Legal Document

Pennsylvania Western District Court
Case No. 1:10-cv-00245-SJM
TULLIO EMANUELE v. MEDICOR ASSOCIATES, INC. et al

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IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, *ex rel.* TULLIO EMANUELE, M.D.,

Plaintiff/ Relator,

CIVIL ACTION NO. 10-245

v.

MEDICOR ASSOCIATES, INC., FLAGSHIP CARDIAC, VASCULAR, AND THORACIC SURGERY OF ERIE, P.C., THE HAMOT MEDICAL CENTER OF THE CITY OF ERIE PENNSYLVANIA, RICHARD W. PETRELLA, M.D., ROBERT J. FERRARO, M.D., CHARLES M. FURR, M.D., TIMOTHY C. TRAGESER, M.D., and DONALD ZONE, M.D.,

Defendants.

AMENDED COMPLAINT FOR DAMAGES AND OTHER RELIEF UNDER THE FALSE CLAIMS ACT (31 U.S.C. § 3730)

INTRODUCTION

1. This is an action by *qui tam* relator Tullio Emanuele, M.D., in the name of the United States Government, to recover penalties and damages arising from defendants' submissions of false and fraudulent billings to the United States Government, pursuant to the federal False Claims Act ("FCA"), 31 U.S.C. § 3729-32, as amended.

2. From at least June 1, 2001 through at least May 31, 2005, and beyond, defendants made or caused to be made false claims and statements to Medicare to obtain reimbursement for

cardiac and vascular surgical and diagnostic procedures that were not medically necessary, that were overbilled, or otherwise improperly billed.

3. As a result of the fraudulent practices described herein, Medicare overpaid for cardiac and vascular surgical and diagnostic services for its beneficiaries. Those patients were placed at significant and unnecessary risk of harm, and substantial public dollars were wasted.

JURISDICTION AND VENUE

4. This is an action to recover damages and civil penalties on behalf of the United States of America arising out of false claims presented by defendants under the federal Medicare program. This action arises under the provisions of Title 31, U.S.C. Section 3729, et sec. popularly known as the False Claims Act ("the Act") which provides that the United States District Courts shall have exclusive jurisdiction of actions brought under the Act.

5. Section 3732(a) of the Act provides that "any action" under section 3730 may be brought in any judicial district in which a defendant can be found, resides, transacts business, or in which any conduct proscribed by section 3729 occurred. One or more of the defendants can be found, resides or transacts business in this judicial district, within the meaning of 31 U.S.C. § 3732(a).

6. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1395.

7. Under the Act, this complaint is to be filed and remain under seal for a period of at least sixty (60) days and shall not be served on defendants until the Court so orders. The government may elect to intervene and proceed with the action within sixty (60) days after it receives both the complaint and the material evidence and information in support of the complaint.

PARTIES TO THE ACTION

8. *Qui Tam* Plaintiff, Tullio Emanuele, M.D. ("Dr. Emanuele" or "Relator"), is a resident of the Commonwealth of Kentucky and brings this action on behalf of the United States of America.

9. As required under the Act, 31 U.S.C. § 3730(b)(2), Relator has provided to the Attorney General of the United States and the United States Attorney for the Western District of Pennsylvania, simultaneous with the filing of this complaint, a statement of material evidence and information related to the complaint. This disclosure statement supports the existence of the false claims submitted by the defendants.

10. Dr. Emanuele gained direct and independent knowledge of the Defendants' fraudulent submission of claims to federal health care programs for medically unnecessary surgical and diagnostic procedures and related hospital charges in his capacity as a practicing cardiologist at Medicor and Hamot Medical Center from 2001 to 2005.

11. Before filing this action, Relator personally and/or through counsel voluntarily provided all material evidence and information of the Defendants' fraudulent practices and false claims to law enforcement offices, officials and agencies responsible for the oversight and enforcement of the claims in question.

12. As of the date this action was filed, there had been no public disclosure of the allegations that are the subject of this action, to the best of Relator's knowledge. Nevertheless, if any such allegations have been the subject of a prior public disclosure, the Relator is an original source of the information on which any such allegations are based, within the meaning of 31 U.S.C. § 3730(e)(4)(A) and (B).

13. Defendant Medicor Associates Inc. ("Medicor") is a professional corporation organized under the laws of the Commonwealth of Pennsylvania, in the business of providing

cardiology services to residents in Western Pennsylvania, Western New York and Northeastern Ohio. Defendant Medicor's principal place of business is located at 120 East 2nd Street, Erie, Pa. 16507-25.

14. Defendant Flagship Cardiac, Vascular, and Thoracic Surgery of Erie, P.C. ("Flagship CVTS") is a professional corporation organized under the laws of the Commonwealth of Pennsylvania, in the business of providing cardiac, vascular and thoracic surgery services to residents in Western Pennsylvania, Western New York and Northeastern Ohio. Defendant Flagship CVTS's principal place of business is located at 120 East 2nd Street, Erie, Pa. 16507-25.

15. Defendant The Hamot Medical Center of the City of Erie, Pennsylvania D/B/A Hamot Medical Center ("Hamot") is a non-profit corporation with its principal place of business at 201 State St., Erie, PA 16550.

16. Defendant Richard W. Petrella, M.D. ("Petrella") is a resident of the Commonwealth of Pennsylvania. He is a shareholder/ employee of Medicor and engaged in the practice of cardiology at 120 East 2nd Street 2nd Floor Erie, PA 16507.

17. Defendant Robert J. Ferraro, M.D. ("Ferraro") is a resident of the Commonwealth of Pennsylvania. He is a shareholder/ employee of Medicor and engaged in the practice of cardiology at 120 East 2nd Street 2nd Floor Erie, PA 16507.

18. Defendant Charles M. Furr, M.D. ("Furr") is a resident of the Commonwealth of Pennsylvania. He is a shareholder/ employee of Medicor and engaged in the practice of cardiology at 120 East 2nd Street 2nd Floor Erie, PA 16507.

19. Defendant Timothy C. Trageser, M.D. ("Trageser") is a resident of the Commonwealth of Pennsylvania. He is a shareholder/ employee of Medicor and engaged in the

practice of cardiology at 120 East 2nd Street 2nd Floor Erie, PA 16507.

20. Defendant Donald Zone, M.D. ("Zone") is a resident of the Commonwealth of Pennsylvania. He is a shareholder/ employee of Medicor and engaged in the practice of cardiology at 120 East 2nd Street 2nd Floor Erie, PA 16507.

Background Information

21. Dr. Emanuele joined Medicor in June of 2001 and worked with the individual Defendants, and other doctors employed by Medicor, as a cardiologist at the Hamot Medical Center. Dr. Emanuele resigned from Medicor and Hamot Medical Center in May of 2005.

22. Hamot Medical Center is part of the Hamot Health Foundation, a healthcare delivery system incorporated in the Commonwealth of Pennsylvania providing medical services throughout Western Pennsylvania, Western New York and Eastern Ohio.

23. Medicor is a cardiology practice located on the main campus of Hamot Medical Center in Erie and is closely affiliated with Hamot as the exclusive provider of cardiology services at Hamot. Each of the physicians employed by Medicor have staff privileges at Hamot and regularly admit patients to Hamot. At all times relevant to this Complaint, Defendants Petrella, Ferraro, Furr, Trageser and Zone were shareholders and employees of Medicor.

24. Until it ceased providing services in July of 2008, Flagship CVTS was a vascular and thoracic surgery practice located on the main campus of Hamot Medical Center in Erie and was closely affiliated with Hamot and Medicor as the exclusive provider of vascular and thoracic surgery services at Hamot.

THE MEDICARE PROGRAM

25. In 1965, Congress enacted Title XVIII of the Social Security Act, known as the Medicare Program, to pay for the costs of certain healthcare services. Entitlement to Medicare is based on age, disability or affliction with end-stage renal disease. *See* 42 U.S.C.§§ 426, 426A.

26. HHS is responsible for the administration and supervision of the Medicare Program. CMS (formerly HCFA) is an agency of HHS and is directly responsible for the administration of the Medicare Program.

27. Part A of the Medicare Program authorizes payment for institutional care, including hospital, skilled nursing facility and home health care. *See* 42 U.S.C. §§ 1395c-1395i-4. Most hospitals, including Hamot, derive a substantial portion of their revenue from the Medicare Program.

28. Under the Medicare Program, CMS (formerly HCFA) makes payments retrospectively (after the services are rendered) to hospitals for inpatient services. Medicare enters into provider agreements with hospitals in order to establish the hospitals' eligibility to participate in the Medicare Program. However, Medicare does not prospectively contract with hospitals to provide particular services for particular patients. Any benefits derived from those services are derived solely by the patients and not by Medicare or the United States.

29. As detailed below, Hamot submitted claims both for specific services provided to individual beneficiaries and claims for general and administrative costs incurred in treating Medicare beneficiaries.

30. To assist in the administration of Medicare Part A, CMS (formerly HCFA) contracts with "fiscal intermediaries." 42 U.S.C. § 1395h. Fiscal intermediaries, typically insurance companies, are responsible for processing and paying claims and auditing cost reports.

31. Upon discharge of Medicare beneficiaries from a hospital, the hospital submits claims for interim reimbursement for items and services delivered to those beneficiaries during their hospital stays. 42 C.F.R. §§ 413.1, 413.60, 413.64. Hospitals submit patient-specific claims for interim payments on a HCFA Form UB-92 (and prior to 1992, on a HCFA Form UB-82).

32. As a prerequisite to payment by Medicare, CMS (HCFA) requires hospitals to submit annually a form HCFA-2552, more commonly known as the Hospital Cost Report. Cost Reports are the final claim that a provider submits to the fiscal intermediary for items and services rendered to Medicare beneficiaries.

33. After the end of each hospital's fiscal year, the hospital files its Hospital Cost Report with the fiscal intermediary, stating the amount of reimbursement the provider believes it is due for the year. *See* 42 U.S.C. §1395g(a); 42 C.F.R. § 413.20. *See also* 42 C.F.R. § 405.1801(b)(1). Hence, Medicare relies upon the Hospital Cost Report to determine whether the provider is entitled to more reimbursement than already received through interim payments, or whether the provider has been overpaid and must reimburse Medicare. 42 C.F.R. §§ 405.1803, 413.60 and 413.64(f)(1).

34. Hamot was, at all times relevant to this complaint, required to submit Hospital Cost Reports to its fiscal intermediary.

35. Medicare payments for inpatient hospital services are determined by the claims submitted by the provider for particular patient discharges (specifically listed on UB-92s/UB-82s) during the course of the fiscal year. On the Hospital Cost Report, this Medicare liability for inpatient services is then totaled with any other Medicare liabilities to the provider. This total determines Medicare's true liability for services rendered to Medicare beneficiaries during the

course of a fiscal year. From this sum, the payments made to the provider during the year are subtracted to determine the amount due the Medicare Program or the amount due the provider.

36. Under the rules applicable at all times relevant to this complaint, Medicare, through its fiscal intermediaries, had the right to audit the Hospital Cost Reports and financial representations made by Hamot to ensure their accuracy and preserve the integrity of the Medicare Trust Funds. This right includes the right to make retroactive adjustments to Hospital Cost Reports previously submitted by a provider if any overpayments have been made. 42 C.F.R. § 413.64(f).

37. Although Hospital Cost Reports are subject to audit review, it is known throughout the health care industry that fiscal intermediaries do not have sufficient resources to perform in-depth audits on the majority of Hospital Cost Reports submitted to them.

38. Providers know that two to three years will elapse from the time Hospital Cost Reports are filed until they are finalized. For these reasons, the cost reporting system relies substantially on the good faith of providers to prepare and file accurate Hospital Cost Reports.

39. Every Hospital Cost Report contains a "Certification" that must be signed by the chief administrator of the provider or a responsible designee of the administrator.

40. For cost reporting periods prior to September 30, 1994, the responsible provider official was required to certify, in pertinent part:

> To the best of my knowledge and belief, it [the Hospital Cost Report] is a true, correct and complete statement prepared from the books and records of the provider in accordance with applicable instructions, except as noted.

Form HCFA-2552-81.

41. Thus, the provider was required to certify that the filed Hospital Cost Report is (1) truthful, i.e., that the cost information contained in the report is true and accurate, (2) correct,

i.e., that the provider is entitled to reimbursement for the reported costs in accordance with applicable instructions, and (3) complete, i.e., that the Hospital Cost Report is based upon all information known to the provider.

42. The "applicable instructions" contained in the pre-September 1994 certification included the requirement that services described in the cost report complied with Medicare program requirements, including the provision outlawing kickbacks, codified in 42 U.S.C.§ 1320a-7b(b).

43. The pre-September 1994 Hospital Cost Report (HCFA-2552-81) reminded providers "intentional misrepresentation or falsification of any information contained in this cost report may be punishable by fine and/or imprisonment under federal law."

44. On September 30, 1994, Medicare revised the certification provision of the Hospital Cost Report to add the following:

> I further certify that I am familiar with the laws and regulations regarding the provision of health care services, and that the services identified in this cost report were provided in compliance with such laws and regulations.

Form HCFA-2552-92.

45. Subsequently, in or about 1996, the Hospital Cost Report was revised again to include the following notice:

> Misrepresentation or falsification of any information contained in this cost report may be punishable by criminal, civil and administrative action, fine and/or imprisonment under federal law. Furthermore, if services identified in this report were provided or procured through the payment directly or indirectly of a kickback or where otherwise illegal, criminal, civil and administrative action, fines and/or imprisonment may result.

46. Hamot and its management, including its chief financial officer, were at all times familiar with the laws and regulations governing the Medicare Program, including requirements relating to the completion of cost reports.

47. A hospital is required to disclose all known errors and omissions in its claims for Medicare reimbursement (including its cost reports) to its fiscal intermediary. 42 U.S.C. § 1320a-7b(a)(3) specifically creates a duty to disclose known errors in cost reports:

> Whoever . . . having knowledge of the occurrence of any event affecting (A) his initial or continued right to any such benefit or payment . . . conceals or fails to disclose such event with an intent fraudulently to secure such benefit or payment either in a greater amount or quantity than is due or when no such benefit or payment is authorized . . . shall in the case of such a . . . concealment or failure . . . be guilty of a felony.

48. Hospital Cost Reports submitted by Hamot were, at all times material to this complaint, signed by the chief financial officer or other hospital official, who attested, among other things, to the certification quoted above.

49. The Medicare Part B Program is a 100% federally subsidized health insurance system for eligible persons aged 65 and older and persons with qualifying disabilities, who may enroll in the program to obtain benefits in return for payments of monthly premiums as established by HHS. The benefits covered by the Medicare Part B Program include medical treatment and services by physicians under 42 § U.S.C. 1395k(a)(2)(B).

50. The United States provides reimbursement for Medicare claims from the Medicare trust fund through CMS. To assist in the administration of Part B of the Medicare Program, CMS contracts with "carriers." 42 § U.S.C. 1395u. Carriers, typically insurance companies, are responsible for processing the payment of Part B claims to providers on behalf of CMS. *Id.* Highmark, Inc. is the carrier responsible for processing the payment of Part B claims to Medicor on behalf of CMS.

51. Pennsylvania providers claim Medicare Part B reimbursement from Highmark pursuant to written provider agreements. Highmark receives, processes, and pays or rejects those claims according to Medicare rules, regulations and procedures.

52. Medicor and Flagship CTVS signed or cause to be executed provider agreements with Medicare that permitted Medicor and Flagship CTVS to submit claims and accept payment for services provided by Medicor and Flagship CVTS physicians.

53. Medicare assigns to each participating provider a unique billing Provider Identification Number ("PIN"). Each of the Medicor and Flagship CVTS physicians submitted an enrollment form to Highmark, which permitted them to submit claim forms through Medicor.

54. A physician who treats a Medicare patient is required to submit an electronic or hardcopy Medicare health insurance claim form ("HCFA/CMS form 1500") to the carrier, who on behalf of CMS, pays for a portion of the claim. In submitting such Medicare claim forms, providers must certify that the information included on the form presents an accurate description of the services rendered and that the services were medically necessary.

55. In particular, Medicor and Flagship CVTS physicians certify to the following language on the HCFA/CMS 1500 claim forms that they submit to Medicare: " I certify that the services shown on this form were medically indicated and necessary for the health of the patient…"

56. By participating in the computerized billing of Medicare claims, Medicor and Flagship CVTS physicians agreed to submit claims using HCFA/CMS form 1500 and were aware of the required certifications.

THE MEDICAID PROGRAM

57. Medicaid is a joint federal-state program that provides health care benefits for certain groups, primarily the poor and disabled. The federal involvement in Medicaid is largely limited to providing matching funds and ensuring that states comply with minimum standards in the administration of the program.

58. The federal Medicaid statute sets forth the minimum requirements for state Medicaid programs to qualify for federal funding, which is called federal financial participation (FFP). 42 U.S.C. §§ 1396, *et seq*.

59. Each state's Medicaid program must cover hospital services. 42 U.S.C. § 1396a(10)(A), 42 U.S.C. § 1396d(a)(1)-(2).

60. In many states, provider hospitals participating in the Medicaid program file annual cost reports with the state's Medicaid agency, or its intermediary, in a protocol similar to that governing the submission of Medicare cost reports.

61. In some states, provider hospitals participating in the Medicaid program file a copy of their Medicare cost report with the Medicaid program, which is then used by Medicaid or its intermediaries to calculate Medicaid reimbursement. In other states, provider hospitals file a separate Medicaid cost report.

62. Providers incorporate the same type of financial data in their Medicaid cost reports as contained in their Medicare cost reports, and include data concerning the number of Medicaid patient days at a given facility.

63. Typically, each state requiring the submission of a Medicaid cost report also requires an authorized agent of the provider to expressly certify that the information and data on the cost report is true and correct.

64. Individual Medicaid programs use the Medicaid patient data in the cost report to determine the reimbursement to which the facility is entitled. The facility receives a proportion of its costs equal to the proportion of Medicaid patients in the facility.

65. Where a provider submits the Medicare cost report with false or incorrect data or information to Medicaid, this necessarily causes the submission of false or incorrect data or information to the state Medicaid program, and the false certification on the Medicare cost report necessarily causes a false certification to Medicaid as well.

66. Where a provider submits a Medicaid cost report containing the same false or incorrect information from the Medicare cost report, false statements and false claims for reimbursement are made to Medicaid.

67. The state directly reimburses physicians for services rendered, with the state obtaining the federal share of the payment from accounts, which draw on funds of the United States Treasury. 42 C.F.R. §§ 430.0-430.30. The federal share of each state's Medicaid program varies state by state.

68. The Commonwealth of Pennsylvania participates in the Medicaid Program, through its Department of Public Welfare ("DPW"), the state agency responsible for administering the Medicaid Program.

69. At all times relevant to the complaint, the United States provided federal funds to Pennsylvania and its DPW through the Medicaid program, pursuant to Title XIX of the Social Security Act 42 U.S.C, §§ 1396 et seq. Enrolled providers of medical services to Medicaid recipients, including each of the Defendants, are eligible for reimbursement for covered medical services under the provisions of Title XIX of the 1995 Amendments to the Federal Social Security Act. By becoming a participating provider in Medicaid, enrolled providers, including

each of the Defendants, agree to abide by the rules regulations policies and procedures governing reimbursement, and to keep and allow access to records and information by Medicaid. In order to receive Medicaid funds, enrolled providers, together with authorized agents, employees and contractors, are required to abide by all the provisions of the Social Security Act, the regulations promulgated under the Act, and all applicable policies and procedures promulgated by DPW.

70. Applicable provisions of 42 CFR, Chapter 4, Subpart D, and other applicable Federal statues, provide for payments for physician services and providers and facilities providing physician services, including Defendants, as long as such services were medically indicated, necessary to the health of the patient, and certified as required by Medicare and Intermediary rules.

THE TRICARE/CHAMPUS PROGRAM

71. TRICARE/CHAMPUS is a federally-funded program that provides medical benefits, including hospital services, to (a) the spouses and unmarried children of (1) active duty and retired service members, and (2) reservists who were ordered to active duty for thirty days or longer; (b) the unmarried spouses and children of deceased service members; and (c) retirees. Hospital services at non-military facilities are sometimes provided for active duty members of the armed forces, as well. 10 U.S.C. §§ 1971-1104; 32 C.F.R. § 199.4(a).

72. In addition to individual patient costs, TRICARE/CHAMPUS reimburses hospitals for two types of costs based on the Medicare cost report: capital costs and direct medical education costs. 32 C.F.R.§ 199.6.

73. A facility seeking reimbursement from TRICARE/CHAMPUS for these costs is required to submit a TRICARE/CHAMPUS form, "Request for Reimbursement of CHAMPUS

Capital and Direct Medical Education Costs" ("Request for Reimbursement") in which the provider sets forth its number of TRICARE/CHAMPUS patient days and financial information which relates to these two cost areas and which is derived from the Medicare cost report for that facility.

74. This Request for Reimbursement requires that the provider expressly certify that the information contained therein is "accurate and based upon the hospital's Medicare cost report."

75. Upon receipt of a hospital's Request for Reimbursement and its financial data, TRICARE/CHAMPUS or its fiscal intermediary applies a formula for reimbursement wherein the hospital receives a percentage of its capital and medical education costs equal to the percentage of TRICARE/CHAMPUS patients in the facility.

76. Hamot submitted Requests for Reimbursement to TRICARE/CHAMPUS that were based on their submissions to Medicare. Whenever those Medicare submissions contained falsely inflated or incorrect data or information, the corresponding Requests for Reimbursement submitted to TRICARE/CHAMPUS were also false.

77. Whenever defendants' Requests for Reimbursement were false due to falsity in their Medicare cost reports, defendants falsely certified that the information contained in their Requests for Reimbursement was "accurate and based upon the hospital's Medicare cost report." (Emphasis added).

78. Defendants knew that false claims contained in their Medicare cost reports often would affect TRICARE/CHAMPUS reimbursement as well.

THE FALSE CLAIMS ACT

79. The False Claims Act, 31 U.S.C. §§ 3729-33, provides for the award of treble damages and civil penalties for, *inter alia*, knowingly causing the submission of false or fraudulent claims for payment to the United States Government and for making or using false statements material to false or fraudulent claims paid by the United States. 31 U.S.C. §§ 3729(a)(1), (2); 31 U.S.C. §§ 3729(a)(B) (May 2009).[1] The False Claims Act (FCA), as amended, provides in pertinent part that:

> (1) Any person who (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; (C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G); . . . or (G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government,
>
> * * *

[1] In May of 2009, the FCA was amended pursuant to Public Law 111-21, Fraud Enforcement and Recovery Act of 2009 (FERA). Although § 3729(a) was amended in its entirety, only § 3729(a)(2), which FERA renumbered as § 3729(a)(1)(B), can be applied retroactively back to and including June 7, 2008 by virtue of § 4(f) of FERA. "The amendments made by this section shall take effect on the date of enactment of the Act and shall apply to conduct on or after the date of enactment, except that (1) subparagraph (B) of section 3729(a)(1), as added by subsection (a)(1), shall take effect as if enacted on June 7, 2008, and apply to all claims under the False Claims Act (31 U.S.C. § 3729 *et seq*.) that are pending on or after that date…" FERA, § 4(f). For conduct that predates the effective dates of the amendments, the relevant portions of the pre-FERA FCA provide:

> (a) Any person who (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval; (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government; (3) conspires to defraud the Government by getting a false or fraudulent claim paid or approved by the Government;. . . or (7) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government.

> 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 (28 U.S. C. 2461 note: Public Law 104-410), plus 3 times the amount of damages which the Government sustains because of the act of that person . . ..
>
> (b) For purposes of this section, the terms "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, and no proof of specific intent to defraud is required.

31 U.S.C. § 3729.

THE ANTI-KICKBACK STATUTE

80. The Anti-kickback Statute, 42 U.S.C. § 1320a-7b(b), arose out of congressional concern that payoffs to those who can influence healthcare decisions will result in goods and services being provided that are medically unnecessary, of poor quality, or even harmful to a vulnerable patient population. To protect the integrity of the program from these difficult to detect harms, Congress enacted a *per se* prohibition against the payment of kickbacks in any form, regardless of whether the particular kickback gave rise to overutilization or poor quality of care. First enacted in 1972, Congress strengthened the statute in 1977 and 1987 to ensure that kickbacks masquerading as legitimate transactions did not evade its reach. *See* Social Security Amendments of 1972, Pub. L. No. 92-603, §§ 242(b) and (c); 42 U.S.C. § 1320a-7b, Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142; Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93.

81. The Anti-kickback Statute prohibits any person or entity from making or accepting payment to induce or reward any person for referring, recommending or arranging for

federally-funded medical services, including services provided under the Medicare, Medicaid and (as of January 1, 1997) TRICARE programs. In pertinent part, the statute states:

> (b) Illegal remuneration
>
> > (1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind --
> >
> > > (A) In return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
> >
> > > (B) In return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
> >
> > Shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.
> >
> > (2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person --
> >
> > > (A) To refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
> >
> > > (B) To purchase, lease, order or arrange for or recommend purchasing, leasing or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

> Shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b(b). Violation of the statute can also subject the perpetrator to exclusion from participation in federal health care programs and, effective August 6, 1997, civil monetary penalties of $50,000 per violation and three times the amount of remuneration paid. 42 U.S.C. § 1320a-7(b)(7) and 42 U.S.C. § 1320a-7a(a)(7).

THE STARK STATUTE

82. Enacted as amendments to the Social Security Act, 42 U.S.C. § 1395nn (commonly known as the "Stark Statute") prohibits a hospital (or other entity providing designated health services) from submitting Medicare claims for designated health services (as defined in 42 U.S.C. § 1395nn(h)(6)) based on patient referrals from physicians having a "financial relationship" (as defined in the statute) with the hospital, and prohibits Medicare from paying any such claims. The regulations implementing 42 U.S.C. § 1395nn expressly require that any entity collecting payment for a healthcare service "performed under a prohibited referral must refund all collected amounts on a timely basis." 42 C.F.R. § 411.353 (2006).

83. The Stark Statute establishes the clear rule that the United States will not pay for designated health services prescribed by physicians who have improper financial relationships with other providers. The statute was designed specifically to prevent losses that might be suffered by the Medicare program due to questionable utilization of designated health services.

84. Congress enacted the Stark Statute in two parts, commonly known as Stark I and Stark II. Enacted in 1989, Stark I applied to referrals of Medicare patients for clinical laboratory services made on or after January 1, 1992, by physicians with a prohibited financial relationship

with the clinical lab provider unless a statutory or regulatory exception applies. *See* Omnibus Budget Reconciliation Act of 1989, P.L. 101-239, § 6204.

85. In 1993, Congress extended the Stark Statute (Stark II) to referrals for ten additional designated health services. *See* Omnibus Reconciliation Act of 1993, P.L. 103-66, § 13562, Social Security Act Amendments of 1994, P.L. 103-432, § 152.

86. The Stark Statute prohibits a hospital from submitting a claim to Medicare for "designated health services" that were referred to the hospital by a physician with whom the hospital has a "financial relationship," unless a statutory exception applies. "Designated health services" include inpatient and outpatient hospital services. 42 U.S.C. § 1395nn(h)(6).

87. In pertinent part, the Stark Statute provides:

> (a) Prohibition of certain referrals
>
> (1) In general
>
> > Except as provided in subsection (b) of this section, if a physician . . . has a financial relationship with an entity specified in paragraph (2), then –
> >
> > (A) The physician may not make a referral to the entity for the furnishing of designated health services for which payment otherwise may be made under this subchapter, and
> >
> > (B) The entity may not present or cause to be presented a claim under this subchapter or bill to any individual, third party payer, or other entity for designated health services furnished pursuant to a referral prohibited under subparagraph (A).

42 U.S. C. § 1395nn(a)(1).

88. Moreover, the Stark Statute provides that Medicare will not pay for designated health services billed by a hospital when the designated health services resulted from a prohibited referral under subsection (a). 42 U.S.C. § 1395nn(g)(1)

89. "Financial relationship" includes a "compensation arrangement," which means any

arrangement involving any remuneration paid directly or indirectly to a referring physician. 42 U.S.C. §§ 1395nn(h)(1)(A) and (h)(1)(B).

90. The Stark Statute and regulations contain exceptions for certain compensation arrangements. These exceptions include, among others, "bona fide employment relationships" and "personal services arrangements."

91. In order to qualify for the Stark Statute's exception for bona fide employment relationships, compensation arrangements must meet, inter alia, the following statutory requirements: (A) the amount of the remuneration is fair market value and not based on the value or volume of referrals, and (B) the remuneration would be commercially reasonable even in the absence of referrals from the physician to the hospital. 42 U.S.C. §§ 1395nn(e)(2)(B) and (e)(2)(C).

92. In order to qualify for the Stark Statute's exception for personal services arrangements, a compensation arrangement must meet, inter alia, the following statutory requirements: (A) the compensation does not exceed fair market value, and (B) is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties (unless it falls within a further "physician incentive plan" exception as described in the statute). 42 U.S.C. § 1395nn(e)(3)(A)(v).

93. A "physician incentive plan" under § 1395nn(e)(3) is defined very narrowly, and only applies to compensation arrangements that "may directly or indirectly have the effect of reducing or limiting services provided with respect to individuals enrolled with the entity." 42 U.S. C. § 1395nn(e)(3)(B)(ii).

94. The Stark Statute also applies to claims for payment under Medicaid, and federal funds may not be used to pay for designated health services through a state Medicaid program.

42 U.S. C. § 1396b(s).

KICKBACKS FOR ILLEGAL PATIENT REFERRALS

95. During the period relevant hereto, Hamot, Medicor, and Flagship CVTS were aware of the prohibitions against kickbacks and legal restrictions on financial relationships between hospitals and physicians. Nevertheless, Hamot entered into a series of contracts with Medicor, Flagship CVTS and other physicians to pay kickbacks to and to engage in unlawful relationships with physicians to induce patient referrals.

96. In approximately 1998, in response to a proposed merger of the cardiology groups at Hamot and its cross-town rival, St. Vincent's Hospital, Hamot devised a scheme to buy the loyalty of the Medicor and Flagship physicians and secure a steady stream of cardiac referrals.

97. Specifically, Hamot offered and paid remuneration to Medicor and Flagship physicians by entering into a series of sham contracts with Medicor and Flagsip for "medical directorships" or other similar personal service arrangements.

98. At the time he was hired by Medicor, Relator was informed by Dr. Furr, the president of Medicor, that Medicor and Flagship CVTS had several "medical directorship" contracts with Hamot and he was immediately assigned to provide services for Medicor pursuant to one of those contracts. See Exhibit 1, attached hereto.

99. That contract purports to require Medicor, through its physicians, to provide "medical supervision and direction of rehab/ restorative cardiovascular services" at Hamot in exchange for $75,000 per year. The contract was for a one-year term and renewed annually during the time that Relator was employed at Medicor, and thereafter.

100. While the contract specifies that "services shall be provided for no fewer than 400

hours per year", nowhere does it specify the particular services to be performed. Rather, the contract references and incorporates a vague "description of duties", in an addendum identified as Exhibit A, that are more in the nature of guidelines or aspirational goals.

101. Neither Medicor, nor Hamot maintained time cards or other billing records to document the services that were provided by Relator pursuant to this medical director contract. A few times a year, Relator was asked to sign a time study form (covering 2 week intervals) that was pre-prepared by an administrator at Medicor, that was not based on information provided by Relator, that was not contemporaneous, that was often inaccurate and invariably overstated the amount of time attributed to the services documented. Moreover, the services documented in the time studies did not correspond to duties identified in Relator's medical director contract. A copy of such a time study form is attached as Exhibit 2.

102. Relator's actual duties, as performed, required less than 10 hours per month, and consisted of conducting a monthly committee meeting that lasted approximately one hour, along with a couple of hours of prep time and a couple of hours of follow-up time.

103. Medicor was grossly overpaid for the services that Relator provided and the actual purpose of the payments was to induce referrals.

104. Hamot entered into at least six other similar contracts with Medicor or Flagship CVTS on an annual basis resulting in payments to Medicor and Flagship CVTS of $525,000 per year, $43,750.00 per month. The other six paid directorships included, (1) Non-Invasive Cardiology, Dr. David Strasser; (2) Invasive Cardiology, Dr. Timothy Trageser; (3) Cardiac Electrophysiology, Dr. James D. Maloney, Dr. Dakas, and Dr. Hayes; (4) Cardiac Surgery, Dr. Richard Long; (5) Vascular (diagnostics/ interventions), Dr. Kish and Dr. George; and (6) Regional Development/ Maintenance, Dr. Richard Petrella and Leo Fitzgibbons.

105. The aforesaid contracts were sham arrangements intended to disguise the actual purpose which was to provide a vehicle for Hamot to pay kickbacks to Medicor and Flagship CVTS to buy the loyalty of the physicians and insure a steady stream of patient referrals.

106. Pursuant to the above described kickback arrangement, and the sham medical directorship contracts, Medicor and Flagship received payments of more than half a million dollars per year and in return referred thousands of patients covered by federal health insurance programs to Hamot on an exclusive basis.

107. The sham medical director contracts were coordinated by, or arranged through, the Vice President and Administrative Director of Hamot's Heart Institute, Gary Maras, who also held a parallel position as the Executive Director of Medicor.

108. It was understood by Medicor, Flagship and Hamot that Hamot would submit claims for payment to Medicare, Medicaid and other federal health insurance programs for patients referred by Medicor, Flagship and their physicians. Indeed, absent the submission of such claims and the receipt of Medicare and Medicaid reimbursements therefore, Hamot would have had no incentive to agree to overpay on the medical director contracts as outlined above. It was also understood and intended by all parties that such referrals would be induced by the payments.

STARK II SELF REFERRALS

109. At all times relevant hereto, Medicor and Flagship CVTS and their physicians maintained significant "financial relationships" with Hamot through the various medical director contracts as set forth above as well as other business arrangements.

110. Medicor and Flagship CVTS and their physicians, including the individual defendants, referred a substantial number of patients to Hamot for in-patient services, outpatient services, and other designated health services within the meaning of Stark II.

111. The sham medical director contracts were coordinated by, or arranged through, the Vice President and Administrative Director of Hamot's Heart Institute, Gary Maras, who also held a parallel position as the Executive Director of Medicor.

113. Hamot knowingly presented or caused to be presented claims to Medicare, Medicaid and other government programs for designated health services pursuant to referrals as set forth in the preceding paragraphs in violation of 42 USC § 1395nn(a)(1)(B).

114. Medicor, Flagship and the individual physician defendants knowingly caused claims to be presented to Medicare, Medicaid and other government programs for designated health services pursuant to referrals as set forth in the preceding paragraphs in violation of 42 USC § 1395nn(a)(1)(B).

ANTI–KICKBACK SAFE HARBORS AND STARK LAW EXCEPTIONS

115. As noted, both the Stark Law and the Anti-kickback Statute have regulatory "safe harbors" that provide protection for certain remuneration relationships between physicians and physician group practices, such as Medicor and Flagship, and providers of Designated Health Services, like Hamot Hospital. As relevant here, those regulatory harbors protect physician compensation relationships. To be protected under a "safe harbor" an arrangement must fit squarely within a "safe harbor" exception, and all of the requirements of a "safe harbor" must be met.

116. Under the Anti-Kickback Statute and the Stark Law, "safe harbor" protection is

extended to personal service and management contracts, such as those that existed between Hamot and Medicor/Flagship if the following requirements are met:

> (1) the agreement must be set out in writing and signed by the parties;
>
> (2) the agreement covers all of the services that will be provided under the contract and specifies the services to be provided;
>
> (3) the agreement is for a term of not less than one year;
>
> (4) the aggregate compensation is consistent with fair market value in arms-length transactions, and is not determined in a manner that takes into account the volume or value of any referrals; and
>
> (5) the aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.

117. While the "safe harbor" provides protection for arrangements that meet all of the requirements of the exception, the U.S. Department of Health and Human Services, Office of the Inspector General ("HHS OIG") has made clear in guidance issued to industry groups that a "well-written" contract that facially complies with the requirements of the 'safe harbors" but which has as its underlying purpose the goal of gaining referrals that would otherwise not occur without the compensation arrangement cannot immunize the arrangement from civil or criminal prosecution.

118. As noted, Hamot entered into at least seven personal services contracts with Medicor and/or Flagship beginning in 1998 in the wake of a threatened merger between the Medicor, Flagship and the cardiology practices at St. Vincent's Hospital, which Hamot feared would result in the diversion of lucrative cardiology referrals from Hamot to St. Vincent's Hospital, causing a large loss of revenue to Hamot.

119. Recognizing that Cardiology procedures, including invasive cardiology procedures like stents, are among the most highly reimbursed inpatient procedures, and responding to the threatened loss of this revenue stream, Hamot created six medical director positions that had not previously existed, The fact that these positions had not previously existed is important, as it suggests that the hospital did not need the services, or the majority of the services, provided under those contracts, or that those services were previously being provided by other physicians who were not being paid.

120. Moreover, There were no significant changes within the hospital in terms of the number of beds, the number of catheterization facilities or the presence of other new cardiology facilities that would have dictated the need for six medical directors where there previously had been none.

121. Clearly, the medical directorship contracts were not " commercially reasonable" and their true purpose was, as alleged, to maintain the flow of referrals to Hamot.

122. Additionally, the positions that were created were given to Medicor and/or Flagship to assign to their doctors, at their discretion. As is detailed below, Dr. Emanuele was not interviewed or evaluated by Hamot personnel to determine whether he had the qualifications to fill the position he held, nor were any of the other Medicor/Flagship doctors interviewed for these positions. Hamot did not advertise these positions nationally or even regionally to determine who was qualified to fill those positions. Instead, the medical director positions were given as rewards to the doctors whose referrals Hamot wished to secure.

123. Further, the medical director contracts did not meet the requirements of the personal services "safe harbor" because the compensation was not based upon Fair Market Value ("FMV") . The arrangements did not meet FMV because the services required by the contracts

were not commercially necessary and reasonable. Not only were the services provided not specified in detail, but most importantly, the Defendants were paid under the contract whether they rendered the quantity of services (in terms of the number of hours) specified monthly by the contract or not.

124. As previously alleged, time sheets were filled out by administrative personnel with no direct knowledge of how much time the doctors' spent fulfilling their contractual duties. The invoices were an afterthought, designed to "paper the file" rather than to reflect time actually spent in performing services for the hospital under the medical director contracts.

125. Neither Hamot, nor Medicor or Flagship made any effort to monitor or audit the contracts to determine if the terms of the contracts were actually being met.

HAMOT'S SUBMISSION OF CLAIMS

126. The majority of all claims submitted by Hamot from October 8, 2004 through present were submitted to federal health insurance programs such as Medicare and Medicaid. In fiscal year 2010, approximately 44 % of net patient revenues were received from Medicare, and approximately 7% of net patient revenues were received from Medicaid. These numbers are consistent with Relator's knowledge and experience gained as a result of his employment as a cardiologist at Medicor during the period from 2001 through May of 2005.

127. Relator has personal knowledge that, from 2001 through May of 2005, Hamot routinely submitted claims to Medicare and Medicaid for patients referred by Medicor and Flagship and its physician as a result of the kickbacks and improper financial relationships discussed above. Relator does not have reasonable pre-discovery access to the specific billing records for such claims.

MEDICALLY UNNECESSARY SURGICAL PROCEDURES

128. As stated above, many of the surgical procedures performed by Medicor physicians Petrella, Ferraro, Furr, Trageser and Zone at Hamot have been furnished to beneficiaries of federal health insurance programs including Medicare, Medicaid, TRICARE, Federal Employees Health Benefits Program, and Railroad Retirement Services.

129. From June 2001, and earlier, and continuing to the present, Medicor and the individual physician Defendants, Petrella, Ferraro, Furr, Trageser, Zone, knowingly, systematically, routinely and repeatedly submitted false claims to, and received reimbursements from, Medicare and other federal health care programs for medically unnecessary cardiac catheterizations and cardiac and vascular surgical procedures, including, but not limited to, Percutaneous Coronary Interventions (PCI). As a result of these false claims, Defendants Petrella, Ferraro, Furr, Trageser, Zone and Medicor fraudulently obtained payments from Medicare and other federal health care programs to which they were not entitled.

130. Pursuant to its exclusive contact with Hamot, and the coordination and cooperation arranged for by Gary Maras in his capacity as CEO of Medicor and in his capacity as Administrative Director of Hamot's Heart Institute, many of the unnecessary procedures referred to in the preceding paragraph also involved services provided by Hamot.

131. From June 2001, and earlier, and continuing to the present, Hamot knowingly, systematically, routinely and repeatedly submitted false claims to and received reimbursements from Medicare and other federal health care programs for hospital services, items and facilities furnished in connection with the medically unnecessary cardiac catheterizations and cardiac and vascular surgical procedures performed by Defendants Petrella, Ferraro, Furr, Trageser, Zone and Medicor at its facilities. As a result of these false claims, Hamot fraudulently obtained

payments from Medicare and other federal health care programs to which it was not entitled.

132. By routinely subjecting patients to medically unnecessary cardiac catheterizations and cardiac and vascular surgical procedures Defendants outrageously compromised the health of their patients and placed them at increased risk of injury and death.

133. In his zeal to establish and promote the rapid development of a competitive cardiovascular surgery program at Hamot, Gary Maras conspired with defendants Petrella, Ferraro, Furr, Trageser, Zone and embarked on a scheme to perform an increased the number of cardiac catheterizations which in turn would provide more opportunities to perform unnecessary Percutaneous Coronary Interventions, for the mutual financial benefit of Hamot, Medicor and the individual physician Defendants.

134. In furtherance of the scheme to increase the volume of procedures and opportunities for interventions, Medicor implemented a policy and practice of allowing non-cardiologist referring physicians to schedule patients directly with the "cath lab" for cardiac catheterization procedures without first consulting with a cardiologist.

135. In furtherance of the scheme, Medicor physicians implemented a policy and practice of serving as "admitting physicians" for referring physicians that did not have admitting privileges at Hamot, regardless of the medical condition for which the patient was seeking admission. Many of the patients admitted to Hamot under the service of Medicor physicians, based on referrals from physicians without admitting privileges, were subjected to unnecessary cardiac catheterizations. This practice allowed the defendants to bill for unnecessary procedures while providing an ostensible basis for an admission by a cardiologist.

136. In furtherance of the scheme, Medicor physicians consistently overstated the extent and severity of stenosis shown on the angiogram films, followed by a recommendation of

surgical intervention. In addition to actually misrepresenting the blockage as shown on the film, the physicians also applied a standard which was far more inclusive than what is accepted and commonly used by expanding the definition of "abnormality" from more than 50% blockage to more than 20% blockage.

137. In furtherance of the scheme, Medicor physicians refused to employ available technologies, such as inner intravascular ultrasound and flow wire pressure gradients, to rule out the need for surgical intervention in questionable cases.

138. Because Medicor had a policy of rotating its cardiologists through different services (i.e. diagnostic testing, analysis/ reading of tests, surgery, follow-up/ recovery), Relator had the opportunity to review medical records and catheterization films for services provided by the other cardiologists at Medicor.

139. Beginning in 2004, Relator began to notice higher rates of intervention among certain physicians in the group. During the period from April 2004 through February 2005, the Cath Lab activity records show that 4,408 catheterizations were performed and that Drs. Petrella, Trageser and Ferraro had a rate of surgical intervention following catheterization of double the junior members of the group. During the period from January 2005 to April 2005 the intervention rates for Drs. Petrella, Trageser and Ferraro were as follows:

Dr. Petrella 45%
Dr. Trageser 51%
Dr. Ferraro 53%

Compared to:

Dr. Emanuele 28%
Dr. Kang 34%
Dr. Agostini 28%

140. Further investigation of the elevated intervention rates revealed a consistent

pattern of over utilization. Many of the patients were subjected to unnecessary surgery, after angiograms were misread so as to overstate the extent and severity of stenosis and where more conservative treatment (i.e. medication) was indicated.

141. By way of example, Dr. Trageser performed an unecessary cardiac catheterization on patient A.R. on November 12, 2004, even though the patient had no symptoms. Instead, Trageser relied on false positive findings on a stress test even though he, and others in the cardiology department at Hamot had previously identified a problem with frequent false positive readings on stress tests. Patient A.R. developed complications from the catheterization procedure and died.

142. In another case, Dr. Trageser performed an unecessary cardiac catheterization on patient J.H. On December 16, 2004, even though Dr. Trageser specifically noted that the particular complaints of chest pain were inconsistent with angina and there were no other indications for a cardiac catheterization. According to the medical records, the catheterization films indicate a stenosis of moderate severity. Instead of undergoing a functional study to further evaluate the extent of the stenosis, Patient J.H. was treated with the implantation of a coronary stent. Because the real cause of J.H.'s condition remained untreated, he continued to have symptoms post operatively, leading to implantation of a second stent a few days later.

143. In another case, Dr. Ferraro performed an unecessary stenting in the proximal circumflex on patient G.B. on November 10, 2004, even though Relator had performed a cardiac catheterization on patient G.B. on October 28, 2004 and diagnosed a moderate stenosis with no significant symptoms and recommended medical therapy.

144. In another case, patient M.B. presented on or about January 17, 2005 with chest pain, which Relator treated medically because of history of recent gastrointestinal bleed. Relator

did not order cardiac catheterization because any cardiac therapeutic procedure would require the administration of anticoagulants that would place patient M.B. at an increased risk of bleeding. M.B. was then diagnosed with cancer. Subsequently, M.B. was subjected to a cardiac catheterization ordered by Dr. Nullet. Even though the angiograms showed coronary artery disease, the procedure was unnecessary because multiple co-morbidities (recent G.I. bleed, cancer and advanced age) precluded procedures other than medical treatment.

145. In another case, Dr. Zone performed an unnecessary cardiac catheterization on patient L.J. on September 12, 2003 and misinterpreted the results by grossly overstating the severity of the stenosis. Patient L.J. was then referred for unnecessary bypass surgery on September 24, 2003. Patient L.J. died on October 18, 2003 due to complications resulting from the bypass surgery.[2]

146. In another case, patient J.L. was subjected to an unnecessary stenting after Dr. Petrella misreported an ostial lesion following catheterization on March 11, 2004. A few months later, the stent restenosed necessitating a second stenting procedure for patient J.L.

147. In another case, patient R.P. presented with chest pain described as atypical. On March 16, 2004, R.P. underwent a coronary stenting of the left main coronary artery with the stent extending in the proximal left anterior descending artery. Even though a single stent was implanted, Dr. Petrella described the procedure as if two separate procedures in two separate vessels were performed so that the procedure could be billed twice.

148. In another case, patient J.M. presented with atrial fibrillation, congestive heart

[2] In its November 8, 2012 order, the Court ruled that a six-year statute of limitations applied to this case and that claims, based on conduct which occurred prior to October 8, 2004, are time barred. Accordingly, the sample cases referenced in paragraphs 145, 146, 147 and 148, for patients L.J., J.L., R.P. and J.M., are not offered for the purposes of establishing liability for these particular claims, but rather are offered merely for the purpose of providing precise illustrations of how the defendants' fraudulent scheme, which extended over many years, was implemented.

failure, and atypical chest pain. According to Dr. Petrella, the cardiac catheterization revealed that lesions found in the right coronary and circumflex artery were not severe enough to cause heart failure or resting angina. Nevertheless, on March 15, 2004, four days after the diagnostic cardiac catheterization was performed, Dr. Petrella implanted stents in both vessels.

SUBMISSION OF CLAIMS BY MEDICOR AND FLAGSHIP

149. The majority of all claims submitted by Medicor and Flagship from October 8, 2004 through present were submitted to federal health insurance programs such as Medicare and Medicaid. In 2004 approximately 53 % of Medicor's claims were submitted to Medicare and approximately 7% were submitted to Medicaid, In 2004 approximately 50% of Flagship's claims were submitted to Medicare and approximately 3% were submitted to Medicaid.

150. Relator does not have reasonable pre-discovery access to the specific billing records for such claims.

THE UNITED STATES HAS BEEN DAMAGED

151. As more particularly described above, defendants have profited and the United States has been damaged monetarily by the practices used by defendants to make false claims to federal health care programs for payment and reimbursement. Defendants have submitted many false claims for excessive and unauthorized payments and reimbursements and have obtained excessive compensation from the United States as a result.

COUNT ONE
Federal False Claims Act 31 U.S.C. § 3729(1)(A)

152. Plaintiff re-alleges and incorporates by reference the allegations contained in Paragraphs 1 through 151 of this complaint.

153. This is a claim for treble damages, civil penalties and attorney's fees, under the Federal False Claims Act, 31 U.S.C. §§ 3729, *et seq.* as amended.

154. By means of the acts described above, defendants have knowingly presented or caused to be presented false or fraudulent claims for payment to the United States. The United States, unaware of the falsity of the claims made, and in reliance on the accuracy thereof, paid for claims that would otherwise not have been allowed.

155. By reason of these payments, the United States has been damaged, and continues to be damaged, in a substantial amount.

COUNT TWO
Federal False Claims Act 31 U.S.C. § 3729(1)(B)

156. Plaintiff re-alleges and incorporates by reference the allegations contained in Paragraphs 1 through 155 of this complaint.

157. This is a claim for treble damages, civil penalties and attorney's fees, under the Federal False Claims Act, 31 U.S.C. §§ 3729, *et seq.* as amended.

158. By means of the acts described above, defendants knowingly made, used, or caused to be made or used, false records or statements material to a false or fraudulent claim in violation of 31 U.S.C. § 3729(a)(1)(B). The United States, unaware of the falsity of the records and statements, and in reliance on the accuracy thereof, paid for claims that would otherwise not have been allowed.

159. By reason of these payments, the United States has been damaged, and continues to be damaged, in a substantial amount.

COUNT THREE
Federal False Claims Act 31 U.S.C. § 3729(1)(C)

160. Plaintiff re-alleges and incorporates by reference the allegations contained in Paragraphs 1 through 159 of this complaint.

161. This is a claim for treble damages, civil penalties and attorney's fees, under the Federal False Claims Act, 31 U.S.C. §§ 3729, *et seq.* as amended.

162. By means of the acts described above, defendants conspired to defraud the United States by getting false or fraudulent claims allowed or paid. The United States, unaware of the conspiracy, and unaware of the falsity of the records, statements and claims made, and in reliance on the accuracy thereof, paid for claims that would otherwise not have been allowed.

163. By reason of these payments, the United States has been damaged, and continues to be damaged, in a substantial amount.

CONCLUSION

164. The defendants are liable to the United States Government for civil penalties and treble damages, pursuant to 31 U.S.C. § 3729(a). In addition, the plaintiffs are entitled to recover reasonable expenses, attorney's fees, and costs incurred in prosecuting this action, pursuant to 31 U.S.C. § 3730(d). Further, the plaintiff is entitled to a share of the recovery obtained by the United States as a result of this action, pursuant to 31 U.S.C. § 3730 (d).

WHEREFORE, plaintiff prays that upon trial or final hearing the Court grant judgment for plaintiff and the United States against the defendants, as follows:

a. For civil penalties of $5,500 to $11,000 for each false claim pursuant to 31 U.S.C. § 3729(a);

b. For three times the amount of damages proved, pursuant to 31 U.S.C. § 3729(a);

c. For costs of court;

d. For pre-judgment and post-judgment interest at the rates permitted by law; and

e. For such other and further relief as may be appropriate and authorized by law.

Plaintiff further prays that he be awarded an appropriate percentage of the amount recovered by and for the United States as a result of this action, together with statutory expenses, plus reasonable attorneys' fees and costs, in accordance with 31 U.S.C. § 3730(d).

DEMAND FOR JURY TRIAL

Plaintiff/Relator Tullio Emanuele, M.D. demands that this case be tried before a jury.

Respectfully submitted,

DATE: NOVEMBER 30, 2012

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CERTIFICATE OF SERVICE

I hereby certify that I have served a copy of the foregoing document by Electronic Filing, or, if the party served does not participate in Electronic Filing, by e-mail or U.S. First Class Mail, on this 30th day of November, 2012, to:

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