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

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| UNITED STATES OF AMERICA<br><br>PLAINTIFF,<br><br>*v.*<br><br>ROBERT C. BURKICH M.D., AND PREVENTATIVE MEDICINE ANTI-AGING & CHELATION, INC.<br><br>DEFENDANTS. | Civil Action No. |

**COMPLAINT**

The United States of America, by Byung J. Pak, United States Attorney, and Paris A. Wynn, Assistant United States Attorney for the Northern District of Georgia, brings this civil action pursuant to the False Claims Act, 31 U.S.C. §§ 3729-3733 (2009) (FCA), under the federal common law theories of payment by mistake and unjust enrichment.

**INTRODUCTION**

1. This action arises from the fact that, although Medicare reimburses healthcare providers for the costs associated with the administration of the drug edetate calcium disodium (EDTA) when used to treat patients suffering from lead poisoning or lead encephalopathy, Medicare does not cover—*and explicitly excludes coverage for*—the use of EDTA as a treatment for *all* conditions other than lead poisoning or lead encephalopathy.

2. Herein, the United States alleges that Defendants violated the FCA by knowingly submitting false claims to Medicare for medically unnecessary and experimental EDTA chelation therapy, which is not reimbursable under Medicare.

3. Specifically, the United States seeks to recover damages, civil penalties and other relief from Defendants Robert C. Burkich, M.D., and Preventative Medicine Anti-Aging & Chelation, Inc. ("PMAC") (collectively "Defendants") for having knowingly submitted – between approximately September 2009 and January 2017 – false claims for medically unnecessary and experimental chelation therapy that Dr. Burkich administered using the drug EDTA, which the FDA has only approved as a treatment for lead poisoning and lead encephalopathy.

4. In connection with their false claims, Defendants received approximately $3.1 million in Medicare reimbursements.

5. Chelation therapy is a treatment that is only indicated for patients suffering from an uncommon condition called heavy metal poisoning (HMP), of which lead poisoning is the most common subset. HMP is the accumulation of potentially toxic heavy metals, such as lead, mercury and cadmium, in toxic amounts, in the soft tissues of the body.[1]

6. A viable diagnosis of HMP is dependent on a symptomatic patient: (1) presenting with a *sufficiently high* amount of heavy metal in his/her body (as generally

[1] Lead poisoning is the most commonly diagnosed form of HMP. Lead encephalopathy, which is a disease that affects the function and structure of the brain, is a condition caused by acute lead poisoning.

confirmed by blood testing), and (2) having been acutely and recently exposed to a potentially dangerous heavy metal, such as lead.

7. In the majority of cases, the only treatment for HMP is the removal of the patient from the source of exposure to heavy metal. However, in an acute case, chelation therapy may be indicated, and it involves providing the patient with a "chelating agent" such as EDTA, which binds itself to the metals in the bloodstream and is then excreted from the body *via* urine, thereby reducing the amount of heavy metals in a patient's body.

8. A provider bills Medicare for chelation therapy by submitting two sets of procedure codes: one for the chosen chelating drug, and one or more for the procedures associated with administering that drug to a patient.

9. For their part, Defendants utilized the procedure code J0600 to indicate the use of EDTA, as well as various additional procedure codes associated with the intravenous administrations of EDTA.

10. Specifically, in intravenously administering EDTA, Dr. Burkich also billed injection and infusion CPT codes (96365, 96366 96367, 96374), which varied based upon the length of infusion time. Additionally, Dr. Burkich billed for the normal saline and 5% dextrose water (HCPCS codes J7040, J7050 and J7060) used in connection with the intravenous administration of EDTA.[2]

[2] Also, using Modifier 25, Dr. Burkich frequently billed Medicare for – in *addition* to the underlying chelation treatments – an additional "office visit," which supposedly occurred on the same day that he chelated the patient, even though he provided no additional service that was significant and separately identifiable from the chelation therapy. (*See*, ¶¶ 228-236)

11. Additionally, claims submitted to Medicare for chelation therapy are generally not payable unless a diagnosis is provided.

12. In billing Medicare for the administration of EDTA to their patients, Defendants – with respect to the bulk ($2.8 million) of the approximately $3.1 million in reimbursements that they fraudulently obtained from the Government – utilized ICD-9 Diagnostic Codes that are associated with HMP, which included, but were not limited to, the following ICD-9 Diagnostic Codes:

- 9612 – Poisoning By Heavy Metal Anti-Infectives,
- 9848 – Toxic Effects Lead Compounds NEC,
- 9849 – Toxic Effects Lead Compounds NOS.

13. In utilizing these HMP related ICD-9 Codes, Defendants represented to the Government that the pertinent claims arose in connection with their administration of EDTA to patients suffering from various types of HMP, such as lead poisoning.

14. In truth, however, these patients were not suffering from HMP, as evidenced by the facts that they: (1) had not been recently and/or acutely exposed to heavy metals; and (2) did not have sufficiently high levels of heavy metals in their bodies to warrant chelation, which is a serious and potentially harmful therapy.

15. For instance, Dr. Burkich submitted numerous claims for reimbursement wherein he indicated – through the use of ICD-9 Codes associated with lead poisoning – that he chelated patients with EDTA that were suffering from lead poisoning. However, these claims were false as the patients were not suffering from lead poisoning, as demonstrated by the fact that the patients: (1) had not been recently and acutely exposed

to lead, and (2) did not have recorded blood lead levels (BLLs) high enough – *e.g.*, BLLs in excess of 50/80 mcg/dL – to warrant the administration of EDTA. [3]

16. Indeed, Dr. Burkich repeatedly chelated patients that he represented to the Government were suffering from lead poisoning, but whom in truth had only *miniscule* amounts (*e.g.*, less than 2 mcg/dL) – *if any* – of lead in their blood.

17. Defendants' inclusion of HMP diagnosis codes on chelation claims they submitted to Medicare rendered such claims false, as the patients (1) were not suffering from HMP, but were actually (2) chelated with EDTA as an experimental or alternative treatment for a variety of *other* conditions – *e.g.*, heart problems, insomnia, fatigue, decreased libido, which are not covered uses of EDTA under Medicare.

18. Even though EDTA is only indicated for lead poisoning and lead encephalopathy, for years, Dr. Burkich trumpeted and administered EDTA chelation as a supposedly "effective" therapy for a wide assortment of conditions, which includes, but is not limited to: (1) atherosclerosis, (2) AIDS, (3) osteoarthritis, (4) fatigue, (5) varicose veins, and (6) paralysis. (See, ¶146)

19. According to Dr. Burkich, "[j]ust about anyone who is breathing and possesses a pulse[,]" is a good candidate for EDTA chelation therapy.

20. As part of his pitch, Dr. Burkich informed potential patients that even low levels of heavy metals caused various health problems, and then utilized the results of widely discredited "provoked urine tests" to tell patients that they had "heightened"

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[3] Chelation may be indicated for a symptomatic patient with a BLL in excess of approximately 50 mcg/dL, but is not indicated for an asymptomatic patient with BLL less than approximately 80 mcg/dL.

levels of heavy metal, which chelation could reduce, thereby alleviating a host of medical problems, such as high blood pressure, poor circulation, premature aging and sexual dysfunction.

21. Indeed, with respect a small subset of the reimbursements that he received from Medicare (*i.e.*, approximately $365,000 of the approximately $3.1 million in reimbursements), Dr. Burkich abandoned any pretense that he was administering EDTA to treat patients with HMP, and submitted claims that included diagnostic codes indicating that he used EDTA to treat conditions such as hypertension, insomnia, sinusitis and decreased libido, even though he had "knowledge" under the FCA that: (1) EDTA is only indicated for lead poisoning or lead encephalopathy, and (2) Medicare does not cover alternative uses of EDTA – *e.g.*, uses outside of the treatment of medically documented instances of lead poisoning or lead encephalopathy.

22. Specifically, pursuant to National Coverage Determination (NCD) No. 20.22, which was issued by the Centers for Medicare and Medicaid Services in 2003, and was in effect throughout the time period in which Defendants submitted the false claims alleged herein, experimental EDTA chelation therapy is not covered by Medicare. Specifically, NCD 20.22 provides that "the use of EDTA as a chelating agent to treat atherosclerosis, arteriosclerosis, calcinosis, *or similar generalized conditions not listed by the FDA as an approved use is not covered. Any such use of EDTA is considered experimental*." (emphasis added.)

23. Additionally, the use of EDTA as a treatment for any condition other than lead poisoning or lead encephalopathy is not reimbursable pursuant to CMS's "off-label" drug

rule, which precludes coverage in instances where a drug is used for purposes outside of the indications approved by the FDA.

24. As the FDA has only approved EDTA for indications of lead poisoning and lead encephalopathy, Dr. Burkich's use of EDTA to treat any other condition – *e.g.*, high blood pressure, poor circulation, premature aging, sexual dysfunction – is excluded from Medicare coverage by NCD 20.22 (as well as CMS's "off-label" drug rule), and is not considered reasonable and/or necessary under Medicare.

25. Nevertheless, for an extended period of time – *i.e.,* between 2009 and 2017 – Dr. Burkich repeatedly submitted claims to Medicare that arose in connection with his use of EDTA as a supposed treatment for a myriad of conditions *other* than lead poisoning, irrespective of the fact that such uses of EDTA are explicitly excluded from Medicare coverage by NCD 20.22 and Medicare's "off-label" drug rule.

26. For several separate and independent reasons, the thousands of EDTA chelation claims that Defendants submitted to Medicare between September 2009 and January 2017 were "false" within the meaning of the FCA:

a. First, the chelation claims that Defendants submitted or caused to be submitted to Medicare were for chelation therapy that was not medically necessary, despite Defendants' false certifications to the contrary.

b. Second, with respect to the largest amount of the reimbursements (*i.e.*, $2.8 of the $3.1 million) they obtained, Defendants erroneously stated on the applicable chelation claims that they submitted (or caused to be submitted) to Medicare that the patients suffered from HMP/lead poisoning, when in truth, they did not.

c. Third, the chelation claims that Defendants submitted or caused to be submitted to Medicare involved alternative and/or experimental chelation therapy for conditions that are excluded from Medicare coverage pursuant to NCD 20.22.

d. Fourth, the chelation claims that Defendants submitted or caused to be submitted to Medicare were for "off-label" uses that were not approved by the FDA, and were therefore not covered by Medicare.

27. Finally, many of Defendants' EDTA reimbursement claims are false for the additional reason that – through the misuse of Modifier 25 – Defendants billed the Government for office visits that Defendants falsely represented were *separate and distinct* from the chelation therapy that Defendants provided to patients during the same encounter.[4]

28. In truth, Dr. Burkich did not provide any services that were separate and distinct from the chelation therapy, and was he therefore not entitled to the additional reimbursements he received as result of his misuse of Modifier 25.

29. Defendants tendered the aforementioned types of false claims to the Government with "knowledge" – as that term is defined by the FCA – of their falsity. Specifically, in submitting the claims, Defendants either had actual knowledge of, or acted in deliberate ignorance or reckless disregard to, the falsity of the claims.

## THE PARTIES

30. Plaintiff is the United States who brings this action on behalf of the United States Department of Health and Human Services (HHS) and the Centers for Medicare and Medicaid Services (CMS), which administers the Medicare program.

31. Defendant Preventative Medicine, Anti-Aging and Chelation Therapy, Inc. ("PMAC") is a corporation organized and existing under the laws of the State of Georgia,

[4] Modifier 25 is intended to be used where a physician – in addition to providing a patient with previously scheduled and/or agreed upon services – performs an additional, significant and separately identifiable service on the same date.

with its principal place of business located at 148 Cobb Parkway, Ringgold, Georgia, 30736. PMAC also maintains an office at 5505 Peachtree Dunwoody Road, Suite 580, Atlanta, Georgia 30341. PMAC is owned and operated by Defendant Dr. Robert C. Burkich for the purpose of, *inter alia*, providing integrative and/or alternative therapies such as EDTA chelation, and submitting, processing and/or receiving, bills, claims, payments and reimbursements associated with such therapies.

32. Defendant Robert C. Burkich, M.D., (Dr. Burkich) at all times relevant to the Complaint, was a licensed physician in the State of Georgia and/or the State of Tennessee. Upon information and belief, Dr. Burkich's primary place of business is 148 Cobb Parkway, Ringold, GA 30736.

33. According to Dr. Burkich, he earned a medical degree from the Ross University School of Medicine in 1989.

34. Dr. Burkich is not board certified in internal medicine (or any other medical discipline or specialty) by the American Board of Medical Specialties (ABMS), which is the nationally recognized not-for-profit organization that – in partnership with its 24 certifying member boards – establishes professional and educational standards for medical specialty practice and certification.

## JURISDICTION AND VENUE

35. This Court has jurisdiction over the subject matter of this action pursuant to 31 U.S.C. § 3730(a) and 28 U.S.C. §§ 1331 and 1345, and supplemental jurisdiction over the United States' common law and equitable claims under 28 U.S.C. § 1367(a).

36. This Court may exercise personal jurisdiction over Dr. Burkich pursuant to 31 U.S.C. § 3732(a) because Dr. Burkich's offices are located in the Northern District of

Georgia and because he transacts business in the Northern District of Georgia. The United States' claims against Dr. Burkich under federal common law and/or Georgia law arise from the same transaction or occurrence as its claims under the 31 U.S.C. § 3729, et seq.

37. The Court may exercise personal jurisdiction over PMAC pursuant to 31 U.S.C. § 3732(a) because it transacts business in the Northern District of Georgia. The United States' claims against PMAC under Georgia law arise from the same transaction or occurrence as its claims under 31 U.S.C. § 3729, et seq. Additionally, PMAC is a Georgia corporation.

38. Venue is proper in the Northern District of Georgia pursuant to 28 U.S.C. §§ 1391(b) and 31 U.S.C. § 3732(a) because Defendants reside and/or transact business in this district, and because they have committed acts proscribed by 31 U.S.C. 3729 in this district.

**THE FALSE CLAIMS ACT**

39. The False Claims Act (FCA), 31 U.S.C. §§ 3729, *et seq.* provides in pertinent part that any person who:

- knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or]
- knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim . . .

is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment

Act of 1990 . . . , plus 3 times the amount of damages which the Government sustains because of the act of that person.

(31 U.S.C. § 3729(a)(1). *See also* 28 C.F.R. § 85.3(a)(9)).

40. The FCA was amended pursuant to Public Law 111-21, the Fraud Enforcement and Recovery Act of 2009 ("FERA"), enacted May 20, 2009. Section 3729(a)(1) of the prior statute applies to conduct that occurred before FERA was enacted, and Section 3729(a)(1)(A) of the revised statute applies to conduct after FERA was enacted. Section 3729(a)(1)(B) is applicable to all claims in this case by virtue of Section 4(f) of FERA.

41. For violations occurring prior to May 20, 2009, the False Claims Act provided in pertinent part that a person is liable to the United States government for each instance in which the person "knowingly presents, or causes to be presented, to an officer or employee of the United States government . . . [a] false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1) (1986).

42. As amended in 2009, the False Claims Act extends liability, both before and after its amendments, to any person who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(B) (2009).

43. The False Claims Act defines the terms "knowing" and "knowingly" to mean that a person, with respect to information: (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information. 31 U.S.C. § 3729(b) (1986); 31 U.S.C. § 3729(b)(1)(A) (2009). The False Claims Act further provides that no proof of

specific intent to defraud is required. 31 U.S.C. § 3729(b) (1986); 31 U.S.C. § 3729(b)(1)(B) (2009).

**THE MEDICARE PROGRAM**

44. In 1965, Congress enacted the Health Insurance for the Aged and Disabled Act, 42 U.S.C. § 1395 *et seq.*, known as the Medicare Program, to pay the costs of certain health care services. A person's entitlement to Medicare is based on age, disability, or affliction with end-stage renal disease. *See* 42 U.S.C. §§ 426, 426-1.

45. The Medicare Program is administered through the U.S. Department of Health & Human Services (HHS), and HHS has delegated direct responsibility for administration of the Medicare Program to the Centers for Medicare and Medicaid Services (CMS).

46. While the Medicare program has several parts (*see*, 42 U.S.C. §§ 1395c–1395i), the allegations herein concern claims submitted by Defendants under Medicare Part B ("Supplementary Medical Insurance for the Aged and Disabled"), which generally covers, *inter alia*, those drugs that are provided incident to a physician's service and cannot usually be self-administered. *See* 42 U.S.C. § 1395k; 42 C.F.R. §§ 410.26, 414.701, 410.10.

47. To assist in the administration of Medicare Part B, CMS initially contracted with "carriers." 42 U.S.C. § 1395u. Carriers, typically private insurance companies, were responsible for processing and paying Part B claims. 42 C.F.R. §§ 421.1–421.3.

48. Beginning in November 2006, Medicare Administrative Contractors (MACs) began replacing carriers and fiscal intermediaries. *See* 42 U.S.C. § 1395kk-1; 42 C.F.R. §

421.400 *et seq.*; 71 F.R. 67960-01, at 68181 (Nov. 24, 2006). MACs generally act on behalf of CMS to process and pay Part B claims and perform administrative functions on a regional level.

49. The Part B MAC for the region that encompassed Georgia between 2009 and 2017 was Cahaba Government Benefit Administrators, LLC (Cahaba).

50. To participate in the Medicare program as a new enrollee, independent clinical laboratories, group practices, and individual providers must submit a Medicare Enrollment Application, CMS Form-855I. These entities must also complete Form CMS-855I to change information or to reactivate, revalidate, and/or terminate Medicare enrollment.[5]

51. CMS Form 855I requires, among other things, signatories to certify:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to me or to the organization listed in Section 4(A) of this application . . . . I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier's compliance with all applicable conditions of participation in Medicare.
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> * * *
>
> I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and I will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity.

[5] Presently, this form may be known as a Form CMS-855B.

52. Additionally, an authorized official must sign the "Certification Section" in Section 15 of Form CMS-855I, which legally and financially binds the signer to all of the laws, regulations, and program instructions of the Medicare program.

53. On June 16, 2008, Dr. Burkich signed the certification statement in Section 15 of Form CMS-855I, indicating that, *inter-alia*, he understood that he and his practice were required to comply with all Medicare laws, regulations, and program instructions.

54. A Medicare provider submits a reimbursement claim for the services provided on a CMS 1500 form ("CMS 1500") or its electronic equivalent known as the "837P Form." Among the information the provider or supplier includes on a CMS 1500 or 837P Form are certain five-digit codes, Current Procedural Terminology Codes ("CPT Codes") and/or Healthcare Common Procedure Coding System Level II Codes ("HCPCS Codes") (collectively, "Procedure Codes") – to indicate to CMS the specific services rendered for which the provider is seeking reimbursement.

55. In addition to Procedure Codes, providers are also required to include a diagnosis code with each claim, which describes the diagnosis or medical condition associated with a particular provider claim to Medicare. *See* 42 C.F.R. § 424.32.

56. For instance, the ICD-9 Code "9840-Toxic Effect Inorganic Lead Compound" denotes a diagnosis of lead poisoning.

57. During the relevant time period, Medicare providers were required to use the diagnostic codes ("ICD-9 Codes") set forth in *International Classification of Diseases, Ninth Revision*.[6]

58. The Medicare statute requires that each request for payment or bill submitted for an item or service payable under Medicare Part B include the name and unique physician identification number for the rendering and referring physicians. 42 U.S.C. § 13951(q)(1).

59. The National Provider Identifier ("NPI") is a standard and unique health identifier for health care providers. All providers and practitioners must have an assigned NPI number prior to enrolling in Medicare.

60. Dr. Burkich's NPI number is 1811936891. PMAC's NPI numbers are 1114459096, 1326307513, 1710142955, 1972541670, 1255879755.

61. When submitting claims to Medicare, providers certify *inter alia*, that (a) the services rendered are "medically indicated and necessary for the health of the patient;" (b) the information on the claim form is "true, accurate and complete;" and (c) the provider understands that "payment and satisfaction of this claim will be from Federal and State funds, and that any false claims, statements, or documents, or concealment of a material fact, may be prosecuted under applicable Federal and State laws."

62. Healthcare providers are prohibited from knowingly presenting or causing to be presented claims that represent a pattern of items or services that the person knew or

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[6] ICD-9 codes are promulgated, revised, maintained and published by the World Health Organization.

should have known were not medically necessary, or knew or should have known were false or fraudulent. 42 U.S.C 1320a-7a(a)(1); 1320a-7(b)(7) (permitting exclusion of providers for the foregoing violations).

63. Medicare only covers items and services that are "reasonable and necessary for the diagnosis or treatment of illness or injury." Items and services that are not reasonable and necessary are excluded from coverage under Medicare. *See* 42 U.S.C. § 1395y(a)(1)(A).

64. Additionally, CMS Medicare Program Integrity Manual, Chapter 3, Section 3.6.2.2, states that items are "reasonable and necessary" and thus covered by Medicare if, *inter alia*, they are "not experimental or investigational."

65. Moreover, the CMS Medicare Program Integrity Manual explains that a particular procedure may be reasonable and necessary – and therefore potentially reimbursable – ***if*** it is furnished in accordance with accepted standards of medical practice for the diagnosis and treatment of the particular medical condition.

66. On June 16, 2008, Dr. Burkich signed the certification statement in Section 15 of Form CMS-855I, and thereby agreed to adhere to, "…Medicare laws, regulations and program instructions[,]" which include, but are not limited to, CMS Medicare Program Integrity Manual, Chapter 3, Section 3.6.2.2.

67. Medicare provides for drug coverage only where the use of a drug has been shown to be safe and effective and is otherwise reasonable and necessary. 41 U.S.C. § 1395y(a)(1)(A).

68. Drugs approved for marketing by the FDA are considered safe and effective when used for the indications specified on the labeling.

69. Medicare may cover a drug for a use that is not included as in indication on the drug's label as approved by the FDA if the MAC determines the use to be medically accepted, taking in consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice. *See* Medicare Benefit Policy Manual, Chapter 15, § 50.4.2.

70. Cahaba did not issue any local coverage determinations regarding EDTA that were in effect during the relevant time period. Moreover, Cahaba never determined that EDTA for non-indicated uses was medically accepted.

71. Because it is not feasible for Medicare personnel to review every patient's medical records for the millions of claims for payments they receive from providers, the program relies on providers to comply with Medicare requirements and trusts providers to submit truthful and accurate certifications and claims.

72. Hence, once a provider submits CMS Form 1500 or 837P Form to Medicare, the claim is paid directly to the provider without any review of supporting documentation, including medical records.

73. As several courts have recognized, "Medicare operates on an honor system," *U.S. v. Adebimpe*, 819 F.3d 1212, 1215-1216 (9th Cir. 2016), whereby any audits of provider claims typically occur *after* payments have been made to them. *See, e.g.*, *Popkin v. M. Burwell*, 172 F. Supp.3d 161, 166, (D.D.C. 2016).

## FACTUAL ALLEGATIONS

### CHELATION AND HEAVY METAL POISONING

74. Chelation is a treatment for an uncommon condition called heavy metal poisoning (HMP), which is the accumulation of heavy metals, in toxic amounts, in the soft tissues of the body.[7] The heavy metals most commonly associated with the poisoning of humans are lead, mercury and cadmium. If heavy metals accumulate in the body in concentrations sufficient to cause poisoning, serious damage may occur.

75. Lead is the heavy metal that humans are most commonly exposed to, and lead poisoning is the most commonly diagnosed form of HMP. Lead encephalopathy is a disease that affects the function and structure of the brain, and is a condition caused by acute lead poisoning.

76. The bulk (*e.g.*, $2.8 million) of the approximately $3.1 million in chelation reimbursements that Defendants obtained from the Government were related to claims that Defendants submitted (or caused to be submitted) to Medicare between 2009 and 2017 that contained ICD-9 Diagnoses Codes associated with HMP or lead poisoning.[8]

77. In the majority of cases, the only treatment for HMP is the removal of the patient from the source of exposure to heavy metal. However, in a sufficiently acute case, as largely determined by the amount of a heavy metal identified in a patient's body by a reliable laboratory test (e.g., a blood test), chelation therapy may be indicated.

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[7] HMP is especially rare amongst the elderly.

[8] A small subset of the reimbursements arose from claims containing ICD-9 Diagnosis Codes associated with conditions other than HMP, such as insomnia, shortness of breath, hypertension.

78. Chelation therapy involves providing a patient (orally, intravenously or through injections) with a "chelating agent," which binds itself to the metals in the bloodstream, where it is then excreted from the body *via* urine, thereby reducing levels of heavy metal.

79. There are a number of chelating agents available, such as Dimercaprol (BAL), Succimer (DMSA), and edetate calcium disodium (EDTA), which is the chelating agent utilized by Dr. Burkich.

80. In terms of potential hazards and side effects, according to the American College of Medical Toxicology (ACMT), "…chelating drugs may have significant side effects, including dehydration, hypocalcemia, kidney injury, liver enzyme elevations, hypotension allergic reactions and essential mineral deficiencies. Inappropriate chelation…risk these harms, as well as neurodevelopmental toxicity, teratogenicity and death." [9]

81. Indeed, EDTA has a black box warning indicating that it "is capable of producing toxic effects which can be fatal." Moreover, the manufacturer indicates that EDTA's adverse side effects include fever, chills, malaise, fatigue, myalgia, arthralgia, hypotension, cardiac rhythm irregularities, acute necrosis of proximal tubules (which

[9] The American College of Medical Toxicology is a professional, nonprofit association of physicians with recognized expertise in medical toxicology, which is a field of medicine dedicated to the evaluation and treatment of poisoned patients. This also includes adverse health effects of medications, occupational and environmental toxins, and biological agents. Medical Toxicology is an officially recognized subspecialty by the ABMS.

may result in fatal nephrosis), nausea, vomiting, hypercalcemia, tremors, headaches, numbness and others.

**EDTA IS ONLY INDICATED FOR LEAD POISONING AND LEAD ENCEPHALOPATHY.**

82. The clear medical consensus is that chelation is a medical treatment that is only indicated for clinically confirmed cases of HMP.

83. Moreover, in the package insert for EDTA, which is the chelating agent employed by Dr. Burkich for his Medicare patients, the manufacturer explicitly references the FDA's determination that EDTA is only: "…indicated for the reduction of blood levels and depot stores of lead in lead poisoning (acute and chronic) and lead encephalopathy."

84. Hence, EDTA, the specific chelating agent principally utilized by Dr. Burkich, is only indicated for lead poisoning and lead encephalopathy.

85. Nevertheless, Dr. Burkich did not administer EDTA as a treatment to patients suffering from clinically confirmed cases of lead poisoning or lead encephalopathy.

86. Instead, Dr. Burkich administered EDTA as an experimental treatment for a myriad of conditions *other* that lead poisoning, which include, but is not limited to, insomnia, hypertension and decreased libido.

**THE STANDARD OF CARE FOR DIAGNOSING HMP/LEAD POISONING**

***A Thorough Differential Diagnosis Is Necessary As There Are Few Dispositive Symptoms of HMP/Lead Poisoning.***

87. There are few dispositive symptoms that a patient is suffering from a form of HMP, such as lead poisoning. For instance, although encephalopathy, foot or wrist drop

and severe abdominal colic are symptoms that are suggestive of severe lead poisoning, very few symptoms – in-and-of-themselves – are dispositive that a patient has lead poisoning.

88. Instead, the majority of lead poisoning symptoms – *e.g.*, headache, nausea, joint pain, muscle pain, fatigue, persistent vomiting, diarrhea and abdominal pain – are commonly associated with a myriad of other ailments.

89. Therefore, a broad medical differential should be performed before concluding that a patient is symptomatic of, and/or actually suffering from lead poisoning, or another form of lead poisoning.

***Recent And Acute Patient Exposure To Heavy Metal Is An Essential Component Of An HMP Diagnosis.***

90. In diagnosing HMP, a critical assessment is whether the patient has experienced a recent and acute exposure to heavy metal. As one article noted, "A history of exposure is the *most critical* aspect of diagnosing heavy metal toxicity."

91. As noted by the Minnesota Department of Health in 2015, "Metal toxicity is rare[,]" and "…does not typically occur in the absence of an *extraordinary* exposure." (emphasis added.)

92. "Even if a clinically significant metal exposure is suspected or possible, the differential diagnosis should remain broad until definitive proof of exposure and toxicity is obtained." *Id.*

93. Patient exposure to heavy metals is largely occupational, and typically occurs in industries such as mining, manufacturing and construction. Indeed, most acute presentations of HMP involve industrial exposure.

***Viable Laboratory Tests Are Necessary To Accurately Diagnose HMP.***

94. Laboratory testing is necessary to diagnose HMP, but is generally only medically necessary where a patient has recently been acutely exposed to heavy metals *and* is symptomatic. [10]

95. In the absence of recent and acute patient exposure to heavy metals, the medical consensus is that diagnostic testing for HMP in response to vague and/or generalized symptoms is not medically necessary.

96. Indeed, the American College of Medical Toxicology (ACMT) has noted that patients should not be screened for heavy metals in the absence of excessive exposure to heavy metals:

> Individuals are constantly being exposed to metals in the environment and often have detectable levels without being poisoned. Indiscriminant testing leads to needless concern[.] Diagnosis of any metal poisoning requires an appropriate exposure history and clinical findings consistent with poisoning by that metal. A patient should only undergo specific metal testing if there is a concern for a specific poisoning based on history and physical findings.

***Blood Tests Are the Most Reliable Indicator of the Amount of Heavy Metal in a Patient's Body.***

97. The medical consensus is that blood tests are the most reliable indicator of whether a toxic amount of heavy metal is present in a patient's body. Hence, in

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[10] In a 2015 bulletin entitled "*Heavy Metal Detection and the Concept of Chelation*," the Minnesota Department of Health states that, "Testing in response to nonspecific symptoms, or testing in the absence of suspected exposure, is of no value."

diagnosing HMP, physicians generally utilize blood tests to assess the amount of heavy metal in a patient's body, and this information largely drives the determination as to whether a patient is suffering from HMP.

98. For example, with respect to suspected lead poisoning, blood tests are utilized to assess the amount of lead within a patient's body, and this metric is known as "BLL," which stands for "blood lead level." [11] As one medical treatise explains:

> The key clinical monitoring test for diagnosing lead toxicity is blood lead level (BLL). Measuring lead in urine, hair or other media is not as accurate or reliable and does not correlate as well with adverse health effects.

***Provoked Urine Tests Are Unreliable, Potentially Dangerous And Should Not Be Utilized In Diagnosing HMP.***

99. With respect to the medical consensus as to diagnosing HMP, blood tests are to be contrasted with "provoked urine tests," which are heavily utilized by practitioners such as Dr. Burkich, who market and administer chelation as an experimental therapy for a variety of conditions. (*See*, ¶¶ 140-146)

100. A provoked urine test is given by administering a chelating agent to a patient, and then collecting a urine sample hours later. Almost *invariably*, the results show the presence of supposedly "heightened" levels of heavy metal, as the chelating agent dislodges heavy metal that is imbedded in the body, which is then excreted in urine.

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[11] Similarly, pursuant to the standard of care, blood tests are utilized to detect levels of other heavy metals such as mercury and cadmium.

101. Provoked urine tests have been repeatedly criticized, and the consensus is that the test is unreliable and potentially dangerous. For instance, on March 30, 2010, ACMT issued the following position statement:

> It is, therefore, the position of the American College of Medical Toxicology that post-challenge urinary metal testing has not been scientifically validated, has no demonstrated benefit, and may be harmful when applied in the assessment and treatment of patients in whom there is concern for metal poisoning.

102. Additionally, ACMT has stated that, "Scientific studies demonstrate that the administration of a chelation agent leads to increased excretion of various metals into the urine, even in healthy individuals without metal related disease. These "provoked" or "challenged" test of urine are not reliable means to diagnose metal poisoning and have been associated with harm."[12]

103. Indeed, on or around January 28, 2011, Dr. Burkich received written notice that the standard of care associated with diagnosing HMP required blood tests, and that urine testing was not appropriate.

104. Moreover, Doctors Data – the firm from whom Defendants ordered provoked urine tests – has admitted that is not appropriate for a physician to use a provoked urine test to tell patients that they have HMP/lead poisoning, and that blood testing is the most appropriate test for lead poisoning.

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[12] Additionally, several private insurers have taken the position that provoked urine testing – as well any HMP diagnosis and/or HMP treatment based upon such testing – is not necessary and/or efficacious and therefore not covered.

**CHELATION IS ONLY INDICATED FOR PATIENTS WITH EXTREMELY HEIGHTENED LEVELS OF HEAVY METAL.**

105. Fundamentally, and as noted by ACMT, "[m]etals are ubiquitous in the environment and all individuals are exposed to and store some quantities of metals in the body. These do not necessarily result in illness."

106. Hence, the medical consensus and standard of care provide that chelation is indicated only where a legitimate laboratory test (*e.g.*, a blood test) – as opposed to a provoked urine test – demonstrates that lead (or another heavy metal) is present in a patient's body at a sufficiently high level.

107. For example, with respect to suspected and confirmed cases of lead poisoning, there are BLL thresholds above which chelation *may* be medically necessary, and below which chelation *is not* medically necessary.

108. While there is some variability as to the precise BLL where chelation is indicated, the consensus is that chelation is only indicated for patients with extremely heightened BLLs.

109. For instance, in a March 2007 article entitled "Recommendations for Medical Management of Adult Lead Exposure" that appeared in a peer reviewed journal published by the National Institute for Health ("NIH"), it was recommended that chelation be considered *only* for adult patients with BLLs greater than 50 mcg/dL and exhibiting significant symptoms or signs of lead toxicity. Absent significant symptoms or signs of lead toxicity, the article recommends chelation only for adults with BLLs equal to (or greater than) 80 mcg/dL.[13]

[13] On some occasions, Dr. Burkich ordered blood tests for patients seeking chelation therapy. The results associated with certain of these blood test *explicitly described the article*

110. Moreover, if a patient's BLL is less than 40 mcg/dL, any symptoms are not likely attributable to lead poisoning, and chelation is therefore neither reasonable nor necessary.[14]

111. For context, the mean BLL in adults in the United States from 2011 to 2012 was only 1.09 mcg/dL, while the medical consensus is that no action whatsoever – *e.g.*, medication, counseling, reduced exposure, *ect*. – is necessary with respect to patients with BLLs less than 5 mcg/dL.

**THE ADMINISTRATION OF CHELATION THERAPY**

112. Once the decision to chelate a patient has been made, a number of chelating agents are available, which include, but are not limited to, Dimercaprol (BAL), Edetate calcium disodium (EDTA) and Succimer (DMSA).

113. BAL is a chelator that is effective in treating lead, arsenic and mercury poisoning, and is administered via deep intramuscular injections.

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*referenced herein* – *i.e.*, "Recommendations for Medical Management of Adult Lead Exposure" – as a source to be consulted in evaluating reported BLLs. Hence, Dr. Burkich received explicit notice that chelation was only indicated for adult patients with BLLs in excess of 50 mcg/DL, but ignored this information, and chelated patients with either no reported BLLs or BLLs less than 2 mcg/dL.

[14] Indeed, with respect to suspected lead poisoning, the medical consensus is that there is no evidence that chelation is beneficial to patients with BLLs of less than 40 mcg/dL:

> If an adult reports clinical symptoms with BLL<40 mcg, the symptoms are not likely attributable to lead poisoning, and other explanations should be sought. There is no evidence that chelation therapy at BLL <40 mcg/dL decreases symptoms or reduces the risk of chronic disease.

114. The most commonly prescribed chelator is DMSA, which is effective in treating lead poisoning, and is administered orally *via* tablets. According to *Goldfranks Toxicological Emergencies*, for mildly symptomatic adults with BLLs between 70 and 100 mcg/dL, DMSA is the recommended chelating agent. [15]

115. Edetate calcium disodium (EDTA) (the chelating agent utilized by Dr. Burkich) is also used to treat lead poisoning, and is administered intravenously, or per the manufacturer, via intramuscular injections. According to *Goldfranks Toxicological Emergencies*, for adult patients with BLLs in excess of 100 mcg/dL, a chelation therapy consisting of BAL and EDTA is recommended.

116. Generally, an oral chelating agent (*e.g.*, DMSA) – as opposed to an intravenous chelating agent (*e.g.*, EDTA) – should be administered. Intravenous chelating agents should be reserved for an incapacitated patient.

117. Finally, chelation therapy should be of limited duration, and should cease when laboratory tests confirm that heavy metals have been reduced to a level where they no longer present an acute health risk to the patient.

**CERTAIN PRACTITIONERS MARKET CHELATION AS AN EXPERIMENTAL TREATMENT FOR A HOST OF CONDITIONS OTHER THAN HMP.**

118. Although the medical consensus is that chelation is generally only indicated for HMP (*e.g.*, lead poisoning), certain practitioners (including Dr. Burkich) of "alternative" and/or "integrative" medicine market and administer chelation as a

[15] *Goldfranks Toxicological Emergencies* is an authoritative source with respect to diagnosing and treating poisoning (including, but not limited to, lead poisoning).

treatment for a variety of ills and conditions, which include, but are not limited to: (1) circulation problems, (2) heart disease, (3) autism, (4) fatigue, and (5) premature aging.

119. Whereas the medical consensus is that chelation is only possibly indicated for patients with extremely high levels of heavy metals (*e.g.* BLLs in excess of 50 mcg/dL (symptomatic patient) or 80 mcg/dL (asymptomatic patient), certain practitioners of "alternative" and/or "integrative" medicine espouse the view that even low levels of heavy metals cause harm, and that therefore chelation is a medically appropriate treatment for patients with relatively low levels of heavy metals.

120. A 2013 editorial entitled "Use and Misuse of Metal Chelation Therapy" that appeared in the *Journal of Medical Toxicology* contains the following observations regarding "alternative" chelation therapy:

- Many of these treatments are performed by practitioners with a world view best described as "if it exists and has been described as harmful in some large amount, then getting rid of any amount will make you better."

- [T]he prevalence of fraudulent testing and misdiagnosis is of great concern to the American College of Medical Toxicology (ACMT) and public health entities.

- Some practitioners who provide post-provocation testing and chelation therapy for the erroneous diagnosis of chronic metal poisoning may just be ignorant[.] Others derive significant profit from the practice.

**MEDICARE DOES NOT COVER ALTERNATIVE OR EXPERIMENTAL EDTA CHELATION THERAPY.**

121. Medicare provides for drug coverage only where the use of a drug has been shown to be safe and effective and is otherwise reasonable and necessary. 41 U.S.C. § 1395y(a)(1)(A).

122. In sworn testimony in 2017, Dr. Burkich acknowledged that Medicare only reimburses for services that are medically appropriate, but offered that "there's a lot of wiggle room with the word 'medically appropriate'."

123. Drugs approved for marketing by the FDA are considered safe and effective when used for indications specified on the labeling.

124. Medicare may cover a drug for a use that is not included as an indication on the drug's label as approved by the FDA if the MAC determines the use to be medically accepted, taking in consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice. *See* Medicare Benefit Policy Manual, Chapter 15, § 50.4.2.

125. Cahaba did not issue any local coverage determinations regarding EDTA that were in effect during the relevant time period. Moreover, Cahaba never determined that EDTA for non-indicated uses was medically accepted.

126. The only indicated uses on the FDA approved label for EDTA are for the reduction of blood levels and depot stores of lead in lead poisoning (acute and chronic) and lead encephalopathy, in both pediatric populations and adults.

127. Moreover, in 2003 – well in advance of the conduct complained of herein – CMS published a National Coverage Determination ("NCD") informing the public and program participants that Medicare does not cover chelation when used as an experimental treatment. Medicare National Coverage Determinations Manual, § 20.22.

128. Specifically, NCD 20.22 provides that, "the use of EDTA as a chelating agent to treat atherosclerosis, arteriosclerosis, calcinosis, *or similar generalized conditions not listed*

*by the FDA as an approved use is not covered. Any such use of EDTA is considered experimental.* (emphasis added.)

129. Therefore, Medicare only covers the use of EDTA for lead poisoning or lead encephalopathy.

130. NCD 20.22 was promulgated in 2003, was in effect throughout the time period in which Defendants submitted the false claims alleged herein (*i.e.*, between 2009 and 2017), and currently remains in effect.

131. Throughout the relevant time period, Dr. Burkich signed certifications (that he then forwarded to CMS) wherein he "agreed to abide by the Medicare laws, regulations and program instructions[,]" and represented that he would not "…submit claims with deliberate ignorance or reckless disregard of their truth or falsity."

132. Hence, between 2009 and 2017, Defendants had "knowledge" under the FCA that Medicare only covers the use of EDTA for lead poisoning or lead encephalopathy, and did not cover experimental uses of EDTA, or the use of EDTA as a treatment for any condition other than lead poisoning or lead encephalopathy.

133. Indeed, on January 28, 2011 and October 11, 2013, Dr. Burkich was provided materials indicating that his EDTA therapy constituted an experimental – and thus non-reimbursable – use of EDTA. These materials explicitly referenced NCD 20.22, and its coverage exclusion for uses of EDTA as a treatment for all conditions other than lead poisoning or lead encephalopathy.

**PRIVATE INSURERS DO NOT COVER EXPERIMENTAL EDTA CHELATION THERAPY.**

134. Similarly, several large private insurers have found "alternative" uses of chelation therapy to be medically unnecessary and/or non-efficacious, and therefore not covered by insurance.

135. For instance, while Aetna considers chelation medically necessary to treat "heavy metal poisoning[,]" its position is that chelation with respect to other conditions (*e.g.*, cancer, heart disease, autism, Alzheimer's) is not covered, as "[t]he safety and effectiveness of this treatment for these indications has not been established."

136. Additionally, Blue Cross Blue Shield has also issued several policy statements regarding chelation, including one for North Carolina, which includes the following exclusions under a heading entitled "**When Chelation Therapy is not covered**":

> Chelation therapy is considered investigational, including, but not limited to, the following conditions:
>
> - Heavy metal toxicity or iron or lead poisoning where toxic levels are not documented by standard testing methods.
> - Atherosclerosis (e.g., coronary artery disease, peripheral vascular disease, secondary prevention in patients with myocardial infarction)
> - Other indications ***not*** listed under "when chelation therapy ***is*** covered"

137. Similarly, WellCare explains that "chelation therapy is considered medically necessary" for HMP when "…confirmed by appropriate laboratory results and clinical findings consistent with toxicity," but cautions that chelation "is considered

experimental and investigational" – and hence not covered, with respect to a variety of conditions – *e.g.* vascular and/or artery disease, fatigue and arthritis.

138. Indeed, on October 11, 2013, Dr. Burkich was forwarded a United Healthcare bulletin entitled "*Chelation Therapy for Non-Overload Conditions*," wherein the insurer asserted that chelation constituted an "unproven" and uncovered therapy when utilized as a treatment for the *very* conditions for which Dr. Burkich had publicly touted EDTA as an "effective" treatment.

139. This October 11, 2013 bulletin also explicitly referenced NCD 20.22, which explicitly excludes EDTA from Medicare coverage when administered as a treatment for any condition other than lead poisoning or lead encephalopathy.

**DR. BURKICH ADMINISTERED EDTA CHELATION TO MEDICARE PATIENTS AS AN EXPERIMENTAL TREATMENT FOR A MYRIAD OF CONDITIONS OTHER THAN LEAD POISONING.**

140. Dr. Burkich is a self-described practitioner of integrative medicine, and has actively touted and administered chelation as an "alternative" or "integrative" treatment for a myriad of conditions.

141. In approximately 2000, Dr. Burkich moved his practice from Tennessee to Georgia based upon his belief that Georgia had more liberal standards concerning what type of treatments he could provide to potential patients.

142. Indeed, in 2017, Dr. Burkich testified that his understanding was that Tennessee only allowed chelation therapy to be rendered as a treatment to patients suffering from HMP.

143. In testimony, Dr. Burkich admitted that he desired the "freedom" to provide chelation for experimental uses, such as treating "atherosclerosis" and "coronary artery disease." [16]

144. Therefore, in approximately 2000, Dr. Burkich moved his practice from Tennessee to Georgia so that he could offer EDTA chelation as an experimental therapy.

145. On their internet web-page "Preventative Medicine Anti-Aging and Chelation Therapy," Defendants asserted that "…humans…do not have the mechanisms to efficiently remove heavy metals from our bodies. This can make us prone to *many illnesses*. In summary, *treatment by chelation therapy creates a cleaner environment for your body to fix itself*." (emphasis added.)

146. Indeed, although the FDA has determined that EDTA is only indicated for lead poisoning, in his publication, "*Preventative Medicine – Guide to Staying Healthy*," Dr. Burkich publicly states that, "EDTA chelation therapy is *effective for many conditions*, including[:]"

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[16] As early as July 2000, Tennessee enacted laws, regulations and/or position statements that provide that, "…the advertising of EDTA's administration in any matter to prevent or cure diseases or medical conditions other than laboratory documented heavy metal poisoning/intoxication/toxicity, without support of the scientific literature contained within the National Library of Medicine or certainly much more than anecdotal evidence of its effective use in the treatment of a disease or medical condition for which a licensee advertises it may be considered to be a violation of T.C.A. 63-9-111 (b) (3), and (9) and/or the rules promulgated pursuant thereto."

| | | | |
|---|---|---|---|
| • Diabetic ulcers | • Cancer | • AIDs | • Paralysis |
| • Heart disease | • Senility | • Schizophrenia | • Osteoporosis |
| • Chronic fatigue | • Hypertension | • Memory loss | • Varicose veins |
| • Lupos | • Parkinson's | • Osteoarthritis | • Alzheimers |
| • Gallbladder Stones | • Multiple sclerosis | • Lou Gehrig's Disease | • Cardiac arrhythmias |

(emphasis added.)

147. Hence, in leaving Tennessee for Georgia, Dr. Burkich – by his own admission – sought to treat patients that came to him seeking EDTA chelation as an experimental treatment for coronary artery disease, as well as several of the conditions identified immediately above in ¶ 147.

148. Despite the fact that NCD 20.22 provides that the use of EDTA as a treatment for atherosclerosis and/or arteriosclerosis (*as well as other similar generalized conditions*) is excluded from Medicare coverage, Dr. Burkich nevertheless touted and administered EDTA chelation to Medicare beneficiaries for experimental treatment for conditions such as those listed above in ¶ 147.

**DR. BURKICH'S PRACTICES ARE CONTRARY TO THE MEDICAL CONSENSUS AND STANDARD OF CARE APPLICABLE TO LEAD POISONING AND OTHER TYPES OF HMP.**

149. Medicare provides that a particular medical procedure may be reasonable and necessary – and therefore potentially reimbursable under Medicare – *if* it is furnished in accordance with accepted standards of medical practice for the diagnosis and treatment of the particular medical condition.

150. While the bulk (*e.g.*, approximately $2.8 of the $3.1 million) of the reimbursements at issue arise from claims wherein Defendants utilized diagnostic codes associated with HMP/lead poisoning, (1) the patients did not have HMP/lead poisoning, and (2) Dr. Burkich was – in truth – utilizing EDTA as an experimental treatment for a variety of conditions *other* than HMP.

151. Indeed, the fact that Dr. Burkich was not administering EDTA as a treatment for HMP/lead poisoning is evidenced by the fact that his EDTA chelation practices were well outside the medical consensus and standard of care related to diagnosing and treating HMP/lead poisoning.

***Prior To Chelating Patients, Dr. Burkich Failed To Perform a Differential Diagnosis.***

152. Prior to chelating patients, Dr. Burkich routinely failed to conduct a viable differential diagnosis. Because few symptoms are strongly indicative of HMP, and most HMP symptoms are associated with other ailments, a broad differential diagnosis should be performed prior to concluding that a patient is symptomatic of, and/or actually suffering from, HMP.

153. Rather than perform a viable differential, Dr. Burkich, in contravention of the medical consensus associated with diagnosing HMP, simply deemed essentially "*any* symptom" as suggestive and/or indicative of HMP.

154. Indeed, in his 2017 testimony, when asked to identify what symptoms were indicative of HMP and/or exposure to heavy metals, Dr. Burkich responded, "[i]t can be *almost any symptom that you could imagine*. It can be fatigue, it can be *any* symptom." (emphasis added.)

155. Dr. Burkich's failure to perform viable differential diagnoses prior to chelating patients is consistent with the fact the patients he chelated generally affirmatively sought him out, wanting to try EDTA chelation as an experimental treatment for several of the conditions for which Dr. Burkich touts EDTA as an effective treatment.

***Dr. Burkich Chelated Patients With No Viable History of Exposure to Potentially Dangerous Heavy Metals, Such As Lead.***

156. As noted above, testing a patient for heavy metals, rendering an HMP diagnosis and chelating a patient, are all actions that are generally unwarranted absent the patient having been recently and acutely exposed to a heavy metal, such as lead.

157. Nevertheless, Dr. Burkich routinely "tested" patients for heavy metal, "diagnosed" such patients with HMP, and then chelated such patients (ostensibly to treat HMP), despite the fact that such patients – as evidenced by the medical records – had *not* been recently or acutely exposed to heavy metals and did not have high concentrations of heavy metals in their blood.

158. Dr. Burkich sidestepped the essential "exposure" component of a valid HMP differential diagnosis with his convenient supposition that *everyone* has been exposed to lead and other heavy metals.

159. In explaining his opinion that everyone has had sufficient exposure to heavy metals to warrant heavy metal testing and possible chelation therapy, Dr. Burkich noted that heavy metals were present in everyday products such as "hair dye," "makeup," and other "cosmetics."

160. According to Dr. Burkich, even if a patient did not use such products, they still have likely been exposed to heavy metals as result of their interaction with – *e.g.*, through the use of door knobs – individuals that have used such products.

161. Indeed, in 2017, Dr. Burkich testified that, "I think that if you've been around other people, then there's a good chance you've been exposed to heavy metals."

162. Although HMP is a rare condition, pursuant to Dr. Burkich's dubious "exposure" reasoning, essentially everyone has been "exposed" to heavy metals, and were thus conceivable candidates for Dr. Burkich's experimental EDTA chelation therapy.

163. Indeed, Dr. Burkich stated that, "[j]ust about anyone who is breathing and possesses a pulse[]" is a candidate for chelation therapy.

***Dr. Burkich Chelated Patients On The Basis Of Discredited And Unreliable Provoked Urine Tests.***

164. As noted above, the medical consensus and/or standard of care is that blood tests are generally the most accurate and reliable means of assessing the amount of lead and other heavy metals in a patient's body. Hence, a blood test is an essential component of a valid HMP differential and/or diagnosis, as well as viable decision to administer EDTA chelation therapy.

165. Nevertheless, in administering EDTA chelation therapy to patients, Dr. Burkich routinely did not order – and/or ignored the results of – blood tests, and instead utilized and relied upon provoked urine tests (and the "results" associated with such tests) to convince patients that they had "elevated" levels of heavy metal, which could be reduced by EDTA chelation, thereby alleviating a myriad of health conditions.

166. In utilizing provoked urine tests, Dr. Burkich ignored the clear medical consensus that such tests are unreliable, potentially dangerous, and should therefore not be used to advise a patient that either heavy metal testing or chelation is warranted.

167. Moreover, in his 2017 testimony, Dr. Burkich admitted that he based his HMP diagnoses primarily on the *graphical illustrations* – as opposed to the numerical and/or textual disclosures and narratives – contained in the reports associated with the provoked urine tests.

168. However, Doctors Data cautioned that (1) physicians should not rely upon such graphical illustrations in diagnosing HMP, (2) HMP diagnoses should not be primarily based on provoked urine test results, and that (3) blood testing is the most reliable test for lead poisoning.

169. Furthermore, Dr. Burkich ignored warnings from his own employees that his use of provoked urine tests was improper. For instance, in January 2011, a medical billing service retained by Defendants informed Dr. Burkich that blood, hair or stool laboratory test – not urine tests – needed to be utilized in connection with patients seeking IV therapies.

***In Contravention Of The Standard Of Care, Dr. Burkich Chelates Patients For As Long As The Patient Wants, Without Reference To Lab Results.***

170. Whereas the standard of care associated with lead poisoning provides that chelation therapy should be of a prescribed and limited duration, and tied to a patient's laboratory confirmed BLLs, Dr. Burkich testified that he was unaware of any restrictions on how long a patient should be chelated.

171. Additionally, Dr. Burkich minimized the importance of lab results when determining how long to treat a patient: "There's an expression you don't treat the labs, you treat the patient."

172. Hence, without reference to the concentration of metals present, Dr. Burkich administered EDTA to individual patients on *scores* of different occasions, as he was willing to provide the therapy as long as the patient reported that he/she kept feeling better.

173. For instance, Dr. Burkich chelated a 64 year old Medicare beneficiary with the initials "L.A." 83 times between June 21, 2010 and August 15, 2014.

174. Indeed, the medical records reveal that Dr. Burkich chelated certain patients 286, 207 and 188 times.

175. Between September 3, 2009 and July 14, 2016, Dr. Burkich chelated a 69 year old Medicare beneficiary with the initials "J.H." 286 times.

176. Additionally, between July 19, 2011 and June 30, 2016, Dr. Burkich chelated a 79 year old Medicare beneficiary with the initials "L.B." 188 times.

177. Finally, between March 4, 2013 and July 1, 2016, Dr. Burkich chelated a 74 year old patient with the initials "J.S." 207 times.

178. The EDTA treatments associated with the aforementioned patients were not medically necessary, as the medical records indicate that they were not suffering from lead poisoning, or any other form of HMP.

**DR. BURKICH VIOLATED THE FCA BY FALSELY CLAIMING $3.1 MILLION IN REIMBURSEMENTS FOR EXPERIMENTAL AND MEDICALLY UNECESSARY CHELATION THERAPY**.

179. Between 2009 and 2017, Dr. Burkich knowingly submitted false claims to Medicare for medically unnecessary and non-covered experimental EDTA chelation therapy.

180. Although EDTA is only indicated for lead poisoning, *for years*, Dr. Burkich touted and administered EDTA chelation as an experimental treatment for wide variety of other conditions.

181. Dr. Burkich had knowledge under the FCA that such experimental EDTA chelation therapy was not reimbursable under Medicare, which only covers EDTA when used to treat lead poisoning.

182. Additionally, Dr. Burkich had knowledge under the FCA that EDTA chelation is only indicated for patients that present with significantly heightened BLLs (*e.g.*, in excess of 50 mcg/dL (symptomatic patient) or 80 mcg/dL (asymptomatic patient)).

183. The bulk of chelation reimbursements ($2.8 million out of $3.1 million) that Dr. Burkich obtained from the Government between 2009 and 2017 arose from claims wherein Dr. Burkich falsely described his experimental EDTA treatments as medically necessary treatments that were provided to patients diagnosed with (and suffering from) HMP/lead poisoning.

184. Specifically, through the use of ICD-9 diagnostic codes associated with lead poisoning and other forms of HMP – (*e.g.*, 9848 – Toxic Effects Other Lead Compounds NEC), Defendants fraudulently certified to the Government that its EDTA chelation

claims were associated with chelation therapy that was medically necessary to treat patients suffering from HMP/lead poisoning.

185. In truth, despite the HMP diagnosis codes employed, Defendants' claims were not associated with patients suffering from HMP/lead poisoning.

186. Indeed, the medical records associated with the patients chelated by Defendants contained no evidence of exposure to toxic amounts of heavy metals, and lacked any credible evidence that the patients had levels of heavy metal levels high enough to warrant chelation.

187. For instance, although Dr. Burkich submitted claims that included ICD-9 Codes associated with lead poisoning, the patient medical records associated with such claims reflect (1) no viable exposure to lead, and (2) no evidence of BLLs high enough (*e.g.* in excess of 50 mcg/dL) to warrant chelation.

188. In reality, and irrespective of their use of ICD-9 diagnostic codes associated with lead poisoning, the EDTA claims that Defendants submitted to the Government were associated with Defendants' experimental use of EDTA as a treatment for a myriad of conditions *other* than lead poisoning or lead encephalopathy – *e.g.* hypertension, sinusitis and anemia, and Defendants had FCA "knowledge" the use of EDTA treat such conditions was not reimbursable under the Medicare program.

189. Indeed, with respect to a small subset of the reimbursements they received from the Government (approximately $365,000 of the $3.1 million), Defendants submitted EDTA claims with diagnostic codes associated with a variety of conditions *other* than lead poisoning or lead encephalopathy, such as hypertension, sinusitis and anemia.

190. Defendants had FCA "knowledge" that the use of EDTA to treat such conditions was not reimbursable under the Medicare program.

191. Thus, the approximately 8210 chelation claims that Defendants submitted to the Government between 2009 and 2017 were false under the FCA due, *inter-alia*, to the omission of some or all of the following information:

a. Contrary to the ICD-9 codes related to HMP/lead poisoning included with most the claims, the EDTA therapy associated with the claims was not administered to treat HMP/lead poisoning.

b. The EDTA treatments were not medically necessary as the patients chelated did not suffer from HMP, and chelation is not efficacious in treating any other condition.

c. The chelation claims were associated with EDTA therapy administered as an experimental treatment for a myriad of conditions, such as heart disease, fatigue, poor circulation and sexual dysfunction, which are excluded from Medicare coverage by NCD 20.22.

d. The claims involved EDTA that was administered as a treatment for conditions *other* than lead poisoning and lead encephalopathy, which are the *only* two conditions for which the FDA has approved EDTA as a treatment.

***Dr. Burkich Knowingly Submitted Chelation Claims That Were False Due To The Erroneous Contention Than He Was Chelating Patients To Treat Lead Poisoning And/Or Other Types of HMP.***

192. Dr. Burkich filed claims that falsely indicated that reimbursement was sought for chelation treatments provided to patients suffering from lead poisoning or another form of HMP, when in truth, the patients were not suffering from HMP/lead poisoning, and Dr. Burkich had administered EDTA as an experimental treatment for a myriad of conditions – *e.g.*, poor circulation, heart disease, fatigue – other than HMP/lead poisoning.

193. Specifically, through the use of ICD-9 Codes associated with HMP/lead poisoning – *e.g.* 9612- Poisoning By Heavy Metal Anti-Infectives, 9848-Toxic Effects Other Lead Compounds and 9849-Toxic Effects Lead Compound NOS – Dr. Burkich repeatedly represented in claims submitted to the Government that he was seeking reimbursement for EDTA chelation treatments provided to patients suffering from HMP/lead poisoning.

194. These statements to Medicare were false under the FCA, as Dr. Burkich was *not* treating Medicare beneficiaries for HMP/lead poisoning as the ICD-9 Codes he employed indicated, but was in truth chelating patients as an experimental remedy for a myriad of different conditions, such as fatigue, anti-aging, and circulation problems.

195. Indeed, by his own admission, Dr. Burkich left Tennessee for Georgia based upon his belief that Tennessee limited the use of EDTA chelation to patients suffering from HMP/lead poisoning, whereas in Georgia, he would be free to administer EDTA as an experimental therapy for multiple conditions other than HMP.

196. As an example, on July 10, 2013, Dr. Burkich submitted a $582.25 claim for reimbursement to Medicare – which was paid on July 13, 2013 – for chelation therapy that

the medical records reflect that he provided to a 74 year old Medicare beneficiary with the initials "J.S." (Patient J.S.) on July 1, 2013. [17] In submitting the claim, Dr. Burkich utilized the HCPCS code for EDTA (J0600) (as well as various additional CPT and HCPCS codes associated the intravenous administration of the EDTA)[18] and the ICD-9 Code 9848 – "Toxic Effects Lead Compounds NEC."

a. This claim was false and/or misleading as, *inter-alia*, the ICD-9 Code associated with the claim (9848 – Toxic Effects Lead Compounds NEC) represents that the patient was chelated with EDTA to treat lead poisoning, when in truth, the patient was not suffering from lead poisoning, and EDTA was not otherwise indicated. [19]

i. The medical records do not reflect that Patient J.S. had recently or acutely been exposed to lead, and such exposure is an integral component of a viable lead poisoning diagnosis.

ii. The medical records indicate that no blood test was administered to detect the level of lead in the blood. (Chelation is only possibly indicated for patients with BLLs greater than 50 mcg/dL (symptomatic patient) or 80 mcg/dL (asymptomatic patient). Clinical symptoms in patients with BLLs less than 40 mcg/dL are

[17] Patient J.S. was chelated a total of 207 times from 3/4/2013 through 7/1/2016.

[18] Specifically, Defendants also billed the Government for the following codes: J7040 - Normal Saline Solution, 96365 and 96366 -Injection/Infusion Codes and 99212 (Modifier 25)-Office/ Outpatient Visit, Est.

[19] This claim was also false due to Burkich's over use of billing E&M with Modifier 25.

not likely attributable to lead poisoning. The medical consensus is that no action whatsoever – *e.g.*, medication, counseling, reduced exposure, *ect*. – is necessary with respect to adult patients with BLLs less than 5 mcg/dL.)

iii. Dr. Burkich chelated Patient J.S. at least partly on the basis of the results of an inherently unreliable provoked urine test that was administered on March 5, 2013.

iv. Dr. Burkich failed to conduct a differential diagnosis to determine whether chelation was warranted with respect to Patient J.S.

v. Additionally, Patient J.S. complained of no present symptoms and came in specifically to be chelated. Patient J.S. has a past history of Chronic Obstructive Pulmonary Disease and Diabetes.

197. Had CMS known that, Dr. Burkich's claims sought reimbursement for chelation treatments that were affirmatively described (through the use of ICD-9 Codes associated with HMP/lead poisoning) as having been rendered to treat patients suffering from HMP/lead poisoning, when, in truth, the patients (1) did not suffer from HMP, but were (2) administered EDTA as an experimental treatment for other conditions, such as heart disease, fatigue and sexual dysfunction, it would not have paid the claims.

***Dr. Burkich Knowingly Submitted Claims To Medicare That Were False As They Sought Reimbursement For Experimental Chelation Therapy That Is Excluded From Coverage By NCD 20.22.***

198. Additionally, as Dr. Burkich administers EDTA chelation as an experimental treatment for conditions such as fatigue, and circulation problems" his chelation claims are legally false under the FCA as they seek reimbursement for uses of

EDTA that are excluded from Medicare coverage by CMS's NCD 20.22, pursuant to which experimental chelation therapy is not covered by Medicare.

199. The medical records and Dr. Burkich's own statements – as well as some of the chelation claims he submitted to Medicare – indicate that Dr. Burkich utilized chelation as an experimental therapy for several conditions other than lead poisoning, even though such experimental chelation therapy is specifically excluded from Medicare coverage by NCD 20.22

200. By his own admission, Dr. Burkich left Tennessee for Georgia based upon his belief that Tennessee limited the use of EDTA chelation to patients suffering from HMP/lead poisoning, whereas in Georgia, he would be free to administer EDTA as an experimental therapy for multiple other conditions.

201. Indeed, a small subset of the reimbursements Defendants obtained from the Government (*i.e.*, approximately $365,000 of the $3.1 million) arose from claims wherein Defendants utilized ICD-9 Diagnostic Codes associated with a variety of conditions – e.g., insomnia, hypertension, sinusitis – for which EDTA is not a reimbursable treatment under Medicare.

202. As an example, on July 21, 2015, Dr. Burkich submitted a $657.79 claim for reimbursement to Medicare – which was paid on July 24, 2015 – for chelation therapy that the medical records reflect that he provided to a 73 year old patient with the initials "J.M." (Patient J.M.) on July 20, 2015. [20] In submitting the claim[21], Dr. Burkich utilized the

[20] Patient J.M. was chelated a total of 86 times from 9/5/2013 through 2/29/2016.

[21]This claim was also false due to Burkich's over use of billing E&M with Modifier 25.

HCPCS code for EDTA (J0600) (as well as various additional CPT and HCPCS codes associated the intravenous administration of the EDTA).[22] Additionally, Dr. Burkich utilized the ICD-9 diagnostic code 2572 – "Testicular Hypofunction NEC," thereby indicating that patient J.M. was chelated with EDTA to treat the condition testicular hypofunction, which is associated with low levels of testosterone. This claim is false and/or misleading for the following reasons:

a. Pursuant to NCD 20.22, EDTA therapy is only reimbursable under Medicare when used to treat lead poisoning or lead encephalopathy, and is not reimbursable to treat other generalized conditions, which include, but are not limited to, testicular hypofunction.

b. Because lead poisoning and lead encephalopathy are the only indications listed on EDTA's FDA label, Defendants' use of EDTA as a treatment for testicular hypofunction is not reimbursable under Medicare, pursuant its "off-label" drug rule.

c. As chelation is only efficacious in treating HMP, Dr. Burkich's use of EDTA chelation as a treatment for testicular hypofunction was not medically necessary, irrespective of his certification to the contrary.

203. On January 18, 2012, Dr. Burkich submitted a $239.58 claim for reimbursement to Medicare – which was paid February 15, 2012 – for chelation therapy that the medical records reflect that he provided to a 79 year old Medicare beneficiary

[22] The following codes were also billed to the Government: J7040 - Normal Saline Solution, 96365 and 96366- Injection/Infusion Codes and 99213 (Modifier 25) - Office/ Outpatient Visit, Est.

with the initials "L.B." (Patient L.B.) on January 19, 2012. [23] In submitting the claim, Dr. Burkich utilized the HCPCS code for EDTA (J0600) (as well as various additional CPT and HCPCS codes associated the intravenous administration of the EDTA)[24] and ICD-9 Code 9612 – "Poisoning By Heavy Metal Anti-Infectives."

a. This claim was false as, inter-alia, the ICD-9 Diagnostic code associated with the claim (i.e., 9612 – Poisoning By Heavy Metal Anti-Infectives") falsely indicates that the patient was suffering from HMP. In truth, the patient was not suffering from HMP, but was administered EDTA as an "alternative" or "experimental" treatment of the type espoused by Dr. Burkich, but which is excluded from Medicare coverage by NDC 20.22.

   i. The medical records do not reflect that Patient L.B. had recently or been acutely exposed to HMP, and such exposure is an integral component of a viable HMP diagnosis.

   ii. No blood test was administered to detect the amount of heavy metals in the blood.

   iii. Instead, Dr. Burkich chelated Patient L.B. at least partly upon the results of an inherently unreliable provoked urine test that was administered on June 28, 2011.

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[23] Patient L.B. was chelated a total of 188 times from 7/19/2011 through 06/30/2016.

[24] The following codes were also billed to the Government: J7040- Normal Saline Solution and Dextrose/Water and 96365 and 96366- Injection/Infusion Codes.

iv. Patient L.B. complained of only generalized symptoms - *e.g.,* knee pain, shortness of breath, fatigue, neck pain and various other symptoms – none of which were strongly suggestive of HMP.

v. Dr. Burkich failed to conduct a differential diagnosis to determine whether Patient L.B.'s symptoms were related to a condition other than HMP.

vi. As the medical records demonstrate that Patient L.B. was not suffering from lead poisoning or lead encephalopathy (the only two conditions for which EDTA chelation indicated), Dr. Burkich plainly chelated Patient L.B. to treat a "…generalized condition not listed by the FDA as an approved use[,]" which constitutes an "experimental" use of EDTA that is explicitly excluded from Medicare coverage by NCD 20.22.

204. On March 19, 2012, Charity Moses, a Nurse Practitioner who worked under Dr. Burkich, submitted a $228.37 claim for reimbursement to Medicare – which was paid on April 13, 2012 – for chelation therapy that the medical records reflect that she provided to a 73 year old patient with the initials "W.B." (Patient W.B) on March 9, 2012.[25] In submitting the claim, Defendants utilized HCPCS code J0600 for EDTA (as well as various additional CPT and HCPCS codes associated with the intravenous

[25] Patient W.B. was chelated a total of 57 times between 4/4/2011 and 3/16/2015.

administration of the EDTA)[26] and ICD-9 Code 9612 – "Poisoning By Heavy Metal Anti-Infectives"

a. This claim was false as, inter-alia, Patient W.B. was not suffering from HMP as indicated by the ICD-9 Diagnostic code associated with the claim (i.e., 9612 – Poisoning By Heavy Metal Anti-Infectives") Instead, the patient was administered EDTA as an "alternative" or "experimental" treatment of the type publicly espoused and marketed by Dr. Burkich, but which is excluded from Medicare coverage by NDC 20.22.

   i. The medical records do not reflect that Patient W.B. had recently or been acutely exposed to HMP, and such exposure is an integral component of a viable HMP diagnosis.

   ii. No blood test was administered to detect the amount of heavy metals in the blood.

   iii. Instead, Defendants chelated Patient W.B. at least partly upon the results of an inherently unreliable provoked urine test that was administered on April 5, 2011.

   iv. Patient W.B. complained of generalized symptoms - *e.g.*, hypertension, insomnia and fatigue – none of which were strongly suggestive of HMP.

[26] The Government was also billed for: J7040 - Normal Saline Solution, 96365 and 96366 - Injection/Infusion Codes and 94760- Noninvasive ear or pulse oximetry for oxygen saturation.

v. Defendants failed to conduct a differential diagnosis to determine whether Patient W.B.'s symptoms were related to a condition other than HMP.

vi. As the medical records plainly demonstrate that Patient W.B. was not suffering from lead poisoning or lead encephalopathy (the only two conditions for which EDTA chelation indicated), Defendants plainly chelated Patient W.B. to treat a "…generalized condition not listed by the FDA as an approved use[,]" which constitutes an experimental use of EDTA that is explicitly excluded from Medicare coverage by NCD 20.22.

205. In promulgating NCD 20.22, CMS determined that experimental EDTA chelation therapy was excluded from Medicare coverage. Had CMS known that Dr. Burkich's claims actually sought reimbursement for experimental EDTA chelation therapy that is excluded from coverage under NCD 20.22, it would not have paid such claims.

***Dr. Burkich Knowingly Submitted Claims To Medicare That Were False As They Sought Reimbursement For The Use Of EDTA To Treat Conditions Not Indicated By The FDA Approved Label For EDTA.***

206. Dr. Burkich had FCA knowledge that Medicare does not reimburse providers that utilize medications for uses not indicated on the medication's FDA approved label, unless such off-label use is specifically allowed by the MAC.

207. The FDA approved label for EDTA explicitly states that EDTA is indicated only for lead poisoning and lead encephalopathy:

- Edetate calcium disodium is indicated for the reduction of blood levels and depot stores of lead in lead poisoning (acute and chronic) and lead encephalopathy, in both pediatric populations and adults.

208. Nevertheless, Dr. Burkich's extensive history of touting and administering EDTA chelation as an experimental treatment demonstrates that Dr. Burkich administered EDTA chelation therapy as an experimental therapy for a host of conditions – *e.g.*, heart disease, fatigue, cancer prevention – other than lead poisoning and lead encephalopathy.

209. Indeed, by his own admission, Dr. Burkich left Tennessee for Georgia based upon his belief that Tennessee limited the use of EDTA chelation to patients suffering from HMP/lead poisoning, whereas in Georgia, he would be free to administer EDTA as an experimental therapy for multiple other conditions.

210. As an example, on April 24, 2013, Dr. Burkich submitted a $628.54 claim for reimbursement to Medicare – which was paid on April 27, 2013 – for chelation therapy that the medical records reflect that he provided to a 67 year old patient with the initials "A.C." (Patient A.C.) on April 22, 2013. [27] In submitting the claim, Dr. Burkich utilized the HCPCS code for EDTA (J0600) (as well as various additional CPT and HCPCS codes associated the intravenous administration of the EDTA)[28] and ICD-9 Code 9848 – "Toxic Effects Lead Compounds NEC."

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[27] Patient A.C. was chelated a total of 53 times from 7/30/2012 through 4/11/2016.

[28] The following codes were also billed to the Government: J7040 and J7050- Normal Saline Solution, 96365, 96366, and 96367- Injection/Infusion Codes and 99212 (Modifier 25)- Office/ Outpatient Visit, Est.

a. This claim was false and/or misleading as, *inter-alia*, the ICD-9 Code associated with the claim (9848 – Toxic Effects Lead Compounds NEC) represents that the patient was chelated with EDTA to treat lead poisoning, when in truth, the patient was not suffering from lead poisoning, and EDTA was not otherwise indicated. [29]

   i. The medical records do not reflect that Patient A.C. had recently or been acutely exposed to lead, and such exposure is an integral component of a viable lead poisoning diagnosis.

   ii. A blood test administered to Patient A.C. on August 1, 2012 detected only 2 mcg/dL in the blood. (Chelation is only possibly indicated for patients with BLLs greater than 50 mcg/dL (symptomatic patient) or 80 mcg/dL (asymptomatic patient). Clinical symptoms in patients with BLLs less than 40 mcg/dL are not likely attributable to lead poisoning. The medical consensus is that no action whatsoever – *e.g.*, medication, counseling, reduced exposure, *ect*. – is necessary with respect to adult patients with BLLs less than 5 mcg/dL.)

   iii. Dr. Burkich chelated Patient A.C. at least partly on the basis of the results of an inherently unreliable provoked urine test that was administered on July 30, 2012.

   iv. Dr. Burkich failed to conduct a differential diagnosis to determine whether chelation was warranted with respect to Patient A.C.

[29] This claim was also false due to Burkich's over use of billing E&M with Modifier 25.

v. Additionally, Patient A.C. specifically came in to be chelated and complained of only generalized symptoms - *e.g.*, joint pain, lack of energy, neuropathy and various other symptoms – none of which were strongly suggestive of lead poisoning.

211. Also, on March 4, 2014, Dr. Burkich submitted a $505.89 claim for reimbursement to Medicare – which was paid on May 1, 2014 – for chelation therapy that the medical records reflect that he provided to a 69 year old patient with the initials "E.D." (Patient E.D.) on September 23, 2013.[30] In submitting the claim, Dr. Burkich utilized HCPCS code J0600 for EDTA (as well as various additional CPT and HCPCS codes associated with the intravenous administration of the EDTA)[31] and ICD-9 Code 9848- "Toxic Effects Lead Compounds NEC."

a. This claim was false and/or misleading as, *inter-alia*, the ICD-9 Code associated with the claim (9848 – Toxic Effects Lead Compounds NEC) represents that patient was chelated with EDTA to treat lead poisoning, when in truth, the patient was not suffering from lead poisoning, and EDTA was not otherwise indicated. [32]

i. The medical records do not reflect that Patient E.D. had recently or been acutely exposed to lead, and such exposure is an integral component of a viable lead poisoning diagnosis.

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[30] Patient E.D. was chelated a total of 79 times between 9/5/2013 and 1/25/2016.

[31] The Government was also billed for the following codes: J7040 - Normal Saline Solution and 99212 (Modifier 25)-Office/ Outpatient Visit, Est.

[32] This claim was also false due to Burkich's over use of billing E&M with Modifier 25.

ii. The medical records indicate that no blood test was administered to detect the level of lead in the blood. (Chelation is only possibly indicated for patients with BLLs greater than 50 mcg/dL (symptomatic patient) or 80 mcg/dL (asymptomatic patient). Clinical symptoms in patients with BLLs less than 40 mcg/dL are not likely attributable to lead poisoning. The medical consensus is that no action whatsoever – *e.g.*, medication, counseling, reduced exposure, *ect*. – is necessary with respect to adult patients with BLLs less than 5 mcg/dL.)

iii. Dr. Burkich chelated Patient E.D. at least partly on the basis of the results of an inherently unreliable provoked urine test that was administered on August 20, 2013

iv. Dr. Burkich failed to conduct a differential diagnosis to determine whether chelation was warranted with respect to Patient E.D.

v. Additionally, Patient E.D. specifically came in to be chelated and complained of only generalized symptoms - *e.g.*, hypertension, gall bladder trouble, hypothyroidism, diabetes and various other symptoms – none of which were strongly suggestive of lead poisoning.

212. Medicare does not reimburse providers for uses of a drug that go beyond their FDA specified indications (as they appear on the manufacturer's label for the drug), unless specifically approved by CMS. Hence, had CMS known that Dr. Burkich's claims

actually sought reimbursement for "off-label" and non-FDA approved uses of EDTA, it would not have paid such claims.

***Dr. Burkich Knowingly Submitted Claims To Medicare That Were False As They Sought Reimbursement For Medically Unnecessary Chelation Therapy.***

213. Dr. Burkich submitted claims for EDTA chelation treatments were not medically indicated or necessary for the health of the patient.

214. EDTA is only indicated as a treatment for lead poisoning or lead encephalopathy.

215. EDTA specifically, and chelation in general, has not been found to be an efficacious or medically necessary treatment for any condition other than HMP/lead poisoning.

216. With respect to the majority of the reimbursements he received from the Government ($2.8 million of the $3.1 million), Dr. Burkich submitted claims with ICD-9 Codes associated with lead poisoning and other forms of HMP, thereby indicating that the pertinent chelation treatments were administered as a medically necessary treatment to patients suffering from HMP.

217. With respect to a small subset of the reimbursements he received from the Government ($365,000 of the $3.1 million), Dr. Burkich submitted claims with ICD-9 Codes associated with conditions *other* than HMP – such as insomnia, hypertension and decreased libido – thereby indicating that he administered EDTA as a medically necessary treatment to patients with such conditions.

218. In truth, the chelation treatments associated with the aforementioned claims are were not medically necessary, as the medical records indicate that the

applicable patients were *not* suffering from HMP/lead poisoning, which is the only condition for which chelation is indicated.

219. Specifically, the Medicare beneficiaries Dr. Burkich chelated did not present with symptoms indicative of HMP, and most sought chelation as an experimental treatment for conditions other than HMP, such as circulation and heart problems.

220. Moreover, Dr. Burkich chelated Medicare beneficiaries with no viable history of exposure to heavy metals, which is an indispensable element of a valid HMP diagnosis.

221. Further, despite the fact that HMP is exceedingly rare amongst the elderly, the overwhelming majority of the patients chelated by Dr. Burkich were the age of 62 or older.

222. Additionally, Dr. Burkich chelated ostensible lead poisoning patients with either no reported BLLs, or extremely low BLLs (e.g., 2 mcg/dL, or less), while chelation is only possibly indicated for patients with lab determined BLLs of in excess of 50 (symptomatic patient) 80 (asymptomatic patient) mcg/dL, and the medical consensus is that, with respect to patients with BLLs less than 5mcg/dL – no action whatsoever is medically necessary.

223. Finally, although Dr. Burkich touted and administered EDTA as an "effective" treatment for a variety of different conditions, chelation has not been found to be an efficacious or medically necessary treatment for any condition other than HMP/lead poisoning.

224. For instance, on November 4, 2011 Charity Moses, a Nurse Practitioner who worked under Dr. Burkich, submitted a $249.95 claim for reimbursement to Medicare –

which was paid on November 9, 2011- for chelation therapy that the medical records reflect that she provided to a 56 year old patient with the initials "S.J." (Patient S.J.) on April 26, 2010.[33] In submitting the claim[34], Ms. Moses utilized the HCPCS code for EDTA (J0600) (as well as various additional CPT and HCPCS codes associated the intravenous administration of the EDTA).[35] Additionally, Defendants utilized the ICD-9 diagnostic code 78079 – "Malaise and Fatigue NEC," thereby indicating that patient S.J. was chelated with EDTA to treat the condition malaise and fatigue, which is associated with extreme tiredness and an overall feeling of discomfort and lack of well-being. This claim is false and/or misleading for the following reasons:

a. Pursuant to NCD 20.22, EDTA therapy is only reimbursable under Medicare when used to treat lead poisoning or lead encephalopathy, and is not reimbursable to treat other generalized conditions, which includes, but is not limited to, malaise and fatigue.

b. Because lead poisoning and lead encephalopathy are the only indications listed on EDTA's FDA label, Defendants' use of EDTA as a treatment for malaise and fatigue is not reimbursable under Medicare.

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[33] Patient S.J. was chelated a total of 63 times from 4/19/2010 through 3/20/2012.

[34] This claim was also false due to Burkich's over use of billing E&M with Modifier 25.

[35] The following codes were also billed to the Government: J7040 - Normal Saline Solution, 96365 and 96366- Injection/Infusion Codes and 99212 (Modifier 25) - Office/ Outpatient Visit, Est.

c. As EDTA chelation is only efficacious in treating HMP, Defendants' use of EDTA as a treatment for malaise and fatigue was not medically necessary, irrespective of their certification to the contrary.

225. On June 23, 2014, Dr. Burkich submitted a $604.57 claim for reimbursement to Medicare – which was paid on June 26, 2014 – for chelation that the medical records reflect that he provided to a 69 year old patient with the initials "H.M." (Patient H.M.) on June 20, 2014.[36] In submitting the claim, Dr. Burkich utilized the HCPCS code for EDTA (J0600) (as well as various additional CPT and HCPCS codes associated with the intravenous administration of the EDTA)[37] and ICD-9 Code 9848 – "Toxic Effects Lead Compounds NEC."

a. This claim was false and/or misleading as, *inter-alia*, the ICD-9 Code associated with the claim (9848 – Toxic Effects Lead Compounds NEC) represents that patient was chelated with EDTA to treat lead poisoning, when in truth, the patient was not suffering from lead poisoning, and EDTA was not otherwise indicated.

i. The medical records do not reflect that Patient H.M. had recently or been acutely exposed to lead, and such exposure is an integral component of a viable lead poisoning diagnosis.

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[36] Patient M.H. was chelated a total of 58 times from 9/18/2009 to 4/9/2015.

[37] The Government was also billed for the following codes: J7040-Normal Saline Solution, 96365 and 96366-Injection/Infusion Codes.

ii. The medical records indicate that no blood test was administered to detect the level of lead in the blood. (Chelation is only possibly indicated for patients with BLLs greater than 50 mcg/dL (symptomatic patient) or 80 mcg/dL (asymptomatic patient). Clinical symptoms in patients with BLLs less than 40 mcg/dL are not likely attributable to lead poisoning. The medical consensus is that no action whatsoever – *e.g.*, medication, counseling, reduced exposure, *ect*. – is necessary with respect to adult patients with BLLs less than 5 mcg/dL.)

iii. Dr. Burkich chelated Patient H.M. at least partly on the basis of the results of an inherently unreliable provoked urine test that was administered on October 7, 2008 and April 5, 2011.

iv. Dr. Burkich failed to conduct a differential diagnosis to determine whether chelation was warranted with respect to Patient M.H.

v. Additionally, Patient H.M. complained of generalized symptoms – *e.g.*, arthritis and fatigue that are not strongly suggestive of lead poisoning.

226. Similarly, on February 10, 2011, Dr. Burkich submitted a $295.79 claim for reimbursement to Medicare – which was paid on February 12, 2011 – for chelation therapy that the medical records reflect that he provided to a 69 year old patient with the initials J.H. (Patient J.H.) on February 3, 2011.[38] In submitting the claim, Dr. Burkich

[38] Patient J.H. was chelated a total of 231 times from 9/3/2009 to 12/14/2015.

utilized HCPCS code J0600 for EDTA (as well as various additional CPT and HCPCS codes associated with the intravenous administration of the EDTA)[39] and ICD-9 Code 9849 - "Toxic Effects Lead Compound NOS."

a. This claim was false and/or misleading as, *inter-alia*, the ICD-9 Code associated with the claim (9849 – Toxic Effects Lead Compounds NOS) represents that patient was chelated with EDTA to treat lead poisoning, when in truth, the patient was not suffering from lead poisoning, and EDTA was not otherwise indicated. [40]

i. The medical records do not reflect that Patient J.H. had recently or been acutely exposed to lead, and such exposure is an integral component of a viable lead poisoning diagnosis.

ii. The medical records indicate that no blood test was administered to Patient J.H. until October 19, 2012, which detected a BLL of only 1 mcg/dL in the blood. (Chelation is only possibly indicated for patients with BLLs greater than 50 mcg/dL (symptomatic patient) or 80 mcg/dL (asymptomatic patient). Clinical symptoms in patients with BLLs less than 40 mcg/dL are not likely attributable to lead poisoning. The medical consensus is that no action whatsoever – *e.g.*,

[39] Specifically, in addition to EDTA, the Government was also billed for: J7040 and J7050 - Normal Saline Solution, 96365, 96366 and 96366- Injection/Infusion Codes, 99212 (Modifier 25)-Office/ Outpatient Visit, Est

[40] This claim was also false due to Burkich's over use of billing E&M with Modifier 25.

medication, counseling, reduced exposure, *ect*. – is necessary with respect to adult patients with BLLs less than 5 mcg/dL.)

iii. Dr. Burkich chelated Patient J.H. at least partly on the basis of the results of an inherently unreliable provoked urine test that was administered on July 24, 2007 and June 29, 2010.

iv. Dr. Burkich failed to conduct a differential diagnosis to determine whether chelation was warranted with respect to Patient J.H.

v. Additionally, Patient J.H. complained of generalized symptoms - *e.g.,* fatigue, menopause and hypertension- that are not strongly suggestive of lead poisoning.

227. Pursuant to 41 U.S.C. § 1395y(a)(1)(A), Medicare only covers drugs and services that are "reasonable and necessary for the diagnosis and treatment of illness or injury." Hence, had CMS known that Dr. Burkich' claims involved medically unnecessary chelation therapy, it would not have paid the claims.

**DEFENDANTS FILED FALSE CLAIMS THROUGH THEIR IMPROPER USE OF MODIFIER 25.**

228. From 2009 to 2017, Defendants increased their Medicare EDTA reimbursements by fraudulently adding Modifier 25 to many of their EDTA chelation claims.

229. Modifier 25 is intended to be utilized where a physician has performed a significant and separately identifiable service on the same day that he/she performed the original and/or underlying services and/or procedures scheduled for the patient. By

utilizing Modifier 25, the physician receives an extra fee for the additional service rendered.

230. With respect to Defendants' intravenous administration of EDTA, the CPT codes associated with the necessary injections and infusions encompass the healthcare professional's time needed to evaluate the patient, perform the injection procedure, and prepare a follow-up plan.

231. Nevertheless, Defendants routinely added Modifier 25 to their EDTA claims. In doing so, Defendants (1) represented that they had performed additional services for the patient that were significant and separately identifiable from the EDTA therapy, and (2) sought reimbursement for such ostensibly separate and identifiable services – *e.g.*, office visits.

232. In truth, however, Defendants added Modifier 25 to their EDTA claims when *no* significant services that were in addition to, and district from, the underlying EDTA treatments had been performed.

233. Hence, by misusing Modifier 25, Defendants overstated the services provided to patients, thereby causing the United States to pay more to Defendants than that to which they were actually entitled.

234. Defendants had "knowledge" under the FCA that they could not utilize Modifier 25 in connection with the intravenous administration of EDTA unless they performed additional services that were significant and separately identifiable from the EDTA treatments.

235. Indeed, on October 11, 2013, a consultant retained by Dr. Burkich informed him that he should not utilize Modifier 25 to bill Medicare for office visits unless EDTA patients were being seen for a reason *other* than the intravenous administration of EDTA.

236. In contravention of this admonition, Dr. Burkich continued to submit false claims to Medicare by abusing Modifier 25 and billing for office visits that reflected no services that were significant or separately identifiable from the underlying EDTA treatments.

**THE FALSITY ASSOCIATED WITH DEFENDANTS' CLAIMS IS MATERIAL.**

237. The FCA defines material as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property."

238. In both the common law and FCA understandings of materiality, one "look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation." Absent special knowledge, if a misrepresentation is such that it would reasonably change a person's decision making process, then it is material. *See, U.S. v. Public Warehousing Company*, 2017 WL 1021745, *5-6, (N.D. Ga. March 16, 2017) (Citing to *Universal Health Servs., Inc. v. United States*, 136 S. Ct. 1989 (2016), court rejected defendants' assertion that Government had not demonstrated materiality.)

239. The falsity associated with Defendants' false claims was not trivial, but material, as evidenced by the fact that the Government has actively promulgated statutes, rules and/or regulations to exclude certain items and services – *such as those reflected in Defendants' claims* – from Medicare coverage, and also would refuse to pay claims for items and services that are excluded from coverage pursuant to these statutes, rules and regulations.

**DEFENDANTS KNOWINGLY SUBMITTED FALSE CLAIMS TO THE GOVERNMENT.**

240. Defendants submitted (or caused the submission of) the aforementioned false claims to the Government with knowledge of the falsity within the meaning of the FCA. Specifically, Defendants submitted the claims with "actual knowledge" of, or were "recklessly indifferent" or "deliberately ignorant" to, the falsity associated with such claims.

241. Defendants knowingly, within the meaning of the FCA, submitted claims to the Government for EDTA chelation therapy that was that was not medically necessary, and associated with experimental treatments and/or conditions that Defendants knew were excluded from coverage by NCD 20.22, as well as Medicare's coverage exclusion for experimental treatments – *i.e.,* the Medicare "off-label" drug rule.

242. Defendants knowingly, within the meaning of the FCA, submitted claims to the Government using ICD-9 codes indicating that the claims were associated with patients suffering from HMP/lead poisoning, when in truth, the patients did not have HMP/lead poisoning, but were administered EDTA as a supposedly effective treatment for myriad of different conditions, which include, but are not limited to, fatigue, heart disease and poor circulation.

243. Defendants knowingly, within the meaning of the FCA, utilized Modifier 25 to increase the amount of reimbursements they received from the Government in connection with many of their EDTA claims, even though they had not performed any additional services that were significant and distinct from the underlying chelation therapy.

**COUNT I: VIOLATIONS OF THE FALSE CLAIMS ACT**
**31 U.S.C. § 3729(a)(1)(A)**

244. The United States re-asserts all previous allegations as if set forth herein.

245. Defendants knowingly presented, or caused to be presented, to officers or employees of the United States Government, false or fraudulent claims for payment of medications and services in connection with their chelation treatment of Medicare beneficiaries. Defendants' claims were false and/or constitute "misleading half-truths" in that they erroneously indicated that reimbursement was sought for chelation therapy that was provided as a treatment for patients suffering from lead poisoning or other forms of HMP, when in truth, the patients did not have HMP/lead poisoning, but were administered EDTA as a supposedly "effective" treatment for myriad of different conditions, which include, but are not limited to, fatigue, heart disease and poor circulation. Additionally, the claims are false and/or constitute "misleading half-truths" in that they seek reimbursement for "alternative" uses outside of the indications on the FDA-approved label for EDTA, and are thus are not covered by Medicare. Finally, the claims are false and/or constitute "misleading half-truths" in the Defendants falsely certified that the chelation treatments associated with such claims were "medically indicated and necessary," when in truth, the treatments were medically unnecessary, as (1) the patients chelated were not suffering from HMP/lead poisoning, and (2) EDTA is not an efficacious or medically necessary treatment for any condition other than lead poisoning. In submitting or causing the submission of these claims, the Defendants acted with actual knowledge, reckless disregard, or deliberate ignorance of the truth or falsity of the claims.

246. The Defendants made – or caused to be made – express representations that the chelation services for which they sought reimbursement were medically necessary to treat patients suffering from HMP. These representations were material to the Government's decision to pay Defendants' claims. When Defendants made these representations, they knew that these representations were false, and would continue to be false. Therefore, Defendants fraudulently induced CMS to pay claims for payment that violated the FCA.

247. Defendants knowingly, within the meaning of the FCA, utilized Modifier 25 in concert with many of their EDTA chelation claims, even though they had not performed any additional services that were significant and distinct from the underlying chelation therapy.

248. By virtue of these false or fraudulent claims, the United States suffered damages in an amount to be determined at trial and is therefore entitled to treble damages under the FCA, to be determined at trial, plus civil penalties of not less than $5,500 and up to $11,000 for each violation.

**COUNT II: VIOLATIONS OF THE FALSE CLAIMS ACT**
**31 U.S.C. § 3729(a)(1)(B) (2009)**

249. The United States re-asserts all previous allegations as if set forth herein.

250. As set forth above, Defendants knowingly or with deliberate ignorance or reckless disregard of the truth, made, used, and caused to be made and used, false records and statements material to false or fraudulent claims in connection with their claims to reimbursement to Medicare.

251. Defendants made and/or caused to be made numerous false records and statements, including false statements in, *inter-alia*, claim forms and CMS Form 8551s that the claims complied with, all applicable laws, regulations, and program instructions for payment, including but not limited the representation that the services were medically necessary. Utilizing these false records and statements, Defendants caused false claims for payment were submitted to Medicare.

252. Defendants knowingly, within the meaning of the FCA, utilized Modifier 25 in concert with many of their EDTA chelation claims, even though they had not performed any additional services that were significant and distinct from the underlying chelation therapy.

253. The United States paid such false or fraudulent claims because of the acts and conduct of Defendants.

254. By reason of Defendants' false statements and false claims, the United States has been damaged in a substantial amount to be determined at trial.

**COUNT III: PAYMENT BY MISTAKE OF FACT**

255. The United States re-asserts all previous allegations as if set forth herein.

256. Defendants have caused the United States to make payment of certain sums of money in the mistaken belief that the Defendants' claims involved chelation therapy that was medically necessary to treat patients suffering from HMP/lead poisoning. Indeed, Defendants' claims falsely indicated that they sought reimbursement for chelation therapy provided to patients suffering from HMP/lead poisoning. In view of, *inter-alia*, the volume of claims submitted to CMS, CMS cannot check each claim for accuracy prior to paying such claim, and therefore relies upon program participants to

only submit accurate claims for items and services that are reasonable and necessary. In such circumstances, payment was by mistake and was not authorized, and it would not be inequitable to require full restitution of such mistaken payments, as Defendants (for the reasons outlined herein) have not acted in good faith or in good conscience in dealing the Government.

257. As a result of the unauthorized payments, the United States has sustained damages in an amount to be determined at trial.

**COUNT IV: UNJUST ENTRICHMENT**

258. This is a claim for the recovery of monies by which the Defendants have been unjustly enriched.

259. The United States re-asserts all previous allegations as if set forth herein.

260. As described above, the Defendants received, and/or have continued to maintain control over, federal monies to which they are not entitled. Defendants were not entitled to the federal monies because Defendants, (1) in violation of 42 U.S.C. § 1395y(a)(1)(A), billed Medicare for services that were not reasonable or necessary, and/or (2) billed Medicare for experimental or "alternative" uses of EDTA that are outside of the indications on the FDA-approved label, and are thus are not covered by Medicare.

261. By directly or indirectly obtaining federal funds to which they were not entitled, Defendants have been unjustly enriched and are liable to account for and pay such amounts, which are to be determined at trial, to the United States.

**PRAYER FOR RELIEF**

WHEREFORE, the United States prays for judgment against Defendants as follows:

(1) On Counts I through II, under the False Claims Act, as amended, for treble the amount of the United States' damages plus interest and such civil penalties as are allowable by law, together with the costs of this action and such other and further relief as may be just and proper;

(2) On Count III, for payment by mistake of fact, for the damages sustained, plus pre-judgment and post-judgment interest, costs, and all such further relief as may be just and proper;

(3) On Count IV, for unjust enrichment, for the amount of unjust enrichment, plus pre-judgment and post-judgment interest, costs, and all such further relief as may be just and proper; and

(4) That judgment be entered in favor of the United States and against the Defendants for actual damages, pre-judgment and post-judgment interest, litigation costs, investigative costs, disgorgement of all profits, and an accounting, to the fullest extent as allowed by law, and for such further relief as may be just and proper.

**JURY DEMAND**

The United States requests a trial by jury with respect to all issues so triable.

Respectfully submitted,

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