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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA, *ex rel.* CHARLES M. HOLZNER, M.D., Plaintiffs, vs. DAVITA INC., a Delaware Corporation; DAVITA KIDNEY CARE, a business entity, form unknown; DAVITA RX, LLC, a Delaware Limited Liability Company, Defendants.	Case No. SACV18-1250-JLS(DFMx) [The Hon. Josephine L. Staton] FOURTH AMENDED COMPLAINT FOR VIOLATIONS OF THE FALSE CLAIMS ACT; REQUEST FOR JURY TRIAL

COMES NOW, Plaintiff and *Qui Tam* Relator Charles M. Holzner, M.D., individually and on behalf of the United States of America, and alleges as follows:

INTRODUCTION

This Complaint alleges a complex fraud schemes based upon the defendants' knowing provision of medically unnecessary services and/or failing to provide equally efficacious and less expensive treatment options. The defendants provided these services, not because they improved the care and treatment of their End Stage Renal Disease (ESRD) patients, but

because the provision of such services optimized defendants profits. This Complaint alleges three different fraud schemes:

(a) The medically unnecessary premature initiation of dialysis treatments and subsequent prophylactic dialysis treatments, which are known to be of no medical benefit and are therefore medically unnecessary to the ESRD patients receiving them and are in fact harmful to senior ESRD patients;

(b) The medically unnecessary prescribing and administering of Sensipar, also known as cinacalcet, to lower the patients parathyroid hormone (PTH) levels and used on the debunked theory that doing so reduces cardiac events and cardiac co-morbidities. However, in 2012 a randomized controlled trial, commonly known as The EVOLVE Trial and funded by cinacalcet's manufacturerer, showed "cinacalcet did not significantly reduce the risk of death or major cardiovascular events in patients with moderate-to-severe secondary hyperparathyroidism who were undergoing dialysis" making the drug's continued use for ESRD patients medically unnecessary and showed the drug had no benefit on extending patients lives nor in reducing cardiac-related events, rendering the drug's continued use medically unnecessary for ESRD patients; and

(c) The medically unnecessary and cost ineffective prescribing and administering of Renagel, a non-calcium based phosphate binder, which can easily be substituted for nearly all ESRD patients with much less expensive over the counter (OTC) calcium based phosphate binders such as TUMS.

Approximately 30% of the annual dialysis treatments provided by defendant DaVita Kidney Care's (DKC) dialysis facilities are initiated prematurely, based upon an estimated creatinine clearance level of between eGFR 25 mL/min and eGFR 10 mL/min which purportedly indicates a worsening of the patient's chronic kidney disease (CKD). These early dialysis initiations are provided by DKC facilities to patients that do not yet have End Stage Renal Disease (ESRD) as such patients do not exhibit symptoms indicating the onset of uremia

or some other compelling medical reason, such as fluid overload, to justify starting dialysis. These premature dialysis initiations and subsequent treatments are given prophylactically, based upon nephrologists' once commonly held, but unsupported, belief that such prophylactic dialysis treatments improve residual kidney function and/or delay the erosion of such residual kidney function. Conversely, many nephrologists once commonly believed, despite the lack of supporting medical research, that waiting until the patient was close to a uremic state was potentially harmful.

Both of these once commonly held beliefs were conclusively disproved in August 2010 when the New England Journal of Medicine (NEJM) published what is known as the IDEAL Study. The IDEAL Study was the first and remains the only randomized controlled trial (RCT) addressing the timing of dialysis initiation. RCTs are considered the gold standard for conclusively determining the safety and efficacy of a particular drug or treatment and are almost universally required by the Federal Drug Administration (FDA) as part of the drug approval process. The IDEAL Study analyzed the timing and effects of "Early" verses "Late" dialysis initiation and treatment by studying 828 ESRD patients over a 3.5 year period. To control variables related to differences in health status and access to pre-dialysis care, the average age of the patients was restricted to 60 years old, all participants had to have received pre-dialysis care from a nephrologists for a year prior to beginning dialysis and except for having CKD, all trial participants were relatively "healthy." Additionally trial participants could not be suffering from any serious comorbidities such as diabetes or vascular disease.

The "Early," i.e., premature, dialysis initiations were randomized for patients to begin once their estimated creatinine clearance levels were between approximately eGFR of 14mL/min and 10 mL/min while the "Late" initiations were to based upon the presentation of clinical symptoms of the onset of uremia and with a target estimated creatinine clearance level of between eGFR 5mL/min and 7mL/min. This difference between Early and Late dialysis initiations resulted in the Late dialysis initiations beginning dialysis treatments, on average, six months after the Early group began their dialysis treatments. After each group's members had received dialysis for 3.5 years approximately 35% of the members in the Early group and

35% of the members in the Late group had died with no significant statistical differences in other comorbidities or hospitalization rates.

The key conclusions drawn from the IDEAL Study are (a) there is no medical benefit to initiating dialysis Early based upon a specific estimated creatinine clearance level such as eGFR between 15 mL/min and 10 mL/min, (b) there is no harm to ESRD patients in waiting to begin dialysis until they have clinical symptoms indicating the onset of uremia or some other compelling medical reason, and (c) prophylactic dialysis does not provide any improvement in residual kidney function. The IDEAL Study's conclusions have been accepted as the best available evidence regarding the timing of dialysis by CDK and ESRD research and policy organizations world wide, including the United States. The cost to Medicare from DaVita and DKC's provision of medically unnecessary premature dialysis treatments are approximately $1 billion to $2 billion per year.

During and between 2011 and 2017, nearly every ESRD patient of defendants was prescribed Sensipar or Renagel from the beginning of the patient's dialysis treatments until the end of their lives. The cost of each of these medications is approximately $700 per month. Between the two medically unnecessary/cost ineffective medications, the defendants charged the Medicare program approximately $1 billion per year in additional claims so the defendants could generate approximately $200 million per year in additional profits.

The ESRD program covers approximately 0.8% of the Medicare population, but consumes close to 10% of the total Medicare budget. Dialysis services cost Medicare approximately $90,000 per patient per year. Due to the stratospheric dialysis expenses involved, this Complaint unmasks one the nation's largest and widespread fraud schemes in the Medicare program's history.

This case also requires the Court to address an issue of first impression regarding the statutory obligations of DKC's dialysis facilities. The ESRD Conditions of Coverage For ESRD Facilities (i.e., 42 C.F.R. §§ 494.1-494.180) were substantially revised in 2008. Pursuant to the new requirements, each dialysis facility through its sole medical director is responsible for all patient care and outcomes. Further, the dialysis facility's medical director

must participate in the development, approval and enforcement of patient care policies and ensure that such policies are followed by all facility staff, included contracted nephrologists. Patients are admitted to a DKC dialysis facility by an initial dialysis prescription from the patient's treating nephrologist. In order to refer and admit ESRD patients to a DKC dialysis facility, the nephrologist must become credentialed by that dialysis facility as a member of the facility's staff. Such nephrologists are referred to as staff nephrologists. This is similar to the process that a hospital undertakes in granting admitting privileges to physicians.

Relator contends and alleges that in light of the IDEAL Study and the adoption of its conclusions by the National Kidney Foundation's (NKF), 2015 K/DOQI updated guidelines, among any others, DKC and its medical directors were required to implement and enforce policies and procedures to review the appropriateness of the all initial dialysis prescriptions to prohibit providing (a) medically unnecessary prophylactic dialysis initiations and treatments given to ESRD patients that do not yet exhibit clinical symptoms indicating the onset of uremia, (b) medically unnecessary dialysis treatments to patients over 85 years old who are all unlikely to survive the first twelve months of dialysis and may benefit from a conservative CKD treatment options rather than hemodialysis.

DKC's medical directors must similarly implement and enforce policies and procedures that require the patient's interdisciplinary team's (IDT) initial patient assessment to identify and potentially discontinue previously initiated medically unnecessary dialysis treatments for the reasons stated above. The Defendant's position is that timing of dialysis initiation is between the patient and their nephrologists, including but not limited to, DKCs' provision of medically unnecessary prophylactic dialysis treatments, as long as such treatments are pursuant to an authentic order from a staff nephrologists. Defendants' position is incorrect as a matter of law and policy as will be shown by the Fourth Amended Complaint

Relator further contends and alleges that in light of the EVOLVE Trials which concluded that Sensipar has no effect on improving ESRD patient's morbidity and all cause mortality, similar policies must be implemented to curtail its use to only those instances when Sensipar is medically necessary. Likewise, Relator contends similar policies must be

implemented to curtail the liberal prescribing of the phosphate blocker Renagel, in light of the paucity of research demonstrating advantages for using it over equally effective, safer and more cost effective calcium based phosphate blockers such as TUMS. Renagel's medical necessity cannot be maintained when it is prescribed chiefly to increase defendants profits as opposed to valid clinical reason. Of course, adopting the policies described hereinabove are not in the Defendants' financial interest as their compliance will cause significant reduction in revenue and profits.

These nationwide frauds caused the United States Government and numerous Medicare Advantage health plans to pay several billion dollars of false and fraudulent claims in violation of the False Claims Act, 31 U.S.C. § 3729(a) et seq.

JURISDICTION AND VENUE

1. Plaintiff and *Qui Tam* Relator Charles M. Holzner, M.D. (Relator) files this action on behalf and in the name of the United States of America (Government) seeking damages and civil penalties against the defendants for violations of 31 U.S.C. § 3729(a).

2. This Court's jurisdiction over the claims for violations of 31 U.S.C. § 3729(a) is based upon 31 U.S.C. § 3732(a). Venue is vested in this Court under 31 U.S.C. § 3732(a) and 28 U.S.C. § 1391(b) because at least one of the defendants can be found in, resides in and/or transacts business in the Central District of California and many acts constituting violations of 31 U.S.C. § 3729(a) occurred in the Central District of California.

THE PARTIES

3. Relator is a citizen of the United States and resident of the State of California. Relator brings this action on behalf of the Government under 31 U.S.C. § 3730(b).

4. At all times relevant, the Government funded the Medicare Program (Medicare) which provides payment of healthcare services for, among others, those 65 years of age and older. Medicare is a health insurance program administered by the Government that is funded by federal taxpayer revenue. Medicare is overseen by the Government's Health and Human Services Department (HHS) and administered by the HHS's Centers for Medicare and Medicaid Services (CMS). Additionally, at all times relevant the Government funds, pays for,

partially funds or partially pays for the Medicaid program administered in each of States in the United States. The Medicaid program provides healthcare benefits to individuals and families having low income and resources.

5. At all times relevant, CMS provided a Medicare option known as Medicare Advantage (MA), previously known as Medicare+Choice, in which eligible Medicare beneficiaries can enroll with a Medicare Advantage organization (MAO) contracted with the Government (for a capitated rate paid by the Government to the MAO) that would provide at least those services provided to standard (i.e., fee-for-service) Medicare beneficiaries.

6. The Civilian Health and Medical Program of the Uniformed Services (CHAMPUS) is a Government-funded program administered by the Government's Department of Defense that provides medical benefits to retired members of the Uniformed Services and to spouses and children of active duty, retired and deceased members of the Uniformed Services, as well as of reservists who were ordered to active duty for 30 days or longer.

7. The Civilian Health and Medical Program of the Veterans Administration (CHAMPVA) provides similar benefits for spouses and children of veterans who are entitled to Veteran's Administration (VA) permanent and total disability benefits and to widows and children of veterans who died of service-related disabilities. The program is administered by the Government's Department of Defense and funded by the Government.

8. Medicare, Medicaid, MAOs, CHAMPUS and CHAMPVA are collectively referred as the "Government Funded Payors," and meet the definition of a federally funded healthcare program or service under 42 U.S.C. § 1320a-7b(f).

9. At all times relevant, defendant DaVita Inc. (DaVita) is and was a corporation formed under the laws of the State of Delaware, and maintained offices and transacted business in, among other places, the Central District of California. DaVita is a Fortune 500 company with over $10 billion in annual revenues.

10. At all times relevant, defendant DaVita Kidney Care (DKC) is and was a wholly owned subsidiary of DaVita whose business form is currently unknown. DKC has locations

in and conducts business in, among other places, the Central District of California. DKC operates and provides administrative services for DaVita's 2,500 dialysis clinics nationwide, serving approximately 195,000 end stage renal disease (ESRD) patients. Federal law requires that all ESRD facilities, such as DKC, are under the control of an identifiable governing body. Relator is informed and believes, and upon such information and belief alleges, that DaVita is the single identifiable governing body of all DKC dialysis facilities.[1]

11. At all times relevant, defendant Davita Rx, LLC (DRX) is and was a limited liability company with its headquarters in Copple, Texas. DRX is a full service pharmacy that specializes in providing medications to DaVita's and DKC's ESRD patients, and transacted business in, among other places, the Central District of California.

12. At all times relevant, defendants contracted with Government Funded Payors to provide dialysis services, supplies, medications and in-home training to patients suffering from ESRD.[2]

13. Relator Charles M. Holzner, M.D. (Relator) has been licensed to practice medicine in California since 1980 and Board Certified in Internal Medicine since 1983. During 1992, Relator was one of the original co-founders of CareMore Health Plan (CareMore) which grew from 6,000 MA enrollees to currently having more than 100,000 MA enrollees in six states. Relator served as CareMore's Chief Hospitalist from 1992 until 2006 where he led a team of hospitalists responsible for overseeing all of CareMore's inpatient care. Relator then was promoted to CareMore's Senior Medical Officer, a position he held until 2016. CareMore's hospitalist program was well recognized in trade journals, the Wall Street Journal, and the Atlantic Monthly for achieving significant reductions in the length of in-

[1] 42 C.F.R. § 494.180 states in part that each ESRD facility "[i]s under the control of an identifiable governing body, or designated person(s) with full legal authority and responsibility for the governance and operation of the facility. The governing body adopts and enforces rules and regulations relative to its own governance and to the health care and safety of patients, to the protection of the patients' personal and property rights, and to the general operation of the facility."

[2] While most ESRD services are paid by Medicare and MAOs, the other Government Funded Payors were responsible as a secondary insurer for some of the subject ESRD treatment costs and in situations where the beneficiary's coverage under Medicare was delayed due to waiting periods to become active or was otherwise denied.

patient stays while simultaneously decreasing the patients' hospital recidivism, an indicator of high quality care. While serving as CareMore's Senior Medical Officer, Relator founded and led CareMore's MA Special Needs Plan (SNP) which had more than 1,500 ESRD enrollees. Beginning in 2007 and continuing to the present, CareMore's SNP contracted with DaVita to provide dialysis and related services to CareMore's ESRD enrollees. Relator learned of the frauds alleged in this complaint through the course and scope of his employment as CareMore's Senior Medical Officer and his responsibilities overseeing CareMore's SNP. During the course and scope of his employment as CareMore's Senior Medical Officer, Relator interacted with defendants on a regular basis and through those interactions learned of defendants' frauds alleged herein.

FACTUAL ALLEGATIONS

Medicare Program Overview

14. Medicare is a federally-operated health insurance program administered by CMS. Parts A and B of the Medicare Program are known as "original" or "fee-for-service" Medicare. Medicare Part A generally covers inpatient and institutional care. Medicare Part B generally covers physician, hospital outpatient, and ancillary services and durable medical equipment.

15. Under Medicare Parts A and B, CMS reimburses healthcare providers (e.g., hospitals, physicians, etc.) using what is known as a "fee-for-service" (FFS) payment system. Under a FFS payment system, healthcare providers submit claims to CMS for reimbursement for each service, such as a physician office visit or a hospital stay. CMS then pays the providers directly for each service. As a condition of payment the CMS claim form requires all providers to certify the services they are attempting to be paid for are medically necessary

16. Medicare payments for patients with chronic kidney disease that require dialysis, also known as End Stage Renal Disease (ESRD) are made under Medicare Parts A and B, depending on what type of services are being provided. 42 U.S.C. § 1395rr(a). Some ESRD patients enroll in the Medicare Advantage program and obtain the Medicare benefits as beneficiary of a particular MAO or enrollee in a special needs plan (SNP), which is a MA plan

comprised of patients with certain higher cost medical conditions, such as ESRD.

17. The Medicare Advantage (MA) program is Medicare's managed care program administered by CMS. The MA program, also known as Medicare Part C, requires the MAO to provide all of the benefits provided under original Medicare and any additional supplemental benefits that have been approved by CMS and made part of that MAO's MA plan. 42 C.F.R. § 422.102(a). Through the MA program, Medicare allows private HMOs and health insurer MAOs to utilize managed healthcare plans to cover their MA beneficiaries. The MA program is based upon and incorporates nearly all of the rules, regulations, requirementsand guidance that governs Medicare Parts A and B. 42 C.F.R. §§ 422.101(b)(1)-(3),[3] 422.310(c)-(d); and Medicare Managed Care Manual, Ch. 4 §10.2. This make sense because all MAOs are required to provide their assigned beneficiaries at least the benefits under Medicare Parts A and B. 42 C.F.R. § 422.100(a).

18. Under the MA program, the Government, through CMS, pays an MAO a per-member-per-month (pmpm) capitation payment in exchange for the MAO providing or arranging for the provision of all covered health care services required by the MA beneficiaries that select such MAO as their MA plan. The capitated amounts paid to MAOs under the MA program are adjusted based on cost increases in the Medicare Part A and B. 42 C.F.R. § 422.308(a). CMS may use risk adjustment data for purposes of, including but not limited to, updating and adjusting the risk adjustment model, coverage determinations, program integrity purposes and to support the administration of the Medicare program. 42 C.F.R. § 422.310(f).

19. As an express condition of payment, Medicare's CMS 1500 claim form requires all Medicare providers to certify that information on the claim form is (a) "true, accurate and complete," (b) that the claim "complies with all applicable Medicare and/or Medicaid laws

[3]42 C.F.R. § 422.101(b)(1)-(3) states in part, ("[e]ach MA organization must meet the following requirements: (1) CMS's national coverage determinations; (2) **General coverage guidelines included in original Medicare manuals and instructions** unless superseded by regulations in this part or related instructions; (3) Written coverage decisions of local Medicare contractors with jurisdiction for claims in the geographic area in which services are covered under the MA plan.") (Emphasis added.)

regulations and program instructions for payment," and (c) that all of the services identified on the claim form "were medically necessary" and personally provided by the provider submitting the claim (or by his/her employee under/his/her's direct supervision). Since approximately 2012, the CMS 1500 claim form was also submitted by MAOs to CMS as a key part of their required encounter data submissions. CMS uses the encounter data to evaluate and review the risk adjustment data submitted to CMS under the HCC Risk Adjustment Model. 42 C.F.R. § 422.310(f).

Dialysis Overview

20. The loss of kidney function is usually irreversible. Kidney failure is typically caused by Type I and Type II diabetes, high blood pressure, polycystic kidney disease, long-term autoimmune attack on the kidney or prolonged urinary tract obstruction. Kidney failure, also known as End Stage Renal Disease or ESRD, is the stage of advanced kidney impairment that requires continued dialysis treatments or a kidney transplant to sustain life. Left untreated, ESRD patients will develop uremia, i.e., a toxic build up of creatinine and urea in the blood stream, and is a life threatening condition. Patients suffering from uremia must undergo dialysis to reduce the levels of toxins in their blood stream. Dialysis is the process of removing of toxins, fluids and salts from the blood of ESRD patients by artificial means. Patients suffering from ESRD generally require dialysis at least three times a week for the rest of their lives. The vast majority of dialysis treatments in the United States are performed in dialysis centers (also referred to as dialysis clinics). ESRD patients typically undergo a procedure called hemodialysis, which is a medical procedure that uses a dialysis machine to filter waste products from the blood and restore its normal constituents.

21. As part of the dialysis treatment, blood is taken from the patient, typically by use of an arteriovenous fistula (fistula) or catheter, cleaned through an artificial filter and returned back into the patient's body. This process typically lasts three to four hours for each session and must be performed at least three times a week. The fistula is a permanent shunt surgically implanted into the patient's artery, typically in the patient's upper arm, which connects an artery directly to a vein to allow access for hemodialysis. The fistula takes three

to four months to mature sufficiently to be used for hemodialysis. The fistula is the preferred method for long term vascular access for ESRD patients that are candidates for this procedure.

Medicare ESRD Payments

22. During 1972, the Social Security Act was amended to extended Medicare coverage to insured individuals, their spouses, and their dependent children with ESRD who require dialysis or kidney transplantation. (Pub. L. 92-603). The statutory authority for ESRD coverage is found in the Social Security Act (hereafter the "Act") Section 1861(e)(9) and (s)(2)(F) [42 U.S.C. § 1395x] and set forth in detail in 42 C.F.R. §§ 494.1-494.180.

23. CMS customarily pays 80% of healthcare costs under FFS Medicare and FFS Medicare patients (or their secondary Government Funded Payors or private insurance carriers, if any) pay the remaining 20%. In many instances, the 20% co-pay and certain non-covered drug expenses are paid by Medicaid, Champus and ChampVA as the secondary payor. Thus, in many instances, when providers submit fraudulent claims for reimbursement, loses are incurred by the Government as both the primary and secondary payor and 100% of the loss caused by the fraud is passed directly to the taxpayers of the United States. Such losses also include false claims submitted by defendants to MAOs. *Universal Health Servs., Inc. v. United States*, 136 S.Ct. 1989, 1996, 195 L.Ed.2d 348 (2016) ["A 'claim' now includes direct requests to the Government for payment as well as reimbursement requests made to the recipients of federal funds under federal benefits programs. See §3729(b)(2)(A)."]

24. At all times relevant, Medicare coverage was and is available for patients with ESRD who require dialysis or kidney transplantation. 42 C.F.R. § 494.1(a)(1). Prior to 2011, Medicare separately reimbursed dialysis providers for the medications required to treat ESRD. As a result, ESRD providers, such as defendants, had perverse financial incentives to increase profits by over-prescribing such medications. In order to curb these financial abuses, the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) amended section 1881(b) of the Social Security Act to require the implementation of an ESRD bundled payment system effective January 1, 2011 and changed the reimbursement method to ESRD facilities to what is known as the prospective payment system (PPS). Under MIPPA, the ESRD PPS

replaced the prior payment system. The ESRD bundle provides defined items and services used to furnish outpatient maintenance dialysis to ESRD patients in an ESRD facility or a patient's home as defined in MIPPA and subsequent CMS regulations. 42 U.S.C. § 1395rr.

25. The ESRD PPS provides a patient-level and facility-level adjusted per treatment (i.e., dialysis) payment to ESRD facilities for renal dialysis services provided in an ESRD facility or in a beneficiary's home. The bundled per-treatment payment includes certain drugs, laboratory services, supplies and capital-related costs related to furnishing maintenance dialysis. The ESRD PPS was phased in over a four year period beginning in 2011 and ending in 2014. 42 C.F.R. § 413.172(b) ["All approved ESRD facilities must accept the prospective payment rates established by CMS as payment in full for covered renal dialysis services as defined in §413.171 or home dialysis services."]. ESRD patients are not charged a 20% co-pay for the services provided under the ESRD bundle. However, for costs and expenses not included in the ESRD bundle the patient is responsible for paying the 20% co-pay.

26. In order to receive payment under the PPS, each dialysis facility has to undergo a review and certification process. The certification is primarily concerned with validating that the facility has implemented the necessary health and safety requirements to provide dialysis treatments, that staff members are properly licensed and have received the appropriate training to maintain such safety standards, and how such issues will be monitored and kept current on into the future.

27. Once certified, the dialysis facility can apply as an institutional Medicare provider. This is accomplished by submitting CMS Form 855a. As part of the Medicare provider application, an authorized person must certify, on behalf of all of the DKC facilities named as defendants herein, that:

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

Medicare." CMS Form 855a, p. 48.

The foregoing certification impliedly includes certifying that all services provided are medically reasonably and necessary as required by Medicare. 42 U.S.C. §§ 1395y(a)(1)(A); 1320c-5(a) and 1395rr(b)(8) and (14)(D)(ii). Relator is informed and believes and upon such information and belief alleges that at all times relevant defendants submitted such certifications to the Government at least annually.

Medical Necessity

28. One of the fundamental maxims of Medicare, including the MA and ESRD programs, is that only services that are medically reasonable and necessary are covered. Under the Social Security Act, Medicare is only authorized to pay for items and services that are "reasonable and necessary" and makes satisfying this condition an express condition of Medicare payment.[4] 42 U.S.C. § 1395y(a)(1) ["(a) Items and services specifically excluded. **Notwithstanding any other provision of this subchapter, no payment may be made under part A or part B of this subchapter for any expenses incurred for items or services**–(1)(A) which, except for items and services described in a succeeding subparagraph or additional preventive services (as described in section 1395x(ddd)(1) of this title), **are not reasonable and necessary** for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."] (Emphasis added.); 42 C.F.R. § 411.15(k)(1) and made applicable to Medicare Advantage by 42 C.F.R. §§ 422.101(b)(1)-(3), 422.310(c)-(d); Medicare Managed Care Manual (MMCM), Ch. 4 § 10.2.

29. Similarly, 42 C.F.R. § 411.15(k)(1) specifically excludes coverage from Medicare services that are not medically necessary and reasonable stating, "The following services are excluded from coverage: . . . (k) Any services that are not reasonable and necessary for one of the following purposes: (1) For the diagnosis or treatment of illness or

[4] 42 U.S.C. § 1395y(a)(1)(A) states in part that "no payment may be made under [the Medicare statute] for any expenses incurred for items or services which ... are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." Because this section contains an express condition of payment – that is, "no payment may be made" – it explicitly links each Medicare payment to the requirement that the particular item or service be "reasonable and necessary."

injury or to improve the functioning of a malformed body member. . . ."

30. A healthcare provider's certification that Medicare covered services are medically necessary and reasonable is an immutable requirement of 42 U.S.C. § 1395y(a)(1)(A) and is set forth as an express condition for any payment and for coverage under the Medicare program. CMS and MAOs[5] require that every healthcare provider's claim, including those from defendants, for payment include a certification that such items and/or services were medically reasonable and necessary. CMS's and MAOs' reliance on such certifications was and is reasonable because, among other things, falsely certifying medical necessity can result in (a) criminal liability, (b) civil liability, and (c) the provider's exclusion from Medicare and all Federally funded health care programs.

31. The criteria for determining medical necessity, as that term is used in the Medicare program, is set forth in 42 U.S.C. § 1320c-5(a)(1) which states, "It shall be the obligation of any health care practitioner and any other person (including a hospital or other health care facility, organization, or agency) who provides health care services for which payment may be made (in whole or in part) under this chapter, to assure, to the extent of his authority that services or items ordered or provided by such practitioner or person to beneficiaries and recipients under this chapter-will be provided economically and only when, and to the extent, medically necessary." In other words, a provider cannot use a more expensive treatment or service when there is a lower cost, equally effective treatment or medication available absent a valid medical reason that is supportable by evidence. Additionally, the statute requires each provider, including a dialysis facility, such as DKC, to impliedly certify (e.g., "to assure") that all claims for items or services are medically necessary as required by § 1320c-5.

32. Similarly, this implied certification is contained in the DKC's Medicare provider application, CMS Form 855a, previously discussed above ["I understand that payment of a

[5]42 U.S.C. § 1395y(a)(1)(A) also applies to MA ["Notwithstanding any other provision of this title . . . ." *See also*, 42 C.F.R. § 422.101(b)(1)-(3); MMCM, Ch. 4 § 10.2 [MA payments to healthcare providers are contingent upon a determination that the service is, among other things, "reasonable and necessary."].

claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions ...."]. This is in addition to the more general implied certification of compliance with all "applicable Federal, state and local laws and regulations pertaining to licensure and any other relevant health and safety requirements" set forth in 42 C.F.R. § 494.20 which is also a precondition to the payment for Medicare covered items and services provided by dialysis facilities.

33. The provisions of 42 U.S.C. § 1320c-5(a)(1) and (3) compel Medicare providers to select treatments and procedures that are cost effective and supported by legitimate and credible medical research, and prohibits Medicare providers, such as DaVita and DKC from selecting treatments, procedures and/or medications for the purpose of increasing such providers' profits. *U.S. ex rel. Kneepkins v. Gambro Healthcare, Inc.*, 115 F. Supp.2d 35, 43 (D. Mass. 2000). Likewise, § 1320c-5(a)(1) prohibits DaVita and DKC from continuing to perform or prescribe services or medications that have been shown by credible medical research to be ineffective and are no longer or were never supported by credible medical research.

34. A physician's or provider's requirement to certify medical necessity is not to be conflated with a physician or provider establishing that they have met the prevailing community standard of care. Failure to practice in accordance with the prevailing standard of care is used to determine professional malpractice. In contrast, certifying medical necessity is a mandatory express condition precedent to both coverage and payment for all Medicare covered services. 42 U.S.C. § 1395y(a)(1)(A). However, Medicare can lawfully exclude services from coverage that are medically necessary. *Goodman v. Sullivan*, 891 F.2d 449, 451 (2nd Cir. 1989). Likewise, medical necessity is not established by FDA approval of a drug or medical device. While FDA approval is a necessary prerequisite for Medicare coverage, such approval does not confer Medicare coverage. Despite FDA approval, a drug or medical device can nonetheless be medically unnecessary. *Almy v. Sebelius,* 679 F.3d 297, 308 (4th Cir. 2012). It is only through the application of 42 U.S.C. § 1320-c-5 that a determination of medical necessity of a particular treatment, drug, procedure or medical device can be made.

35. The submission of claims for medically unnecessary services constitutes a fraud upon the Government. 42 U.S.C. § 1320a-7a(a)(1)(E) ["Any person (including an organization, agency, or other entity, but excluding a beneficiary, as defined in subsection (i)(5) of this section) that--(1) knowingly presents or causes to be presented to an officer, employee, or agent of the United States, or of any department or agency thereof . . . a claim (as defined in subsection (i)(2) of this section) that the Secretary determines--(E) is for a pattern of medical or other items or services that a person knows or should know are not medically necessary; shall be subject, in addition to any other penalties that may be prescribed by law, to a civil money penalty of not more than $20,000 for each item or service."].

36. The Medicare Program Integrity Manual, Ch. 4 § 4.2.1 explains common types of Medicare fraud, stating in relevant part, "The most frequent kind of fraud arises from a false statement or misrepresentation made, or caused to be made, that is material to entitlement or payment under the Medicare program." The section identifies several examples of Medicare fraud including medically unnecessary services, stating, "Billing non-covered or non-chargeable services as covered items." This statement includes medically unnecessary items and services because such services cannot be reimbursed by Medicare. 42 U.S.C. § 1395y(A)(1)(a); Medicare Program Integrity Manual, Ch. 4 §4.2.1, available at www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c04.pdf. Courts have reached the same conclusion holding that submitting Medicare claims for services that are medically unnecessary or otherwise not reimbursable is the submission of a false claim. *Peterson v. Weinberger,* 508 F.2d 45, 52 (5th Cir. 1975).

Medical Necessity In the False Claims Act

37. The lack of medical necessity is a well established basis for liability under the False Claims Act (FCA). *See, United States ex rel. Riley v. St. Luke's Episcopal Hosp*., 355 F.3d 370, 376 (5th Cir. 2004) ["[c]laims for medically unnecessary treatment are actionable under the FCA."]; *United States ex rel. Polukoff v. St. Mark's Hosp.*, 895 F.3d 730, 742 (10th Cir. 2018) [collecting cases]; and *United States ex rel. Kneepkins v. Gambro Healthcare, Inc.*, 115 F.Supp.2d 35, 41-42 (D.Mass. 2000) [medical procedures that are deleterious or

performed solely for profit are not medically necessary and therefore actionable under the FCA].

38. For a Medicare covered item or service to be reimbursable, it has to comply with the provisions of 42 U.S.C. § 1320c-5, which requires in relevant part that any provider, including but not limited to defendants, must impliedly certify that all items and services ordered or provided to Medicare beneficiaries "will be provided economically and only when, and to the extent, medically necessary." 42 U.S.C. § 1320c-5(a)(1). CMS required claim forms contain express certifications of medical necessity. Express certifications of medical necessity are found in the CMS Claim Forms 1500 and 1450, aka UB40, which CMS requires physicians and facilities to use. 42 C.F.R. § 424.32(b). Physicians must submit claims to Medicare using the 1500 form or its electronic equivilent while facilities/institutional providers are required to utilize the 1450 form. Each Medicare claim form contains express certification that all services are medically reasonable and necessity.

39. Courts that have examined this issue have held that lack of medical necessity is a valid theory of FCA liability. In order to satisfy the 42 U.S.C. § 1320c-5 medical necessity criteria, Medicare physicians and providers are required to make cost-effective treatment decisions as opposed to treatment decisions designed to optimize profits. *United States ex rel. Bergman v. Abbot Laboratories,* 995 F.Supp.2d 357, 369-370 (D.Penn. 2014) [Lack of medical necessity for off label drug was valid theory for FCA liability]; *United States ex rel. Vainer v. Davita, Inc.*, 2012 WL 12832381 at *6 (D.Ga. March 3, 2012) [Allegation that DaVita unreasonably and unnecessarily increased the quantity of medications provided to their patients, without regard to medical necessity, stated a valid cause of action under the FCA.]; *United States ex rel. Kneepkins v. Gambro Healthcare, Inc.*, 115 F.Supp.2d 35, 41-42 (D.Mass. 2000) [allegation that defendant intentionally increased the quantity of test without regard to medical necessity stated a valid cause of action under the FCA].

40. As previously discussed, medical necessity is an immutable cornerstone for the coverage and payment of any services provided under Medicare. 42 U.S.C. § 1395y(a)(1);

42 C.F.R. § 411.15(a)(1)[6]. Physicians and other providers, such as dialysis facilities, must certify that all Medicare covered items and services provided are medically necessary in accordance with criteria set forth in 42 U.S.C. §1320c-5(a)(1)-(3). FCA liability based on the lack of medical necessity does not involve a debate regarding the applicable standard of care. Rather, such cases turn on a showing that the items or services were provided to increase profits because such services were of little or no value, were deleterious or there were more economical options that were as efficacious.

41. Liability under FCA extends to a MAO's subcontractor, such as defendants, without the requirement of presenting a claim directly to the Government. 31 U.S.C. § 3729(b)(2)(A).[7] Defendants subcontract with many MAOs and/or SNPs to provide dialysis services to their MA beneficiaries. Because the MA program is calibrated to fee-for service Medicare, increases from medically unnecessary dialysis expenses inflate the costs of both traditional Medicare and the MA program.

Medicare ESRD Coverage and Dialysis Facilities Requirements

42. During 2008, CMS finalized new conditions of coverage for ESRD facilities providing dialysis treatment that were first introduced in 2005. The new rules were published in the April 15, 2008 Federal Register, Vol. 73, at pages 20370-20454 as part of the "Medicare Program: Conditions for Coverage for End-Stage Renal Disease Facilities" (the "2008 Conditions of Coverage"). The 2008 Conditions of Coverage set forth rules that all ESRD facilities must meet in order to be certified under the Medicare program while purposefully

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[6]42 U.S.C. § 13295y(a)(1)(A) states "**(a) Items or services specifically excluded-** Notwithstanding any other provision of this subchapter, no payment may be made under part A or part B of this subchapter for any expenses incurred for items or services--(1)(A) which, except for items and services described in a succeeding subparagraph . . . , are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." Similarly, 42 C.F.R. § 411.15(a)(1) excludes from coverage any item or service that is not medically necessary or reasonable (i.e., "Examinations performed for a purpose other than treatment or diagnosis of a specific illness, symptoms, complaint, or injury, ...").

[7]31 U.S.C. § 3729(b)(2)(A); *Universal Health Servs., Inc. v. United States*, 136 S.Ct. 1989, 1996, 195 L.Ed.2d 348 (2016) ["A 'claim' now includes direct requests to the Government for payment as well as reimbursement requests made to the recipients of federal funds under federal benefits programs. See §3729(b)(2)(A)."]

strengthening ESRD patients' rights and significantly expanding and strengthening the role and responsibilities of ESRD facilities' medical directors. See, fn 9, below.

43. As a result of the 2008 Coverage Conditions, 42 C.F.R. § 494.150 requires that each ESRD facility have one medical director who is ultimately responsible for delivery of all dialysis treatment and services to the facility's ESRD patients, is responsible for quality of care and outcomes, and can chose to participate and direct the care of any of the ESRD patients. §494.150(c); 73 Fed.Reg. 20340, 20400 (April 15, 2008). The medical director's responsibilities include participating in the creation of and implementation of policies and procedures relative to all aspects of patient care. By definition, this includes addressing what medications are used, determining the criteria for initiating dialysis treatments, and ensuring that all services provided are continuously certifiable as medically necessary pursuant to 42 C.F.R. § 1320c-5(a)(1) and (3). 42 C.F.R. 494.150(c); 73 Fed Reg. 20340, 20427.

44. The medical director must, among other things, participate in the development of "patient care policies and procedures manual" for the facility and must also ensure that all policies and procedures relative to patient care are adhered to by all individuals who treat patients in the facility, including attending physicians and non-physician providers. 42 C.F.R. § 494.150(c). The purpose of this requirement is to make clear that the ESRD facility and its medical director are responsible for prescribing, delivering and overseeing the dialysis treatments given to ESRD patients.[8]

45. As a result of the 2008 Conditions of Coverage, 42 C.F.R. § 494.80 requires, among other things:

> (1) that each ESRD facility must have an interdisciplinary team, consisting of, at the minimum, the patient or the patient's designee, a registered nurse, a

[8] In discussing the adoption of §494.150, CMS states "In response to comments, we have added language at §494.150 to state explicitly that ''The medical director is accountable to the governing body for the quality of medical care provided to patients.'' In addition, the medical director has the responsibility of ensuring that all policies and procedures relative to patient care and safety are followed by all who treat the patient, as required at §494.150(c)(2). **This modification clearly holds the medical director responsible for the care that is furnished.** Each facility must have a single medical director to carry out the responsibilities of this position." (Emphasis added.) 73 Fed.Reg. 20340, 20427 (April 15, 2008).

physician treating the patient for ESRD, a social worker, and a dietitian;

(2) within the first 30 days or 13 dialysis treatments, whichever is later, the interdisciplinary team must complete a comprehensive assessment of each of the ESRD facility's patients; and

(3) the assessment must include, but is not limited to, the following:

(i) an evaluation of the appropriateness of the dialysis prescription;

(ii) an evaluation of factors associated with anemia, such as hematocrit, hemoglobin, iron stores and potential treatment plans for anemia;

(iii) an evaluation of factors associated with renal bone disease;

(iv) an evaluation of dialysis access type and maintenance (for example, arteriovenous fistulas, arteriovenous grafts, and peritoneal catheters).

(v) an evaluation of suitability for a transplantation referral, based on transplantation center criteria; and

(vi) documentation in the patient's medical record of any basis for nonreferral for kidney transplantation. 42 C.F.R. § 494.80(a)-(b).

46. A follow-up comprehensive reassessment must occur within 3 months after the completion of the initial assessment to adjust the patient's "plan of care" as set forth in 42 C.F.R. § 494.90 and at least annually thereafter. 42 C.F.R. § 494.80(b).

47. As a result of the 2008 Conditions of Coverage, 42 C.F.R. § 494.90 requires, among other things, that:

a. The interdisciplinary team develop and implement a written, individualized comprehensive plan of care that specifies the services necessary to address each ESRD patient's needs, as identified by the comprehensive assessment;[9]

[9] 42 C.F.R. § 494.90(a)(7)(ii) requires, " When the patient is a transplant referral candidate, the interdisciplinary team must develop plans for pursuing transplantation. The patient's plan of care must include documentation of the--

(A) Plan for transplantation, if the patient accepts the transplantation referral;

(B) Patient's decision, if the patient is a transplantation referral candidate but declines the transplantation referral; or

b. The plan of care must include measurable and expected goals and objectives and estimated timetables to achieve these outcomes;

c. The outcomes specified in the patient plan of care must be consistent with current evidence-based professionally-accepted clinical practice standards; and

d. If the patient is unable to achieve the plan of care's goals and objectives, the reasons why must be documented and an amended plan of care implemented which is intended at addressing such reasons.

48. The plan of care must include but is not limited to all of the following: (a) dialysis dose and frequency, (b) nutritional status, (c) mineral metabolism and prevention of renal bone disease, (d) anemia, (e) vascular access, and (f) a plan for achieving a kidney transplant unless it is documented that the patient is not a transplant candidate and that status remains unchanged. Each of the members of the interdisciplinary team must sign the ESRD facility's plan of care. 42 C.F.R. § 494.90(b).

Overview of Allegations

49. The allegations contained in this Fourth Amended Complaint (FAC) involve the knowing provision of medically unnecessary treatments and medications rendered or prescribed for the purposes of increasing DaVita, DKC and/or DRX's profits in violation of 42 U.S.C. §§ 1395y(a)(1)(A) and 1320c-5(a), and in violation of key provisions of the Conditions for Coverage for ESRD Facilities, 42 C.F.R. §§ 494.70-494.90 and 494.150. These services were rendered with disregard for certifying medical necessity of the dialysis treatments provided, the medical necessity for drugs prescribed and with regards to Renagel, in disregard to the facts that safer, equally efficacious and less expensive treatment options were available.

50. Specifically, this Fourth Amended Complaint alleges three primary fraudulent schemes:

(C) Reason(s) for the patient's nonreferral as a transplantation candidate as documented in accordance with §494.80(a)(10)."

(1) Knowingly providing medically unnecessary, prophylactic, hemodialysis treatments, which following a 2010 landmark RCT it was conclusively known such dialysis treatments **conferred no medical benefits**.

(2) Knowingly over prescribing, medically unnecessary Sensipar also known as cinacalcet, which was prescribed to reduce ESRD patients' cardiac comorbidities and decrease mortality rates by lowering patients' parathyroid hormone (PTH) output. However, following a 2012 landmark RCT it was conclusively shown that Sensipar had no effect in reducing ESRD patients' cardiac comorbidities nor in decreasing ESRD patient mortality rates.

(3) Knowingly over prescribing Renagel, an expensive non-calcium based phosphate binder, instead of much less expensive over the counter (OTC) calcium-based phosphate binders such as TUMS, because defendants could and did bill Government Funded Payors for Renagel due to its highly profitable reimbursement rate.

51. Defendants submitted to Government Funded Payors claims for payment, including but not limited to using CMS form 1500 claim forms, CMS cost reports, CMS institutional claim forms (UB-40), encounter data reports, CMS Form 2728-End Stage Renal Disease Evidence of Medical Entitlement reports and compliance attestations pursuant to 42 C.F.R. § 422.504(*l*)(2)-(3) (a) since 2011 for premature dialysis treatments that were not medically necessary, (b) since 2013 for medically unnecessary Sensipar, and (c) since 2013 for cost-ineffective Renagel.

52. Defendants' claims for payment did not disclose, nor did the Government Funded Payors know, that such claims included claims for premature dialysis treatments that were medically unnecessary, Sensipar that was medically unnecessary, and/or Renagel that was cost-ineffective. Such claims were paid by the Government and by Government Funded Payors.

53. Although defendants utilized the 2006 K/DOQI guidelines, which were commonly interpreted to recommend to begin dialysis once a particular estimated creatinine

clearance level was reached which was commonly expressed as an estimated GFR value (i.e., eGFR). The 2015 updated K/DOQI guidelines changed its recommendation and methodology, based on the August 2010, IDEAL study, to no longer use an eGFR value but to wait until the patient exhibits clinical symptoms indicating the onset of uremia. This change was made to avoid providing medically unnecessary premature dialysis treatments.

Premature Dialysis Fraud

54. Approximately 30% of the annual dialysis treatments provided by defendant DaVita Kidney Care's (DKC) dialysis facilities are initiated prematurely, based upon an estimated creatinine clearance level of between eGFR 25 mL/min and eGFR 10 mL/min which purportedly indicates a worsening of the patient's chronic kidney disease (CKD). These early dialysis initiations are provided by DKC facilities to patients that do not yet have End Stage Renal Disease (ESRD) as such patients do not exhibit symptoms indicating the onset of uremia or some other compelling medical reason, such as fluid overload, to justify starting dialysis. These premature dialysis initiations and subsequent treatments are given prophylactically, based upon nephrologists' once commonly held, but unsupported, belief that such prophylactic dialysis treatments improve residual kidney function and/or delay the erosion of such residual kidney function. Conversely, many nephrologists once commonly believed, despite the lack of supporting medical research, that waiting until the patient was close to a uremic state was potentially harmful.

55. Both of these once commonly held beliefs were conclusively disproved in August 2010 when the New England Journal of Medicine (NEJM) published what is known as the IDEAL Study. The IDEAL Study was the first and remains the only randomized controlled trial (RCT) addressing the timing of dialysis initiation. RCTs are considered the gold standard for conclusively determining the safety and efficacy of a particular drug or treatment and are almost universally required by the Federal Drug Administration (FDA) as part of the drug approval process. The IDEAL Study analyzed the timing and effects of "Early" verses "Late" dialysis initiation and treatment by studying 828 ESRD patients over a 3.5 year period. To control variables related to differences in health status and access to pre-

dialysis care, the average age of the patients was restricted to 60 years old, all participants had to have received pre-dialysis care from a nephrologists for a year prior to beginning dialysis and except for having CKD, all trial participants were relatively "healthy." Additionally, trial participants could not be suffering from any serious comorbidities such as diabetes or vascular disease.

56. The "Early," i.e., premature, dialysis initiations were randomized for patients to begin once their estimated creatinine clearance levels were between approximately eGFR of 14mL/min and 10 mL/min ,while the "Late" initiations were to based upon the presentation of clinical symptoms of the onset of uremia and with a target estimated creatinine clearance level of between eGFR 5mL/min and 7mL/min.[10] This difference between Early and Late dialysis initiations resulted in the Late dialysis initiations beginning dialysis treatments, on average, six months after the Early group began their dialysis treatments. After each group's members had received dialysis for 3.5 years, approximately 35% of the members in the Early group and 35% of the members in the Late group had died. There was no significant statistical differences in other comorbidities or hospitalization rates between the two groups.

57. The key conclusions drawn from the IDEAL Study are (a) there is no medical benefit to initiating dialysis Early based upon a specific estimated creatinine clearance level such as eGFR between 15 mL/min and 10 mL/min, (b) there is no harm to ESRD patients in waiting to begin dialysis until they have clinical symptoms indicating the onset of uremia or some other compelling medical reason, and (c) prophylactic dialysis does not provide any improvement in residual kidney function. The IDEAL Study's conclusions have been accepted as the best available evidence regarding the timing of dialysis by CDK and ESRD

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[10]The clinical findings used to detemine when to initiate dialysis is the creatinine and urea clearance levels estimated by the glomerular filtration rate (GFR) which estimates the rate the kidneys remove these toxins from the body. In 2006, the 2006 National Kidney Association guidelines suggested considering dialysis when the GFR is at 15 mL/min. This figure has been conclusively rejected by the IDEAL study which recommends that patients be closely monitored and dialysis initiation begins upon the patient having the onset of uremia, fluid overload or other clinical findings that require immediate dialysis treatment. Further target GMR should be no more 7 mL/min but can be electively delayed to a lower GFR if the patient does not present the clinical symptoms requiring dialysis (i.e., onset of uremia, fluid overload or other clinical findings that require immediate dialysis.) New Eng. J. Med. Vol. 363 at pp. 615-616.

research and policy organizations world wide, including the United States.

58. The IDEAL Study's conclusions, that premature dialysis initiations and prophylactic dialysis treatments provided yno clinical benefits, were widely adopted as the final word regarding any lingering controversy over the topic. International organizations such as, The International Society of Nephrology in cooperation with the National Kidney Foundation updated its 2012 KDIGO (i.e., Kidney Disease Initiative Global Outcome) guidelines, Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease, Journal of the International Society of Nephrology Vol 3, Issue 1, Jan. 1, 2013 available at www.kidney-international.org updated its guidelines to eschew dialysis treatments based upon estimated GFR in favor of waiting until the patient exhibited clinical symptoms indicating the onset of a uremic state. Likewise, the National Kidney Foundation updated its K/DOQI 2015 guidelines stating **"**Published in 2010, results of the IDEAL (Initiating Dialysis Early and Late) trial explored this issue, and **data from this trial constitute the best evidence regarding timing of dialysis initiation, motivating the update of this guideline.**" (Emphases added.) The 2015 KDOQI Guidelines recommends initiating dialysis only after the patient exhibits clinical symptoms of uremia. KDOQI Clinical Practice Guideline for Hemodialysis Adequacy: 2015 Update, Am J Kidney Dis. 2015, Vol. 66, Issue 5, p 884-930 at 892, 896-97, available at, https://www.kidney.org /professionals/guidelines/hemodialysis2015. In addition, the American Board of Internal Medicine (ABIM) Foundation in conjunction with American Society of Nephrology (Choosing Wisely © 2016) cited the IDEAL Study's conclusions in its informational patient brochure. The IDEAL study and its conclusions have been well reviewed and approved by scores of medical researchers and is frequently cited when discussing the risks associated with undergoing prophylactic dialysis initiations.

59. In spite of the fact that the 2010 IDEAL Study was the stated catalyst for the changes to the 2015 updated K/DOQI guidelines, before and after 2015 defendants continued to provide and bill for medically unnecessary premature dialysis treatments because such practice increased defendants' profits. Further, Relator is informed and believes and upon such information and belief alleges that defendants' premature dialysis treatment scheme and

billing practices continued from 2015 to the present.

60. The uncontroverted findings of the IDEAL study, which proved that premature prophylactic dialysis treatments were medically unnecessary and of no benefit, required DaVita and DKC to prohibit medically unnecessary, premature and prophylactic dialysis initiations and adopt the well-established and then confirmed protocol to start dialysis only when the patient is diagnosed with uremia based on clinical findings discussed in footnote 10 *supra.* Failure to timely make this policy change meant that many of DKC's dialysis treatments were medically unnecessary in violation of 42 U.S.C. §§ 1395y(a0(1)(A), 1320c-5(a)(1); 42 C.F.R §§ 494.80, 494.90, 494.150 and 494.180; in addition to violating the False Claim Act. 31 U.S.C. § 3729(a)(1)(A),(B) and (G).

61. DKC's dialysis facilities' practices were to accommodate any dialysis prescriptions for prophylactic dialysis treatments requested by that DKC facility's staff nephrologist; provided such nephrologist executed the CMS Form 2728's physician attestation which certified the medical necessity for the prescribed dialysis treatments. As a result, during and between 2011 and the present, in excess of 30% of all hemodialysis treatments performed by DKC dialysis facilities were prophylactic dialysis treatments; initiated six months to one year prior to when such treatments could beneficially aid in prolonging the patients life. These early dialysis initiations were routinely performed on patients regardless of age and with estimated creatinine clearance levels of between eGFR 25mL/min and eGFR 10mL/min. These prophylactic dialysis treatments were provided by DKC's dialysis facilities despite the facts that (a) these patients had no clinical symptoms indicating the onset of a uremic state, (b) these patients did not have any compelling medical need or reason to initiate dialysis, such as fluid overload, (c) the August 2010 publication of the internationally accepted, landmark, RCT IDEAL Study conclusively determined that prophylactic dialysis treatments **provided no medical benefits**, (d) providing the prophylactic dialysis violated 42 C.F.R. §§ 494.70-494.90 and 494.150 of CMS conditions of coverage for ESRD facilities, and (e) the one year mortality rate for initiating dialysis on patients 85 years old and above is in excess of 70%. One-Year Mortality After Dialysis Initiation Among Older Adults, Melissa W. Wachterman,

et.al., JAMA Internal Medicine, 2019 Jul., Vol. 179 , Iss. 7, P. 987-990 Mortality Table, available at,https://www.ncbi.nlm.nih.gov/pubmed/31009039/?utm_source=gquery &utm_ medium=referral&utm_campaign=CitationSensor

62. Since the prophylactic dialysis treatments provided no medical benefit, by definition such treatments were medically unnecessary. DKC patients that were provided such dialysis treatments endured six months to one year's worth of thrice weekly dialysis treatments before such treatments were medically necessary. Such treatments are typically uncomfortable and for some patients, painful. All dialysis treatments are potential harmful due to the treatment's serious side effects making receiving medically unnecessary dialysis treatments also deleterious. Potentially harmful side effects of dialysis treatments, include but are not limited to, an increased incidence of cardiac arrest and other cardiac events, an increased incident of strokes, microemboli which can lead to leg amputations, and catheter related infections. Older ESRD patients routinely experience significant decrease in cognitive function as well. These risks from dialysis related side effects increase logarithmically with age. For those age 85 and above, 45% do not survive the first three months of dialysis and 70% will not survive the first twelve months of dialysis treatments. *Supra*, One-Year Mortality After Dialysis Initiation Among Older Adults.

63. Defendants purposefully and knowingly ignored the IDEAL Study's conclusions and 2015 K/DOQI guidelines so DKC's dialysis facilities could maintain their longstanding practices of allowing the patients' nephrologists to unilaterally determine the timing and manner of patient's dialysis initiations and treatments. 30%-40% of all dialysis treatments are medically unnecessary premature and/or prophylactic dialysis treatments. Defendants' practices allow and encourage the provision of medically unnecessary prophylactic dialysis initiations and treatments. Further, such practices fail to comply with the conditions of coverage for ESRD facilities which require the dialysis facility's medical directors to develop, implement and enforce patient care policies that use current technology and advances in medical science to improve outcomes and patient safety. Defendants ongoing refusals to empower its medical directors to enforce such policies against staff nephrologists optimizes

defendants profits by continuing to allow medically unnecessary prophylactic dialysis treatments to be prescribed and provided without abatement. Requiring DKC's dialysis facilities to implement patient care policies based on the 2015 K/DOQI guidelines would prevent further medically unnecessary dialysis treatments but also cause the dialysis facilities revenues to decrease by 30% or more.

64. Each of these prophylactic dialysis treatments provided at a DKC dialysis facility are performed pursuant to an initial dialysis prescription from a referring nephrologist credentialed as a DKC staff nephrologist (referring-staff nephrologist). Although the initial dialysis prescriptions are supposed to be reviewed for appropriateness, such reviews only examined the prescription's distillate volume and flow rate. 42 C.F.R. §494.80(a)(2). DKC facilities had no policies or mechanisms to review and do not review the appropriateness of the referring-staff nephrologist's initial dialysis prescription with regards to the medical necessity of the proposed dialysis treatment or the suitability of the treatment modality in light of the patient's age and health status. During and between 2011 and the present, DKC's dialysis facilities' practice was to permit its referring-staff nephrologists to unilaterally determine the timing and manner of the dialysis treatments provided at DKC's dialysis facilities. Further, during this time frame, DKC medical directors were not authorized to impose any policies or restrictions regarding the timing and manner of dialysis treatments upon any referring-staff nephrologists for hemodialysis treatments provided at such medical director's DKC facility.[11]

65. During and between 2011 and the present, DKC's dialysis facilities and its medical directors treated the timing of dialysis initiation and the suitability of the patient's dialysis modality as subjects that reside exclusively between the patient and their referring-staff nephrologist. These topics were treated as if they were beyond the DKC dialysis facility

[11]This is not to say that DKC prohibited the medical directors from adopting and using evidence-based dialysis initiation criteria that prohibited medically unnecessary dialysis treatments, nor any other sound patient care practice, with regards to ESRD patients whom the medical director had referred to DKC's dialysis facilities from their own private medical practice, just that such medical directors were not authorized to implement such a policy and impose its requirements upon other staff nephrologists.

and its medical director's sphere of influence and control.

66. Relator's contends that DKC and its medical directors are incorrect as a matter of law and policy. Contrary to the practices adopted by DKC's dialysis facilities, allowing the staff nephrologists to unilaterally determine the timing and manner of the dialysis treatments provided at DKC's dialysis facilities violates several key ESRD conditions of coverage, fails to ensure that only services that are medically necessary and cost effective are provided, and violates the False Claims Act (FCA). 31 U.S.C. § 3729(a)(1).

67. Pursuant to the ESRD conditions of coverage, DKC's dialysis facilities, via their medical directors, are unequivocally responsible for all dialysis treatments provided at such DKC facilities. 42 C.F.R. 494.150(a). By contrast, DKC's staff nephrologists, are responsible for participating as members of their patients' IDT which, pursuant 42 C.F.R. §§ 494.80 and 494.90, must conduct comprehensive initial patient assessments which is incorporated into the patient's plan of care. The patient's initial comprehensive assessments are not due until the latter of 30 days or 13 dialysis sessions . The patient's plan of care is due 30 days thereafter.

68. Therefore, neither the initial assessment nor plan of care are able to timely safeguard DKC's ESRD patients from being subjected to medically unnecessary prophylactic dialysis initiations and treatments pursuant to a defective initial dialysis prescription. Such safeguards can only be achieved by patient care policies which require a detailed review of the initial dialysis prescription to ensure that DKC's dialysis facilities do not provide medically unnecessary prophylactic dialysis treatments. Such policies should also identify high risk frail and/or older patients and delay dialysis initiations until reviewed by the IDT due to the high near term mortality rate of such patients.

69. Instead of implementing current evidence -based patient care policies to prohibit medically unnecessary prophylactic dialysis treatments and/or harmful dialysis due to the patient's age and health status, as required by 42 C.F.R. §§ 494.80, 494.90 and 494.150, DaVita and DKC purportedly relied upon the physician certification contained on the End Stage Renal Disease Medical Evidence Report Medicare Entitlement and/or Patient Registration, CMS Form 2728, which states:

> "I certify, under penalty of perjury, that the information on this form is correct to the best of my knowledge and belief. Based on diagnostic tests and laboratory findings, I further certify that this patient has reached the stage of renal impairment that appears irreversible and permanent and requires a regular course of dialysis or kidney transplant to maintain life. I understand that this information is intended for use in establishing the patient's entitlement to Medicare benefits and that any falsification, misrepresentation, or concealment of essential information may subject me to fine, imprisonment, civil penalty, or other civil sanctions under applicable Federal laws."

Pursuant to the general instructions, CMS Form 2728 must be completed within 45 days of the initial dialysis prescription. From CMS Form 2728's instruction No. 19, it is evident that CMS Form 2728 is completed by and at the patient's DKC facility. Although the attestation is not a model of clarity, it is evident from instruction No. 23 that the physician attestation is certifying the medical necessity for the hemodialysis treatments indicated on treating nephrologist's initial dialysis prescription. Dr. Holzner is informed and believes and upon such information and belief alleges that DKC facilities' rely upon the physician attestation contained in CMS Form 2728 to certify the medical necessity of the dialysis initiations and treatments provided at DKC's dialysis facilities.

70. DaVita and DKC's longstanding practice of allowing its referring-staff nephrologist to unilaterally determine the timing and manner of dialysis provided at DKC dialysis facilities and its equally longstanding failure to ensure that DKC's dialysis facilities and its medical directors implemented and enforced current evidence-based policies to prohibit medically unnecessary prophylactic dialysis treatments, violate material provisions of the ERSD conditions of coverage, specifically 42 C.F.R. §§ 494.80, 494,90 and 494.180. DaVita and DKC's knowing violation of these statutes resulted in DKC patients routinely receiving medically unnecessary and harmful premature dialysis treatments, but further defendants' goal of increasing profits through additional billings to Government Funded Payors for premature dialysis treatments. Seeking payment for such medically unnecessary and/or harmful dialysis treatments results in (a) the submission of false and fraudulent claims for services in violation of the False Claims Act (FCA), (b) uses false statements in documents material such claims

in violation of the FCA, and (c) makes untruthful various express and implied certifications of compliance with the foregoing statutory provisions, certifications of medical necessity and certifications of compliance with Medicare program requirements in violation of the FCA.

71. Dr. Holzner is informed and believes and upon such information and belief alleges that DaVita and DKC knowingly failed to implement current evidenced-based policies to prohibit medically unnecessary prophylactic dialysis treatments because doing so would cause DKC's dialysis facilities to refuse providing (and billing for) approximately 30% or more of its annual hemodialysis treatments. Additionally, declining to allow referring-staff nephrologists to admit CDK patients to DKC dialysis facilities to receive medically unnecessary prophylactic hemodialysis treatments risks causing such nephrologists to refer patients to Fresenius, DaVita's chief competitor.

72. During and between 2011 and the present, DKC dialysis facilities knowingly and routinely provided its ESRD patients medically unnecessary prophylactic dialysis treatments at the request of their referring-staff nephrologists. These prophylactic dialysis treatments were provided in violation of the conditions of coverage for ESRD facilities 42 C.F.R. §§ 494.80, 494.90, 494.150 and 494.180 which require, among other things, that DKC's dialysis facility's medical directors approve and enforce patient care policies that addresses the patients' admissions to DKC's dialysis facilities and ensure that such policies are followed by DKC's referring-staff nephrologists. 42 C.F.R. § 494.150(c)(1) and (2)(i). Further, such conditions of coverage require that ESRD patient's interdisciplinary team's "individualized and comprehensive assessment" includes an "evaluation of current health status and medical condition, including co-morbid conditions" and an "**evaluation of the appropriateness of the dialysis prescription**, blood pressure, and fluid management needs." 42 C.F.R. § 494.80(a)(1) and (2). (Emphasis added.)

73. Likewise, the IDT's plan of care which is based upon the initial assessment, "[m]ust include measurable and expected outcomes and estimated timetables to achieve these outcomes. The outcomes specified in the patient plan of care **must be consistent with current evidence-based professionally-accepted clinical practice standards**." 42 C.F.R. § 494.90.

(Emphasis added.) 42 C.F.R. § 494.180 requires that DKC's dialysis facilities are under the control of an identifiable governing body, or designated person(s) with full legal authority and responsibility for the governance and operation of the facility. Dr. Holzner is informed and believes and based upon such information and belief thereupon alleges that DaVita is that governing body.

74. Dr. Holzner further alleges that in violation of the above conditions of coverage, DKC does not allow its medical directors to adopt nor enforce patient care policies designed review initial dialysis prescriptions and to deny the patient admission if such prescription requires to DKC to provide medically unnecessary prophylactic dialysis treatments. 42 C.F.R. 4949.150(c)(1) and (2)(i). Further, DKC and DaVita do not allow their medical directors to adopt or enforce patient care policies that require the patient's IDT to review the initial dialysis prescription, as part of its initial patient assessment (which takes place upon the latter of 30 days after patient admission or 13 dialysis treatments), to ensure that such prescriptions do not request DKC to provide medically unnecessary prophylactic dialysis treatments and to immediately suspend such prophylactic dialysis treatments until the patient's referring-staff nephrologist's documents clinical symptoms indicating the onset of a uremic state. 42 C.F.R § 494.80(a)(2).

75. Similarly, DKC does not allow its medical directors to adopt or enforce patient care policies that require the patients' plans of care to be consistent with current evidenced-based professionally-accepted clinical practice standards. 42 C.F.R. § 494.90. During and between 2011 and the present, DKC's patient care policies fail to incorporate current technology from scientific advances and current evidenced-based national guidelines regarding the initial timing and ongoing dialysis treatments at DKC facilities. Relevant here is DKC's failure to have its patient care policies reflect the settled conclusions rendered from the August 2010 publication of the IDEAL Study which conclusively determined that there was no medical benefit from initiating dialysis treatments based on estimated creatinine clearance rate (e.g., eGFR 15 mL/min) prior to the patient exhibiting clinical symptoms indicating the onset of a uremic state (i.e., medically unnecessary prophylactic dialysis treatments), The Ideal

Study's conclusions were incorporated into the 2015 K/DOQI guidelines which are nationally recognized practice standards. Defendant's failure to have its patient care policies reflect such guidelines is because **it would require DKC to stop providing medically unnecessary dialysis treatments which represents in excess of 30% of the dialysis treatments performed each year since 2011.**

76. During and between 2007 and 2015, Dr. Holzner served as one of CareMore Healthplan's (CareMore) Chief Hospitalist and Medical Director. In that capacity he was responsible for, among other things, all of CareMore's ESRD patients. During or about 2007 CareMore set up the CareMore ESRD Special Needs Plan (the "CareMore SNP") under the Medicare Advantage program for which Dr. Holzner was also chiefly responsible. The CareMore SNP was at the time one of the nation's few if not only ESRD SNP. The CareMore SNP contracted with DaVita to arrange for DKC dialysis facilities to provide dialysis services to a majority of CareMore's ESRD patients. As a result of the foregoing job duties, Dr. Holzner became knowledgeable about DaVita's and DKC's operations and learned of the frauds alleged in this Fourth Amended Complaint.

77. Beginning in 2007 and continuing through most of 2015, Dr. Holzner established and supervised CareMore's ESRD Program which engaged in patient surveillance, as well as nephrologists monitoring and education in an effort to improve ESRD patient outcomes, decrease patient mortality rates, reduce ESRD patient hospitalization rates and lower overall treatment costs. The ESRD Program consisted of bi-monthly meetings with CareMore staff to carefully review CareMore's ESRD patients' outcomes, treatments and hospitalizations resulting from the dialysis treatments, drug utilization and related services provided by DKC dialysis facilities. CareMore's ESRD Program attemptted to accomplish the foregoing by educating CareMore's ESRD Program's staff so they could attempt to educate DaVita-contracted nephrologists and DKC's medical directors regarding more cost-effective and efficacious ESRD treatment methods.

78. The CareMore ESRD Program consisted of bi-monthly meetings at CareMore's Cerritos, California corporate offices with all of the ESRD Program's staff. ESRD Program

staff included, but was not limited to, physicians, pharmacists, nurse practitioners (NPs), physician assistants (PAs), social workers, dieticians and statisticians, among others. The ESRD Program staff conducted patient surveillance of CareMore's ESRD patients by reviewing medical records, pharmacy records, hospital admission records, interviewing patients regarding their dialysis treatments, medications and other services provided by DKC, and speaking with DKC's physicians and staff. At each meeting, approximately twenty ESRD patient files were reviewed in detail to analyze, among other things, dialysis initiation, treatments and medication usage.

79. At the conclusion of CareMore's bi-monhtly ESRD Program meetings, Dr. Holzner would begin telephoning CareMore's contracted nephrologists that were also credentialed staff nephrologists at DKC dialyses facilities and/or DKC facility's medical directors to persuade individual nephrologists and DKC facility medical directors to adopt CareMore's ESRD patient care strategies regarding dialysis initiations, and Sensipar and Renagel utilization.

80. During and between 2007 and 2015, Dr. Holzner's understanding of DKCs patient care practices regarding dialysis initiation and treatments and his knowledge of any related policies resulted from (a) information that DaVita and/or DKCs made publically available, (b) discussions with DKCs' and/or DaVita's contracted nephrologists and medical directors that participated in CareMore patients' dialysis initiation and treatments, (c) telephone conversations with CareMore's ESRD Program staff who spoke to CareMore contracted nephrologists that were also DKCs staff nephrologists (i.e., credentialed to admit patients to particular DKC facility), (d) information and data obtained from reviewing CareMore ESRD patient files who received dialysis treatments from DKCs, (e) information obtained from patient accounts and patient data DKCs provided to CareMore, (f) conversations with CareMore's ESRD Program staff that had spoken to CareMore ESRD patients regarding their dialysis treatments and other services they received from DKCs, (g) Dr. Holzner's conversations with CareMore ESRD patients regarding the dialysis treatments and other services they received from DKCs, and (h) telephone conversations with Dr. Allen Nissenson,

DaVita's Cheif Medical Officer.

81. During and between 2007 and 2015, Dr. Holzner had several telephone conversations with Dr. Nissenson, regarding DKC patient care policies. Dr. Holzner's understanding from these telephone conversations was that DKCs' patient care policies and procedures regarding DKCs' facility access, patient admissions and patient care were created and approved by DaVita and Dr. Nissenson, not by DKC's dialysis facility's medical directors.

82. Dr. Holzner's above understandings were also confirmed by telephone conversations he held with DKCs' medical directors following CareMore's ESRD Program's bi-monthly meetings. The foregoing DKC's medical directors that Dr. Holzner telephonically spoke with, included but are not limited to, Dr. Chawdry, Dr. Elsharwy, Dr. Carlos Gonzales, Dr. Mark Lee, Dr. Boroujerdi, Dr. Kyaw Moe, Dr. Nirada Gandhi, Dr, Jorge Mendelbaum, Dr. Adarsh Baswani, Dr. Rodrigo Rocha, Dr. Marco Martinez, Dr. Daswaswni, Dr. Ronald Fishman, Dr. Wassily and Dr. Victor Carabello (collectively the "DKC Medical Directors").

83. As a result of Dr. Holzner's ongoing telephone conversations with the DKC Medical Directors as part of overseeing CareMore's ESRD Program, Dr. Holzner confirmed that during and between 2007 and 2015, with respect to the DKC dialysis facilities that CareMore had utilized throughout southern California and also in Phoenix Arizona, DKC's patient care policy for patient admission and dialysis initiation is that the patient's referring-staff nephrologist is allowed to unilaterally choose the timing and manner of dialysis initiation. DKC facilities had no enforceable patient care policies allowing its medical directors to restrict patient admissions or otherwise prevent DKC from providing medically unnecessary dialysis treatments requested by a staff nephrologists initial dialysis prescription. Dr. Holzner is informed and believes and upon such information and belief alleges that the foregoing accurately describes a nationwide practice carried out at all of DKC's dialysis facilities throughout the United States.

84. During and between 2016 and the present, Dr. Holzner had several conversations with Dr. V. Carabello and Dr. R. Fishman, both DKC medical directors at multiple southern

California DKC dialysis facilities. These medical directors informed Dr. Holzner that there had been no changes from the previously described policies, or lack there of, regarding DaVita or DKC changing existing nor implementing any new patient care policies designed to prevent the provision of medically unnecessary prophylactic dialysis treatments at DKC dialysis facilities nor restrict the admission of patients to receive such medically unnecessary treatments. Further, shortly after the service of the Third Amended Complaint upon DaVita and DKC, DaVita published an article on its website dated April 19, 2019, What is Dialysis and When Do I Start?, available at DaVita.com. The article takes the position that DKC dialysis facilities and its medical directors are not involved in determining when or under what circumstances ESRD patients start and continue dialysis treatments at DKC's dialysis facilities, and that is purportedly a decision between the patient and their referring-staff nephrologist. The DaVita article states that early dialysis initiations may be considered wise by some nephrologists and therefore, DKC would provide such prophylactic dialysis treatments if a staff nephrologist prescribed it. The article also falsely states that DKC's dialysis facilities follow the K/DOQI guidelines which may have been truthful in 2006 but no longer is in light of the 2015 updated K/DOQI guidelines..

85. Based upon the foregoing, Dr. Holzner is informed and believes and based upon such information and belief thereupon alleges that during and between 2016 and the present DaVita and DKC continued to allow and advocate via What is Dialysis and When Do I start? for the provision of medically unnecessary prophylactic dialysis treatments, and are at a minimum tacitly requesting their staff nephrologists write initial dialysis prescriptions for same. Dr. Holzner is further informed and believes and upon such information and belief alleges that during and between 2016 and the present DaVita and DKC continue to engage in their nationwide scheme of failing to have appropriate patient care policies prohibiting the provision of medically unnecessary prophylactic dialysis treatments, enforceable by DKC's medical directors, in violation of the conditions of coverage for ESRD facilities 42 C.F.R.§§494.80, 494.90 494.150 and 494.180 and the FCA.

86. Following the publication of the IDEAL Study during 2010, Dr. Holzner helped

convince some of the DKC medical directors that he worked closely with to discontinue providing medically unnecessary premature dialysis initiations of CareMore ESRD patients based on the evidence published in the IDEAL study. However, Dr. Holzner subsequently learned from discussions with DKC medical directors, DaVita's Chief Medical Director Allen Nissenson, M.D., and information published on DaVita's website that DaVita and DKC dialysis facilities have continued until the present to advocate providing medically unnecessary, premature and prophylactic dialysis initiations nationwide.

87. To date, DaVita and DKC continue to initiate premature dialysis treatments to their ESRD patients. As a result, approximately 30% of DaVita and DKC dialysis treatments are medically unnecessary premature initiations of dialysis treatments performed without the patient needing or benefitting from the premature dialysis treatments.[12] DaVita and DKC's callous pursuit of profits reprehensibly exploited vulnerable, chronically ill ESRD patients to undergo medically unnecessary premature dialysis.[13] As the nation's largest provider of dialysis services, DaVita and DKC's actions also resulted in one of the largest frauds perpetrated on the Medicare program and secondary Government Funded Payors. Dr. Holzner estimates that DaVita and DKC's medically unnecessary premature dialysis initiations cost the Government and Government Funded Payors between $1.12 and $2.25 billion dollars per year for each of the last eight years. This estimate is based on 50,000 annual ESRD patients given medically unnecessary, premature and prophylactic administrations of dialysis treatments for six months to one year at an annual cost of $45,000 per patient.

DaVita DCK and DRX Medically Unnecessary Sensipar Fraud

88. ESRD causes many significant physiological problems. One such problem is the

[12]The IDEAL study concluded that approximately 45% of the dialysis treatments were started premature resulting in six months to one year of medically unnecessary dialysis treatments for such patients. During on or about 2011 Stanford University Medical School researchers including Dr. Graham Abra reviewed CareMore's ESRD data from DKC. Dr Abra and his colleagues informed Dr. Holzner and Dr.David Martinez that in more than 30% of the dialysis treatments performed on CareMore ESRD patients were premature and prophylactic medically unnecessary dialysis treatments which conferred no clinical benefit to such patients and were likely harmful.

kidneys' failure to produce vitamin D, which is necessary for the body to metabolize calcium. The lack of vitamin D causes calcium to be leached from the bones, making them weak and brittle. In response to low calcium levels, the parathyroid gland produces more parathyroid hormone (PTH), which increases serum calcium levels by demineralizing bone. Increased levels of PTH are characteristic of patients with ESRD. This constant over-taxing of the parathyroid eventually leads to secondary hyperparathyroidism. Some ESRD patients develop tertiary hyperparathyroidism, where the parathyroid produces PTH autonomously, regardless of calcium levels. Tertiary hyperparathyroidism can only be cured by surgically removing the parathyroid. To help mitigate these symptoms, ESRD patients are given calcium supplements and vitamin D is added to their dialysate. Taking high doses of calcium may lead to calcium toxicity, which can cause calcium deposits to form in the patient's vascular system and corneas of the eyes. Dangerous levels of calcium usually take four to five years to manifest. ESRD patients must closely monitor their Vitamin D, calcium and phosphorus levels. Managing these levels are a constant challenge for ESRD patients and their healthcare providers. Cardiovascular co-morbidities are a common cause of death in ESRD patients. The mechanisms causing cardiovascular co-morbidities in ESRD patients are not understood and there are no proven therapies.

89. Cinacalcet, manufactured under the brand name Sensipar by Amgen, was introduced during or about 2002 specifically to reduce ESRD patients' cardiovascular co-morbidities by lowering parathyroid hormone (PTH) levels in ESRD patients suffering from secondary hyperthyroidism. Approximately 50% of DaVita and DKC's ESRD patients have elevated levels of PTH and are prescribed Sensipar. When Sensipar was originally introduced it was presumed that reducing ESRD patients' PTH levels would reduce cardiovascular co-morbidities and events, and thereby measurably improve the morbidity of ESRD patients. Reducing cardiovascular co-morbidities and events by lowering ESRD patients' PTH levels was the sole reason for prescribing ESRD patients Sensipar.

90. The first major double blind study designed to investigate Sensipar's effectiveness on improving ESRD patients' mortality by reducing their cardiovascular co-

morbidities by reducing PTH levels was the Phase 3, EVOLVE (i.e., EValuation Of Cinacalcet HCl Therapy to Lower CardioVascular Events) trials, underwritten by Amgen, Sensipar's manufacturer and published during November 2012 in the New England Journal of Medicine, (Effect of Cinacalcet on Cardiovascular Disease in Patients Undergoing Dialysis, The EVOLVE Trial Investigators N Engl J Med 2012 Vol367, pp:2482-2494. The results of The EVOLVE Trials conclusively proved that although Sensipar reduced PTH levels in ESRD patients, such reduction in PTH levels had no effect on reducing cardiovascular co-morbidities events, and therefore made no improvement in ESRD patients' morbidity. The EVOLVE Trials also proved that there is no casual relationship between lowering PTH levels and cardiac related health issues. The presumed causal link between reducing PTH levels and lowering cardiovascular health problems was the entire rational for prescribing Sensipar and for ESRD patients taking Sensipar. Since The Evolve Trials showed that Sensipar failed to make any impact on reducing ESRD patients' cardiovascular co-morbidities, does not reduce the frequency or severity of cardiac events nor does it prolong the life span of ESRD patients, there is no reason to prescribe Sensipar to ESRD patients and no medical necessity supporting it use. New Eng. J. Med. (Nov. 3, 2012), Vol. 367, pp. 2482-2494.

91. Sensipar was a drug that was originally supposed to be part of the PPS bundle payment that was phased-in over four years beginning in 2011. Due to lobbying from Amgen Sensipar's manufacturer, a legislative exemption that delayed Sensipar's phase-in into the PPS bundle until 2019 with a two year phase-in beginning in 2018. As a result, instead of the cost of Sensipar being charged against DKC's monthly PPS bundle payment, DKC could charge Medicare and Government Funded Payors an amount equal to Sensipar's average retail price plus 6%. Sensipar was expensive, with a year's supply cost approximately $9,000. Once patients started taking Sensipar, it was likely they would continue taking it for the remainder of the lives. As a result of Sensipar not being part of the ESRD PPS Bundle until 2018, Sensipar was a source of additional profit to defendants equal to the 6% surcharge over theaverage retail price plus whatever wholesale discount DRX could obtain from being a large purchaser of the drug. Relator estimates that DRX was able to obtain a discount of

approximately 14% which would result in a 20% profit stream from Sensipar or approximately $1,800 per year for each patient taking Sensipar. However, the damage to the Medicare program was the entire annual costs of the drug, (i.e., $9000 per year for each patient taking Sensipar.)

92. After the publication of The EVOLVE Trials, DaVita, DKC, and DKC's medical directors were required to discontinue prescribing Sensipar and DKC's medical directors were required to develop and implement policies and procedures prohibiting its use because it was not medically necessary. The EVOLVE Trials debunked and disproved the casual link of reducing CardioVascular health problems from lowering PTH levels by administering Sensipar. Sensipar was expensive and the medical research available concluded it was not efficacious as once believed. There was no medical research supporting an off label use so that Sensipar as of November 2012 was established as not medically necessary pursuant to the statutory criteria set forth at 42 U.S.C. §1320c-5(a). Without being able to certify Sensipar's medical necessity, it was no longer reimbursable pursuant to 42 U.S.C. § 1395y(a)(1)(A) and knowingly submitting claims for a medically unnecessary drug, like Sensipar, is a false claim in violation of the FCA.

93. During and between 2013 and 2017, nearly all of DKC's medical directors failed to adopt new patient care policies prohibiting the use of medically unnecessary Sensipar. Neither DKC, its governing body nor DaVita took any steps to correct DKC's medical directors failure to prohibit the use of Sensipar because of its lack of medical necessity. Dieticians employed by DKC that served on multiple interdisciplinary teams continue to insist that all patients with elevated PTH levels be prescribed Sensipar resulting in prompt fulfilment by DRX who continued to drop-ship oversized monthly supplies of Sensipar to DKC facilities to be furnished to DKC's patients and/or directly to DKC's patients homes. No steps were taken to reduce or prohibit the use of Sensipar at DKC dialysis facilities by its medical directors.

94. Dr. Holzner is informed and believes and based upon such information and belief alleges that following the publication of The EVOLVE Trials, DaVita and DKC promoted

and/or instructed its employed medical directors, nurse practitioners (NPs), dieticians and contracted and/or affiliated physicians to prescribe Sensipar to all of their ESRD patients with elevated PTH levels purportedly to reduce such ESRD patients' cardiovascular co-morbidities and thereby improve their mortality. Prior to 2013, Sensipar was prescribed to ESRD patients despite the lack of evidence or medical research establishing a causal link between elevated PTH levels and cardiac co-morbidities in ESRD patients (or any other types of patients). The 2012 EVOLVE trials conclusively proved that no such causal link existed and made clear that Sensipar was not efficaciousness and failed to reduce the cardiac events and improve cardiac co-morbidities as intended. After the EVOLVE trials publication, DaVita and DKC's decision to allow their employed medical directors, NPs, dieticians and contracted and/or affiliated physicians to continue prescribe medically unnecessary Sensipar was purely for DaVita, DKC and DRX's financial gain.

95. Sensipar was all times relevant before 2018 excluded from the ESRD PPS payment bundle.[14] As a result, DKC and DRX billed the Government and other Government Funded Payors separately for Sensipar at 6% above the manufacturer's Average Sales Price (ASP) for Sensipar reimbursement. This surcharge combined with the wholesale volume discount DRX was able to obtain from being one of the major purchasers of Sensipar created a tremendous financial incentive for DaVita to continue to have its subsidiaries prescribe and furnish the medically unnecessary Sensipar after the EVOLVE trials publication.[15]

96. Typically, the patient's interdisciplinary team's DKC-employed dieticians made the initial order for the patient's Sensipar prescription. This order was for at least a month's supply and was quickly fulfilled by DRX by drop shipping the Sensipar directly to the

[14]Sensipar began a two year phase-in into the ESRD bundle coverage starting in 2018.

[15]At an estimated 14% wholesale volume discount price, said defendants derived approximately $100 million per year of additional profit (after deducting the cost acquiring the Sensipar) from medically unnecessary Sensipar prescriptions. Due to Sensipar's expense and said defendants' pervasive use of this medically unnecessary drug, the additional cost to Government and MA plans for such Sensipar prescriptions is estimated to be in excess of $500 million per year for each of the last six years. This estimate is based on Sensipar at $8,400 per year per patient for approximately 60,000 patients.

patient's home and/or the patient's DKC facility. It was customary for the treating nephrologists to forgo attending the statutorily required weekly interdisciplinary team meetings to review the adequacy of the dialysis treatments pursuant to 42 C.F.R. § 494.90(a)(1) because the nephrologists are not compensated by Medicare nor DKC for attending.[16] Instead the patient's treating nephrologist typically made unscheduled monthly or more frequent visits to the DKC dialysis facility to sign previously filled prescriptions for Sensipar.

97. DKC staff nephrologists rarely attended their patient's scheduled IDT meetings because the nephrologists did not receive additional compensation for attending. DKC medical directors were not supposed to try to compel their statutorily required attendance but instead allowed the staff nephrologist to make ad-hoc appearances as a substitution for attending the IDT meetings. All the other eders of the IDT were DKC employees. In the staff nephrologist's absence the dietician would recommend to the IDT that the patient be prescribed either Sensipar or Renagel which ever drug the dietician thought was most appropriate. In the nephrologists absence and without having and written or verbal orders regarding prescribing either drugs for the patient in question the dietician would undertake the following steps:

1. Arrange for the patient to immediately be given their first dose of Sensipar or Renagel while onsite at DKC's dialysis facility (the drug would furnished from DKCs' readily available Sensipar or Renagel samples);

2. Arrange for DaVita Rx, DaVita's in house pharmacy, to drop-ship the first of three, 90 day supplies of Sensipar or Renagel to be dropped shipped to the patient's residence;

3. Prepare the physician's order authorizing the foregoing and the Sensipar prescription for an initial 90 day supply plus two refills to be signed by the patient's treating nephrologists during such nephrologists next ad-hoc appearance; and

4. Ensure that the physician's orders and Sensipar prescriptions were signed by the

[16] In contrast, treating nephrologists receive compensation from Medicare or other Government Funded Payors of approximately $250.00-$350.00 per month for every patient's dialysis sessions. This can be a significant part of the nephrologist annual compensation because there is very little overhead associated with these payments. The nephrologists is not required to be present in order to bill and receive this compensation.

nephrologists at his/her next appearance at the DKCs location.

The foregoing steps where also a long standing practice at most if not all DKC' dialysis facilities nationwide to be used for drugs charged outside the ESRD payment bundle)

98. Sensipar was a source of additional profit to DaVita because (a) DKC billed the Government and Government Funded Payors separately for Sensipar at 6% above the manufacturer's Average Sales Price (ASP), and (b) DRX was able to obtain volume wholesale discounts from being one of the major purchasers of Sensipar. This came to an end beginning in 2018 when 25% of the Sensipar's cost was shifted into the ESRD PPS bundle, as part of a two year phase-in. Relator is informed and believes and upon such information and belief alleges that the 25% cost shift offset the additional profit generated by prescribing Sensipar and made its continued use an additional expense to DaVita. As a result, beginning in 2018 DaVita discontinued DRX's operations and instructed DKC to no longer have its interdisciplinary teams request or authorize prescriptions for Sensipar. .

99. DaVita has been a partner in a MA Special Needs Plan (SNP) with SCAN Healthplan located in Long Beach, California since about 2007 and continuing to the present. For the SNP, drugs that are not in the ESRD bundle, such Sensipar, are an additional expense to the SNP, which was partially owned by DaVita. Pursuant to instructions from the SNP's medical director, DKC's interdisciplinary teams assigned to the DaVita-SCAN MA SNP patients, did not prescribe Sensipar to ESRD patients enrolled to the DaVita-SCAN SNP However, California's Medicaid program known as Medi-Cal, would cover the cost of Sensipar for dual eligible patients (i.e., patients enrolled in Medicare and Medi-Cal.) As a result, during and between 2012 and 2017 the DaVita SNP's interdisciplinary teams prescribed Sensipar to its dual eligible patients. This practice stopped in 2018 when Sensipar started to be phased into the ESRD PPS bundle. Dr. Holzner is informed and believed and upon such information and belief alleges that during and between 2012 and 2017 there were no peer reviewed medical research or other evidence that supported Sensipar's manufacturer's claims that Sensipar was efficacious for reducing cardiac co-morbidities in ESRD patients nor in improving such patient's life spans as promoted.

100. DaVita and DKC's interdisciplinary teams' actions of not recommending or prescribing Sensipar and primarily prescribing OTC phosphate binders instead of Renagel to DaVita-SCAN MA SNP patients when DaVita is financially on the hook for the expense, but aggressively recommending and prescribing Sensipar and Renagel whenever it can be billed separately and serve as an additional profit source, is evidence of DaVita and DKC's knowledge that such medications were not medically necessary, cost-effective nor efficacious. Further, such actions are evidence of defendants' knowledge and fraudulent intent to recommend and over-prescribe Sensipar and Renagel for profit although it was not cost effective, efficacious nor medically necessary to do so.

101. DKC's medical director must also ensure that the interdisciplinary team, including the patient's personal nephrologists, adhere to such policies and procedures. *Id*. at §494.150(c)(2). Based on the New England Journal's publication of The EVOLVE Trials that informed DaVita and DKC that Sensipar had no impact at reducing the number or severity of cardiac events and failed to improve ESRD patients' mortality rates, as of 2013, DaVita and DKC should have required its medical directors to adopt policies and procedures that prohibited using, prescribing and furnishing medically unnecessary Sensipar to DKC's ESRD patients. Further, DaVita and/or DKC had to ensure that its medical directors required adherence to such policies and procedures by DKC's employees and employed and contracted nephrologists that participated as DKC interdisciplinary team members.

102. DaVita and DKC failed to implement the above described changes to discontinue recommending, prescribing and furnishing medically unnecessary Sensipar to their ERSD patients. Instead, DaVita and DKC maintained the status quo and continued to recommend and prescribe Sensipar to their patients with elevated PTH levels (i.e., approximately 50% of their ESRD patients) for as long as Sensipar was an additional source of profit. The EVOLVE trials that Amgen sponsored and published in the New England Journal of Medicine proved that reducing PTH levels with Sensipar had no effect in reducing the frequency or severity of ESRD patients cardiovascular co-morbidities nor improved the mortality of such ESRD patients. Since reducing cardiac co-morbidity was the specific reason for prescribing Sensipar,

The EVOLVE Trials' repudiation of Sensipar's efficaciousness made its continued use medically unnecessary and therefore not reimbursable under Medicare and other federally funded health care programs. 42 U.S.C. 1320c-5(a) and 1395y(a)(1)(A). As a result, during and between 2013 and 2017 all DaVita, DKC and DRX's claims for Sensipar submitted to Medicare and other Government Funded Payors contained false statements and false implied and express false certifications of medical necessity in violation of 42 U.S.C. §§ 1395y(a)(1)(A), 1320c-5(a)(1) and the False Claims Act. Had CMS known that Sensipar was not medically necessary for DaVita's and DKC's ESRD patients, CMS would have denied all claims for payment because medical necessity is an expressed condition precedent to all Medicare payments pursuant to 42 C.F.R. § 1395y(a)(1)(A).

103. As a result of Relator's own research and investigations and from discussing the topic with numerous DaVita and DKC nephrologists during and between 2007 and 2017, Relator confirmed that Sensipar was routinely prescribed and furnished to most of DaVita's and DKC's ESRD patients with elevated PTH levels. This practice was nationwide and continued at most DKC locations after the publication of the EVOLVE trials until the first year of Sensipar's cost being phased into the ESRD PPS bundle. The continued prescribing and furnishing of Sensipar during and between 2013 and 2017 was unquestionably with DaVita's, DKC's and DRX's knowledge that Sensipar was not efficacious for the use intended and therefore not cost effective nor medically necessary.

104. During and between 2011 and 2017, DaVita through its subsidiaries DKC and DRX, routinely prescribed and furnished Sensipar, a drug that was claimed to reduce ESRD patients' cardiac events and decrease patient's mortality rates presumably caused by increased levels of parathyroid hormones (PTH). As ESRD patients' CKD progresses, their parathyroid gland begins increasing its output of PTH. Over a period of typically three to five years, this progresses to secondary hyperparathyroidism and eventually progresses to tertiary hyperparathyroidism where the production of PTH becomes uncontrollable. ESRD patients can tolerate secondary-hyperparathyroidism without difficulty and it does not ordinarily need to be treated. ESRD patients with tertiary-hyperparathyroidism usually experience increased

discomfort and a higher rate of bone demineralization. However, since the average mortality rate of ESRD patients (i.e., CKD patients receiving dialysis) is approximately 5 years, not all ESRD patients live long enough to develop tertiary-hyperparathyroidism and depending on other comorbidities and overall health status, treating it may not be a high priority. The simplest treatment for tertiary-hyperparathyroidism is to surgical remove the parathyroid gland, assuming that the ESRD patient's health is such that they can tolerate undergoing the surgical procedure.

105. Sensipar was developed specifically to improve ESRD patients' mortality rates by reducing cardiac events presumably caused by increased PTH levels due to secondary-hyperparathyroidism. Evidence of this fact is found in the EVOLVE Trials which studied this claim by and whose efforts were financially underwritten by Amgen, the drug's manufacturer. Except for this presumptive reason, there is no medical literature demonstrating a medical benefit for treating secondary-hyperparathyroidism. The EVOLVE Trial study involved nearly 4,000 ESRD patients and randomly gave half a placebo while the other half where given Sensipar. The study found that Sensipar provided no clinical benefit in reducing mortality from any cause nor did it have any impact on reducing cardiac comorbidities and events.

106. The FDA approved Sensipar on a surrogate measure meaning it was approved by demonstrating the drug lowered PTH levels. It was not approved based on any scientific research that demonstrated that Sensipar conferred any clinical benefit on those patients who took the drug. Report to Congress: Medicare Payment Policy Ch. 6, MedPac p. 189 March 2020. After the EVOLVE Trial demonstrated that there was no causal link between PTH levels and cardiac comorbidities in ESRD patients and that Sensipar had no effect at improving patient mortality, prescriptions for Sensipar somehow increased. Following the Evolve Trial another the following study was published, Cincalcet in patients with Chronic Kidney Disease: A Cumulative Meta-Analysis of Radomized Controlled Trials ("Cinacalcet in Patients with CKD") which in April 2013 stated, "Within a decade of the first small randomized trials for cinacalcet and despite an earlier Meta-analysis showing no evidence for benefit on a clinical outcomes, cinacalcet prescribing has become the largest single drug cost for dialysis patients

in the United States, with an annual expenditure of at least $260 million." Chronic Kidney Disease: A Cumulative Meta-Analysis of Randomized Controlled Trials, Suetonia C. Plamer et al., PLOS Medicine , April 2013 Vol. 10, Issue 4 p 1-13 available at www.plosedicine.org.

107. Despite the EVOLVE Trial and Cinacalcet in Patients with CKD both concluding that Sensipar has no impact on ESRD patient mortality its use to treat ESRD patients consistently increased to over $1.2 billion during 2017. Report to Congress: Medicare Payment Policy Ch. 6, MedPac p. 189 March 2020. It is still unclear what the medical purpose an measurable objective outcome associated with the use of Sensipar when given to ESRD patients. Likewise, 2017 KDIQO Guideline Updates, determined after reviewing the EVOLVE Trial that there appeared to be no need to prescribe Sensipar as it does not improve mortality. KDOQI US Commentary on the 2017 KDIGO Clinical Practice Guideline Update of the Diagnosis, Evaluation Prevention and Treatment of CDK-Mineral Bone Disorder, Tarmara Isakova MD, et al., American Journal of Kidney Disease, 2017, Vol 70, Issue 6, P. 737-75 at P. 742 . Relator is unable to identify any medical research that supports the continued use of Sensipar.

108. DKC has refused to adopt appropriate patient care policies to curtail the medically unnecessary use of Sensipar and prohibits its medical director fro adopting and enforcing such patient care policies. The Defendants' financial motivations appear to be the only explanation for Sensipars continued use and for the ongoing failure to comply with key provisions of the coverage conditions for esrd 're the only reason for its significant use, which is a disqualifying reason when establishing the drug's medical necessity as required by law. 42 U.S.C §§1395y(a)(1)(A), 1320c-5(a).

109. Although originally scheduled to be part of the ESRD payment bundle, powerful interests managed to keep Sensipar temporarily exempt until 2020 with a two year phase in beginning in 2018. As a result instead of Sensipar being viewed as an expense by the defendants where each prescription increases costs against a fixed bundle payment amount the opposite has occurred. Each Sensipar prescription is an opportunity for the defendants to make modest profit but a significant costs to the Medicare fisc. While outside the ESRD

payent bundle DaVita is able to receive the average retail price of the drug plus 6%. That formula alone should allow DaVita to make some money on every prescription because they are receiving 6% above retail. However if DaVita can purchase the drug at wholesale instead of retail then a significant profit can be derived. In response DaVita established DaVita Rx and in house pharacy set up to drop ship a 90 day supply at a time. Since Sensipar was designed as a drug used only by ESRD patients, DaVita is in position to be the largest purchaser of the drug and its market share to drive down the wholesale price in exchange for large orders. Sensipar was expensive costing approximately $7000 per year for each patient. With its wholesale position of plus 6% retail pricessss Dr. Holzner estimates that DaVita was earning be a profit of 15-20% of the retail price for every prescription. Or approximately $1000 to $1400 per prescription.

110. Sensipar was one of small number of drugs that was approved by the FDA without any clinical trials demonstrating the drugs efficacy in addressing its intended use of improving ESRD patients mortality rates. While there is no dispute that Sensipar does in-fact reduce the production of PTH by the parathyroid gland achieving this outcome is only consequential if there is a legitimate medical benefit conferred to the patient as a result.

111. In December 2012, the New England Journal of Medicine published the landmark RTC EVOLVE Trails, underwritten by Amgen, Sensipar's manufacturer. The purpose of the EVOLVE Trails was to quantify the causal link between increased levels of PTH due to secondary-hyperparathyroidism and ESRD patients mortality rates and thereby the value of using Sensipar to lower such PTH levels and decrease the mortality rate of ESRD patients. Unfortunately to Amgen's surprise the EVOLVE Trials conclusively showed that there was no causal link between increased PTH levels and ESRD patient mortality. Likewise the study found no causal link between increased PTH levels and an increase in cardiac event or cardiac related comorbidities in ESRD patients. As a result of the foregoing Sensipar's legitimate use is limited to treat tertiary-hyperparathyroidism in those ESRD patients that would not be able to tolerate the surgical removal or otherwise would not be good candidates for that surgical procedure.

112. During and between 2009 and the present, the overwhelming majority of DKC dialysis facilities and their medical directors improperly allowed DKC's ESRD patients to be prescribed Sensipar (also known as cinacalcet) despite the fact there was no medical benefit for this drug. The reason that Sensipar was prescribed was that it was initially exempted from the PPS bundle. As a result, prescribing Sensipar was an additional source of profit for DaVita and DRX. DKC's medical directors are responsible for all patient care and quality issues for DKC facilities' ESRD patients. 42 C.F.R. § 494.150(c). DKC's medical directors were required to establish comprehensive patient care policies and procedures that govern, among other things, the administration of Sensipar or the its nonuse. All services provided by DKC dialysis facilities must be medically necessary in order to be reimbursable under Medicare and other federally funded healthcare programs. 42 U.S.C. §§ 1320c-5, 13995y(a)(1)(A). In order to satisfy the medical necessity criteria of §1320c-5(a), Sensipar has to be an economical choice, prescribed only as medically necessary under the circumstances and supported by valid, credible and current medical research demonstrating that it is efficacious. Despite the inability to certify Sensipar's medical necessity, during and between 2009 until 2018 DKC and DKC's medical directors allowed Sensipar to be routinely prescribed DKC's patients and arranged for such prescriptions to be fulfilled by DRX.

113. As a result of the foregoing, DaVita, DKC, DRX were all involved in fraudulent scheme to prescribe and furnish medically unnecessary Sensipar and to improperly seek reimbursement from Medicare and other Government Funded Payors. To be reimbursed for Sensipar, the DKC or its designee impliedly and expressly certified that Sensipar was medically necessary. These certifications were made knowing that they were false. The true facts were that Sensipar was only being prescribed as a source of additional profit for DaVita, DKC and DRX. Due to the lack of medical necessity pursuant to 42 C.F.R. § 1320c-5(a), all claims for Sensipar made during and between 2009 and 2017 were not reimbursable pursuant to 42 C.F.R. § 1395y(a)(1)(A) and their submission to Medicare, MAOs or other federally funded health care programs resulted in false claims in violation of the FCA.

114. Although Relator's interactions with defendants focused on DKC dialysis

facilities in southern California and Arizona, Relator is informed and believes and upon such information and belief alleges that defendants' utilization and billing of Government Funder Payors for premature dialysis treatments, medically unnecessary Sensipar, and cost-ineffective Renagel was performed at its facilities nationwide.

DaVita, DKC and DRX's Fraudulent Use of Renagel

115. During and between 2009 and the present, the overwhelming majority of DKC dialysis facilities and their medical directors improperly allowed DKC's ESRD patients to be prescribed Renagel (also known as sevelamer) despite the fact that due to its high costs it could not be legitimately certified as medically necessary for the vast majority of DKC's ESRD patients. The reason that Renagel was prescribed to DKC's ESRD patients was becasue its temporary exemption from the PPS bundle and high cost made it an additional source of profit for DaVita and DRX. DKC's medical directors are responsible for all patient care and quality issues for DKC's ESRD patients. 42 C.F.R. § 494.150(c) DKC's medical directors are required to establish comprehensive patient care policies and procedures that govern, among other things, the administration of phosphate binders and when and if it is medically necessary to prescribe a very expensive phosphate binder, such as Renagel.

116. In order to satisfy the criteria established at 42 U.S.C.§1320c-5(a) for reimbursement under Medicare, Renagel cannot be prescribed simply because it is the most profitable and most expensive treatment option. One of the criteria it must meet is to be cost effective. medical necessity criteria, Renagel has to be an economical choice, prescribed as medically necessary under the circumstances and supported by valid, credible and current medical research supporting such medical necessity. Because there are inexpensive and equally safe and effective over the counter phosphate binders, such as calcium acetate and calcium carbonate (i.e., Tums), it is impossible to satisfy the cost effective reimbursement criteria for Renagel. The exception would be for a patient that could not tolerate the calcium based phosphate binders. Renagels use by DKC was becaseu it generated additional profit as a result of the reiubursent process. This only worked if drugs were expensive, DaVita and DKC cannot take advantage of the public fisc by over prescribing Renagel so that it becoes its

own profit center for daVita at the tax payors expense. Not when there are equally safe and effective OTC medications that can be easily used in almost every case. The difference in cost to the Medicare program is well over $1 billion dollars per year. Despite the cost effective criteria not being meet nor achievable, during and between 2009 and 2017, DKC prohibited its medical directors fro creating, implementing and enforcing patient care policies to curtail the overuse of Renagel. Insted DKC diticians would arrange for Renagle to furnished and dropped shipped to patiens' hoes without written or verbal physician orders. These requests would be fulfilled by DRX.

117. As a result of the foregoing, DaVita, DKC, DRX were all involved in a fraudulent scheme to prescribe and furnish medically unnecessary Renagel to DKC's ESRD patients and to improperly seek reimbursement from Medicare and other Government Funded Payors. To be reimbursed for Renagel, DKC or its designee impliedly and/or expressly certified that Renagel was cost effective in the context of 42 U.S.C. 1320c-5 These certifications were made knowing that they were false. The true facts were that Renagel was only being prescribed and administered as a source of additional profit for DaVita, DKC and DRX. Due to the cost effectiveness pursuant to 42 C.F.R. § 1320c-5(a), nearly all claims for Renagel made during and between 2009 and 2017 were not reimbursable pursuant to 42 C.F.R. § 1395y(a)(1)(A) and their submission to Medicare and other Government Funded Payors resulted in false claims in violation of the FCA.

118. ESRD prevents the kidneys from removing phosphorous from the blood and phosphorous is not removed by dialysis. Phosphorous is present in many foods and is absorbed through the digestive tract into the blood stream. Having increased levels of phosphorous causes a the demineralization of calcium from the bones and severely depleting calcium stores in the bones, thus weakening them. As a result, ESRD patients, whether or not they are on dialysis, are prescribed a low phosphorous diet and some type of phosphate binder to block the intestinal absorption of dietary phosphorous.

119. Renagel, (also known as sevelamer) manufactured by GenTex Corp., is a non-calcium based prescription phosphate binder that was one of the drugs along with Sensipar

temporally excluded from the ESRD bundle. Like Sensipar, Renagel is also quite expensive, costing approximately $700 per month per patient. In addition to Renagel, there are OTC calcium based phosphate binders such as calcium acetate and calcium carbonate, the active ingredient in the antacid "Tums." Both are equally effective as Renagel in reducing phosphorous levels in ESRD patients, but unlike Renagel, they are both inexpensive and are available OTC without a prescription. *See*, Calcium Based Phosphate Binders Are Appropriate in Chronic Renal Failure, Eli A Friedman, M.D., CSJAN July 2006 ; 1(4), 704-709, ["The case for continuing prescription of calcium based phosphate binders stands on the following: (1) flawed clinical trials that favor sevelamer as a replacement; (2) week evidence that oral calcium intake modulates vascular and/or cardiac calcification (3) clinical trials that reinforce safety and efficacy of calcium-based phosphate binders; and (4) the inordinate relative cost of sevelamer."] Calcium acetate is more cost effective than sevelamer and is effective in controlling serum phosphate; it remains an accepted first -line drug. *Id*. at 709 (Additional citations omitted). However, long term use (i.e., 4-5 years) of OTC phosphate binders at the dosages required can cause unsafe levels of calcium to build up. Since Renagel cannot cause calcium toxicity, it is an appropriate medication for ESRD patients who no longer can tolerate calcium based phosphate binders because of increased calcium levels or otherwise.

120. As a tactic to improperly increase profits, during and between June 2008 and 2017, DaVita and DKC failed to prohibit their medial directors, NPs, dieticians and/or contracted or affiliated physicians from recommending, administering and prescribing Renagel to most of DaVita and DKC's ESRD patients as their primary phosphate binder. Moreover, Dr. Holzner is informed and believed and upon such information and belief alleges that DaVita and DKC actively promoted and instructed their medical directors, NPs, dieticians and contracted and/or affiliated physicians to prescribe Renagel to DKC's ESRD patients as their initial phosphate binder despite the lack of cost effectiveness for Renagel's use. Such ESRD patients' Renegal prescriptions typically continued for the remainder of such patients' lives. Because Renegal was not included in the ESRD PPS bundle prior to 2018, DKC and DRX billed Medicare and other Government Funded Payors for such Renagel and were reimbursed

at 6% over the manufacturer's average sales price (ASP).[17] This surcharge combined with the wholesale volume discount DRX was able to obtain from being a major purchaser of Renagel created a tremendous financial incentive to prescribe medically unnecessary Renagel instead of using much less expensive OTC phosphate binders.[18] As a result of the foregoing, no efforts were made by said defendants to utilize the less expensive OTC phosphate binders for most patients.

121. Typically, the patients' interdisciplinary team's DKC-employed dieticians made the initial order for the patient's Renagel prescription. This order was for at least a month's-plus supply and was immediately forwarded to DRX to furnish the medication by drop shipping the Renagel directly to the patient's home. It was customary for the treating nephrologists to forgo attending the statutorily required weekly interdisciplinary team meetings as the nephrologists were not compensated by Medicare nor DKC for attending, Instead, the patient's personal nephrologists typically made unscheduled monthly or more frequent visits to the DKC dialysis facility to sign previously filled prescriptions for Renagel. Once started on Renagel, DKC's systems were set up to continuously drop ship the medications to the patient's home typically for the remainder of the patient's life (the National Kidney Foundation estimates the average life expectancy of ESRD patients on dialyses is five to ten years). It was common for the patient to be prescribed a quantity of Renagel in excess of their monthly needs so that after several months there was a stockpile of the medication.

122. The DaVita/DKC-employed members of the interdisciplinary team recommended the use of Renagel and failed to disclose to the treating nephrologists, who frequently signed the prescription for Renagel, that at DaVita's joint venture SNP, the employed team members

[17]Renagel began a two year phase-in into the ESRD bundle coverage starting in 2018.

[18]At an estimated 14% volume discount/wholesale price, DaVita, DKC and DRX received approximately $100 million per year of additional profit (after deduction for the Renagel cost) for each of the last six years from improper Renagel use and prescriptions. Because a year's supply of Renagel costs approximately $8,400 per patient and was so widely over-prescribed by DaVita and DKC's physicians, the cost to the Government and MAOs for this fraud is estimated at $500 million per year for each of the past six years based on approximately 60,000 ESRD patients receiving annual Renagel prescriptions.

advocated the use of OTC phosphate binders instead of Renagel for DaVita's SNP patients because Renagel was not cost effective nor more efficacious than OTC phosphate binders. Had defendants recommended the use of OTC phosphate binders and/or disclosed to the treating nephrologists the true facts (i.e., that Renagel was not medically necessary because equally efficacious and less expensive OTC phosphate binders were utilized instead of Renagel for DaVita's SNP patients) the treating nephrologists would have refused to sign the requested Renagel prescriptions. Because the vast majority of ESRD patients could be as effectively treated with much less expensive OTC phosphate binders, such as Tums, prescribing and administering Renagel was not cost-effective pursuant to 42 U.S.C. §1320c-5(a)(1) which requires assurances that all items and services "will be provided economically and only when, and to the extent, medically necessary."

123. The DaVita and DKC interdisciplinary teams' use of Renagel was not cost effective and/or efficacious because equally effective and much less expensive OTC phosphate binders, such as Tums, were available. As previously discussed, 42 U.S.C. § 1320c-5(a)(1) requires healthcare providers to ensure that services, "will be provided economically and only when, and to the extent, medically necessary."[19] DaVita, DKC and DRX's nationwide scheme to knowingly recommend and/or over-prescribe Renagel to increase their profits, resulted in the submission of false and fraudulent claims to the Government and other Government Funded Payors because defendants knew that Renagel is not a cost-effective and/or efficacious medication unless and until the patient can no longer tolerate the equally effective and much less expensive OTC calcium based phosphate binder. 42 U.S.C. §§ 1320c-5(a)(1) and (3), 1395y(a)(1)(A); 31 U.S.C. § 3729(a). DaVita has been a partner in a MA Special Needs Plan (SNP) with SCAN Healthplan located in Long Beach, California since about 2007 and continuing to the present. For the SNP, drugs that are not in the ESRD bundle, such as Renagel and Sensipar, are an additional expense to the SNP, which was partially owned by DaVita. In contrast to the Sensipar and Renagel frauds previously described above, DaVita and DKC's

[19] Additionally, § 1320c-5(a)(3) requires assurances that items and services, "will be supported by **evidence** of medical necessity and quality.... " (Emphasis added.)

employed interdisciplinary team members who treated the ESRD beneficiaries assigned to the DaVita-SCAN MA SNP advocated that Sensipar not be prescribed and further advocated the use of OTC calcium based phosphate binders, such as Tums, and only recommended or prescribed Renagel when medically necessary in cases where the patient could no longer tolerate such calcium based medications. DaVita and DKC's actions of not recommending and prescribing Sensipar and utilizing OTC phosphate binders when DaVita is financially on the hook for the expense, but aggressively recommending and prescribing Sensipar and Renagel whenever it can be billed separately and serve as a source of additional profit, reflects DaVita and DKC's knowledge and fraudulent intent to recommend and over-prescribe Renagel only when they could bill Government Funded Payors for such medications. When such medications could not be billed to Government Funded Payors, defendants instead provided their ESRD patients with Tums.

124. Renagel was a source of additional profit to DaVita because (a) DKC was able to charge Medicare or other Government Funded Payors 6% above the ASP as reimbursement for Renagel, and (b) DRX, as one of the nation's major purchasers of the drug, was able to obtain volume wholesale discounts. This came to an end beginning in 2018 when 25% of the Renagel's cost was shifted into the ESRD PPS bundle, as part of a two year phase-in. Relator is informed and believes and upon such information and belief alleges that the first year 25% cost shift into the ESRD PPS bundle offset the additional profit generated by prescribing Renagel and made its continued use an additional expense to DaVita. As a result, beginning in 2018, DaVita discontinued DRX's operations and instructed DKC to no longer have its interdisciplinary teams request or authorize prescriptions for Renagel.

125. Renagel's immediate disuse by DaVita, DKC and DRX as soon as it was no longer a source of additional profit, due to the partial cost shift, reflects that its prior use during and between 2008 and 2017 was done to improperly increase profits and knowledge of the drugs lack of medical necessity throughout.

126. As a result of Relator's own research and investigations and from discussing the topic with numerous DaVita and DKC nephrologists during and between 2007 and 2017,

Relator confirmed that Renagel was routinely prescribed and furnished by DKC and DRX to DaVita's and DKC's non-SNP ESRD patients as its first and only phosphate binder and that such practice was carried out at DKC dialysis facilities throughout the nation. This practice occurred despite DaVita's, DKC's and DRX's knowledge that Renagel was not a cost effective for most ESRD patients. Had CMS known that Renagel was being prescribed as scheme to increase DaVita, DKC and DRx profits and not for a legitimate purpose for the vast majority of DKC's ESRD patients, CMS and other Government Funded Payors would have denied all claims for payment pursuant to 42 U.S.C. § 1320c-5

FIRST CLAIM FOR RELIEF

(Violation of 31 U.S.C. § 3729(a) against all defendants)

127. Relator realleges and incorporates by reference all prior paragraphs of this complaint as though fully set forth at length.

128. At all times mentioned, defendants, and each of them, routinely and repeatedly violated 31 U.S.C. § 3729(a)(1) by:

i. Knowingly presenting and/or causing to present to agents, contractors or employees of the Government false and fraudulent claims for payment and approval;

ii. Knowingly making, using, and/or causing to make or use false records and statements to get false and excessive claims paid or approved by Medicare;

iii. 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 Government, or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money to the Government in violation of 31 U.S.C. § 3729(a)(1)(G).

129. Relator is informed and believes, and upon such information and belief alleges, that as a result of defendants' fraudulent misconduct, the Government was damaged in excess of $1 billion.

130. As a result of defendants' conduct, defendants are liable to the Government for three times the amount of damages sustained by the Government as a result of the false and fraudulent misconduct alleged above.

131. As a result of defendants' conduct, 31 U.S.C. § 3729(a) provides that defendants are liable to the Government for civil penalties between $5,000 and $10,000 for each such false and fraudulent claim for payment.

132. Relator is also entitled to recover attorneys fees, costs and expenses from defendants pursuant to 31 U.S.C. § 3730(d).

PRAYER FOR RELIEF

WHEREFORE, Plaintiff and *Qui Tam* Relator prays for relief as follows:

FOR THE FIRST CLAIM FOR RELIEF

1. Treble the Government's damages according to proof;

2. Civil penalties according to proof;

3. A Relator's award of up to 30% of the amounts recovered by or on behalf of the Government;

4. Attorneys fees, expenses, and costs; and

5. Such other and further relief as the Court deems just and proper.

HANAGAMI LAW
A Professional Corporation

THE ZINBERG LAW FIRM
A Professional Corporation

Dated: May 1, 2020

By: */s/Abram J. Zinberg*
Abram J. Zinberg
Attorneys for Plaintiff and *Qui Tam* Relator,
Charles M. Holzner, M.D.

REQUEST FOR JURY TRIAL

Plaintiff and *Qui Tam* Relator hereby requests a trial by jury.

HANAGAMI LAW
A Professional Corporation

THE ZINBERG LAW FIRM
A Professional Corporation

Dated: May 1, 2020

By: */s/Abram J. Zinberg*
Abram J. Zinberg
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Charles M. Holzner, M.D.