THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

UNITED STATES OF AMERICA EX REL., ALON J. VAINER, M.D., F.A.C.P. and DANIEL D. BARBIR, R.N.,	)	
PLAINTIFFS,	)	**Civil Action File No. 1:07-CV-2509**
v.	)	
	)	**QUI TAM ACTION**
DAVITA, INC. and GAMBRO HEALTHCARE, INC., and their respective subsidiaries and affiliated companies,	)	**JURY TRIAL DEMANDED**
DEFENDANTS.	)	

PLAINTIFFS' FOURTH AMENDED COMPLAINT

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FOURTH AMENDED COMPLAINT

COME NOW, Alon J. Vainer, M.D. and Daniel D. Barbir, Plaintiffs/Relators in the above-styled action, by and through their counsel of record and file this, their Fourth Amended Complaint.

I. OVERVIEW

1. This is a civil action brought by Relators on behalf of the United States of America ("United States") against Defendants, DaVita, Inc. ("DaVita") and Gambro Healthcare, Inc. ("Gambro"), and their respective subsidiaries and affiliated companies, pursuant to the False Claims Act, 31 U.S.C. §§ 3729, *et seq.* ("False Claims Act").

2. This case involves fraudulent billing schemes designed and implemented by Defendants from at least 2003 through 2010. At all times relevant hereto, DaVita and Gambro were major providers of dialysis services in the United States and many other countries.

3. The fraudulent billing practices and actions of Defendants described herein relate to Defendants' submission of false and fraudulent claims to the United States (also referred to herein as "Government") from physicians, clinics, medical providers and medical facilities for otherwise non-reimbursable charges related to the intentional waste of dialysis medications paid for by the taxpayers of the

United States.

4. Gambro has agreed to several previous fraud settlements with the Government. In 2000, Gambro operated 580 dialysis clinics, most of which were located in the United States. Gambro entered into a settlement involving an affiliated company named Vivra, Inc. ("Vivra") in 2000, in which Gambro agreed to pay $53,000,000 to the Government. This fraud settlement arose out of Government charges relating to unnecessary laboratory tests and kickback violations. Kent Thiry, the current Chief Executive Officer of DaVita, was the CEO of Vivra at the time of the improper conduct relevant to the settlement. Even after entering into a five-year Corporate Integrity Agreement with the Government with respect to the Vivra settlement, Gambro was again accused by the Government of fraud and Gambro agreed to settle the charges for $350,000,000 in 2004. Subsequently, DaVita acquired Gambro's United States clinics through a merger in 2005 and is now the second largest dialysis provider in the United States.

5. DaVita and Gambro, prior to their merger in 2005 and thereafter, directed and controlled the administration of dialysis medications through corporate protocols and corporate dosing grids. Defendants, through intentional fraud and manipulations of their protocols, guidelines and corporate dosing grids for each dialysis medication, created and caused excessive, unnecessary waste for purposes

of fraudulently increasing their revenue at the expense of the taxpayer. As will be explained hereafter, these corporate protocols and corporate dosing grids were designed to create waste in order to obtain fraudulent reimbursements from Medicare. The corporate protocols and corporate dosing grids were also designed to increase volume rebates and discounts to Defendants from the manufacturers of the medications at issue.

6. Medicare reimburses dialysis providers for dialysis-related medications, such as Epogen, iron and vitamin D. Prior to January of 2011, Medicare reimbursed for certain drugs differently than others. Medicare did not pay for waste of Epogen, but did pay for unavoidable wastage of iron and vitamin D medications. Medicare never knowingly paid for avoidable or unnecessary wastage.

7. The purpose of Defendants' fraudulent schemes described herein was to obtain significantly higher reimbursements from the Government and private insurers. Because of the actions of Defendants, these medical providers submitted fraudulent claims for reimbursement through the unlawful and fraudulent conduct described herein in express violation of federal and state statutes, rules and regulations.

8. Defendants have systematically, on a local, regional and national basis,

fraudulently manipulated administration procedures and the frequency, dosage, selection of the medication vendor, vial combination and size of purchased single-use (or single-dose) vials to be used in the injection and administration of essential dialysis medications needed for the treatment of chronic kidney disease for dialysis patients. The net result of the fraud was that Defendants intentionally created waste and submitted claims for such waste to the United States for reimbursement, in violation of the False Claims Act.

II. THE PARTIES

A. Alon J. Vainer, M.D., F.A.C.P.

9. Plaintiff, Alon J. Vainer, M.D., F.A.C.P. ("Relator Vainer") is a citizen of the United States and is a resident of Fulton County, Georgia.

10. Relator Vainer is a board certified nephrologist licensed by the State of Georgia and a Diplomate of the American Board of Internal Medicine.

11. Relator Vainer was the Medical Director of the following DaVita and Gambro healthcare dialysis clinics in Georgia: DaVita North Fulton (1995-2010), DaVita Cumming (2000-2010), DaVita North Fulton PD clinic (2006-2010), Gambro Ralph McGill/DaVita Ford Factory (1994-2005), DaVita Ellijay (2001-2007) and Gambro Acute dialysis at North Fulton Hospital (1997-2005). All of these clinics were previously owned by Gambro.

12. Relator Vainer was also the President and CEO of Dialysis of Georgia LLC, which opened *de novo* and operated four dialysis clinics offering in-center and in-home dialysis services (peritoneal dialysis) and an acute dialysis program at Lanier Hospital in Gainesville, Georgia. DaVita acquired Dialysis of Georgia LLC in 2002.

13. Relator Vainer is the president of and a physician affiliated with Vainer and Vainer Nephrology & Hypertension Consultants, Inc. ("Vainer Nephrology"), located in Atlanta, Georgia. The physicians of Vainer Nephrology were medical directors of DaVita Dialysis Gainesville (2003-2007) and DaVita Dialysis Woodstock (2002-2003). A physician with Vainer Nephrology is also the current Medical Director of DaVita Dialysis Newnan (2003-present). Relator Vainer has admitting privileges at multiple DaVita dialysis clinics.

14. Relator Vainer has been recognized nationally by Gambro for outstanding anemia management related to dialysis treatment.

15. Relator Vainer was the Medical Director of American Renal Care, Home Dialysis and Prison Dialysis Services from 2002-2003. Relator Vainer is currently the Medical Director of Union County Dialysis in Blairsville, Georgia (2001-present) and is the Medical Director of Renal Care Partners of Dahlonega dialysis clinic (2008-present).

16. Relator Vainer was previously the Assistant Clinical Professor of Medicine at the Medical College of Georgia and is regularly called upon to provide peer review for the Georgia Medical Care Foundation.

17. Relator Vainer is currently a Fellow of the American College of Physicians. The Fellowship is an honorary mark of designation given to recognize ongoing individual service and contributions to the practice of medicine.

B. Daniel D. Barbir, R.N.

18. Plaintiff Daniel D. Barbir, R.N. ("Relator Barbir") is a citizen of the United States and is a resident of Forsyth County, Georgia.

19. Relator Barbir is a Registered Professional Nurse ("RN") licensed through the Georgia Board of Nursing.

20. Relator Barbir is presently employed as a hemodialysis RN/Shift Nurse Manager at Emory University Hospital Midtown in Atlanta, Georgia and as a RN/Facility Administrator at RCP of Dahlonega, Georgia.

21. During the period 2000 through 2006, Relator Barbir was employed by Gambro/DaVita Cumming Georgia as the Clinic Director.

22. From 1997 through 2000, Relator Barbir was employed by Gambro in Atlanta, Georgia as a hemodialysis RN.

23. Relator Barbir has over 14 years of experience as a hemodialysis nurse with

extensive knowledge in the chronic and acute hospital setting. Relator Barbir opened two *de novo* dialysis clinics with two different companies in the State of Georgia in accordance with all state and federal regulations. Relator Barbir is certified in basic biomedical research by the Collaborative Institutional Training Initiative. Relator Barbir successfully completed the Advanced User/Trainer Program for the NxStage System One hemodialysis machine for home dialysis and for the ICU setting.

24. Relator Barbir was recognized nationally by Gambro for outstanding anemia management related to dialysis treatment.

25. Relator Vainer and Relator Barbir (collectively, "Relators") bring this *qui tam* action based upon direct and unique information obtained by them during their periods of employment at dialysis clinics owned and operated by Gambro and DaVita.

C. DaVita, Inc.

26. DaVita, a Fortune 500 Company, is a for-profit Delaware corporation with headquarters in Denver, Colorado.

27. DaVita is a provider of kidney care in the United States, delivering dialysis services to patients with chronic kidney failure, also known as end stage renal disease ("ESRD").

28. DaVita is currently the second largest independent provider of dialysis services in the United States.

29. As of December 31, 2010, DaVita operated or provided administrative services at 1,612 dialysis facilities across the United States and treated approximately 125,000 patients.

30. DaVita's clinics are located in 42 states, including Georgia and the District of Columbia.

D. Gambro Healthcare, Inc.

31. Gambro Healthcare, Inc. is a for-profit Delaware corporation with headquarters in Lakewood, Colorado.

32. Gambro, during the relevant times described hereafter, owned and operated hundreds of dialysis clinics in the United States, including clinics in Georgia.

33. Gambro (subsequently known as DVA Renal Healthcare, Inc.) sold its United States clinics to DaVita in October 2005.

34. DaVita has successor liability for the wrongful acts of Gambro because after purchasing Gambro in 2005, DaVita continued to engage in the wrongful practices and procedures carried out by Gambro that are at issue here.

35. In fact, DaVita and Gambro were independently and simultaneously engaging in similar wrongful practices and procedures prior to the merger. After

the merger, DaVita intentionally implemented additional wrongful practices and procedures at Gambro facilities and implemented certain of Gambro's wrongful practices and procedures in its DaVita legacy clinics as well, as described hereafter.

III. JURISDICTION AND VENUE

36. Defendants are subject to the jurisdiction of this Court with proper venue.

37. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1345 and 31 U.S.C. §§ 3732(a) and 3730.

38. Venue is appropriate as to each Defendant, in that one or more of the Defendants can be found in, reside in and/or transact business in this judicial district. Additionally, acts proscribed by the False Claims Act have been committed by one or more of the Defendants in this judicial district.

39. Therefore, within the meaning of 28 U.S.C. § 1391(c) and 31 U.S.C. § 3732(a), venue is proper.

40. Relators have made appropriate voluntary disclosures to the United States prior to the filing of this lawsuit as required by 31 U.S.C. § 3730(b)(2).

41. This Court has jurisdiction to entertain a *qui tam* action.

42. Relators are "original sources" of the material information set forth herein and bring this action in the name of the United States as contemplated by the False

Claims Act.

IV. FACTUAL ALLEGATIONS

A. Dialysis Process

43. 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 ("ESRD"), is the stage of advanced kidney impairment that requires continued dialysis treatments or a kidney transplant to sustain life. Dialysis is the removal of toxins, fluids and salt 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 clinics). 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.

44. DaVita contracts with a nephrologist or a group of affiliated nephrologists to provide medical director services at each of their centers or clinics. In addition, other nonaffiliated nephrologists may apply for practice privileges to treat their

patients at those centers. Each center has an administrator, typically a registered nurse, who supervises the day-to-day operations of the center and its staff. The staff of each center typically consists of registered nurses, licensed practical or vocational nurses, patient care technicians, a social worker, a registered dietitian, biomedical technician support and other administrative and support personnel.

45. As part of the dialysis treatment, blood is taken from the patient, typically by use of a graft/fistula or catheter, cleaned through an artificial filter and returned back into the patient's body. During that process, which normally lasts three to four hours for three visits each week, three different medications are usually added to the patient's blood: (a) iron supplements ("iron"), (b) vitamin D analogs ("vitamin D") and (c) a glycoprotein hormone called Erythropoietin ("hormone"). The iron and the hormone are both used to treat the anemia associated with ESRD and the vitamin D treats the bone and mineral disorder associated with ESRD.

46. The medications at issue in this case are Venofer (iron), Zemplar (vitamin D) and Epogen (hormone).

47. These medications are generally referred to as "separately billable medications" ancillary to dialysis treatment. Each of these medications is administered differently and billed separately according to specific reimbursement guidelines determined by the Government, as set forth hereafter.

B. Medicare/Medicaid Background

48. Reimbursement for Venofer, Zemplar and Epogen are provided by the Medicare and Medicaid Programs as well as certain other government programs.

49. The Medicare Program ("Medicare") is a health insurance program administered by the United States that is funded by Federal taxpayer revenue. The program was designed to assist participating states in providing medical services and durable medical equipment to persons over 65 years of age and others, including the disabled, who qualify for Medicare. Medicare is overseen by the United States Health and Human Services Department.

50. The Medicaid Program ("Medicaid") is a health insurance program administered by the United States government that is funded by State and Federal taxpayer revenue. This program was designed to assist participating states in providing medical services, durable medical equipment and prescription medications to financially-needy individuals that qualify for Medicaid. It is overseen by the United States Health and Human Services Department.

51. The Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS") is a government-funded program that provides medical benefits to retired members of the Uniformed Services and to spouses and children of active duty, retired and deceased members, as well as reservists who were ordered to

active duty for 30 days or longer. The program is administered by the Department of Defense and funded by the Federal Government.

52. The Civilian Health and Medical Program of the Veterans Administration ("CHAMPVA") provides similar benefits for spouses and children of veterans who are entitled to 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 Department of Defense and funded by the Federal Government.

53. Medicare, Medicaid, CHAMPUS and CHAMPVA are collectively referred to herein as the "Government" or "Government Payors."

54. Center for Medicare and Medicaid Services ("CMS") is a government organization that, among other things, administers the Medicare program and works in partnership with state governments to administer Medicaid.

55. CMS customarily pays 80% of healthcare costs and Medicare patients or their secondary government payors or private insurance carriers pay the remaining 20%. In many instances, the 20% co-pay is paid by Medicaid 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.

C. The Medicare Reimbursement Process in General

56. Medicare statutes and regulations provide generally for the reimbursement for medications and specifically for reimbursement for dialysis-related medications, such as Venofer, Zemplar and Epogen. See 42 U.S.C. § 1395rr.

57. At all relevant times discussed herein, CMS paid for certain dialysis services under a type of bundled rate methodology, called a "composite rate." In addition, CMS paid additional per-dose reimbursements for certain dialysis-related medications. The per-dose reimbursements were paid at rates 6% above the manufacturers' average sales price ("ASP").[1] Thus, providers were receiving per-dose reimbursements higher than the actual cost they paid for the medications. As a result, the greater the amount of medications that providers used, the greater the revenue they would generate.

58. In reimbursing providers for per-dose use of certain dialysis medications, such as iron and vitamin D, Medicare paid a provider for not only the amount of a medication that was actually administered, but also for the unavoidable or "necessary" waste that remained after administering the medication. See Dept. of Health & Human Services, Centers for Medicare and Medicaid Services, CMS

[1] Prior to January 1, 2005, CMS paid the average wholesale price ("AWP").

Manual System Pub 100-04, Medicare Claims Processing, Transmittal 1104, Nov. 3, 2006).

59. Necessary waste occurs when providers use medications that are only available in certain size vials, but a patient's dose is less than the entire amount of the smallest vial size. Thus, after the medication is administered, there is still medication remaining in the vial that the provider must discard. For example, assume a medication is only available in a 2-mcg single-use vial and a patient's dose is 1-mcg. When the 1-mcg is administered to the patient, 1-mcg will remain in the vial as waste through no fault of the provider. This is "necessary" waste that the Government will appropriately consider for reimbursement.

60. Wastage will not be reimbursed when a provider has utilized a larger vial size when a smaller, more appropriate size was available. For example, if the doctor ordered the administration of 2-mcg of a specific medication and the clinic administered it using a 5-mcg vial, but a 2-mcg vial was available, the excess waste created by using the 5-mcg vial instead of the 2-mcg vial is not covered.

61. Government medication reimbursement laws are clear and health care providers are aware that when the government allows for reimbursement for waste, it only does so for necessary waste. The government does not pay for unnecessary waste due to either intentional acts of waste or waste caused by reckless disregard

of such mandate. Unnecessary waste is never legally eligible for reimbursement and the submission of a claim seeking reimbursement for unnecessary waste is a violation of the False Claims Act.

62. The Federal Government reimburses providers for the "reasonable costs" of services provided to Medicare beneficiaries through private organizations known as "fiscal intermediaries." The intermediaries serve as administrators of the Medicare program by reviewing claims for reimbursement, making disbursements to providers, auditing records of providers to ensure proper payments and recovering overpayments made to providers. See 42 C.F.R. §§ 421.100(b), (c), (e), (f) and 421.120(e).

63. Intermediaries reimburse Medicare providers in accordance with standards established by the Medicare statutes, accompanying regulations and interpretive manuals.

64. Fiscal intermediaries must only pay claims for services that are covered by Medicare; this responsibility includes the contractual obligation to Medicare to make coverage determinations in accordance with (i) the Medicare statutes, (ii) formal agency regulations and rulings and (iii) less formal agency instructions such as instructional manuals and intermediary letters. See 42 C.F.R. § 421.100(a).

65. By statute and regulations, Medicare is prohibited from paying for provider

services (including dialysis ESRD services) that are "unreasonable" and "unnecessary." 42 U.S.C. § 1395y(a)(1)(A).

66. Under the Social Security Act, 42 U.S.C § 1395y(a)(1), Medicare is only authorized to pay for items and services that are "reasonable and necessary." (emphasis supplied).

67. Section 1395y(a)(1)(A) of the Medicare statute states 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." (emphasis supplied).

68. Compliance with all "applicable Federal, state and local laws and regulations pertaining to licensure and any other relevant health and safety requirements" is a condition of the Government's payment for medical care provided by dialysis facilities. 42 C.F.R. § 494.20; 42 C.F.R. § 405.2135.

69. As stated, Medicare does not pay for medical care that is not "reasonable and necessary for the diagnosis or treatment of illness or injury." 42 U.S.C. §

1395y(a)(1)(A) (emphasis supplied). Federal regulations reiterate the requirement that medical care be reasonable and necessary. For example, 42 C.F.R § 411.15(k) excludes from coverage medical services that are "not reasonable and necessary" for the diagnosis or treatment of illness.

70. 42 U.S.C. § 1320c-5(a)(1) provides that the practitioner shall assure that the service "will be provided economically and only when, and to the extent, medically necessary."

71. Medicare fiscal intermediaries have repeatedly used local coverage directives, articles, letters and bulletins to further clarify that such waste must be "unavoidable."

72. In addition to the above statutes and regulations governing requirements for reimbursement to Medicare providers, the Secretary is authorized to issue interpretive manuals of such statutes and regulations. The Centers for Medicare and Medicaid Services issue manuals which instruct Medicare and the Medicare Fiscal Intermediary ("FI") about Medicare regulations.

73. "…[I]f a physician, hospital or other provider must discard the remainder of a single-use vial or other single-use package after administering a dose/quantity of the drug or biological to a Medicare patient, the program provides payment for the amount of the drug or biological discarded along with the amount administered, up

to the amount of the drug or biological as indicated on the vial or package label." Chapter 17, Section 40 – Discarded Drugs and Biologicals (Rev 1248, issued 05-25-07: Effective 07001-07) (emphasis supplied).

74. Medicare bulletins routinely inform providers of the reimbursement policies regarding waste. A few examples are below:

July 5, 2000 Medicare Bulletin #1916 (Georgia FI):

> Drug Wastage: In some cases the physician or physician extender must discard the remainder of the drug vial after administering a dosage to a Medicare patient. In these cases, Medicare covers the amount of drug discarded along with the amount of drug administered. The medical record must contain documentation showing the amount of drug administered and the amount of drug discarded.

October 1, 2002 Medicare Bulletin #2033 (Georgia FI):

> The most appropriate size, given the MD order, must be utilized for the patient. Ensuring availability of the most frequently used medication amounts will ensure minimal wastage. Wastage will not be covered when a provider has utilized a larger dosage because a smaller, more appropriate size was not on hand. An example: The MD most often orders 2 mg of a specific medication and the clinic stocks only the 4 mg vials. The medication is available in both the 2 mg and 4 mg vials. In this instance, it is inappropriate for the clinic to bill for wastage when using the 4 mg vial, when in fact wastage was avoidable.

November 14, 2002 Medicare Bulletin #2035 (Georgia FI), Drug Billing: Wastage:

> As noted in previous edition of the "Medicare Alert Bulletin",

> Medicare does reimburse in instances of unavoidable drug wastage. We have noted occurrences of billing for "wastage" when in fact the wastage was avoidable. We expect providers to order and maintain stock of the medications in the amounts most commonly utilized resulting in the least possible wastage. For example, if a medication is available in 2 mg and 4 mg ampules, it would be inappropriate to maintain stock of only the 4 mg ampules when in fact 2 mg was the most commonly prescribed dosage. Administration of the drug plus the amount wasted must be documented in the medical record. Failure to document the wastage may result in denial of that amount.

April 7, 2003 MEDICARE BULLETIN #2057 (Georgia FI) (CMS again expressly authorizes reuse of single-use vials. CMS specifies that re-entry into to single-use vials is expected):

> The FI expects ESRD clinics to plan drug administration responsibly to ensure prudent, efficient utilization of medications. Only in those circumstances when wastage is absolutely unavoidable would we expect to see wastage billed on a claim.

December 14, 2006 Medicare Bulletin #2203, p. 11 (Georgia FI):

> Will Medicare Reimburse for Drug Wastage When Wastage is Unavoidable?
>
> Yes, Medicare will reimburse for drug wastage when wastage is unavoidable. However, there must be clear documentation present in the medical record to support the billed amount. ….The most appropriate size, given the MD order, must be utilized for the patient. Wastage will not be covered when a provider has utilized a larger dose because a smaller, more appropriate size was not on hand.

July 23, 2007 Trailblazer Health Enterprises Bulletin (FI), Drug Wastage:

> Trailblazer will consider payments for the discarded amount of a single-use drug/biological product after administering what is reasonable and necessary for the patient's condition. …
>
> If a physician, hospital or other provider must discard the remainder of a single-use vial or other single-use package after administering a dose/quantity of the drug/biological to a Medicare patient, the program provides payment for a reasonable amount of drug/biological discarded along with the amount administered up to the amount of the drug or biological indicated on the vial or package label. …
>
> Drug wastage must be documented in the patient's medical record with date, time, amount wasted and reason for wastage.

75. Dialysis providers submit claims for payment for separately-billable medications on CMS form UB-92 (now UB 04 as of 2007), which expressly contain an express certification that all information provided in the claim form is true and correct. See Dept. of Health & Human Services, Centers for Medicare and Medicaid Services, CMS Manual System Pub 100-04, Medicare Claims Processing, Transmittal 1104 (Nov. 3, 2006). Defendants provided false data in these forms as to the reasonable and necessary amounts of Venofer and Zemplar wasted and billed. Defendants never disclosed to the Government that they intentionally wasted these medications. Submission of the form is required for

payments by the Government.

76. Dialysis providers, including Defendants, must also submit an annual cost report (HCFA-265) to Medicare. The HCFA-265 report is required from all dialysis facilities that submit bills to and receive payment from the Federal Government. The cost report includes the following express certification of adherence to federal laws and regulations:

> I hereby certify that I have read the above certification statement and that I have examined the accompanying electronically filed or manually submitted cost report and the Balance Sheet Statement of Revenue and Expenses prepared by _____ (Provider Name(s) and Number(s)) for the cost reporting period beginning _____ and ending _____ and that to the best of my knowledge and belief, this report and statement are true, correct, complete and prepared from the books and records of the provider in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding the provision of health care services, and that the services identified in this cost report were provided in compliance with such laws and regulations.

(emphasis supplied).

77. The tender of the cost data and the certification in HCFA-265 are conditions of coverage. 42 C.F.R §§ 405.2138, 413.20(b) and 494.180(h)(3). Defendants provided false data in these cost reports as to the reasonable and necessary amounts of Venofer and Zemplar wasted and billed. Defendants never disclosed to the

Government that they had intentionally wasted these medications.

78. For the reasons stated in this complaint, Defendants have knowingly, in reckless disregard and/or in deliberate ignorance of the truth or the falsity of the information involved, made or used false or fraudulent records and statements in order to get false or fraudulent claims paid or approved, in violation of the False Claims Act. 31 U.S.C. § 3729(a)(1)(A) and (a)(1)(B).

D. The Medications at Issue

79. The medications at issue here, Venofer (iron), Zemplar (vitamin D) and Epogen (hormone), are administered by using a syringe to take the medication from a vial and then inserting that syringe into a patient's IV tube port (intravenous access).

80. Venofer and Zemplar only come in single-use vials, i.e., vials that the manufacturer intends to be entered with a needle only once.

81. At all relevant times, Venofer was available in only one size: a single-use vial containing 100-mg.

82. At all relevant times, Zemplar was available in the following single-use size vials: 2 mcg/ml; 5 mcg/ml; and 10 mcg/ml (5 mcg/ml x 2 ml).

83. Unlike Venofer and Zemplar, Epogen is available in both single-use (or single-dose) vials of different concentrations and multi-use (or multi-dose) vials.

Epogen's multiple dose vials can be repeatedly entered by the provider and used for multiple patients over time, leaving no waste.

84. At all relevant times, Epogen has been available in the following size vials: 1 ml single-use, preservative free solution in 2000, 3000, 4000, 10,000 and 40,000 units/ml; 2 ml multiple dose, preserved solution in 10,000 units/ml; and 1 ml multiple dose, preserved solution in 20,000 units.

85. In the case of Zemplar and Epogen, multiple single-use vial combinations may be used to reach the desired dosage. While a patient's IV tube port may receive multiple "sticks" from a syringe to combine these vials, a patient's arm does not suffer multiple sticks when multiple vials are combined to administer the dosage. In other words, there is no additional physical discomfort to patients from using multiple vial combinations to reach the desired dosage.

86. A patient generally undergoes dialysis treatment three times a week. Zemplar and Epogen are usually administered during each of the three days per week of a patient's regular dialysis treatment. Venofer is administered anywhere from three times a week to once a week to every two weeks to once a month, depending on the iron corporate protocol in place at the dialysis center.

E. CDC and Medicare Guidelines for Use of Single-use and Multi-Use Vials

87. The practices of re-entering and combining vials of medication are ways to

prevent or lessen waste. If a provider does not use all of one vial on one patient, re-entry allows the provider to use the remaining medication on another patient. The practice of combining vials to achieve a desired dose without waste is a very common practice in the dialysis industry. Done correctly, these practices are safe, accepted and encouraged.

88. Re-entry of single-use vials was standard procedure in the dialysis industry until 2001 when the Center for Disease Control ("CDC") recommended no re-entry of single-use vials because of an outbreak of infection believed to have been caused from re-entering Epogen vials.

89. However, a year later in 2002, the CDC, after discussions with the Food and Drug Administration ("FDA"), changed its policy and stated that the re-entry of single-use vials of Epogen, Zemplar and Venofer was allowed as long as proper sterile procedures were followed. The CDC stated that re-entry and re-use of single-use vials of Venofer, Zemplar and Epogen would have a low risk of patient infection as long as proper procedures were followed. See July 5, 2002 letter from William R. Jarvis, M.D., CDC to Sean Tunis, M.D., CMS, a true and correct copy of which is attached hereto as Exhibit 1.

90. In 2002, the CMS followed the CDC's recommendation and allowed the re-entry of single-use vials of Epogen, Zemplar and Venofer. See September 12,

2002 memorandum from CMS, a true and correct copy of which is attached hereto as Exhibit 2.

91. The policy of allowing re-entry of single-use vials was in place until July 2008 and all dialysis providers in the United States could re-enter Epogen, Venofer and Zemplar to avoid wastage using proper techniques during that time.

92. DaVita claims that it played an important pivotal key role in convincing the CDC to reverse its recommendation in 2002 and to again allow re-entry of single-use vials. In fact, in one of DaVita's publications, DaVita CEO, Kent Thiry stated, "We went to the CDC with our science, and then sat down and designed, with the CDC, some new scientific studies that demonstrated that with proper technique this is totally safe." See Exhibit 3.

93. DaVita CEO Kent Thiry took credit for convincing the CDC and CMS to allow re-entry of single-use vials, stating, "We said this is a terrible thing for the American Healthcare System because if you do not do re-entry you're going to have significantly more wastage, and the American taxpayer is going to spend a lot more money reimbursing us for all those instances in which you cannot just prescribe 100% of the vials." He went on further to state "with proper technique this is totally safe and therefore prudent public policy as compared to wasting medications." Id.

F. Reimbursement for the Medications at Issue

94. Medicare reimburses for Venofer and Zemplar differently than for Epogen based on the vial type available for these medications.

95. At all relevant times, the Government reimbursed by the vial, and not by the dose, for the single-use vials of Venofer and Zemplar. Thus, the Government reimbursed for necessary waste which, as described above, is the portion of the vial that "necessarily" could not be used because the patient's dosage was less than the full single-use vial amount.

96. Epogen was reimbursed by the units administered to the patient, and not by the vial, however. The government does not reimburse for any waste for Epogen since providers always have the option to choose to use the multiple dose vials, effectively eliminating all waste.

97. Importantly, despite adopting the 2002 CDC recommendation allowing for re-entry of single-use vials as outlined above, the reimbursement policy for all three medications remained the same through 2010, meaning that necessary waste from single-use vials of Venofer and Zemplar, but not Epogen, remained eligible for reimbursement, even after the re-entry approval changed.

G. Defendants' Use of the Medications at Issue

98. At all relevant times discussed herein, the Government reimbursed providers

for the dosage that was, in fact, administered and given to a patient. As to Venofer and Zemplar (but not Epogen), the Government also paid for the waste (unused portion) in single-use vials if the waste was necessary and reasonable.

99. In an effort to fraudulently increase their revenue, and in direct contravention of the reimbursement regulations, Defendants purposefully created and sought reimbursement for intentional, unnecessary and unreasonable waste of Venofer and Zemplar. As a result of this fraudulent activity, Defendants fraudulently increased their revenue from creating unnecessary waste by receiving the standard reimbursement rate of 6% over the ASP for the unnecessary waste. By wasting Venofer and Zemplar, Defendants also increased the volume of the medications purchased, which allowed them to receive larger discounts and rebates. Larger discounts increased Defendants' net revenues.

100. On the other hand, Defendants took a very different approach to Epogen use. Defendants limited their use of Epogen to doses that fit into existing vial sizes, required the combination of multiple single-use vials of different concentrations, and required the use of the entire contents of every Epogen vial, whether single or multiple use vials, including all assumed overfill of medication available in the Epogen vials, as discussed below.

101. Defendants' approach to Epogen use ensured that not a drop of Epogen was

wasted.

102. From 2002 to 2008, when the re-entry of single-use vials of Venofer and Zemplar was allowed by the CDC and CMS, Defendants could have, and should have, implemented similar practices for Venofer and Zemplar, but they intentionally did not do so in order to purposefully create and maximize their waste and receive significantly higher reimbursements and revenue for Venofer and Zemplar usage.

H. Defendants' Fraudulent Schemes to Create Unnecessary Waste

103. Defendants created unnecessary waste in five ways: (a) Defendants prohibited re-entry in single-use vials of Venofer or Zemplar (although such practice was allowed from 2002-2008) while during the same period, allowing re-entry in Epogen single-use vials, even though multi-use vials of Epogen were available; (b) Defendants implemented an iron corporate protocol that intentionally spread out dosages of Venofer over several treatments instead of one treatment solely to increase reimbursements and revenue; (c) Defendants manipulated and dictated vial size and vial combinations to ensure the highest amount of waste; (d) Defendants implemented a corporate protocol that dictated fractional increases in dosages of Zemplar to create waste where none was necessary, again without a corresponding medical benefit; and (e) Defendants failed to implement best

practices to avoid waste.

104. These schemes were implemented in DaVita and Gambro clinics across the country.

105. Based upon the Relators' first-hand observations, Defendants' practices to intentionally increase unnecessary waste continued with little to no change until January 1, 2011, when the new Medicare bundling payment system was implemented, which eliminated the benefit of creating unnecessary waste from Venofer and Zemplar. When the illegal revenues were removed, the wastage schemes stopped immediately.

I. Scheme #1: No Re-entry or Combination of Single-use Vials of Venofer and Zemplar

1. Re-entry of Single-use Vials of Venofer and Zemplar Was Prohibited

106. Despite claiming credit for changing the CDC and CMS recommendations allowing for re-entry of single-use vials in 2002 in an effort to avoid a "terrible thing for the American Healthcare System," DaVita only selectively implemented a policy of re-entering single-use vials based purely on its scheme to fraudulently increase its revenue.

107. Defendants selectively implemented a corporate policy mandating re-entry of only the Epogen single-use vials and not the Venofer or Zemplar single-use vials even though the directives regarding the safety implications of re-entering

and re-using those medications were the same.

108. Amgen, the manufacturer of Epogen, overfills all of its vials (single and multi-use vials) purportedly to ensure that the full amount of the volume stated on the label may be administered to the patient from the vial. The single-use vials contain more overfill than the multi-use vials, however. Defendants used single-use vials rather than multi-use vials of Epogen because single-use vials contain more overfill than multi-use vials.

109. Prior to the merger in 2005, both companies took advantage of the free overfill in single-use vials of Epogen and re-entered those vials. Yet, prior to the merger, neither DaVita nor Gambro allowed re-entry into their iron medications (Venofer and Ferrlecit) or vitamin D (Zemplar) and after the merger, the no re-entry policy continued.

110. The corporate policy regarding re-entry was based solely on the fact that the Government did not reimburse for waste of Epogen, but did reimburse for waste of Venofer and Zemplar.

111. Defendants have re-entered Epogen single-use vials for years despite the availability of multi-use vials.

112. Defendants exploited this extra overfill difference, re-entering and re-using Epogen single-use vials to capture all of the assumed overfill because the

Government did not reimburse for Epogen waste.

113. Between 2002 and 2008, the re-entry of single-use vials of Venofer and Zemplar was allowed by the CDC and CMS, allegedly through the efforts of DaVita itself, as touted by its CEO, yet DaVita refused to allow the practice with respect to Venofer and Zemplar and thereby intentionally created unnecessary waste that it sought reimbursement for in its scheme of maximizing revenue through fraudulent billings for reimbursement. If Defendants had used the same re-entry policy for Venofer and Zemplar that Defendants used for Epogen, hundreds of millions of dollars of unnecessary wastage could have been eliminated.

2. Combinations of Single-use Vials of Zemplar that Did Not Waste were Prohibited

114. Similar to its revenue-maximizing policy of not allowing re-entry of single-use vials of Venofer and Zemplar, yet allowing re-entry of Epogen, Defendants had different policies regarding the combination of different concentrations of Zemplar and Epogen based purely on revenue-maximization.

115. Defendants intentionally did not allow the combination of certain Zemplar single-use vials in administering Zemplar to a patient that would have prevented waste (e.g., the combination of a 5-mcg vial and a 2-mcg vial for a 7-mcg dose was prohibited), but did allow others (e.g., the combination of a 10-mcg vial and a 5-

mcg vial for a 12-mcg dose was mandated). See Gambro and DaVita Zemplar Dosing Grids, true and correct copies of which are attached hereto as Exhibits 4 and 5, respectively.

116. Defendants claim they enacted this policy because there is an alleged risk in combining different concentrations of medications. However, Defendants allowed its nurses to combine different concentrations of Epogen, and Defendants prohibited its nurses from combining Zemplar vials of the same concentration. Thus, Defendants prohibited the use of three 2-mcg vials of Zemplar to administer a 6-mcg dose (a combination of three identical vials), but mandated the use of two 10,000 unit vials, two 4,000 unit vials, and one 3,000 unit vial of Epogen to administer a 34,100 unit dose (a combination of three different vial sizes and concentrations and five vials total). See, e.g., DaVita Epogen Dosing Grid, a true and correct copy of which is attached hereto as Exhibit 6.

117. Defendants' policies were implemented to mandate a wasteful combination of different vials sizes of Zemplar, while at the same time, prohibiting non-wasteful combinations of different Zemplar vials sizes.

118. Defendants routinely administered doses of 6-mcg and 8-mcg of Zemplar. Both of these doses could be given by a combination of multiple 2-mcg vials, using the entire contents of each single-use vial. Instead, for any dose above 5-mcg,

Defendants required that nurses use a 10-mcg vial, creating significant unnecessary waste that was then billed to and reimbursed by the Government.

119. Unlike their Zemplar corporate protocols, Defendants' Epogen corporate protocols required the combinations of multiple single-use vials of different concentrations, despite the availability of multi-use vials. Since Epogen was reimbursed by the unit administered to the patient and not by the vial, waste was not reimbursed by the Government. Thus, Defendants implemented Epogen corporate protocols to maximize its revenue by using all of the contents of every vial and capturing the higher overfill present in single-use vials. For many years, DaVita and Gambro both allowed the combination of multiple Epogen vials of the same or different concentration. See, e.g., Frequently Asked Questions about Single-dose Vial (SDV) Epogen Titration Methodology, a true and correct copy of which is attached hereto as Exhibit 7.

120. As explained above, according to the manufacturer, each Epogen single-use vial contains overfill. DaVita assumed a minimum 10% overfill in each single-use vial of Epogen and, unlike its use of Zemplar single-use vials, required all patient doses to be written specifically to take advantage of all assumed overfill in the vial and use the full content of every vial with no waste.

121. For example, Defendants assumed that a 3,000 unit vial provides 3,300 units

of Epogen for administration to a patient. Defendants ordered all patient doses of Epogen as a combination of single-use vials. For example, the dose of 9,900 units of Epogen is given as three single-use vials of 3,000 units. Defendants assume that the patient actually receives 900 extra units from the overfill, which totals the dosage of 9,900 units. Thus, Defendants allowed the combination of three 3,000 unit vials of Epogen, but would not allow the combination of three 2-mcg vials of Zemplar, as set forth above. Compare Exhibits 4 and 5 with Exhibit 6.

122. Despite the existence of multi-use vials, members of Defendants' nursing staffs were instructed to follow the corporate protocol and use only single-use vials of Epogen in the dictated combinations, including combinations of different concentrations, rather than use only one multi-use vial. This ensured that each Epogen vial was fully used, including the assumed overfill, and then billed to the Government. By doing so, Defendants did not waste any Epogen and also billed for the assumed overfill, for which it did not pay. Had Defendants followed the same policies with Zemplar that they mandated with Epogen, hundreds of millions of dollars of unnecessary wastage could have been eliminated.

3. Physicians Did Not Know the Corporate Dosing Grids

123. At all relevant times, physicians did not know how the ordered medication dosage was administered. Physicians did not know what vial sizes were used or

what vial combinations were allowed. Physicians were not aware of the contradictions between the Epogen corporate dosing grids, which required the use of vial sizes and combinations of vials to prevent waste, and the Zemplar corporate dosing grids, which required the use of vial sizes and combinations of vials to create waste.

124. Physicians, dialysis clinic administrators and the nursing staff were not allowed to change the dictated Zemplar vial size or vial combinations to prevent waste.

125. Physicians did not know if the residual medication left in the vial could have been used for another patient. Physicians were also not aware of the waste associated with the no re-entry policy. Physicians, dialysis clinic administrators and the nursing staff were not allowed to order re-entry of Venofer or Zemplar vials.

126. Similarly, Physicians were also not aware of the contradiction in the single-use vial re-entry policy of not allowing Venofer or Zemplar re-entry, while regularly re-entering Epogen single-use vials.

J. Scheme #2: Defendants' Iron Corporate Protocol Fraudulently Spread Out Dosages Over Several Treatments

127. In or around the spring and summer of 2004, Relators witnessed a strong

push to increase pharmacy revenue for the then Gambro outpatient dialysis clinics. Relator Barbir worked for the Gambro clinic in Cumming, Georgia (which became a DaVita clinic), as the clinic director from 2000 until 2006, when he resigned. Relator Vainer was the Medical Director of that clinic.

1. 2004 Clinical Directors Meeting

128. Every month Relator Barbir attended a meeting of all the company's clinic directors. Regional Directors, Regional Vice Presidents, and sometimes the Quality Improvement/Educator for the region also attended these meetings. Medical Directors of the clinics were not invited. Relator Vainer, as was true for other physicians, was not present at these meetings.

129. At these meetings, many aspects of the dialysis business were discussed, including budget issues and how to maximize pharmacy revenue. The Regional Directors kept minutes of the meetings. These same topics were not discussed at medical directors meetings. Thus, physicians were not privy to the information discussed at these meetings.

130. In the summer of 2004, Relator Barbir attended a meeting of Gambro clinical directors at the regional office at the Southern Lane Gambro clinic training room. One of the major issues discussed was anemia management (specifically the use of iron supplements with the dialysis patients).

131. At that time, Gambro was using both Ferrlecit and Venofer products for iron replacement therapy for dialysis patients. The clinic that Relator Barbir worked in used Ferrlecit. During the meeting, the attendees, including Relator Barbir, were told that they needed to convert all patients from Ferrlecit to Venofer because the Government reimbursement for Venofer was greater than the reimbursement for Ferrlecit.

132. The reason the reimbursement was greater with Venofer was because the vials were larger. Ferrlecit came only in a 62.5-mg ampule and Venofer came only in a 100-mg vial. The 62.5-mg ampule of Ferrlecit was equal to 50-mg of Venofer. Thus, if a patient's dosage was 50-mg of Venofer (or 62.5-mg of Ferrlecit) and the patient received a 62.5-mg ampule of Ferrlecit, no waste was created. Whereas, if the patient's dosage was 50-mg of Venofer, a 100-mg vial of Venofer had to be used, thereby creating 50-mg of waste.

133. Because the 100-mg Venofer vial is a single-use vial, Defendants would bill for and the Government would reimburse for the full 100-mg at the rate of ASP plus 6%, even if only a portion of the vial was used.

134. Relator Barbir was told at the meeting that another reason for switching from Ferrlecit to Venofer was that Gambro had a purchasing agreement contract, which if it were met, would result in higher rebates for the company. No clinical

justification for the conversion from Ferrlecit to Venofer was provided.

135. The other directive given at this meeting was to change Gambro's iron protocol to decrease every patient's iron dose to a smaller dose, which was to be given weekly.

136. Protocols are clinical tools. Protocols set forth how a prescribed dosage is calculated and how that prescribed dosage may change over the course of a patient's treatment. The protocol determines the initial dosage of a medication to be administered by evaluating certain clinical parameters. The doctor then orders that dose. For example, in the case of iron, if a patient's iron level falls, the protocol will require a certain dosage. Or, in another example, if a doctor wants to achieve certain levels of iron, the protocol dictates that a certain amount will be given and over what period of time. Further, a protocol may call for doses to be increased or decreased. See Zemplar and Venofer protocols, true and correct copies of which are attached hereto as Exhibit 8 and Exhibit 9, respectively.

137. In the case of Venofer, Defendants' protocols also determined how a dosage was divided over time (whether given all at once or divided into multiple administrations over time).

138. In the case of Zemplar, Defendants' protocols also determined when a medication dosage was rounded up or down from its original dose.

139. Since Gambro was reimbursed per vial, including the waste remaining in the vial, increasing the number of vials used would increase Gambro's pharmacy revenue and result in higher rebates and discounts.

140. In addition, since dialysis clinics were also paid an administration fee each time a medication was administered, the more times a medication was administered, the more times Gambro would receive an administration fee.

141. Relator Barbir and the others in attendance were also told that instead of giving eight doses of Ferrlecit (125-mg/dose) for a cycle of iron replacement, the new corporate protocol was to give 10 doses of Venofer. Dialysis clinics were also paid an administration fee each time a medication would be administered. Thus, giving 10 injections instead of eight meant that Gambro could also bill for the extra two medication administrations.

142. For example, if Gambro had a patient who was supposed to receive 100-mg of Venofer each month, the new directive said to divide that dose into four separate doses and give Venofer in doses of 25-mg each on a weekly basis. This way Gambro would use four 100-mg vials per month instead of one and administer the medication four separate times – quadrupling revenue and reimbursements solely by increasing wastage.

2. The New Iron Corporate Protocol Concerned Relators

143. Relator Barbir raised concerns with the Gambro management present at the summer 2004 meeting regarding the extra nursing work and the increase in inventory/purchasing for the clinic caused by the push to use smaller doses.

144. Another clinic director at the meeting also expressed concern that some physicians would not want to change from Ferrlecit, the iron product that was in use at the time because Ferrlecit was an effective and widely used iron supplement.

145. Relator Barbir also expressed concern regarding the lack of a medical justification for the switch to Venofer and for splitting the doses into the smallest amounts possible.

146. At that point of the meeting, one of the Regional Educators/Quality Improvement personnel said to Relator Barbir, "Why are you so stubborn?" Relator Barbir's Regional Director Nancy Marshman intervened and said, "Let's call the Regional Vice President Greg Santulli to come in and clarify some of these questions."

147. When Santulli came in, he told the group, "Guys, you are all adults and you all know that the pharmacy revenue will make you or break you regarding the budget."

148. Santulli also said, "We all want a nice bonus at the end of the year and

meeting the budget is a huge part of it," making it clear that the changes were being made in order to bill the Government for the increased waste resulting from the changes.

149. Santulli further said, "If medical directors object to these changes, have them call one of the regional directors or me personally." Santulli told the group that the changes came from "above the Division Vice President" and that the company was "not playing." Santulli told the group that the company wanted to see changes immediately and that the Division Vice President Steve Pirri would be visiting all the clinics in the state to ensure that these initiatives were implemented immediately.

150. Relator Barbir and staff were told by the Regional Vice President and the quality improvement educators to go to the clinics and tell the physicians that the company had new corporate protocols and to write orders to change the individual doses to the smallest amounts possible.

151. After the meeting, Relator Barbir returned to the clinic and told Relator Vainer that he felt uncomfortable with these directives. Relator Barbir told Relator Vainer that he believed that he was being asked to commit fraud. Relator Vainer told him not to conform to the Gambro directives if he felt it was wrong. However, Relator Vainer had no control over the Gambro protocols at issue. Gambro

controlled the dosage administration.

152. Relator Barbir also told Relator Vainer that the clinic directors were not given any medical justification for the splitting of the dose or the change of the iron product and that "We do not have any patients who have had any problems with the iron product Gambro was using (Ferrlecit) in this clinic and have experienced excellent results." In fact, while using Ferrlecit, the dialysis clinic in which Relator Barbir and Relator Vainer worked was given awards by Gambro for overall best anemia management in the country. Ferrlecit was working well for the patients.

153. In response to speaking with Relator Barbir, Relator Vainer shared his concerns to his superiors at Gambro, but to no avail. Relator Vainer called the Chief Medical Officer of Gambro, as well as the Regional Vice President, Greg Santulli, but received no answers.

154. Since Relator Barbir had excellent results with anemia in the clinic through the use of Ferrlecit, and along with Relator Vainer, had been recognized nationally by Gambro for outstanding anemia management, he resisted making the change to Venofer immediately. However, a couple of months later, Relator Barbir was instructed to conform to the corporate directive or else there would be trouble for him.

155. Relator Barbir told his secretary who was in charge of inventory, the nurses, the dialysis technicians, the dietitian and the social worker about the corporate directive to increase pharmacy revenue through unnecessary waste and to expect the changes described above. Relator Barbir told them that he was under too much pressure and that he would have to do what he was told. Relator Barbir did not have the authority to resist these orders from his superiors. While he objected to his immediate supervisors about the corporate orders, his protests were ignored.

3. Merger of DaVita and Gambro

156. Prior to the merger, DaVita had only one iron protocol, which required the use of Venofer and mandated that the lowest dose be given up to three times per week.

157. Prior to the merger, Gambro allowed the use of Venofer or Ferrlecit and had four iron protocols, some of which resulted in zero waste. See Gambro iron protocols, a true and correct copy of which is attached hereto as Exhibit 10.

158. After the 2005 merger, only the pre-merger DaVita protocol was allowed company-wide. Out of at least five available protocols, only the most wasteful iron protocol was adopted for the combined company – allowing only for the use of Venofer administered in small doses, up to three times per week. While multiple other equally clinically safe and effective iron protocols were available, DaVita

chose to eliminate all other options and only offer as its corporate protocol the option that resulted in the creation of the maximum amount of unnecessary waste.

159. A typical prescribed dosage of Venofer is 100-mg once or twice a month. After the merger, Defendants' iron protocol dictated that this typical dosage was to be spread out over time in small doses in order to create unnecessary waste and unlawfully increase its revenue.

160. If, for example, a patient was to receive 200-mg of Venofer a month, instead of administering 100-mg of Venofer every two weeks with no waste, Defendants' iron protocol was to administer the 200-mg across two dialysis treatments per week. This meant that over one month, a patient would receive 25-mg from a 100-mg vial twice a week. As a result of this iron corporate protocol, Defendants used 800 mg to administer 200-mg of Venofer – which resulted in 300% unnecessary waste that was billed to and paid for by the Government.

161. There was no medical benefit to giving 100-mg of Venofer in multiple sittings versus a single sitting. Defendants divided the dosages purely to create unnecessary waste and unlawfully increase its revenue.

162. In addition to reaping significant increased revenue from waste, by physically giving more injections of Venofer, Defendants also billed the Government for more administrations of the medication per month.

163. As in the above example, administering eight 25-mg doses of Venofer over the course of a month rather than two 100-mg doses allowed Defendants' to bill the Government for six extra administrations.

4. Physicians Did Not Know How Venofer Was Administered

164. Defendants, not physicians, controlled the way Venofer was administered.

165. Physicians would fill out a "Hemodialysis Admission Orders" form for each patient to set forth the treatments they were to receive. See a sample blank Hemodialysis Admission Orders form, a true and correct copy of which is attached hereto as Exhibit 11.

166. When treating "anemia," which calls for the administration of iron, physicians at DaVita were given only one option to choose: "DaVita Iron Protocol," as set forth above, which was pre-filled out on the form. See id.

167. Physicians had no knowledge that DaVita was not allowing re-entry of single-use vials of Venofer. Physicians did not know that when administering 25-mg of Venofer, 75-mg would be wasted. The physicians had no knowledge that DaVita was ordering doses to be unnecessarily divided such that unnecessary waste was created solely to generate increased revenue. Physicians only saw the iron corporate protocol, which did not set forth how Venofer was administered (i.e., the number of vials used, when they were administered, or whether re-entry

was allowed). See Exhibit 8.

168. While physicians approved the iron protocol, the protocol did not describe, quantify, or even mention any waste associated with the administration of the medications. The corporate administration policies were not set forth in detail to the physicians in the protocols that the physicians were required to approve.

169. Once a physician approved the protocol, the physician could not change its implementation. Defendants, through the Snappy computer system described below, or otherwise, would dictate the administration details to the nursing staff.

170. Anemia managers, who are usually RNs, monitored the implementation of the Venofer iron corporate protocol. Yet, the only change they were allowed to make in a patient's treatment was to change the actual calendar day of administration of Venofer (for example, changing a 25-mg dose from a Monday to a Friday). Defendants, through the Snappy computer system, or otherwise, would dictate the administration details to the nursing staff. Anemia managers could not change the amount of the dose at any particular time.

171. The anemia manager could not bypass or override the Snappy computer system. For example, if Snappy provided that a patient was to receive 25-mg of Venofer once a week for four weeks, they could not combine those doses into one monthly dose of 100-mg or two monthly doses of 50-mg. Unnecessary wastage

was effectively hard-wired into the DaVita computer system.

K. Scheme #3: Defendants Manipulated and Dictated Vial Size Combinations

172. As explained above, CMS reimbursed facilities for Zemplar by the vial (that is the amount of Zemplar that was actually administered to a patient plus any amount necessarily remaining in a vial after the required dosage was reached). For example, if a patient's dosage of Zemplar was 3-mcg, CMS recognized that a dialysis clinic would have to use two 2-mcg vials because there was no 3-mcg vial of Zemplar on the market and therefore, reimbursed a facility for the 1-mcg that was necessarily wasted.

173. Defendants took advantage of the Government's recognition of the reality that some waste of Zemplar may be truly unavoidable by manipulating vial size combinations to create the greatest amount waste possible for various dose sizes.

1. Defendants' Use of Corporate Dosing Grids to Create Waste

174. Defendants created dosage grids, also known as administration charts, that dictated the vial size of the medications used when administering any particular amount of a medication. Defendants' dosage grids were strictly enforced and deviation was not allowed.

175. The corporate dosing grids were for the use of the nursing staff. The corporate dosing grids instructed the nurses as to the vial sizes that must be used

and the combinations that must be used in order to administer the ordered dosages. Physicians saw corporate protocols, but did not see the corporate dosing grids.

176. DaVita and Gambro intentionally developed dosing grids that created unnecessary waste for the sole purpose of unlawfully increasing revenue from reimbursements.

177. Shortly after instructing clinic directors at the 2004 clinic directors' meeting to begin using Venofer to maximize revenue, Gambro told Relator Barbir and staff at another meeting of clinic directors to be aggressive in the dosages used with another product – Zemplar. All the clinic directors were shown the corporate dosing grids to follow when administering Zemplar.

178. Again Relator Barbir and staff were directed to waste medication in order to unlawfully increase revenue from reimbursements.

179. Through the implementation of their dosage grids, Defendants dictated the combinations of vials of Zemplar that unnecessarily maximized waste and prohibited the combination of vials that would minimize or eliminate waste.

180. The Gambro dosage grid allowed for the use of 2-mcg vials only when the dosage was 2-mcg or less. See Exhibit 4.

181. If a prescribed dose was between 2.1-mcg and 5-mcg, Gambro nurses were required to use a 5-mcg vial. See id. This procedure was to be followed even if 2-

mcg vials could be combined to produce no waste, as in the case of a 4-mcg dose.

182. Equally egregious was the fact that for a prescribed dose between 5.1-mcg and 10-mcg, Defendants' nurses were required to use a 10-mcg vial. See id. This procedure was mandated even if smaller vials could be combined to produce no waste, as in the case of a 6-mcg, 7-mcg, or 8-mcg dose.

183. For example, a 6-mcg dose could be given with three 2-mcg vials, a 7-mcg dose could be given with one 5-mcg vial and one 2-mcg vial, and an 8-mcg dose could be given with four 2-mcg vials. In the case of a 6-mcg or 8-mcg dose, not only would zero waste be created using the alternative combination of vials, but the combination of medications would be from the same concentration levels.

184. Because of the limitation on the use of 2-mcg vials (only for dosages of 2-mcg or less), Gambro created hundreds of millions of dollars of unnecessary waste, for which the Government was billed, in order to unlawfully increase revenue from government reimbursements. See id.

185. Prior to the merger, both companies primarily used Zemplar as their vitamin D medication and did not allow re-entry into Zemplar vials.

186. Gambro utilized a corporate dosing grid that allowed nurses to utilize 2-mcg vials of Zemplar only when administering doses of 2-mcg or less. Meaning that a nurse could not combine two 2-mcg vials to administer a 4-mcg dose. See id.

187. Prior to the merger, DaVita utilized a dosing grid that allowed nurses to utilize 2-mcg vials of Zemplar for doses of 2-mcg or less and specifically for 4-mcg doses (allowing the combination of two 2-mcg vials to administer a 4-mcg dose). See Exhibit 5.

188. Prior to the merger, neither DaVita nor Gambro allowed the combination of vials of 5-mcg and 2-mcg to achieve dosage amounts and required the use of a 10-mcg vial for any dose over 5-mcg. See Exhibits 4 and 5. For a brief period of time from mid-2005 through 2006, DaVita changed its Zemplar dosing grid to allow a 6-mcg dose to be given out of three 2-mcg vials.

189. After the merger, Defendants continued with their respective dosage grids for Zemplar until sometime in 2007. At that time, Defendants adopted a unified dosing grid that continued to be wasteful. The unified corporate dosing grid continued to prohibit the combination of 5-mcg and 2-mcg vials and the combination of 2-mcg vials for 6-mcg and 8-mcg doses and required that any dose higher than 5-mcg must be given from a 10-mcg vial. DaVita's short-lived practice of allowing a 6-mcg dose to be given out of three 2-mcg vials was not part of the unified corporate dosing grid.

190. As was the case with the post-merger decisions regarding iron supplements, Defendants again implemented the most wasteful dosing grid for Zemplar.

2. Clinic Directors Voice Concerns

191. At the meeting of clinic directors when the Zemplar dosage grid changes were introduced, Relator Barbir and other clinic directors questioned the Regional Directors Nancy Marshman and Mike Marshman and the Quality Improvement/Educator Theresa Gonzales regarding the waste. They asked why they were not going to be allowed to combine vials to administer the prescribed dosage and reduce wastage.

192. Relator Barbir and the other clinic directors were told that the directive came from the company's corporate office and that any questions should be directed to the Regional Vice President Greg Santulli and Division Vice President Steve Pirri. The staff was made to understand that the decision was being made at the regional and national levels, and therefore, this corporate protocol could not be altered locally.

193. There was no medical or clinical justification for these policy changes.

194. A few years after Relator Barbir stopped working at the DaVita Cumming dialysis clinic, Relator Vainer, at one of the quarterly quality assurance meetings in 2009, asked the acting Facility Administrator, Ling Ling Bao, R.N., why they were not allowed to combine Zemplar vials that would avoid waste. Her answer was that "everybody knows that DaVita wants to waste a lot so it can bill for it and

make a lot of money."

3. Physicians Were Unaware of the Dosing Grids

195. DaVita offered one Zemplar protocol for treating "mineral and bone disorder management: DaVita Zen Tool Protocol," which is pre-filled out on the form. See Exhibit 11.

196. Defendants controlled vial size selection very carefully.

197. Physicians were never aware of the waste created by Defendants' Zemplar dosing grids. In fact, the corporate dosing grid was never shown to them. Only the Zemplar corporate protocol was shown to doctors, which did not show the vial sizes required to be used to administer the prescribed dosages. See Exhibit 4 and 5.

198. The selection of vial size and combination was not a decision made by physicians or nurses at the Defendants' clinics. Physicians would see "Rounding reports," and those reports do not show the amounts wasted. See, e.g., Rounding Report dated September 15, 2010, a true and correct copy of which is attached hereto as Exhibit 12. This report only shows the dose given to the patient and the date, but does not show the vial size, the number and combination of vials, or the resulting waste associated with the administration of the prescribed dosage. See id.

199. Physicians could not override the dosage grid and could not themselves

instruct the nursing staff regarding what vial size or combination to use. Thus, even if physicians wrote their own dosing protocols, the vial sizes were still pre-determined by Defendants. The dosing grids mandated by DaVita were implemented and enforced uniformly across the DaVita dialysis clinics in 42 states.

200. For example, if a physician developed a separate dosing protocol that called for 6-mcg of Zemplar, the corporate dosing grid – not the physician – would instruct the nursing staff as to the size of the vials from which 6-mcg prescribed dose could be administered. The corporate dosing grid required a nurse to use a 10-mcg vial to administer a 6-mcg dosage of Zemplar, which created 4-mcg of waste. A physician could not change this corporate mandated practice and instead administer the 6-mcg dose with three 2-mcg vials. The resulting 4-mcg wastage per dose from this corporate protocol was the same whether the patient was in Georgia, Florida, Texas, or any of the other 42 states impacted by these fraudulent practices. DaVita, not the physicians, created and required the Zemplar wastage.

L. Scheme #4: Defendants Implemented a Corporate Protocol That Dictated Fractional Increases in Dosages of Zemplar Without a Corresponding Medical Benefit

201. Not satisfied with only the additional Zemplar waste created from the corporate dosing grids, Defendants created corporate protocols to increase the

actual dose amounts of Zemplar administered to patients.

202. In 2005, after implementing the new Zemplar corporate dosing grids, Relators and other staff at Gambro were told to increase the dosages by 0.5-mcg so that more vials of 5-mcg were used instead of 2-mcg vials.

203. This corporate protocol created unnecessary waste. Without the rounding requirement, for example, a 2-mcg dosage would create zero waste. The rounding requirement to change a 2-mcg dose to a 2.5-mcg dose created 2.5-mcg of waste because Gambro required that it be administered from a 5-mcg vial.

204. The rounding requirement also increased a 5-mcg dose to a 5.5-mcg dose and the Zemplar corporate dosing grids required that any dose over 5-mcg be given from a 10-mcg vial, which in the case of a 5.5-mcg dose, created 4.5-mcg of waste. Before the rounding requirement, a 5-mcg dose would be given out of a 5-mcg vial, which would have created no waste.

205. There was no medical benefit to patients from increasing the dosages of Zemplar by 0.5-mcg.

206. DaVita had the same corporate protocol, called "the Zen Tool Protocol for Zemplar," which required that the rounding of dosages be done up to the nearest 0.5-mcg, not vial size.

207. In stark contrast, the Defendants' protocols for Epogen dictated that if there

was an increase or decrease in certain clinical parameters for a particular patient, then the Epogen dosage should be rounded up or down to the nearest vial size or exact vial combination (with assumed overfill). See, e.g., Epogen corporate protocol, a true and correct copy of which is attached hereto as Exhibit 13.

208. Regardless of any changes in the patient's clinical parameters, Defendants would not create any waste through its Epogen corporate protocol, whereas with Zemplar, the rounding requirements resulted in an increase in waste that otherwise would not have occurred.

209. Gambro Quality Improvement/Educator Theresa Gonzales told Relator Barbir that he had too many patients who were using 2-mcg vials and that he needed to make the necessary rounding changes. Relator Barbir asked the dietitian to check to see if their patients were dosed appropriately before increasing the dosages by 0.5-mcg. She checked and said that they were being dosed appropriately. As directed, Relator Barbir went to his dietitian and told her to check all the patients who were using the 2-mcg vials to see which patients they could unilaterally designate for the increase by 0.5-mcg in order to use the larger 5-mcg vial that Gambro was requiring.

210. Relator Barbir and staff followed the company directive and increased the doses for many patients by 0.5-mcg in order to accomplish what they were told to

do and what they had no choice but to do. There was no medical benefit to patients from rounding up the dosages of Zemplar to the nearest 0.5-mcg.

211. Relator Barbir complained about this new corporate practice at the meetings of the clinic directors, but his superiors, including Quality Improvement/Educator Theresa Gonzales, Regional Director Nancy Marshman and Regional Vice President Greg Santulli, told him that all the clinic directors must uniformly implement the required corporate protocols without exception, because all of the dialysis clinics from all regions in the United States would be ranked and compared.

212. The Regional Directors Nancy Marshman and Mike Marshman and the Regional Vice President Greg Santulli said that Gambro was in the process of reviewing every dialysis clinic in the country to ensure that the number of patients receiving medication out of 2-mcg vials of Zemplar was reduced and that the number of patients receiving medication out of 5-mcg vials of Zemplar was increased. These executives emphasized again that any clinic that did not make the expected changes would receive a visit from the Division Vice President Steve Pirri. All the regions in the country were evaluated, ranked and compared.

213. Within a short period of time after dictating the fractional Zemplar dose increases, the Regional Quality Improvement/Educator Theresa Gonzales visited

Relator Barbir's Cumming clinic to evaluate the implementation level. While in the hallway talking with Theresa Gonzales and the Dietitian Diane Horn, the Regional Educator Theresa Gonzales said, "Guys, they are not playing, they are serious and jobs are on the line." Neither the dietitian nor Relator Barbir wanted to lose their jobs at that point, so they complied. Relator Barbir informed Theresa Gonzales that the clinic was doing as instructed.

214. At the same time, Gambro created a special projects position that was filled by Anthony Johnson. Johnson had the clearance and access via computer to every clinic's inventory system in the region. Johnson was responsible for providing reports to the executive team regarding the number of vials of Venofer and Zemplar used at every clinic in order to measure the progress of the implementation of the wasteful initiatives.

215. Also, Ling Ling Bao, R.N., a nurse from another DaVita clinic (Gainesville) came to work for a couple of days per week in the Cumming clinic where the Relators worked. This nurse was surprised to see that in Cumming they used Zemplar vials of 2-mcg, 5-mcg and 10-mcg. She said that in her Gainesville clinic they used only the 10-mcg vials in order to increase the billing and reimbursement by waste from the vials of 10-mcg regardless of the dose given.

M. Scheme #5: Defendants Failed to Implement Best Practices to Reduce Waste

216. Defendants could have avoided the creation of massive amounts of unnecessary waste by allowing the proper Zemplar vial combinations and by allowing re-entry of Zemplar and Venofer vials (between 2002-2008) that would have allowed whole vials of medication to be used at one time so there would be no waste.

217. For example, for a patient with a dosage of 6-mcg, DaVita protocol required this dosage to be administered using a 10-mcg vial, which created 4-mcg of waste. As discussed above, the dosage grid requirement creates 4-mcg of waste when none is required because DaVita could give a 6-mcg dose out of three 2-mcg vials with no waste. During 2002-2008 DaVita could have avoided even the 4-mcg of waste also by allowing re-entry of the vial, so the residual dose could have been administered to another patient. DaVita never allowed these less-wasteful options to be used.

218. Regardless of the medication, corporate protocol, or corporate dosing grid, in all instances Defendants chose the option that resulted in the greatest revenue to the company, even if the option chosen involved unnecessary waste and/or the corporate dosage grids and corporate protocols of different medications directly conflicted with each other.

219. DaVita purchased Gambro in 2005. At that time, according to the United States Renal Data System, a government-funded registry of dialysis data, Gambro had the highest per patient per month cost of vitamin D medications. Gambro mainly used Zemplar as its vitamin D medication at that time. DaVita, on the other hand, had the highest per patient per month cost for iron, using Venofer exclusively.

220. In dialysis treatment, the corporate protocols and corporate dosage grid requirements for medication usage should be consistent across the board regardless of whether waste is reimbursed. The goal should be to administer medications in a manner that meets patient care needs and does not unnecessarily waste so that the Government is not charged excessively.

221. CMS expected DaVita, Gambro and all other dialysis facilities to make all efforts to avoid creating waste of medications for which it reimbursed, just as a company's shareholders would expect it to avoid creating waste of medications for which waste is not reimbursed by CMS at all.

222. Yet, as discussed above, the protocols and dosage grids in place for the use of Epogen, Zemplar and Venofer by DaVita were not consistent at all. The differences in the diametrically opposite corporate protocols and corporate dosage grids were not based on how the medications were supposed to be used or

based on patient care, but were based simply on how the Defendants could best increase revenue from the use and reimbursement of waste of those medications.

223. While, in theory, some physicians might have attempted to bypass Defendants' pre-determined protocols and write their own protocols, there was no reason for them to have done so. Physicians trusted that DaVita or Gambro had chosen the best and most cost effective protocols just as DaVita and Gambro represented.

224. Physicians in general, and nephrologists in particular, rely on protocols designed by the Defendants. If physicians had to write their own protocols for each individual patient, they would have no time for anything else. Protocols, developed for the right reasons (not just to create waste), are to assist physicians to provide care to the patients.

225. In the case of Zemplar, regardless of the protocol chosen, Defendants created intentional and unnecessary waste. Even if physicians had written their own protocols, the administration would have been subject to Defendants' dosing grids, which mandated waste. So while a physician, for example, could write an order for a patient to be given 7-mcg of Zemplar, the physician could not instruct the nurses to give it out of 5-mcg vial and a 2-mcg vial. Defendants required administration of the dosage out a 10-mcg vial, according to the corporate dosing

grids. See Exhibits 4 and 5. A physician who developed his own protocol also could not instruct the nurses to administer the residual amount of medication remaining in the vial to another patient.

226. All of Defendants' protocols were implemented on a daily basis by dietitians and nurses on staff. Some dietitians and nurses had specific designations as anemia managers. In the case of Venofer, if a physician had written his or her own protocol, the physician would have had to train the dietitians and nurses on his protocol and would have risked confusion between their knowledge of different protocols, which could compromise patient safety. Physicians trusted that Defendants' protocols would be the best and most cost efficient for the patients as Defendants represented.

227. Physicians had no reason to doubt DaVita, which was at all times a leading provider of kidney care in the United States and represented to physicians that it delivered best-in-class clinical outcomes. Therefore, physicians accepted DaVita's protocols, without being aware of the huge waste associated with those protocols.

228. Defendants' purposeful and intentional waste cost the Government and taxpayers hundreds of millions of dollars.

N. DaVita's Corporate Culture Created Waste and Generated Excess Revenue, Ignoring Patient Care

229. The United States Renal Data System ("USRDS") is a national data system

that collects, analyzes and distributes information about dialysis patients in the United States. The USRDS is funded directly by the National Institute of Diabetes and Digestive and Kidney Diseases in conjunction with CMS. USRDS staff collaborates with members of CMS, the United Network for Organ Sharing and the dialysis networks, sharing datasets and actively working to improve the accuracy of dialysis patient information.

230. According to USRDS, DaVita has historically had the highest cost per patient per month for iron (Venofer) and vitamin D supplements (Zemplar) of all dialysis providers in the United States. See 2007 Per Patient Per Month ("PPPM") costs for intervention, by unit affiliation, a true and correct copy of which is attached hereto as Exhibit 14.

231. For example, in 2007, DaVita's cost for vitamin D was $120 per patient per month versus $50 for Dialysis Clinic, Inc. ("DCI"), one of the three largest dialysis providers in the country.

232. Despite its extremely high level of medication use and contrary to its claims, USRDS also shows that DaVita does not have the best patient outcomes. The best outcomes are achieved by DCI, with the lowest cost.

233. In 2006, DaVita actually had the highest hospitalization rate out of all large dialysis provider organizations. See 2006 Hospitalization and Mortality Ratios, a

true and correct copy of which is attached hereto as Exhibit 15.

234. DaVita's revenue maximizing decisions, including not to re-enter vials of Zemplar and Venofer and to choose Venofer over Ferrlecit, as well as mandating the most wasteful Zemplar vial combinations and adopting the most wasteful iron protocol, were revenue-based and not for clinical or efficiency purposes. Money, not clinical concerns, dictated protocols within DaVita.

O. Snappy Computer Program

235. In 2006 or 2007, DaVita developed a computer program called "Snappy," that made the process of dialysis medication administration even more rigid.

236. Snappy is a computer operational system that forces clinics to implement medication protocols without deviation. It instructed on which vials each dose of medication needed to be drawn from, how to combine vials, what syringes to use and how many, and printed the exact labels for each medication and syringe, among other things.

237. The main way Snappy controlled the implementation of Defendants' protocols was that the system printed out labels for the nurses to use to obtain medication. The nurses did not decide which vials to use. The Snappy system told them. The labels were pre-printed with the vial sizes and number of vials they were to use to administer the medication. See, e.g., a print out of labels from

Snappy, a true and correct copy of which is attached hereto as Exhibit 16.

238. DaVita programed Snappy to create waste.

239. For example, Exhibit 16 is a label dictating that a 5.5-mcg dose of Zemplar must be given out of a 10-mcg vial. This labeled directive creates 4.5-mcg of waste, when three 2-mcg vials would have provided the same dosage with only 0.5-mcg of waste.

240. Proof of the Venofer and Zemplar waste is available through the "Snappy" system. Snappy can generate a "Medication Reconciliation Report," which includes information about what size vials were used, what vial combinations were used and how much was administered to the patient and how much was wasted.

P. DaVita's Billing System

241. There were no differences between the billing processes of Gambro and DaVita that led to their billings to the Government for unnecessary waste.

242. DaVita's billing process is centralized and controlled in Tacoma, Washington. Gambro's billing process was handled out of Nashville, Tennessee prior to the merger.

243. Administrative assistants in the billing departments of individual clinics entered information into a computerized billing system that was transferred to Tacoma or Nashville for submission to CMS.

244. Prior to the implementation of the Snappy computer program, billing administrative assistants would enter information from "flow sheets" into a billing system, including a combined total of the amount of medication used and wasted.

245. For example, if a flow sheet said that 25-mg of Venofer was administered, then the billing administrative assistant would enter 100-mg into the billing system.

246. After the merger, the Snappy computer system handled all billing. For example, if a patient required 6 mcg of Zemplar, Snappy told the nurse that a 10-mcg vial had to be used, 4-mcg of waste was generated, and all information was electronically transmitted to Tacoma, where the billing occurred.

Q. Defendants Billed the Government for Unnecessary Waste

247. Defendants benefited from unnecessary waste because they billed the Government for it. More waste equaled increased revenue, higher rebates and increased discounts.

248. Defendants' protocols led to exorbitant amounts of unnecessary waste of both Venofer and Zemplar, which in turn led to excessive billings for waste from Defendants to CMS.

1. Venofer Billing

249. In a mere two month period at the DaVita clinic in Roswell, Georgia, the

DaVita iron protocol caused 19,750-mg of waste, although only 9,625-mg of Venofer was actually administered to patients. More than half of the Venofer that DaVita billed to the Government for reimbursement in this two month period was unnecessary waste and not medication that served any patient's needs. See August 13, 2007 to October 12, 2007 excerpt from Medication Reconciliation Report for Venofer/Iron Sucrose at the DaVita clinic located in Roswell, Georgia, a true and correct copy of which is attached hereto as Exhibit 17.

250. All of this waste could have been avoided, and thus was unnecessary, because DaVita forced the use of Venofer over Ferrlecit, required dosing to be spread out over multiple days, and refused to allow re-entry of single-use vials when it was allowed by the CDC and CMS.

251. DaVita billed for this unnecessary waste thousands of times on a daily basis.

252. The following are some examples of DaVita billing for unnecessary waste of Venofer.

253. Patient HN[2] Example. Patient HN received 200-mg of Venofer over four weeks in August and September. See Exhibit 12, Rounding Report for Patient HN, including the weeks ended August 21, 2010, August 28, 2010, September 4, 2010

[2] Patient initials are used in lieu of full names and patient names are redacted in attached exhibits to protect patient privacy.

and September 11, 2010.

254. Exhibit 12 shows that on the Mondays and Fridays of the weeks ending August 21, 2010, August 28, 2010, September 4, 2010 and September 11, 2010 (August 16, 20, 23, 27 and 30 and September 3, 6 and 10), Patient HN received his dosage of 200-mg in eight separate dosages of 25-mg each, instead of simply two dosages of 100-mg. See id.

255. DaVita billed for eight vials of 100-mg of Venofer when it could have billed for only two. See Electronic Medicare Summary Notices for Patient HN for August 2010 and September 2010, true and correct copies of which are attached hereto as Exhibits 18 and 19. Thus, DaVita billed for 600-mg of unnecessary waste – or 300%.

256. Exhibit 18 (at page 3) includes five separate charges of $785.00 for "100 J756 – Injection, Iron Sucrose, 1 Mg," which is 100-mg of Venofer, on August 16, 2010, August 20, 2010, August 23, 2010, August 27, 2010 and August 30, 2010, five of the dates set forth in Paragraph 254 above. See id.

257. Exhibit 19 (at page 2) includes three separate charges of $785.00 for "100 J756 – Injection, Iron Sucrose, 1 Mg" on September 3, 2010, September 6, 2010 and September 10, 2010, the remaining three dates set forth in Paragraph 254 above. See id.

258. Patient HN could have received the 200-mg of Venofer in two doses, which would have created zero waste. In fact, on September 13, 2010, Patient HN received his prescription of 100-mg in one dosage. See Exhibit 12.

259. DaVita billed the Government for only one vial of 100-mg of Venofer at $785.00 for the September 13, 2010 dosage. See Exhibit 19. DaVita billed this amount four times in August to give the same dosage.

260. Patient WN Example #1. Patient WN received 200-mg of Venofer in October. See Rounding Report for Patient WN, including the weeks ended October 9, 2010 and October 16, 2010, a true and correct copy of which is attached hereto as Exhibit 20.

261. Exhibit 20 shows that on the Monday (October 4), Wednesday (October 6) and Friday (October 8) of the week ending October 9, 2010 and on the Monday (October 11) of the week ending October 16, 2010, Patient WN received his dosage of 200-mg in four separate dosages of 50-mg each, instead of simply two dosages of 100-mg each. See id.

262. DaVita billed for four vials of 100-mg of Venofer when it could have billed for only two. See CMS Medicare Summary Report for Patient WN dated February 11, 2011, a true and correct copy of which is attached hereto as Exhibit 21. Thus, DaVita billed for 200-mg of unnecessary waste – or 200%.

263. Exhibit 21 (at page 2) includes four separate charges of $785.00 for "Iron sucrose injection (J1756)," which is Venofer, between October 1, 2010 and October 29, 2010, which includes the dates that the 50-mg doses listed in Paragraph 261 were administered. See id.

264. Patient WN Example #2. Patient WN also received 100-mg of Venofer in November and December of 2010. See Exhibit 20, including the weeks ended November 20, 2010, and Rounding Report for Patient WN, including the weeks of November 27, 2010, December 4, 2010 and December 11, 2010, a true and correct copy of which is attached hereto as Exhibit 22.

265. Exhibits 20 and 22 show that on the Mondays of each of the weeks listed above, which were November 15, 2010, November 22, 2010, November 29, 2010 and December 6, 2010, Patient WN received his dosage of 100-mg in four separate dosages of 25-mg each, instead of simply one dosage of 100-mg. See Exhibits 20 and 22.

266. DaVita billed for four vials of 100-mg of Venofer when it could have billed for only one. See Exhibit 21. Thus, DaVita billed for 300-mg of unnecessary waste – or 300% waste.

267. Exhibit 21 (at pages 3-4) shows three separate charges of $785.00 for "Iron sucrose injection (J1756)," which is Venofer, between November 1, 2010 and

November 29, 1010 and one charge of $785.00 for "Iron sucrose injection (J1756)" between December 1, 2010 and December 31, 2010, which includes the dates that the 25-mg doses listed in Paragraph 265 were administered. See id.

268. In these examples of patient WN taken together, DaVita billed CMS for eight vials of 100-mg of Venofer, when it could have billed for only three. DaVita billed the government for an entire vial, 100-mg, to administer doses of 25-mg and 50-mg. DaVita created 500-mg – 166% – of unnecessary waste over eight days for one patient and billed the Government for it.

2. Zemplar Billing

269. In a six-month period at the DaVita clinic in Cumming, Georgia, the DaVita Zemplar protocol caused 2,301.75-mcg of waste, although only 6,416.25-mcg of Zemplar was actually administered to patients. Over one-third of DaVita's billings for Zemplar in six months were for waste. See Medication Reconciliation Report for Zemplar for the period of April 1, 2006 through October 8, 2007 excerpt from the DaVita clinic located in Cumming, Georgia, a true and correct copy of which is attached hereto as Exhibit 23.

270. All of this waste was intentional and unnecessary because DaVita added fractional dosages of 0.5-mcg to all 2-mcg doses, required use of a larger than necessary vial sizes, mandated specific and wasteful combinations of vial sizes to

administer Zemplar doses and refused to allow re-entry of single-use vials.

271. DaVita billed the Government for this unnecessary waste. The following are some examples of DaVita billing for unnecessary waste of Zemplar.

272. Patient MP Example #1. Patient MP received two injections of 7-mcg of Zemplar over one week in March 2010. See Rounding Report for Patient MP, including the week ended March 20, 2010, a true and correct copy of which is attached hereto as Exhibit 24.

273. Exhibit 24 shows that on the Monday (March 15) and Wednesday (March 17) of the week ended March 20, 2010, Patient MP received injections of 7-mcg of Zemplar. See id.

274. DaVita used and billed for one vial of 10-mcg of Zemplar for each injection, which created 3-mcg of waste for each injection – when it could have used and billed for one vial of 5-mcg and one vial of 2-mcg with no waste. See MyMedicare.gov – Claim Details for the month of March 2010 for Patient MP, a true and correct copy of which is attached hereto as Exhibit 25.

275. Exhibit 25 (at page 2), shows charges of $713.00 for 10 units of "J2501 – Injection Paricalcitol, 1 Mcg," which is 10 units of Zemplar, on March 15, 2010 and March 17, 2010, the dates set forth in Paragraph 273 above. See id.

276. The DaVita dosing grid led to the administration of injections of 7-mcg each

out of vials of 10-mcg each – or 42% waste for each.

277. Because Patient MP was given injections of 7-mcg from vials of 10-mcg (instead of from one vial of 5-mcg and one vial of 2-mcg), DaVita billed for 3-mcg – or 42% – of unnecessary waste for each dosage.

278. Patient MP Example #2. Patient MP also received two injections of 11-mcg of Zemplar over one week in June 2010. See Rounding Report for Patient MP, including the week ended June 5, 2010, a true and correct copy of which is attached hereto as Exhibit 26.

279. Exhibit 26 shows that on the Wednesday (June 2) and Friday (June 4) of the week ended June 5, 2010, Patient MP received injections of 11-mcg of Zemplar. See id.

280. DaVita used and billed for one vial of 10-mcg and one vial of 5-mcg of Zemplar for each injection, which created 4-mcg of waste for each injection – when it could have used and billed for one vial of 5-mcg and three vials of 2-mcg, which would have created zero waste. See MyMedicare.gov – Claim Details for the month of June 2010 for Patient MP, a true and correct copy of which is attached hereto as Exhibit 27.

281. Exhibit 27 (at page 2), shows charges of $1,069.50 for 15 units of "J2501 – Injection Paricalcitol, 1 Mcg," which is 15 units of Zemplar, on June 2, 2010 and

June 4, 2010, the dates set forth in Paragraph 279 above. See id.

282. The DaVita dosing grid led to the administration of injections of 11-mcg each out of vials of 10-mcg and 5-mcg.

283. Because Patient MP was given injections of 11-mcg from vials of 10-mcg and 5-mcg (instead of from one vial of 10-mcg and one vial of 2-mcg), DaVita billed for 4-mcg of unnecessary waste for each dosage.

284. Patient MP's example also demonstrates that DaVita did not prohibit all combinations of vials. DaVita allowed the combination of vials that created waste.

285. Patient JB Example. Patient JB received 13 injections of 2.5-mcg of Zemplar in November 2009. See Rounding Report for Patient JB, including the weeks ended November 7, 2009, November 14, 2009, November 21, 2009, November 28, 2009 and December 5, 2009, a true and correct copy of which is attached hereto as Exhibit 28.

286. Exhibit 28 shows that on the Mondays, Wednesdays and Fridays in November of the weeks listed in Paragraph 285 (November 2, 4, 6, 9, 11, 13, 16, 18, 20, 23, 25, 27 and 30), Patient JB received injections of 2.5-mcg of Zemplar. See id.

287. DaVita used and billed for two vials of 2-mcg of Zemplar for each injection – 13 injections using 26 vials – when it could have used and billed for only 13

vials. See CMS Medicare Summary Report for Patient JB dated July 30, 2010, a true and correct copy of which is attached hereto as Exhibit 29.

288. Exhibit 29 (at pages 1-2) includes 13 separate charges of $279.50 for "Paricalcitol (J2501)," which is 4-mcg of Zemplar, between November 2, 2009 and November 30, 2009, which includes the dates that the 13 2.5-mcg doses listed in Paragraph 286 were administered. See id.

289. The DaVita protocol led to the administration of dosages of 2.5-mcg each instead of 2-mcg each.

290. Because Patient JB was given injections of 2.5-mcg each instead of 2-mcg each, DaVita billed for 13 additional, unnecessary vials of 2-mcg of Zemplar.

R. Defendants' Claims for Unnecessary Waste Violated the Fair Claims Act

291. When DaVita and Gambro submitted their claims for reimbursement and annual cost reports, they failed to disclose their intentional wastage, which they knew was legally non-reimbursable. This failure to disclose constituted a factually false representation, an express and implied legally-false certification in violation of the False Claims Act.

292. The provider must demonstrate all information sufficient to show that the payment for a particular claim is due. Submission by providers for wastage reimbursement must be submitted on UB-92 forms.

293. These UB-92 forms require that the information provided be true and correct. Such forms contain spaces for "covered" and "non-covered" services and for the provider to inform Medicare of other information under a space marked "remarks."

294. As a basis of payment, Section 1833(e) of the Act states, "No payment shall be made to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due…."

295. Additionally, Federal regulations, 42 C.F.R. § 424.5(a)(6), require providers to furnish sufficient information, upon request, to determine whether payment is due and, if so, the amount to be paid. "As a basis for Medicare payment, the following conditions must be met…(6) Sufficient information. The provider, supplier, or beneficiary, as appropriate, must furnish to the intermediary or carrier sufficient information to determine whether payment is due and the amount of payment."

S. DaVita Changed Its Protocols and Dosage Grids for Venofer and Zemplar Immediately After Reimbursement for Waste Was Stopped

296. Earlier this year, CMS changed the reimbursement guidelines for dialysis services and separately billable medications, including Venofer and Zemplar.

297. DaVita changed its protocols and dosage grids for Venofer immediately

after CMS made this reimbursement policy change in January of 2011.

298. There were no medical indications that caused the change of Defendants' protocol. Instead, only the reimbursement guidelines changed. DaVita is no longer paid for the waste, so now no waste is allowed.

299. According to the new bundling guidelines, all payments for the medications administered with dialysis, such as Epogen, Venofer and Zemplar, are included in one fixed payment.

300. As a result of these changes, DaVita stopped using Zemplar, and adopted the use of Hectorol, which is available in more vial sizes.

301. DaVita also adopted a new Venofer corporate protocol, allowing only for a weekly administration of 50-mg or 100-mg of Venofer (the two vial sizes in which Venofer is now available). No other doses are allowed and only one weekly administration (instead of three per week) is allowed. Doses such as 25-mg, which were the norm prior to bundling, are now prohibited by DaVita.

302. Thus, after bundling, the Venofer corporate protocol was re-written specifically to conform to the vials size available – as has always been the case for Epogen. DaVita's policies that resulted in over 100% waste prior to the new bundling system now result in 0% (zero) waste. This remarkable reversal in policies directly and unequivocally equates to the fact that the Government no

longer reimburses for wastage.

303. DaVita's new Venofer protocol relies on medical information from 1989-2006, demonstrating that the same, less wasteful protocol, would have been medically sound during the time that DaVita was promoting its alternative protocol that created unnecessary waste. See, e.g., information provided to physicians regarding the new DaVita iron protocol in place in 2011, a true and correct copy of which is attached hereto as Exhibit 30.

304. During 2002-2008, when the CDC and CMS presented their recommendations allowing re-entry of single-use vials of Epogen, Venofer and Zemplar, Defendants did not change their corporate policies that prohibited re-entry of Zemplar and Venofer. This is true despite the fact that DaVita claimed that it played a key role in convincing the CDC to reverse its recommendation against re-entry of single-use vials in 2002.

305. It was only after a change on the money side that no longer allowed reimbursement for any waste – not a change on the medical side – that Defendants made changes that eliminated completely the Venofer waste and that significantly reduced the Vitamin D waste.

306. Before bundling, physicians were never told to make efficient use of resources, but now they are specifically told to do so by DaVita.

307. Now DaVita does not allow physicians to continue with the old Venofer corporate protocol because it does not meet the criteria for the new 2011 corporate emphasis regarding the "efficient use of resources." After the bundling reimbursement process went into effect in 2011, if physicians want to have a protocol different than DaVita's, physicians have to show equal or superior outcomes. All non-DaVita iron management protocols require approval from the Office of Chief Medical Officer and Clinical Operations. As a practical matter, it is impossible to order a different protocol.

308. Because DaVita now receives bundled reimbursement payments for its dialysis-related medications, their new corporate protocols minimize and virtually eradicate waste. As stated above, revenues drive DaVita's decisions, even if those decisions involve fraudulent practices.

V. CLAIMS FOR RELIEF

A. COUNT I –VIOLATION OF 31 U.S.C. § 3729(a)(1)(A)

309. Relators incorporate by reference Paragraphs 1-308 of this Fourth Amended Complaint as though the same were set forth herein at length.

310. Defendants knowingly, in reckless disregard and/or in deliberate ignorance of the truth presented and/or caused to be presented false and fraudulent claims for payment and approval for medications administered to patients insured by

federally-funded health insurance programs, including Medicare, when they submitted claims for payment and approval to CMS for unreasonable and unnecessary medication and waste caused by the following policies: (a) Defendants did not allow re-entry in single-use vials of Venofer or Zemplar (although such practice was allowed from 2002-2008) while allowing re-entry in Epogen single-use vials, even though multi-use vials of Epogen were available; (b) Defendants implemented an iron protocol that intentionally spread out dosages of Venofer over several treatments instead of one treatment solely to maximize revenue; (c) Defendants manipulated and dictated vial size and vial combinations to ensure the highest amount of waste; (d) Defendants implemented a protocol that dictated fractional increases in dosages of Zemplar to create waste where none was necessary, without a corresponding medical benefit; and (e) Defendants failed to implement best practices to avoid waste.

311. Defendants knowingly, in reckless disregard and/or in deliberate ignorance of the truth presented and/or caused to be presented false and fraudulent cost reports to the Government when they submitted cost reports that included unreasonable and unnecessary medication and waste caused by the following policies: (a) Defendants did not allow re-entry in single-use vials of Venofer or Zemplar (although such practice was allowed from 2002-2008) while allowing re-

entry in Epogen single-use vials, even though multi-use vials of Epogen were available; (b) Defendants implemented an iron protocol that intentionally spread out dosages of Venofer over several treatments instead of one treatment solely to maximize revenue; (c) Defendants manipulated and dictated vial size and vial combinations to ensure the highest amount of waste; (d) Defendants implemented a protocol that dictated fractional increases in dosages of Zemplar to create waste where none was necessary, without a corresponding medical benefit; and (e) Defendants failed to implement best practices to avoid waste.

312. CMS, unaware of the falsity of the claims and statements made or caused to be made by the Defendants, and in reliance on the accuracy of these claims and statements, paid for unreasonable and unnecessary medication and wastage of medication provided to patients insured by federally-funded health insurance programs, including Medicare.

313. Had the Government known that the bills presented or caused to be presented by Defendants for payment were false and misleading, payments would not have been made for such claims.

314. Defendants did not disclose their intentional wastage and non-compliance with requirements as to "medication wastage" in the claims, reports, forms, or other information they submitted to CMS.

315. Defendants by their fraudulent manipulation of their corporate protocols and medication dosing and administration grids intentionally caused wastage to fraudulently increase revenue through billing for otherwise avoidable and unreasonable wastage; the fraudulent schemes also greatly increased Defendants' volume rebates and discounts from medication manufacturers supplying such medications to Defendants.

316. As a result of these schemes, Defendants caused Medicare and the other government payors to incur significant damage and those damages are continuing to accrue.

B. COUNT II – VIOLATION OF 31 U.S.C. § 3729(a)(1)(B)

317. Relators incorporate by reference Paragraphs 1-316 of this Fourth Amended Complaint as though the same were set forth herein at length.

318. Defendants knowingly, in reckless disregard and/or or in deliberate ignorance of the truth made, used and/or caused to be made or used, a false record and statements material to a false and fraudulent claim to obtain approval and payment from the Government when they submitted claims for payment and approval, as well as cost reports, to CMS for unreasonable and unnecessary medication and waste caused by the following policies containing claims for medication and unnecessary waste caused by the following policies: (a)

Defendants did not allow re-entry in single-use vials of Venofer or Zemplar (although such practice was allowed from 2002-2008) while allowing re-entry in Epogen single-use vials, even though multi-use vials of Epogen were available; (b) Defendants implemented an iron protocol that intentionally spread out dosages of Venofer over several treatments instead of one treatment solely to maximize revenue; (c) Defendants manipulated and dictated vial size and vial combinations to ensure the highest amount of waste; (d) Defendants implemented a protocol that dictated fractional increases in dosages of Zemplar to create waste where none was necessary, without a corresponding medical benefit; and (e) Defendants failed to implement best practices to avoid waste.

319. CMS, unaware of the falsity of the claims and statements made or caused to be made by the Defendants, and in reliance on the accuracy of these claims and statements, paid for unreasonable and unnecessary medication and wastage of medication provided to patients insured by federally-funded health insurance programs, including Medicare.

320. Had the Government known that the bills presented or caused to be presented by Defendants for payment were false and misleading, payments would not have been made for such claims.

321. Defendants did not disclose their intentional wastage and non-compliance

with requirements as to "medication wastage" in the claims, cost reports, forms, or other information they submitted to CMS.

322. Defendants by their fraudulent manipulation of their corporate protocols and medication dosing and administration grids intentionally caused wastage to fraudulently increase revenue through billing for otherwise avoidable and unreasonable wastage; the fraudulent schemes also greatly increased Defendants' volume rebates and discounts from medication manufacturers supplying such medications to Defendants.

323. As a result of these schemes, Defendants caused Medicare and the other government payors to incur significant damage and those damages are continuing to accrue.

C. COUNT III – VIOLATION OF 31 U.S.C. 3729(a)(1)(C)

324. Relators incorporate by reference Paragraphs 1-323 of this Fourth Amended Complaint as though the same were set forth herein at length.

325. Defendants knowingly, in reckless disregard and/or in deliberate ignorance of the truth conspired to present and/or cause to be presented false and fraudulent claims for payment and approval for medications administered to patients insured by federally-funded health insurance programs, including Medicare, when they developed and implemented the following policies that led to the submission of

claims for payment and approval to CMS for unreasonable and unnecessary medication and waste: (a) Defendants did not allow re-entry in single-use vials of Venofer or Zemplar (although such practice was allowed from 2002-2008) while allowing re-entry in Epogen single-use vials, even though multi-use vials of Epogen were available; (b) Defendants implemented an iron protocol that intentionally spread out dosages of Venofer over several treatments instead of one treatment solely to maximize revenue; (c) Defendants manipulated and dictated vial size and vial combinations to ensure the highest amount of waste; (d) Defendants implemented a protocol that dictated fractional increases in dosages of Zemplar to create waste where none was necessary, without a corresponding medical benefit; and (e) Defendants failed to implement best practices to avoid waste.

326. Defendants knowingly, in reckless disregard or in deliberate ignorance of the truth conspired to present and/or cause to be presented false and fraudulent cost reports to the Government when they developed and implemented the following policies that led to the submission of cost reports that included unreasonable and unnecessary medication and waste caused by the following policies: (a) Defendants did not allow re-entry in single-use vials of Venofer or Zemplar (although such practice was allowed from 2002-2008) while allowing re-entry in

Epogen single-use vials, even though multi-use vials of Epogen were available; (b) Defendants implemented an iron protocol that intentionally spread out dosages of Venofer over several treatments instead of one treatment solely to maximize revenue; (c) Defendants manipulated and dictated vial size and vial combinations to ensure the highest amount of waste; (d) Defendants implemented a protocol that dictated fractional increases in dosages of Zemplar to create waste where none was necessary, without a corresponding medical benefit; and (e) Defendants failed to implement best practices to avoid waste.

327. Defendants knowingly, in reckless disregard or in deliberate ignorance of the truth conspired to make, use and/or cause to be made or used, a false record and statements material to a false and fraudulent claim to obtain approval and payment from the Government for false and fraudulent claims when they developed and implemented the following policies that led to the submission of claims for approval and payment, as well as cost reports, to CMS for unreasonable and unnecessary medication and waste: (a) Defendants did not allow re-entry in single-use vials of Venofer or Zemplar (although such practice was allowed in 2002) while allowing re-entry in Epogen single-use vials, even though multi-use vials of Epogen were available; (b) Defendants implemented an iron protocol that intentionally spread out dosages of Venofer over several treatments instead of one

treatment solely to maximize revenue; (c) Defendants manipulated and dictated vial size and vial combinations to ensure the highest amount of waste; (d) Defendants implemented a protocol that dictated fractional increases in dosages of Zemplar to create waste where none was necessary, without a corresponding medical benefit; and (e) Defendants failed to implement best practices to avoid waste.

328. CMS, unaware of the falsity of the claims and statements made or caused to be made by the Defendants as a result of the conspiracy, and in reliance on the accuracy of these claims and statements, paid for unreasonable and unnecessary medication and wastage of medication provided to patients insured by federally-funded health insurance programs, including Medicare.

329. Had the Government known that the bills presented or caused to be presented by Defendants for payment through the conspiracy were false and misleading, payments would not have been made for such claims.

330. Defendants did not disclose their intentional wastage and non-compliance with requirements as to "medication wastage" through the conspiracy in the claims, reports, forms, or other information they submitted to CMS.

331. Defendants by their conspiracy to fraudulently manipulate their corporate protocols and medication dosing and administration grids intentionally caused

wastage to fraudulently increase revenue through billing for otherwise avoidable and unreasonable wastage; the fraudulent schemes also greatly increased Defendants' volume rebates and discounts from medication manufacturers supplying such medications to Defendants.

332. As a result of the conspiracy, Defendants caused Medicare and the other government payors to incur significant damage and those damages are continuing to accrue.

VI. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs/Relators, acting on behalf of and in the name of the United States, demand and pray that judgment be entered in favor of the United States against each Defendant, jointly and severally, as follows:

(a) The amount of the United States' damages in an amount to be proven at trial;

(b) Treble the amount of the United States' damages in an amount to be proven at trial;

(c) Civil penalties of $11,500 for each false claim submitted, especially in view of the fact that the Defendants' fraud is so egregious as to justify debarment from all federal health care programs;

(d) Reasonable costs and attorney's fees;

(e) The maximum allowed to Plaintiffs under 31 U.S.C. § 3730(d);

(f) Trial by jury as to the allegations against each Defendant; and

(g) Such other and further relief as this Court deems to be just and proper.

This 25th day of July 2011.

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