

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

THE UNITED STATES OF AMERICA and THE
COMMONWEALTH OF MASSACHUSETTS ex
rel. JOHN DOES 1 and 2,

Plaintiffs,

v.

REGIONAL HOME CARE, INC. DOING
BUSINESS AS NORTH ATLANTIC MEDICAL
SERVICES ALSO DOING BUSINESS AS
NORTH ATLANTIC MEDICAL- TOLMAN
CLINICAL LABORATORY AND AS NORTH
ATLANTIC MEDICAL,

Defendant.

CIVIL ACTION NO.

U.S. DISTRICT COURT
DISTRICT OF MASS.

**FILED IN CAMERA
and UNDER SEAL**

COMPLAINT

SEALED CASE – DO NOT PUT ON PACER

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INTRODUCTORY STATEMENT

1. This is an action brought on behalf of the United States of America by Plaintiffs John Does 1 and 2 (hereafter referred to as “Relators” or “Plaintiffs”) against Defendant Regional Home Care, Inc. doing business as North Atlantic Medical Services, North Atlantic Medical -Tolman Clinical Laboratory, and North Atlantic Medical (collectively hereafter referred to as “NAMS”) pursuant to the *Qui Tam* provisions of the Federal Civil False Claims Act, 31 U.S.C. §§ 3729-33 (“Federal FCA” or “FCA”), and on behalf of the Commonwealth of Massachusetts under its False Claims Act, Mass. Gen. Laws ch. 12, §§ 5A, *et seq.* (“Massachusetts FCA”) (together referred to herein as “*Qui Tam* Action”). Pursuant to 31 U.S.C. § 3730(b)(2), and the comparable provisions in the Massachusetts FCA, this action is brought *in camera* and under seal.

2. The Relators have direct, first-hand knowledge that Defendant has violated and is continuing to violate the Federal and Massachusetts FCA by failing to comply with the Medicare

and Medicaid reimbursement rules governing Durable Medical Equipment for respiratory therapy, including oxygen therapy and sleep therapy. In violation of these rules, Defendant has, among other things, been using unlicensed personnel rather than licensed respiratory therapists to perform certain services and in other instances its respiratory therapists are not conducting required follow up patient visits. By failing to comply with these rules, NAMS has since at least 2002 (for oxygen therapy) and since at least 2006 (for sleep therapy) submitted (or caused to be submitted) thousands of false or fraudulent claims to Medicare, Medicaid and other government health care programs in violation of the Federal and Massachusetts FCAs.

3. In addition, by failing to return or refund or notify the United States and/or the Commonwealth that NAMS has received overpayments from Medicare and/or Medicaid and other government health care programs, the Defendant is violating and is continuing to violate the Federal and Massachusetts FCAs.

4. The use of unlicensed personnel and failure to provide follow up visits by licensed personnel in contravention of federal and state law endangers the patient's quality of care, health, and safety. On information and belief, the practices complained of herein are continuing.

JURISDICTION AND VENUE

5. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331, 28 U.S.C. § 1367 and 31 U.S.C. § 3732, the last of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3729 and 3730, and has supplemental jurisdiction over the Massachusetts FCA claim pursuant to 28 U.S.C. § 1367.

6. To Relators' knowledge, this action is not barred by any provision of the Federal or the Massachusetts FCA. In particular, the Federal FCA bars contained in 31 U.S.C. §

3730(e)(1) or (4) do not apply to Relators: there is no civil suit or administrative proceeding involving the allegations and transactions herein to which the United States is a party, there has been no statutorily defined “public disclosure” of these allegations or transactions or any allegations or transactions that are substantially the same, and, in any event, Relators are each an “original source” within the meaning of the FCA. For the same reasons, the comparable bars contained in the Massachusetts FCA do not apply. *See* Mass. Gen. Laws ch. 12, § 5G (3).

7. This Court has personal jurisdiction and venue over the Defendant pursuant to 28 U.S.C. § 1391(b) and 31 U.S.C. § 3732(a) because those sections authorize nationwide service of process and because Defendant has minimum contacts with the United States. Moreover, Defendant can be found in, resides, and transacts business in this District.

8. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) because Defendant transacts business in this judicial district, and acts proscribed by 31 U.S.C. § 3729 have been committed by Defendant in this District. Therefore, venue is proper within the meaning of 28 U.S.C. § 1391(b) and (c) and 31 U.S.C. § 3732(a).

PARTIES

9. The real parties in interest to this *Qui Tam* Action are the United States of America and the Commonwealth of Massachusetts. Accordingly, at this time, Relators are pursuing this action on behalf of the United States of America and the Commonwealth. *See* 31 U.S.C. § 3730(b)(1); Mass. Gen. Laws ch. 12, § 5C.

10. Plaintiffs/Relators John Does 1 and 2 are citizens of the United States of America who have direct first hand knowledge of the activities of Defendant NAMS.

11. Defendant Regional Home Care, Inc. is a corporation with a principal place of business at 125 Tolman Avenue, Leominster, Massachusetts. On information and belief, it owns

and does business as North Atlantic Medical Services, and also does business as North Atlantic Medical-Tolman Clinical Laboratory and as North Atlantic Medical and as North American Medical Services (“NAMS”). In addition to its principal place of business in Leominster, Massachusetts, NAMS also has offices in Woburn, Worcester, Stoughton, and Springfield, Massachusetts, as well as in Bedford (and at one point in Epping), New Hampshire, and Biddeford and Auburn, Maine.

12. Defendant NAMS was founded in 1982, and it is a supplier of Durable Medical Equipment (“DME”) including oxygen therapy and sleep therapy equipment and services. NAMS sells and ships DME products nationwide. It also supplies DME and provides set up and initiation of respiratory therapies to patients in their homes, at NAMS’ centers, and occasionally in a hospital or other facility setting, including to patients in Massachusetts, Rhode Island, New Hampshire, Maine, and possibly Connecticut. A large percentage of its patients/customers are covered by Medicare and/or Medicaid or other government health insurance programs.

FEDERAL AND STATE HEALTH INSURANCE PROGRAMS

Government Health Care Programs

13. The Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395, *et seq.*, (hereinafter “Medicare”), is a Health Insurance Program administered by the Government of the United States that is funded by taxpayer revenue. The program is overseen by the United States Department of Health and Human Services (“HHS”). Medicare was designed to be a health insurance program and to provide for the payment of hospital services, medical services and durable medical equipment to persons over sixty-five (65) years of age and others that qualify under the terms and conditions of the Medicare Program, as well as to provide

certain prescription drug coverage. Individuals who receive benefits under Medicare are commonly referred to as "beneficiaries."

14. Reimbursement for Medicare claims is made by the United States through HHS's Center for Medicare and Medicaid Services ("CMS") which contracts with private insurance carriers known as fiscal intermediaries ("FIs") (for Part A) or carriers (for Part B) or private insurance companies who administer the plans (for Part C) to administer and pay claims, directly or indirectly, from the Medicare Trust Fund.

15. The Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v (hereafter "Medicaid"), is a Health Insurance Program administered by the Government of the United States and the various individual States and is funded by State and Federal taxpayer revenue. The Medicaid Program is overseen by HHS through CMS. Medicaid was designed to assist participating states in providing medical services, durable medical equipment and prescription drugs to financially needy individuals that qualify for Medicaid.

16. In addition to Medicare and Medicaid, there are other federal and state programs providing health insurance. For example, the Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS") (now known as "TRICARE"), 10 U.S.C. §§ 1071-1106, provides benefits for health care services furnished by civilian providers, physicians, and suppliers to members of the Uniformed Services and to spouses and children of active duty, retired and deceased members. The program is administered by the Department of Defense and funded by the Federal Government. CHAMPUS pays for, among other items and services, tests and procedures, durable medical equipment, and prescription drugs for its beneficiaries.

17. Another example is the Federal Employees Health Benefits Program ("FEHBP") which provides health care benefits for qualified federal employees and their dependents. It pays

for, among other items and services, tests and procedures, durable medical equipment, and prescription drugs for its beneficiaries.

18. Together Medicare and Medicaid, and any other government funded healthcare programs, may be referred to herein as “Federal Health Care Programs” or “Government Health Care Programs”.

Rules Governing Durable Medical Equipment Suppliers

19. Medicare provides coverage for and pays claims for durable medical equipment (“DME”) provided by suppliers (such as Defendant NAMS) on certain conditions and has issued rules and regulations governing reimbursement for such equipment and supplies provided to Medicare beneficiaries. *See generally* 42 U.S.C. § 1395m (§§ 1834(j)(5) and 1861(s)(6) of the Social Security Act); 42 C.F.R. §§ 424.57-424.58 “Special Payment Rules for Items Furnished by DMEPOS Suppliers and Issuance of DMEPOS Supplier Billing Privileges”; Medicare National Coverage Determinations Manual, Chapter 1, Part 4, Sections 240.2 (home oxygen) and 240.4 (continuous positive airway pressure (CPAP) therapy for obstructive sleep (OSA)); Medicare Claims Processing Manual, Chapter 20, “Durable Medical Equipment, Prosthetics and Orthotics, and Supplies (DMEPOS)”; Medicare Benefit Policy Manual, Chapter 15, “Covered Medical and Other Health Services,” § 110; Medicare Program Integrity Manual Chapter 5.

20. To be eligible to participate and be paid under the Medicare DMEPOS benefit, a supplier must meet numerous conditions that are set out, *inter alia*, in the statutes, regulations, and manuals noted, *supra*, as well as in the provider or supplier enrollment agreement entered into with the Medicare program, *see* Medicare Enrollment Application Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Suppliers CMS-855S, copy attached as **EXHIBIT A**.

21. The Medicare DMEPOS rules provide, *inter alia*, that the supplier must: (a) adhere to all the requirements and certifications contained in the DMEPOS Medicare Provider Enrollment Agreement (copy attached as **EXHIBIT A**); (b) be accredited by an independent accreditation organization approved by CMS; and (c) meet and certify in its application for Medicare billing privileges that it meets and will continue to meet the standards requiring it to operate its business and furnish Medicare-covered items in compliance with applicable federal regulatory requirements *and* state licensure and regulatory requirements. *See, e.g.*, 42 C.F.R. § 424.57. In particular, 42 C.F.R. § 424.57(c) (1) states that: “If a State requires licensure to furnish certain items or services, a DMEPOS supplier—(A) Must be licensed to provide the item or service; (B) Must employ the licensed professional on a full-time or part-time basis ... [subject to exceptions that do not apply in this case].” Failure to comply with these standards is material to payment by Medicare, and will result in CMS revoking the supplier’s billing privileges. 42 C.F.R. § 424.57(d).

22. In addition to governing rules and law, CMS has published DMEPOS “Quality Standards” (2006 and 2012 editions). These publications state that they contain information which is only intended to be a general summary and are not intended to and do not take the place of the law or regulations. These Standards provide, *inter alia*, that suppliers must comply with: (a) these Quality Standards in order “to obtain or maintain Medicare billing privileges” (*see* 2012 edition p. 2); (b) all “Medicare statutes, regulations, manuals, program instructions and contractor policies and articles” (*id.* at p. 5); and (c) enrollment standards under the regulations, *supra*, the Medicare National Coverage Determination, *supra*, and State law (*id.*). The Standards also provide that “Professional personnel [such as respiratory therapists] must be licensed, certified, or registered and function within their scope of practice as required by the State

standards under which the professional is licensed, certified, or registered.” *Id.* at p. 6. These standards further provide that the supplier “shall implement the requirements stated in Appendices A through C, as applicable to its business.” *Id.* at p. 10. Appendix A governs “Respiratory Equipment Supplies, and Services” including Continuous Positive Airway Pressure (CPAP) devices and various oxygen equipment. Per Appendix A, the supplier must comply with applicable the American Association for Respiratory Care (“AARC”) Clinical Practice Guidelines for oxygen therapy. A copy of the 2006 and 2012 Standards and the AARC Guideline for oxygen therapy are attached as **EXHIBIT B**.

23. The “AARC Guideline: Oxygen Therapy in the Home or Alternative Site Health Care Facility” (“Oxygen Therapy Guideline”) provides that only licensed and/or credentialed respiratory therapists may perform services and must do so “in accordance with applicable federal, state, and local law, specifically the respiratory therapy practice act in that state.” *See* Section 10.3 (**EXHIBIT B** attached).

24. Each of the states in which Defendant NAMS is supplying DME (including oxygen and positive airway pressure equipment and services such as CPAP) has licensing requirements for the practice of “respiratory care”, the definition of which encompasses, *inter alia*, oxygen and PAP services. For example, in the Commonwealth of Massachusetts the practice of respiratory care is governed by M.G.L. c. 13, § 11B and M.G.L. c. 112, §§ 23R-23BB, and through regulations promulgated at 261 CMR 2.00-5.00 by the Department of Public Health (“DPH”) acting through the Board of Respiratory Care. DPH and the Board are charged with interpreting these laws and protecting the public health, safety and welfare through regulation of the practice of respiratory care in the Commonwealth of Massachusetts in accordance with the statutes.

25. Massachusetts law defines “respiratory care” as follows:

‘Respiratory care’, is a health profession that, under direction of a licensed physician, who has special expertise in respiratory care, utilizes the application of scientific principles for the identification, prevention, remediation, research, and rehabilitation of acute or chronic cardiopulmonary dysfunction thereby promoting optimum health and function. Respiratory care practice includes, but is not limited to, the therapeutic and diagnostic use of the following as ordered by a physician: medical gases, gas administering devices, humidification and aerosols, administration of aerosol medications, support services for mechanically ventilated patients, postural drainage, bronchopulmonary hygiene, breathing exercises, respiratory rehabilitation, cardiopulmonary resuscitation, maintaining natural and artificial airways, the understanding and reporting of tests as aids to diagnosis or the planning of treatment programs. Respiratory care shall also include the measuring ventilatory volumes, pressures and flows, collecting specimens of blood and other materials, pulmonary function testing, hemodynamic and other related physiologic monitoring of the cardiopulmonary system. Respiratory care shall also include teaching both patient and family respiratory care procedures as part of a patient’s ongoing program; consultation services for the health educational and community agencies. Respiratory care shall also include teaching of the knowledge, skills, and attitudes necessary to perform the above mentioned activities.

See M.G.L. c. 112, § 23R. The Code of Massachusetts Regulations adopts this statutory definition, and adds two sentences at the end as follows: “Respiratory Care is a changing and evolving profession and shall also include procedures described by the Clinical Practice Guidelines of the AARC, and duties consistent with the training and education of respiratory care personnel or related to the practice of respiratory care, as approved by the Board.” *See* 261 CMR 2.02.

26. Under Massachusetts law, “respiratory therapists” are persons who are duly licensed to practice “respiratory care” in the Commonwealth of Massachusetts in accordance with M.G.L. c. 112, § 23S. *See* M.G.L. c. 112, § 23R. Generally speaking, a license is required to perform respiratory care in the Commonwealth unless the service or person providing it falls into certain specified statutory or regulatory exceptions. *See* M.G.L. c. 112, § 23SV; 261 CMR

2.05. To be licensed, a person must meet certain educational and clinical requirements with a specific focus on respiratory courses and care.

27. While a respiratory care license is not required to transport or deliver compressed gas cylinders or other respiratory care devices to a home, hospital or other location or to clean, sterilize, disinfect, assemble and disassemble respiratory care equipment, *only a licensed respiratory therapist* may set up and initiate therapies such as CPAP, BiPAP, suction or nebulizers with medications, and *only a licensed respiratory therapist* may instruct a patient and/or the patient's family on the patient's respiratory therapy. See 261 CMR 2.05 (5) and (8); Board of Respiratory Care Frequently Asked Questions About the Practice of Respiratory Care (RC Board FAQs (Interpretations) Final 10-1-12 at pp. 3-4, 7 (replacing Interpretations of respiratory care services in the home and by unlicensed individuals, issued 1994) and citations, copy attached as **EXHIBIT C**. See also Board of Respiratory Care Interpretations of Statutes and Regulations October 1994 at p. 2 no. 4. ("Unlicensed individuals rendering therapies defined as "Respiratory Care" such as adult nasal CPAP, oral suction, and nebulizers with medications, would be in violation of the law."), copy attached as **EXHIBIT D**.

28. As to oxygen, the Board also "recognizes that oxygen therapy is unique because of the need for continuous administration" to a patient, and has opined that an unlicensed individual who has been properly trained to change the oxygen source, may change the source of oxygen, provided certain conditions are met, including that a licensed individual visits the patient within 24-48 hours after the patient arrives at home and documents that he or she has verified the prescribed therapy, instructed the patient/family, and evaluated the patient relative to the oxygen therapy. See Board of Respiratory Care Frequently Asked Questions About the Practice of Respiratory Care (RC Board FAQs (Interpretations) Final 10-1-12 at pp. 7-8

(replacing Interpretations of respiratory care services in the home and by unlicensed individuals, issued 1994) and citations (copy attached as **EXHIBIT C**). *See also* Board of Respiratory Care Interpretations of Statutes and Regulations October 1994 at pp. 2-3 no. 5 (copy attached as **EXHIBIT D**).

29. Other states in which Defendant NAMS is delivering and setting up and initiating respiratory therapies have requirements similar to those of Massachusetts for PAP and for oxygen. *See generally e.g.*, New Hampshire Respiratory Care Practitioners Law, N.H. RSA-326-E; Connecticut General Statutes, Chapter 381a, §§ 19a-149c0, 20-162n-20-162q; Maine Revised Statutes Title 32, Chapter 97, §§ 9702, *et seq.*; Rhode Island Rules and Regulations for Licensing Respiratory Care Practitioners [R23-39-RCP].

30. DMEPOS provided by a supplier such as Defendant NAMS is reimbursed under Medicare Part B by the supplier submitting a completed and signed claim on CMS Form 1500, a copy of which is attached as **EXHIBIT E**. There is no separate reimbursement for the services necessary to deliver, set up and monitor the DME such as PAP and oxygen; rather, the reimbursement for such services is subsumed in the reimbursement rate for the DME. *See, e.g.*, Medicare National Coverage Determinations Manual (“NCD”), Chapter 1, Part 4, Sections 240.2 (no professional component for respiratory therapists’ services in the home use of oxygen and oxygen equipment); Medicare Claims Processing Manual, Chapter 20, “Durable Medical Equipment, Prosthetics and Orthotics, and Supplies”, *supra* at section 60. The amount of the reimbursement is based on a fee schedule for DME published by CMS.

31. Medicaid also provides coverage for and pays claims for DMEPOS provided by suppliers such as Defendant NAMS on certain conditions, and has issued rules and regulations

governing reimbursement for such equipment provided to Medicaid beneficiaries. As with Medicare, Medicaid DME claims are submitted using CMS Form 1500 (**EXHIBIT E** attached).

32. For example, in Massachusetts, all Medicaid DME suppliers must enroll in MassHealth, enter into a provider contract, and comply with 130 CMR 409.000 and 450.000 and the “Commonwealth of Massachusetts MassHealth Durable Medical Equipment Manual” and other relevant manuals. Among the MassHealth requirements are that the provider participates in Medicare as a DME provider, is accredited by a body acceptable to CMS, meets all applicable federal, state, and local requirements, certifications, and registrations, complies with 130 CMR 409.000 and 450.000, and adheres to the CMS DME supplier standards. *See* Commonwealth of Massachusetts MassHealth Durable Medical Equipment Manual incorporating 130 CMR 409.404-405. MassHealth DME providers are reimbursed according to rates and regulations established by the State. *Id.* at 409.427.

FEDERAL FALSE CLAIMS ACT, 31 U.S.C. §§ 3729, et seq.

33. The Federal FCA, 31 U.S.C. § 3729(a)(1)(A), makes “knowingly” presenting or causing to be presented any false or fraudulent claim for payment or approval, a violation of federal law for which the United States may recover three times the amount of the damages the government sustains and a civil monetary penalty of between \$5,500 and \$11,000 per claim for claims made on or after September 29, 1999.

34. The Federal FCA, 31 U.S.C. § 3729(a)(1)(B), makes “knowingly” making, using, or causing to be used or made, a false record or statement material to a false or fraudulent claim, a violation of federal law for which the United States may recover three times the amount of the damages the Government sustains and a civil monetary penalty of between \$5,500 and \$11,000 per claim for claims made on or after September 29, 1999.

35. The Federal FCA, 31 U.S.C. § 3729(a)(1)(G), makes it illegal for any person to “knowingly” make, use or cause to be made or used a false record or statement material to an obligation to pay or transmit money or property to the Government, or to knowingly conceal or knowingly and improperly avoid or decrease an obligation to pay or transmit money or property to the Government, a violation of federal law for which the United States may recover three times the amount of the damages the Government sustains and a civil monetary penalty of between \$5,500 and \$11,000 per claim for claims made on or after September 29, 1999.

36. The Federal FCA defines a “claim” to include any request or demand, whether under contract or otherwise, for money or property which is made to a contractor, grantee, or other recipient if the United States Government provides any portion of the money or property which is requested or demanded, or if the Government will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested. 31 U.S.C. § 3729(b)(2).

37. The FCA, 31 U.S.C. § 3729(b)(1) provides that “(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 (B) require no proof of specific intent to defraud.”

38. The FCA, 31 U.S.C. § 3729(b)(4) provides that “(4) the term ‘material’ means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.”

MASSACHUSETTS FALSE CLAIMS ACT, MASS. GEN. LAWS CH. 12, §§ 5A-O

39. The Massachusetts FCA closely tracks the Federal FCA. The Massachusetts

False Claims Act applies, *inter alia*, to the state portion of Medicaid losses caused by false Medicaid claims to the jointly federal-state funded Medicaid program and failure to report and return any overpayments therefrom. The Massachusetts FCA contains *qui tam* provisions governing, *inter alia*, a relator's right to claim a share of the Commonwealth's recovery.

40. The Massachusetts FCA, Mass. Gen. Laws ch. 12, § 5B(1), makes "knowingly" presenting or causing to be presented to any false or fraudulent claim for payment or approval, a violation of law for which the affected government party may recover three times the amount of the damages, including consequential damages, the government sustains and a civil monetary penalty of between \$5,000 and \$10,000 per violation.

41. The Massachusetts FCA, Mass. Gen. Laws ch. 12, § 5B(2), makes "knowingly" making, using, or causing to be used or made a false record or statement to get a false or fraudulent claim paid or approved a violation of law for which the affected government party may recover three times the amount of the damages, including consequential damages, the government sustains and a civil monetary penalty of between \$5,000 and \$10,000 per violation.

42. The Massachusetts FCA, Mass. Gen. Laws ch. 12, § 5B(8), makes "knowingly making, using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or to transmit money or property to the commonwealth or political subdivision thereof; a violation of law for which the affected government party may recover three times the amount of the damages, including consequential damages, the government sustains and a civil monetary penalty of between \$5,000 and \$10,000 per violation.

43. The Massachusetts FCA, Mass. Gen. Laws ch. 12, § 5A, defines "knowing and knowingly" to mean "possessing actual knowledge of relevant information, acting with deliberate ignorance of the truth or falsity of the information, or acting in reckless disregard of

the truth or falsity of the information and no proof of specific intent to defraud is required.”

44. The Massachusetts FCA, Mass. Gen. Laws ch. 12, § 5A, defines a “claim” to include any request or demand, whether under contract or otherwise, for money or property which is made to an officer, employee, agent or other representative of the commonwealth, political subdivision thereof or to a contractor, subcontractor, grantee, or other person if the commonwealth or any political subdivision thereof provides any portion of the money or property which is requested or demanded, or if the commonwealth or any political subdivision thereof will reimburse directly or indirectly such contractor, subcontractor, grantee, or other person for any portion of the money or property which is requested or demanded.”

FACTS AND ALLEGATIONS

45. The allegations of this Complaint arise from the Relators’ first-hand knowledge of the Defendant’s unlawful conduct resulting in the fraudulent and false billing of Government Health Care Programs for DME equipment and services provided by unlicensed personnel, and services not provided, and for NAMS’ failure to repay monies (i.e. overpayments) due and owing to those programs.

Defendant’s Business as a DME Supplier

46. At all times relevant to this Complaint, NAMS was a DME supplier accredited by the Joint Commission on Accreditation of Healthcare Organizations (“JCAHO”) and enrolled in the Medicare and Medicaid programs (and other government health care programs) as a DMEPOS supplier.

47. At all times relevant to this Complaint, NAMS has supplied DME and provided set up and initiation of respiratory therapies to patients in their homes, at NAMS’ centers, and occasionally in a hospital or facility setting. Among the DME provided by NAMS is: (a)

oxygen equipment; and (b) positive airway pressure (“ PAP”) equipment, including Continuous Positive Airway Pressure (“CPAP”), bi level CPAP(“BiPAP”), BiPAP STs, and Adept Servo Ventilation (“ASV”).

48. Oxygen therapy is delivered via nasal cannula or mask and O₂ used to treat patient with compromised lungs and/or heart, for example, pneumonia, congestive heart failure, and asthma.

49. All PAP therapies deliver positive air pressure via interface (mask), but each is used for different health problems. CPAP is used to treat obstructive sleep apnea (“OSA”) and BiPAP is used for treatment of OSA, asthma, and respiratory inefficiencies. BiPAP ST and BiPAP ASV are considered non-invasive ventilation because of a timed backup rate. BiPAP ST is used for treatment of patients with neuromuscular issues and central sleep apnea. BiPAP ASV is used to treat congestive heart failure, central sleep apnea, and complex sleep apnea (combination of OSA and central).

50. A large percentage of NAMS’ patients/customers are covered by Medicare and/or Medicaid or other government health insurance programs.

51. To provide respiratory therapies and related DME, NAMS has employed and continues to employ licensed respiratory therapists. However, it also has employed and continues to employ unlicensed persons or “liaisons”. NAMS pays these unlicensed liaisons considerably less than it pays its licensed respiratory therapists. For example, in 2011, NAMS paid its liaisons \$19/hour and paid its respiratory therapists \$34/hour.

52. To be licensed as a respiratory therapist (for example, in Massachusetts) a person is required to have post high school education (e.g., two years of college or community college) with a focus on study of respiratory care as well as a certain amount and type of clinical

experience. In contrast, the liaisons hired and used by NAMS lacked these credentials and often were high school graduates, with no prior job, work, or clinical experience in respiratory care (or any health care field). Once hired, these liaisons received one month of on the job training at NAMS: two weeks in the office with another liaison and two weeks on the road with liaisons and respiratory therapists. After that, they were permitted and expected to work on their own doing DME set up and initiating patient therapies, instructing patients, etc., in other words, services requiring a licensed respiratory therapist.

53. NAMS began using unlicensed liaisons about 5-6 years ago. Initially they were used as “gophers” to run errands and help the licensed respiratory therapists. Over time, however, their jobs evolved into providing the same types of respiratory care services the licensed respiratory therapists were providing. About six years ago, NAMS had about 200 new PAP patients per month; that grew to over approximately 800 new PAP patients per month, and is now in the range of approximately 600-700 new PAP patients per month.

54. On average NAMS employed or employs about 5-6 liaisons at any given time. In 2010-2011, each of these liaisons was performing on average 30-35 PAP set ups per month (depending on how busy the territory was).

55. In addition, NAMS employed on average about 11-16 respiratory therapists at any given time. Depending on the territory, each of these respiratory therapists was performing on average as many as 45 PAP set ups per month. At one point in time, the numbers of liaisons was growing while the numbers of respiratory therapists employed by NAMS was declining. NAMS also uses a number of personnel on a per diem basis, especially in Maine.

56. The DME delivery and set up process begins once NAMS has verified the insurance coverage of a new PAP patient. After that, the liaison or the respiratory therapist

contacts the patient to schedule an appointment at their home or at a NAMS center (occasionally services were provided elsewhere such as a hospital). On the day of the appointment, the liaison or therapist gets the appropriate DME off the shelf at NAMS and either goes to the patient's home or meets the patient in center. The employee would then set up the DME and initiate PAP therapy.

57. All PAP therapies are prescriptions which are to be "filled" by a licensed professional (respiratory therapist, medical doctor, or registered nurse). Initial setup consists of setting pressure (i.e. filling prescription), describing to the patient (and family) why therapy is medically necessary, thoroughly instructing the patient (and family) on use, features, cleaning procedures, importance of providing proper interface (mask), and answering patient's clinical questions.

58. Proper set up and initiation is critical to the patient's health and safety, as well as material to whether the prescription has its intended effect. Complications can occur from improper set up and initiation, for example: an improper interface (mask) would negate therapy; not understanding a BiPAP prescription can result in the patient receiving a completely different therapy than intended and unintentionally hypo/hyperventilate the patient; setting pressure too high can cause harm to lung compromised patients; and improperly setting backup rates on ST/ASV can cause respiratory instability.

59. By way of further example, if a patient is discharged from the hospital after being admitted with respiratory failure and treated with BiPAP, and the doctor prescribes that at home he or she receive auto BiPAP imax 25/emin 6, an unlicensed person who misunderstands the prescription or does the set up and initiation incorrectly may set the BiPAP to 25/6, in which case respiratory failure is likely to re-occur sending patient right back to hospital (or worse).

60. The liaisons and therapists had various NAMS forms to complete and in some instances sign, including without limitation: Initial Assessment and Plan of Service and Medical Supply; Work in Progress Reports; Patient Assignment Reports; Activity Logs; and Order Forms.

61. With oxygen DME the process and routine used by NAMS was similar except that the delivery and set up/initiation services were provided by an oxygen technician (“tech”). The oxygen techs (who were and are not licensed) did the initial equipment set ups and patient instruction to initiate the oxygen therapy. However, there was never the follow up visit by a respiratory therapist within 24-48 hours after initiation of oxygen therapy as required by law.

62. With oxygen therapy, the initial setup consists of equipment instruction and how to use it. There is no clinical evaluation or explanation to the patient or the patient’s family of the prescription and medical necessity of treatment. Thus, the law requires a home visit by a licensed respiratory therapist within 24-48 hours later to provide such services.

63. In addition, the unlicensed (respiratory) liaisons were and are performing pulse dose evaluations of oxygen patients. Pulse dose evaluations are entirely clinical and are respiratory services that require licensed personnel. A pulse dose evaluation consists of evaluating the patient’s heart rate, O₂ saturation, and liter flow of O₂ while keeping an eye on the patient’s respirations; this is done both while the patient is at rest as well as while ambulating. These results are given to medical doctor who may adjust patient’s prescription according to findings.

64. Many of the patient appointments the oxygen techs have are to refill the large liquid O₂ containers at patients' homes. Part of the paperwork for refills requires writing in the amount of pounds it took to refill the container. One of the relators observed that a seasoned

oxygen tech appeared to be “just writing down a number” for how many pounds it took to refill the container; when asked how he determined that figure, he said words to the effect that he “guesstimated” because the scale on the truck didn't work and hadn't worked for years (and didn't work on any of the trucks). So for instance, he would lift the container and if it was an 80 lb container and felt half full to him, he would write in that NAMS delivered 50 lbs. Relator understood that the proper procedure was that each time a tech filled a container, the tech was supposed to weigh it prior to filling and after.

Defendant NAMS Knowingly Violated DME Rules

65. Since approximately 2006/2007, the liaisons and the respiratory therapists have been part of the respiratory care department of NAMS headed by Dennis LaFreniere, a respiratory therapist licensed in Massachusetts and Connecticut.

66. As a licensed respiratory therapist Mr. LaFreniere had and has actual knowledge of the requirement of at least Massachusetts and Connecticut laws governing the provision of respiratory care services, including the DME supplied by NAMS. For example, he recently received a copy of the Board of Respiratory Care Frequently Asked Questions About the Practice of Respiratory Care (RC Board FAQs (Interpretations) Final 10-1-12, *supra*, copy attached as **EXHIBIT C**. Moreover, he is charged as a matter of law with being knowledgeable about all applicable legal requirements.

67. As an accredited DMEPOS Medicare supplier subject to the terms and conditions of the Medicare and Medicaid Provider Enrollment Agreements and other Medicare and Medicaid statutes, regulations and rules, NAMS has actual knowledge of the DMEPOS billing and reimbursement rules, including the obligation to comply with relevant state licensing

requirements. Moreover, NAMS is charged as a matter of law with being knowledgeable about all applicable legal requirements.

68. Furthermore, in early 2012, JCAHO (who is the organization that accredited NAMS) investigated a complaint that NAMS was illegally using unlicensed personnel and not doing oxygen follow up visits. This investigation included, *inter alia*, visiting NAMS and interviewing some liaisons and some respiratory therapists. On information and belief, JCAHO concluded that NAMS was improperly using unlicensed personnel (i.e. the liaisons) to provide respiratory care services, reported these findings and conclusions to NAMS, and instructed NAMS to cease doing so. In particular, on information and belief, in about late February-March 2012, JCAHO concluded and reported to NAMS that it could not use these unlicensed personnel to do: (1) PAP equipment set up and therapy initiation; (2) pressure settings; or (3) pulse dose evaluations, and was required to do oxygen follow up visits required by law. NAMS was still allowed to use unlicensed personnel to do an equipment exchange (e.g., if a machine had broken down).

69. Following the JCAHO report, NAMS acknowledged and announced the results internally. NAMS, through Mr. LaFreniere, offered to provide an in service training for any employee who needed a refresher on how to do the 24-48 hour oxygen follow up visits and what they required.

70. However, NAMS never really changed their behavior and has continued to use liaisons and not perform the oxygen follow up visits required by law. Liaisons are continuing to not only deliver PAP DME, but to do set up and initiate therapy, and instruct patients, and to do pulse dose evaluations for oxygen patients. While oxygen follow ups are now occasionally being done by licensed respiratory therapists, they are routinely not being done within the 24-48 hour

timeframe; indeed sometimes it is some 2-6 weeks later that the patient is contacted for a follow up.

71. What has changed is how NAMS handles the paperwork. Liaisons have been instructed not to sign the paperwork that is handed into NAMS on a patient visit. Rather, the signature line is left blank. On information and belief, Mr. LaFreniere is subsequently signing this paperwork.

72. NAMS is continuing to bill Government Health Care Programs for DME supplied in violation of federal and state law.

Defendant NAMS Knowingly Failed to Return Overpayments From its False DME Billings

73. In addition, despite the JCAHO report, and NAMS' own actual and imputed knowledge of the rules governing the supplying, billing, and reimbursement of DME, and requirements of state licensing laws, NAMS has, on information and belief, taken no steps to inform any Government Health Care Program that NAMS has received and is retaining overpayments received over the last 5-6 years for PAP DME and over the last 10 years or more for oxygen DME.

74. NAMS is using false records and statements, including without limitation, improperly signed paperwork, to conceal, avoid and/or decrease its obligation to refund monies to the Government Health Care Programs.

Damages Caused by Defendant NAMS

75. Relators estimate that since 2002, NAMS has had over 5,000 oxygen patients for whom the company has set up and initiated home oxygen therapy without performing the required follow up by a licensed respiratory therapist; and of those approximately 80% were or are covered by Medicare. During this time period, NAMS has been growing, so the numbers of

patients are greater each year. Relators estimate that of the total number of NAMS' oxygen patients covered by Government Health Care Programs, 100% were or are being improperly serviced up until at least March 2012, and as a result, NAMS has violated DMEPOS billing and reimbursement rules.

76. Relators further estimate that since 2006, NAMS has had approximately 38,000 PAP patients for whom the company has set up and initiated PAP equipment and therapy; and of those approximately 30-35% were or are covered by Medicare. During this time period, NAMS has been growing, so the numbers of patients are greater each year. Relators estimate that of the total number of NAMS' PAP patients covered by Government Health Care Programs, 20-25% were or are being improperly serviced by unlicensed NAMS personnel/liaisons, and as a result, NAMS has violated DMEPOS billing and reimbursement rules.

77. By violating the DMEPOS billing rules, NAMS was not entitled to receive any reimbursement for its DME claims. With an average DME Medicare reimbursement of approximately \$1,000/patient/month for PAP, and an average DME Medicare reimbursement of approximately \$200/patient/month for oxygen, Relators estimate damages of over \$3 million from 2006 to date and continuing for PAP and over \$10 million from 2002 to date and continuing for oxygen. Relators further estimate that 50 pulse dose evaluations have been done by unlicensed liaisons since 2010.

78. In addition, DMEPOS reimbursement rates subsume and assume a certain cost for the professional services of the DME supplier's employees. By using unlicensed personnel who NAMS paid \$19/hour instead of licensed employees whom they paid \$34/hour, NAMS unlawfully profited from the DMEPOS reimbursement it received.

79. Furthermore, doctors and other health care professionals whose patients are

serviced by NAMS are misled into believing that NAMS is providing the level and quality of care required by law. Patients and their families are being similarly misled.

80. In addition to economic harm to Government Health Insurance Programs, NAMS' use of unlicensed personnel and failure to do follow up oxygen visits and resulting violations of DMEPOS laws, regulations, and rules raises concerns about quality of care and patient health, safety, and welfare. States like Massachusetts regulate and require licensing of persons providing respiratory care services precisely because these services require certain education, training, and skill in order to properly care for patients and to properly instruct patients and their caregivers on the use of these therapies.

CLAIMS FOR RELIEF

COUNT ONE

Violations of the Federal False Claims Act, 31 U.S.C. §3729(a)(1)(A)

Presenting or Causing to be Presented False or Fraudulent Claims

81. Plaintiffs/Relators and the United States reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

82. This is a claim brought by Plaintiffs and the United States to recover treble damages, civil penalties and the cost of this action, under the Federal False Claims Act, 31 U.S.C. § 3730, for Defendant's violations of 31 U.S.C. §§ 3729 *et seq.*

83. The Federal False Claims Act, 31 U.S.C. § 3729(a)(1)(A) provides:

“Liability for certain acts. Any person who--

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

Id.

84. By virtue of the above-described acts, among others, Defendant knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval, and continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the United States, in violation of 31 U.S.C. § 3729(a)(1)(A).

85. Plaintiff United States, unaware of the falsity of the claims that Defendant submitted, or caused to be submitted to the United States, and in reliance on the accuracy thereof, paid Defendant for claims that would otherwise not have been allowed.

86. It was foreseeable and in fact the intended result that those claims would be submitted. Further, at all times relevant to the Complaint, Defendant acted with the requisite scienter, and Defendant's compliance with DME requirements was a precondition of payment that was not met.

87. The amounts and nature of the false or fraudulent claims to the United States were material. Plaintiff United States, being unaware of the falsity of the claims and/or statements caused to be made by Defendant, which were a precondition to payment, and in reliance on the accuracy thereof paid and continues to pay for such false or fraudulent claims.

88. It is believed that as a result of Defendant's violations of 31 U.S.C. § 3729 (a)(1)(A), the United States has suffered substantial losses and is therefore entitled to treble damages under the False Claims Act, to be determined at trial, plus a civil penalty of \$5,500 to \$11,000 for each such false claim presented or caused to be presented by Defendant.

COUNT TWO

Violations of the Federal False Claims Act, 31 U.S.C. §3729(a)(1)(B)

Creation or Use of False Statements or Records Material to a False or Fraudulent Claim

89. Plaintiffs/Relators and the United States reallege and incorporate by reference each and every one of the foregoing paragraphs as if fully set forth herein.

90. This is a claim brought by Plaintiffs and the United States to recover treble damages, civil penalties and the cost of this action, under the Federal False Claims Act, 31 U.S.C. § 3730 for Defendant's violations of 31 U.S.C. §§ 3729 *et seq.*

91. The Federal False Claims Act, 31 U.S.C. § 3729(a)(1)(B) provides:

“Liability for certain acts. Any person who--

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

Id.

92. By virtue of the above-described acts, among others, Defendant knowingly made used or caused to be made or used false records or statements material to false or fraudulent claims paid by the United States, and continues to do so, in violation of 31 U.S.C. § 3729(a)(1)(B).

93. For those records and/or statements that Defendant made or used or caused to be made or used, it was foreseeable and in fact the intended result that those statements and/or records would result in the payment of false or fraudulent reimbursement claims, and Defendant's compliance with DME requirements was a precondition of payment that was not met.

94. Further, at all times relevant hereto, Defendant acted with the requisite scienter.

95. The amounts of the false or fraudulent claims caused to be paid pursuant to Defendant's false records and statements made or used or caused to be made or used to the United States were material.

96. As a result of Defendant's violations of 31 U.S.C. § 3729 (a)(1)(B), the United States has suffered substantial losses and is entitled to treble damages under the False Claims Act, to be determined at trial, plus a civil penalty of \$5,500 to \$11,000 for each such false record and/or statement made or used or caused to be made or used by Defendant.

COUNT THREE

Violations of the Federal False Claims Act, 31 U.S.C. §3729(a)(1)(G)

Making, Using or Causing to be Made or Used, a False Record or Statement Material to an Obligation to pay or Transmit Money or Property to the United States or Concealing, Improperly Avoiding or Decreasing an Obligation to Pay or Transmit Money or Property to the United States

97. Plaintiffs/Relators and the United States reallege and incorporate by reference each and every one of the foregoing paragraphs as if fully set forth herein.

98. This is a claim brought by Plaintiffs and the United States to recover treble damages, civil penalties and the cost of this action, under the Federal False Claims Act, 31 U.S.C. § 3730, for Defendant's violations of 31 U.S.C. §§ 3729 *et seq.*

99. The Federal False Claims Act, 31 U.S.C. § 3729(a)(1)(G) provides:

“Liability for certain acts. Any person who--

(G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government ...”

Id. The term “obligation” means:

“an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment...”

31 U.S.C. § 3729(b)(3).

100. By virtue of the above-described acts, among others, Defendant knowingly made, used, or caused to be made or used false records or statements, and continue to do so, in violation of 31 U.S.C. § 3729(a)(1)(G). Defendant knows that its violations of the DME reimbursement rules have led to NAMS being overpaid for years, and its compliance with DME rules and regulations was a precondition or payment. Yet Defendant has failed to take the required and appropriate steps to satisfy the obligation owed to the United States, refund or return such overpayments, or to inform Medicare or Medicaid or other Government Health Care Programs of the overbilling, and instead continue to retain the same, and to overbill the Government Health Care Programs.

101. As a result of Defendant’s violations of 31 U.S.C. § 3729 (a)(1)(G), the United States has suffered substantial losses and is entitled to treble damages under the False Claims Act, to be determined at trial, plus a civil penalty of \$5,500 to \$11,000 for each such violation.

COUNT FOUR

Violations Of The Massachusetts FCA, Mass. Gen. Laws Ch. 12, § 5B(1)

Presenting or Causing to be Presented False or Fraudulent Claims

102. Plaintiffs/Relators and the Commonwealth of Massachusetts reallege and incorporate herein by reference each and every one of the foregoing paragraphs as if fully set forth herein.

103. The Defendant knowingly presented or caused to be presented false or fraudulent

claims to Government Health Care Programs and the Commonwealth of Massachusetts, all in violation of the Massachusetts False Claims Act, Mass. Gen. Laws ch. 12, § 5B(1).

104. It is believed that as a result of Defendant's violations of the Massachusetts FCA, the Commonwealth of Massachusetts paid said claims and has sustained substantial damages, and is therefore entitled to treble damages, including consequential damages, under the False Claims Act, to be determined at trial, plus a civil penalty of \$5,000 to \$10,000 for each such false claim presented or caused to be presented by Defendant.

COUNT FIVE

Violations Of The Massachusetts FCA, Mass. Gen. Laws Ch. 12, § 5B(2)

Creation or Use of False Statements or Records to get to a False or Fraudulent Claim Paid

105. Plaintiffs/Relators and the Commonwealth of Massachusetts reallege and incorporate herein by reference each and every one of the foregoing paragraphs as if fully set forth herein.

106. The Defendant knowingly made, used or caused to be made or used false statements to get false or fraudulent claims paid by Government Health Care Programs and the Commonwealth of Massachusetts, all in violation of the Massachusetts False Claims Act, Mass. Gen. Laws ch. 12, § 5B(2).

107. It is believed that as a result of Defendant's violations of the Massachusetts FCA, the Commonwealth of Massachusetts paid said claims and has sustained substantial damages, and is therefore entitled to treble damages, including consequential damages, under the False Claims Act, to be determined at trial, plus a civil penalty of \$5,000 to \$10,000 for each such violation by Defendant.

COUNT SIX

Violation Of The Massachusetts False Claims Act: Mass. Gen. Laws ch. 12, § 5B(8)

Making, Using, Or Causing To Be Made Or Used, A False Record Or Statement To Conceal, Avoid, Or Decrease An Obligation To Pay Or To Transmit Money Or Property To The Commonwealth

108. Plaintiffs/Relators and the Commonwealth of Massachusetts reallege and incorporate herein by reference each and every one of the foregoing paragraphs as if fully set forth herein.

109. The Massachusetts FCA, Mass. Gen. Laws ch. 12, § 5B(8), makes “knowingly” making, using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or to transmit money or property to the commonwealth or political subdivision thereof a violation of law for which the affected government party may recover three times the amount of the damages, including consequential damages, the government sustains and a civil monetary penalty of between \$5,000 and \$10,000 per violation.

110. Defendant knowingly presented or caused to be presented to Government Health Care Programs and the Commonwealth of Massachusetts false or fraudulent claims for payment and approval, claims which failed to disclose the material violations of law, and Defendant knowingly made, used, or caused to be made or used, a false record or statement material to a false or fraudulent claim, all in violation of the Massachusetts FCA, as described above.

111. By virtue of the above-described acts, among others, Defendant knows that its violations of the DME reimbursement rules have led to NAMS being overpaid for years. Yet Defendant has failed to take the required and appropriate steps to satisfy the obligation owed to the Commonwealth of Massachusetts, refund or return such overpayments, or to inform

Massachusetts Medicaid of the overbilling, and instead continue to retain the same, and to overbill Massachusetts Medicaid.

112. It is believed that as a result of Defendant's violations of the Massachusetts FCA, the Commonwealth of Massachusetts has sustained substantial damages, and is therefore entitled to treble damages, including consequential damages, under the False Claims Act, to be determined at trial, plus a civil penalty of \$5,000 to \$10,000 for each such violation.

PRAYERS FOR RELIEF

WHEREFORE, Relators, acting on behalf of and in the name of the United States of America and the Commonwealth of Massachusetts, and on their own behalf, demand and pray that judgment be entered as follows:

- (a) In favor of the United States against the Defendant for treble the amount of damages to Government Health Care Programs from the violations of the Federal FCA, plus maximum civil penalties of Eleven Thousand Dollars (\$11,000.00) for each violation;
- (b) In favor of the Relators for the maximum amount allowed pursuant to 31 U.S.C. § 3730(d) to include reasonable expenses, attorney fees and costs;
- (c) For all costs of the Federal FCA civil action;
- (d) In favor of the Relators and the United States for such other and further relief as this Court deems to be just and equitable;
- (e) In favor of the Relators and the Commonwealth of Massachusetts against Defendant in an amount equal to three times the amount of all damages that the Massachusetts Medicaid program has sustained as a result of the Defendant's

actions, as well as a civil penalty against the Defendant of a statutory maximum for each violation of the Massachusetts FCA;

- (f) In favor of the Relators for the maximum amount as a relators' share allowed pursuant to the Massachusetts FCA;
- (g) In favor of the Relators for all costs and expenses associated with the Massachusetts FCA claims, including attorney's fees and costs;
- (h) In favor of the Commonwealth of Massachusetts and the Relators for all such other relief as the Court deems just and proper; and
- (i) Such other relief as this Court deems just and appropriate.

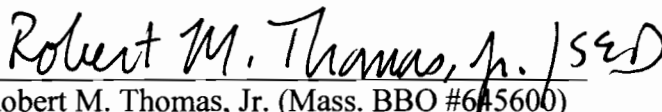
PLAINTIFFS/RELATORS DEMANDS A TRIAL BY JURY ON ALL COUNTS

Dated: October 23, 2012

Respectfully submitted,



Suzanne E. Durrell (Mass. BBO #139280)
DURRELL LAW OFFICE
180 Williams Avenue
Milton, Massachusetts 02186
(617) 333-9681
Fax: (617) 333-0014
Email: suzanne.durrell@verizon.net



Robert M. Thomas, Jr. (Mass. BBO #645600)
THOMAS & ASSOCIATES
280 Summer Street, 5th Floor
Boston, MA 02210-1131
(617) 371-1072
Fax: (888) 676-7420
Email: rmt@thomasandassoc.net