

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

UNITED STATES OF  
AMERICA,

Plaintiff,

v.

CHARLES C. ADAMS, MD,  
and CHARLES C. ADAMS,  
MD, PC, d/b/a PERSONAL  
INTEGRATIVE MEDICINE  
PLLC,

Defendants.

CIVIL ACTION FILE NO.  
4:18-CV-0191-HLM

ORDER

This is an action filed under the False Claims Act (the “FCA”), 31 U.S.C. §§ 3729, et seq. The case is before the Court on Defendants’ Motion to Dismiss [14].

## **I. Standard Governing a Motion to Dismiss**

Federal Rule of Civil Procedure 12(b)(6) allows the Court to dismiss a complaint, or portions of a complaint, for “failure to state a claim upon which relief can be granted.” Fed. R. Civ. P. 12(b)(6). When reviewing a motion to dismiss, the Court must take the allegations of the complaint as true and must construe those allegations in the light most favorable to the plaintiff. Alvarez v. Att’y Gen. for Fla., 679 F.3d 1257, 1261 (11th Cir. 2012).

Although a court is required to accept well-pleaded facts as true when evaluating a motion to dismiss, it is not required to accept the plaintiff’s legal conclusions. Chandler v. Sec’y of Fla. Dep’t of Transp., 695 F.3d 1194, 1199 (11th Cir. 2012) (per curiam) (citing Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009)). The Court also does not accept as true “unwarranted deductions of fact[] or legal conclusions

masquerading as facts.” Snow v. DirecTV, Inc., 450 F.3d 1314, 1320 (11th Cir. 2006) (internal quotation marks and citation omitted).

Finally, the Court may dismiss a complaint if it does not plead “sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.” Simpson v. Sanderson Farms, Inc., 744 F.3d 702, 708 (11th Cir. 2014) (internal quotation marks omitted) (quoting Iqbal, 556 U.S. at 678). In Bell Atlantic Corp. v. Twombly, 550 U.S. 544 (2007), the Supreme Court observed that a complaint “requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.” 550 U.S. at 555. Although factual allegations in a complaint need not be detailed, those allegations “must be enough to raise a right to relief above the speculative level on the assumption that all the allegations in the complaint are true (even if doubtful in

fact).” Id. Moreover, “[a] claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” Iqbal, 556 U.S. at 678. The mere possibility that the defendant might have acted unlawfully is not sufficient to allow a claim to survive a motion to dismiss. Id. Instead, the well-pleaded allegations of the complaint must move the claim “across the line from conceivable to plausible.” Twombly, 550 U.S. at 570.

## **II. Plaintiff’s Allegations**

### **A. The Parties**

Plaintiff is the United States, and it 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 administer the Medicare program. (Compl. (Docket Entry No. 1) ¶ 21.) Defendant Personal

Integrative Medicine, PLLC (“PIM”) is a Tennessee corporation with its principal place of business in Ringgold, Georgia. (Id. ¶ 22.) Defendant Charles C. Adams, M.D. (“Dr. Adams”) owns and operates PIM. (Id.) During the time period relevant to this action, Dr. Adams was a licensed physician in Georgia and did business in Ringgold. (Id. ¶ 23.) Defendant Charles C. Adams, M.D., P.C., d/b/a Full Circle Medical Center (“FCMC”) was a Tennessee corporation with its principal place of business in Ringgold, and Dr. Adams operated it. (Id. ¶ 24.) Plaintiff alleges that Defendants “perpetuated a scheme between November 2008 and September 2015 involving the knowing submission of false claims for medically unnecessary and ‘alternative’ chelation therapy that Dr. Adams administered using the drug calcium disodium versentate, or edetate calcium disodium (EDTA), which the [Food and Drug Administration

(“FDA”)] only approved for indications of lead poisoning and lead encephalopathy.” (Id. ¶ 1.) According to Plaintiff, “Defendants received approximately \$1.5 million in Medicare reimbursements” from this scheme. (Id.)

### **B. The FCA**

The FCA imposes civil penalties on a person who “knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval,” or who “knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.” (Compl. ¶ 33.) Public Law 111-21, the Fraud Enforcement and Recovery Act of 2009 (“FERA”), which was enacted on May 20, 2009, amended the FCA. (Id. ¶ 34.) According to Plaintiff, § 3729(a)(1) of the prior statute applies to conduct that occurred before FERA’s enactment, while § 3729(a)(1)(A) of the revised statute applies to conduct that

occurred after FERA's enactment. (Id.) Plaintiff alleges that § 3729(a)(1)(B) applies to all claims in this case. (Id.)

According to Plaintiff, for violations that occurred before May 20, 2009, the FCA provided that a person would be liable to the United States “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.’” (Compl. ¶ 35 (quoting 31 U.S.C. § 3729(a)(1) (1986).) “As amended in 2009, the [FCA] 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.’” (Id. ¶ 35 (quoting 31 U.S.C. § 3729(a)(1)(B) (2009).) As defined in the FCA, “knowing” and “knowingly” “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.” (Id. ¶ 37.) According to Plaintiff, the FCA “provides that no proof of specific intent to defraud is required.” (Id.)

### **C. Medicare and Claims Submission Overview**

Congress enacted the Health Insurance for the Aged and Disabled Act, known as the Medicare Program, in 1965 to pay for the costs of certain health care services. (Compl. ¶ 38.) Entitlement to Medicare depends on age, disability, or affliction with end-stage renal disease. (Id.) HHS administers Medicare, and it delegated responsibility for administering Medicare to CMS. (Id.) Medicare has several parts, and this action concerns claims submitted under Medicare Part B, Supplementary Medical Insurance for the Aged and Disabled, which applies to “those drugs that are

provided incident to a physician's service and cannot usually be self-administered." (Id. ¶ 40.)

CMS initially contracted with carriers, typically private insurance companies, to process and pay Part B claims. (Compl. ¶ 41.) Beginning in November 2006, Medicare Administrative Contractors ("MACs") began to replace carriers and fiscal intermediaries. (Id. ¶ 42.) MACs act on CMS's behalf to process and pay Part B claims, and they perform administrative functions on a regional level. (Id. ¶ 43.) Between 2009 and 2015, Cahaba Government Benefit Administrators, LLC ("Cahaba") was the Part B MAC for the region that included Georgia. (Id. ¶ 43.)

Independent clinical laboratories, group practices, and individual providers must submit CMS Form 855I, a Medicare Enrollment Application to participate in Medicare as new enrollees. (Compl. ¶ 44.) Those entities also must complete

that form to change information or to reactivate, revalidate, or terminate Medicare enrollment. (Id.) By signing CSM Form 855I, signatories certify that: (1) they “agree to abide by the Medicare laws, regulations, and program instructions” that apply to them or to their organizations; (2) they “understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions . . . and on the supplier’s compliance with all applicable conditions of participating in Medicare”; (3) they “will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare”; and (4) they “will not submit claims with deliberate ignorance or reckless disregard of truth or falsity.” (Id. ¶ 45.) “[A]n 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.” (Id. ¶ 46.) Dr. Adams signed the certification statement on Section 15 of Form CMS-855I on November 10, 2016. (Id. ¶ 47.)

Medicare providers submit reimbursement claims for services provided on a CMS 1500 form (the “CMS 1500”) or its electronic equivalent, the 837P Form. (Compl. ¶ 48.) Providers or suppliers include certain five digit codes, Current Procedural Terminology Codes (“CPT Codes”) or Healthcare Common Procedure Coding System Level II Codes (“HCPSC Codes”) (collectively, the “Procedure Codes”) on CMS 1500 or 837P Forms to indicate to CMS the services rendered for which the providers or suppliers seek reimbursement. (Id.) Providers also must include a diagnosis code with each claim to Medicare, which describes

the diagnosis or medical condition associated with the claim. (Id. ¶ 49.)

During the time period relevant to this action, Medicare providers were required to use the diagnostic codes set forth in the International Classification of Diseases, Ninth Revision (the “ICD-9 Codes”). (Compl. ¶ 51.) The ICD-9 Code 9840-Toxic Inorganic Lead Component indicates a diagnosis of lead poisoning. (Id. ¶ 50.)

42 U.S.C. § 13951(q)(1) “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.” (Id. ¶ 52.)

The National Provider Identifier (“NPI”) is used for health care providers, and all providers and practitioners must have an NPI number before enrolling in Medicare. (Compl. ¶ 53.)

Dr. Adams' and FCMC's NPI number is 1437192465. (Id. ¶ 54.)

When they submit claims to Medicare, providers certify “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.” (Compl. ¶ 55.) Federal law prohibits healthcare providers “from knowingly presenting or causing to be presented claims that represent a pattern of items or services that the person knew or should have known were not medically necessary, or knew or should have known were false or fraudulent.” (Id. ¶ 56.)

#### **D. Chelation Therapy and Medicare Coverage**

Plaintiff alleges that “[c]helation therapy is a rare treatment that is generally only indicated for patients suffering from an uncommon condition called heavy metal poisoning (HMP), of which lead poisoning is the most common subset.” (Compl. ¶ 2.) According to Plaintiff, “HMP is the accumulation of heavy metals, such as lead, mercury and cadmium, in toxic amounts, in the soft tissues of the body.” (Id. (footnote omitted).)<sup>1</sup> “Lead poisoning is the most commonly diagnosed form of HMP.” (Id. ¶ 67.) Lead encephalopathy is caused by acute lead poisoning. (Id.)

Plaintiff alleges that an HMP diagnosis “generally requires a symptomatic patient who (1) has been acutely and recently exposed to lead or other heavy metals, and (2) had

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<sup>1</sup> Paragraph 66 of the Complaint contains similar allegations. (Compl. ¶ 66.)

a blood test indicating a sufficiently high amount of heavy metal in the patient's body." (Compl. ¶ 3.) According to Plaintiff, for most cases, "the only treatment for HMP is the removal of the patient from the source of exposure to heavy metal." (Id. ¶ 4.)<sup>2</sup> In some acute cases, however, "chelation therapy may be indicated." (Id. ¶¶ 4, 69.) This treatment "involves providing a 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." (Id.; see also id. ¶ 70.) Other chelating agents include Dimercaprol ("BAL") and Succimer ("DMSA"). (Id. ¶¶ 71, 100-03.) Chelating drugs, including EDTA, can have serious side effects. (Id. ¶¶ 72-73.) Plaintiff alleges that "[g]enerally,

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<sup>2</sup> Paragraph 69 of the Complaint contains a similar allegation. (Compl. ¶ 69.)

an oral chelating agent (e.g., DMSA) - as opposed to an intravenous chelating agent (e.g., EDTA) – should be administered,” while “[i]ntravenous chelating agents [such as EDTA] should be reserved for an incapacitated patient.” (Id. ¶ 104.) According to Plaintiff, “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.” (Id. ¶ 105.)

Plaintiff asserts that patients with HMP have few dispositive symptoms, and that the majority of HMP symptoms are associated with several other ailments. (Compl. ¶¶ 77-78.) According to Plaintiff, “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 HMP.” (Id. ¶ 79.) Plaintiff

alleges that a critical assessment in diagnosing HMP “is whether the patient has experienced a recent and acute exposure to heavy metal,” and it contends that metal toxicity does not usually occur absent an extraordinary exposure. (Id. ¶¶ 80-81.) Most acute HMP presentations involve industrial exposure to heavy metals. (Id. ¶ 83.)

Laboratory testing is required to diagnose HMP, but it is generally medically necessary only if a patient has had a recent acute exposure to heavy metals and the patient is symptomatic. (Compl. ¶¶ 84-85.) According to Plaintiff, the American College of Medical Toxicology (the “ACMT”) determined that patients should not be screened for heavy metals absent excessive exposure to heavy metals. (Id. ¶ 86.)

Blood tests are the most reliable indicator of whether a patient has a toxic amount of heavy metal present in his or

her body. (Compl. ¶ 87.) Physicians use blood tests to diagnose HMP by assessing the amount of heavy metal in a patient's body. (Id.) Physicians also sometimes use urine tests in conjunction with blood tests for certain heavy metals, such as mercury. (Id. at 21 n.11.) For suspected lead poisoning, physicians use blood tests to assess the amount of lead within a patient's body, or blood lead level ("BLL"). (Id. ¶ 88.)

A provoked urine test, on the other hand, involves administering a chelating agent to a patient and collecting a urine sample some hours later. (Compl. ¶ 90.) According to Plaintiff, the results almost invariably "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." (Id.) Plaintiff alleges that "[p]rovoked urine tests have been repeatedly

criticized, and the consensus is that the test is unreliable and potentially dangerous.” (Id. ¶ 91.)

According to Plaintiff, “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.” (Compl. ¶ 94.) Although “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.” (Id. ¶ 96.)

According to Plaintiff, chelation is not reasonable or necessary for a patient with a BLL of less than 40 mcg/dL, and there is no evidence that chelation is beneficial to patients with suspected lead poisoning and BLLs of less than 40 mcg/dL. (Id. ¶ 98 & n.14.) Plaintiff alleges that “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 . . . is necessary with respect to patients with BLLs less than 5 mcg/dL.” (Id. ¶ 99.)

According to Plaintiff, “although the medical consensus is that chelation is generally only indicated from HMP,” some alternative or integrative medical practitioners, such as Dr. Adams, market and administer it for a variety of conditions, including circulation issues, autism, heart disease, premature aging, and fatigue. (Compl. ¶ 106.) Certain “alternative” or “integrative” medicine practitioners “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,” even though “the medical consensus is that chelation is only possibly indicated for patients with extremely high levels of

heavy metal.” (Id. ¶ 107.) Plaintiff cited a 2013 editorial from the *Journal of Medical Toxicology* that contained observations about alternative chelation therapy. (Id. ¶ 108.) Plaintiff contends that National Coverage Determination (“NCD”) No. 20.22, which was issued by CMS in 2003 and was effective during the time period relevant to this action, provided that alternative chelation therapy was not covered by Medicare. (Id. ¶ 15.) Specifically, NCD 20.22 stated 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,” and “[a]ny such use of EDTA is considered experimental.” (Id. (internal quotation marks and footnote omitted).) Chapter 3, Section 3.6.2.2 of the CMS Medicare Program Integrity Manual provides that items are reasonable and necessary if, among other things, they are

not experimental or investigational. (Id. at 6 n.44.) According to Plaintiff, because the FDA approved EDTA only for indications of lead poisoning and lead encephalopathy, Dr. Adams' use of it for anti-aging, bone growth, cancer prevention, and circulation problems was not covered by Medicare, as provided in NCD 20.22, and was not considered reasonable and necessary. (Id. ¶ 16.)

Plaintiff further alleges that “[t]he clear medical consensus is that chelation is a medical treatment that is generally only indicated for clinically confirmed cases of HMP, such as lead poisoning.” (Compl. ¶ 74.) EDTA's package insert states that the FDA determined that EDTA is “indicated for the reduction of blood levels and depot stores of lead in lead poisoning (acute and chronic) and lead encephalopathy.” (Id. ¶ 75.) According to Plaintiff, EDTA “is

only indicated for lead poisoning and lead encephalopathy.”  
(Id. ¶ 76.)

### **E. Defendants’ Chelation Therapy and Claims**

Dr. Adams practices integrated medicine. (Compl. ¶ 123.) Plaintiff alleges that, “[a]lthough EDTA chelation is only indicated for lead poisoning and lead encephalopathy, for years, Dr. Adams has advertised and administered EDTA chelation as an ‘alternative’ treatment for a myriad of other conditions.” (Compl. ¶ 9; see also id. ¶ 123 (containing similar allegations).) Plaintiff asserts that Dr. Adams’ webpage “explicitly touted chelation as an ‘alternative medical therapy,’ which can be used as an ‘anti-aging’ treatment, to ‘improve circulation problems,’ and to ‘. . . stimulate bone growth, improve cholesterol and lower blood pressure.’” (Id. ¶ 10 (alteration in original); see also id. ¶ 126 (same).) Plaintiff alleges that, in approximately 2001, Dr.

Adams stated on his webpage, under the heading, “Where alternative medicine is prevention,” that:

- Chelation Therapy with EDTA helps you feel younger by reversing the accelerated decline of your body. Chelation Therapy helps you achieve healthy aging.
- The tremendous benefits experienced by thousands and thousands of people in the areas of heart disease, cancer prevention, diabetes, and chronic fatigue make Chelation Therapy a logical and practical choice for those fortunate enough to take advantage of it.

(Id. ¶ 11; see also ¶ 125 (same).) Plaintiff also complained that, even though NCD 20.22 provided that Medicare excluded coverage for the use of EDTA for atherosclerosis and arteriosclerosis, Dr. Adams’ webpage marketed EDTA chelation as a treatment for those and other similar heart conditions. (Id. ¶ 127.) Plaintiff also alleged that Dr. Adams testified in 2018 “that chelation is effective in improving vision, increasing energy, reducing headaches and

promoting an overall sense of well-being.” (Id. ¶ 128 (internal quotation marks omitted).)

According to Plaintiff, even though “chelation is a serious and potentially dangerous treatment, Dr. Adams represented on his webpage that, ‘chelation therapy is delivered while the patient relaxes in a recliner chair, perhaps watching TV, chatting, or reading.” (Compl. ¶ 12; see also id. ¶ 129 (same).) Dr. Adams stated that “the basic course of treatment is thirty to forty treatments.” (Id. ¶ 129 (internal quotation marks omitted).) Dr. Adams also told “potential patients that heavy metals caused various health problems, and then utilized the results of widely discredited ‘provoked urine tests’ to tell patients that they had ‘heightened’ levels of heavy metal, which chelation could reduce, thereby alleviating medical problems, such as high

blood pressure, poor circulation and premature aging.” (Id. ¶ 13.)

Plaintiff further alleges that Dr. Adams routinely failed to conduct viable differential diagnoses before chelating patients. (Compl. ¶ 131.) According to Plaintiff, this failure “is consistent with the fact the patients he chelated generally affirmatively sought him out seeking EDTA chelation as an alternative therapy for circulation problems, as well as other conditions for which Dr. Adam[s] marketed EDTA chelation as an alternative or integrative treatment.” (Id. ¶ 132 (internal quotation marks omitted).) Plaintiff alleges that “Dr. Adams 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 metal.” (Id. ¶ 134

(internal quotation marks omitted).) Plaintiff contends that “Dr. Adams sidestepped the essential heavy metal exposure aspect of a valid HMP differential diagnosis with his supposition that, because of the presence of lead in gasoline between 1930 and 1995, anyone that drove during this period has been exposed to lead, and thus may be an appropriate candidate for heavy metal testing and/or chelation therapy.” (Id. ¶ 135 (internal quotation marks, emphasis, and footnote omitted).) Dr. Adams stated that he would advise a patient who sought chelation, but who had no possible exposure to lead other than use of the roads, that chelation therapy was reasonable. (Id. ¶ 136.)

Plaintiff also alleges that, contrary to the medical consensus, Dr. Adams “ordered blood tests only to avoid problems with the medical board, and did not base his decision whether to chelate a patient on blood tests results.”

(Compl. ¶ 137 (footnote omitted).) Instead, Dr. Adams relied on provoked urine tests, and he used the results of those tests to convince patients that they had elevated heavy metals levels that could be reduced by chelation with EDTA. (Id. ¶ 138.) Plaintiff contends that Dr. Adams ignored the medical consensus that provoked urine tests are unreliable, are potentially dangerous, and should not be used to advise a patient that heavy metal testing or chelation is warranted. (Id. ¶ 139.) Plaintiff alleges that “Dr. Adams knew that EDTA chelation is only indicated for adult patients with significantly heightened BLLs.” (Id. ¶¶ 152-53.)

Plaintiff also alleges that, although the standard of care provides that chelation therapy should be of limited duration, and tied to laboratory confirmed levels, Dr. Adams admitted that he chelated patients for as long as the patient wanted. (Compl. ¶ 140.) Between March 2, 2009 and December 30,

2009, Dr. Adams chelated an 83-year-old Medicare beneficiary, M.D., thirty-six times, stating that it was the patient's call because she felt badly. (Id. ¶¶ 141-42.) Dr. Adams chelated other patients 108, 117, and 168 times. (Id. ¶¶ 143-46.)

Providers bill Medicare "for chelation 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." (Compl. ¶ 5.) Defendants used procedure code J0600 to indicate use of EDTA, and they used various other procedure codes associated with intravenous administrations of EDTA. (Id.)

According to Plaintiff, "claims submitted to Medicare for chelation therapy are generally not payable unless a diagnosis is provided." (Compl. ¶ 6.) Plaintiff alleges that, "in billing Medicare for EDTA chelation treatments,

Defendants routinely used ICD-9 Codes that are associated with lead poisoning and/or other types of HMP, which included, but were not limited to” ICD-9 Code 9848, for Toxic Effect Lead Compounds NEC, ICD-9 Code 9840, for Toxic Effect Inorganic Lead Compound, and ICD-9 Code 9851, for Toxic Effect Arsenic. (Id.; id. ¶ 150 (stating that Dr. Adams submitted, or caused to be submitted, thousands of such claims); id. ¶ 160.) Plaintiff claims that, although Defendants used diagnostic codes that are associated with lead poisoning, the patients that Dr. Adams chelated did not suffer from lead poisoning, as demonstrated by the fact that they generally had BLLs at a miniscule level or far below the BLL level that would warrant chelation. (Id. ¶ 7; id. ¶¶ 158-59.) Plaintiff also alleges that the patients that Dr. Adams chelated “had generally not been recently and acutely exposed to lead or any other heavy metal, which is an

essential element of lead poisoning diagnosis.” (Id.; id. ¶¶ 148-49, 158.) According to Plaintiff, Dr. Adams testified in 2017 “that he does not actually treat lead poisoning or heavy metal toxicity,” but instead treats “an altogether different condition that he called ‘excess body burden of heavy metals.’” (Id. ¶ 7; id. ¶ 149.) Plaintiff claims that “Defendants’ inclusion of HMP related diagnosis codes on claims submitted to Medicare was false and fraudulent, and designed to secure Medicare reimbursement for Dr. Adams’ use of chelation as a form of ‘alternative’ or ‘experimental’ therapy, which is not covered by Medicare.” (Id. ¶ 8; id. ¶¶ 154-55, ¶ 164.) Plaintiff alleged that Dr. Adams knew that such alternative chelation therapy would not be covered by Medicare, but he routinely billed Medicare for alternative chelation therapy between November 2008 and September 2015. (Id. ¶¶ 155-157.)

Plaintiff alleges that, “[i]f Dr. Adams had submitted claims to Medicare for his ‘alternative’ and/or ‘experimental’ EDTA chelation therapy and included diagnoses codes or descriptions of ‘poor circulation,’ ‘high blood pressure,’ ‘anti-aging’ or ‘cancer prevention,’ such claims would not have been paid.” (Compl. ¶ 14; id. ¶ 163 (noting that CMS would not have paid the claims if it had known that the claims sought reimbursement for chelation treatments for conditions other than lead poisoning or another form of HMP); id. ¶ 167 (stating that CMS would not have paid the claims if it had known that the claims sought reimbursement for alternative or experimental chelation therapy excluded from coverage under NCD 20.22); id. ¶ 185 (noting that CMS would not have paid the claims if it had known that the claims were for medically unnecessary chelation therapy).) Plaintiff alleges that, “to circumvent these coverage exclusions, and obtain

Medicare reimbursements for his ‘alternative’ chelation therapy, between November 2008 and September 2015, Dr. Adams concocted and executed a scheme whereby he knowingly mischaracterized . . . his ‘alternative’ chelation treatment, as medically necessary treatments for patients suffering from lead poisoning and/or other types of HMP.” (Id. ¶ 17.) According to Plaintiff, in approximately 4,500 claims submitted to Medicare, Dr. Adams, by using diagnostic codes associated with lead poisoning or other types of HMP, falsely represented that those claims “were for medically necessary chelation to treat patients suffering from lead poisoning or other forms of HMP, but which are conditions that Dr. Adams has admitted that he does not diagnose or treat.” (Id. ¶ 18.) Specifically, Plaintiff claims that the chelation claims that Defendants submitted to Medicare from November 2005 to September 2015 were

false, as provided in the FCA because: (1) the claims “were for chelation therapy that was not medically necessary” (id. ¶ 19a); (2) the claims stated that the “patients suffered from the ‘toxic effects’ of lead, mercury and arsenic, even though Dr. Adams has admitted that he does not treat patients for heavy metal toxicity” (id. ¶ 19b); (3) the claims “involved ‘alternative’ and/or ‘experimental’ chelation therapy for conditions that are excluded from Medicare coverage pursuant to NDC 20.11” (id. ¶ 19c); and (4) the claims “were for indications that were not approved by the FDA, and were therefore not covered by Medicare” (id. ¶ 19d).<sup>3</sup> Plaintiff provides examples of claims submitted by Dr. Adams that included false ICD-9 codes and other false information. (Id. ¶¶ 162, 166, 171-72, 182-84.) Plaintiff also alleges that Dr.

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<sup>3</sup> Paragraphs 160 and 161 contain similar allegations. (Compl. ¶¶ 160-61.)

Adams submitted claims for chelation treatments that were not medically indicated or necessary, but he falsely stated that the patients were suffering from HMP and that the chelation treatments were medically necessary, even though the treatments were for alternative treatment. (Id. ¶¶ 174-182.)

Plaintiff alleges that Defendants submitted those claims with knowledge of their falsity, meaning that “Defendants either had actual knowledge that, or acted in deliberate ignorance or reckless disregard of the falsity of the claims.” (Compl. ¶ 20 (emphasis omitted); id. ¶ 189 (same).) Specifically, Plaintiff contends that: (1) Defendants knowingly submitted claims that were not medically necessary and that were associated with alternative, integrative, or experimental treatments that were excluded from Medicare coverage (id. ¶ 190); (2) Defendants knowingly submitted claims to the

Government using ICD-9 codes indicating that the claims were associated with lead poisoning or other forms of HMP, even though Defendants did not treat lead poisoning or HMP (id. ¶ 191).) Indeed, approximately \$1.2 million of the chelation-related claims that Defendants submitted to Medicare between November 2008 and September 2005 contain diagnoses associated with lead poisoning. (Id. ¶ 68.)

### **III. Procedural Background**

On August 27, 2018, Plaintiff filed this lawsuit. (Docket Entry No. 1.) Plaintiff asserted a number of claims, including: (1) in Count I, a claim for violations of the FCA, 31 U.S.C. § 3729(a)(1)(A), based on the submission of false claims for payment (Compl. ¶¶ 192-95); (2) in Count II, a claim for violations of the FCA, 31 U.S.C. § 3729(a)(1)(B), based on the making of false records and statements used to submit false claims for payment to Medicare (id. ¶¶ 196-200); (3) in

Count III, a claim for payment by mistake of fact (id. ¶¶ 201-03); and (4) in Count IV, a claim for unjust enrichment (id. ¶¶ 204-07).

On November 28, 2018, Defendants filed their Motion to Dismiss. (Mot. Dismiss (Docket Entry No. 13).) The briefing process for that Motion is complete, and the Court finds that the matter is ripe for resolution.

#### **IV. Discussion**

##### **A. FCA Claims**

Defendants moved to dismiss Plaintiff's FCA claims, arguing that the Complaint does not allege sufficiently that Dr. Adams knowingly submitted false claims in violation of the FCA because: (1) the Complaint fails to allege adequately that Dr. Adams' claims for chelation treatment are false; (2) alleged violations of sub-regulatory guidance do not provide sufficient bases for FCA liability; and (3) the

Complaint does not allege scienter. The Court first sets forth general standards governing FCA claims, and then addresses Defendants' arguments in turn.

### **1. General Standards Governing FCA Claims**

31 U.S.C. § 3729(a)(1)(A) provides for liability for “any person who . . . knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval.” 31 U.S.C. § 3729(a)(1)(A). 31 U.S.C. § 3729(a)(1)(B), in turn, provides for liability for “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). These claims are known respectively as presentment claims and use claims, and they have different elements. United States ex rel. Bibby v. Wells Fargo Bank, N.A., 906 F. Supp. 2d 1288, 1298 (N.D. Ga. 2012).

“To allege a presentment violation under 31 U.S.C. § 3729(a)(1), a [plaintiff] must plead: (1) a false or fraudulent claim; (2) which was presented, or caused to be presented, by the defendant to the United States for payment or approval; (3) with knowledge that the claim was false.” Bibby, 906 F. Supp. 2d at 1298 (internal quotation marks and citation omitted).

To plead an FCA violation based on the use of a false document under § 3729(a)(2), a plaintiff “must allege: (1) the defendant made a false record or statement for the purpose of getting a false claim paid or approved by the government; and (2) the defendant’s false record or statement caused the government to actually pay a false claim, either to the defendant itself, or to a third party.” Bibby, 906 F. Supp. 2d at 1298 (internal quotation marks and citation omitted). This type of claim “does not demand proof that the defendant

presented or caused to be presented a false claim to the government or that the defendant's false record or statement was ever submitted to the government." Bibby, 906 F. Supp. 2d at 1301 (internal quotation marks and citation omitted). Instead, "to state a use of false documents claim under the FCA[,] a Plaintiff must plead that a defendant made a false record or statement for the purpose of getting a false claim paid or approved by the government and that the government did, as a result, pay or approve a claim to the defendant or a third party." Bibby, 906 F. Supp. 2d at 1301 (internal quotation marks and citation omitted); see also United States ex rel. Ramsey-Ledesma v. Censeo Health, L.L.C., Civil Action No. 3:14-CV-00118-M, 2016 WL 5661644, at \*10 (N.D. Tex. Sept. 30, 2016) ("The creation of a false record, when it is made with the requisite intent,

satisfies the statute. There is no additional presentment requirement.” (citations omitted)).

In this Circuit, a party must plead an FCA violation with particularity under Rule 9(b). United States ex rel. Clausen v. Lab. Corp. of Am., Inc., 290 F.3d 1301, 1308-09 (11th Cir. 2002). To satisfy Rule 9(b), a complaint must set forth facts concerning the who, what, when, where, and how of the fraud. Corsello v. Lincare, Inc., 428 F.3d 1008, 1012 (11th Cir. 2005). Rule 9(b)’s purpose “is to alert defendants to the precise misconduct with which they are charged and protect defendants against spurious charges.” United States ex rel. Matheny v. Medco Health Solutions, Inc., 671 F.3d 1217, 1222 (11th Cir. 2012) (internal quotation marks, alterations, and citation omitted). Importantly, however, in an FCA action, “Rule 8’s pleading standard is supplemented but not

supplanted by [Rule] 9(b).” Urquilla-Diaz v. Kaplan Univ., 780 F.3d 1039, 1051 (11th Cir. 2015).

**2. Whether the Complaint Adequately Alleges that the Chelation Claims Were False**

Defendants first argue that the Complaint fails to allege adequately that the chelation therapy claims were false, noting that Plaintiff’s allegations rest on differences of medical opinion about chelation therapy, which cannot be false. (Br. Supp. Mot. Dismiss (Docket Entry No. 13) at 12-19).) Some courts have concluded that “[e]xpressions of opinion, scientific judgments, or statements as to conclusions about which reasonable minds may differ cannot be false.” United States ex rel. Jones v. Brigham & Women’s Hosp., 678 F.3d 72, 87 (1st Cir. 2012); see also United States ex rel. Hill v. Univ. of Med. & Dentistry of N.J., 448 F. App’x 314 (3d Cir. 2011) (noting that FCA liability would not attach

“[b]ecause [e]xpressions of opinion, scientific judgments or statements as to conclusions which reasonable minds may differ cannot be false” (second alteration in original) (internal quotation marks and citation omitted)); United States ex rel. Riley v. St. Luke’s Episcopal Hosp., 355 F.3d 370, 376 (5th Cir. 2004) (“The district court concluded . . . that expressions of opinion or scientific judgments about which reasonable minds may differ cannot be false. We agree in principle with the district court and accept that the FCA requires a statement known to be false, which means a lie is actionable but not an error.”); United States v. AseraCare, Inc., 176 F. Supp. 3d 1282, 1285 (N.D. Ala. 1282) (“When two or more medical experts look at the same medical records and reach different conclusions about whether those medical records support the certifying physicians’ [opinions as to hospice eligibility], all that exists is a difference of opinion. This

difference of opinion among experts regarding the patients' hospice eligibility alone is not enough to prove falsity, and the Government has failed to point the court to any objective evidence of falsity." (emphasis omitted)). Other courts have disagreed. See United States ex rel. Polukoff v. St. Mark's Hosp., 895 F.3d 730, 742 (10th Cir. 2018) ("It is possible for a medical judgment to be 'false or fraudulent' as proscribed by the FCA."); United States v. Paulus, 894 F.3d 267, 275 (6th Cir. 2018) ("[O]pinions are not, and have never been, completely insulated from scrutiny. At the very least, opinions may trigger liability for fraud when they are not honestly held by their maker, or when the speaker knows of facts that are fundamentally incompatible with his opinion."). Indeed, the United States Court of Appeals for the Tenth Circuit held "that a doctor's certification to the government that a procedure is 'reasonable' and 'necessary' is 'false'

under the FCA if the procedure was not reasonable and necessary under the government's definition of the phrase." Polukoff, 895 F.3d at 743.

For purposes of this Order, the Court agrees with those courts that have concluded that a physician's subjective medical opinions or judgments can be false for purposes of the FCA. Defendants therefore are not entitled to dismissal based on this argument.

Further, most of the cases that Defendants cite involve decisions on summary judgment. Brigham & Women's Hosp., 678 F.3d at 87; United States ex rel. Wall v. Vista Hospice Care, Inc., No. 3:07-CV-00604-M, 2016 WL 3449833, at \*16-19 (N.D. Tex. June 20, 2016); AseraCare, Inc., 176 F. Supp. 3d at 1284. In contrast, courts have noted that determinations as to medical necessity or reasonable interpretations of Medicare guidance are inappropriate at the

motion to dismiss stage. See United States v. Snap Diagnostics, LLC, No. 1:14-CV-3988, 2018 WL 2689270, at \*3 (N.D. Ill. June 5, 2018) (“Defendants’ arguments about a reasonable interpretation of the Medicare Guidance and disagreements about medical necessity are inappropriate at this stage of litigation. Each of these arguments asks the Court to make a factual determination at the motion to dismiss stage, which the Court cannot do.”); United States ex rel. Groat v. Boston Heart Diagnostics Corp., 255 F. Supp. 3d 13, 28 (D.D.C. 2017) (noting, in connection with a motion to dismiss, that “the Court cannot determine that the relator’s allegations regarding medical necessity necessarily involve a difference of clinical judgment because to do so would require the Court to weigh the evidence, which is inappropriate at this stage of the litigation”). The Court agrees with those courts, and it declines to dismiss Plaintiff’s

FCA claims based on Defendants' contention that the claims involve a difference of medical judgment or opinion.

Defendants' "opinion" argument fails even at the motion to dismiss stage. Plaintiff's Complaint alleges that the medical consensus associated with chelation therapy specifies that this therapy should be administered only to patients with BLLs in excess of 50 or 80 mcg/dL, and that Dr. Adams chelated patients who had much lower BLLs and who were not clinically indicated for EDTA chelation therapy. (Compl. ¶¶ 93-99, 174-85.) Plaintiff's Complaint also alleges that the medical consensus is that chelation therapy has not been found to be appropriate or medically necessary to treat the conditions for which Dr. Adams administered EDTA. (*Id.* ¶¶ 74-76, 93-99.) Dr. Adams cannot avoid those allegations simply by arguing that, in his own view, the treatments he administered were medically necessary. See United States

ex rel. Ryan v. Lederman, No. 04-CV-2483, 2014 WL 1910096, at \*6 (E.D.N.Y. May 13, 2014) (“It is up to HHS and its designees . . . to decide which types of treatment will be covered. As one court put it in denying a defendant’s motion to dismiss a [FCA] case, [if] physician determinations of reasonableness and necessity controlled claim payment, there would be no need for a claim reimbursement process at all.” (third alteration in original) (internal quotation marks and citation omitted)). Instead, the allegations, viewed in the light most favorable to Plaintiff, indicate that Dr. Adams’ use of EDTA for chelation therapy was not medically necessary or appropriate.

Moreover, Plaintiff alleged that Defendants presented claims with diagnosis codes that were unsupported, including codes for HMP/lead poisoning, but that the patients for whom the claims were submitted were not diagnosed with, or

treated for, lead poisoning or HMP. (Compl. ¶¶ 6-8, 147-49, 160-62.) Plaintiff provided several examples and dates of such claims. (Id. ¶¶ 6-8, 17-19, 93-99, 160-62, 174-85.) This case is therefore distinguishable from AseraCare, on which Defendants rely. See Graves v. Plaza Med. Ctrs. Corp., 276 F. Supp. 3d 1335, 1341 (S.D. Fla. 2017) (distinguishing AseraCare where “the defendants have admitted that many of the challenged codes are unsupported and that the patient did not have the coded condition, which means there are no conflicting views of physicians at all, and there are material disputes of fact regarding whether the defendants exercised clinical judgment at all” (internal quotation marks and citation omitted)). Indeed, “proof of an objective falsehood is not the only means of establishing an FCA claim.” United States v. Robinson, Civil No. 13-cv-27-GFVT, 2015 WL 1479396, at \*5 (E.D. Ky. Mar. 31, 2015).

“[E]ven if the question of whether [Defendants’] services were necessary involves some measure of a subjective determination on [Dr. Adams’] part, if [Plaintiff] can show that [Defendants] violated [their] continuing duty to comply with the regulations on which payment is conditioned, or that [they] engaged in upcoding [their] services, such falsity is sufficient for an FCA claim.” Robinson, 2015 WL 1479396, at \*5 (internal quotation marks and citations omitted). Here, Plaintiff has alleged that Defendants submitted claims that contained false diagnoses and that misrepresented that Defendants administered EDTA to treat patients diagnosed with, and suffering from, HMP or lead poisoning. Under those circumstances, Defendants’ opinion argument fails.

In sum, Defendants’ “difference in medical judgment” argument does not warrant dismissing Plaintiff’s FCA claims.

The Court therefore denies this portion of Defendant's Motion to Dismiss.

**2. Whether NCDs and Subregulatory Guidance Provide Sufficient Basis for FCA Liability**

Defendants next argue that Plaintiff failed to allege that the claims Defendants submitted were not reasonable and necessary because Plaintiff "failed to identify any binding law or regulation that prohibits Dr. Adams from submitting claims for chelation therapy." (Br. Supp. Mot. Dismiss at 19.) According to Defendants, Plaintiff simply relies on the CMS Program Manual and on a 2003 National Coverage Determination, which are non-binding. (Id. at 19-20.) Defendants further argue that internal Department of Justice ("DOJ") policies "direct DOJ attorneys to refrain from filing civil cases based on sub-regulatory guidance." (Id. at 20.)

All of Defendants' arguments fail. "An NCD is a determination by the Secretary of whether a particular item or service is covered nationally under Medicare." 42 C.F.R. § 405.1060. The United States Court of Appeals for the Third Circuit explained:

The Secretary of Health and Human Services decides "whether a particular medical service is 'reasonable and necessary' . . . by promulgating a generally applicable rule or by allowing individual adjudication." Heckler v. Ringer, 466 U.S. 602, 617, 104 S. Ct. 2013, 80 L.Ed.2d 622 (1984) (emphasis added). The *former* course involves a "national coverage determination" that announces "whether or not a particular item or service is covered nationally." 42 U.S.C. § 1395ff(f)(1)(B). In the absence of a national coverage determination, local Medicare contractors may issue a "local coverage determination" that announces "whether or not a particular item or service is covered" by that contractor. Id. § 1395ff(f)(2)(B).

Polukoff, 895 F.3d at 735 (alteration and emphasis in original). "NCDs are considered substantive rules, which carry the force of law." Advanced Diabetes

Treatment Ctrs., L.L.C. v. Sebelius, Case No.: 09-61698-ZLOCH/GOODMAN, 2011 WL 13268857, at \*4 (S.D. Fla. Apr. 7, 2011). Defendants thus cannot avoid liability based on their argument that NCDs are non-binding.

Here, Plaintiff has alleged that Defendants presented false claims because they sought reimbursement for experimental chelation therapy that was excluded from Medicare coverage by NCD 20.22. Plaintiff alleged that NCD 20.22 provided 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.” (Compl. ¶¶ 113-17.) Plaintiff further alleged that the only indicated use for EDTA on the FDA-approved label was the treatment of lead poisoning. (Id. ¶¶ 113, 147-

48.) Plaintiff alleged that Defendants submitted claims for various conditions other than lead poisoning, and it provided detailed examples of such claims. (Id. ¶¶ 113, 123-26, 147-48, 166, 171-72.) Under those circumstances, the Court finds that Plaintiff adequately alleged that Defendants submitted false claims by submitting claims to Medicare in contravention of NCD 20.22.

“LCDs, like agency interpretations contained in policy statements, manuals, and enforcement guidelines, are not entitled to the force of law.” Advanced Diabetes Treatment Ctrs., L.L.C., 2011 WL 13268857, at \*6 (internal quotation marks and citation omitted). Although LCDs are not binding on courts, they are entitled to substantial deference where they apply. Id.; see also Lederman, 2014 WL 1910096, at \*4 (noting that LCDs could be conclusive as to matters that they addressed). Thus, contrary to Defendants’ arguments,

claims submitted in contravention of an LCD may still be false for purposes of the FCA.

Pronouncements in manuals, “which do not have the force of law, are entitled to less deference than an interpretation arrived at after a formal adjudication or notice-and-comment rulemaking.” Cnty. Hosp. of Monterey Peninsula v. Thompson, 323 F.3d 782, 791 (9th Cir. 2003). The weight to be given such pronouncements depends on “those factors which give it power to persuade, if lacking power to control.” Id. at 799 (internal quotation marks and citation omitted). Courts have imposed FCA liability based on violations of Medicare program manuals. See United States v. Mount Sinai Hosp., 256 F. Supp. 3d 443, 452 (S.D.N.Y. 2017) (“[T]here have been numerous cases imposing FCA liability, and even criminal false claims liability, based on violations of Medicare manual provisions.”); In re

Cardiac Devices Qui Tam Litig., 221 F.R.D. 318, 351-52 (D. Conn. 2004) (same) (collecting cases). For purposes of the instant Motion, the Court finds that Plaintiff can state an FCA claim based on an alleged violation of the Medicare Program Integrity Manual.<sup>4</sup> Absent further information, the Court cannot conclude that the DOJ memorandum cited by Defendants precludes such claims. See Memorandum on Limiting Use of Agency Guidance Documents in Affirmative Civil Enforcement Cases from Rachel Brand, Associate Attorney General, to Heads of Civil Litigating Components United States Attorneys (Jan. 25, 2018) at 2 (stating that the memorandum “is not intended to, does not, and may not be

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<sup>4</sup> Plaintiff explained that its claims arise from Defendants’ violation of 41 U.S.C. § 1395y(a)(1)(A)’s reasonable and necessary requirement. (Resp. Mot. Dismiss (Docket Entry No. 23) at 16-17 n.9.) The Government further noted that it cited the Medicare Program Integrity Manual as support for its contention that Defendants’ claims were not reasonable and necessary, as defined by Medicare. (Id.)

relied upon to, create any rights, substantive or procedural, enforceable at law by any party in any matter civil or criminal”) (available at <https://www.justice.gov/file/1028756/download>). Defendant thus is not entitled to dismissal of Plaintiff’s FCA claims based on these arguments.

### **3. Whether Plaintiff Adequately Pleaded Scier**

Next, Defendants argue that Plaintiff failed to plead scier. (Br. Supp. Mot. Dismiss at 21-25.) The FCA defines the terms “knowing” and “knowingly” as meaning that a person “has actual knowledge of the information,” “acts in deliberate ignorance of the truth or falsity of the information,” or “acts in reckless disregard of the truth or falsity of the information.” 31 U.S.C. § 3729(b)(1)(A). Importantly, those terms “require no proof of specific intent to defraud.” 31

U.S.C. § 3729(b)(1)(B). The statute's language, however, "makes plain that liability does not attach to innocent mistakes or simple negligence." Urquilla-Diaz, 780 F.3d at 1058.

For purposes of the FCA, "[a]ctual knowledge requires subjective awareness of the falsity of the claim, record, or statement." Graves, 276 F. Supp. 3d at 1343 (internal quotation marks and citation omitted). Under the reckless disregard standard, "[l]iability attaches to [o]nly those who act in gross negligence—those who fail to make such inquiry as would be reasonable and prudent to conduct under the circumstances." Urquilla-Diaz, 780 F.3d at 1058 (second alteration in original) (internal quotation marks and citation omitted). "Congress did not intend to turn the [FCA], a law designed to punish and deter fraud, into a vehicle either punish[ing] honest mistakes or incorrect claims submitted

through mere negligence or imposing a burdensome obligation on government contractors rather than a limited duty to inquire.” Id. (second alteration in original) (internal quotation marks and citations omitted). Reckless disregard instead is “akin to an extension of gross negligence or an extreme version of ordinary negligence.” Id. (internal quotation marks and citation omitted). Finally, for purposes of the FCA, “[d]eliberate ignorance requires an even higher showing and plainly demands even more culpability than that needed to constitute reckless disregard.” Graves, 276 F. Supp. 3d at 1343 (internal quotation marks and citation omitted).

With all due respect to Defendants, the Complaint, at a minimum, contains sufficient allegations to allege scienter based on reckless indifference or deliberate ignorance. Plaintiff’s Complaint, viewed in the light most favorable to

Plaintiff, alleges that Defendants tendered false claims with knowledge that the claims were false. (Compl. ¶¶ 20, 189-91, 193, 197.) Importantly, Plaintiff need not plead scienter with particularity. Bibby, 906 F. Supp. 2d at 1295. Plaintiff's Complaint, taken as a whole, adequately alleges facts showing that Defendants had actual knowledge of the NCD and Medicare policies at issue, and further alleged that Defendants used EDTA chelation in contravention to the medical consensus concerning HMP and lead poisoning. (Compl. ¶¶ 17, 19-20, 45-47, 57-63, 155, 158, 168, 190, 193.) Plaintiff also alleged that Dr. Adams knew that the claims for EDTA treatment that he submitted to Medicare were for patients who were not suffering from lead poisoning, and that Dr. Adams testified that he does not treat lead poisoning. (Id. ¶¶ 8, 17-18, 147-62, 166, 171, 181-84.)

Those allegations, viewed in the light most favorable to Plaintiff, are enough to plead scienter.

In sum, Plaintiff's Complaint adequately alleges scienter. The Court therefore denies this portion of Defendants' Motion to Dismiss.

#### **4. Plaintiff Adequately Alleged Falsity**

The Court also finds that Plaintiff adequately alleged that the claims Defendants presented for payment were factually false. Taking Plaintiff's allegations as true, as the Court must, Plaintiff has alleged that Defendants presented claims with diagnosis codes that were unsupported, including codes for HMP/lead poisoning, but that the patients for whom the claims were submitted were not diagnosed with, or treated for, lead poisoning or HMP. (Compl. ¶¶ 6-8, 147-49, 160-62.) Plaintiff provided several examples and dates of such claims. (Id. ¶¶ 6-8, 17-19, 93-99, 160-62, 174-85.)

Here, Plaintiff has alleged that Defendants submitted claims that contained false diagnoses and that misrepresented that Defendants administered EDTA to treat patients diagnosed with, and suffering from, HMP or lead poisoning. Under those circumstances, Plaintiff has adequately alleged that Defendants' claims are factually false. See United States v. Rite Aid Corp., 2018 WL 4214887, at \*3 (E.D. Cal. Sept. 5, 2018) (finding that the Government adequately alleged that the defendant submitted false claims where the Government alleged that the defendant submitted codes with false billing codes).

Further, taking Plaintiff's allegations as true, Plaintiff alleged that Defendants ordered chelation with EDTA knowing that this course of treatment was unnecessary. Under those circumstances, Plaintiff has adequately alleged falsity. St. Luke's Episcopal Hosp., 355 F.3d 370, 376-77.

Defendants therefore are not entitled to dismissal of Plaintiff's FCA claims.

**B. Unjust Enrichment and Payment by Mistake**

Defendants also seek to dismiss Plaintiff's claims for unjust enrichment and payment by mistake. (Br. Supp. Mot. Dismiss at 26-30.) As an initial matter, even though such claims may be duplicative of Plaintiff's FCA claims, Plaintiff can plead its claims in the alternative. United States v. Medica-Rents Co., 285 F. Supp. 2d 742, 776 (N.D. Tex. 2003), aff'd sub nom. United States v. Medica Rents Co., No. 03-11297, 2008 WL 3867307 (5th Cir. Aug. 19, 2008); see also United States v. Rite Aid Corp., No. 2:12-CV-01699-KJM-EFB, 2018 WL 4214887, at \*8 (E.D. Cal. Sept. 5, 2018) (noting that the Government could plead unjust enrichment and payment by mistake claims in the alternative to its FCA claims); United States v. Diagnostic Physicians Grp., P.C.,

Civil Action No. 11-0364-KD-B, 2014WL 2155363, at \*10 n.2 (S.D. Ala. May 22, 2014) (“In a False Claims Act case, the government may generally plead theories in the alternative, even if different claims seek relief for the same injury, so long as there is ultimately only one recovery.”). Dismissal therefore is not warranted based on Defendants’ argument that these claims are derivative of the FCA claims.<sup>5</sup>

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<sup>5</sup> Defendants cite United States v. Aegis Therapies, Inc., 2015 WL 1541491 (S.D. Ga. Mar. 31, 2015), to support their argument that the unjust enrichment and payment by mistake claims are derivative of the FCA claims. In that case, the court granted summary judgment for the defendant on unjust enrichment and payment by mistake claims, noting that “[t]hese claims are purely derivative of the FCA claims.” 2015 WL 1541491, at \*14. The Court finds that Aegis Therapies, Inc. is distinguishable from this action. See United States v. Crumb, Civil Action 15-0644-WS-N, 2016 WL 4480690, at \*17 n.26 (S.D. Ala. Aug. 23, 2016) (“Nothing in *Aegis Therapies* can be read as barring the Government from pursuing common-law claims on theories such as unjust enrichment and payment by mistake, side by side with FCA causes of action. Indeed, *Aegis Therapies* cannot reasonably be read as mandating dismissal of unjust enrichment and payment by mistake claims whenever FCA claims are also pleaded.”).

The Court also is not persuaded that dismissal of the unjust enrichment and payment by mistake claims is required based on Plaintiff's alleged failure to specify whether it asserts the claims under federal or state law.<sup>6</sup> Some courts have applied a federal common law standard to unjust enrichment and payment by mistake claims asserted by the Government in FCA cases. Diagnostic Physicians Grp.,

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<sup>6</sup> Defendants rely on United States of America ex rel. Saint Joseph's Hospital, Inc. v. United Distributors, Inc., 918 F. Supp. 2d 1306 (S.D. Ga. Jan. 11, 2013), to support dismissal of Plaintiff's unjust enrichment and payment by mistake claims. That case granted a motion to dismiss "[b]ecause it is unclear from the complaint whether the Government's claims of unjust enrichment and payment by mistake were pled under federal common or Georgia state law." Id. at 1316. As an initial matter, that case is not binding on this Court. In any event, the court in that case permitted the Government to submit an amended complaint to attempt to re-plead those claims, although it questioned whether a valid unjust enrichment claim could exist. Id. at 1316 & n.10. The case does not stand for the proposition that failure to specify whether unjust enrichment and payment by mistake claims are pleaded under federal or state law justifies dismissal of the claims with prejudice.

P.C., 2014 WL 2155363, at \*10; United States v. Halifax Hosp. Med. Ctr., No. 6:09-CV-1002-ORL-31, 2013 WL 6017329, at \*7 (M.D. Fla. Nov. 13, 2013); United States v. Rogan, 459 F. Supp. 2d 692, 728 (N.D. Ill. 2006). The Court finds those case persuasive, and it applies federal common law to the unjust enrichment and payment by mistake claims for purposes of this Order.

**1. Whether the Complaint States an Unjust Enrichment Claim**

Unjust enrichment applies in “situations where there is no legal contract, but where the person sought to be charged is in possession of funds which in good conscience and justice should not be retained, but should be delivered to the rightful owner.” Medica-Rents Co., 285 F. Supp. 2d at 777 (internal quotation marks and citation omitted). The elements of a federal common law unjust enrichment claim

are: “(1) the Government had a reasonable expectation of payment, (2) [the defendant] should reasonably have expected to pay, or (3) society’s reasonable expectations of person and property would be defeated by nonpayment.” Rogan, 459 F. Supp. 2d at 728 (internal quotation marks and citation omitted).<sup>7</sup>

Here, Defendants contend that “[t]he government cannot be allowed to force a failed FCA claim to become an unjust enrichment claim based on allegations that exist only in the FCA context.” (Br. Supp. Mot. Dismiss at 29.) The Court rejects this argument for the reasons discussed above.

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<sup>7</sup> Unjust enrichment claims arising under Georgia law have similar elements. See Clark v. Aaron’s, Inc., 914 F. Supp. 2d 1301, 1309 (N.D. Ga. 2012) (noting that the essential elements of an unjust enrichment claim arising under Georgia law “are that (1) a benefit has been conferred, (2) compensation has not been given for receipt of the benefit, and (3) the failure to so compensate would be unjust”).

Defendants also contend that Plaintiff's unjust enrichment claim fails "[b]ecause Dr. Adams treated the patients according to his medical judgment and submitted claims for services that were actually rendered." (Br. Supp. Mot. Dismiss at 29.) To the extent that Defendants rely on Dr. Adams' "medical judgment," the Court finds that this argument does not warrant dismissal for the reasons discussed supra Part III.A.1. Moreover, Plaintiff's allegations, viewed in the light most favorable to Plaintiff, indicate that Dr. Adams billed Medicare for claims that were not reasonable and necessary, and that Medicare paid those claims. Those allegations are sufficient to state an unjust enrichment claim at this stage of the litigation, and the Court therefore denies the Motion to Dismiss as to the unjust enrichment claim.

## **2. Whether the Complaint States a Viable Payment by Mistake Claim**

Under the doctrine of payment by mistake, “[t]he Government by appropriate action can recover funds which its agents have wrongfully, erroneously, or illegally paid.” Medica-Rents Co., 285 F. Supp. 2d at 776 (internal quotation marks and citation omitted). “No statute is necessary to authorize the United States to sue in such a case[; t]he right to sue is independent of statute.” Medica-Rents Co., 285 F. Supp. 2d at 776 (alteration in original) (internal quotation marks and citation omitted); see also Diagnostic Physicians Grp., P.C., 2014 WL 3155363, at \*10 (“The claim is available to the United States and is independent of statute.” (internal quotation marks and citation omitted)). For such a claim, “the government is entitled to reimbursement for payments . . . where it is shown: (1) payments were made (2) under the

belief that they were properly owed; (3) that belief being erroneously formed; and (4) the mistaken belief was material to the decision to pay.” Medica-Rents Co., 285 F. Supp. 2d at 776 (alteration in original) (internal quotation marks and citation omitted); see also Halifax Hosp. Med. Ctr., 2013 WL 6017329, at \*7 (“To prevail on a claim of payment by mistake, the Government must show that it made payments under an erroneous belief which was material to the decision to pay.” (internal quotation marks and citation omitted)); Rogan, 459 F. Supp. 2d at 728 (“If agents of the federal government, acting on behalf of the United States, paid claims submitted by Edgewater as a result of Rogan’s actions under an erroneous belief which was material to the decision to pay, [the Government] is entitled to recover the payments under a mistake-of-fact theory.” (alteration in original) (internal quotation marks and citation omitted)). The

Government, however, need not plead “that the defendants knew that the payments were mistaken.” Medica-Rents Co., 285 F. Supp. 2d at 776.<sup>8</sup>

Here, Plaintiff has alleged that, based on Defendants’ representations, Medicare paid Defendants’ claims under the belief that the claims were for treatment necessary to treat lead poisoning, although the patients at issue did not actually suffer from lead poisoning, and the claims were for treatments that would not have been reimbursable under Medicare. Those allegations state a viable claim for payment by mistake. The Court therefore denies the Motion to Dismiss as to Plaintiff’s payment by mistake claim.

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<sup>8</sup> A payment by mistake claim under Georgia law prohibits recovery of money “unless the circumstances are such that the person to whom it was paid can not in good conscience return it.” Time Ins. Co. v. Fulton-DeKalb Hosp. Auth., 211 Ga. App. 34, 35, 438 S.E.2d 149, 151 (1993) (internal quotation marks and citation omitted).

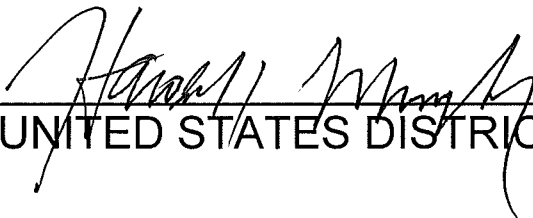
### **C. Summary**

In sum, Plaintiff's Complaint states viable claims for relief. The Court therefore denies the Motion to Dismiss.

### **V. Conclusion**

ACCORDINGLY, the Court **DENIES** Defendants' Motion to Dismiss [13].

IT IS SO ORDERED, this the 8<sup>th</sup> day of March, 2019.

  
UNITED STATES DISTRICT JUDGE