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CLERK U.S. DISTRICT COURT
NORTHERN DISTRICT OF OHIO
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UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO

UNITED STATES OF AMERICA ex rel. SAM GHOUBRIAL, M.D. 3454 SKYE RIDGE DRIVE RICHFIELD, OH 44286 BRINGING THIS ACTION ON BEHALF OF THE UNITED STATES OF AMERICA Plaintiff and Relator V THE CLEVELAND CLINIC FOUNDATION d.b.a. THE CLEVELAND CLINIC HEALTH SYSTEM, Defendant.	:	Civil Action No. 1:14 CV 487 Judge JUDGE WELLS Filed Under Seal Pursuant to 31 U.S.C. 3720(b)(2) and MAG. JUDGE McHARGH DO NOT SERVE OR PUT ON PACER

<u>COMPLAINT FOR VIOLATIONS OF THE FALSE CLAIMS ACT</u>

I. INTRODUCTION:

1. *Qui Tam* Relator, Sam Ghoubrial, M.D., brings this action on behalf of the United States for treble damages and civil penalties arising from the Defendant's conduct in violation of the United States Civil False Claims Act, 31 U.S.C. §3729-3733. The violations arise out of Defendant's false claims for reimbursement, unnecessary diagnostic testing and unnecessary interdepartmental referrals. These claims are submitted to various federally-funded healthcare programs, including Medicare, Medicaid, CHAMPUS, TRICARE, the Veterans Administration, as well as others.

2. This complaint details several areas of illegal conduct by Defendant which caused and continues to cause the submission to federally-funded healthcare programs of thousands of false claims in violation of the FCA. These claims revolve around improper and excessive billing for numerous referrals, tests and procedures, many of which have already been done.

These diagnostic tests include, but are not limited to, repeated stress tests, echocardiograms, catheterizations, MRI, CT, biopsies, and many others.

3. Each claim for reimbursement submitted to federally-funded healthcare program which resulted from an instance of any of the conduct described in the paragraph above constitutes a false claim.

II. JURISDICTION AND VENUE

4. Subject-matter jurisdiction lies pursuant to 31 U.S.C. §3732(a) and 28 U.S.C. §1345.

5. The acts proscribed by 31 U.S.C. §3729(a) and complained of herein occurred within the Northern District of Ohio, and Defendant does business therein. Venue thus lies under 31 U.S.C. §3732(a).

6. The facts and circumstances which give rise to Defendant's violations of the False Claims Act have not been publicly disclosed as that term is defined in the False Claims Act.

7. Relator is the original source of the information upon which this complaint is based, as that phrase is used in the False Claims Act.

8. The allegations set out herein have been disclosed to the United States prior to the filing of this Complaint.

III. PARTIES

A. Defendant

9. Defendant, The Cleveland Clinic Foundation d.b.a. Cleveland Clinic Health Systems (hereinafter "Cleveland Clinic") is a nonprofit, multi-specialty academic medical center located in Cleveland, Ohio.

10. The Cleveland Clinic includes within its health system the Main Hospital Campus; 17 Family Health Centers serving the Cleveland suburbs; and nine regional hospitals serving the greater Cleveland area.

B. Plaintiff and Relators

11. The United States of America is the real party in interest.

12. Sam Ghoubrial, M.D. is a medical doctor who was licensed to practice medicine in the State of Ohio. Dr. Ghoubrial was board certified and recertified by the American Board of Internal Medicine.

IV. FEDERAL RULE OF CIVIL PROCEDURE 9(b) ALLEGATIONS

13. Much of the documentary evidence necessary to prove the allegations contained herein is in the exclusive possession of either the Defendant or the United States.

14. The allegations of fact in this Complaint is personally known to the Relator unless specifically identified as being made on information and belief. Each allegation made on information and belief identifies a situation in which the Relator has, based upon his knowledge and experience, a reasoned factual basis to make the allegation, but lacks complete details.

V. LEGAL BACKGROUND

15. The Medicare program was created in 1965 as a part of the Social Security Act (SSA), 42 U.S.C. §1395, *et seq*. Under the authority of that Act, the Secretary of HHS administers the Medicare Program through Centers of Medicare and Medicaid Services (CMS). The Secretary also promulgates rules and regulations governing the payment of claims, 42 C.F.R., Parts 400-end.

16. The Medicare program consists of two parts. Medicare Part A authorizes the payment of federal funds for hospitalization and post hospitalization care. 42 U.S.C. §1395c,

1395i(2)(1992). Medicare Part B authorizes the payment of federal funds for medical and other health services, including without limitation physician services, supplies and services incident to physician services, laboratory services, outpatient therapy, diagnostic services, and radiology services. 42 U.S.C. §1395(k), 1395(i), 1395(s).

17. The Medicaid program was also created in 1965 as part of the Social Security Act, which authorized federal grants to States for medical assistance to low-income persons, blind, disabled, or members of families with dependent children or qualified pregnant women or children. The Medicaid program is jointly financed by the Federal and State governments. Health Care Financing Administration administers Medicaid on the federal level. Within broad Federal rules, each State decides eligible groups, types and range of services, payment levels for services, administrative and operating procedures. The state directly pay providers, with the states obtaining the federal share of the payment from accounts which draw on funds belonging to the United States Treasury. 42 C.F.R. §430.0 430.30 (1994). Various other federally funded medical coverage programs exist to help their enrollees cover the costs associated with medical care, including the Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS"), TRICARE, and the Department of Veterans Affairs, among others.

18. Medicare contracts with private companies to process claims for Medicare payment. Part A reimbursement is processed through fiscal intermediaries. Part B reimbursement is processed through Medicare carriers.

19. In order to understand this complaint, one must understand the DRG (Diagnosis Related Group) billing system. DRG is a system used to categorize hospital cases into one of approximately 467 groups. The systems classification was developed by Robert B. Fetter at the Yale School of Management and John D. Thompson at the Yale School of Public Health. The

purpose was to develop a classification system that identifies "products" that the patient receives. When a patient is admitted to the hospital, they are placed into one of these groups. The hospital receives payment according to which one of the DRG groups the patient falls into. All services provided within 72 hours of matriculation into the hospital are bundled into the DRG group and are not billing separately. DRGs are assigned by a "grouper" program based on ICD (International Classification of Diseases) diagnoses, procedures, age, sex, discharge status, and the presence of complications or comorbidities. DRGs have been used in the United States since 1982 to determine how much Medicare pays the hospital for each "product", since patients within each category are clinically similar and are expected to use the same level of hospital resources. To meet those evolving needs, the DRG system has expanded its scope.

20. In a nutshell, the DRG system is a way to classify a hospital stay into a Diagnosis Related Group (DRG) for the purpose of billing. So when a patient comes to a hospital and is admitted for an inpatient stay, all the care rendered by the institution to include surgery, diagnostic tests, therapeutic and diagnostic modalities, those will all bundled into one DRG. That DRG is then submitted to Medicare for reimbursement. If a patient is tested within 72 hours of being admitted to a hospital, all of those tests are bundled within the DRG, and the insurance company is only required to pay one bundled fee no matter how long the patient stays. The DRG code depends on the complexity of the stay.

Example: This is an example of how the DRG systems works. A patient is admitted for gallbladder surgery to have his gallbladder removed. The DRG will pay the hospital approximately $4,000.00. A second patient is admitted for a coronary artery bypass graft and is on a ventilator and dialysis. That DRG may pay the hospital approximately $35,000.00. The reason for the discrepancy in the DRG is the system was designed in such a

way as to reimburse the hospital according to the complexity of the patient. The more complex the patient is, the higher the DRG reimbursement.

VI. FACTUAL ALLEGATIONS:

21. When a patient is referred to the Cleveland Clinic from a referral source, The Cleveland Clinic will repeat tests that have been already done to confirm a diagnosis that has already been made for the purpose of financial gain. The Cleveland Clinic is very careful to do these outside the 72 hour window in order to escape the 72 hour bundling. The previous testing has been billed to Medicare, or any of the other Federal Agencies through the original provider's medical provider number. The Cleveland Clinic then bills for repeated services through their own provider number, and therefore, are able to redo the tests, generate additional referrals to doctors within their organization, redo imaging studies, redo lab work, redo diagnostic modalities prior to the therapeutic modality. The repetitive billing is not apparent to the insurer since the original provider's medical provider number is different than the Cleveland Clinic's medical provider number. The following is an illustration to make this fraud easier to understand:

Patient A is referred to The Cleveland Clinic for a heart valve repair in March of 2010. Prior to being seen, Patient A has already had a cardiology evaluation by their own cardiologist, an echocardiogram, a clinical evaluation, a laboratory evaluation, and the cardiologist has concluded that this patient needs a valve repair. The Cleveland Clinic will take the patient on March 1st and will frequently and unnecessarily repeat many or all of the following tests that have been done within the preceding six months to include another echocardiogram, another cardiac consult, another stress test, and repeated lab work. Also, they will pass the patient to their pre-surgical clearance department to obtain a surgical clearance which has already been

done by the initial referring cardiologist. The Cleveland Clinic will then frequently pass the patient on from department to department for numerous interdepartmental evaluations many of which have already been done and frequently are unnecessary. They will also perform additional tests to include CT scan, another stress test, and even a heart catheterization in some cases. They do this in order to maximize their full revenue knowing full well that any of the tests that were done prior to the 72 hours before the surgery will paid individually. So in this case of a valve repair, the DRG may be, for purpose of illustration, $35,000.00. The Cleveland Clinic supplements its income by performing another echocardiogram which may cost $500.00, a stress test which may cost $1,000.00, a comprehensive pre-admission testing which may cost another $1,000.00, a heart catheterization which may cost $7,000.00. This adds approximately, in this illustration, $10,000.00 to the patient's care. This is one example in a series of thousands. The tests are unnecessary because they have already been done by the referring physician. The patient simply does not need many of these tests before the surgery. The Cleveland Clinic will simply do these tests to increase their reimbursement at the expense of the patient. Bear in mind, the standard of care for good medical practice requires the physician to review and have knowledge of any tests that were previously conducted for the patient. However, the Cleveland Clinic will expose the patient to unnecessary radiation, unnecessary tests, and unnecessary financial hardship. Medicare, as well as the patient, is incurring the loss. This is simply one type of a fraudulent activity on behalf of The Cleveland Clinic and is the backbone of this Complaint.

22. The Cleveland Clinic itself acknowledges that unnecessary testing is both financially and clinically detrimental as per their own physicians as published in the Cleveland Clinic Journal of Medicine. The article is titled "The Role of Testing in Preoperative Evaluation". This article was published by David L. Hepner, M.D. The abstract of this article reads as

follows: "Preoperative laboratory and electrocardiographic testing should be driven by the patient's history and physical examination and the risks of the surgical procedure. A test is likely to be indicated only if it can correctly identify abnormalities and will change the diagnosis, the management plan, or the patient's outcome. Needless testing is expensive, may unnecessarily delay the operation, and puts the patient at risk for unnecessary intervention. Preoperative evaluation centers can help hospitals standardize and optimize preoperative testing while fostering more consistent regulatory documentation and appropriate coding for reimbursement.

23. In summary, The Cleveland Clinic utilizes the DRG system, but supplements its reimbursement through the implementation of a series of unnecessary consults, referrals, tests, imaging studies, and diagnostic studies. Keeping in mind, they are also very careful to make sure that these referrals are done within their own organization. They take the DRG system, which is designed to save money, and skirt it by avoiding the 72 hour window, and supplementing that with tests referenced above. They simply could have admitted the patient to the hospital, performed all the tests they needed to perform including the consultations, and then the surgery. Therefore, all of this would have been bundled and the DRG would be cost effective for the patient and the system. They would have saved a great deal of time for the patient as well as a financial hardship for the system as well as the patient. Caveat, providing many of these tests would have been necessary. The Cleveland Clinic has decided to engage in fraud through escaping the 72 hour window and running unnecessary tests and referrals under the guise of good patient care. Most of these patients, as has already been stated, have received their diagnosis prior to matriculating into the Cleveland Clinic for their surgical procedure. This, however, is not enough for the Cleveland Clinic. They simply cannot do a procedure and a

consultation. It is not financially lucrative enough to practice medicine that way. They choose to add on a systemic wholesale massive basis, tens of millions dollars, in unnecessary procedures, consults, etc. in order to maximize their reimbursement.

24. The Relator is a physician who has had occasion to refer patients to the Cleveland Clinic and has witnessed many of these events firsthand through his patients, through his friends, through his family, and as a referring practitioner. The institution was asked by the Relator why things were done in such a cumbersome, costly manner. Their replay was: "This is the way we do things."

25. This process is rampant throughout all surgical departments, and is not just limited to cardiovascular surgery but also to neurosurgery, ophthalmology, ENT, vascular surgery, and others to include cardiology.

2. Representative Examples

26. Patient X (The identity of the patient has been withheld to protect the patient's privacy) was referred to The Cleveland Clinic for a total prostatectomy. He had the diagnosis confirmed through biopsies and had been cleared for surgery. He was seen by The Cleveland Clinic Department of Urology who agreed that the patient needed a prostatectomy. Instead of simply admitting the patient and performing the prostatectomy, The Cleveland Clinic chose to have the patient first seen by the urologist, then seen by the cardiology department for stress testing, then undergo an echocardiogram, then undergo an internal medicine complete physical examination, then finally matriculate for surgery. These tests and procedures were simply unnecessary and were done for the sole purpose of padding the bill. The patient was admitted to The Cleveland Clinic, had a surgery done and was released.

27. Patient Y (The identity of the patient has been withheld to protect the patient's privacy), an elderly female who had severe mitral regurgitation,was seen and evaluated by a

board certified cardiologist. An echocardiogram was performed and she was referred to The Cleveland Clinic for mitral valve repair. She had been cleared for surgery. Instead of simply performing the surgery, they arranged for a cardiology consultation which is appropriate. The cardiologist then ordered a stress test, a heart catheterization, a CT scan, pre-admission testing, and a repeat echocardiogram. This patient had to go back and forth up to The Cleveland Clinic several times for no reason whatsoever other than to run tests that had already been performed for the sole purpose of padding their DRG. The patient then had valve repair surgery and was released. Once again, The Cleveland Clinic was very careful to run all these tests prior to the 72 hour DRG.

COUNT 1: FALSE CLAIMS ACT VIOLATIONS

28. Relator hereby incorporates and re-alleges paragraphs 1 through 27 as if fully set forth herein.

29. Defendant, by and through its agents, officers and employees, knowingly presented or caused to be presented to officers or employees of the United States false claims for payment or approval in violation of 31 U.S.C. §3729(a)(1)(A) for unnecessary, repeated diagnostic testing and, and unnecessary intra-department referrals for the sole purpose of financial gain.

30. By engaging in the conduct alleged above, the Defendant defrauded the United States of America in violation of 31 U.S.C. §3729.

31. As a result of the Defendant's systemic, long-term, and ongoing violations of 31 U.S.C. §3729, the United States has suffered damages in an amount to be determined at trial.

PRAYER FOR RELIEF

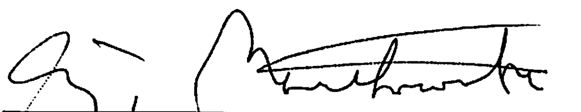
WHEREFORE, Relator, on behalf of himself and the United States, demands judgment against Defendant, as follows:

A. That this Court enter judgment against the Defendant in an amount equal to three times the amount of damages the United States government has sustained because of Defendant's actions, plus a civil penalty of $11,000.00 for each false claim, together with the costs of this action, with interest, including the cost to the United States Government for its expenses related to this action;

B. That Relator be awarded all costs incurred, including his attorney's fees;

C. That in the event the United States Government intervenes in this action, Relator be awarded twenty-five (25%) of any proceeds of the claim, and that in the event the United States Government does not intervene in this action, Relator be awarded thirty (30%) of any proceeds;

D. That the United States and Relator receive all relief, both in law and in equity, to which they are entitled.



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