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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

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| UNITED STATES ex rel. ELMA F. DRESSER,<br><br>Plaintiffs,<br><br>v.<br><br>QUALIUM CORPORATION d/b/a BAY SLEEP CLINIC d/b/a CPAP SPECIALIST, TAHEREH NADER a/k/a TARA NADER, ANOOSHIRAVAN MOSTOWFIPOUR and AMERIMED CORPORATION d/b/a AMERIMED SLEEP DIAGNOSTICS d/b/a AMERIMED CPAP SPECIALISTS<br><br>Defendants. | No. C 12-1745 PSG<br><br>**UNITED STATES' COMPLAINT IN INTERVENTION**<br><br>**DEMAND FOR JURY TRIAL** |

1. The United States of America ("United States") brings this action to recover losses from false claims submitted to the Medicare program as a result of the sustained fraudulent conduct of Defendants Qualium Corporation (doing business as Bay Sleep Clinic and CPAP Specialist), Tahereh (Tara) Nader, Anooshiravan Mostowfipour, and Amerimed Corporation (doing business as Amerimed Sleep Diagnostics and Amerimed CPAP Specialists) (collectively, "Defendants"). This action is brought under the False Claims Act,

31 U.S.C. § 3729, *et seq*. ("FCA"), seeking treble damages and civil penalties, and also under common law theories of recovery.

2. This action alleges that from April 4, 2002 to present, Defendants knowingly submitted, or caused to be submitted, over 14,000 false claims to Medicare for diagnostic sleep studies performed in locations that violated federal law and/or performed by technologists who were not licensed or certified, in violation of federal law. Defendants also knowingly submitted, or caused to be submitted, false claims to Medicare for durable medical equipment ("DME") based on those studies, and supplied such DME in violation of federal law. As a result of this fraudulent conduct, Defendants received millions of dollars from the Medicare program. The United States would not have paid Defendants' claims had it known of Defendants' fraudulent conduct.

3. Defendants Nader and Mostowfipour own Qualium Corporation, which operated twenty sleep clinics doing business as Bay Sleep Clinic. Sleep clinics must go through an application and approval process before being permitted to treat Medicare patients. Defendants only obtained approval to treat Medicare patients at two Bay Sleep Clinic locations. However, Defendants treated Medicare patients at all Bay Sleep Clinic locations and fraudulently represented to Medicare that the patients had been treated at one of the two approved locations. Defendants also deliberately employed unqualified sleep technicians who lacked state or national certifications, in violation of Medicare rules.

4. Defendants also fraudulently dispensed DME, in the form of sleep disorder-related devices, to Medicare patients. DME dispensaries must apply and receive approval from Medicare prior to supplying DME to Medicare patients, and the approval is location-specific and company-specific. Defendants Nader and Mostowfipour attempted and failed to

obtain Medicare approval for their company, Amerimed Corporation, to serve as a DME supplier. Despite failing to obtain approval, Amerimed Corporation distributed DME to Medicare beneficiaries. Defendants wrongfully billed Medicare for this DME by fraudulently representing that it had been distributed by Qualium Corporation, doing business as CPAP Specialist. Defendants also wrongfully distributed DME from multiple Bay Sleep Clinic locations, in violation of both their DME license (which allowed for distribution from only one location) and Medicare rules which prohibit providers of diagnostic sleep tests from also supplying DME.

## I. JURISDICTION AND VENUE

5. This action arises under the False Claims Act, as amended, 31 U.S.C. §§ 3729-33, and under common law theories of payment by mistake of fact and unjust enrichment. This Court has jurisdiction over this action under 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1331, 1345 and 1367(a).

6. This Court may exercise personal jurisdiction over Qualium Corporation d/b/a Bay Sleep Clinic, Tara Nader, Anooshiravan Mostowfipour, and Amerimed Corporation pursuant to 31 U.S.C. § 3732(a).

7. Venue is proper in the Northern District of California pursuant to 28 U.S.C. § 1391(b) and 31 U.S.C. § 3732(a), because Defendants can be found in, reside in, and/or have transacted business within this Court's jurisdiction, and acts that they committed in violation of the FCA occurred within this district.

## II. THE PARTIES

8. Plaintiff, the United States of America, is suing on behalf of the United States Department of Health and Human Services ("HHS") and, specifically, its operating division,

the Centers for Medicare & Medicaid Services ("CMS"). At all times relevant to this Complaint, CMS administered the Health Insurance Program for the Aged and Disabled established by Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395 *et seq.* ("Medicare").

9. Relator Elma F. Dresser is an individual residing in Sunnyvale, California. Dresser is a former employee of defendant Qualium Corporation d/b/a Bay Sleep Clinic, and worked for the company as a sleep technician from June 2002 through December 2010. Dresser became a registered polysomnographic technologist in 2010.

10. Defendant Qualium Corporation is a private corporation incorporated in the State of California in 2002, with an address in Saratoga, California. Qualium Corporation is 100% owned by defendants Nader and Mostowfipour. At all times relevant to this Complaint, Qualium Corporation owned a chain of clinics located in California doing business as Bay Sleep Clinic. The clinics provide diagnostic services and treatment for sleep disorders. For a period of time Qualium Corporation also dispensed durable medical equipment, doing business as CPAP Specialist.

11. CPAP Specialist and Qualium Corporation shared a National Provider Identification number (1801940085); an address (14981 National Avenue, Suite 1, Los Gatos, CA 95032-2600), a Tax Identification number (260028585), and a DME Supplier Number (4813680002).

12. Defendant Tara Nader is an individual residing in Saratoga, California. Together with defendant Mostowfipour, Nader owns and operates defendants Qualium Corporation d/b/a Bay Sleep Clinic d/b/a CPAP Specialist and Amerimed Corporation. Nader serves as

the Chief Executive Officer of Qualium Corporation and Managing Director of Bay Sleep Clinics. Nader and Mostowfipour are married.

13. Defendant Anooshiravan Mostowfipour is an individual residing in Saratoga, California. Together with defendant Nader, Mostowfipour owns and operates defendants Qualium Corporation d/b/a Bay Sleep Clinic d/b/a CPAP Specialist and Amerimed Corporation. Mostowfipour serves as the President of Qualium Corporation. Mostowfipour is a registered polysomnographic technologist.

14. Defendant Amerimed Corporation is a private corporation incorporated in the State of California in 2006, with an address in Saratoga, California. Amerimed is owned by defendants Nader and Mostowfipour. Amerimed is in the business of dispensing DME products. Amerimed has also conducted business using the names Amerimed Sleep Diagnostics and Amerimed CPAP Specialists.

15. There exists, and at all time since April 4, 2002, existed, a unity of interest and ownership between Defendants Mostowfipour, Nader and Qualium Corporation, such that any individuality and separateness between Qualium Corporation, and Mostowfipour and Nader does not exist, and Qualium Corporation is the alter ego of Mostowfipour and Nader in that Mostowfipour and Nader have been controlling the business and daily operations of Qualium Corporation.

16. Similarly, there exists, and at all time since its incorporation existed, a unity of interest and ownership between Defendants Mostowfipour, Nader and Amerimed Corporation, such that any individuality and separateness between Amerimed Corporation, and Mostowfipour and Nader does not exist, and Amerimed Corporation is the alter ego of

Mostowfipour and Nader in that Mostowfipour and Nader have been controlling the business and daily operations of Amerimed Corporation.

17. Defendants Mostowfipour and Nader are the sole shareholders of Qualium Corporation and Amerimed Corporation, and also serve as the sole directors of the companies. During the relevant time period, Defendants Mostowfipour and Nader were the ultimate financial beneficiaries of all revenues billed and collected, including Medicare funds, by Qualium Corporation and Amerimed Corporation.

18. During the relevant time period, Defendants Mostowfipour and Nader exclusively controlled Qualium Corporation and Amerimed Corporation, including by controlling all employment decisions, activities, policies, and practices relating to diagnostic tests and durable medical equipment and billing of Medicare for such services. Defendant Mostowfipour approved the hiring of all employees of Qualium Corporation and Amerimed Corporation, including employees hired to administer sleep tests.

19. Defendants Mostowfipour and Nader have operated Qualium Corporation and Amerimed Corporation without regard for the separateness between themselves and the corporate entities, including by intermingling company assets with their own personal assets. For example, in 2012, Mostowfipour and Nader funded renovations on their San Francisco condominium with money from Qualium Corporation's business account.

20. Adherence to the fiction of the separate existence of Qualium Corporation and Amerimed Corporation as entities distinct from Mostowfipour and Nader would permit an abuse of the corporate privilege and would sanction fraud and promote injustice. Mostowfipour and Nader control the budgets and spending of Qualium Corporation and Amerimed Corporation, and the United States believes that Qualium Corporation's and

Amerimed Corporation's ability to pay their liabilities is dependent upon Mostowfipour and Nader.

## III. THE FEDERAL FALSE CLAIMS ACT

21. The FCA provides for the award of treble damages and civil penalties for, *inter alia*, knowingly presenting or causing to be presented false or fraudulent claims for payment to the United States government and for knowingly making or using false records or 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)(1)(A), (a)(1)(B) (as amended).

22. The FCA provides, in pertinent part, that a person who:

> (a)(1)(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; or
>
> (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 $5,500 and not more than $11,000, 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. . . .

31 U.S.C. § 3729.[1]

23. For purposes of the False Claims Act,

> (1) the terms "knowing" and "knowingly"—
>
> (A) mean that a person, with respect to information—
> (i) has actual knowledge of the information;
> (ii) acts in deliberate ignorance of the truth or falsity of the information; or
> (iii) acts in reckless disregard of the truth or falsity of the information; and

[1] The FCA 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, Sections 3279(a)(1) and 3729(a)(2) of the prior statute, and Section 3729(a)(1)(A) and 3729(a)(1)(B) of the revised statute are all applicable here. Sections 3729(a)(1) and 3729(a)(2) apply to conduct that occurred before FERA was enacted, and sections 3729(a)(1)(A) and 3729(a)(1)(B) apply to conduct after FERA was enacted. Section 3729(a)(1)(B) is applicable to all claims in this case pending on or after June 7, 2008, by virtue of Section 4(f) of FERA.

(B) require no proof of specific intent to defraud[.]

31 U.S.C. § 3729(b)(1).

24. The standard of proof under the FCA is preponderance of the evidence. 31 U.S.C. § 3731(d).

## IV. BACKGROUND

### a) The Medicare Program

25. 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. 42 U.S.C. §§ 426, 426A. Medicare is administered by CMS.

26. Medicare is divided into four parts: Part A, Part B, Part C, and Part D. This case concerns payments made under Medicare Part B. Medicare Part B covers, among other things, payment for physicians' services, services and supplies incident to physicians' services, diagnostic tests, and DME for use in beneficiaries' homes.

27. All Medicare providers must enroll in the program as providers, and are expected to deal honestly with the Government and with patients.

28. Clinics must enter into participation agreements with Medicare using Form CMS-855B to establish eligibility to participate in the Medicare program. Clinics also complete CMS-855B to change information or to reactivate, revalidate and/or terminate Medicare enrollment.

29. Medicare regulations require providers and suppliers to comply with applicable statutes, regulations and guidelines in order to be reimbursed by Medicare. When participating in Medicare, a provider has a duty to be knowledgeable of the statutes,

regulations, and guidelines for coverage of services. 42 C.F.R. § 424.516(a)(1); 42 C.F.R. § 424.516(a)(2).

30. Form CMS-855B is the Medicare Enrollment Application for independent diagnostic testing facilities. An authorized official must sign the "Certification Section" in Section 15 of Form CMS-855B, which "legally and financially binds [the] supplier to the laws, regulations, and program instructions of the Medicare program." The individual signing the certification statement also certifies that the information contained in the enrollment form is "true, correct, and complete."

31. Defendants Mostowfipour and Nader designated themselves the authorized officials for Qualium Corporation d/b/a Bay Sleep Clinic, and signed the certification statement in Section 15 of Forms CMS-855B submitted by Qualium Corporation, indicating that they understood that they were legally and financially required to comply with Medicare laws, regulations, and program instructions.

32. Form CMS-855S is the Medicare Enrollment Application for durable medical equipment suppliers. An authorized official must sign the "Certification Section" in Section 15 of Form CMS-855S, which "legally and financially binds [the] supplier to the laws, regulations, and program instructions of the Medicare program." The individual signing the certification statement also certifies that the information contained in the enrollment form is "true, correct, and complete."

33. Defendants Mostowfipour and Nader designated themselves the authorized officials for Qualium Corporation d/b/a CPAP Specialist, and signed the certification statement in Section 15 of Forms CMS-855S submitted by Qualium Corporation, indicating

that they understood that they were legally and financially required to comply with Medicare laws, regulations, and program instructions.

34. The National Provider Identifier ("NPI") is a standard and unique health identifier for health care providers and is assigned by the National Plan and Provider Enumeration System. All providers and practitioners must have an assigned NPI number prior to enrolling in Medicare. A provider is required to use its NPI to identify itself on all standard transactions that it conducts where its health care provider identifier is required. 45 C.F.R. § 162.410(a).

35. To obtain Medicare reimbursement for certain outpatient items or services, 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 Codes, or CPT codes, that identify the services rendered and for which reimbursement is sought.

36. The United States reimburses Medicare providers with payments from the Medicare Trust Fund, through CMS, as supported by American taxpayers. CMS, in turn, contracts with private contractors referred to as "fiscal intermediaries," "carriers," and Medicare Administrative Contractors ("MACs"), to act as agents in reviewing and paying claims submitted by healthcare providers. 42 U.S.C. § 1395h; 42 C.F.R. §§ 421.3, 421.100.

37. National Government Services was the MAC responsible for processing Medicare Part B claims in the State of California from at least April 1, 2002 through August 31, 2008.

38. Palmetto GBA ("Palmetto") was the MAC responsible for processing Medicare Part B claims in the State of California from September 1, 2008 through August 31, 2013.

39. Noridian Healthcare Solutions, LLC ("Noridian") has been the MAC responsible for processing Medicare Part B claims in the State of California from September 1, 2013 to present.

40. Durable Medical Equipment Administrative Contractors (DMACs) are responsible for providing coverage guidance on CPAP devices. Noridian was the DMAC responsible for providing coverage guidance during the relevant time period.

41. During the relevant time period, Defendants knowingly submitted and caused to be submitted claims to Medicare through National Government Services, Palmetto and Noridian.

42. The Social Security Act governs Medicare payments for all services. Medicare covers services that it considers "reasonable and necessary," including services used to diagnose or treat a disorder. Social Security Act § 1862(a)(1)(A); 42 U.S.C. § 1395y(a)(1)(A). MACs may specify additional coverage requirements through Local Coverage Determinations ("LCDs"). CMS, *Medicare Program Integrity Manual*, Pub. No. 100-08, ch. 13, § 13.1.3.

43. Because it is not feasible for the Medicare program, or its contractors, to review the patient files for the millions of claims for payments it receives from providers, the Medicare program relies upon the providers to comply with the Medicare requirements, and trusts the providers to submit truthful and accurate claims.

44. All Medicare providers must have, in each of their patients' files, the medical documentation to establish that the Medicare items or services for which they have sought Medicare reimbursement are reasonable and medically necessary. 42 U.S.C. § 1395y(a)(1)(A); 42 U.S.C. § 1395g(a).

**b) Diagnostic Sleep Testing and Treatment**

45. An Independent Diagnostic Testing Facility ("IDTF") is an entity that is independent of a physician office or hospital. Its purpose is to furnish diagnostic tests. 42 C.F.R. § 410.33.

46. Sleep clinics claim to help detect and treat sleep disorders, such as sleep apnea (a potentially lethal condition where the patient stops breathing during sleep) and narcolepsy (a syndrome characterized by abnormal sleep tendencies). A sleep clinic is enrolled by Medicare as an IDTF unless it is owned by a physician or group of physicians. Medicare Claims Processing Manual, Pub. 100-04, Ch. 35, § 10.1. The clinics at issue in this case, operating under the name Bay Sleep Clinic, are not owned by a physician or group of physicians, and therefore are classified as IDTFs.

47. Sleep clinics use diagnostic tests, such as a polysomnogram, to detect sleep disorders. A polysomnogram (informally referred to simply as a "sleep test" in this Complaint), is a multiple-component test that continuously measures and electronically records physiological activities while a patient sleeps. The data is then analyzed by qualified medical personnel to determine whether the patient has a sleep disorder. Generally, the sleep test is conducted in one night. Polysomnographic sleep tests are covered and reimbursed by Medicare Part B. 42 C.F.R. § 410.10(e); 42 C.F.R. § 410.33(a).

48. If sleep apnea is detected during the sleep test, the patient returns for a second night for a continuous positive airway pressure ("CPAP") titration test to determine the appropriate pressure required to alleviate the apnea. In the titration test, a sleep technician will set varying levels of air pressure on the CPAP device and evaluate the results to determine the optimum pressure for the patient.

49. In some situations, when severe sleep apnea is discovered during the first part of a sleep test, the second half of the night may be used for the CPAP titration test, such that both tests are completed in the same night. Such testing is generally called a "split night with CPAP testing."

50. Breathing devices, such as a CPAP device or a bi-level positive airway pressure (BiPAP) device, may be prescribed if sleep apnea is diagnosed as a result of a sleep test. The devices deliver pressurized air through tubing to a nasal mask or pillow fitted to a patient's head. CPAP and BiPAP devices are covered by Medicare under certain conditions, and are both classified as DME. Medicare National Coverage Determination Manual, Pub. 100-03, § 240.4.

51. Providers bill Medicare for polysomnography services performed in an IDTF using CPT codes 95805, 95807, 95808, 95810 or 95811. All polysomnography services consist of two components: the administration of the test (the technical component) and the physician's interpretation of the test (the professional component).

52. Sleep technicians (also called sleep technologists) assist in the evaluation and care of patients with sleep disorders by assisting with the clinical assessment and physiological monitoring and testing of patients. A registered polysomnographic technologist ("RPSGT") is a fully-trained sleep technologist who has met the rigorous requirements to become credentialed by the Board of Registered Polysomnographic Technologists.

**c) Medicare Rules Applicable to IDTFs**

**i. Requirement to Accurately State Location of Service**

53. Medicare requires IDTFs to submit a Medicare Enrollment Application, CMS-855B, for each practice location.

54. The information is required to determine whether the enrolling supplier meets all of the IDTF standards.

55. More specifically for IDTFs, CMS has set forth "standards that IDTFs must meet in order to bill the Medicare program." In particular, CMS requires:

> The IDTFs must separately enroll each of their practice locations (with the exception of locations that are used solely as warehouses or repair facilities). This means that each enrolling IDTF can only have one practice location on its CMS-855B enrollment application; thus, if an IDTF is adding a practice location to its existing enrollment, it must submit a new, complete CMS-855B application for that location and have that location undergo a separate site visit.

*Implementation of New Compliance Standards for Independent Diagnostic Testing Facilities (IDTFs)*, CMS Manual System, Pub. 100-08, Transmittal 216 (July 13, 2007), at 4.19.1(B).

56. The CMS Manual also states that "each IDTF must certify on its CMS-855B enrollment application" that it "[p]rovides complete and accurate information on its enrollment application. Any change in enrollment information must be reported to the designated fee-for-service contractor on the Medicare enrollment application within 30 calendar days of the change." *Id.*

57. Regulations codified at 42 C.F.R. § 410.33(g) set forth standards that IDTFs must meet in order to enroll, and maintain enrollment, in the Medicare program.

58. CMS will deny enrollment to providers who fail to meet these requirements. 42 C.F.R. § 410.33(h) ("If an IDTF fails to meet one or more of the standards in paragraph (g) of this section at the time of enrollment, its enrollment will be denied."). If the failure to meet the requirement occurs after enrollment (or CMS does not become aware of the failure until after enrollment), CMS will revoke the supplier's billing privileges. *Id.* ("CMS will

revoke a supplier's billing privileges if an IDTF is found not to meet the standards in paragraph (g) or (b)(1) of this section.").

59. The requirements include, among other things, that the IDTF permit CMS to conduct unannounced, on-site inspections to confirm the IDTF's compliance with regulatory requirements and that the IDTF have a comprehensive liability insurance policy of at least $300,000 per location. 42 C.F.R. § 410.33(g).

60. All new IDTF applications receive both a desk review and a mandatory site review prior to approval of the enrollment application. *Implementation of New Compliance Standards for Independent Diagnostic Testing Facilities (IDTFs)*, CMS Manual System, Pub. 100-08, Transmittal 216 (July 13, 2007), at 4.19.6. The purpose of the mandatory site review is to validate the information provided by the applicant and ensure that the location meets all of the IDTF regulatory requirements. *Id.*

61. An IDTF location is not permitted to bill Medicare until its application is approved. The regulations expressly state that the effective date of billing privileges for a newly enrolled IDTF is the *later* of either "the filing date of the Medicare enrollment application that was subsequently approved," or "the date the IDTF first started furnishing services at its new practice location." 42 C.F.R. § 410.33(i).

**ii. Requirement to use licensed or certified nonphysician personnel.**

62. Medicare requires that personnel performing sleep tests at IDTFs be qualified to do so. Specifically, the Medicare regulations state:

> 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 C.F.R. § 410.33(c) (emphasis added).

63. In 2007, a provision was added regarding certification standards for IDTFs:

> The IDTF must certify in its enrollment application that it meets the following standards and related requirements: . . . **(12) Have technical staff on duty with the appropriate credentials to perform tests. The IDTF must be able to produce the applicable Federal or State licenses or certifications of the individuals performing these services** . . . .

42 C.F.R. § 410.33(g) (emphasis added).

64. CMS will deny enrollment to providers who fail to meet this requirement. 42 C.F.R. § 410.33(h) ("If an IDTF fails to meet one or more of the standards in paragraph (g) of this section at the time of enrollment, its enrollment will be denied.").

65. If the failure to meet the requirement occurs after enrollment (or CMS does not become aware of the failure until after enrollment), CMS will revoke the supplier's billing privileges. Id. ("CMS will revoke a supplier's billing privileges if an IDTF is found not to meet the standards in paragraph (g) or (b)(1) of this section.").

66. The purpose of this rule is to ensure that beneficiaries are receiving the quality of care that can only be administered by appropriately licensed or credentialed personnel. *See* Medicare Program Payment Policies, 73 Fed. Reg. 69726, 69763 (Nov. 19, 2008) (codified at 42 C.F.R. pts. 405, 409-411, 413-415, 423, 424, 485, 486 and 489).

67. CMS has set forth "standards that IDTFs must meet in order to bill the Medicare program." *Implementation of New Compliance Standards for Independent Diagnostic Testing Facilities (IDTFs)*, CMS Manual System, Pub. 100-08, Transmittal 216 (July 13, 2007). Among the standards listed, an IDTF must "[h]ave technical staff on duty with the appropriate credentials to perform tests. The IDTF must be able to produce the applicable

Federal or State licenses or certifications of the individuals performing these services." *Id.* at 4.19.1(A)(12). This requirement is reiterated on the provider enrollment form, Form CMS-855B, Attachment 2 (containing "a list of the performance standards that an IDTF must meet in order to obtain or maintain their Medicare billing privileges").

68. CMS also requires that "[e]ach non-physician who performs IDTF diagnostic tests must be listed. These persons are often referred to as technicians." *Id.* at 4.19.4. The IDTF is required to attach a copy of each technician's license or certification with its enrollment application. *Id.* With regard to technicians hired after the enrollment form is submitted, CMS notes: "If a technician has been recently added or changed, the updated information must be reported via a CMS-855B change request. The new technician must have met all of the necessary credentialing requirements at the time any tests were performed." *Id.*

69. In addition, Palmetto issued a Local Coverage Determination (L28292) that reiterated: "Diagnostic testing that is routinely performed by Independent Diagnostic Testing Facilities for Sleep Disorders may be covered even in the absence of **direct** supervision by a physician, however, a trained, qualified attendant must be present to assess and monitor the patient." (Emphasis in original.) By stating that a "trained, qualified attendant must be present," Palmetto expressly provided notice that trained and qualified personnel are a condition of coverage (and therefore payment) for diagnostic testing provided by IDTFs.

70. Noridian issued a Local Coverage Determination (LCD 33483) that also stated, "Diagnostic testing that is routinely performed by Independent Diagnostic Testing Facilities for Sleep Disorders may be covered even in the absence of **direct** supervision by a physician, however, a trained, qualified attendant must be present to assess and monitor the patient."). (Emphasis in original). By stating that a "trained, qualified attendant must be present,"

Noridian expressly provided notice that trained and qualified personnel are a condition of coverage (and therefore payment) for diagnostic testing provided by IDTFs.

71. Defendants billed Medicare for tests performed by employees who had no license or certification by any State entity or national credentialing body. National Government Services, Palmetto, and Noridian would not have paid the claims for sleep and titration tests submitted by Defendants if they had been aware that the tests were not performed by licensed or registered personnel, as required.

72. Additionally, IDTFs are required to submit the names of their licensed or certified staff members when they submit their Medicare Form CMS-855B application, and are required to amend the application if the licensed or certified personnel change. Section D of Attachment 2 to the CMS-Form 855B application (which requests information about all nonphysician personnel who perform tests) states:

> If a reported technician does not have either a State license or certification, or certification from a national credentialing body, he/she cannot perform the IDTF diagnostic tests and should not be reported. The only exception to this is when there is no State license or certification and there is no generally accepted national credentialing body. When this situation occurs, the technician performing the test must be reported. The IDTF must submit any educational/credentialing and/or experience that the person has. Notarized or certified true copies of the State license or certificate should be attached.

73. Section 15 of the application contains a certification statement which states:

> I have read the contents of this application. My signature legally and financially binds this supplier to the laws, regulations, and program instructions of the Medicare program. By my signature, I certify that the information contained herein is true, correct, and complete and I authorize the Medicare fee-for-service 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 fee-for-service contractor of this fact immediately.

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**d) Rules Applicable to DME Dispensors**

74. In order to maintain Medicare billing privileges, DME suppliers must comply with the supplier standards set forth at 42 C.F.R. § 424.57(b) and (c), which include the surety bond requirements set forth in 42 C.F.R. § 424.57(d). A DME supplier must properly enroll each separate physical location where it provides DME (unless those locations are solely warehouses or repair facilities). 42 C.F.R. § 424.57(b)(1).

75. Under federal law, a DME supplier must obtain a license from the state in which it operates if the state "requires licensure to furnish certain items or services." 42 C.F.R. § 424.57(c)(1)(ii). This requirement applies in California, which issues Home Medical Device Retailer ("HMDR") licenses to entities that supply prescription medical devices or DME for use in the home to treat acute or chronic illnesses or injuries. *See* Cal. Health & Safety Code § 111656 *et seq*. California also requires a separate license for each facility location supplying medical devices. The license must be renewed every year, and may not be transferred to another location or business. It is unlawful under California law (and therefore a violation of federal CMS requirements) to operate a DME facility without a valid license or to conduct business at a new location without a new application. Id.

76. The process of enrolling a facility either for medical-device dispensing or for sleep-study testing under both federal (CMS) and California (Department of Health) programs is no mere technicality. Among other things, the federal and state health programs will assign an investigator or auditor to physically visit and inspect the proposed site, seek information about licensing and credentialing of personnel rendering services, and otherwise review the proposed facilities for program compliance or violations. Problems in the

enrollment and inspection process may result in non-approval of the facility for Medicare and other purposes. Id.; 42 C.F.R. §§ 424.57, 424.58.

77. In order to dispense prescription devices from an HMDR-licensed DME facility in California, a supplier must employ either a licensed pharmacist or a licensed HMDR "exemptee." (a person exempt from being a licensed pharmacist). An exemptee must meet a number of requirements under California law to be properly licensed, which requirements also are necessary to qualify for federal health-care program reimbursement. Most notably for the purposes of this complaint, a valid DME dispensing license requires: a minimum of one year of paid work experience related to the distribution or dispensing of dangerous drugs or dangerous devices, and an appropriate training course covering enumerated applicable subjects, including relevant state and federal laws, quality control and safe storage and handling of home medical devices, and other prescription information. *See id*. § 111656.4(a). A licensed home medical-device operator may submit a license application on behalf of an employee for a particular facility, so long as the applicant meets all of the legal requirements.

78. California law further requires that the licensed pharmacist or exemptee working for a DME supplier "shall be on the premises at all times that prescription devices are available for sale or fitting unless the prescription devices are stored separately from other merchandise and are under the exclusive control of the licensed pharmacist or exemptee." *Id*. § 111656.4(b). It is unlawful for a DME supplier to dispense prescription devices without a properly licensed exemptee on the premises.

79. Medicare regulations since January 1, 2009, prohibit fixed-based IDTFs such as the Bay Sleep Clinics from sharing a location with a DME supplier. The regulations state:

> With the exception of hospital-based and mobile IDTFs, a fixed-base IDTF is prohibited from the following:

> (i) Sharing a practice location with another Medicare-enrolled individual or organization[.]

42 C.F.R. § 410.33(g)(15)(i).

80. In proposing the rule promulgated in the Federal Regulations, CMS explained:

> We believe that allowing fixed-based (physical site) IDTFs to commingle office space (including waiting rooms), staff (including supervising physicians, nonphysician personnel, or receptionists), or equipment through subleasing agreements may allow an IDTF to circumvent Medicare enrollment and billing requirements. These types of arrangements also raise concerns because they may implicate the physician self-referral prohibition and the anti-kickback prohibition.

72 Fed. Reg. 38171 (July 12, 2007).

81. CMS has long been concerned about the existence of a financial relationship between the entity performing the sleep and titration tests and the entity providing DME based on those tests. As such, CMS has implemented rules to prevent reimbursement when such a relationship exists. The regulations (entitled "payment prohibition") state:

> No Medicare payment will be made to the supplier of a CPAP device if that supplier, or its affiliate, is directly or indirectly the provider of the sleep test used to diagnose the beneficiary with obstructive sleep apnea.

42 C.F.R. § 424.57(f).

82. CMS defined "affiliate" as "a person or organization that is related to another person or organization through a compensation arrangement or ownership." 42 C.F.R. § 424.57(a); *see also* 73 Fed. Reg. 69856, 69860 (Nov. 19, 2008).

83. As CMS explained in the Federal Register when publishing the final rule:

> We believe that Medicare beneficiaries and the Medicare program are vulnerable if the provider of a diagnostic test has a financial interest in the outcome of the test itself. This creates incentive to test more frequently or less frequently than is medically necessary and to interpret a test result with a bias that favors self-interest. In the specific context of this rule, we believe that the provider of a sleep test has self-interest in the result of that test if that provider is affiliated with a supplier of the CPAP device that would be covered by the Medicare program.

73 Fed. Reg. 69856 (Nov. 19, 2008).

84. An exception to this rule exists "if the sleep test is an attended facility-based polysomnogram." 42 C.F.R. § 424.57(f). The regulation defines "attended facility-based polysomnogram" as "a comprehensive diagnostic sleep test including at least electroencephalography, electro-oculography, electromyography, heart rate or electrocardiography, airflow, breathing effort, and arterial oxygen saturation furnished in a sleep laboratory facility in which a technologist supervises the recording during sleep time and has the ability to intervene if needed." 42 C.F.R. § 424.57(a).

85. This exception applies to a properly attended test performed according to Medicare regulations—*i.e.*, a test performed in an approved location by a licensed or certified technologist. A test that is not attended by an appropriately qualified individual, or that occurs in an unapproved facility, does not qualify as an "attended facility-based polysomnogram." 42 C.F.R. § 410.33(c), § 410.44(g)(2), § 410.33(g)(12). Accordingly, such tests are subject to the payment prohibition in 42 C.F.R. § 424.57(f).

86. As defined, DME "does not include such equipment furnished by a supplier who has used, for the demonstration and use of specific equipment, an individual who has not met such minimum training standards as the Secretary may establish with respect to the demonstration and use of such specific equipment. 42 U.S.C.A. § 1395x(n).

## V. DEFENDANTS' FRAUDULENT SCHEME

87. From April 4, 2002 to present, Defendants engaged in a scheme to (1) conduct sleep and titration tests in unapproved locations; (2) employ unqualified personnel to conduct such tests; and (3) dispense DME to Medicare patients based upon such tests and in violation of Medicare rules.

88. Defendants used a billing agency, Access Medical Consultants, Inc., to prepare and submit claims to Medicare. Access Medical Consultants used information supplied by Defendants to prepare and submit claims to Medicare.

**a) Tests in Unapproved Locations**

89. Defendants knowingly submitted, or caused the submission, of claims for diagnostic tests that were performed in unapproved locations.

90. During the relevant time period, Defendants operated sleep clinics in the following locations:

| LOCATION | NPI NUMBER |
|---|---|
| 3031 Telegraph Avenue, Suite 100, Berkeley, CA 94705-2051 | 1245384312 |
| 901 Campus Drive, Suite 306, Daly City, CA 94015 | 1265665038 |
| 1999 Mowry Avenue, Suite D, Fremont, CA 94538 | 1912168683 |
| 9360 No Name Uno Road, Suite 230, Gilroy, CA 95020 | 1871754556 |
| 6 Hughes, Suite 110, Irvine, CA 92618 | 1548545445 |
| 12301 Wilshire Blvd., Suite 325, Los Angeles, CA 90025 | 1407165319 |
| 14981 National Avenue, Suite 1, Los Gatos, CA 95032 | 1275618811 |
| 830 Menlo Avenue, Suite 109, Menlo Park, CA 94025 | 1922152107 |
| 950 Cass Street, Suite C, Monterey, CA 93940 | 1770882946 |
| 105 South Drive, Suite 120, Mountain View, CA 94040 | 1427219195 |
| 2939 Summit Street, Oakland, CA 94609 | 1043590276 |
| 5720 Stoneridge Mall Road, Suite 360, Pleasanton, CA 94588 | 1790924660 |
| 39 Birch Street, Suite B, Redwood City, CA 94062 | 1497916175 |

| | |
|---|---|
| 18275 Meadow Song Way, Salinas, CA 93908 | 1184924029 |
| 1375 Sutter Street, Suite 216, San Francisco, CA 94109 | 1508910928 |
| 175 North Jackson Avenue, Suite 208, San Jose, CA 95116 | 1023279700 |
| 3121 Park Ave., Suite C, Soquel, CA 95073 | 1710237920 |
| 225 Spruce Ave., Suite 1, South San Francisco, CA 94080 | 1700215704 |
| 108 La Casa Via, Suite 100, Walnut Creek, CA 94598 | 1851445944 |
| 2050 Peabody Road, Vacaville, CA 95687 | 1255609798 |

91. Defendants only enrolled two locations—Los Gatos and San Francisco—as Medicare-approved IDTFs. Defendants did not enroll their other locations in Medicare as IDTFs.

92. Despite only receiving approval from Medicare to treat beneficiaries at two locations—the San Francisco and Los Gatos locations—Defendants performed sleep tests on Medicare beneficiaries in multiple other unapproved locations. Defendants then falsely stated on their payment claim forms that the tests had occurred at either the San Francisco or Los Gatos approved locations.

93. Specifically, paper claim Form CMS 1500 (or its electronic equivalent) is used by IDTFs to bill Medicare for services, typically by submitting the claim to the MAC. Form CMS 1500 (or its electronic equivalent) requires the provider to put, in box 24B, the Place of Service where the technical component of the diagnostic test was performed. When Defendants performed sleep and titration tests on beneficiaries in unapproved locations, *i.e.*, any location other than the Los Gatos or San Francisco location, Defendants falsely represented—by putting the NPI number for the Los Gatos or San Francisco location in the

"Place of Service"—that the tests had occurred at one of the Medicare-approved locations, when they had not.

94. Defendants were aware that they could apply for Medical approval to enroll their other locations as Medicare-approved IDTFs. However, Defendants failed to submit enrollment forms for their other locations to undergo the qualification process to become Medicare-approved IDTFs.

95. Because Defendants failed to apply for enrollment for their other locations, Medicare was unaware that its beneficiaries were being treated at those locations. It was also unable to conduct the mandatory site inspection required of all IDTF applicants (*see* Paragraphs 59-60, *supra*) to ensure that the locations met all requirements for approval as IDTFs.

96. The Bay Sleep Clinic locations were not all open every day. Instead, approximately half of the clinics would be open at a time, based on patient demand and sleep technician availability. Defendants failed to post and maintain regular business hours for the clinics, in violation of Medicare's requirements for IDTFs contained in 42 C.F.R. § 410.33(g)(14).

97. Defendants were aware that the location of the test was material to Medicare's payment determination and that Medicare would not pay for a test performed at an unapproved location. This is why Defendants falsely claimed that the tests had occurred at either the Los Gatos or San Francisco location when they had not.

98. Defendants knowingly submitted, or caused the submission of, these false claims to Medicare for sleep and titration tests performed at locations other than the Los Gatos or San Francisco location, and received payment from Medicare for these claims.

**b) Use of Unqualified Technicians**

99. Since at least April 4, 2002, Defendants knowingly submitted, or caused the submission, of claims for diagnostic tests that were not performed by licensed or certified technologists, as required by law. 42 C.F.R. § 410.33(f).

100. Defendants knowingly assigned these non-certified, non-licensed employees to perform sleep and titration tests on Medicare beneficiaries.

101. The provider enrollment application, Form CMS-855B, under a listing of "mandatory" supporting documents in Section 17, requires IDTFs to submit "[c]opy(s) of all documentation verifying IDTF Supervisory Physician(s) proficiency and/or State licenses or certification for IDTF non-physician personnel."

102. Form CMS-855B, in the section requesting information about "Personnel (Technicians) Who Perform Tests," specifically asks the following questions:

> Is this technician State licensed or State certified? Yes No
>
> License/Certification Number (if applicable)
>
> License/Certification Issue Date (if applicable)
>
> Is this technician certified by a national credentialing organization? Yes No
>
> Name of credentialing organization (if applicable)
>
> Type of Credentials (if applicable)

103. Defendants deliberately concealed the identities of these unqualified and unlicensed employees that were performing tests by not listing them on Form CMS-855B, as required. Instead, Defendants disclosed on the Forms CMS-855B only the individuals who were certified and qualified to perform such tests.

104. For example, in the Form CMS-855B that Defendants submitted in July 2010 to update the location of their Los Gatos Bay Sleep Clinic facility, Defendants only listed two technicians—Elma Dresser and Mladenka Kaluderovic—and attested that both had obtained certification as registered polysomnographic technologists. Defendants deliberately did not list other, unqualified and unlicensed sleep technicians they employed, despite the directive on the form that Defendants provide information about "**all** non-physician personnel who perform tests for this IDTF."

105. Defendants also misrepresented the "effective date" for Ms. Dresser and Ms. Kaluderovic on the Form CMS-855B they submitted in July 2010. They listed an effective date for Ms. Dresser as 07/01/2004, even though Ms. Dresser did not obtain certification as an RPSGT until 2010. Similarly, they listed the effective date for Ms. Kaluderovic as 08/13/2006, even though Ms. Kaluderovic did not obtain certification as an RPSGT until April 2009.

106. Defendants were aware of the importance of certified, qualified sleep technicians. However, Defendant Mostowfipour—who made all of the hiring decisions for Qualium Corporation—believed that licensed or registered sleep technicians were too costly to employ. Instead, Defendants purposely hired unqualified sleep technicians and paid them a lower salary per hour than the salary demanded by registered sleep technicians.

107. On October 23, 2009, the State of California enacted S.B. 132 (codified at Cal. Bus. & Prof. Code §§ 3575-79). S.B. 132 requires individuals engaging in the practice of polysomnography to register with the Medical Board of California, and sets forth requirements for registration. S.B. 132 also required the Medical Board to promulgate regulations regarding the qualifications individuals need to meet to be registered in California

as polysomnographic technologists, polysomnographic technicians, and polysomnographic trainees. The Medical Board of California promulgated the regulations, codified at 16 C.C.R. §§ 1379.40 *et seq.*, on February 18, 2012.

108. Prior to February 18, 2012, Defendants were required to ensure that technicians performing sleep and titration tests on Medicare beneficiaries were certified by "an appropriate national credentialing body." 42 C.F.R. § 410.33(c) ("In the absence of a State licensing board, the technician must be certified by an appropriate national credentialing body.").

109. Defendants failed to ensure that employees performing sleep and titration tests on Medicare beneficiaries were certified by a national credentialing body. To the contrary, Defendants deliberately hired personnel knowing that they were not certified by a national credentialing body to perform sleep and titration tests.

110. For example, Defendants hired Lejla Velic as an administrative assistant when she moved to the United States from Bosnia in 2005. Ms. Velic had no prior background or training in conducting sleep tests. Despite this fact, Mostowfipour assigned Velic to perform sleep tests.

111. Defendants knew that Medicare would only pay for sleep and titration tests performed by licensed or registered sleep technicians. For example, Defendants hired Glenn Tan as a sleep technician in July 2008. Mr. Tan was not a registered or certified sleep technician at the time he was hired. In June 2011, Mr. Tan expressed his concern that it would be wrong for him to continue performing sleep and titration tests on Medicare beneficiaries because he was not licensed or registered to do so. Defendants agreed not to

assign Medicare beneficiaries to Mr. Tan, but continued to assign Medicare beneficiaries to other unlicensed and unregistered sleep technicians.

112. After February 18, 2012, Defendants were required to ensure that technicians performing sleep and titration tests on Medicare beneficiaries were registered by the State of California.

113. Defendants failed to ensure that employees performing sleep and titration tests on Medicare beneficiaries were registered by the State of California, as required. To the contrary, Defendants deliberately hired personnel knowing that they were not registered by the State of California to perform sleep and titration tests.

114. Technicians did not have a fixed schedule for performing sleep and titration tests. Instead, technologists were directed to call into the Bay Sleep Clinic office in Los Gatos every morning to learn which clinic to report to, and how many patients they would be treating.

115. Technicians were typically assigned 12-hour shifts. At times only one technician would be assigned per facility. When that happened, patients undergoing sleep tests would be unsupervised during periods when the technicians took restroom or meal breaks.

116. A record of which technologist attended the sleep or titration study is kept in the study report for each test. Technologists were instructed to enter their initials in the box titled "Technologist comments" in the report.

117. As an example of Defendants' wrongful conduct, the Government identifies the following individuals who were employed by Defendants to perform sleep tests even though they were not licensed or registered to do so. This is not an exhaustive list of individuals who Defendants employed to perform sleep tests on Medicare beneficiaries despite their lack

of license or registration, and the Government expects to identify additional individuals during discovery.

a. Defendants hired relator Elma Dresser in June 2002 even though she was not licensed or registered to perform sleep and titration tests. Ms. Dresser performed sleep and/or titration tests on Medicare beneficiaries and Defendants wrongfully submitted, or caused the submission, of claims for such tests to Medicare. Defendants wrongfully received money from Medicare for such tests.

b. Defendants hired Mladenka Kaluderovic in August 2006 even though she was not licensed or registered to perform sleep and titration tests. Ms. Kaluderovic performed sleep and/or titration tests on Medicare beneficiaries and Defendants wrongfully submitted, or caused the submission, of claims for such tests to Medicare. Defendants wrongfully received money from Medicare for such tests.

c. Defendants hired Diana Posilero in August 2007 even though she was not licensed or registered to perform sleep and titration tests. Ms. Posilero performed sleep and/or titration tests on Medicare beneficiaries and Defendants wrongfully submitted, or caused the submission, of claims for such tests to Medicare. Defendants wrongfully received money from Medicare for such tests.

d. Defendants hired Jasna Redzic in August 2007 even though she was not licensed or registered to perform sleep and titration tests. Ms. Redzic performed sleep and/or titration tests on Medicare beneficiaries and Defendants wrongfully submitted, or caused the submission, of claims for such tests to Medicare. Defendants wrongfully received money from Medicare for such tests.

e. Defendants hired Helen Tan in June 2008 even though she was not licensed or registered to perform sleep and titration tests. Ms. Tan performed sleep and/or titration tests on Medicare beneficiaries and Defendants wrongfully submitted, or caused the submission, of claims for such tests to Medicare. Defendants wrongfully received money from Medicare for such tests.

f. Defendants hired Glenn Tan in July 2008 even though he was not licensed or registered to perform sleep and titration tests. Mr. Tan performed sleep and/or titration tests on Medicare beneficiaries and Defendants wrongfully submitted, or caused the submission, of claims for such tests to Medicare from July 2008 through at least June 2011. Defendants wrongfully received money from Medicare for such tests.

g. Defendants hired Jenna Victory in November 2009 even though she was not licensed or registered to perform sleep and titration tests. Ms. Victory performed sleep and/or titration tests on Medicare beneficiaries and Defendants wrongfully submitted, or caused the submission, of claims for such tests to Medicare. Defendants wrongfully received money from Medicare for such tests.

h. Defendants hired Richelle DeVera Pacis in November 2009 even though she was not licensed or registered to perform sleep and titration tests. Ms. Pacis performed sleep and/or titration tests on Medicare beneficiaries and Defendants wrongfully submitted, or caused the submission, of claims for such tests to Medicare. Defendants wrongfully received money from Medicare for such tests.

i. Defendants hired Carolyn Dubbel in February 2010 even though she was not licensed or registered to perform sleep and titration tests. Ms. Dubbel performed

sleep and/or titration tests on Medicare beneficiaries and Defendants wrongfully submitted, or caused the submission, of claims for such tests to Medicare. Defendants wrongfully received money from Medicare for such tests.

j. Defendants hired Nedina Guzman in February 2010 even though she was not licensed or registered to perform sleep and titration tests. Ms. Guzman performed sleep and/or titration tests on Medicare beneficiaries and Defendants wrongfully submitted, or caused the submission, of claims for such tests to Medicare. Defendants wrongfully received money from Medicare for such tests.

k. Defendants hired Eric Espinueva in March 2010 even though he was not licensed or registered to perform sleep and titration tests. Mr. Espinueva performed sleep and/or titration tests on Medicare beneficiaries and Defendants wrongfully submitted, or caused the submission, of claims for such tests to Medicare. Defendants wrongfully received money from Medicare for such tests.

l. Defendants hired Joseph Yee in June 2010 even though he was not licensed or registered to perform sleep and titration tests. Mr. Yee performed sleep and/or titration tests on Medicare beneficiaries and Defendants wrongfully submitted, or caused the submission, of claims for such tests to Medicare. Defendants wrongfully received money from Medicare for such tests.

m. Defendants hired Ryan Penny in November 2010 even though she was not licensed or registered to perform sleep and titration tests. Ms. Penny performed sleep and/or titration tests on Medicare beneficiaries and Defendants wrongfully submitted, or caused the submission, of claims for such tests to Medicare. Defendants wrongfully received money from Medicare for such tests.

n. Defendants hired Shane Nair in February 2011 even though he was not licensed or registered to perform sleep and titration tests. Mr. Nair performed sleep and/or titration tests on Medicare beneficiaries and Defendants wrongfully submitted, or caused the submission, of claims for such tests to Medicare. Defendants wrongfully received money from Medicare for such tests.

o. Defendants hired Noel Schreckengost in February 2011 even though she was not licensed or registered to perform sleep and titration tests. Ms. Schreckengost performed sleep and/or titration tests on Medicare beneficiaries and Defendants wrongfully submitted, or caused the submission, of claims for such tests to Medicare. Defendants wrongfully received money from Medicare for such tests.

p. Defendants hired Jansen Borromeo in August 2011 even though he was not licensed or registered to perform sleep and titration tests. Mr. Borromeo performed sleep and/or titration tests on Medicare beneficiaries and Defendants wrongfully submitted, or caused the submission, of claims for such tests to Medicare. Defendants wrongfully received money from Medicare for such tests.

q. Defendants hired Martha Nieves in August 2011 even though she was not licensed or registered to perform sleep and titration tests. Ms. Nieves performed sleep and/or titration tests on Medicare beneficiaries and Defendants wrongfully submitted, or caused the submission, of claims for such tests to Medicare. Defendants wrongfully received money from Medicare for such tests.

r. Defendants hired Tyler Schnadarle in August 2011 even though he was not licensed or registered to perform sleep and titration tests. Mr. Schnadarle performed sleep and/or titration tests on Medicare beneficiaries and Defendants

wrongfully submitted, or caused the submission, of claims for such tests to Medicare. Defendants wrongfully received money from Medicare for such tests.

s. Defendants hired Devon Watts in August 2011 even though she was not licensed or registered to perform sleep and titration tests. Ms. Watts performed sleep and/or titration tests on Medicare beneficiaries and Defendants wrongfully submitted, or caused the submission, of claims for such tests to Medicare. Defendants wrongfully received money from Medicare for such tests.

t. Defendants hired Jaqueline Black in September 2011 even though she was not licensed or registered to perform sleep and titration tests. Ms. Black performed sleep and/or titration tests on Medicare beneficiaries and Defendants wrongfully submitted, or caused the submission, of claims for such tests to Medicare. Defendants wrongfully received money from Medicare for such tests.

u. Defendants hired Linda Haynes-Hernandez in September 2011 even though she was not licensed or registered to perform sleep and titration tests. Ms. Hernandez performed sleep and/or titration tests on Medicare beneficiaries and Defendants wrongfully submitted, or caused the submission, of claims for such tests to Medicare. Defendants wrongfully received money from Medicare for such tests.

v. Defendants hired Maria Montoya in September 2011 even though she was not licensed or registered to perform sleep and titration tests. Ms. Montoya performed sleep and/or titration tests on Medicare beneficiaries and Defendants wrongfully submitted, or caused the submission, of claims for such tests to Medicare. Defendants wrongfully received money from Medicare for such tests.

w. Defendants hired Marlaine Khloth in November 2011 even though she was not licensed or registered to perform sleep and titration tests. Ms. Khloth performed sleep and/or titration tests on Medicare beneficiaries and Defendants wrongfully submitted, or caused the submission, of claims for such tests to Medicare. Defendants wrongfully received money from Medicare for such tests.

x. Defendants hired Hamed Rohani in November 2011 even though he was not licensed or registered to perform sleep and titration tests. Mr. Rohani performed sleep and/or titration tests on Medicare beneficiaries and Defendants wrongfully submitted, or caused the submission, of claims for such tests to Medicare. Defendants wrongfully received money from Medicare for such tests.

y. Defendants hired Jennifer Chang in November 2011 even though she was not licensed or registered to perform sleep and titration tests. Ms. Chang performed sleep and/or titration tests on Medicare beneficiaries and Defendants wrongfully submitted, or caused the submission, of claims for such tests to Medicare. Defendants wrongfully received money from Medicare for such tests.

z. Defendants hired Leah Williamson in February 2012 even though she was not licensed or registered to perform sleep and titration tests. Ms. Williamson performed sleep and/or titration tests on Medicare beneficiaries and Defendants wrongfully submitted, or caused the submission, of claims for such tests to Medicare. Defendants wrongfully received money from Medicare for such tests.

aa. Defendants hired Mackensie Longford in March 2012 even though she was not licensed or registered to perform sleep and titration tests. Ms. Longford performed sleep and/or titration tests on Medicare beneficiaries and Defendants

wrongfully submitted, or caused the submission, of claims for such tests to Medicare. Defendants wrongfully received money from Medicare for such tests.

bb. Defendants hired Neill Mercado in June 2012 in even though he was not licensed or registered to perform sleep and titration tests. Mr. Mercado performed sleep and/or titration tests on Medicare beneficiaries and Defendants wrongfully submitted, or caused the submission, of claims for such tests to Medicare. Defendants wrongfully received money from Medicare for such tests.

cc. Defendants hired Alice Segbefia in June 2012 even though she was not licensed or registered to perform sleep and titration tests. Ms. Segbefia performed sleep and/or titration tests on Medicare beneficiaries and Defendants wrongfully submitted, or caused the submission, of claims for such tests to Medicare. Defendants wrongfully received money from Medicare for such tests.

dd. Defendants hired Diana Flores in August 2012 even though she was not licensed or registered to perform sleep and titration tests. Ms. Flores performed sleep and/or titration tests on Medicare beneficiaries and Defendants wrongfully submitted, or caused the submission, of claims for such tests to Medicare. Defendants wrongfully received money from Medicare for such tests.

ee. Defendants hired Pardis Irannejad in October 2012 in even though she was not licensed or registered to perform sleep and titration tests. Ms. Irannejad performed sleep and/or titration tests on Medicare beneficiaries and Defendants wrongfully submitted, or caused the submission, of claims for such tests to Medicare. Defendants wrongfully received money from Medicare for such tests.

//

**c) Violation of DME Rules and Regulations**

118. During the relevant time period, Defendants Qualium Corporation and Amerimed Corporation dispensed DME from the Bay Sleep Clinic facilities, using the names Bay Sleep Clinic, CPAP Specialist, Amerimed the CPAP Specialist, and Amerimed Sleep Diagnostics, in violation of Medicare rules.

119. Defendants Mostowfipour and Nader initially used Qualium Corporation, doing business as Bay Sleep Clinic and/or CPAP Specialist, to dispense DME to Medicare beneficiaries. Qualium Corporation received approval from CMS to dispense DME to Medicare beneficiaries.

120. Defendants attempted to enroll Amerimed Corporation in Medicare as a DME supplier. However, CMS denied Amerimed's application to become a DME supplier in January 2009. Amerimed was never approved by CMS to dispense DME to Medicare beneficiaries.

121. At the direction of Mostowfipour and Nader, Amerimed dispensed DME to Medicare beneficiaries despite not being approved by Medicare to do so. At the direction of Mostowfipour and Nader, Qualium Corporation then billed Medicare for the DME dispensed by Amerimed.

122. Claims submitted to Medicare for DME dispensed by Amerimed are false. Defendants wrongfully submitted, or caused the submission, of claims for this DME to Medicare, and Defendants wrongfully received money from Medicare for such DME.

123. Additionally, the DME license is location-specific, *i.e.* separate licenses are required for each location dispensing DME and each location receives a separate supplier number. 42 C.F.R § 424.57(b)(1), (b)(2).

124. Defendants only enrolled one location—for Qualium Corporation—in Medicare as a DME supplier: 14981 National Avenue, Suite 1, Los Gatos, CA 95032. However, Defendants dispensed DME from other Bay Sleep Clinic locations, despite not applying for or receiving approval from Medicare to dispense DME from those locations. Defendants arranged for the Los Gatos location to receive the DME, and directed their employees to pick up the DME from the Los Gatos location and take it to other locations. Patients could then pick up the DME at the same location they had their sleep and titration tests, instead of traveling to the Los Gatos location to pick up the DME.

125. DME dispensed from unapproved locations is not covered by Medicare. 42 C.F.R. § 424.57(c)(24) ("All DMEPOS supplier locations, whether owned or subcontracted, must meet the DMEPOS quality standards and be separately accredited in order to bill Medicare.").

126. Among other requirements, a DME location must be open to the public a minimum of 30 hours per week. 42 C.F.R. § 424.57(c)(30). Defendants dispensed DME from Bay Sleep Clinic locations that not only were unapproved, but that were also not open the minimum thirty hours per week. Such locations would not have been approved as DME suppliers even if Defendants had applied for such approval.

127. Accordingly, claims submitted to Medicare for DME dispensed from locations other than the Los Gatos location are false. Defendants wrongfully submitted, or caused the submission, of claims for this DME to Medicare, and Defendants wrongfully received money from Medicare for such DME.

128. Defendants also simultaneously provided sleep tests and DME to beneficiaries, in violation of the payment prohibition in 42 C.F.R. § 424.57(f) ("No Medicare payment will be

made to the supplier of a CPAP device if that supplier, or its affiliate, is directly or indirectly the provider of the sleep test used to diagnose the beneficiary with obstructive sleep apnea.").

129. As discussed in Paragraphs 84-85, *supra*, an exception to the payment prohibition exists "if the sleep test is an attended facility-based polysomnogram." 42 C.F.R. § 424.57(f). This exception only applies to a properly attended test performed according to Medicare regulations—*i.e.*, a test performed in an approved location by a licensed or certified technologist. 42 C.F.R. § 410.33(c), § 410.44(g)(2), § 410.33(g)(12).

130. Sleep and titration tests performed at Bay Sleep Clinic locations other than San Francisco and Los Gatos, as discussed *supra* Paragraphs 89-98, do not qualify as "attended facility-based polysomnograms" and are subject to the payment prohibition in 42 C.F.R. § 424.57(f). Accordingly, DME supplied by Defendants to beneficiaries who received such tests is not reimbursable by Medicare. Defendants knowingly submitted, or caused the submission of, these false claims to Medicare for DME.

131. Additionally, sleep and titration tests that were not attended by an appropriately qualified individual, as discussed *supra* Paragraphs 99-117, do not qualify as "attended facility-based polysomnograms" and are subject to the payment prohibition in 42 C.F.R. § 424.57(f). Accordingly, DME supplied by Defendants to beneficiaries who received such tests is not reimbursable by Medicare. Defendants knowingly submitted, or caused the submission of, these false claims to Medicare for DME.

## VI. EXAMPLES OF FALSE CLAIMS

132. The United States provides illustrative examples of false claims below. To protect patient privacy, the United States identifies the individuals by initials only. Upon entry of a Protective Order governing disclosure of protected patient health information, the

United States will serve Defendants with a spreadsheet (Complaint Attachment A) identifying 14,005 false claims for sleep tests, titration tests, and DME. For each false claim, the spreadsheet lists the patient name, patient identification number, date of service, procedure code, and amount of payment by Medicare to Defendants. The list is illustrative only and the United States reserves the right to identify additional false claims during discovery.

133. Defendants knowingly submitted or caused to be submitted to Medicare numerous false or fraudulent claims for Medicare reimbursement for sleep tests performed in unapproved locations and/or by unqualified personnel, as shown by some examples below:

a. Defendants wrongfully billed Medicare for two split sleep and titration tests, CPT code 95811, performed on Medicare beneficiary H.R. at the Bay Sleep Clinic Menlo Park location on March 12, 2012, and April 9, 2012, and were reimbursed $631.13 and $743.13, respectively, from Medicare for each test. Richelle De Vera Pacis, *supra* Paragraph 117(h), performed the test on March 12, 2012, and Jansen Borromeo, *supra* Paragraph 117(p), performed the test on April 9, 2012.

b. Defendants wrongfully billed Medicare for two split sleep and titration tests, CPT code 95811, performed on Medicare beneficiary M.K. at the Bay Sleep Clinic Mountain View location on August 2, 2011, and September 13, 2011, and were reimbursed $821.05 from Medicare for each test. Martha Nieves, *supra* Paragraph 117(q), performed the test on September 13, 2011.

c. Defendants wrongfully billed Medicare for a sleep test, CPT code 95810, and a titration test, CPT code 95811, performed on Medicare beneficiary J.K. at the Bay Sleep Clinic Salinas location on October 28, 2010, and March 24, 2011,

respectively, and were reimbursed $766.41 and $763.48, respectively, from Medicare for such tests. Glenn Tan, *supra* Paragraph 117(f), performed the test on October 28, 2010.

d. Defendants wrongfully billed Medicare for a titration test, CPT code 95811, performed on Medicare beneficiary L.M. at the Bay Sleep Clinic Berkeley location on August 12, 2010, and were reimbursed $926.04 from Medicare for such test. Jenna Lee Victory, *supra* Paragraph 117(g), performed the test.

e. Defendants wrongfully billed Medicare for a sleep test, CPT code 95810, and a split sleep and titration test, CPT code 95811, performed on Medicare beneficiary B.M. at the Bay Sleep Clinic Daly City location on February 18, 2012, and March 5, 2012, and were reimbursed $870.75 and $928.91, respectively, from Medicare for such tests. Tyler Schnadarle, *supra* Paragraph 117(r), performed the test on February 18, 2012, and Hamed Rohani, *supra* Paragraph 117(x), performed the test on March 5, 2012.

134. Defendants also knowingly submitted or caused to be submitted to Medicare numerous false or fraudulent claims for Medicare reimbursement for DME dispensed in violation of Medicare rules, as shown by some examples below.

a. Defendants wrongfully billed Medicare for DME supplied to beneficiary H.R., *supra* Paragraph 133(a), from their Menlo Park location on May 14, 2012, June 14, 2012, July 14, 2012, August 14, 2012, August 24, 2012, September 14, 2012, October 14, 2012, November 14, 2012, November 20, 2012, December 14, 2012, January 14, 2013, February 14, 2013, March 14, 2013, April 11, 2013, and May 14, 2013, and were reimbursed a total of $7,790.40 from Medicare for such DME.

b. Defendants wrongfully billed Medicare for DME supplied to beneficiary M.K., *supra* Paragraph 133(b), from their Menlo Park location on September 30, 2011, October 30, 2011, November 30, 2011, December 30, 2011, January 30, 2012, February 6, 2012, February 29, 2012, March 30, 2012, April 30, 2012, May 30, 2012, June 30, 2012, July 30, 2012, August 9, 2012, August 30, 2012, November 30, 2012, March 6, 2013, and June 28, 2013, and were reimbursed a total of $9,450.98 from Medicare for such DME.

c. Defendants wrongfully billed Medicare for DME supplied to beneficiary J.K., *supra* Paragraph 133(c), from their Salinas location on April 8, 2011, May 8, 2011, June 8, 2011, July 8, 2011, August 8, 2011, September 8, 2011, October 8, 2011, November 8, 2011, December 8, 2011, January 8, 2012, February 8, 2012, March 8, 2012, April 8, 2012, and November 30, 2012, and were reimbursed a total of $5,684.02 from Medicare for such DME.

d. Defendants wrongfully billed Medicare for DME supplied to beneficiary L.M., *supra* Paragraph 133(d), from their Berkeley location on October 11, 2010, and were reimbursed a total of $1,292.58 from Medicare for such DME.

e. Defendants wrongfully billed Medicare for DME supplied to beneficiary B.M., *supra* Paragraph 133(e), from their Daly City location on March 23, 2012, and were reimbursed a total of $2,711.88 from Medicare for such DME.

**FIRST CAUSE OF ACTION**
**(False Claims Act: Presentation of False Claims)**
**(31 U.S.C. § 3729(a)(1) and (a)(1)(A))**

135. The United States repeats and realleges the preceding paragraphs of this Complaint as if fully set forth herein.

136. Defendants knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval to the United States, including claims for reimbursement by Medicare, for services and DME provided in violation of Medicare rules and regulations.

137. Said claims were presented with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

138. By virtue of the false or fraudulent claims that Defendants made 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: Using False Statements to Get False Claims Paid)**
**(31 U.S.C. § 3729(a)(2) and 31 U.S.C. § 3729(a)(1)(B))**

139. The United States repeats and realleges the preceding paragraphs of this Complaint as if fully set forth herein.

140. Defendants made, used, and caused to be made or used, false records or statements to get false or fraudulent claims paid and approved by the United States. Defendants knowingly misrepresented the location where diagnostic tests were performed when such tests were performed in locations not approved by Medicare as IDTFs. Defendants also knowingly concealed the identities of unqualified sleep technicians by not disclosing them, as required, on CMS provider enrollment forms. Further, Defendants knowingly falsely certified that they would abide by Medicare rules and regulations material to payment.

141. Defendants' false representations and certifications were made for the purpose of getting false or fraudulent claims for services and DME paid, and payment of the false or

fraudulent claims was a reasonable and foreseeable consequence of the Defendants' statements and actions.

142. The false certifications and representations made and caused to be made by Defendants were material to the United States' payment of the false claims.

143. Said false records or statements were made with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

144. By virtue of the false or fraudulent claims that Defendants made 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**
**(Payment by Mistake)**

145. The United States repeats and realleges the preceding paragraphs of this Complaint as if fully set forth herein.

146. This is a claim for the recovery of monies paid by the United States to Defendants (directly or indirectly) as a result of mistaken understandings of fact. The United States paid Defendants for diagnostic tests rendered in unapproved locations and/or by unqualified personnel, and for DME prescribed as a result of such tests and/or in violation of payment rules, without knowledge of material facts, and under the mistaken belief that Defendants were entitled to receive payment for such claims when they were not. The United States' mistaken belief was material to its decision to pay Defendants for such claims. Accordingly, Defendants are liable to make restitution to the United States of the amounts of the payments made in error to them by the United States, an amount to be determined at trial.

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**FOURTH CAUSE OF ACTION**
**(Unjust Enrichment)**

147. The United States repeats and realleges the preceding paragraphs of this Complaint as if fully set forth herein.

148. This is a claim for the recovery of monies by which Defendants have been unjustly enriched.

149. By directly or indirectly obtaining government funds to which they were not entitled, Defendants were unjustly enriched at the expense of the United States, and Defendants are liable to account for and pay such amounts, or the proceeds therefrom, which are to be determined at trial, 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 and Second Counts under the False Claims Act, for the amount of the United States' damages, trebled as required by law, and such civil penalties as are authorized by law, together with all such further relief as may be just and proper.

II. On the Third and Fourth Counts for payment by mistake and unjust enrichment, for the damages sustained and/or amounts by which Defendants were unjustly enriched or 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**

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, the United States demands a jury trial in this case.

Respectfully submitted,

BRIAN J. STRETCH
Acting United States Attorney

Dated: September 2, 2015

By: /s/ *Kimberly Friday*
KIMBERLY FRIDAY
ROBIN M. WALL
Assistant United States Attorneys