UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF KENTUCKY
LOUISVILLE DIVISION

UNITED STATES OF AMERICA
EX REL. DANIEL PURNELL,

Plaintiffs,

v.

SEALED CIVIL ACTION
NO. 3:11CV-235-S

AMERICAN SLEEP MEDICINE, LLC; and
ADVANTACARE HEALTH, INC.

Defendants.

SECOND AMENDED COMPLAINT FOR DAMAGES AND OTHER RELIEF UNDER THE QUI TAM PROVISIONS OF THE FEDERAL FALSE CLAIMS ACT [31 U.S.C. §3729, et seq.]

FILED IN CAMERA AND UNDER SEAL

On behalf of himself and the United States of America, Plaintiff-Relator Daniel Purnell ("Relator"), in his Second Amended Complaint against American Sleep Medicine, LLC and Advantacare Health, Inc., alleges based upon personal knowledge, relevant documents, and information and belief, as follows:

I. INTRODUCTION AND OVERVIEW

A. Overview of Case

1. This is an action to recover damages and civil penalties on behalf of the United States of America arising from false and/or fraudulent statements, records, and claims made by Defendant American Sleep Medicine, LLC and Defendant Advantacare,

Inc. and/or their agents, employees, and co-conspirators in violation of the Federal False Claims Act, 31 U.S.C. §3729, *et seq*.

2. The American Academy of Sleep Medicine (AASM) recognizes a number of different sleep disorders which, taken together, affect millions of Americans. Some of the most common of these disorders are insomnia, narcolepsy/excessive daytime sleepiness, restless leg syndrome, REM behavior disorders, and obstructive sleep apnea ("OSA").

3. The most common tool used to diagnose sleep disorders, particularly OSA, is polysmnographic diagnostic sleep testing. Polysomnography is a comprehensive recording of the biophysiological changes that occur during sleep. The polysomnogram test is capable of monitoring multiple body functions including brain activity, eye movements, muscle and skeletal-muscle activation, heart rhythm, and respiratory airflow and effort.

4. Defendant American Sleep Medicine owns and operates diagnostic sleep testing centers throughout the United States, including Kentucky and California, for patients suffering from sleep disorders such as obstructive sleep apnea. A large percentage of the patients referred to Defendant for medical services and products are beneficiaries of federal health care programs including Medicare, Medicaid, CHAMPUS/TRICARE, CHAMPVA, and the Federal Employee Health Benefit Program.

5. Contrary to federal program requirements upon which eligibility for reimbursement is conditioned, Defendant regularly bills federal healthcare programs for initial sleep studies that are conducted by technicians employed by Defendant who have neither licenses nor certifications as sleep test technicians (hereafter referred to as "non-

credentialed" technicians), who are otherwise inadequately trained to perform such functions, who do their work without physician supervision, who alter test results and patient files and who prepare "Physicians' Reports" without physician input or meaningful review.

6. Defendant's technicians thereafter regularly conduct follow-up studies and prescribe treatment in the same inappropriate manner and without determination by treating physicians that such additional testing and treatment is warranted or that it is being administered in a medically appropriate manner.

7. In addition, Defendant unlawfully attracts referrals to its businesses through kickback arrangements in which Defendant invites physicians to bill federal health care programs for professional sleep study interpretation and reports—services which federal regulations mandate be performed by physicians but which Defendant's technicians actually perform without physician oversight and without genuine physician review. Federal law prohibits payment by any federally-funded healthcare program of claims tainted by such kickback arrangements.

8. As a result of Defendant's knowing misconduct, for at least the past six years, Medicare, Medicaid and other federally funded healthcare programs routinely have been billed for, and have paid, technical and professional fees for diagnostic sleep study services that are not properly payable. The services are not properly payable under such programs both because such services have not been conducted in accordance with conditions of payment related directly to how, when and by whom such services must be provided in order to be eligible for federal health care program reimbursement, and/or because the entire series of transactions has been tainted by kickbacks that render all

associated claims for diagnostic studies, treatment, and associated professional services ineligible for federal reimbursement.

B. The Federal False Claims Act

9. The federal False Claims Act (the "FCA") was originally enacted during the Civil War, and was substantially amended in 1986 and again in 2009. Both series of amendments were enacted by Congress in order to enhance the Government's ability to recover losses sustained as a result of fraud against the United States, after finding that fraud in federal programs was pervasive and that the FCA was in need of modernization in order to more effectively combat such fraud. Congress has characterized the FCA as the primary tool for combating fraud against the Government.

10. The liability provisions of the FCA provide that any person who knowingly submits, or causes the submission of, a false or fraudulent claim for United States funds for payment or approval, or who makes or causes to be made false records and statements in support of such claims, is liable for a civil penalty of up to $11,000 for each such claim, plus three times the amount of damages sustained by the Government.

11. The "qui tam" provisions of the FCA allow any person having information about violations of the liability provisions of the Act to bring an action for himself and the Government, and to share in any recovery. The FCA requires that the complaint be filed under seal for a minimum of sixty days (without service on the defendant during that time) to allow the Government time to conduct its own investigation and to determine whether to join the suit.

12. The statute of limitations for violations under the federal False Claims Act is at least six years from the date of the violation and as long as ten years after such

violation, provided that, for claims over six years old, United States officials charged with responsibility to act under the circumstances were not on actual or constructive notice of such older violations sued upon for more than three years before claims were brought regarding those older violations. Separate limitations periods run with respect to each distinct false claim made (or other substantive False Claims Act violation). The period of time alleged to be relevant to the claims raised in this Complaint is thus at least the six-year period, and presumptively the ten-year period immediately prior to the filing of this Complaint.

II. PARTIES

13. Relator Daniel Purnell is a resident of Santa Cruz, California. He was employed as a polysomnography technician at American Sleep Medicine, LLC, 12980 Saratoga Avenue, Saratoga, California from March 2009 until January 2010. Relator is not a Registered Polysomnograph Technician.

14. Defendant American Sleep Medicine, LLC ("ASM" or "Defendant") headquartered at 7900 Beltford Parkway, Jacksonville, Florida, was founded in 2002. ASM operates 19 diagnostic sleep testing centers throughout the United States. The company's primary business is the operation of diagnostic sleep testing centers. Patients are referred to ASM by their treating physicians for polysomnographic sleep testing. Based on the results of those tests, patients may be diagnosed with one of several sleep disorders. ASM purports to conduct 30,000 sleep studies on an annual basis. These tests are reimbursable by Medicare. Based upon observations of the Relator more than 90% of these tests are reimbursable by government healthcare programs.

15. Defendant Advantacare Health, Inc. ("Advantacare") is headquartered at 5 Mandeville Court, Monterey, California 93940 and also has offices in Capitola and Sunnyvale, California. Advantacare offers a full range of CPAP and BiLevel systems, as well as masks, to sleep testing centers such as Defendant American Sleep Medicine.

III. JURISDICTION AND VENUE

16. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331, 28 U.S.C. §1367, and 31 U.S.C. §3732, the latter of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§3729 and 3730. ASM resides in and transacts business in the Western District of Kentucky. This Court has personal jurisdiction over Defendants pursuant to 31 U.S.C. §3732(a) because that section authorizes nationwide service of process and because the Defendants have minimum contacts with the United States. Moreover, as stated, ASM can be found in, resides in, or transacts business in the Western District of Kentucky.

17. There has been no statutorily relevant public disclosure of the "allegations or transactions" in this Complaint that could stand as a potential barrier to the jurisdiction of this Court over Relator's claims pursuant to 31 U.S.C. §3730(e). Moreover, even had such a public disclosure occurred within the meaning of the False Claims Act, Relator would qualify under that section of the False Claims Act as an "original source" of the allegations in this Complaint, thus preserving this Court's jurisdiction over his claims.

18. This Complaint was originally filed in the United States District Court for the Northern District of California. Upon application by Relator and the United States of America, the case was transferred to this Court on April 21, 2011. Venue is proper in this Court pursuant to 28 U.S.C. § 1404, which allows a district court to transfer a case for the

convenience of parties and witnesses, or in the interest of justice, so long as the matter could have been brought in the original forum. 28 U.S.C. § 1404(a); see also *Commodity Futures Trading Comm'n v. Savage*, 611 F. 2d 270, 279 (9th Cir.1979). Pursuant to 31 U.S.C. §3732(a), the Complaint could have been brought in this Court originally because the Defendant ASM can be found in, resides in, or transacts business in the Western District of Kentucky. In addition, the False Claims Act violations, as alleged herein, occurred, and continue to occur, in this District.

19. To Relator's knowledge, no other qui tam actions have been filed which allege the same or substantially similar allegations as those set forth herein.

IV. BACKGROUND FACTS AND REGULATORY FRAMEWORK

A. Federally Funded Health Care Programs—Statutory and Regulatory Framework

1. The "Reasonable and Necessary" Requirement

20. Medicare provides for payment of certain medical expenses for persons who are over 65, who are disabled, or who suffer from End Stage Renal Disease. Medicare Part B, 42 U.S.C. §1395j, *et seq*., covers "medical and other health services" not included within Medicare Part A (which covers expenses related to hospital services, home health services, and hospice care). Diagnostic tests such as the polysomnographic sleep tests at issue here are included in the Medicare Part B definition of "medical and other health services."

21. Services and items (such as medical devices) are excluded from coverage under Medicare Part B if they "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member[.]" 42 U.S.C. §1395y(a)(1)(A).

22. Similar requirements exist for other federally funded health care programs. For example, CHAMPUS/TRICARE, a program administered by the Department of Defense for individuals and dependents affiliated with the armed forces, pays for "medically necessary services and supplies required in the diagnosis or treatment of illness or injury[.]" 32 C.F.R. §199.4(a)(1)(i). CHAMPVA, a program administered by the Department of Veterans Affairs for the families of veterans with 100 percent service-related disabilities, covers expenses for "medical services and supplies that are medically necessary and appropriate for the treatment of a condition[.]" 38 C.F.R. §17.272(a).

2. Medicare and CHAMPUS/TRICARE Regulations, CMS Guidance, and Local Coverage Determinations

23. The Department of Health and Human Services (HHS) has promulgated numerous regulations which implement the statutory provisions governing Medicare. These regulations designate specific items and services that are covered under Medicare Part B and others that are not. In doing so, the regulations concretize the meaning of the "reasonable and necessary" requirement.

24. Diagnostic tests such as polysomnographic sleep tests are included in the definition of "medical and other health services," for purposes of Medicare Part B coverage. 42 C.F.R. §410.10(e).

25. Defendant ASM's diagnostic sleep testing centers are designated "Independent Diagnostic Testing Facilities" (IDTFs) for Medicare Part B purposes. According to regulations in effect since 1999, non-physician personnel who are employed by an IDTF to perform diagnostic tests must be qualified to perform the tests in question, as evidenced by licensure or certification from an appropriate state health or education department or national credentialing body, in order for those tests to qualify for Medicare

reimbursement. IDTFs are required to maintain documentation of their employees' credentials. 42 C.F.R. §410.33(c).

26. The diagnosis of sleep disorders is considered a "physician's service." Medicare Part B pays for the diagnosis of sleep disorders only if the service is performed by a licensed physician. 42 C.F.R. §§410.20(a), (b).

27. In order to be reimbursable under Medicare, all procedures performed by an IDTF must be specifically ordered, in writing, by a patient's treating (referring) physician. IDTFs may not add any procedures based on their own internal protocols without a written order from the treating physician. Tests and other procedures must be ordered by a beneficiary's treating physician only, not by a supervising physician employed by the IDTF. Diagnostic tests that are not ordered by a treating physician do not qualify as reasonable and necessary. 42 C.F.R. §§410.32(a), 410.33(d).

28. Diagnostic tests must be performed under an appropriate level of physician supervision. 42 C.F.R. §410.32(b)(1). For most diagnostic tests, including polysomnographic sleep tests, only "general supervision" by a physician is required. 42 C.F.R. §410.32(b)(3). Although, to satisfy the criteria for providing "general supervision," a physician is not required to be present during the performance of the test, the physician must exercise overall direction and control over the procedure. Additionally, the training of non-physician personnel who actually conduct the tests is the responsibility of the supervising physician. 42 C.F.R. §410.32(b)(3)(i).

29. The Department of Defense has promulgated regulations governing the CHAMPUS/TRICARE program. Among other things, those regulations provide for administrative remedies for "fraud, abuse, and conflict of interest." 32 C.F.R. §199.9.

These administrative remedies are "in addition to, and not in lieu of, any other remedies or sanctions authorized by law or regulation." 32 C.F.R. §199.9(a)(3).

30. Included in the definition of fraud under CHAMPUS/TRICARE is the submission of "falsified or altered . . . claims or medical or mental health patient records which misrepresent . . . the name(s) of the individual(s) who provided the services." 32 C.F.R. §199.9(c)(7).

31. The practice of "reciprocal billing" is also a forbidden form of fraud under CHAMPUS/TRICARE. This is defined as, "[b]illing or claiming services which were furnished by another provider or furnished by the billing provider in a capacity other than as billed or claimed." 32 C.F.R. §199.9(c)(10). Examples of "reciprocal billing" include: "[o]ne provider performing services for another provider and the latter bills as though he had actually performed the services" and "billing for professional services when the services were provided by another individual who was an institutional employee…" 32 C.F.R. §§199.9(c)(10)(i), (iii).

3. Federal Health Care Program Provider Certifications

32. In order to participate in the Medicare program as a provider of medical or other health services IDTFs, as well as other types of providers, must submit an Enrollment Application to CMS. This application includes a certification that the provider will abide by all applicable Medicare laws, regulations, and program instructions, and that payment of a claim by Medicare is conditioned upon the claim and its underlying transaction complying with such laws, regulations, and program instructions. Form CMS-855B, "Medicare Enrollment Application: Clinics/Group Practices and Other Suppliers," p.30.

33. Any entity that wishes to participate in the CHAMPUS/TRICARE program as a "Corporate Services Provider" (a category which includes "Freestanding Sleep Disorder Diagnostic Centers") must submit an enrollment application to a TRICARE Program Regional Administrator. The application for TRICARE includes a certification that the provider will comply with "applicable provisions of 32 CFR 199 and related TRICARE policy."

34. Under explicit and/or implied certification and related legal theories, Medicare and other claims involving federal reimbursement may be false if they claim reimbursement for services or costs that are either not reimbursable or were not rendered as claimed.

B. The Federal Anti-Kickback Statute

35. The federal health care Anti-Kickback statute, 42 U.S.C. §1320a-7b(b), arose out of Congressional concern that payoffs to those who can influence health care decisions will result in goods and services being provided that are medically inappropriate, unnecessary, of poor quality, or even harmful to a vulnerable patient population. To protect the integrity of federal health care programs from these difficult to detect harms, Congress enacted a prohibition against the payment of kickbacks in any form, regardless of whether the particular kickback actually gives rise to overutilization or poor quality of care.

36. 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 the furnishing of, or payment for, any item or service for which payment may be made under any federal health care program. 42 U.S.C. §1320a-7b(b). Under

this statute providers of medical and other health services (including diagnostic testing) may not offer or pay any remuneration, in cash or in kind, directly or indirectly, to induce physicians to refer patients for services that may be paid for by a federal health care program. The law not only prohibits outright bribes and rebate schemes, but also prohibits any payment that has as one of its purposes inducement of a physician to refer a patient to a particular entity for the provision of covered services or treatment. Compliance with the Anti-Kickback statute is a prerequisite to a provider's right to receive or retain reimbursement payments from federal health care programs.

37. Compliance with the Anti-Kickback statute is a precondition to participation as a health care provider under Medicare and other federal health care programs. With regard to Medicare, any physician or other health care provider who wishes to participate in the program must submit an Enrollment Application which contains a Certification Statement that specifically requires that the provider comply with the Federal Anti-Kickback statute as a condition for receiving reimbursement under the Medicare program. See Forms CMS-855B, p.30; CMS-855S, p.31.

38. Violation of the Anti-Kickback statute subjects the violator to exclusion from participation in federal health care programs, civil monetary penalties of up to $50,000 per kickback violation, and imprisonment of up to five years per violation. 42 U.S.C. §§1320a-7(b)(7), 1320a-7a(a)(7), 1320a-7b(b).

V. DEFENDANTS' ILLEGAL AND FRAUDULENT PRACTICES

A. Defendant ASM Employs Non-Credentialed Technicians for the Administration of Medicare-Reimbursed Sleep Tests

39. At all times material to this Complaint, ASM has knowingly employed technicians at its diagnostic sleep testing centers who have neither licenses nor certifications as sleep study technicians (*i.e.*, "non-credentialed" technicians).

40. Defendant knows that Medicare rules, referenced above, require that polysomnographic sleep tests be performed on Medicare patients only by licensed or certified sleep technicians (if not by physicians) in order to qualify for reimbursement for such testing services.

41. Notwithstanding such knowledge, Defendant has never made any effort whatsoever to ensure that only credentialed technologists administer tests to Medicare patients. Indeed, Defendant has failed even to make an effort to maintain enough credentialed technologists on staff to handle the Medicare patients who are tested at Defendant's facilities.

42. As a result, non-credentialed technicians routinely test and care for Medicare patients. Consequently, Defendant has and continues to knowingly make false claims and collect Medicare reimbursement for the technical component of polysomnographic tests that are performed by non-certified sleep technicians.

43. For example, Defendant's sleep clinic located in Saratoga, California employed Relator Daniel Purnell, Princess Dauz, Frank Bijenveld, Tess Zavala and Santa Gallardo as sleep technicians. During their employment, none of these individuals were Registered Polysomnographic Sleep Technicians ("RPSGST"), yet each one conducted sleep studies independently and without the assistance or supervision of a certified sleep technician. The following claims were submitted by ASM to Medicare for tests conducted by non-certified sleep technicians:

a. CPAP test conducted on 05/06/2009 by D. Purnell, billed to Medicare on 01/05/2010;

b. SPLIT test conducted on 05/07/2009 by D. Purnell, billed to Medicare on 01/05/2010;

c. NPSG test conducted on 06/24/2009 by D. Purnell and F. Bijenveld, billed to Medicare on 09/11/2009;

d. SPLIT test conducted on 06/24/2009 by P. Dauz and T. Zavala, billed to Medicare on 09/13/2009;

e. CPAP test conducted on 07/17/2009 by D. Purnell, billed to Medicare on 09/11/2009;

f. SPLIT test conducted on 09/02/2009 by D. Purnell, billed to Medicare on 01/05/2010;

g. NPSG test conducted on 09/11/2009 by T. Zavala and S. Gallardo, billed to Medicare on 01/05/2010;

h. SPLIT test conducted on 01/05/2010 by T. Zavala and S. Gallardo, billed to Medicare on 01/05/2010;

i. NPSG test conducted on 09/29/2009 by P. Dauz and D. Purnell, billed to Medicare on 01/05/2010;

j. NPSG test conducted on 10/08/2009 by S.Gallardo and T. Zavala, billed to Medicare on 01/05/2010.

44. Based on information obtained from other past and present technicians, Relator understands and therefore alleges that Defendant's practice of billing Medicare for tests performed by unlicensed sleep technicians began at least as early as 2002 and

occurred at Defendant's sleep centers on a nationwide basis. Furthermore, the practice has continued unabated up to and including the present time.

B. Defendant ASM's Sleep Technicians Analyze the Results of Polysomnographic Diagnostic Sleep Tests, Make Diagnoses of Sleep Disorders, and Prepare Physicians' Reports

45. During Relator's employment by Defendant, the results of patients' first round of polysomnographic sleep testing were routinely "scored" by the company's sleep technicians. "Scoring" of sleep studies involves analyzing the polysomnogram read-out and noting data that suggests the existence of a sleep disorder.

46. In some cases, Defendant's sleep technicians would alter test results to qualify patients for health care benefit reimbursement.

47. During his employment with Defendant, Relator was pressured by Defendant's Directors of Clinical Services, to prepare Physicians' Reports which should have been prepared by supervising physicians.

48. Based on information obtained from other technicians employed by Defendant, Relator also alleges that Defendant's practice of having sleep technicians, rather than physicians, analyze the results of polysomnographic sleep tests, diagnose sleep disorders based on their analysis, and prepare Physicians' Reports containing the technicians' analysis and diagnosis, began several years before Relator was hired and has continued unabated up to and including the present time.

49. The initial diagnosis of sleep disorders, the preparation of Physicians' Reports, and the determination of the appropriate pressure settings for individual patients' Continuous Positive Airway Pressure (CPAP) devices are all "physician's services"

under Medicare, Medicaid, and other federal health care programs rules and regulations. These services are not reimbursable if they are performed by a non-physician.

50. When the referring physicians or other reading physicians under contract with Defendant have not actually performed the Professional Component of the tests, their submission of claims for reimbursement under Medicare, Medicaid, and other federal health care programs is fraudulent. Defendant's participation in the submission of those claims subjects Defendant to liability along with the physicians.

C. Defendant ASM Performs CPAP Titration Sleep Studies Without Prior Written Orders from Patients' Treating Physicians

51. After patients' initial polysomnographic diagnostic tests are scored by Defendant's technicians, Defendant routinely orders a second round of testing (CPAP Titration sleep studies) without seeking or receiving a physician's order.

52. During Relator's employment by Defendant, patients sometimes complained to him that they had never been told the results of their initial diagnostic tests, nor had they met with their treating physicians, prior to their first or second round of testing.

53. Based on information obtained from other technicians employed by Defendant, Relator also alleges that Defendant's practice of performing CPAP Titration studies without receiving a prior written order from patients' treating physicians began several years before his employment with the company, and has continued unabated up to and including the present time.

54. All diagnostic tests performed by an IDTF must be ordered, in writing, by a patient's treating physician in order to be reimbursable under Medicare, Medicaid, or

other federal health care programs. Tests performed without such a prior written order are not reasonable and necessary, and thus are not reimbursable.

55. Defendant has nevertheless routinely performed, and continues to perform, CPAP Titration studies on Medicare, Medicaid and other federal health care program beneficiaries without prior written orders from those patients' treating physicians. Defendant submits reimbursement claims to such federal health care programs for those tests and has received, and continues to receive, federal and state funds as payment on those claims.

56. At all times relevant to this complaint, Defendant has known that CPAP Titration studies are conducted by the company without prior written orders from patients' treating physicians.

D. Licensed Physicians Employed by Defendant ASM Do Not Exercise Sufficient Supervision Over Medicare-Reimbursed Sleep Tests

57. During Relator's employment with Defendant, the supervising physicians did not participate in the training of Relator or any of the other sleep technicians. They did not observe any of the sleep tests conducted by Relator.

58. Based on information obtained from other technicians employed by Defendant, Relator also alleges that the level of supervision at other diagnostic sleep testing centers operated by Defendant is essentially the same as that which Relator experienced; that this level of supervision had been in place for several years before Relator was hired; and that it has not changed in the months since he left the company.

59. Although only general supervision by a physician is required for poly-somnographic sleep tests, the level of physician supervision by Defendant fails to meet

even that standard. Defendant does not exercise overall direction and control over the testing procedures and has also failed to fulfill its responsibility to train Defendant's non-physician personnel in polysomnographic testing procedures. These failures by Defendant constitute violations of the Medicare regulations' physician supervision requirements.

60. Any polysmnographic diagnostic sleep tests performed by Defendant's sleep technicians under insufficient physician supervision are not reimbursable under Medicare.

61. Defendant has nevertheless routinely submitted, and continues to submit, Medicare reimbursement claims for polysomnographic diagnostic tests that are conducted under insufficient physician supervision. Defendant has received, and continues to receive, federal funds as payment on those claims.

62. At all times relevant to this Complaint, Defendant has known that supervising physicians do not exercise adequate supervision over diagnostic tests performed at their sleep centers. Defendant also knows that supervising physicians do not fulfill their responsibility to train their sleep technicians.

E. Defendant ASM Participates in an Illegal Kickback Scheme with Referring Physicians

63. The scoring of polysomnographic diagnostic sleep tests and the determination of individualized CPAP settings by Defendant sleep technicians, without prior prescriptions, are part of illegal kickback arrangements between Defendant and referring physicians.

64. As part of Defendant's marketing strategy the company offers to have Defendant's technicians analyze the results of initial polysomongraphic diagnostic sleep

tests and subsequent CPAP Titration studies. The analyses are then typed up as "Physicians' Reports" and forwarded to referring physicians for their signatures. The physicians are then able to bill Medicare, Medicaid, and other federal health care programs for the Professional Component of the sleep tests, as an inducement to continue and/or increase their referrals of patients to Defendant.

65. Relator is informed and believes that in return for Defendant's offers to have technicians perform work for which referring physicians can receive reimbursement from the federal government, the physicians agree to increase or continue their referrals of patients to Defendant.

66. Relator is informed and believes that as another component of Defendant's marketing strategy the company associates with certain referring doctors who, in addition to being permitted to charge for professional services associated with sleep studies administered to patients they personally refer to Defendant, are also designated as "interpreting physicians" for sleep tests provided to patients of other referring doctors. These physicians do not, however, perform the actual work of interpreting test results and preparing Physicians' Reports. Rather, as noted above, these tasks are performed by Defendant's technicians. The "Physicians' Reports" are then forwarded to the "interpreting physicians" for their signatures. These physicians are then able to bill Medicare, Medicaid, and other federal health care programs for the Professional Component of the sleep tests.

67. These arrangements between Defendant and "interpreting physicians" are illegal and fraudulent in that the physicians submit claims to federal health care programs for services that they did not perform. Moreover, the arrangements violate the federal

health care Anti-Kickback Statute in that Defendant offers or pays remuneration (the preparation of Physicians Reports which can be submitted for reimbursement) in exchange for the physicians' implicit recommendation of Defendant's services through the use of their names by Defendant as part of the company's marketing efforts. The use of these physicians' names in its marketing efforts also causes Defendant to attract additional referrals to its sleep centers, which it would not receive but for the illegal arrangements with those "interpreting physicians." In fact, Defendant would not be able to effectively compete with other sleep testing facilities that are owned and operated by professional practice groups which include certified sleep medicine specialists who provide genuine physician-interpretation services in association with sleep testing, but for its arrangement with the so-called "interpreting physicians."

68. During Relator's employment with ASM, the physicians whom he knows agreed to serve as "interpreting physicians" for Defendant's sleep tests were Dr. Wei Wang and Dr. Daniel Katzenberg.

69. Compliance with the federal health care Anti-Kickback statute is a prerequisite for participation in any federal health care program.

70. The Anti-Kickback statute, 42 U.S.C. §1320a-7b(b), forbids the provision of anything of value in exchange for patient referrals. Here, the value given by Defendant in exchange for referrals is the work performed by the company's technicians for which referring physicians then bill Medicare, Medicaid, and other federal health care programs. The physicians receive payments from the federal government for work that they have not performed.

71. While being compensated as consultants for ASM, Drs. Wang and Katzenberg referred patients for sleep diagnostic testing to ASM and interpreted patient test results.

72. Additionally, Drs. Wang and Katzenberg receive office space at ASMs' Saratoga, California facility free of charge, at which they see patients not associated with ASM.

73. Any services or items provided to federal health care program beneficiaries which are tainted by an illegal kickback scheme are not reimbursable under those programs.

74. Virtually all tests performed by Defendant on federal health care program beneficiaries, are tainted by the illegal kickback arrangements between Defendant and referring physicians, and thus are not reimbursable.

75. Defendant nevertheless routinely has submitted, and continues to submit, reimbursement claims to Medicare, Medicaid and other federal health care programs for the performance of sleep tests. Defendant has received, and continues to receive, federal and State funds as payment on those claims.

76. The illegal arrangements between Defendant and referring and "interpreting" physicians amount to a conspiracy to submit false claims to federal and State governments, in that each of the parties agrees that the physicians will submit reimbursement claims to Medicare, Medicaid, and other federal health care programs for services which are actually preformed by technicians employed by Defendant.

F. Defendant ASM Participates in an Illegal Kickback Scheme with Defendant Advantacare

77. Defendant ASM has entered into an illegal kickback arrangement with Defendant Advantacare. As a result of this kickback scheme, Defendant ASM's Saratoga clinic orders all CPAP devices from Advantacare. In order to assure that ASM patients continue to only use Advantacare equipment, Advantacare provides kickbacks to ASM. For example, an Advantacare sales representative has given several CPAP devices to the clinic and to clinic personnel free of charge. Each of these devices retails for more than $1800. In addition, Advantacare has agreed to recruit patients for ASM in exchange for ASM agreeing to refer patients only to Advantacare as opposed to other DME providers. In fact, ASM would fax the paperwork required to obtain CPAP devices or other equipment for patients directly to Advantacare to ensure that the patients would order their devices from Advantacare. ASM would not inform the patients that they had a choice as to which DME provider to use in order to obtain their devices.

78. The provision of these kickbacks, including free CPAP devices, to ASM in exchange for ASM agreeing to use Advantacare equipment with regard to its Medicare and other government healthcare program patients constitutes illegal kickbacks in violation of the federal Anti-Kickback Statute. Reimbursement claims submitted for Advantacare devices used by ASM patients are tainted by the illegal kickback arrangement between Advantacare and ASM and thus constitute false or fraudulent claims under the False Claims Act.

VI. DAMAGES RESULTING FROM DEFENDANTS' MISCONDUCT

79. Relator does not yet know the precise amount of overcharges the United States has paid as a result of Defendant's misconduct. However, he estimates that total

damages amount well into the millions of dollars over the period of conduct relevant to this action.

80. Medicare, CHAMPUS/TRICARE reimbursement claims for initial polysomnographic diagnostic tests are filed under CPT code 95810 and were reimbursed by Medicare at a rate of $745.13 per test in 2009. The "Technical Component" -- the actual testing procedure, conducted by Defendant -- accounted for $573.74 of the total reimbursement. The "Professional Component" -- the interpretation of the test results and the diagnosis of particular sleep disorders, which should have been performed by patients' referring physicians -- accounted for the additional $171.39 of the total.

81. Medicare, CHAMPUS/TRICARE reimbursement claims for the second round of polysomnographic testing, the CPAP Titration study, are filed under CPT code 95811 and are reimbursable and were reimbursable by Medicare at a rate of $819.44 in 2009. The Technical Component accounted for $635.32 of the total, while the Professional Component accounted for $184.12.

Count I

Federal False Claims Act
31 U.S.C. §§ 3729(a)(1), (a)(2) and (a)(3) (1986)
31 U.S.C. §§ 3729(a)(1)(A), (a)(1)(B) and (a)(1)(C) (2009)
as to Defendant American Sleep Medicine

82. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 81 of this Complaint.

83. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §3729, et seq., as amended in 1986 and again in 2009.

84. Through the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the United States Government for payment or approval.

85. Through the acts described above, Defendant knowingly made, used, or caused to be made or used false or fraudulent records and statements, and omitted material facts, to induce the Government to approve and pay such false or fraudulent claims.

86. Through the acts described above, Defendant conspired to present false or fraudulent claims to the United States government for payment or approval; and conspired to make, use, or caused to be made or used, false or fraudulent records and statements to induce the Government to approve and pay such false or fraudulent claims.

87. Each reimbursement claim submitted by Defendant for polysomnographic diagnostic sleep tests and CPAP Titration studies was a false or fraudulent claim for payment, because the conditions under which the tests were conducted, scored and interpreted violated multiple federal regulations that are conditions of payment for the technical and professional components of such tests. Further, the tests were tainted by an illegal kickback scheme.

88. Each diagnosis of a sleep disorder made by Defendant's technicians and submitted to referring and/or interpreting physicians to be signed by such physicians and falsely represented by such physicians as their own work was a false or fraudulent record or statement made and/or caused to be made by Defendant.

89. Each reimbursement claim submitted by physicians for the Professional Component of sleep tests, based on such false or fraudulent records and statements, represents a false or fraudulent claim for payment that Defendant caused to be made.

90. In addition, Defendant Advantacare provided kickbacks to ASM in exchange for Defendant ASM ensuring that Medicare (and other government healthcare program) patients would use Advantacare devices. Reimbursement claims submitted for Advantacare devices used by ASM patients are tainted by the illegal kickback arrangement between Advantacare and ASM and thus constitute false or fraudulent claims under the False Claims Act.

91. The United States Government and its officers, employees and agents, are unaware of the falsity of the records, statements, and claims made or caused to be made by the Defendant, paid and continues to pay claims that would not be paid but for the Defendant's illegal and fraudulent practices.

92. By reason of the Defendant's acts, the United States has been damaged, and continues to be damaged, in substantial amount to be determined at trial. Federal health care programs have paid thousands of claims, amounting to millions of dollars, for diagnostic tests that were not legally reimbursable.

Count Two

Federal False Claims Act
31 U.S.C. §§ 3729(a)(1), (a)(2) and (a)(3) (1986)
31 U.S.C. §§ 3729(a)(1)(A), (a)(1)(B) and (a)(1)(C) (2009)
as to Defendant Advantacare

93. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 81 of this Complaint.

94. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §3729, et seq., as amended in 1986 and again in 2009.

95. Defendant Advantacare provided kickbacks to ASM in exchange for Defendant ASM ensuring that Medicare (and other government healthcare program) patients would use Advantacare equipment. Reimbursement claims submitted for Advantacare CPAP devices used by ASM patients are tainted by the illegal kickback arrangement between Advantacare and ASM and thus constitute false or fraudulent claims under the False Claims Act.

96. Through the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the United States Government for payment or approval.

97. Through the acts described above, Defendant knowingly made, used, or caused to be made or used false or fraudulent records and statements, and omitted material facts, to induce the Government to approve and pay such false or fraudulent claims.

98. Through the acts described above, Defendant conspired to present false or fraudulent claims to the United States government for payment or approval; and conspired to make, use, or caused to be made or used, false or fraudulent records and statements to induce the Government to approve and pay such false or fraudulent claims.

99. The United States Government and its officers, employees and agents, are unaware of the falsity of the records, statements, and claims made or caused to be made by the Defendant, paid and continues to pay claims that would not be paid but for the Defendant's illegal and fraudulent practices.

100. By reason of the Defendant's acts, the United States has been damaged, and continues to be damaged, in substantial amount to be determined at trial. Federal health care programs have paid thousands of claims, amounting to millions of dollars, for diagnostic tests that were not legally reimbursable.

Count Three

Defendant American Sleep Medicine's Violation of 31 U.S.C. § 3730(h) with regard to Relator

101. Relator realleges and incorporates by reference the allegations of paragraphs 1-81 of this complaint.

102. In violation of the False Claims Act § 3730(h), Defendant American Sleep Medicine took negative employment actions against Relator as a result of lawful actions taken by Relator in furtherance of his qui tam action including investigation of Defendant's fraudulent activities.

103. As a result of Defendant's retaliatory and discriminatory conduct, Relator has suffered damages.

PRAYER

WHEREFORE, Relator prays for judgment against the Defendants as follows:

1. that Defendants cease and desist from violating 31 U.S.C. §3729 et seq.

2. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the United States has sustained because of Defendants' actions, plus a civil penalty of not less than $5500 and not more than $11,000 for each violation of 31 U.S.C. §3729;

3. that Relator be awarded the maximum amount allowed pursuant to §3730(d) of the False Claims Act;

4. that Relator be awarded the maximum amount allowed pursuant to §3730(h);

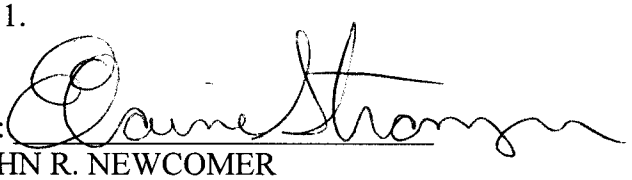
5. that Relator be awarded all costs of this action, including attorneys' fees and expenses; and

6. that Relator recover such other relief as the Court deems just and proper.

Demand for Jury Trial

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relator hereby demands a trial by jury.

Respectfully submitted this 8th day of June, 2011.



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COUNSEL FOR RELATOR

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Second Amended Complaint has been furnished by Certified Mail, Return Receipt Requested, this 8th day of June, 2011 to the following:

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