Eric R. Havian (CA State Bar No 102295)
Jessica T. Moore (CA State Bar No. 183431)
Ari Yampolsky (CA State Bar No. 290753)
CONSTANTINE CANNON LLP
4 Embarcadero Center, 14th Floor
San Francisco, CA 94111
Telephone: (415) 426-5666
Facsimile: (650) 636-9709
jmoore@constantinecannon.com

Attorneys for *Qui Tam* Plaintiff, Elma F. Dresser

**UNITED STATES DISTRICT COURT**
**NORTHERN DISTRICT OF CALIFORNIA**
**SAN JOSE DIVISION**

| | |
|---|---|
| UNITED STATES OF AMERICA, *ex rel*. ELMA F. DRESSER,<br>Plaintiff,<br>vs.<br>QUALIUM CORPORATION, TAHEREH aka TARA NADER, ANOOSHIRAVAN MOSTOWFIPOUR, BAY SLEEP CLINIC, CPAP SPECIALIST, AMERIMED CORPORATION, ACCESS MEDICAL CONSULTANTS INC., and DOES 1 THROUGH 50, INCLUSIVE,<br>Defendants. | Case No. C-12-cv-01745 PSG<br><br>FIRST AMENDED COMPLAINT FOR DAMAGES AND OTHER RELIEF UNDER THE FALSE CLAIMS ACT; DEMAND FOR JURY TRIAL |

In light of the United States of America's recent intervention as co-plaintiff in this matter, *qui tam* Plaintiff Elma F. Dresser ("Relator"), through her attorneys, Constantine Cannon LLP, hereby amends her original Complaint against Defendants—which include Qualium Corporation, dba Bay Sleep Clinic, and dba CPAP Specialist, Tara Nader (aka Tahereh Nader), Anooshiravan Mostowfipour, and Amerimed Corporation, dba Amerimed Sleep Diagnostics (collectively "the Qualium Defendants"), as well as Access Medical Consultants, Inc. ("AMC"), and Does 1 through 50—to incorporate by reference the substantive False Claims Act allegations to be set forth in the United States's complaint in intervention, and to additionally allege, based on Relator's personal knowledge, relevant documents, and information and belief, as follows:

## I. INTRODUCTION

### A. Overview

1. This is an action to recover damages and civil penalties on behalf of the United States of America for false and/or fraudulent statements, records, and claims made or caused to be made by Defendants, as well as their affiliates, departments, subsidiaries, agents, employees, and co-conspirators, in violation of the federal False Claims Act ("FCA"), 31 U.S.C. §§ 3729 et seq., and the federal Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b).

2. Since 2002, the Qualium Defendants have owned and operated twenty polysomnographic testing facilities, or sleep clinics, as well as a similar number of related durable-medical-device supply facilities, in California. The Qualium Defendants have knowingly submitted false claims to federal healthcare programs for diagnostic sleep studies and for sleep-disorder-related medical devices. Defendant Access Medical Consultants, Inc., an entity the Qualium Defendants hired to submit claims to federal healthcare programs, knowingly submitted false claims for payment to the government on behalf of the Qualium Defendants. Defendants submitted or caused the submission of false claims to federal healthcare programs that include, but are not limited to, Medicare and CHAMPVA.

3. The claims the Qualium Defendants submitted or caused to be submitted were false because the Qualium Defendants: 1) hired non-credentialed technologists to perform the studies; 2) conducted studies on Medicare patients at sleep centers that were not approved by Medicare program, but nevertheless billed Medicare for such patients as if the studies had been conducted at a different, approved center; 3) unlawfully dispensed medical-devices/durable-medical-equipment (DME) to Medicare beneficiaries from locations not approved by Medicare; 4) engaged in unlawful self-dealing by supplying CPAP medical devices following sleep-studies they conducted; 5) operated a medical-device company from the same locations as the sleep clinics 6) hired non-licensed or fraudulently licensed personnel to dispense medical devices to patients; 7) provided financial remuneration to doctors intended to induce patient-referrals for diagnostic sleep studies;

and 8) routinely waived Medicare co-payments without inquiry into patients' financial circumstances.

4. Defendant Access Medical Consultants (AMC) submitted or caused to be submitted false claims to federal health-care programs because AMC knew the Qualium Defendants engaged in the conduct described above and knowingly assisted Qualium falsely to bill the programs as if the services or equipment had been provided in Medicare-approved or otherwise lawful locations by appropriately credentialed personnel.

5. Defendants' knowing submission of false and fraudulent claims for payment constitutes a violation of the FCA, 31 U.S.C. §§ 3729 et seq., and the AKS, 42 U.S.C. § 1320a-7b(b). Defendants' claims for reimbursement resulted in substantial payments that the government would not have paid but for Defendants' misconduct. As a result of their wrongful conduct, Defendants have caused the United States to sustain a direct loss of funds and damage to its interests.

6. Relator does not know whether Defendants have completely ceased their misconduct after learning of Relator's allegations by means of the federal investigation that followed the filing of the Complaint. To the extent any such misconduct continues, Relator intends that this Amended Complaint address and remedy it.

**B. The False Claims Act and the Anti-Kickback Statute**

7. Defendants' conduct alleged in this Amended Complaint violates the federal False Claims Act, 31 U.S.C. §§ 3729 et seq. The federal False Claims Act was originally enacted during the Civil War. Congress substantially amended the Act in 1986 to enhance the ability of the United States Government to recover losses sustained due to fraud against it. Congress amended the Act after it found that fraud in federal programs was pervasive and that the Act, which Congress characterized as the primary tool for combating government fraud, was in need of modernization. Congress intended the amendments to create incentives for individuals with knowledge of fraud against the Government to disclose the information without fear of reprisals or Government inaction, and to encourage the private bar to commit legal resources to prosecuting fraud on the Government's behalf.

8. The FCA establishes liability to the United States for "any person," whether an individual or an entity, who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," or "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." *Id*. § 3729(a)(1)(A)–(B). "Knowingly" is defined to include actual knowledge, reckless disregard, and deliberate indifference. *Id*. § 3729(b)(1). No proof of specific intent to defraud is required. *Id*. Any person who violates the FCA is liable for a civil penalty of up to $11,000 for each violation, plus three times the amount of the damages the United States sustains. *Id*. § 3729(a)(1).

9. In May 2009, Congress amended and renumbered the False Claims Act pursuant to Public Law 111-21, the Fraud Enforcement and Recovery Act of 2009 ("FERA"). Section 3279(a)(1)(B) was formerly section 3729(a)(2) and applies to Defendants' conduct for the entire time period alleged in the Amended Complaint by virtue of Section 4(f) of FERA. Section 3279(a)(1)(A) (formerly section 3729(a)(1)) of the FCA prior to FERA, and as amended in 1986, applies to conduct on or after May 20, 2009.

10. Section 3729(a)(1) of the pre-FERA FCA provides that any person who

> "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" is liable 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."

11. The FCA allows any person having information about an FCA violation to bring an action on behalf of the United States and to share in any recovery. The FCA also awards reasonable attorneys' fees and costs to the prevailing qui tam plaintiff as a matter of right. *Id.* § 3730(d). The FCA requires the Complaint be filed under seal for a minimum of 60 days (without service on the defendant during that time) to allow the government time to conduct its own investigation and to determine whether to join the suit.

12. The Anti-Kickback State (AKS) prohibits entities from "knowingly and willfully offer[ing] or pay[ing] any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person . . . to purchase . . . or arrange for or recommend purchasing . . . . Any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(2). Payments by sleep clinics or DME providers to doctors to induce the latter to refer patients whose services and DME are reimbursed by federal healthcare programs is an example of such illegal remuneration.

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

14. As codified in the Patient Protection and Affordable Care Act of 2010 ("PPACA"), Pub. L. No. 111-148, § 6402(f), 124 Stat. 119, codified at 42 U.S.C. § l320a-7b(g), "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the FCA]." According to the legislative history of the PPACA, this amendment to the AKS was intended to clarify "that all claims resulting from illegal kickbacks are considered false claims for the purpose of civil actions under the False Claims Act[.]" 155 Cong. Rec. S10854.

15. Compliance with the AKS is a condition of payment under the federal healthcare programs. Claims for payment resulting from violations of the AKS are "false claims" under the FCA. 42 U.S.C. § 1320a-7b(g). By providing kickbacks to physicians to induce them to refer patients to Defendants' sleep clinics and follow-on DME business, Defendants submitted and/or caused the submission of false claims to federal healthcare programs.

16. Based on these provisions, *Qui Tam* Plaintiff and Relator Elma Dresser seeks to recover all available damages, civil penalties, and other relief for federal and state-law violations alleged in this Amended Complaint in every jurisdiction to which Defendants' misconduct has extended.

## II. JURISDICTION

17. The Court has subject matter jurisdiction to entertain this action under 28 U.S.C. § 1331, 28 U.S.C. § 1367, and 31 U.S.C. § 3732, the last of which confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3729 and 3730. Under 31 U.S.C. § 3730(e), there has been no statutorily relevant public disclosure of the "allegations or transactions" in this complaint.

18. The Court may exercise personal jurisdiction over Defendants pursuant to 31 U.S.C. § 3732(a), which authorizes nationwide service of process, and because Defendants have minimum contacts with the United States. Moreover, Defendants can be found in, reside, and/or transact or have transacted business in this District.

## III. VENUE

19. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and 1395(a), and 31 U.S.C. § 3732(a) because Defendants can be found in and/or transact or have transacted business in this District. At all times relevant to this Amended Complaint, Defendants regularly conducted substantial business, maintained employees, and/or made significant sales in this District. In addition, statutory violations, as alleged in this Amended Complaint, occurred in this District.

## IV. INTRADISTRICT ASSIGNMENT

20. Assignment to the San Jose Division is proper because a substantial part of the events or omissions giving rise to this action occurred in the county of Santa Clara.

## V. PARTIES

21. Plaintiff-Relator Elma F. Dresser, is, and at all times was, a citizen of California residing in Santa Clara County, California. Beginning in 2002, Relator worked as a sleep technician for the Qualium Defendants. In 2006, Qualium assigned Relator marketing duties, for which she visited doctors' offices to discuss Qualium's services. Qualium compensated Relator in part based upon the number of referrals she generated. In July 2010, after qualifying to become a registered sleep technician, Relator ceased her sales role and worked full time for Qualium as a Senior Technologist. On occasion, Qualium required Relator to dispense DME. Relator's employment at Qualium ended in December 2010.

22. Defendant Qualium Corporation, which operates or operated approximately twenty sleep clinics doing business as Bay Sleep Clinic, is a California corporation located at 14851 Sobey Road in Saratoga, California. On information and belief, Defendants Mostowfipour and Nader own, operate, and are the principal officers of Defendant Qualium Corporation dba Bay Sleep Clinic. The corporation's address is the same as the home of Defendants Mostowfipour and Nader.

23. Defendant Qualium Corporation, which operated approximately fourteen durable medical equipment facilities doing business as CPAP Specialist or CPAP Specialists (hereinafter "CPAP Specialist"), is a California corporation located at 14851 Sobey Road in Saratoga, California (alternate corporate locations are listed at 14981 National Ave., Suite 1, Los Gatos, California, and 15195 National Ave., Suite 203, Los Gatos, California). On information and belief, Defendants Mostowfipour and Nader own, operate, and are the principal officers of Defendant Qualium Corporation dba CPAP Specialist. CPAP Specialist's Sobey Road address is the same as the home of Defendants Mostowfipour and Nader.

24. Defendant Amerimed Corporation is a California corporation, also located at 14851 Sobey Road in Saratoga, California. Amerimed sometimes operates as an affiliate of CPAP Specialist, and distributes DME under the name Amerimed Sleep Diagnostics in approximately 10 facilities (some of which share an address with addresses associated with CPAP Specialist). On information and belief, Defendants Mostowfipour and Nader own, operate, and are the principal

officers of Defendant Amerimed. The corporation's address is the same as the home of Defendants Mostowfipour and Nader.

25. Defendants Anooshiravan Mostowfipour (also known as Anoosh Mostowfipour and Anoosh Mostowfi) and Tara Nader are individuals married to each other who are, and at all times relevant were, citizens of California residing in Santa Clara County. On information and belief, Defendants Mostowfipour and Nader own, operate, and are the principal officers of Defendants Qualium (and its dbas) and Amerimed. Relator understands that Defendant Mostowfipour is or was a credentialed sleep technologist. Defendants Nader and Mostowfipour, and each of them, are or were personally involved in, directed, or otherwise controlled the conduct alleged herein (as further detailed below) that resulted in false claims.

26. Defendant Access Medical Consultants Inc. is a California corporation located at 186 Belwood Gateway in Los Gatos, California. AMC is a full-service medical billing office for sleep clinics. In that capacity, AMC handles for its clients billing issues raised by patients and payers, including federal healthcare programs. On information and belief, Faraneh H. Javanmardian (also known as Faraneh Javan) and Farhad A. Javanmardian (also known as Fred Javan), former friends of Defendants Mostowfipour and Nader, own, operate, and are the principal officers of Defendant AMC.

27. Relator is informed and believes that there exists, and at all times herein mentioned there existed, a unity of interest and ownership between Defendants Qualium (and its dbas Bay Sleep Clinic and CPAP Specialist) and Amerimed, on the one hand, and Defendants Nader and Mostowfipour and other entities they control, including Sinarose Holdings LLC, on the other hand, such that any individuality and separateness between Defendants Qualium and Amerimed and Defendants Nader and Mostowfipour have ceased; as a result, both Defendants Qualium and Amerimed are the alter ego of Defendants Nader and Mostowfipour, and Defendants Qualium and Amerimed are each the alter ego of one another. "Sinarose" is a word combing the names of Defendants Mostowfipour's and Nader's children, and Sinarose Holdings (owned by Mostowfipour and Nader) purchased and owns the real property at the location of Qualium's Los Gatos facility.

Defendants Qualium and Amerimed are, and at all relevant times were, the alter egos of Defendants Nader and Mostowfipour. There exists, and at all relevant times has existed, a unity of interest and ownership between Defendants Qualium and Amerimed, on the one hand, and Defendants Nader and Mostowfipour, on the other, such that any separateness has ceased to exist, in that Defendants Nader and Mostowfipour used assets of Defendants Qualium and Amerimed for their personal uses and/or for the use of other entities they control, caused assets of Defendants Qualium and Amerimed to be transferred to them without adequate consideration, and withdrew funds from Defendants Qualium and Amerimed bank accounts for their personal use or the use of other entities they control. Defendants Qualium and Amerimed are, and at all relevant times were, mere shells and shams. Defendants Qualium and Amerimed were conceived, intended, and used by Defendants Nader and Mostowfipour as devices to avoid individual liability and for the purpose of substituting financially insolvent corporations in the place of Defendants Nader and Mostowfipour and other entities they control. Adherence to the fiction of the separate existence of Defendants Qualium and Amerimed as entities distinct from Defendants Nader and Mostowfipour and other entities they control would permit an abuse of the corporate privilege, sanction fraud, and promote injustice.

28. Relator does not presently know the identities of the remaining Doe Defendants who have knowingly submitted false and fraudulent claims to the government. For example, given the number of different companies and dbas involved in the conduct alleged herein, Relator potentially does not yet know all of the owners, operators, and persons responsible, or all of the potential holding companies (*e.g.*, Sinarose Holdings LLC), answerable for the alleged conduct. Further information on the details and extent of the fraud the Doe Defendants committed are contained within Defendants' records.

29. All Defendants and all additional Doe Defendants served as contractors, agents, partners, and/or representatives of one another in the fraud, concealment, and submission of false and fraudulent claims to the United States, and were acting within the course, scope, and authority of such contract, agency, partnership, and/or representation for the conduct described in this Amended Complaint.

## VI. FACTUAL BACKGROUND AND REGULATORY FRAMEWORK

### A. Federal Healthcare Programs

30. In 1965, Congress enacted Title XVIII of the Social Security Act, known as the Medicare Program ("Medicare"), to pay for certain medical services for persons aged 65 years or older and those with disabilities. Medicare is divided into four parts and the allegations in this Amended Complaint pertain to Medicare Part B, the Voluntary Supplemental Insurance Plan, which covers "medical and other health services." *See* 42 U.S.C. § 1395j, et seq. Among other things, Medicare Part B pays for physicians' services, services and supplies incident to physicians' services, diagnostic tests, and DME for use in beneficiaries' homes. The Centers for Medicare and Medicaid Services ("CMS"), an agency of the Department of Health and Human Services ("HHS"), administers the Medicare program.

31. CHAMPVA, which the United States Department of Veterans Affairs administers, is a healthcare program for the families of veterans with 100-percent service-connected disabilities.

### B. The "Reasonable and Necessary" Requirement

32. Medicare will only pay for a service or device that is medically reasonable and necessary to diagnose or treat an injury or improve the functioning of a malformed body member; services and items that "are not reasonable and necessary" are excluded from coverage under Medicare Part B. 42 U.S.C. §1395y(a)(l)(A).

33. Similar requirements exist for other federal healthcare programs, including CHAMPVA, which covers expenses for "medical services and supplies that are medically necessary and appropriate for the treatment of a condition[.]" 38 C.F.R. §17.272(a).

34. Medicare spends significant amounts on sleep-testing services. The U.S. Department of Health and Human Services, Office of Inspector General, reports that Medicare paid over 1 million claims for polysomnography services in 2011 alone – almost $565 million in allowed Medicare spending. The HHS-OIG's 2015 Work Plan specifically recognizes sleep testing procedures as prone to potentially abusive practices and an area to examine closely for non-compliant practices and inappropriate Medicare payments.

**C. Sleep Centers and Polysomnography**

35. There are a number of recognized sleep disorders that affect millions of Americans, including sleep apnea and hypopnea, parasomnias, and narcolepsy. Sleep apnea and hypopnea -- when a patient stops breathing during sleep due to collapsed airways -- is a potentially lethal condition. Parasomnias and narcolepsy can cause physical injuries or worse. Sleep disorders are associated with serious illnesses, comorbidities, such as heart disease, high blood pressure, and Type II diabetes.

36. The polysomnographic diagnostic sleep test is a common method of diagnosing sleep disorders. Polysomnography is a complex process of continuous monitoring, recording, and assessing physiologic data during sleep. During testing, sleep is staged and recorded, including a 1-4 lead electroencephalogram (EEG), an electrooculogram (EOG), and a submental electromyogram (EMG). Additional parameters are measured, including airflow, ventilation and respiratory effort, extremity muscle activity, motor activity, snoring, and blood pressure.

37. Polysomnography borrows and adapts technology from many medical fields. Thus, accurate performance of the studies requires specific skills and knowledge. Sleep technologists who perform polysomnographic procedures must be familiar not only with the equipment used in a sleep laboratory, but also with the sleep/wake pathologies and the physiological changes that occur during sleep, so that they can intervene when necessary.

38. Generally, the initial sleep test is conducted in one night. Qualified medical personnel analyze the data to determine whether the patient has a sleep disorder, such as sleep apnea. If sleep apnea is discovered, the patient returns on a second night for a continuous positive airway pressure ("CPAP") titration test. Sometimes both the initial and titration test are conducted in the same night; this is known as a "split-night" test. The CPAP titration test is a second-level diagnostic test used to determine the appropriate pressure required to alleviate the apnea. It involves a technician setting air pressure on a CPAP device and evaluating the resulting measurements. The technician adjusts the air pressure variously and continues monitoring until she obtains the optimum pressure to reduce the number of apnea and hypopnea events.

39. If sleep apnea or hypopnea is diagnosed as a result of a sleep test, a physician may prescribe breathing devices to help the patient get more air into their lungs. Examples of such devices include a CPAP device or a bi-level positive airway pressure ("BiPAP") device. The devices deliver pressurized air through tubing to a nasal mask or nasal pillow fitted around a patient's head. Such devices are defined as DME. Medicare National Coverage Determination Manual, Pub. 100-03, § 240.4. Medicare pays the provider furnishing the device an amount based on a fee schedule that is subject to yearly updates.

**D. Federal Requirements for Sleep Centers and Related Medical Devices**

**1. Qualifications of non-physician sleep clinic technologists employed at sleep-testing centers**

40. Polysomnographic sleep tests are included in Medicare's definition of "medical and other health services." 42 C.F.R. §410.10(e).

41. The Qualium Defendants' approximately twenty polysomnographic testing facilities are classified as Independent Diagnostic Testing Facilities ("IDTFs"), which are facilities that furnish diagnostic tests and operate independent of a physician's office or hospital. 42 C.F.R. § 410.33.

42. In order to bill Medicare for sleep tests, an IDTF must employ qualified sleep technologists and other non-physician personnel to perform them. 42 C.F.R. § 410.33(c). A state health or education department must license or certify non-physician personnel. *Id.* IDTFs are required to maintain documentation of their employees' credentials. *Id.*

43. In states that do not have a specialty-specific licensing board, non-physician personnel "must be certified by an appropriate national credentialing body." *Id.* Examples of such credentialing bodies include the Board of Registered Polysomnographic Technologists (BRPT), which provides Registered Polysomnography Technologist (RPSGT) credentials, and the American Board of Registration of Electroencephalographic and Evoked Potential Technologists (ABRET), which provides Registered Electroencephalographic Technologist (R. EEG T.) Polysomnography credentials.

44. In California, individuals "responsible for the treatment, management, diagnostic testing, control, education, and care of patients with sleep and wake disorders" must register with the Medical Board of California. Cal. Bus. & Prof. Code § 3575(a)(2) (effective Oct. 23, 2009); *see also* Cal. Code Regs. tit. 16, §§ 1379.40, et seq. (effective Feb. 18, 2012). California law thus sets "the basic qualifications to perform the tests in question," as well as the "training and proficiency" standards, required of sleep-clinic personnel. 42 C.F.R. § 410.33(c).

45. A facility (IDTF) that seeks approval to provide services to Medicare beneficiaries must employ properly certified technologists and certify in its enrollment application that it has "technical staff on duty with the appropriate credentials to perform tests"; as well, it "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). If an IDTF receives approval to bill Medicare and later fails to meet these requirements, "CMS will revoke [its] billing privileges[.]" 42 C.F.R. § 410.33(h). In addition, an IDTF must submit the names of all of its licensed or certified staff members in its initial Medicare application, and must amend the application if the licensed or certified personnel change within 90 days. *See* 42 C.F.R. § 410.33(g)(2); Medicare Enrollment Application, Form CMS-855B, Attachment 2 & Section 15: Certification Statement.

46. An applicant must certify that it understands the requirements it "must meet and maintain in order to bill the Medicare program." *Id*. An applicant must also must "agree to abide by the Medicare laws, regulations and program instructions" and to certify that it "understand[s] that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions and on the supplier's compliance with all applicable conditions of participation in Medicare." *Id*.

**2. Requirement of Medicare approval for each sleep clinic location**

47. In order to bill Medicare Part B for diagnostic services, an IDTF must separately enroll each of its practice locations, each of which must list all licensed technical staff on duty, have in its possession all licenses and certifications of such staff, and timely amend its application to reflect any change in licensed or certified personnel (as described above). *See* CMS IOM Program

Integrity Manual, Publication 100-08, Chapter 10, Section 4.19(B); *see also* Medicare Enrollment Application, Form CMS-855B, Section 4: Practice Location Information. An IDTF can have only one practice location on its Form CMS-855B enrollment application. If an IDTF adds a practice location to its existing enrollment, it must submit a new complete Form CMS-855B application for that location and undergo a separate site visit there. Each separately enrolled practice location of the IDTF must meet all applicable IDTF requirements. The location's failure to comply with any of these requirements will result in the revocation of its Medicare billing privileges.

**3. Enrollment requirements for suppliers of durable medical equipment**

48. Medicare Part B pays for durable medical equipment (DME) under certain circumstances. In order for Medicare to pay for DME, an enrolled supplier must meet conditions set forth in regulations and Medicare's supplier enrollment agreement. *See generally* 42 C.F.R. § 424.57; Medicare Enrollment Application, Form CMS-855S. If a DME supplier does not meet certain of these requirements, CMS will revoke its billing privileges. 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).

49. 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.

50. 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.

**4. Qualifications of personnel who dispense medical devices (DME)**

51. 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.

52. 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.

**5. Prohibition on co-location of sleep clinics and DME providers**

53. Federal law also requires a DME supplier to maintain a physical facility at "an appropriate site." 42 C.F.R. § 424.57(c)(7). Since 2008, Medicare has prohibited independent

sleep-testing clinics (IDTFs) from sharing a sleep-clinic location with a DME supplier. 42 C.F.R. § 410.33. With the exception of hospital-based and mobile IDTFs, a fixed-based IDTF may not share with another Medicare-enrolled individual or organization a practice location or diagnostic testing equipment used in the initial diagnostic test, nor may it lease or sublease its operations or practice location to another Medicare-enrolled individual or organization. 42 C.F.R. § 410.33(g)(15). In proposing this rule, CMS stated:

> [A]llowing 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. 38169, 38171 (July 12, 2007).

54. Similarly, Medicare has prohibited DME suppliers "from sharing a practice location with any other Medicare supplier or provider" since August 2010. 42 C.F.R. § 424.57(c)(29).

**6. Prohibition on financial relationships between sleep clinics and certain DME providers**

55. Medicare prohibits payments to suppliers of CPAP devices where a financial relationship exists between the entity performing a sleep study and the entity providing DME based on that study. 42 C.F.R. § 424.57(f). CMS explained its rationale:

> 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. 69726, 69856 (Nov. 19, 2008)

56. An exception to the rule exists "if the sleep test is an attended facility-based polysomnogram." 42 C.F.R. § 424.57(f). But the exception only applies to a properly attended test performed according to Medicare regulations. For example, a properly attended study must be performed in a center approved by Medicare and by a properly credentialed sleep-test technologist. Sleep tests administered by improperly credentialed technologists, in an unlawful location, and in the context of an inappropriate financial relationship with a medical device supplier, create the unacceptable risk that a physician or DME dispenser cannot accurately determine the medical necessity of CPAP, BiPAP, and other sleep devices for which it bills Medicare.

**E. Prohibition on the Routine Waiver of Medicare Co-Payments**

57. Federal healthcare programs, including Medicare, require beneficiaries to pay a certain portion of the cost of the healthcare service, device, or product the patient receives. The amount the patient must pay is generally referred to as "coinsurance." Medicare Part B pays 80 percent of what Medicare considers a "reasonable charge" for most covered items or services; in such cases, the beneficiary is responsible for the remaining 20 percent.

58. Providers are required to bill patients for (and collect from patients) any such coinsurance amounts. Providers may only waive patient coinsurance obligations after establishing that the payment would cause the patient financial hardship. HHS-OIG and the Medicare regulations both warn that routine waivers of patients' coinsurance obligations may constitute false claims, violations of the Anti-Kickback Statute, and excessive utilization of items and services for which Medicare pays.

59. Medicare regulations specifically provide that waiving a patient's coinsurance obligation constitutes illegal remuneration for purposes of the anti-kickback statute unless the waiver is not offered as part of any advertisement or solicitation; the provider does not routinely waive coinsurance amounts; and the provider waives coinsurance amounts after determining in good faith that the individual is in financial need. 42 C.F.R. § 1003.101. The HHS Office of the Inspector General ("OIG") has warned that "[t]his hardship exception . . . must not be used routinely" and "should be used occasionally to address the special financial needs of a particular patient." *See* OIG

Special Fraud Alert, 59 Fed. Reg. 242 (Dec. 19, 1994); *see also* Medicare Program Integrity Manual, Chapter 4, § 4.22.1.1 (same).

60. With respect to the government's concern that routine co-payment waivers may lead to excessive utilization of items and services for which Medicare pays, OIG has explained:

> At first glance, it may appear that routine waiver of copayments and deductibles helps Medicare beneficiaries. By waiving Medicare copayments and deductibles, the provider of services may claim that the beneficiary incurs no costs. In fact, this is not true. Studies have shown that if patients are required to pay even a small portion of their care, they will be better health care consumers, and select items or services because they are medically needed, rather than simply because they are free.
>
> Ultimately, if Medicare pays more for an item or service than it should, or if it pays for unnecessary items or services, there are less Medicare funds available to pay for truly needed services.

OIG Special Fraud Alert, 59 Fed. Reg. 242.

**F. Federal Healthcare Program Provider Certifications**

61. As noted above, sleep clinics licensed as IDTFs must submit an Enrollment Application to CMS to participate in the Medicare program. *See* Medicare Enrollment Application, Form CMS-855B. This application includes a certification that the provider will abide by all applicable Medicare laws, regulations, and program instructions. *See id*. Attachment 2 & Section 15: Certification Statement. An applicant also must certify that it "understand[s] that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions and on the supplier's compliance with all applicable conditions of participation in Medicare." *Id*. The CMS enrollment application for Durable Medical Equipment, Form CMS855-3, has similar certification requirements.

62. Separately, all Medicare Part B and CHAMPVA providers submit claims using Form CMS-1500. Providers submit codes on this form that identify the services rendered and for which they seek reimbursement. CMS Form 1500 requires providers to certify 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."

63. Finally, providers that participate in any federal healthcare program may not make false statements or misrepresentations, or causing others to make false statements or misrepresentations, of material facts concerning payment requests. *See* 42 U.S.C. § 1320a-7b(a)(1)–(2).

## VII. DEFENDANTS' SCHEMES

### A. The Qualium Defendants

#### 1. The Qualium Defendants unlawfully hired non-credentialed technologists to perform sleep studies and concealed this fact from CMS

64. Since at least 2002, the Qualium Defendants have knowingly submitted fraudulent claims for diagnostic sleep-tests by knowingly hiring non-credentialed technologists to perform such tests. In 2002, Qualium opened two sleep clinics, one in Los Gatos and one in San Francisco, California, and those two centers became Medicare approved for sleep testing. Each year after that, Qualium opened more centers and eventually owned and operated many more sleep test clinics in California, including facilities in: Menlo Park, Redwood City, San Jose, Berkeley, Oakland, Walnut Creek, Daly City, Fremont, Mountain View, Gilroy, Pleasanton, Salinas, Monterey, Irvine, and Los Angeles. None of the clinics other than the Los Gatos and San Francisco facilities was ever enrolled or approved as a Medicare provider.

65. Despite operating so many sleep-testing centers, from at least 2002 until 2010, Qualium employed only one sleep technician, Lan Pei, who was actually registered and who regularly performed sleep studies in a Medicare-enrolled facility -- the San Francisco location. While Defendant Mostowfipour also apparently is or was a registered sleep technologist, Mostowfipour did not conduct sleep studies either at the two Medicare-enrolled clinics or at any of the Qualium Defendants' other clinics that Relator witnessed or heard about. Rather, he only entered clinic premises to fix equipment or computers, or occasionally to attend meetings.

66. Instead of hiring credentialed technicians to cover sleep studies at its twenty centers, the Qualium Defendants hired numerous unqualified and non-credentialed persons. Such persons included Relator, who was not credentialed until year 2010. After 2010, the Qualium Defendants

had a few technicians on staff who became registered. But Qualium did not hire nearly the number of registered technicians to cover all of the sleep testing that it was actually performing. Therefore, most of the sleep studies conducted at Qualium facilities were performed by non-registered technicians. The technicians that Relator knew or heard about from other Qualium employees who conducted sleep tests while non-credentialed included: Starrie Bakhti (aka Starrie Amini Filabadi), Mandana Khosravi, Glenn Tan, Helen Tan, Jonathan (last name unknown), Rayan Penny, Mladenka Kaluderovic, Richelle de Vera, Marta (last name unknown), Eric (last name unknown), Hamed (last name unknown), Jenna Victory, James Harbor, Diana Posilero, Lejla Velic, Nadina Guzman, and others. The Qualium Defendants have possession of the full names of all unregistered technicians hired to conduct sleep studies.

67. By hiring non-credentialed technologists, the Qualium Defendants were able to pay them at below-market rates. Relator has knowledge of actual market rates from her continued work as a polysomnographic technician outside of Qualium, which rates are some $30-32 or more per hour, plus overtime as required by law and a "night-shift differential" (added pay for night shifts). During Relator's tenure, Qualium paid non-registered technicians as low as approximately $15, and their highest rate for non-registered technicians was around $25 per hour. Qualium provided Relator with a raise that was closer to market rates when she received her sleep technician credentials. Qualium also took advantage of its unregistered technicians by failing to pay overtime (night shifts are 12-hours) or the night-shift differential. Relator observed that, typically, when Qualium's unregistered technicians finally became registered, they left Qualium for companies that paid market rates for registered technicians.

68. Defendants Mostowfipour and Nader were present during government inspections of their two Medicare-enrolled facilities and both were responsible for statements made on the enrollment applications. The Qualium Defendants, including Defendants Mostowfipour and Nader, falsely represented to CMS representatives and on the enrollment applications that properly credentialed technicians, including Defendant Mostowfipour, were to conduct sleep studies at its clinics. In fact, Defendant Mostowfipour had no intention of personally conducted sleep studies and

proceeded with employing non-registered personnel for such purposes. When, eventually, the Qualium Defendants had a few registered technicians on staff, they placed those persons' names on Medicare enrollment applications for the two approved centers even if those technicians did not regularly work there and had no intention of doing so.

69. The Qualium Defendants, and each of them, made claims for payment to CMS and other government healthcare programs for sleep studies knowing that non-credentialed technicians provided the underlying diagnostic services and thus Defendants were not entitled to payment. The Qualium Defendants took steps to conceal the fact that non-credentialed technicians unlawfully provided sleep studies. Among other means, the Qualium Defendants, specifically Defendants Mostowfipour and Nader, directed non-credentialed personnel not to "clock in" for work in order to conceal who was actually performing services at each clinic. Instead, Defendant Mostowfipour would "clock in" as if he were the sleep technologist when, in fact, he was not.

**B. The Qualium Defendants unlawfully billed Medicare for tests conducted at sleep clinics that were not enrolled in the Medicare program**

70. The Qualium Defendants did not test and diagnose beneficiaries of federal healthcare programs in its two Medicare-approved facilities only. Rather, the Qualium Defendants tested such beneficiaries at its non-approved centers as well. To receive government reimbursement for all government-insured patients, the Qualium Defendants, and each of them, falsely represented that sleep testing for such beneficiaries had been provided at one of its two Medicare-approved facilities. To conceal the fact that they billed Medicare for sleep studies performed at unapproved clinics, the Qualium Defendants with the assistance of biller Defendant AMC, submitted claims representing that the sleep studies occurred in Los Gatos or San Francisco.

71. Thus, for the above-stated reasons, nearly all of the Qualium Defendants' claims for payment for sleep studies conducted on federal health care program beneficiaries were false because they were performed by non-credentialed technicians, or were provided in non-Medicare-approved facilities, or both. Moreover, the Qualium Defendants procured Medicare-approval of its two enrolled facilities through knowing material misrepresentations on the applications regarding staff

and their appropriate credentials; had CMS known of these misrepresentations, it would not have approved the facilities and would not have paid for services at them. For this additional reason, all claims for payment made from services actually or ostensibly conducted at the two approved facilities are false.

**C. The Qualium Defendants' DME business**

72. Defendants Mostowfipour and Nader own and operate a durable medical equipment (DME) business run as CPAP Specialist (a Qualium dba) and Amerimed Corporation. The Qualium Defendants' DME business offers a full range of sleep-disorder medical devices —including CPAP, BiPAP, Adept Servo Ventilation (ASV) systems, masks, and tubing—to patients, including those tested in the Qualium Defendants' sleep clinics. Qualium's website describes Amerimed as its "sister company."

73. Relator estimates that of the 70% of patients that had a CPAP titration test at the Qualium Defendants' sleep clinics, approximately 80% received DME products from the Qualium Defendants. Defendants' DME business typically dispensed medical products to patients on an ongoing basis. The DME misconduct further alleged herein occurred with the personal involvement, direction, and control of Defendants Nader and Mostowfipour.

**D. The Qualium Defendants' dispensed DME from non-Medicare-enrolled facilities and made claims to Medicare for payment**

74. The Qualium Defendants dispensed medical devices to Medicare and other federal health care program beneficiaries out of locations that were not approved. During the relevant time period, the Defendants' DME business operated out of every (or nearly every) Qualium sleep clinic location. Not every location, however, was Medicare-approved to dispense DME. In fact, while several locations had California licenses to dispense home medical devices on a retail level, only one facility, Los Gatos, was potentially properly enrolled in Medicare. To facilitate dispensing and deliveries in non-approved locations, Qualium owned several vehicles painted with company logos including CPAP Specialist in conjunction with Bay Sleep Specialist. These vehicles were used to bring medical devices to all sleep clinic locations, whether or not the facilities were approved

Medicare or California locations. Moreover, the Amerimed Corporation was never approved by Medicare as a DME supplier. Therefore, any claims to Medicare for DME supplies dispensed by Amerimed are false.

75. To cover up the fact that they dispensed DME in facilities that were not properly enrolled in Medicare, the Qualium Defendants falsely represented in the bills they submitted to Medicare that DME products were dispensed at an enrolled facility. All such claims were therefore false.

**E. The Qualium Defendants' sleep clinics and DME business have a financial relationship prohibited by the Medicare program**

76. Medicare will not pay for CPAP devices where a financial relationship exists between the entity performing the sleep study and the entity providing CPAP on the basis of that study. CMS implemented this regulation out of a concern that beneficiaries would be vulnerable if the provider of a diagnostic sleep test had a financial interest in the outcome of the test as a supplier of CPAP. The Qualium Defendants', including Defendants Mostowfipour's and Nader's, simultaneous ownership of a DME business dispensing CPAP devices and the entity performing a sleep study violates this Medicare regulation against self-interested transactions by sleep-test providers. The exception to this rule, that the sleep test is a facility-based polysomnogram, does not apply where, as here, the facility is not approved for Medicare and where the polysomnogram was not attended by a lawfully credentialed technician.

**F. The Qualium Defendants unlawfully co-located their DME companies and sleep clinics**

77. Since 2008, CMS has prohibited fixed-based IDTFs such as Qualium's sleep-clinics from sharing a location with a DME supplier. CMS's concern was that such co-mingling might allow the circumvention of Medicare enrollment and billing requirements, and also raised concerns about unlawful self-referrals and kickbacks. In contravention of the co-location prohibition, since the prohibition has been in effect, the Qualium Defendants, and each of them, directed and

controlled their DME businesses out of each and every one of their sleep clinics, including the two Medicare-enrolled clinics.

78. The Qualium Defendants knew about federal prohibitions on IDTF and DME co-location. To address the issue, the Qualium Defendants attempted to move its DME operations to a facility in Redwood City, under the corporate name, Amerimed. At one time, the facility had a large banner on it stating "Amerimed/CPAP Specialist." The Qualium Defendants, however, failed to complete the Medicare enrollment and approval process for the Redwood City facility. The Qualium Defendants, therefore, continued to dispense DME at the same locations as its various sleep-testing facilities, including the two Medicare enrolled facilities.

**G. The Qualium Defendants hired non-licensed personnel and fraudulently obtained licenses for employees to dispense DME**

79. The Qualium Defendants hired non-licensed personnel and directed them to dispense medical devices to Medicare beneficiaries and other patients. The Qualium Defendants also fraudulently procured licenses for employees to dispense DME who did not meet the qualifications to do so. Because federal healthcare programs condition billing privileges on compliance with state credentialing requirements, all reimbursement claims the Qualium Defendants made for DME that non-credentialed personnel supplied to patients were false.

80. Early on, Qualium had two licensed dispensers (HMDR exemptees): Defendant Tara Nader and an employee named Carolyn Dubbel, who commenced employment in 2003 and dispensed from the Menlo Park facility (which was not Medicare enrolled). As stated above, Defendants dispensed DME out of many locations (its sleep clinic locations) – far more than two persons could or did cover. State law requires that licensed personnel be on site at all times that medical devices are dispensed.

81. In order to boost its roster of "licensed" DME dispensers, Defendant Nader signed license applications for employees, falsely stating that the employees had worked for the requisite year in the business as required by law. These representations were false. In fact, most such employees had not worked for a year – some worked for only a week or so before Defendant Nader

signed applications for them. Moreover, the unlicensed employees were left to dispense on their own after very little or no training, and without a licensed dispenser on the premises. For example, Defendant Mostowfipour's sister, Soosan Mostowfipour, did not complete the requisite one year's work to receive her credentials, but rather was trained for approximately one week before she dispensed DME on her own. For at least one employee, Defendant Nader signed the license application after the employee had worked for a year in the Defendants' DME business; that employee's "work," however, consisted of her dispensing on her own while unlicensed and without a licensed exemptee (such as Defendant Nader) on premises. Defendants also used their housekeeper, first name Aline, to dispense without an appropriate license. Relator is aware of the identities of additional unlicensed personnel who dispensed medical devices, including, Dr. Moiz (first name unknown), Jasmin (last name unknown), Lora (last name unknown), Nermina (last name unknown), Jackie (last name unknown), Erica Vega, Anel Catic. The Qualium Defendants have possession of the full names of all unlicensed personnel hired to dispense DME.

82. To cover up the use of non-licensed personnel to fit and sell DME, the Qualium Defendants falsely represented in claims to federal healthcare programs that one of its few licensed employees had dispensed DME rather than providing the true names of non-credentialed personnel that actually dispensed the products. During one government site-inspection of the Los Gatos facility, Defendant Nader required Ms. Dubbel (a licensed exemptee) to come to the facility to represent to the auditor that she split her time between the Los Gatos and Menlo Park facilities, when in fact she only worked in the Menlo Park facility.

83. Medicare and other federal health programs would not have paid DME claims for reimbursement had the true facts of the location of and the identity of personnel doing the dispensing been known.

**H. The Qualium Defendants unlawfully waived Medicare co-payments**

84. The Qualium Defendants routinely waived Medicare co-payments for their sleep clinic patients. Qualium would allow such waivers, particularly if a patient seemed unsure whether to undergo a sleep test, without inquiry into the circumstances of the patient's financial hardship. In

fact, in Relator's role in sales for Qualium, the Qualium Defendants instructed her to tell the doctors that Qualium routinely waived Medicare co-payments. Defendants Mostowfipour and Nader also instructed Relator to the tell doctors that even if their patients received a bill from Qualium for the copay, Qualium would not seek to collect on it.

85. To conceal the Qualium Defendants' unlawful waiver practice, Defendant Nader directed Lori Palfreeman, former Operations Manager at Bay Sleep Clinic, to instruct employees to cease calling the Medicare waivers "waivers," and instead to state that Qualium would "accept the Medicare reimbursement as payment in full." At Nader's direction, Ms. Palfreeman explained in a meeting that another clinic entity had been required to return money to government healthcare programs because of unlawful co-payment waivers, indicating the Qualium Defendants knew that such waivers were unlawful. Later, when Defendant Nader realized the changed phrase was problematic as well, Relator was told that Nader directed Ms. Palfreeman to change it yet again, instructing employees to say that Qualium would "accept whatever they will pay us."

**I. The Qualium Defendants participated in an illegal kickback scheme with referring physicians**

86. The Qualium Defendants delivered checks, or caused checks to be delivered, to physicians in exchange for referring patients to their Defendants' sleep clinics. These payments were putatively for "consultation services," but in reality were a flat-fee payment per study. Defendant Nader directed employees as to how to present the money in exchange for "consultation" services. The "consultation" ostensibly being paid for was the doctors' consultation with their own patients after the sleep studies (instead of Bay Sleep conducting the consultation). The Qualium Defendants directed employees to deliver these payments regardless of whether a referring physician provided an actual consultation and regardless of whether the physician had expertise in reading sleep studies. For example, the Qualium Defendants caused checks to be paid to ear-nose-and throat doctors in Los Gatos—including Drs. William Lewis, and David Arnsten—for "consultation." The checks were in an amount calculated at $100 per referral for sleep studies. The Qualium Defendants directed Relator to deliver such checks to doctors, and Relator saw or heard of others doing so as

well. Relator also saw quarterly checks for aggregate amounts of these payments, *e.g.*, $1,000 to $1,500, made out to the doctors. The Qualium Defendants knew that paying money to doctors to induce referrals was illegal.

**J. The Qualium Defendants knew they submitted false claims for payment**

87. The Qualium Defendants, including Defendants Mostowfipour and Nader, knew they were submitting requests for payment to government health care programs when they were not entitled to payment, knew of the prohibitions against submitting false claims to the government during the relevant time period, and were aware of the laws and regulations for billing Medicare and other federal healthcare programs. The Qualium Defendants knew that it was wrong to provide money to doctors to induce them to send referrals, including Medicare patients, to Bay Sleep Clinic's testing facilities. The Qualium Defendants also knew that it was wrong to routinely waive Medicare co-pays for services.

88. The Qualium Defendants, including Defendants Mostowfipour and Nader, operated two Medicare approved IDTFs (the sleep clinics), a Medicare-enrolled DME facility, participated personally in government site inspections and audits to qualify their facilities, and endeavored to have an additional facility Medicare-approved for DME. As a Medicare provider subject to the terms and conditions of Medicare enrollment agreements, as well as a host of federal laws that bind Medicare providers, the Qualium Defendants, and each of them, had actual knowledge of federal healthcare program billing and reimbursement rules.

89. Among other things, the Qualium Defendants' awareness was based on information contained in the initial and subsequent Medicare enrollment applications they submitted for their enrolled sleep clinics and DME businesses, as well as information found in CMS-1500 claim forms they prepared and submitted to federal healthcare programs for payment. Defendants Mostowfipour and Nader personally assisted and completed the enrollment forms, along with Defendant Access Medical Consulting, as detailed below. Defendants Mostowfipour and Nader were personally present for CMS site audits of the San Francisco facility and the Los Gatos facility when the facilities underwent address changes. The Medicare enrollment application for IDTFs, for example,

required the Qualium Defendants to certify that they would abide by all applicable Medicare laws, regulations, and program instructions. *See* Medicare Enrollment Application, Form CMS-855B, Attachment 2 & Section 15: Certification Statement. The Qualium Defendants also had to certify that they "understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions and on the supplier's compliance with all applicable conditions of participation in Medicare." *Id*.

90. Further, the standard CMS application form required the Qualium Defendants to certify the truthfulness of the information they submitted:

> 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.

91. Moreover, the Qualium Defendants held monthly meetings of sales employees and sleep technicians that further evidence knowledge of their wrongdoing. These meetings included Defendant Nader, and sometimes Defendant Mostowfipour. At these meetings, Lori Palfreeman, Qualium's Operations Manager for sleep clinics, stated repeatedly that sleep technicians must be properly credentialed.

92. The Qualium Defendants' knowledge of Medicare enrollment requirements is further evidenced by a discussion Relator had with Defendant Nader. When Defendants Nader and Mostowfipour were contemplating moving the Los Gatos facility to a larger building, Relator and other Qualium employees discussed with Defendant Nader the possibility of moving into the new building as soon as possible due to overcrowding. Defendant Nader replied that it would take a while to make the move because the change in address would result in a delay of Medicare payments, stating, "everything goes through Los Gatos." The statement that "everything goes through Los Gatos" referred to the fact that billings for all sleep studies and medical devices provided to Medicare patients, even those conducted in or dispensed from the Qualium Defendants' non-Medicare-enrolled facilities, were processed as if they had occurred in the Medicare-enrolled

Los Gatos clinic. Defendant Nader's statement that she was unwilling to move the Los Gatos facility until she had assurances of Medicare approval indicates that she knew that Medicare would not pay for services provided in non-enrolled centers. It also evidences her knowledge and implementation of the scheme to submit false bills for such services through enrolled centers.

93. Before the Los Gatos site visit, Relator observed Qualium personnel segregating and working on files that contained documents related to Medicare claims and certifications. Once the files were deemed "cleaned," a round colored-sticker was placed on the file and it was placed back in the Medicare file cabinet.

94. At a monthly sales meeting at which Defendant Nader was present, Manager Lori Palfreeman specifically discussed the prohibition against Qualium's sleep clinic business sharing space with its DME business. Relator understood from Ms. Palfreeman and other employees that a purpose behind launching "Amerimed" and moving the DME operations to a Redwood City facility was to attempt to address the co-location problem. Defendants had attempted to enroll Amerimed in the Redwood City location in Medicare, which effort ultimately was not successful. To Relator's knowledge, when CMS inspected the Redwood City facility (as well as others), the Qualium Defendants did not inform CMS that improperly credentialed personnel dispensed DME devices, that the same people directly or indirectly owned the DME and sleep center entities, and that the DME business unlawfully shared space with sleep-study operations.

95. Despite their knowledge of all of the reasons they were not entitled to payment from Medicare and other government health care programs, including knowledge of the illegality of kickbacks to doctors and routine waivers of patient copayments, the Qualium Defendants submitted claims for payment to CMS and other programs, and in so doing, knowingly and deliberately presented false claims, statements, and records, to the United States.

**K. Defendant Access Medical Consultants Knowingly Submitted, or Caused the Submission of, False Claims**

96. Access Medical Consultants (AMC) is a billing service located in Los Gatos, California that specializes in sleep clinics. Its owners and principal officers, Faraneh H.

Javanmardian (also known as Faraneh Javan) and Farhad A. Javanmardian (also known as Fred Javan), are former friends of Defendants Mostowfipour and Nader. On its now-defunct website, www.billing4sleepclinics.com, AMC held itself out as "a team of dedicated billing consultants who have an extensive knowledge in managing the medical billing and business operation of the sleep clinics." Describing itself as "more than [j]ust a medical billing office," AMC detailed its services:

> We specialize in sleep clinics.
>
> We make a thorough analysis of your current billing procedure and utilize the result to provide you with the highest quality of billing services possible.
>
> We constantly monitor your cash flow and your business procedures, which are directly related to your billing and revenue generating operation.
>
> We make a thorough review of your business trend and constantly remain on the cutting edge of the changes in the sleep disorder industry.
>
> We give you expert advice and participate in your contract negotiations with the insurance companies.
>
> We conduct a quarterly survey of our overall performance and make recommendations to you or make an adjustment in our operation to better serve you and your medical practice.
>
> We realize that all providers and their offices are not the same, and for that reason we offer the widest range of options to fulfill virtually every need, including your need to maintain control over your data and the billing related issues . . . .

97. The Qualium Defendants hired AMC for comprehensive services, including assisting Qualium to complete and submit Medicare enrollment applications for the Los Gatos and San Francisco sleep clinics, as well as for licensing of its DME business, including the attempted enrollment of the Redwood City location. The Qualium Defendants also hired AMC to receive and process patients' billing information, including information about the services provided, and to bill payors, including government healthcare programs. AMC billed these programs both for sleep studies the Qualium Defendants provided and for DME products they furnished.

98. AMC specifically assisted Qualium in submitting Medicare enrollment applications for Qualium's address changes in the Los Gatos and San Francisco facilities. AMC's Ms. Javanmardian would come to the facility site with the application in hand, and Mr. Javanmardian would call or also be present on site for information-gathering during this process.

The information AMC gathered, through its owners and operators the Javanmardians, included the required information about credentialed personnel on staff to conduct the sleep testing. Typically, the enrollment process also would have required the Defendants to have on hand and produce copies of licenses and credentials. AMC listed the few credentialed sleep technicians that Qualium had on such applications, including Defendant Mostowfipour. At one point in 2010 after Relator became a registered technologist, Defendant Mostowfipour, in the presence of Ms. Javanmardian, directed that Relator's name be placed on an application rather than Mostowfipour's. With these representations, AMC and Qualium represented to CMS that the few registered technicians listed were regularly on staff at these particular locations, and that only these technicians conducted sleep testing there.

99. AMC, through the Javanmardians, knew that only credentialed technicians could be listed as providing services at particular centers. The Javanmardians knew that Qualium operated up to twenty (or more) facilities in California. The Javanmardians knew that Defendant Mostowfipour did not conduct sleep studies himself, despite apparently being a registered sleep technician. The Javanmardians knew the identities of the actual sleep technicians who conducted the testing from service-specific information they received for billing purposes. The Javanmardians knew the locations in which the technicians worked also from the service and billing information. AMC knew, therefore, that the registered technicians listed on the applications did not and could not conduct all of the sleep testing at the facilities being enrolled, and more broadly, work at all of the facilities and provide services to Medicare and other government program beneficiaries. AMC therefore misrepresented or assisted in misrepresenting facts to CMS that, had CMS been aware of the truth, would have resulted in CMS not enrolling the centers.

100. Defendant AMC also provided billing services to the Qualium Defendants. To do so, AMC processed patient information and payment claims for the sleep clinics. AMC received patient and billing information from sleep technicians and also through computer systems. The first computer system was known as ACT, and then, beginning in approximately 2009, Defendant Mostowfipour, an experienced software programmer, created the "Medusa" system. These

information systems permitted AMC to take in and process data about sleep studies and DME dispensing, including patient, facility, billing, and insurance data.

101. Specifically, Qualium sleep technicians sent to Defendant AMC a copy of a patient's insurance card, information about the date and true place of service, information about the identity of the actual technician who conducted the study (whether or not registered), the types of tests performed, and the sleep study report. Defendant AMC therefore received and had knowledge of the true patient and billing data when submitting claims to payors and processing payments from them. While Defendant AMC did much of this work remotely, the Javanmardians personally visited some of the Qualium Defendants' facilities several times a year to personally collect facts and data for their services to Qualium, and occasionally to attend meetings.

102. In contrast to the sleep-services information sent to AMC, when Qualium provided sleep study reports to referring physicians, they removed identifying information about the technicians who performed the studies. Relator understands that the Qualium Defendants did this to make it difficult to identify whether properly credentialed staff performed the services.

103. Despite having the true information about where sleep-testing services were provided to Medicare beneficiaries, Defendant AMC submitted claims, or caused the submission of claims, to Medicare and other federal healthcare programs that altered the true location of services. Defendant AMC and the Qualium Defendants represented that sleep-testing services occurred in Medicare-enrolled facilities when they were not. Defendant AMC therefore provided, or caused to be provided, false information, records, and statements to federal healthcare programs to obtain payments for Qualium, and the programs reimbursed for services and products on the basis of that false information.

104. The Qualium Defendants also contracted with Defendant AMC to handle billing for DME products. Qualium communicated data concerning DME dispensing and sales through the Medusa system. Through its access to the Medusa data system, AMC knew the Qualium Defendants dispensed DME that resulted from sleep study tests the Qualium Defendants performed. With the Medusa data, and because the Javanmardians visited the Qualium Defendants' facilities, AMC knew

that the DME dispensing operations shared space with the Qualium Defendants' sleep clinics and that the Qualium Defendants dispensed DME from non-enrolled locations. Moreover, when assisting Qualium in licensing their locations for medical device dispensing, AMC knew about the limited HMDR exemptee licenses actually held by Qualium personnel. Yet AMC submitted claims, or caused the submission of claims, to federal healthcare programs for DME dispensed by improperly or unlicensed personnel at non-enrolled locations by falsely representing that DME was instead dispensed through an enrolled facility through licensed personnel.

105. As noted above, AMC holds itself out as a specialist in sleep-clinic billing that "participate[s] in [a sleep clinic's] contract negotiations with [] insurance companies" and "constantly remain[s] on the cutting edge of the changes in the sleep disorder industry." As well, Ms. Javanmardian, one of AMC's principal officers, teaches or previously taught courses on proper medical billing at a community college in Saratoga, California. AMC is fully aware of the requirements of government health care program licensing, credentialing, and billing, and aware of the facts that showing that the Qualium Defendants were not entitled to payment on the government claims presented. Defendant AMC, therefore, knowingly submitted or caused the submission of, and knowingly made, used, or caused to be made or used a false record or statement material to false claims for payment to the government on behalf of the Qualium Defendants.

**L. Defendants' Billing of Federal Healthcare Programs**

106. Based on insurance cards that Relator saw and on information obtained from other technicians, a substantial number of the Qualium Defendants' patients are beneficiaries of federal healthcare programs, including Medicare and CHAMPVA. Relator also learned from the filtering capabilities of Qualium's Medusa data system that Medicare was the payer Qualium billed for services specific patients received at Qualium's sleep centers, including those not enrolled in Medicare. Relator also has direct awareness of the significant number of Medicare patients through her roles in sales for Qualium and as a sleep technician who personally received and transmitted insurance information.

107. Regardless of whether a location at which services were provided to Medicare beneficiaries was enrolled in Medicare as a sleep clinic or DME supplier, the Qualium Defendants submitted to Medicare claims for payment for such services by routing such claims through enrolled locations. Some of the locations at which the Qualium Defendants conducting sleep-tests and dispensed DME are as follows, by NPI number:

- 1275618811 Los Gatos CA 95032-2600
- 1922152107 Menlo Park CA 94025-4751
- 1184924029 Salinas CA 93908
- 1770882946 Monterey CA 93940-4546
- 1548545445 Irvine CA 92618-2059
- 1265431803 Menlo Park CA 94025-4751
- 1801940085 Los Gatos CA 95032-2600
- 1508910928 San Francisco CA 94109-5438
- 1245384312 Berkeley CA 94705-2051
- 1851445944 Walnut Creek CA 94598-3013
- 1265665038 Daly City CA 94015-4900
- 1407165319 Los Angeles CA 90025-1007
- 1043590276 Oakland CA 94609-3404
- 1912168683 Fremont CA 94538-1738
- 1427219195 Mountain View CA 94040-4317
- 1497916175 Redwood City CA 94062-1483
- 1447304548 Redwood City CA 94062-1483
- 1023279700 San Jose CA 95116-1909
- 1871754556 Gilroy CA 95020-3540
- 1790924660 Pleasanton CA 94588-2828

108. The Qualium Defendants may have recently started to relocate some of its sleep clinics and medical-device/CPAP business in a belated attempt to address the co-location prohibition.

109. All or nearly all federal healthcare program claims the Qualium Defendants made for sleep-testing were false because Qualium provided services for beneficiaries at non-Medicare-enrolled facilities, but deceptively billed as if they occurred at enrolled facilities; employed non-registered technicians to conduct the tests; performed the services in a sleep clinic that unlawfully shared ownership and space with a medical-device/CPAP supplier; or provided the tests in

Medicare-enrolled centers for which Medicare approval was fraudulently induced due to false statements on those applications.

110. Similarly, all or nearly all government healthcare program claims the Qualium Defendants made for medical-devices (DME) were false because Qualium personnel dispensed DME from a non-enrolled facility, but deceptively billed federal healthcare programs as if it dispensed those devices at enrolled facilities; allowed non-licensed or fraudulently licensed personnel to dispense DME; or supplied DME through an entity that unlawfully shared ownership and space with a Qualium sleep clinic.

111. In addition, reimbursement claims for sleep studies that properly credentialed technicians happened to conduct, or DME that properly credentialed personnel happened to dispense, are still false due to the Qualium Defendants' multifaceted and ongoing pattern of false and fraudulent conduct. Had CMS or other health care programs known all of the true facts about the Qualium Defendants' and Defendant AMC's patterns of conduct, they would have denied all claims for payment.

112. Relator cannot at this time specifically identify all of the false claims for payments that Defendants submitted or caused to be submitted because such information is in the possession and control of Defendants, including Defendant AMC. If the data in the Medusa system is authentic and has not been tampered with, it should reveal additional details of the false claims at issue. An example of a false claim includes Qualium's request to Medicare for payment for sleep-study testing provided in 2009 to a female patient with the initials A.M., born in 1927. Other examples of false claims include all claims reflected in the publicly available Medicare Provider Utilization and Payment Data, specifically for Qualium NPI numbers 1275618811 and 1508910928. This data reflects actual CMS payments allowed and paid to Qualium, and types and numbers of services provided, for years 2012 and 2013.

113. The Qualium Defendants directed and ratified all billing practices, submitted or caused the submission of claims for payment, and received federal government payments. Defendant AMC facilitated and conducted the fraudulent billing practices and submitted or caused

the submission of claims for payment. All Defendants' knowing submission of false and fraudulent information resulted in Medicare and CHAMPVA receiving and paying claims for diagnostic sleep studies and medical devices that were not properly payable. The federal healthcare programs would not have paid these false claims had the true facts been known to them. The falsity underlying and accompanying the Qualium Defendants' claims for payment resulted in or otherwise affected government payment of the claims.

114. Based on the facts alleged above, the Qualium Defendants and Defendant AMC are liable for all civil damages, including penalties, arising out of their submission of false claims.

## VIII. CAUSES OF ACTION

**Count One**
**Federal False Claims Act**
**31 U.S.C. §§ 3729(a)(1)–(2) (1986)**
**31 U.S.C. § 3729(a)(1)(A)–(B) (2009)**
**against the Qualium Defendants**

115. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 114 of this Complaint.

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

117. Through the acts described above, for all conduct that occurred before May 20, 2009, the Defendants knowingly presented, or caused 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. 31 U.S.C. §§ 3729(a)(1) (1986). Through the acts described above, for all conduct that occurred on or after May 20, 2009, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the United States Government for payment or approval. 31 U.S.C. § 3729(a)(1)(A) (2009).

118. Through the acts described above, Defendants knowingly made, used, or caused to be made or used, a false record or statement material to a false or fraudulent claim. 31 U.S.C. §§ 3729(a)(1)(B) (2009).

119. Relator cannot now identify all of the false claims for payment that Defendants' conduct caused. Relator has no control over such entities and no access to records they possess.

120. The United States Government, unaware of the falsity of the records, statements, and claims that Defendants made or caused to be made, paid and continues to pay the claims that would not be paid but for Defendants' illegal conduct.

121. Defendants have damaged, and continue to damage, the United States in a substantial amount to be determined at trial.

122. Additionally, the United States is entitled to the maximum penalty of up to $11,000 for each and every violation alleged herein.

**Count Two**
**Federal False Claims Act**
**31 U.S.C. §§ 3729(a)(1)–(2) (1986)**
**31 U.S.C. § 3729(a)(1)(A)–(B) (2009)**
**against Defendant Access Medical Consultants, Inc.**

123. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 114 of this Complaint.

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

125. Through the acts described above, for all conduct that occurred before May 20, 2009, Defendants knowingly presented, or caused 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. 31 U.S.C. §§ 3729(a)(1) (1986). Through the acts described above, for all conduct that occurred on or after May 20, 2009, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the United States Government for payment or approval. 31 U.S.C. § 3729(a)(1)(A) (2009).

126. Through the acts described above, Defendants knowingly made, used, or caused to be made or used, a false record or statement material to a false or fraudulent claim. 31 U.S.C. §§ 3729(a)(1)(B) (2009).

127. Relator cannot now identify all of the false claims for payment that Defendants' conduct caused. Relator has no control over such entities and no access to records they possess.

128. The United States Government, unaware of the falsity of the records, statements, and claims that Defendants made or caused to be made, paid and continues to pay the claims that would not be paid but for Defendants' illegal conduct.

129. Defendants have damaged, and continue to damage, the United States in a substantial amount to be determined at trial.

130. Additionally, the United States is entitled to the maximum penalty of up to $11,000 for each and every violation alleged herein.

## IX. PRAYER

WHEREFORE, Relator prays for judgment against Defendants as follows:

131. That Defendants cease and desist from violating 31 U.S.C. § 3729 et seq.;

132. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the United States has sustained because of Defendants' actions, plus the maximum civil penalty permitted for each violation of the False Claims Act;

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

134. That Relator be awarded all fees, costs, and expenses incurred in connection with this action, including attorneys' fees, costs, and expenses; and

135. For such other relief as the Court deems just and proper.

## X. DEMAND FOR JURY TRIAL

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

Dated: September 2, 2015

Respectfully submitted,

By: */s / Jessica T. Moore*

Eric R. Havian
Jessica T. Moore
Ari Yampolsky
CONSTANTINE CANNON LLP
4 Embarcadero Center, 14th Floor
San Francisco, CA 94111
Telephone: (415) 426-5666
Facsimile: (650) 636-9709
jmoore@constantinecannon.com