### UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF FLORIDA

UNITED STATES and the STATE OF FLORIDA ex rel. WILLARD REVELS,

Plaintiffs,

v.

Case No. 8:10-cv-319-T-27MAP

BAY AREA SLEEP ASSOCIATES, LLC, d/b/a SOMNOMEDICS LLC; AND EDWARD KILLMER, JR.,

Defendants.

### **UNITED STATES' COMPLAINT IN INTERVENTION**

The United States of America ("United States" or "Government") brings this action to recover damages from false claims submitted to the Medicare program and the TRICARE program, as a result of the sustained fraudulent course of conduct of the defendants, Bay Area Sleep Associates, LLC d/b/a SomnoMedics, LLC and Edward Killmer, Jr. ("collectively "Defendants"). Beginning in 2004, Defendants began submitting, or causing to be submitted, claims to federal health care programs for diagnostic sleep tests that were performed by non-certified sleep technicians in direct contravention of federal program requirements. By knowingly submitting, or causing to be submitted, false claims for reimbursement, Defendants violated the False Claims Act ("FCA"), 31 U.S.C. § 3729, *et seq.*, were unjustly enriched, and were paid by mistake.

### I. NATURE OF ACTION

1. The United States brings this action to recover treble damages and civil penalties under the FCA and to recover damages and other monetary relief under the common law or equitable theories of unjust enrichment and payment by mistake.

 The United States bases its claims on Defendants submitting and causing to be submitted false or fraudulent claims to federal health care programs in violation of 31 U.S.C. § 3729(a)(1), § 3729(a)(1)(A), and § 3729(a)(1)(B).

3. Within the time frames detailed below, Defendants knowingly submitted, or caused to be submitted, thousands of false claims to Medicare and TRICARE for reimbursement which resulted in millions of dollars of reimbursement that would not have been paid but for Defendants' misconduct.

#### **II. JURISDICTION AND VENUE**

This Court has jurisdiction over the subject matter of this action pursuant to 28
 U.S.C. §§ 1331, 1345.

This Court may exercise personal jurisdiction over Defendants pursuant to 31
 U.S.C. § 3732(a) and because Defendants reside and transact business in the Middle District of Florida.

6. Venue is proper in the Middle District of Florida under 31 U.S.C. § 3732 and 28U.S.C. § 1391(b) and (c) because Defendants reside and transact business in this District.

### III. PARTIES

7. The United States brings this action on behalf of: 1) the Department of Health and Human Services ("HHS") and the Centers for Medicare & Medicaid Services ("CMS"), which administers the Medicare program; and 2) the Department of Defense's TRICARE Management Activity ("TRICARE").

8. Willard Revels ("Relator") is a resident of Lakeland, Florida. He was employed by SomnoMedics as a diagnostic sleep technician from January 2008 through March 2009. In January 2010, Relator filed an action alleging violations of the FCA on behalf of himself and the United States pursuant to the *qui tam* provisions of the FCA, 31 U.S.C. § 3730(b)(1).

Defendant Bay Area Sleep Associates, LLC, doing business as SomnoMedics,
 LLC ("SomnoMedics"), is a Florida limited liability company headquartered at 1323 W. Fletcher
 Avenue, Tampa, Florida 33612. SomnoMedics is wholly owned by Health Care Solutions, LLC.

10. SomnoMedics currently operates ten sleep laboratories throughout central Florida.

11. SomnoMedics performs polysomnographic sleep tests on individuals suffering from potentially life-threatening sleep disorders such as sleep apnea.

12. Defendant Edward Killmer, Jr. ("Killmer"), is the founder and sole owner of Health Care Solutions, LLC. Through Health Care Solutions, LLC, Mr. Killmer controls the operations of SomnoMedics.

#### IV. THE LAW

#### A. <u>The False Claims Act</u>

13. The FCA, 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. 31 U.S.C. § 3729(a)(1).

14. The FCA provides, in pertinent part, that:

(a)(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;

(a)(1)(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(a)(1)(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; . . .;

\* \* \*

is liable to the United States Government for a civil penalty of not less than \$5,000 and not more than \$10,000, . . . plus 3 times the amount of damages which the Government sustains because of the act of that person. . . .

31 U.S.C. § 3729.<sup>1</sup> For purposes of the False Claims Act,

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(b) (1986).

# V. THE MEDICARE PROGRAM

15. In 1965, Congress enacted Title XVIII of the Social Security Act, 42 U.S.C.

§ 1395 et seq., known as the Medicare program. Entitlement to Medicare is based on age, disability, or affliction with end-stage renal disease. *See* 42 U.S.C. §§ 426, 426A. Medicare is administered by CMS, which is part of HHS. At all times relevant to this complaint, CMS contracted with private contractors referred to as "fiscal intermediaries," "carriers," and "Medicare Administrative Contractors," to act as agents in reviewing and paying claims submitted by healthcare providers. *See* 42 U.S.C. § 1395h; 42 C.F.R. §§ 421.3, 421.100.

<sup>&</sup>lt;sup>1</sup> The False Claims Act was amended pursuant to Public Law 111-21, the Fraud Enforcement and Recovery Act of 2009 ("FERA"), enacted May 20, 2009. Given the nature of the claims at issue, Section 3279(a)(1) of the statute prior to FERA, and as amended in 1986, and Section 3729(a)(1)(A) are both applicable here. Section 3729(a)(1) applies to conduct before FERA was enacted, and section 3729(a)(1)(A) applies to conduct after FERA was enacted. Section 3729(a)(1)(B) was formerly Section 3729(a)(2), and is applicable to all claims in this case by virtue of Section 4(f) of FERA.

16. To participate in the Medicare program, health care providers enter into agreements with HHS-CMS in which the provider agrees to conform to all applicable statutory and regulatory requirements for reimbursement from Medicare, including the provisions of Section 1862 of the Social Security Act and Title 42 of the Code of Federal Regulations. Among the legal obligations of participating providers is the requirement not to make false statements or misrepresentations of material facts concerning payment requests. *See* 42 C.F.R. §§ 1320a-7b(a)(1)-(2), 413.24(f)(4)(iv), 1001.101(a)(1); 42 U.S.C. § 1320a-7b(a)(1)-(2).

#### A. <u>Submitting Claims for Reimbursement</u>

17. For outpatient treatment, all Medicare reimbursement is subject to Part B. *See* 42
U.S.C. §§ 1395j-1395w-4. Polysomnographic sleep tests are included in the definition of
"medical and other health services" for purposes of Medicare Part B coverage. *See* 42 C.F.R.
§ 410.10(e).

18. To obtain Medicare reimbursement pursuant to Part B, providers submit claims using forms known as CMS 1500s. Among the information the provider includes on a CMS 1500 form are certain five-digit codes, known as Current Procedural Terminology, or CPT codes, that identify the services rendered and for which reimbursement is sought.

19. Services 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).

20. Any provider seeking Medicare reimbursement through Part B must certify on a CMS Form 1500 that "the services shown on this form were medically indicated and necessary for the health of the patient and were personally furnished by me or were furnished incident to my professional service by my employee under my immediate personal supervision."

## B. Medicare Guidance Regarding Independent Diagnostic Testing Facilities

21. The polysomnographic testing facilities operated by SomnoMedics are considered

Independent Diagnostic Testing Facilities ("IDTFs") for Medicare Part B purposes.

22. As a general rule, diagnostic testing procedures performed at an IDTF may be

reimbursed under Medicare Part B. See 42 U.S.C. § 410.33(a).

23. According to CMS regulations,

Any nonphysician personnel used by the IDTF to perform tests must demonstrate the basic qualifications to perform the tests in question and have training and proficiency as evidenced by licensure or certification by the appropriate State health or education department. In the absence of a State licensing board, the technician must be certified by an appropriate national credentialing body. The IDTF must maintain documentation available for review that these requirements are met.

42 U.S.C. § 410.33(c).

24. Thus, Medicare Part B will not pay for diagnostic tests performed by

nonphysician personnel who do not possess a license from the appropriate state health

department or a certification from an appropriate national credentialing body.

25. Furthermore, federal regulations require that the IDTF certify in its enrollment application that it has technicians on staff who maintain the appropriate credentials to perform the services provided. *See* 42 U.S.C. 410.33(g)(12).

26. Failure to employ technicians with the appropriate state license or nationallyrecognized credential to perform diagnostic tests may result in the revocation of a provider's billing privileges. *See* 42 U.S.C. § 410.33(h).

27. During the period in question, the state of Florida did not issue licenses to nonphysician technicians performing polysomographic sleep testing.

28. During the period in question, there were four nationally recognized entities issuing credentials to polysomnographic sleep technicians.

### VI. THE TRICARE PROGRAM

29. TRICARE is a managed health care program established by the Department of Defense. 10 U.S.C. §§ 1071-1110. TRICARE provides health care benefits to eligible beneficiaries, which include, among others, active duty service members, retired service members, and their dependents.

30. For purposes of the TRICARE program, SomnoMedics is considered a "corporate services provider." *See* 32 C.F.R. § 199.6(f)(1)(i).

31. The regulatory authority establishing the TRICARE program delegated to its director or designee the authority to develop additional regulatory requirements for program participants. *See* 32 C.F.R. 199.6(f)(1)(iv)(A).

32. TRICARE does not cover services performed at a "corporate services provider" if a technologist is neither "licensed by the state in which the procedure is rendered or who is certified by a Qualified Accreditation Organization." TRICARE Policy Manual, 6010.54-M, Chap. 11, Sect. 12.1(II)(C)(3).

33. TRICARE similarly does not cover services performed at a "corporate services provider" if the provider does not meet the Medicare conditions of participation or conditions of coverage for substantially comparable services. *See id.*, at (II)(C)(7).

#### VII. DEFENDANTS' SCHEME

#### A. <u>Defendants' Diagnostic Sleep Testing Business</u>

34. Defendants have been providing polysomnographic sleep testing services to patients in Florida since 1996.

35. Among the sleep testing services provided by SomnoMedics are diagnostic polysomnograms. These tests, which are identified under CPT code 95810, measure different heart, lung, and brain functions to determine whether a patient is at risk of a potentially life-threatening sleep disorder.

36. While the patient is undergoing the diagnostic examination, SomnoMedics employs a sleep technician called an "acquisition technician" to monitor the patient's condition and document his or her heart, lung, and brain activity.

37. After the test is completed, SomnoMedics employs a "scoring technician," who may or may not be the same person as the "acquisition technician," to review the results of the test and identify all information necessary for a physician to examine in order to interpret the diagnostic polysomnogram.

38. If a patient is diagnosed with a sleep disorder such as sleep apnea, SomnoMedics may subsequently perform a titration study, which is identified under CPT 95811. In a titration study, a patient is attached to a continuous positive airway pressure machine to determine the proper course of treatment for the individual.

39. Titration studies are conducted in a matter similar to diagnostic polysomnograms. An "acquisition technician" is present to monitor the patient's condition and record heart, lung and brain activity, and after the fact a "scoring technician" reviews the results of the study and prepares a report for the reviewing physician identifying abnormalities or other issues of note.

40. Based on the results of the titration study, a physician may prescribe a continuous positive airway pressure machine and specific settings for the patient to use while sleeping at home.

### B. <u>Acquisition of a Medicare Provider Number</u>

41. In 2004, Defendant Killmer decided to expand SomnoMedics' business to include providing polysomnographic sleep testing services to beneficiaries of federal health care providers such as Medicare.

42. Defendant Killmer was responsible for evaluating relevant Medicare regulations on behalf of SomnoMedics.

43. Defendants submitted an application to CMS to obtain a Medicare provider number in June or July 2004. Defendant Killmer signed the application on June 4, 2004, acknowledging that "[b]y my signature, I certify that the information contained herein is true, correct, and complete, to the best of my knowledge, and I authorize the Medicare program contractor to verify this information. If I become aware that any information in this application is not true, correct, or complete, I agree to notify the Medicare program contractor of this fact immediately."

44. SomnoMedics provided additional application materials to Medicare on August 5, 2004 and August 12, 2004. On both occasions, Mr. Killmer signed the application and acknowledgement that he was providing true, correct, and complete information to Medicare.

45. The application for a Medicare provider number listed seven polysomnographic sleep technicians employed by SomnoMedics. Each of these sleep technicians maintained a certification from a national credentialing body demonstrating he or she met the national standard for credentialed sleep technicians.

46. At the time SomnoMedics submitted its application to CMS, it employed numerous non-certified polysomnographic sleep technicians.

47. SomnoMedics did not disclose the name or employment status of these noncertified sleep technicians to CMS at the time it submitted its application for a Medicare provider number.

48. On August 26, 2004, CMS conducted a site visit at one of the facilities operated by SomnoMedics. Defendant Killmer was present for the site visit.

49. During the site visit, the names of two additional certified polysomnographic sleep technicians were added to the list of technicians providing diagnostic sleep testing services at SomnoMedics.

50. Defendant Killmer did not advise CMS of the names of non-certified technicians employed by SomnoMedics who provided diagnostic sleep testing services to patients.

51. SomnoMedics thereafter received a Medicare provider number on September 16,2004 and subsequently began billing Medicare for services provided to Medicare beneficiariesthat same month.

52. SomnoMedics has continued to bill Medicare for services rendered to program beneficiaries from September 2004 to the present.

53. SomnoMedics began billing TRICARE for services provided to TRICARE beneficiaries in January 2005 and continues to do so.

### C. <u>SomnoMedics' Billing of CPT Codes 95810 and 95811</u>

54. According to federal health program regulations, an independent testing facility such as SomnoMedics may bill federal health care programs for diagnostic testing services provided to a program beneficiary by a nonphysician if the nonphysician maintains a state license or, for states that do not maintain a state licensing board, a certification from an appropriate national credentialing body.

55. Beginning at least in 2004, SomnoMedics employed both certified and noncertified sleep technicians to conduct diagnostic sleep tests and titration studies at its facilities.

56. SomnoMedics staffed each of its facilities with either one or two sleep technicians depending on the size of the facility and the number of patients scheduled for diagnostic tests during a particular time period.

57. In most instances, SomnoMedics did not make staffing decisions based on the certification status of the sleep technician. Primarily, a sleep technician was assigned to work at a particular facility (or facilities).

58. If two SonmoMedics sleep technicians were on duty at the same time, in most instances SomnoMedics did not assign patients to a technician based on the certification status of the sleep technician.

59. As a result, SomnoMedics assigned non-certified, non-licensed sleep technicians to perform both diagnostic polysomnograms and titration studies on federal health care program beneficiaries.

60. SomnoMedics then submitted claims for reimbursement to federal health care programs for these procedures despite knowing that it was against program regulations to do so.

61. The following table lists examples, identified through a Government record review, of false claims Defendants submitted pursuant to this scheme. In each instance identified below, the acquisition technician administering the diagnostic test or titration study did not possess a certificate from a nationally recognized credentialing organization or a license from the state of Florida.

PATIENT	DATE OF SERVICE	NON-CERTIFIED TECHNICIAN	CPT CODE BILLED	AMOUNT PAID
А	10/22/2008	Anthony Ward	95810	\$491.84
В	9/30/2008	Jim Oyer	95811	\$543.12
С	1/15/2009	Elijah Demitrious	95810	\$488.10
D	2/23/2009	Jim Oyer	95810	\$458.99
E	9/14/2008	Matt Brookens	95811	\$543.12
F	2/3/2009	Jim Oyer	95811	\$508.26
G	9/16/2008	Nick Bashline	95810	\$623.70
Н	1/14/2009	Nohelia Orozco	95811	\$655.55
Ι	9/23/2008	Jim Oyer	95810	\$491.84
J	11/18/2008	Jeffrey Adams	95811	\$543.12
K	9/17/2008	Aaron Johnson	95811	\$543.12
L	12/3/2008	Elijah Demitrious	95810	\$623.70
М	11/19/2008	Nick Bashline	95811	\$543.12
Ν	9/11/2008	Elijah Demitrious	95810	\$491.84
0	10/31/2008	Nohelia Orozco	95811	\$543.12
Р	10/23/2008	Jim Oyer	95811	\$543.12
Q	10/16/2008	Willard Revels	95810	\$491.84
R	10/20/2008	Elijah Demitrious	95811	\$684.74
S	1/29/2009	Elijah Demitrious	95811	\$655.55
Т	9/5/2008	Matt Brookens	95810	\$491.84
U	12/19/2008	Nohelia Orozco	95811	\$543.12
V	11/25/2008	Willard Revels	95811	\$543.12
W	11/6/2008	Jim Oyer	95811	\$684.74
X	1/30/2009	Nohelia Orozco	95810	\$458.99
Y	1/12/2009	Nick Bashline	95811	\$400.26
Z	11/9/2008	Nohelia Orozco	95811	\$543.12

62. Defendants' fraudulent scheme resulted in their receipt of payments from federal health care programs to which they were not entitled. Between 2004 and 2010, SomnoMedics submitted claims for approximately 5,800 claims under CPT code 95810 or 95811 and received approximately \$3.3 million in total reimbursement from Medicare and TRICARE for these claims.

63. Based upon records obtained from Defendants, approximately 60 percent of the claims submitted under CPT code 95810 or 95811 were performed by a non-certified or unlicensed sleep technician. Thus, SomnoMedics received approximately \$2.0 million from Medicare and TRICARE for claims the SomnoMedics knew were ineligible for payment.

#### D. <u>Defendants Knowledge Of Its False Claims for Payment</u>

64. At all times relevant to the allegations in this complaint, defendant Killmer was responsible for understanding Medicare regulations on behalf of SomnoMedics and ensuring Medicare compliance.

65. In 2008, SomnoMedics sleep technicians approached defendant Killmer and SomnoMedics' clinical director regarding a settlement between the United States and a sleep laboratory in Texas using non-licensing technicians to perform polysomnograms and titration studies on Medicare beneficiaries.

66. SomnoMedics' clinical director initially responded to these inquiries by stating that defendant Killmer did not want to pay the extra cost associated with hiring licensed or registered sleep technicians to perform polysomnograms and titration studies on Medicare beneficiaries.

67. Mr. Killmer later responded directly to these inquiries by stating that he would sell his business if he was ever forced to use only licensed or registered technicians to perform polysomnograms and titration studies.

68. In 2009, CMS contacted SomnoMedics and announced it was conducting a compliance audit of the SomnoMedics facility located in Lutz, Florida. The audit was targeted at whether or not SomnoMedics was properly using a billing modifier when it was performing only the technical component (rather than the technical and professional component) of a diagnostic sleep test.

69. When defendant Killmer became aware of the CMS audit, defendant Killmer contacted SomnoMedics' clinical director and inquired as to the technician scheduled to work at the Lutz facility that evening.

70. On the evening in question, a non-certified technician was scheduled to perform polysomnograms at the Lutz facility.

71. Defendant Killmer, aware that it was against Medicare regulations for a noncertified technician to perform a polysomnogram, instructed the clinical director to re-assign the non-certified technician to another facility and staff the Lutz facility with a certified technician.

72. In order to give the appearance of compliance with Medicare regulations, SomnoMedics directed a certified technician to perform the sleep studies at the Lutz facility while the CMS auditor was present.

#### FIRST CAUSE OF ACTION

(False Claims Act: Presentation of False Claims) (31 U.S.C. § 3729(a)(1) and (a)(1)(A))

73. The United States repeats and realleges the preceding paragraphs as if fully set forth herein.

74. Defendants SomnoMedics and Killmer knowingly presented and caused to be presented false or fraudulent claims for payment or approval to the United States by submitting claims for polysomnographic sleep tests that were ineligible for payment.

75. By virtue of the false or fraudulent claims that defendants made and/or caused to be made, the United States suffered damages and therefore is entitled to treble damages under the False Claims Act, to be determined at trial, plus civil penalties of not less than \$5,500 and up to \$11,000 for each violation.

### SECOND CAUSE OF ACTION

(False Claims Act: Presentation of False Statements to Get False Claims Paid) (31 U.S.C. § 3729(a)(1)(B))

76. The United States repeats and realleges the preceding paragraphs as if fully set forth herein.

77. Defendants Somnomedics and Killmer knowingly made, used, or caused to be made or used false records or statements to get false or fraudulent claims paid by the United States for polysomnographic sleep tests that were ineligible for payment.

78. By virtue of the false or fraudulent claims that Defendants made and/or caused to be made, the United States suffered damages and therefore is entitled to treble damages under the False Claims Act, to be determined at trial, plus civil penalties of not less than \$5,500 and up to \$11,000 for each violation.

### THIRD CAUSE OF ACTION

(Unjust Enrichment)

79. The United States repeats and realleges the preceding paragraphs as if fully set forth herein.

80. The United States claims the recovery of all monies by which Defendants have been unjustly enriched.

81. As a consequence of the acts set forth above, Defendants were unjustly enriched at the expense of the United States in an amount to be determined which, under the circumstances, in equity and good conscience should be returned to the United States.

### **FOURTH CAUSE OF ACTION**

(Payment by Mistake)

82. The United States repeats and realleges the preceding paragraphs as if fully set forth herein.

83. The United States claims the recovery of all monies by which SomnoMedics hasn paid by mistake.

84. As a consequence of the acts set forth above, SomnoMedics was paid by mistake at the expense of the United States in an amount to be determined which, under the circumstances, in equity and good conscience, should be returned to the United States.

### PRAYER FOR RELIEF

WHEREFORE, the United States demands and prays that judgment be entered in its favor against defendants as follows:

I. On the First Count under the False Claims Act, for the amount of the United States' damages, trebled as required by law, and such civil penalties as are required by law, together with all such further relief as may be just and proper.

II. On the Second Count under the False Claims Act, for the amount of the United States' damages, trebled as required by law, and such civil penalties as are required by law, together with all such further relief as may be just and proper.

III. On the Third Count for unjust enrichment, for the damages sustained and/or amounts by which Defendants were unjustly enriched or by which Defendants retained illegally obtained monies, plus interest, costs, and expenses, and for all such further relief as may be just and proper.

V. On the Fourth Count for payment by mistake, for the damages sustained and/or amounts by which Defendants were paid by mistake or by which Defendants retained illegally obtained monies, plus interest, costs, and expenses, and for all such further relief as may be just and proper.

### **DEMAND FOR JURY TRIAL**

The United States demands a jury trial in this case.

Respectfully submitted,

TONY WEST ASSISTANT ATTORNEY GENERAL

ROBERT E. O'NEILL UNITED STATES ATTORNEY

Dated: June 14, 2011

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# **CERTIFICATE OF SERVICE**

I hereby certify that on June 14, 2011, I caused a true and accurate copy of the foregoing to be filed using the Court's CM/ECF system, which will send an electronic notice of filing to all counsel of record.

/s/ Lacy R. Harwell, Jr. LACY R. HARWELL, JR. Assistant United States Attorney