a fistulagram and an angioplasty and billed theses services to Medicare in the amount of $3,683.00; Medicare paid $1,128.21. FVC discharged Patient N and scheduled a follow-up appointment for June 29, 2017.

353. On September 22, 2017**,** Patient N appeared at FVC; the medical records indicate the reason for this visit as a timed "clinical evaluation." FVC's files did not contain a referral for this visit. FVC performed a fistulagram and an angioplasty and billed these procedures to New Jersey Medicaid in the amount of $3,583.00. FVC received reimbursement in the amount $286.59. Upon discharge, FVC scheduled Patient N's follow-up appointment for January 18, 2018.

354. FVC saw Patient N on February 5, 2018, with the medical records noting the reason for the visit as a timed "clinical evaluation." The file did not contain a referral for the visit. FVC performed a fistulagram and an angioplasty and billed these procedures to New Jersey Medicaid in the amount of $3,679.00. New Jersey Medicaid subsequently reimbursed FVC $440.64. Upon discharge, FVC scheduled a follow-up appointment for June 8, 2018. Patient N returned to FVC as scheduled and the records indicate the reason for a visit as a timed "clinical evaluation." However, FVC's records did not contain a referral for the visit. Without a referral, FVC performed a fistulagram and an angioplasty and billed New Jersey Medicaid $16,790.00 for the procedures, which subsequently resulted in a payment of $1,343.14. Upon discharge, FVC scheduled a follow-up appointment for October 18, 2018.

355. Throughout the time during which FVC scheduled repeat appointments for Patient N, the treating nephrologist and dialysis team referred the patient to FVC for specific issues that impaired dialysis administration on May 23, 2014, March 15, 2016, May 5, 2017, and August 2, 2017. The associated referrals typically specified the reason for the referral, e.g swollen arm or

clotted access, support the conclusion that Patient N's treatment team actively participated in monitoring the patient's condition.

*iii. Patient O*

356. Patient O experienced at least two timed unnecessary fistulagrams and angioplasties at a New Jersey FVC center, Verona Veins at Access Care Physicians, between August 2014, and May 2018. FVC billed these unnecessary procedures to New Jersey Medicaid and received reimbursement for them, as well.

357. Patient O visited FVC on August 5, 2014, for a timed "clinical evaluation" and aneurysm evaluation. FVC's files did not contain a referral for this visit. FVC performed a fistulagram and an angioplasty and billed New Jersey Medicaid $2,472.00 for these procedures. FVC ultimately received reimbursement in the amount of $98.93. Upon discharge, FVC scheduled a follow-up appointment for November 6, 2014. Patient O returned to FVC for this appointment, noted as a timed "clinical evaluation." The file contained no referral for this visit. FVC performed a fistulagram and an angioplasty and billed New Jersey Medicaid in the amount of $7,172.00. FVC received $732.50 reimbursement for these services.

358. Throughout the time period of Patient O's visits at FVC, the treating nephrologist and dialysis team made referrals to FVC for specific issues that impaired the administration of dialysis on October 15, 2015, January 30, 2017 and November 20, 2017. The specified reason for the referrals, e.g. prolonged bleeding, demonstrated that Patient O's treating nephrologist and dialysis team were actively monitoring his condition.

359. During this same period, FVC treated Patient O numerous other times without a referral at intervals that strongly indicate a pattern of unnecessary "clinically timed evaluations," including on November 20, 2014*, March 12, 2015, July 21, 2015, March 4, 2016*, June 8, 2016*, November 4, 2016*, December 5, 2016**, May 1, 2017*, February 12, 2018*, and May 14, 2018.

The * visits purportedly occurred to address an aneurysm and the ** visit occurred one month after a catheter insertion.

C. Examples of New York FVACs Performing Unnecessary Procedures

*i. Patient B*[12]

360. 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. New York Medicaid paid, at least in part, for these visits and the procedures performed by Defendants at those visits.

361. At these 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."

362. To justify proceeding with an angioplasty, Patient B'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 B 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."

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

[12] This is the same Patient B that is referred to in paragraphs 242–248 of the Federal Amended Complaint-in-Intervention.

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

365. Of the 29 dates of service, Patient B's records indicate only three legitimate referrals. Over the course of six years, Patient B's dialysis records 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 repeated vascular access issues.

366. Defendants were aware that Patient B continuously and repeatedly returned to the FVAC in the Bronx for CTE appointments. *See* Exhibit 1 at rows 14038–14039.

*ii. Patient C*[13]

367. Patient C is a 58-year-old with ESRD who has received dialysis treatment for 14 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. New York Medicaid paid, at least in part, for these visits and the procedures performed by Defendants at those visits.

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

369. To justify proceeding with an angioplasty, Patient C's records always record stenoses of over 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.

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

[13] This is the same Patient C that is referred to in paragraphs 249–256 of the Federal Amended Complaint-in-Intervention.

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

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

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

374. Defendants were aware that Patient C continuously and repeatedly returned to the FVAC in Bronx for CTE appointments. *See* Exhibit 1 at rows 25350–25353.

*iii. Patient G*[14]

375. 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. New York Medicaid paid for these visits and the procedures performed by Defendants at those visits, at least in part.

376. 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.

377. 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.

[14] This is the same Patient G that is referred to in paragraphs 276–287 of the Federal Amended Complaint-in-Intervention.

378. 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.

379. 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.

380. 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.

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

382. To justify proceeding with an angioplasty, Patient G's records always record stenoses of over 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.

383. In total for this period, after a fistulagram, FVAC interventionalists, including Miller, performed at least 15 medically unnecessary angioplasties on Patient G.

384. 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 to make transportation arrangements. Following those instructions, Patient G visited the FVAC on each follow-up date.

385. 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.

386. Defendants were aware that Patient G continuously and repeatedly returned to the FVAC in Brooklyn for CTE appointments. *See* Exhibit 1 at rows 24939–24943.

D. Summary

387. In sum, from about January 1, 2012 through June 30, 2018, Defendants repeatedly performed medically unnecessary fistulagrams and angioplasties. The specific fraudulent practices described in this Complaint-in-Intervention are not limited to the particular patients detailed above, and these findings do not constitute the entirety of the false claims at issue in this action.

388. Exhibit 1 to the Federal Amended Complaint-in-Intervention is fully incorporated into this Complaint-in-Intervention (Dkt. Nos. 63-1, 63-2, and 63-3), and the statements, descriptions, data, and other facts described in that Exhibit are alleged as if fully set forth in the body of this Complaint-in-Intervention.

## CLAIMS FOR RELIEF

### CLAIMS OF THE STATE OF GEORGIA

#### Count One – Violation of the Georgia False Medicaid Claims Act (O.C.G.A. § 49-4-168.1(a)(1))

389. The State of Georgia re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

390. Defendants knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval to the Georgia Medicaid Program in violation of O.C.G.A. § 49-4-168.1(a)(1).

391. Under the Georgia False Medicaid Claims Act, O.C.G.A. § 49-4-168, "Knowing" and "knowingly" require no proof of specific intent to defraud and mean that a person, with respect to information:

(A) Has actual knowledge of the information;

(B) Acts in deliberate ignorance of the truth or falsity of the information; or

(C) Acts in reckless disregard of the truth or falsity of the information.

392. Defendants, by and through their agents, officers, and employees, knowingly submitted false claims to Georgia Medicaid for services provided to Medicaid beneficiaries that were not medically necessary, were not clinically appropriate, and were not properly documented.

393. Defendants submitted false claims to Georgia Medicaid for services that were not performed according to Georgia Medicaid policies. Defendants certified to Georgia Medicaid that they would comply with the Georgia Medicaid policies and procedures, including but not limited to the Part I manual. The materiality of Defendants' violations of Georgia Medicaid policies to the payment of claims is demonstrated by the certifications of compliance in the Electronic Funds Transfer agreement and the Verification of Policy Manuals statement, and by statements of policy in the DCH Part I manual. Because Defendants may not submit claims for payment that are rendered in violation of the Georgia Medicaid policies and procedures, all of the claims that Defendants presented to the Georgia Medicaid Program in violation of Georgia Medicaid policies and procedures are false or fraudulent. If the State of Georgia had known Defendants' claims were submitted in violation of Georgia Medicaid policies and procedures as alleged above, and their subsequent falsity, it would not have paid the claims.

394. Defendants had actual knowledge of or acted in deliberate ignorance or reckless disregard of the falsity of the submitted claims, and therefore knowingly presented or caused to be

presented false or fraudulent claims for payment or approval in violation of O.C.G.A. § 49-4-168.1(a)(1).

395. As a direct and proximate result of the false or fraudulent claims Defendants knowingly presented or caused to be presented, the State of Georgia has suffered actual damages in an amount to be determined at trial and is entitled to damages plus a civil penalty in the amount of three times the amount of any excess benefit or payment, plus a civil penalty for each false claim presented.

**Count Two – Violation of the Georgia False Medicaid Claims Act (O.C.G.A. § 49-4-168.1(a)(2))**

396. The State of Georgia re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

397. The Georgia False Medicaid Claims Act, O.C.G.A. § 49-4-168.1(a)(2), imposes liability on any person who knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim.

398. Defendants, by and through their agents, officers, and employees, knowingly made, used, or caused to be made or used false records or statements material to false or fraudulent claims paid or approved by the Georgia Medicaid Program, in violation of O.C.G.A. § 49-4-168.1(a)(2). Defendants made, used and/or caused to be made or used numerous false records and statements, including false statements in, inter-alia, Electronic Funds Transfer Agreements, wherein Defendants agreed to abide by all federal and state laws governing the Georgia Medicaid Program, as well as to comply with all Georgia Medicaid policies. Defendants further made, used, or caused to be made or used false records or statements by adding soft indicators of impaired vascular access and inflated indicators of stenosis to patient medical records to justify medically unnecessary

procedures. Utilizing these false records and statements, Defendants submitted or caused to be submitted false claims for payment to Georgia Medicaid.

399. If the State of Georgia had known of the falsity of Defendants' representations, it would not have paid the claims.

400. Defendants had actual knowledge of or acted in deliberate ignorance or reckless disregard of the falsity of their representations, and therefore knowingly made, used, or caused to be made or used false records or statements material to false or fraudulent claims in violation of O.C.G.A. § 49-4-168.1(a)(2).

401. As a direct and proximate result of the false or fraudulent records and statements Defendants knowingly made, used or caused to be made or used, the State of Georgia has suffered actual damages in an amount to be determined at trial and is entitled to damages plus a civil penalty in the amount of three times the amount of any excess benefit or payment, plus a civil penalty for each false claim presented.

**Count Three – Violation of the Georgia False Medicaid Claims Act (O.C.G.A. § 49-4-168.1(a)(7))**

402. The State of Georgia re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

403. The Georgia False Medicaid Claims Act, O.C.G.A. § 49-4-168.1(a)(7), imposes liability on any person who knowingly and improperly avoids or decreases an obligation to pay or transmit property or money to the Georgia Medicaid Program.

404. Defendants, by and through their agents, officers, and employees, knowingly and improperly avoided their obligation to pay or transmit property or money to the Georgia Medicaid Program, in violation of O.C.G.A. § 49-4-168.1(a)(7).

405. Defendants knew that they were submitting claims for services that were not medically necessary as required by Georgia Medicaid and were therefore not covered by Georgia Medicaid.

406. Defendants knew that they received payments from Georgia Medicaid for these claims.

407. Defendants therefore had an obligation to pay or transmit the funds received pursuant to these claims back to Georgia Medicaid.

408. Defendants did not pay or transmit these funds back to Georgia Medicaid.

409. Defendants had actual knowledge of or acted in deliberate ignorance or reckless disregard of their obligation to pay or transmit property or money to the Georgia Medicaid Program, and therefore knowingly and improperly avoided said obligation in violation of O.C.G.A. § 49-4-168.1(a)(7).

410. As a direct and proximate result of Defendants' knowing and improper avoidance of their obligation to pay or transmit property or money to the Georgia Medicaid Program, the State of Georgia has suffered actual damages in an amount to be determined at trial and is entitled to damages plus a civil penalty in the amount of three times the amount of any excess benefit or payment, plus a civil penalty for each false claim Defendants failed to pay or transmit back to Georgia Medicaid.

**Count Four – Fraud and Deceit**

411. The State of Georgia re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

412. Per Georgia statute, "[f]raud, accompanied by damage to the party defrauded, always gives a right of action to the injured party." O.C.G.A. § 51-6-1.

413. Defendants knowingly made or caused to be made fraudulent statements to the United States and the State of Georgia, and specifically to the Medicare and Medicaid Programs, regarding patient referrals and diagnoses.

414. Defendants made the fraudulent statements with the intent and purpose of deceiving the State of Georgia regarding the amount it owed in rebates to the Georgia Medicaid Program.

415. Georgia reasonably relied upon Defendants fraudulent misrepresentations.

416. As a result of Defendants' conduct, the State of Georgia suffered harm and is entitled to recovery of actual damages plus prejudgment interest.

## CLAIMS OF THE STATE OF NEW JERSEY

### Count Five
### Violation of the New Jersey False Claims Act: N.J.S.A. 2A:32C-1 *et seq.*

417. The State of New Jersey repeats and realleges the allegations contained in all of the preceding paragraphs as if fully set forth herein.

418. The NJ FCA, N.J.S.A. 2A:32C-2, provides the following definitions relative to false claims:

"Claim" means any request or demand, under a contract or otherwise, for money or property, whether or not the State has title to the money or property, or for services, that is made to any employee, officer, or agent of the State, or is made to any contractor, grantee, or other recipient if the money, property or service is to be spent or used on the State's behalf or to advance a State program or interest, if the State provides or has provided any portion of the money, property, or services requested or demanded or if the State will reimburse the contractor, grantee, or other recipient for any portion of the money, property or services requested or demanded.

"Knowing" or "knowingly" means, with respect to information, that a person:

(1) has actual knowledge of the information; or

(2) acts in deliberate ignorance of the truth or falsity of the information; or

(3) acts in reckless disregard of the truth or falsity of the information.

No proof of specific intent to defraud is required.

"Material" means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.

"Obligation" means an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment.

419. Through the acts set forth above, Defendants, acting with actual knowledge or with deliberate ignorance or reckless disregard of the truth, presented, either directly or indirectly, false or fraudulent claims for payment to the State of New Jersey.

420. Through the acts set forth above, Defendants, by and through their agents, officers, and employees, knowingly presented, or caused to be presented, to the State of New Jersey, false or fraudulent claims for reimbursement of unnecessary and unreasonable services provided to Medicaid beneficiaries. Accordingly, Defendants presented false submissions to the State of New Jersey for reimbursement of Medicaid expenditures in violation of NJFCA, N.J.S.A. 2A:32C-2.

421. Defendants submitted false claims to New Jersey Medicaid for services that they did not perform according to the State's Medicaid policies and procedures. Though Defendants agreed to comply with these directives, they materially disregarded and violated policies related to the submission of claims for unnecessary services. If the State of New Jersey had known of the Defendants practices and the falsity of the claims submitted, it would not have paid the claims.

422. As a direct and proximate result of the false or fraudulent claims Defendants knowingly presented or caused to be presented, the State of New Jersey has suffered actual damages in an amount to be determined at trial and is entitled to damages, plus a civil penalty in the amount of three times the amount of any excess benefit or payment, plus a civil penalty for each false claim presented.

423. Therefore, the State of New Jersey seeks relief against Defendants under Section 2A:32C-2 of the NJ FCA.

**Count Six**
**Violation of the New Jersey False Claims Act**
**N.J.S.A. 2C:32-3**

424. The State of New Jersey repeats and realleges the allegations contained in all of the preceding paragraphs as if fully set forth herein.

425. In the context of this litigation, the NJ FCA imposes civil liability for any person who commits any of the following acts:

a. Knowingly presents or causes to be presented, a false or fraudulent claim for payment or approval;

b. Knowingly makes, uses or causes to be made or used a false record or statement material to a false or fraudulent claim;

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 State, or knowingly conceals or knowingly avoids or decreases an obligation to pay or transmit money or property to the State.

426. As set forth above, Defendants knowingly presented or caused to be presented false and/or fraudulent claims for payment or approval to the New Jersey Medicaid Program.

427. Furthermore, Defendants used, or caused to be made, a false record or statement material to a false or fraudulent claim. Defendants provided indicators of vascular access impairment and stenosis to patient records to justify medically unnecessary procedures. By creating these false records of patient conditions, Defendants knowingly made material statements relating to a false or fraudulent claim.

428. If the State of New Jersey had known of Defendants' false representations, it would not have paid the claims.

429. Under N.J.S.A. 2A:32C-3.g, a person shall be jointly or severally liable to the State for a civil penalty of not less than and not more than the civil penalty allowed under the federal False Claims Act (31 U.S.C. § 3729, *et seq.*). This amount may be adjusted in accordance with the inflation adjustment procedures prescribed in the Federal Civil Penalties Inflation Adjustment Act of 1990, Pub.L.101-410, for each false or fraudulent claim, plus three times the amount of damages which the State sustains.

430. Through the acts set forth above, Defendants, acting with actual knowledge or with deliberate ignorance or reckless disregard of the truth, presented, either directly or indirectly, false or fraudulent claims for payment to the State of New Jersey, by and through their agents, officers, and employees, knowingly presented, or caused to be presented, to the State of New Jersey, false or fraudulent claims for reimbursement of unnecessary and unreasonable services provided to Medicaid beneficiaries. Accordingly, Defendants presented false submissions to the State of New Jersey for reimbursement of Medicaid expenditures in violation of the NJFCA.

431. Defendants, by and through their agents, officers and employees, knowingly and improperly avoided their obligations to pay or transmit property or money to the State of New Jersey's Medicaid Program.

432. Defendants knowingly submitted claims for medically unnecessary services in violation of New Jersey Medicaid policies. Consequently, New Jersey Medicaid would deem those claims as not covered.

433. Defendants knew that payments received for these uncovered claims created an obligation to return the funds back to New Jersey Medicaid.

434. Defendants did not remit any funds back to New Jersey Medicaid.

435. Defendants had actual knowledge of or acted in deliberate ignorance or reckless disregard of their obligation to pay or transmit property or money to the New Jersey Medicaid Program, and therefore, knowingly and improperly avoided said obligation in violation of N.J.S.A. 2A:32C-3.g.

436. As a direct and proximate result of the Defendants submission of: (1)false or fraudulent claims under N.J.S.A. 2A:32C-3.a, (2) false or fraudulent records and statements under N.J.S.A. 2A:32C-3.b, both of which Defendants knowingly made, used or caused to be made or used, to submit for false payments to New Jersey Medicaid; and (3) Defendants knowing and improper failure to remit payments to New Jersey Medicaid in violation of its obligation to pay or transmit property or money to the State of New Jersey under N.J.S.A. 2A:32C-3.g, the State of New Jersey has suffered actual damages in an amount to be determined at trial and is entitled to damages plus a civil penalty in the amount of three time the amount of any excess benefit or payment, plus a civil penalty for each false claim presented.

**Count Seven**
**Common Law Fraud**

437. The State of New Jersey repeats and realleges the allegations contained in all of the preceding paragraphs as if fully set forth herein.

438. In New Jersey, the elements of common-law fraud are:

(1) a material misrepresentation of a presently existing or past fact;

(2) knowledge or belief by the defendant of its falsity;

(3) an intention that the other person rely on it;

(4) reasonable reliance thereon by the other person; and

(5) resulting damages.

439. Defendants made and/or caused to be made fraudulent statements to the United States and the State of New Jersey, and specifically to the Medicare and Medicaid Programs, regarding patient referrals and diagnoses.

440. Defendants made and/or caused to be made these fraudulent material misrepresentations, failing to disclose material facts that they had a duty to disclose, with actual knowledge or belief of the false and fraudulent nature of those misrepresentations and/or with reckless disregard for the truth.

441. Defendants intended that the State of New Jersey act or refrain from acting in justifiable reliance on these fraudulent misrepresentations.

442. The State of New Jersey reasonably relied on Defendants' fraudulent misrepresentations.

443. As a result, the State of New Jersey paid Defendants amounts to which they were not entitled, by paying the Medicaid claims on the basis of Defendants' fraudulent misrepresentations.

444. Consequently, the State of New Jersey suffered harm and is, therefore, entitled to recovery of actual damages, in an amount to be determined at trial, plus prejudgment interest.

**Count Eight**
**Unjust Enrichment**

445. The State of New Jersey repeats and realleges the allegations contained in all of the preceding paragraphs as if fully set forth herein.

446. Through the acts set forth above, Defendants received Medicaid payments from the State of New Jersey to which they were not entitled and therefore have been unjustly enriched. The State of New Jersey paid claims submitted to Medicaid by Defendants based on false statements and records.

**CLAIMS OF THE STATE OF NEW YORK**

**Count Nine – Violation of the New York False Claims Act**
**(N.Y. State Fin. Law § 189(1)(a))**

447. The State of New York repeats and realleges the allegations contained in all of the preceding paragraphs as if fully set forth herein.

448. The State of New York seeks relief against Defendants under Section 189(1)(a) of the New York False Claims Act.

449. Through the acts set forth above, Defendants, acting with actual knowledge or with deliberate ignorance or reckless disregard of the truth, presented, either directly or indirectly, false or fraudulent claims for payment to the State.

450. Defendants, by and through their agents, officers, and employees, knowingly presented, or caused to be presented to New York State false or fraudulent claims for reimbursement of services provided to Medicaid beneficiaries that were not reasonable and necessary, were not clinically appropriate, and were not properly documented. Accordingly, Defendants presented false submissions to the State of New York for reimbursement of Medicaid expenditures in violation of New York's False Claims Act, New York State Finance Law § 189(1)(a).

451. New York made payments to Defendants because of the false or fraudulent claims.

452. If New York had known that Defendants had made false claims, it would not have reimbursed Defendants for those claims.

453. By reason of the false or fraudulent claims, the State of New York has sustained damages in a substantial amount to be determined at trial and is entitled to treble damages plus a civil penalty for each violation.

**Count Ten – Violation of the New York False Claims Act**
**(N.Y. State Fin. Law § 189(1)(b))**

454. The State of New York repeats and realleges the allegations contained in all of the preceding paragraphs as if fully set forth herein.

455. The State of New York seeks relief against Defendants under Section 189(1)(b) of the New York False Claims Act.

456. Through the acts set forth above, Defendants, acting with actual knowledge or with deliberate ignorance or reckless disregard of the truth, made, used, or caused to be made or used false records and statements material to false or fraudulent claims to the State. Specifically, Defendants, by and through their agents, officers, and employees, acting with actual knowledge or with deliberate ignorance or reckless disregard of the truth, made, used, or caused to be made or used, false records or statements material to false or fraudulent claims paid or approved by New York State for reimbursement of services provided to Medicaid beneficiaries that were not reasonable and necessary, were not clinically appropriate, and were not properly documented. Accordingly, Defendants presented false submissions to the State of New York for reimbursement of Medicaid expenditures in violation of New York's False Claims Act, New York State Finance Law § 189(1)(b).

457. If New York had known that the records and statements were false, it would not have paid the claims.

458. By reason of these false records and statements, the State of New York has sustained damages in a substantial amount to be determined at trial and is entitled to treble damages plus a civil penalty for each violation.

**Count Eleven – Violation of the New York False Claims Act**
**(N.Y. State Fin. Law § 189(1)(g) and (h))**

459. The State of New York repeats and realleges the allegations contained in all of the preceding paragraphs as if fully set forth herein.

460. Defendants, by and through their agents, officers, and employees, acting with actual knowledge or with deliberate ignorance or reckless disregard of the truth, made, used, or caused to be made or used, a false record or statement material to an obligation to pay or transmit money to the state.

461. Defendants, acting with actual knowledge or with deliberate ignorance or reckless disregard of the truth, concealed or improperly avoided or decreased an obligation to pay or transmit money to the State of New York in violation of New York State Finance Law § 189(1)(g) and (h).

462. By reason of these false records and statements, the State of New York has sustained damages in a substantial amount to be determined at trial and is entitled to treble damages plus a civil penalty for each violation.

**Count Twelve – Violation of New York Social Services Law**
**(N.Y. Soc. Serv. Law § 145-b)**

463. The State of New York repeats and realleges the allegations contained in all of the preceding paragraphs as if fully set forth herein.

464. New York Social Services Law § 145-b provides, in pertinent part, that: "It shall be unlawful for any person, firm or corporation knowingly by means of a false statement or representation, or by deliberate concealment of any material fact, or other fraudulent scheme or device, on behalf of himself or others, to attempt to obtain or to obtain payment from public funds for services or supplies furnished or purportedly furnished pursuant to this chapter."

465. As set forth above, Defendants knowingly, or acting with deliberate ignorance or in reckless disregard for the truth, made or used false statements or misrepresentations—in the form of false certifications, false referrals, and false diagnoses—and deliberately concealed that they had made or used these false statements or representations, to improperly obtain payments from the New York Medicaid Program.

466. By reason of the foregoing, Defendants are liable, pursuant to New York Social Services Law § 145-b, to the State of New York for treble damages, penalties, and costs.

**Count Thirteen – Repeated and Persistent Fraud**
**(N.Y. Exec. Law § 63(12))**

467. The State of New York repeats and realleges the allegations contained in all of the preceding paragraphs as if fully set forth herein.

468. New York Executive Law § 63(12) makes "repeated fraudulent . . . acts or . . . persistent fraud . . . in the carrying on, conducting or transaction of business" actionable by the Attorney General of the State of New York.

469. By engaging in the acts and practices described above, Defendants have engaged in repeated fraudulent acts or persistent fraud in violation of New York Executive Law § 63(12).

470. By reason of the foregoing, Defendants are liable to the State of New York for damages in an amount to be determined at trial.

**Count Fourteen – Repeated and Persistent Illegal Conduct**
**(N.Y. Exec. Law § 63(12))**

471. The State of New York repeats and realleges the allegations contained in all of the preceding paragraphs as if fully set forth herein.

472. New York Executive Law § 63(12) makes "repeated . . . illegal acts or . . . persistent . . . illegality in the carrying on, conducting or transaction of business" actionable by the Attorney General of the State of New York.

473. Defendants' violations of the New York False Claims Act, State Finance Law § 189(1), and of New York Social Services Law § 145-b constitute repeated and persistent illegal conduct in violation of New York Executive Law § 63(12).

474. By engaging in the acts and practices described above, Defendants have engaged in repeated illegal acts or persistent illegal conduct in violation of New York Executive Law § 63(12).

475. By reason of the foregoing, Defendants are liable to the State of New York for damages, in an amount to be determined at trial.

**Count Fifteen – Misappropriation of Public Property**
**(N.Y. Exec. Law § 63-c)**

476. The State of New York repeats and realleges the allegations contained in all of the preceding paragraphs as if fully set forth herein.

477. The acts and practices of Defendants complained of herein constitute a misappropriation of public property, in violation New York Executive Law § 63-c.

478. By reason of the foregoing, the State of New York is entitled to restitution from Defendants in an amount yet to be determined, but at least in the amount of the illegally retained and obtained Medicaid funds, plus the maximum amount of interest available under law.

**Count Sixteen – Common Law Fraud**

479. The State of New York repeats and realleges the allegations contained in all of the preceding paragraphs as if fully set forth herein.

480. Defendants made and/or caused to be made fraudulent statements to the United States and the State of New York, and specifically to the Medicare and Medicaid Programs, regarding patient referrals and diagnoses.

481. Defendants made and/or caused to be made these fraudulent material misrepresentations, failing to disclose material facts that they had a duty to disclose, with actual knowledge or belief of the false and fraudulent nature of those misrepresentations and/or with reckless disregard for the truth.

482. Defendants intended that the State of New York act or refrain from acting in justifiable reliance on these fraudulent misrepresentations.

483. The State of New York did, in fact, rely on Defendants' fraudulent misrepresentations. As a result, the State of New York paid Defendants amounts to which they were not entitled, by paying the Medicaid claims on the basis of Defendants' fraudulent misrepresentations.

484. As a result of Defendants' conduct, the State of New York suffered harm and is entitled to recovery of actual damages, in an amount to be determined at trial, plus prejudgment interest.

**Count Seventeen – Unjust Enrichment**

485. The State of New York repeats and realleges the allegations contained in all of the preceding paragraphs as if fully set forth herein.

486. Through the acts set forth above, Defendants received Medicaid payments from the State of New York to which they were not entitled and therefore have been unjustly enriched. The

State of New York paid claims submitted to Medicaid by Defendants based on false statements and records.

487. The circumstances of these payments are such that Defendants have been unjustly enriched. In equity and good conscience, Defendants should not retain these payments, and are liable to account for and pay such amounts, which are to be determined at trial, to the State of New York.

**Count Eighteen – Payment Under Mistake of Fact**

488. The State of New York repeats and realleges the allegations contained in all of the preceding paragraphs as if fully set forth herein.

489. The State of New York seeks relief against Defendants to recover monies paid under mistake of fact.

490. The State of New York paid money to Defendants based on the claims and certifications submitted by Defendants, under the erroneous belief that Defendants' claims were truthful and that Defendants' certifications of compliance with federal and state law and regulation were truthful.

491. In making such payments, the State of New York relied upon and assumed the truth of those certifications and claims. This erroneous belief was material to the State of New York's decision to pay Defendants the amounts paid. In such circumstances, the State of New York's payments to Defendants were by mistake and were not authorized.

492. Because of these payments by mistake, Defendants received monies to which they are not entitled.

493. By reason of the foregoing, the State of New York was damaged in a substantial amount to be determined at trial.

## PRAYER FOR RELIEF

WHEREFORE, the Intervening States request that judgment be entered in their favor and against Defendants on each count of this Complaint and that the Court impose damages, including treble damages, and penalties as described above and to the full extent allowed by law and in equity and award all costs and fees as applicable under state law.

## DEMAND FOR JURY TRIAL

The Intervening States demand a jury trial for all issues so triable.

Dated: New York, New York
October 2, 2023

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