UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

THE UNITED STATES OF AMERICA *ex rel.* [UNDER SEAL] Plaintiffs, v. [UNDER SEAL] Defendants.	Civil Action No. **Filed Under Seal Pursuant to** **31 U.S.C. § 3720(b)(2)**

COMPLAINT FOR VIOLATIONS OF THE FALSE CLAIMS ACT

SEALED CASE – DO NOT PUT ON PACER

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THE UNITED STATES OF AMERICA *ex rel.* MICHAEL PELLETIER, Plaintiffs, v. LIFEWATCH SERVICES, INC., LIFEWATCH AG, CARDIONET, INC., AND BIOTELEMETRY, INC., Defendants.	Civil Action No. **Filed Under Seal Pursuant to** **31 U.S.C. § 3720(b)(2)**

COMPLAINT FOR VIOLATIONS OF THE FALSE CLAIMS ACT

I. INTRODUCTION

1. This is an action to recover damages, civil penalties, and other relief on behalf of the United States for false and/or fraudulent statements, records, and claims made and caused to be made, and overpayments retained, by the Defendants LifeWatch Services, Inc., LifeWatch AG, CardioNet, Inc., and BioTelemetry, Inc. (hereinafter collectively "Defendants") and/or their agents and employees and subsidiaries to Government Health Care Programs in violation of the federal False Claims Act, 31 U.S.C. §§ 3729, et seq. ("FCA")

A. The Fraudulent Scheme

2. Since at least 2017, Defendants have induced enrollment and reimbursement for expensive multi-purpose ambulatory cardiac telemetry monitoring devices and related services regardless of medical necessity and reasonableness. Because reimbursement for telemetry monitoring far exceeds amounts paid for cardiac event monitoring, this misconduct resulted in millions of dollars of false and fraudulent claims to Government Health Care Programs. On information and belief, these fraudulent practices are nationwide in scope.

3. As described more fully below, Defendants had a policy to enroll patients in telemetry monitoring automatically and only to move patients to less-expensive event monitoring when insurance did not reimburse telemetry. Defendants' enrollment portal was configured to default to telemetry even though doctors ordered event monitoring. In short, Defendants provided monitoring services to patients based not on their medical symptoms and conditions or on the preferences of their physicians but instead on what would maximize their reimbursements.

B. The False Claims Act

4. The FCA was enacted during the Civil War, and later amended to enhance the ability of the Government to recover losses sustained as a result of fraud against it. Congress intended that the amendments would create incentives for individual citizens with knowledge of fraud against the Government to disclose the information without fear of reprisals or Government inaction and would encourage the private bar to commit legal resources to prosecuting fraud on the Government's behalf.

5. The FCA prohibits, inter alia: knowingly presenting (or causing to be presented) a false or fraudulent claim for payment or approval; knowingly 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 Government; knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the Government; and, conspiring to commit any of these acts. 31 U.S.C. §§ 3729(a)(1)(A), (B), (G), and (C).

6. The FCA provides that any person who violates the FCA "is liable for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 … plus 3 times the amount of damages which the Government sustains because of the act of that person." 31 U.S.C. § 3729(a)(1). The Civil

Penalties Inflation Adjustment Act Improvement Act of 2015, 28 U.S.C. § 2461 note, further increases the civil penalty. 82 Fed. Reg. 9131, 9133 (February 3, 2017).

7. For purposes of the FCA, a person "knows" a claim is false if that person: "(i) has actual knowledge of [the falsity 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." 31 U.S.C. § 3729(b)(1). The FCA does not require proof that a defendant specifically intended to commit fraud. *Id.* Unless otherwise indicated, whenever the words "know," "learn," "discover" or similar words indicating knowledge are used in this Complaint, they mean "knowingly" as defined in the FCA.

8. 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 requires that the Complaint be filed under seal (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. The person bringing the action is known under the FCA as the "relator."

C. The Instant Action

9. Based on the foregoing federal FCA provisions, *qui tam* Plaintiff-Relator seeks, through this action, to recover damages and civil penalties arising from the Defendants' knowing fraud against the United States.

10. The allegations set forth in this Complaint have not been publicly disclosed within the meaning of the FCA, as amended, 31 U.S.C. § 3730(e)(4). In the alternative, if the Court finds that there was a public disclosure of such allegations before the filing of this Complaint, Relator is an "original source" as that term is used in the FCA.

11. To Relator's knowledge, there are no prior pending complaints against Defendants alleging similar facts related to Defendants' fraudulent schemes.

12. Prior to the filing of this Complaint, Relator made substantive disclosures to the Government of facts and evidence underlying the allegations in this Complaint.

13. This action is filed in camera and under seal pursuant to the requirements of the federal and state false claims acts.

II. PARTIES

A. Plaintiffs/Relator

14. The United States of America is the real party in interest to all claims arising under the False Claims Act as set forth herein.

15. Relator Michael Pelletier is a citizen of the United States. He is familiar with the Defendants' marketing and patient enrollment operations through his employment as a supervisor in the cardiopulmonary department of a hospital. Further details regarding Relator and Relator's knowledge have been and will be provided to the United States.

B. Defendants

16. Defendant LifeWatch Services, Inc. ("LifeWatch") is a Delaware corporation with its principal place of business in Rosemont, Illinois. LifeWatch manufactures and supplies mobile cardiac monitoring devices to health care providers such as physicians and hospitals. These devices include cardiac event monitors and mobile cardiac telemetry monitors (sometimes known as "ambulatory cardiac telemetry" or "ACT" monitors). It also operates as an Independent Diagnostic Testing Facility ("IDTF") providing remote cardiac monitoring services to health care providers. LifeWatch's IDTF facilities are located in: Rosemont, Illinois; Philadelphia, Pennsylvania; and, San Francisco, California. They are staffed by technicians who collect, monitor, analyze and report data for patients across the country. Technicians provide cardiac monitoring services for a national provider base, including clients in this District.

17. Defendant LifeWatch AG is a Swiss corporation headquartered in Zug, Switzerland, and listed on the SIX Swiss Exchange under stock symbol LIFE. LifeWatch AG has operating subsidiaries in the United States, Switzerland, Israel, and Turkey. Defendant LifeWatch Services, Inc., is its wholly-owned U.S. subsidiary.

18. Defendant CardioNet, Inc. ("CardioNet") is a Delaware corporation that represents itself as "the world's leading supplier of Mobile Cardiac Outpatient Telemetry (MCOT)." It developed one of the earliest mobile cardiac telemetry monitors and operates as an IDTF providing cardiac monitoring services. In 2010, CardioNet merged with Defendant BioTelemetry, Inc. ("BioTel") and later became a wholly-owned subsidiary of BioTel.

19. Defendant BioTelemetry, Inc. ("BioTel") (NASDAQ: BEAT) is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. It provides cardiac monitoring services and original equipment manufacturing of cardiac monitoring devices. BioTel was formerly known as CardioNet, Inc. In 2013, CardioNet reincorporated as BioTelemetry, Inc. and adopted a holding company structure under which CardioNet became a wholly-owned subsidiary of BioTel.

20. In February 2014, BioTel acquired MedNet Technology, Inc., a manufacturer and supplier of cardiac monitoring devices and an IDTF, which became a wholly-owned subsidiary of BioTel.

21. In July 2017, BioTel acquired LifeWatch AG, which became a wholly-owned subsidiary of BioTel.

22. In February 2018, BioTel combined its remote cardiac monitoring services under the brand BioTel Heart. It provides monitoring services and devices under the names BioTel Heart, LifeWatch, CardioNet, MedNet, and Braemar. BioTel Heart describes itself as a pioneer

in remote patient monitoring and claims to monitor over one million patients each year, with referrals from over 30,000 unique physicians per month.

III. JURISDICTION AND VENUE

23. This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1345 and 31 U.S.C. § 3732, which confers jurisdiction over actions brought pursuant to 31 U.S.C. §§ 3729 and 3730.

24. This Court has personal jurisdiction over Defendants pursuant to 31 U.S.C. § 3732(a) because one or more Defendants can be found in, resides in, and transacts substantial business in this district, including business related to Defendants' misconduct.

25. Venue is proper in this district, pursuant to 28 U.S.C. § 1391(b) and (c) and 31 U.S.C. §3732(a), because Defendants operate and transact business within this district and facts forming the basis of this Complaint occurred within this district.

IV. APPLICABLE FEDERAL LAW

A. Government Health Insurance Programs

26. The Medicare program ("Medicare") is a health insurance program administered by the Government of the United States that is funded by taxpayer revenue. The United States Department of Health and Human Services ("HHS"), through its Centers for Medicare and Medicaid Services ("CMS"), oversees Medicare.

27. Medicare was designed to assist in providing medical services and durable medical equipment to persons over sixty-five (65) years of age and certain others who qualify for Medicare because of disability or end stage renal disease. Generally speaking, if you are eligible for Medicare, Part A covers hospital, inpatient, nursing home, and other institutional care; Part B covers doctor visits and outpatient services; and Part D provides prescription drug coverage. 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 United States Government and the States and is funded jointly by state and federal taxpayer revenue. CMS and HHS oversee Medicaid jointly with agencies in each State.

28. Medicaid is designed to assist participating States in providing medical services, medical equipment, and prescription drugs to needy individuals. The States and the United States share reimbursement costs. States directly pay providers, and then obtain the federal contribution from accounts drawn on the United States Treasury. 42 C.F.R. §§ 430.0- *et seq.* Federal funding for the Medicaid Program includes support for Medicare Savings Programs which help qualifying Medicare beneficiaries pay Part A and B premiums, co-payments, co-insurance, and deductibles. The Medicare Savings Programs consist of the Qualified Medicare Beneficiary Program, 42 U.S.C. § 1396d(p)(1), the Specified Low-Income Medicare Beneficiary Program, 42 U.S.C. § 1396a(a)(10)(E)(iii), the Qualifying Individual Program, 42 U.S.C. § 1396a(a)(10)(E)(iv), and the Qualified Disabled and Working Individuals Program, 42 U.S.C. § 1396d(s). Medicaid may serve as the primary insurer, or in some instances as the secondary insurer (e.g., with Medicare or private insurance providing primary coverage). Medicaid sets forth minimum requirements for state Medicaid programs to qualify for federal funding and each participating state adopts its own state plan and regulations governing the administration of the state's Medicaid program.

29. The Civilian Health and Medical Program of the United States (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. TRICARE pays for, among other things, medical devices and surgeries for its beneficiaries. CHAMPVA, administered by

the United States Department of Veterans Affairs ("VA"), is a health care program for the families of veterans with 100-percent service-connected disability, or for those who died from a VA-rated-service-connected disability.

30. The Federal Employee Health Benefits Program ("FEHBP") provides healthcare benefits for qualified federal employees and their dependents. It pays for, among other things, medical devices and surgeries for its beneficiaries. Under the FEHBP, the federal employee is covered by private payer health insurance which is in turn subsidized in part by the federal government. As a result, fraud on a patient covered by the FEHBP constitutes fraud on the federal government and the loss of federal funds.

31. The federal government operates hospitals, including through its Departments of Defense and VA, and receives and uses federal funds to provide medication to patients treated at these facilities and otherwise, as well as outpatient services. A network of already established VA hospitals and services make up the VA health care system.

32. The Office of Workers' Compensation Programs ("OWCP") of the U.S. Department of Labor ("DOL") administers federal workers' compensation programs under four statutes: (1) the Federal Employees' Compensation ("FECA"), 5 U.S.C. §§ 8101 *et seq.*; (2) the Longshore and Harbor Workers' Compensation Act ("LHWCA"), 33 U.S.C. §§ 901 *et seq.*; (3) the Federal Black Lung Benefits Act ("FBLBA"), 30 U.S.C. §§ 901 *et seq.*; and (4) the Energy Employees Occupational Illness Compensation Program Act ("EEOIC") (also known as the "Beryllium Exposure Compensation Act"), 42 U.S.C.A. §§ 7384 *et seq.*

33. The largest of these workers' compensation programs is the FECA program, which provides coverage for approximately three million federal and postal workers for employment-related injuries and occupational diseases. Under the provisions of FECA, OWCP

authorizes payment for medical services, including prescription drugs, and establishes limits on the maximum payment for such services.

34. Together, the programs described above, and any other government-funded healthcare programs, are referred to as "Government Health Care Programs."

B. Obtaining Reimbursement Under Federal Health Care Programs

35. Reimbursement practices under all Government Health Care Programs closely align with the rules and regulations governing Medicare reimbursement. The most basic reimbursement requirement under Medicare, Medicaid, and other Government Health Care Programs is that the service provided must be reasonable and medically necessary. *See, e.g.*, 42 U.S.C. § 1395y(a)(1)(A) (Medicare does not cover items or services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."); 42 U.S.C. § 1396, *et seq.* (Medicaid); 42 C.F.R. §§ 410.50, 411.15(k)(1), 411.406; *Moore ex rel. Moore v. Reese*, 637 F.3d 1220, 1232 (11th Cir. 2011) ("Although the standard of 'medical necessity' is not explicitly denoted in the Medicaid Act, it has become a judicially accepted component of the federal legislative scheme") (citing *Beal v. Doe*, 432 U.S. 438, 444 (1977)); *United States v. Rutgard*, 116 F.3d 1270, 1275 (9th Cir. 1997) (TRICARE and Railroad Retirement Health Insurance Program plan follow the same rules and regulations as Medicare) (citing, *e.g.*, as to TRICARE, 10 U.S.C. § 1079(a)(13); 32 C.F.R. § 199.4).

36. Medical providers are not permitted to bill the government for medically unnecessary services, which includes services that harm a patient or are performed for no reason other than obtaining a profit. *See, e.g., United States ex rel. Kneepkins v. Gambro Healthcare, Inc.*, 115 F. Supp. 2d 35, 41-42 (D. Mass. 2000) (services billed to Medicare must be reasonable

and medically necessary, and they must be provided economically…procedures chosen solely for defendants' economic gain and that were deleterious and inferior are not "medically necessary.").

37. Health care providers must certify that services or items ordered or provided to patients will be provided "economically and only when, and to the extent, medically necessary" and "will be of a quality which meets professionally recognized standards of health care" and "will be supported by evidence of medical necessity and quality." 42 U.S.C. § 1320c-5(a)(1)-(3).

38. Moreover, all Government Health Care Programs require that adequate documentation exist in the medical records. *See, e.g.*, 42 USC § 1395l(e) (Medicare); § 1396(a)(27) (Medicaid); *Rutgard*, 116 F.3d 1270, 1286 (9th Cir. 1997); *U.S. ex rel. Trim v. McKean*, 31 F. Supp. 2d 1308 (W.D. Okla. 1998); *cf. Lama v. Borras*, 16 F.3d 473, 480-81 (1st Cir. 1994); *Valendon Martinez v. Hosp. Presbiterano*, 806 F.2d 1128, 1134 (1st Cir. 1986); *Garcia v. United States*, 697 F. Supp. 1570, 1573-74 (D. Colo. 1988) (professional medical standards say part of the duty of care owed to a patient by his physician, nurse, etc. is proper record keeping and poor record keeping can give rise to an inference of negligence.).

39. Moreover, coverage for Medicare reimbursement for a particular service may be defined at the national level through a National Coverage Determination (NCD) or pursuant to a Local Coverage Determination (LCD) issued by the Medicare contractor within a particular jurisdiction.

40. Claims for payment of outpatient services from the federal health care programs must be submitted on Form CMS-1500. The form provides fields prompting the provider submitting the claim to provide appropriate Current Procedural Terminology codes ("CPT codes") and ICD-10 codes for identifying the particular service for which reimbursement is sought and the basis for its medical necessity.

41. CPT codes are numbers assigned to every task and service a medical practitioner may provide to a patient, including medical, surgical and diagnostic services. CPT codes are then used by insurers, including the federal health care programs, to determine the amount of reimbursement received. For purposes of this Complaint, the relevant CPT codes for ambulatory cardiac telemetry are 93228 and 93229.

42. The ICD-10-CM is the official system for assigning codes to describe diagnoses or clinical signs or symptoms associated with the conditions for which health care goods and services are rendered in the United States.

43. Reimbursement rules issued by the federal health programs identify acceptable ICD-10 codes required to demonstrate medical necessity for particular covered goods and services. Eligibility for reimbursement from the federal health programs requires consistency between all diagnosis codes submitted by the provider and the patient's symptoms and conditions. The ICD-10 codes reported in support of the medical necessity of the associated CPT-code must reflect conditions and diagnoses fully supported by medical documentation in the patient's record.

44. Each of the Government Health Care Programs requires every provider who seeks payment from the program to promise and ensure compliance with the provisions of the Anti-Kickback Statute and with other federal laws governing the provision of health care services in the United States.

45. For example, physicians, hospitals, and IDTFs enter into Provider Agreements with CMS in order to establish their eligibility to seek reimbursement from the Medicare Program. As part of that agreement, without which the hospitals and physicians may not seek

reimbursement from Federal Health Care Programs, the provider must sign the following certification:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to [me]. The Medicare laws, regulations, and program instructions are available through the [Medicare] contractor. I 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 (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the [provider's] compliance with all applicable conditions of participation in Medicare.

Form CMS-855A; Form CMS-8551 (effective 2001). In addition, the claims themselves as submitted contain a similar certification. *See, e.g.*, Form CMS-1500.

46. When a provider submits a claim for payment, he or she does so subject to and under the terms of its certification to the United States that the services for which payment is sought were delivered in accordance with federal law.

47. In addition to the general provider enrollment requirements for reimbursement under the federal health care programs, IDTFs such as Defendants LifeWatch and CardioNet must comply with a number of specific conditions to maintain federal health care program billing privileges, including the requirement to "[o]perate[] its business in compliance with all applicable Federal and State licensure and regulatory requirements for the health and safety of patients." 42 C.F.R. 410.33(g).

C. Federal False Claims Act

48. The Federal FCA creates liability for "any person who," among other things:

a. "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A).

b. "knowingly makes, uses, or causes 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).

c. "conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G)." 31 U.S.C. § 3729(a)(1)(C).

d. "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." 31 U.S.C. § 3729(a)(1)(G).

49. The FCA further provides that any person who violates the FCA "is liable to the United States for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 . . . , plus 3 times the amount of damages which the Government sustains because of the act of that person." 31 U.S.C. § 3729(a)(1). The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, 28 U.S.C. § 2461 note, further increases the civil penalty. 82 Fed. Reg. 9131, 9133 (Feb. 3, 2017).

50. The FCA provides that "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." 31 U.S.C. § 3729(b)(1).

51. The FCA provides that "the term 'claim' – (A) means any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that— (i) is presented to an officer, employee, or agent of the United States; or (ii) is made to a contractor, grantee, or other recipient, if the money or

property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government— (I) provides or has provided any portion of the money or property requested or demanded; or (II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded." 31 U.S.C. § 3729(b)(2).

52. The FCA provides that "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). Moreover, in the health care context, such as Medicare and Medicaid, the term "obligation" is further defined as "Any overpayment retained by a person after the deadline for reporting and returning the overpayment…is an obligation (as defined [in the FCA])", and an overpayment must be reported "By the later of…60 days after the date on which the overpayment was identified…or the date any corresponding cost report is due, if applicable." Patient Protection and Affordable Care Act, March 23, 2010 ("PPACA"), Pub. L. 111-148 (Mar. 23, 2010), Section 6404(a), codified at 42 U.S.C. § 1128J9(d). See also 42 U.S.C. § 1320a-7k(d).

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

V. FEDERAL REIMBURSEMENT FOR CARDIAC MONITORING DEVICES

54. Medicare covers costs associated with the diagnosis of cardiac arrhythmias. Reimbursable services are defined by CPT codes.

55. Cardiac arrhythmias are occurrences of abnormal heart rhythms. Arrhythmias may be accompanied by symptoms (e.g., palpitations, fainting, dizziness, weakness, shortness of breath) or present asymptomatically. Arrhythmias can occur infrequently and unpredictably.

56. Some cardiac conditions can be diagnosed upon physical examination or in-office testing. However, if a physician cannot diagnose a patient's condition this way, a variety of ambulatory electrocardiographic monitoring devices may be used to assist with diagnosing the patient. The degree and frequency of arrhythmias symptoms dictates the appropriate type and duration of cardiac monitoring.

A. Types of Cardiac Monitoring Devices

57. There are three main types of ambulatory cardiac monitors—Holter monitors, cardiac event monitors, and mobile cardiac telemetry monitors (sometimes known as ambulatory cardiac telemetry ["ACT"] devices). These monitors and the interpretation of the results are reimbursed at differing rates by Medicare. The highest reimbursement is for telemetry.

58. Holter monitors record heart rhythms continuously for up to 48 hours. The entire uninterrupted recording is captured on the device's internal storage. After patient recording concludes, the patient must return the device and recorded media to the physician or technician, who then interprets a computer-generated report providing analysis of the data. Holter monitors are appropriate for patients with demonstrated symptoms occurring at a daily frequency.

59. Cardiac event monitors ("CEM") are sometimes referred to as "event monitors" or "event recorders." They record heart rhythms intermittently for up to 30 days. These devices begin recording heart rhythms upon activation. Most event monitors can be activated by the patient upon experiencing symptoms; in addition, many are designed to be automatically triggered by a pre-set computer algorithm intended to detect arrhythmias. Older-style monitors required the patient to return the device before its data could be reviewed and interpreted or to

transmit its data telephonically over landlines. More recently, event monitors have the capability to automatically transmit data wirelessly. Cardiac Event monitors are generally used for patients with infrequent or irregular presentation of symptoms.

60. Mobile cardiac telemetry ("MCT") devices record heart rhythms continuously for up to several weeks. Segments of recorded data can be transmitted wirelessly through a cellular signal to a designated remote technician who reviews the data in real-time for occurrences or trends warranting physician notification. Telemetry services have a much narrower use than Holter and event monitors and are only medically necessary when symptoms of arrhythmias are suspected but are rare and difficult to capture by other means. MCT services are reimbursed by Medicare at a much higher rate than Holter or event monitors.

B. Reimbursement for Cardiac Monitoring Devices

61. Medicare generally covers Holter and event monitoring for diagnostic purposes. Such monitors are approved for Medicare reimbursement when a physician requires the additional information to evaluate a patient's condition because a diagnosis could not be made on physical examination of the patient.

62. Mobile cardiac telemetry monitoring is covered and payable by Medicare only in limited circumstances, as described below. Billing for MCT is divided into a professional and technical component. Beginning in January 2009, CMS assigned CPT code 93228 to professional telemetry services and CPT code 93229 to technical telemetry services.

63. Providers such as doctors or hospitals seek reimbursement under CPT code 93228 for the professional component of cardiac monitoring telemetry services—including the rental cost of the device, concurrent computerized real-time data analysis, and the physician's review and interpretation component.

64. IDTFs such as LifeWatch and CardioNet seek reimbursement under CPT code 93229 for the technical component of telemetry services—including attended surveillance of reported data and transmission of data reports based upon physician-specified criteria and/or frequency.

65. Prior to January 2009, CMS required billing of telemetry services under CPT code 93271, which corresponds to the technical component of cardiac event monitors. Reimbursement for CPT code 93271 was approximately $200 prior to January 2009 and is currently $174.60.

66. Beginning in January 2009, reimbursement for the technical component of mobile telemetry was initially set at approximately $1,120, which CMS subsequently reduced. The current rate for mobile telemetry technical services (CPT code 93229) is $743.39.

67. MCT monitoring is covered and payable by Medicare only in limited circumstances, as described below. Reimbursement of telemetry services is not addressed by a Medicare National Coverage Determination. Coverage of telemetry services turns on the statute and regulations and is subject to Local Contractor Determinations (LCDs) issued by Medicare contractors in the jurisdictions where services are rendered.

68. Section 1862(a)(1)(A) of the Social Security Act states that no Medicare payment may be made for items or services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury …." 42 U.S.C. § 1395y(a)(1)(A).

69. Section 1833(e) prohibits payment to any provider for any claim that lacks the necessary information to process the claim. 42 U.S.C. § 1395l(e).

70. 42 C.F.R. § 410.32(a) provides that all diagnostic tests "must be ordered by the physician who is treating the beneficiary" and that [t]ests not ordered by the physician who is treating the beneficiary are not reasonable and necessary."

71. LCDs approving telemetry under limited circumstances have been issued by Medicare contractors for each of the fifty states, the District of Columbia, and territories.

72. For example, Novitas Solutions, Inc. serves as the Medicare Part A and Part B contractor in eleven states and the District of Columbia, including Pennsylvania, where BioTel's headquarters and one of LifeWatch's IDTFs is located.

73. Novitas issued an LCD establishing the narrow criteria under which mobile telemetry services may be covered and the effective date of coverage for such claims. *See, e.g.*, Local Coverage Determination (LCD), Real-Time, Outpatient Cardiac Telemetry (L34997) (stating criteria for telemetry coverage, effective October 1, 2015).

74. In an on-line brochure describing its monitoring services, LifeWatch includes a disclaimer in which it refers specifically to the coverage guidance of the Novitas LCD and acknowledges that any monitoring service "must be reasonable and necessary in the specific case and must meet the criteria specified in this determination." LifeWatch Services Comprehensive Diagnostic Monitoring Solutions, p.6 (2017), link available at https://www.lifewatch.com/Healthcare-Professionals.html.

75. Under the Novitas LCD, telemetry is not reasonable and necessary if "other testing (*e.g.*, ECG, 24 hour Holter, etc.) could be expected to provide the data/information needed for the diagnosis and/or treatment of the patient's condition/symptoms." Likewise, telemetry "is not covered when used for screening."

76. Telemetry is reasonable and necessary "only in circumstances where traditional Holter monitoring and/or other cardiac event monitoring is not expected to provide adequate information or has been unsuccessful in the diagnosis and/or treatment of the patient."

77. Coverage for telemetry services is limited to "patients who have demonstrated a specific need for this type of cardiac telemetry service." Moreover, "[a] test not ordered by a physician … treating the beneficiary will be denied as non-covered."

78. Even when telemetry services are approved, "[t]he use of multiple forms of cardiac surveillance services (e.g., Holter monitor, other event recorder) provided to the same patient on the same day is NOT medically necessary" and thus not covered.

79. The Novitas LCD lists the ICD-10 codes that *may* support a claim that a patient's condition or diagnosis meets the covered indications identified by LCD as medically necessary. The submission of an ICD-10 code alone is not determinative of medical necessity. For example, the LCD specifies that telemetry is not to be considered reasonable and necessary "for *all* patients with symptoms such as palpitations, dizziness, or weakness" (emphasis added). Rather, "[t]o be considered medically necessary, the ordering physician must document that he/she has concluded that the patient's symptoms are severe enough to warrant further investigation, an underlying dysrhythmia is a likely cause of their symptoms, and that the identification of the suspected dysrhythmia can only be determined through the use of this service." Moreover, "[t]his information must be clearly documented in the patient's medical record."

VI. FACTS AND ALLEGATIONS

80. Defendants conspired to establish a marketing, enrollment, and billing scheme through which use of LifeWatch and CardioNet mobile cardiac telemetry devices would result in the greatest possible rate of reimbursement from federal health care programs (and certain

private payors whose members may be enrolled in the FEHBP) solely for their own profit and regardless of medical necessity or reasonableness.

81. BioTel markets multiple MCT devices. https://www.gobio.com/heart-monitoring/. Two of those are manufactured by LifeWatch, and three by CardioNet.

82. Both of the LifeWatch devices are "three-in-one" devices, which combine the capabilities of three different types of cardiac monitors – Holter monitors, cardiac event monitors, and MCT monitors -- in a single device.

83. The CardioNet device is a "two-in-one" device offering both MCT and wireless event monitoring.

84. Defendants marketed these MCT devices based upon a patient's insurance coverage rather than his or her symptoms and conditions and without regard for the medical judgment of the patient's physician. Even though the devices offered both MCT and event monitoring functionality, Defendants automatically enrolled patients in telemetry, even when a patient's physician had ordered less-expensive event monitoring.

85. Relator's hospital used one of the LifeWatch three-in-one devices. Even though Relator made clear to Defendants' representatives that physicians wanted wireless event monitoring, not telemetry, LifeWatch's enrollment portal did not permit selection of wireless cardiac event monitoring as an option. Instead, the LifeWatch Connect enrollment screen required hospital personnel to select the MCT monitors for the more-expensive telemetry. The only event monitors offered were devices using older technology, which required the use of land lines for transmission of data and were not suitable for most patients served by Relator's facility.

86. When questioned about this practice, Defendants' representatives told Relator and others that it was "policy" to enroll patients in telemetry initially but, if insurance would not cover it, switch later to event monitoring.

87. On information and belief, CardioNet engages in the same practice. Even where physicians have ordered event monitoring, CardioNet sets up the device for telemetry, then downgrades it to event recording if insurance does not reimburse telemetry.

A. BioTel Heart – CardioNet & LifeWatch

88. Following its acquisition of LifeWatch in July 2017, BioTel began marketing LifeWatch and CardioNet cardiac monitoring devices as BioTel Heart. BioTel's website displays a logo consisting of the name BioTel, with the "i" dotted with a wireless symbol and the "o" as a three-chambered heart, with the word "HEART" below. Beneath that logo appear the names CardioNet & LifeWatch. https://www.gobio.com/heart-monitoring.

89. LifeWatch's website states "LifeWatch is now BioTel Heart," above the BioTel Heart logo and directs visitors to the BioTel website. https://www.lifewatch.com/.

90. CardioNet's website similarly declares "CardioNet and LifeWatch are Now BioTel Heart" and encourages visitors to learn about BioTel Heart by clicking on a link that redirects them to BioTel's website. https://www.cardionet.com/

91. LifeWatch manufactures and markets all three types of mobile cardiac monitors under the BioTel Heart brand. The LifeWatch product line includes a Holter monitor, three cardiac event monitors, and two mobile cardiac telemetry devices.

92. LifeWatch's mobile cardiac telemetry devices are the MCT Lead Patch ("MCT 1LP") and the MCT 3 Lead ("MCT 3L"). The MCT 3L was originally known as LifeStar Ambulatory Cardiac Telemetry III ("Act III"). The ACT III is a 3-lead device and has been in

use in the United States since at least 2008. The MCT 1LP entered the market much more recently.

93. Both of LifeWatch's MCT devices are 3-in-1 monitors. Of particular relevance to this case is their ability to operate as either telemetry monitors or as cardiac event monitors. LifeWatch's website specifically notes that the devices can "switch from the MCT 3L system … to an Auto-Detect / Auto-Send 3-channel cardiac event monitor." https://www.lifewatch.com/Healthcare-Professionals/Mobile-Cardiac-Telemetry.html

94. BioTel's website has links to the LifeWatch MCT monitors but omits any mention of the monitors' ability to switch from telemetry to event monitoring. https://www.gobio.com/device/mct-3-lead/ ; https://www.gobio.com/device/mct-1-lead-patch/

95. In contrast to its MCT 3-in-1 devices, LifeWatch's standalone cardiac event monitors do not wirelessly transmit data to IDTFs; instead, data stored on its event monitors must be transmitted via a land line or retrieved after the device has been returned.

96. CardioNet also manufactures and markets all three types of mobile cardiac monitors under the BioTel Heart brand. The CardioNet product line includes a Holter monitor, three event monitors, and two MCT devices.

97. One of the MCT devices, MCOT OS can be operated either as a telemetry device or as a wireless event recorder.

98. These MCT devices wirelessly transmit data to the IDTFs using cellular technology. As noted above, LifeWatch and CardioNet operate Independent Diagnostic Technical Facilities (IDTFs) where technicians monitor data reported by the devices and provide physicians with reported results and analysis. The reports produced by the IDTFs display the

BioTel Heart logo on the top and the names "BioTel HEART, CardioNet & LifeWatch" across the bottom.

B. Defendants Acted And Conspired To Manipulate Providers, Billing Technicians, And Other Health Professionals Into Completing Telemetry Enrollments Regardless Of Medical Necessity

1. Background

99. Relator has many years of experience working as a supervisor in the cardiopulmonary department of a hospital. His responsibilities include meeting with equipment vendors and evaluating and recommending monitoring products for use in the hospital. Prior to 2006, his hospital had used its own cardiac event recorders ("King of Heart" monitors) and Holter monitors and had conducted its own monitoring and analysis for both.

100. In or about 2006, Relator's department began using an outside company, MedNet, to supply cardiac event monitors while continuing to provide Holter monitors in-house. MedNet provided the hospital with wireless cardiac event monitoring devices as well as monitoring and reporting services.

101. In 2012, after a presentation by representatives of a different company, Spectocor, cardiologists in Relator's hospital agreed to try a new telemetry device.

102. After using the Spectocor telemetry monitor from April 2012 through January 2013, the hospital's cardiologists requested that the hospital return to cardiac event monitoring and discontinue telemetry. They found detailed telemetry reports to be unnecessary and believed event monitoring reports provided them with adequate information to diagnose and/or treat their patients.

103. As a result, the hospital stopped using telemetry and switched back to MedNet. MedNet provided the hospital with wireless cardiac event monitoring devices and reporting from January 2013 until October 2017.

104. Since discontinuing Spectocor in January 2013, cardiologists and other physicians at Relator's hospital have not wanted, nor have they sought to order, mobile cardiac telemetry monitoring for their patients.

105. A BioTel sales representative, George ("Geo") Balestino, falsely told Relator that BioTel was discontinuing the MedNet line of products and that the hospital had to switch to LifeWatch monitors. In fact, MedNet products continued to be available through BioTel, including the ECAT wireless device that had been in use at Relator's hospital for several years. https://www.gobio.com/brand/heartrak/ (showing Mednet devices available through BioTel).

106. Because of this misrepresentation and after receiving Balestino's assurances that the LifeWatch monitor would meet the hospital's needs for wireless event monitoring, Relator's hospital switched from MedNet to LifeWatch in or about October 2017.

2. Defendants' Enrollment Portal Forced the Hospital to Select Telemetry Even Though Physicians Had Ordered Cardiac Event Monitoring

107. Defendants designed their enrollment portal to enroll patients in cardiac telemetry monitoring services to maximize reimbursements from private and government payors, regardless of the reasonableness or medical necessity of such services.

108. As noted above, providers in Relator's hospital did not want and did not order mobile cardiac telemetry services for their patients after about January 2013. In fact, when Relator's hospital system implemented a new electronic medical records system (EPIC), the system did not even include mobile telemetry as an option for cardiac monitoring. The only two options were Holter monitors and event recorders.

109. The EPIC system became operational in about March 2017, prior to the time that LifeWatch became the hospital cardiac monitor supplier.

110. Relator told Balestino, BioTel's sales representative, that the hospital's physicians were not interested in telemetry services and did not have the ability to order them on EPIC. He informed Balestino that the hospital did not want Holter monitors or telemetry, only wireless event monitors. Balestino assured him that would not be a problem.

111. Thereafter, on November 2, 2017, Balestino and his "boss" came to the hospital for training and orientation with Relator and his staff. During the training, Balestino demonstrated how to enroll patients using the LifeWatch enrollment portal. On information and belief, Balestino's boss was BioTel's regional sales director, Matthew Malfara.

112. Relator observed that, in his demonstration, Balestino was enrolling patients for LifeWatch's MCT 3L telemetry device instead of event monitoring. Relator also noticed that the LifeWatch event monitors used landlines, rather than wireless technology, to transmit data. Because many of the hospital's patients do not have landlines, that older technology is inappropriate for their needs.

113. Relator reiterated to Balestino that the hospital wanted wireless event monitoring, not telemetry. As noted above, the LifeWatch device used by the hospital, MCT 3L, is a 3-in-1 monitor and can operate either as a telemetry monitor or as a wireless cardiac event monitor.

114. Although the device could be switched to event monitoring to comply with the directions of Relator's hospital and its physicians, Balestino said that the "policy" was to enroll patients in telemetry first and, if insurance did not pay for telemetry, to change to wireless event monitoring.

115. This statement was made to Relator in front of other hospital employees who were participating in the training and in front of Malfara. Balestino repeated it on more than one occasion that day in Malfara's presence.

116. Consistent with the policy articulated to Relator, LifeWatch's enrollment portal is designed to enroll patients for telemetry services even where their physician has requested CEM.

117. Physicians in Relator's hospital order cardiac monitoring for patients by entering an order for either an event recorder or a Holter monitor on the EPIC system, along with the patient's diagnosis (if one is not already in the system). As noted above, the hospital's EPIC system does not offer telemetry as a cardiac monitoring option.

118. After a physician's event monitor order has been entered into EPIC, Relator's department enrolls the patient using the LifeWatch portal. LifeWatch's portal includes default values that cannot be changed by the hospital, which result in patients being automatically enrolled in telemetry, in contravention of the doctors' orders.

119. Under "Service Set-up," there is a field called "Customized Monitor Programming." Although the MCT 3L is customizable to offer only CEM, not telemetry, that field on LifeWatch's portal is automatically set to "Default Settings," which reflect telemetry monitoring. The hospital does not have any ability to modify that value, so all of the hospital's patients – for whom doctors had determined that event monitoring was medically appropriate – are enrolled in telemetry services at increased cost to Government Health Care Programs.

120. The enrollment portal also includes a field called "Prior Test," which is automatically populated with the phrase "Medical Necessity Criteria." Relator's department has nothing to do with that entry, and he does not know its purpose. The entry is included as a default by LifeWatch and does not reflect any representation by hospital personnel about whether prior testing was performed or whether telemetry is medically necessary. As noted, physicians at the hospital have determined that telemetry is not medically necessary for their

patients and order event monitoring instead. To the best of Relator's knowledge, very few – if any – patients enrolled by LifeWatch would have received prior cardiac event monitoring.

121. Notwithstanding the physicians' preferences and express orders in EPIC, the LifeWatch enrollment portal automatically adds language that purports to reflect physicians' orders; however, the ordering physicians are not aware of that language (since they do not make entries on the LifeWatch portal), and it misrepresents their medical judgment.

122. The language on the portal states:

> By submitting the following order, I certify that this patient requires ambulatory cardiac telemetry and my order is based on the patient's diagnosis, history and physical. I certify that the patient meets the criteria listed below:
>
> - There is a low likelihood of a potentially life threatening cardiac event
> - Other testing and/or monitoring have been unrevealing or are inappropriate for this patient
> - It is anticipated that the results of this service will provide diagnostic and treatment information

123. This language is automatically included on all patient summary reports that LifeWatch generates. It appears designed to meet the requirements of the Novitas LCD described above regarding the narrow circumstances when Medicare coverage for mobile cardiac telemetry is available. The language, however, misrepresents and is contrary to the judgments of the hospital's physicians regarding the necessity of telemetry.

124. The hospital's physicians did not want and did not order telemetry for their patients. Thus, they did not and would not "certify" that their patients required "ambulatory cardiac telemetry" and that "[o]ther testing and/or monitoring have been unrevealing or are inappropriate for this patient."

125. LifeWatch's patient summary reports also include a purported instruction from the ordering physician authorizing the monitoring service to be changed from telemetry to CEM "[i]f the patient does not meet MCT 3 Lead (MCT) enrollment criteria," and that "[b]y selecting "yes" below I attest that this change will still meet the clinical needs of my patient," followed by the entry "Yes."

126. This purported attestation is not made by ordering physicians, who do not make entries on the portal. Relator's staff selects "yes," because the physicians want patients to receive CEM and not telemetry.

3. Defendants Persisted in Enrolling Patients in Telemetry Even After the Hospital Began Expressly Stating on Each Enrollment Form that an Event Monitor Had Been Ordered, Not Telemetry

127. After Relator's hospital began using the LifeWatch monitor, its physicians received mostly telemetry end-of-study reports, not the event monitoring reports they and the hospital had requested. The relatively small number of CEM reports received were for patients whose insurance did not cover telemetry or who did not have insurance (see discussion below).

128. Relator received a complaint from one of the hospital's cardiologists reiterating that he and the other cardiologists did not want telemetry reports from LifeWatch, which they found unnecessarily long, detailed, and confusing for their purposes, but wanted only CEM reports.

129. In or about March 2018, Balestino stopped by the hospital to meet with Relator on a routine sales visit. Relator again emphasized that the hospital wanted only event monitoring, not telemetry, and he conveyed the complaints of the cardiologists that they were receiving telemetry reports but had ordered event monitoring. At that meeting, Relator expressed concerns to Balestino that LifeWatch's enrollment practices were fraudulent.

130. Balestino expressed irritation at Relator's persistence on this issue and suggested that, if Relator were so concerned about it, he could add a statement in the comment section of the patient enrollment form saying, "event recorders only, not telemetry (MCT)."

131. Shortly after this meeting, in or about April 2018, Relator directed the staff at his hospital to add this comment on the enrollment forms of every patient, so that the forms would clearly state the type of monitoring the physician was ordering. In June 2018, he instructed the staff at another hospital in the same health system to do likewise.

132. Even after Relator's meeting with Balestino and the addition of these notations on the enrollment form, LifeWatch continued its practice of automatically enrolling patients in telemetry. That practice is ongoing. Relator has observed that patient reports bearing the notation "event recorders only, not telemetry (MCT)" nevertheless reflect that monitors were programmed with "default settings" (telemetry). He also has observed that the more-detailed telemetry reports continue to be sent to physicians at the hospital.

4. Defendants Converted Telemetry to Event Monitoring When Reimbursement was Denied for Telemetry

133. As described above, Defendants deliberately disregarded the hospital's instructions to enroll its patients in CEM, not telemetry. When insurance reimbursement was not available for telemetry, however, Defendants simply converted the LifeWatch monitoring service from telemetry to CEM.

134. Relator has examples of non-Medicare patients who were initially started on telemetry (per the enrollment "policy") only to be downgraded to CEM after a few days. In such cases, the hospital was not consulted about changing the patient's monitoring status; rather, LifeWatch would make the change on its own. The hospital would learn of the change only when it began receiving the less-detailed CEM reports, rather than telemetry reports.

135. On information and belief, LifeWatch made these changes after determining that patients' insurance did not reimburse telemetry monitoring or that the patient lacked insurance and was a cash patient.

136. As noted above, LifeWatch's enrollment system includes a blanket permission (which purports to be from physicians) authorizing a change from telemetry to event monitoring if a patient "does not meet MCT 3 Lead (MCT) enrollment criteria."

137. The aforementioned "enrollment criteria" are not based on the reasonableness and medical necessity of telemetry services but, rather, on the availability of reimbursement through patients' insurance for telemetry.

5. CardioNet Engaged in a Similar Fraudulent Scheme

138. On information and belief, CardioNet also has a policy and practice of disregarding physicians' orders for cardiac event monitoring and instead enrolling patients in telemetry in order to receive higher reimbursements.

139. In June 2018, Relator had a conversation with a counterpart at a hospital in Massachusetts. This person told Relator that her hospital had switched from MedNet to CardioNet for wireless event monitors. Even though doctors at her hospital ordered event recording, CardioNet would set up the devices as telemetry initially, then change the monitoring service to event recording if insurance would not pay for telemetry. That hospital has since changed to a new vendor.

140. In June 2018, Relator spoke with a counterpart at a hospital in Vermont. This hospital had previously used CardioNet for both wireless event monitoring and telemetry but has since changed to another vendor. When using CardioNet devices, the hospital had problems with telemetry being provided when physicians had ordered only event monitoring. This problem has not occurred with the new vendor.

141. When Balestino and Malfara visited Relator's hospital for training, their business cards showed that they worked for BioTel Heart, which includes CardioNet. The address on the cards was BioTel's headquarters located in Malvern, Pennsylvania, and their emails were on the BioTel domain (gobio.com).

142. In addition, Malfara describes himself on his LinkedIn profile as having "[l]ead the integration of BioTelemetry and LifeWatch Sales Representatives in the Northeast Region through a dynamic company merger."

143. The statement of "policy" made by Balestino in Malfara's presence, their positions as representatives of BioTel (not just LifeWatch), and the reports of these two hospitals strongly support an inference that CardioNet also was fraudulently enrolling patients in telemetry without regard to medical necessity or the orders of their physicians.

6. Defendants Knew Their Conduct Resulted in False Claims

144. Defendants were aware that they were submitting false and fraudulent claims for to government health care programs.

145. In recent years, there has been intense scrutiny over the medical necessity of mobile telemetry devices, including settlements in this district.[1] Indeed, both LifeWatch and BioTel have settled cases under the False Claims Act alleging that they improperly billed Medicare for mobile cardiac outpatient telemetry services that were not reasonable or medically necessary.

146. In March 2012, LifeWatch Services, Inc., entered into a Settlement Agreement with the Department of Justice to resolve allegations in two separate *qui tam* actions that it

[1] *See* https://www.justice.gov/opa/pr/cardiac-monitoring-companies-and-executive-agree-pay-1345-million-resolve-false-claims-act (June 26, 2017 settlement with Spectocor for $13.45M); https://www.justice.gov/usao-nj/pr/new-jersey-cardiac-monitoring-company-agrees-pay-over-135-million-resolve-claims-it-paid (November 15, 2016 settlement with MedNet for $1.35M).

improperly billed Medicare for ambulatory cardiac telemetry services. LifeWatch was alleged, among other things, to have induced physicians to use incorrect diagnosis codes to support claims for telemetry services for patients whose actual diagnoses permitted payment only for event monitoring, which was reimbursed at a lower rate. In addition, LifeWatch was accused of improper sales practices for removing its cardiac event monitors from physicians' offices and requiring them either to "upgrade" to its telemetry device or to move to another vendor. These fraudulent practices were alleged to have been done to take advantage of the much-higher Medicare reimbursement rate for telemetry devices as compared to cardiac event monitors.

147. Pursuant to that settlement, LifeWatch agreed to pay the United States $18.5 million. In addition to the monetary settlement, LifeWatch entered into a comprehensive Corporate Integrity Agreement (CIA) with the Office of Inspector General of the U.S. Department of Health and Human Services. According to the Department of Justice's press release announcing the settlement, pursuant to the CIA: "The chief executive officer at LifeWatch as well as other corporate executives will be required to personally certify compliance with our five-year CIA, which includes provisions to monitor LifeWatch's claim submission process, sales force activities and relationships with some types of business referrals." https://www.justice.gov/opa/pr/united-states-settles-false-claims-act-allegations-against-illinois-based-lifewatch-services

148. In March 2015, BioTel entered into a Settlement Agreement with the Department of Justice to resolve allegations that its subsidiary CardioNet had improperly billed Medicare for mobile cardiac outpatient telemetry services that were not reasonable or medically necessary. CardioNet was alleged to have knowingly submitted false telemetry claims by using inaccurate diagnosis codes for patients experiencing only mild or moderate palpitations. These inaccurate

diagnosis codes caused Medicare to pay inflated claims for telemetry services for patients whose actual diagnoses only supported reimbursement for cardiac event monitoring. https://www.justice.gov/usao-wdwa/pr/second-cardiac-monitoring-company-pays-64-million-settle-allegations-it-overbilled

149. In addition, LifeWatch has included a "disclaimer" on a marketing brochure for its monitoring services, which states:

> DISCLAIMER: This brochure is for informational purposes only. Physicians should always exercise independent medical judgment in their ordering of services for patients. It is the provider's responsibility to select codes carried out to the highest level of specificity and selected from the ICD-10-CM code book appropriate to the year in which the service is rendered or the claim(s) submitted. The service must be reasonable and necessary in the specific case and must meet the criteria specified in this determination. ICD-10-CM codes can be used with the conditions listed in the Indications and Limitations of Coverage and/or Medical Necessity section of the Novitas LCD.

150. Both this "disclaimer" and the language that LifeWatch automatically adds to patients' records during enrollment demonstrate that Defendants know that telemetry monitoring is covered and payable by Medicare only in limited circumstances.

151. Nonetheless, Defendants constructed an enrollment, marketing, and billing scheme designed to generate large numbers of claims for costly mobile telemetry services to Medicare and certain other payors.

7. Damages Caused by Defendants to Government Health Care Programs

152. Relator's hospital (and sister hospital) began using LifeWatch monitors in October 2017. Since that time, Defendants' fraudulent practices have resulted in all of the hospitals' Medicare patients automatically being enrolled in telemetry.

153. At the time Relator's hospital switched to LifeWatch for monitoring, Defendants' fraudulent enrollment practices already were ongoing. At the November 2, 2017 training and

orientation meeting discussed above, Balestino stated in front of his regional sales director that it was "policy" to enroll patients initially in telemetry, then switch them to CEM if insurance did not cover telemetry.

154. Thus, the fraudulent enrollment practices already were well-established by fall 2017. Moreover, those practices were widespread. Malfara's business card showed that he was the regional sales director for the northeast division of BioTel Heart, so it can be inferred that the fraudulent policy was in effect for at least that division. Malfara's LinkedIn profile states that, at the time LifeWatch was acquired by BioTel, his region encompassed 13 states and was the top region in revenue generation and new account acquisition.

155. Moreover, since there is a single enrollment portal for LifeWatch patients, the fraudulent practices arising from its improper default values are presumably occurring nationwide.

156. As a result of Defendants' fraudulent marketing, enrollment, and billing practices, federal health care programs have paid for millions of dollars in medically unnecessary telemetry services.

157. Medicare reimburses the technical component of telemetry monitoring at a rate of approximately $743.39 for an enrolled beneficiary, much higher than for event monitoring, which is reimbursed at $174.60.

158. In its press release dated July 12, 2017, announcing its acquisition of LifeWatch AG, BioTel stated that the acquisition "solidifie[d] BioTelemetry's Leadership Position in Remote Cardiac Monitoring" and described LifeWatch Services, Inc., as "a leading U.S.-based provider of cardiac monitoring services." www.gobio.com/news/biotelemetry-inc-completes-lifewatch-ag-acquisition/

159. LifeWatch has a large share of the market for cardiac monitoring. Its marketing materials assert: "Our remote diagnostic monitoring services are used by >60% of the top cardiac care hospitals in the USA." https://www.lifewatch.com/Healthcare-Professionals.html

160. At the time of its acquisition, LifeWatch had the second-largest share of the mobile cardiac monitoring market. BioTel had the largest.

161. BioTel currently claims to monitor over one million patients per year and to receive over 30,000 referrals from physicians per month.

162. Fraudulent marketing and billing practices by cardiac monitoring companies cost the federal government millions of dollars in medically unnecessary services. Indeed, spending for telemetry services has sharply risen in recent years. In 2011, annual Medicare expenditures for the technical component of telemetry (CPT code 93229) totaled $73 million. By 2016, such expenditures had risen to nearly $190 million, and CPT code 93229 was 80th highest among CPT codes ranked based on the amount of Medicare charges allowed.

https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareFeeforSvcPartsAB/Downloads/LEVEL1CHARG16.pdf?agree=yes&next=Accept

VII. CLAIMS FOR RELIEF

Count I

Federal False Claims Act – False Claims
31 U.S.C. § 3729(a)(1)(A) (2009)

163. Relator realleges and incorporates by reference the allegations contained in the foregoing paragraphs as though fully set forth herein.

164. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §§ 3729, *et seq.* as amended.

165. By and through the acts described above, Defendants have knowingly presented or caused to be presented false or fraudulent claims for payment or approval.

166. The Government, unaware of the falsity of all such claims made or caused to be made by Defendants, has paid and continues to pay such false or fraudulent claims that would not be paid but for Defendants' illegal conduct.

167. By reason of Defendants' acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

168. Additionally, the United States is entitled to the maximum penalty provided for by law for each and every violation alleged herein.

Count II

Federal False Claims Act – False Records or Statements
31 U.S.C. § 3729(a)(1)(B) (2009)

169. Relator realleges and incorporates by reference the allegations contained in the foregoing paragraphs as though fully set forth herein.

170. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §§ 3729, *et seq.* as amended.

171. By and through the acts described above, Defendants knowingly made, used, or caused to be made or used false records or statements material to false or fraudulent claims.

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

173. By reason of Defendants' acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

174. Additionally, the United States is entitled to the maximum penalty provided for by law for each and every violation alleged herein.

Count III

Federal False Claims Act – Reverse False Claims
31 U.S.C. § 3729(a)(1)(G) (2009)

175. Relator realleges and incorporates by reference the allegations contained in the foregoing paragraphs as though fully set forth herein.

176. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §§ 3729, *et seq.* as amended.

177. By and through the acts described above, Defendants have knowingly made, used, or caused to be made or used a false record or statement material to an obligation to pay money to the Government and they have concealed and improperly avoided an obligation to pay money to the Government, including specifically Defendants' obligation to report and repay past overpayments of Medicare and other government health care program claims for which Defendants knew they were not entitled to and therefore refunds were properly due and owing to the United States.

178. The Government, unaware of the concealment by the Defendants, has not made demand for or collected the years of overpayments due from the Defendants.

179. By reason of Defendants' acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

180. Additionally, the United States is entitled to the maximum penalty provided for by law for each and every violation alleged herein.

Count IV

Federal False Claims Act - Conspiracy
31 U.S.C. § 3729(a)(1)(C) (2009)

181. Relator realleges and incorporates by reference the allegations contained in the foregoing paragraphs above as though fully set forth herein.

182. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §§ 3729, *et seq.* as amended.

183. By and through the acts described above, Defendants conspired to commit violations of 31 U.S.C. § 3729(a)(1)(A), (B), and (G). Further to Defendants' conspiracy and fraudulent scheme, despite knowing that payments from the federal government have been received in violation of the False Claims Act, Defendants have refused and failed to refund these payments and have continued to submit false or fraudulent claims, statements, and records to the United States.

184. The Government, unaware of the Defendants' conspiracy and fraudulent schemes, has paid and continues to pay claims that would not be paid but for Defendants' illegal conduct.

185. By reason of Defendants' acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

186. Additionally, the United States is entitled to the maximum penalty provided for by law for each and every violation alleged herein.

VIII. PRAYERS FOR RELIEF

WHEREFORE, Relator Michael Pelletier, acting on behalf of the United States, requests that this Court enter an order:

A. That Defendants violated the False Claims Act;

B. That Defendants pay an amount equal to three times the amount of damages the United States has sustained because of Defendants' actions, plus a civil penalty against each Defendant for each FCA violation in the maximum statutory amount;

C. That Defendants cease and desist from violating the False Claims Act;

D. That Relator be awarded all costs of this action, including attorneys' fees, expenses, and costs pursuant to the False Claims Act, pursuant to 31 U.S.C. § 3730(d);

E. That the Relator be awarded the maximum amount allowed as a relator share pursuant to 31 U.S.C. § 3730(d);

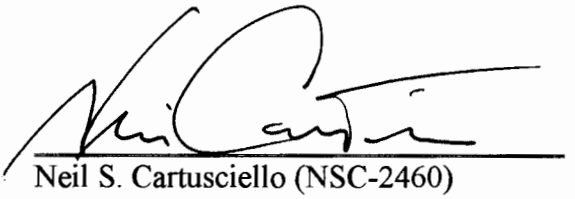
F. That the United States Government and Relator receive all relief, both at law and in equity, to which they may reasonably appear entitled.

DEMAND FOR JURY TRIAL

Plaintiff requests, pursuant to Federal Rule of Civil Procedure 38(b), that all of the issues in this matter be tried to a jury.

July 5, 2018

Respectfully submitted,



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