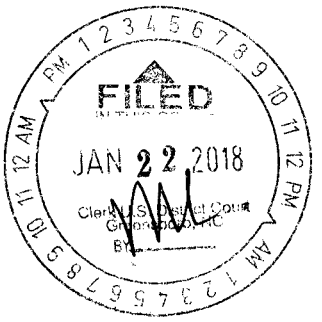
IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF NORTH CAROLINA



United States, *ex. rel.* REBECCA KOVALICH, BRINGING THIS ACTION ON BEHALF OF THE UNITED STATES OF AMERICA, and THE STATE OF NORTH CAROLINA, Plaintiffs, v. PREFERRED PAIN MANAGEMENT & SPINE CARE, P.A., DR. DAVID SPIVEY, individually, and MRS. SHERRY SPIVEY, individually. Defendants.	**CASE NO.:** 1:18CV44 **COMPLAINT and JURY DEMAND** **ORIGINAL COMPLAINT FILED IN CAMERA AND UNDER SEAL, PURSUANT TO 31 U.S.C. §3730(b)(2)** ****DO NOT PLACE IN PRESS BOX**** ****DO NOT ENTER ON PACER****

NOW COMES PLAINTIFF-RELATOR, Rebecca Kovalich, by and through her attorney, Sean F. Herrmann of Van Kampen Law, PC, and brings this action under 31 U.S.C. §§3729–3732 (the "federal False Claims Act"), and N.C.G.S. §§1-605 to 1-608 (the "North Carolina False Claims Act"), to recover all damages, penalties, and other remedies established by the federal False Claims Act and North Carolina False Claims Act on behalf of the United States, the State of North Carolina, and herself, and shows the Court as follows:

I. OVERVIEW

1. Qui Tam Relator Rebecca Kovalich brings this action on her own behalf and on behalf of the United States of America to recover civil damages and penalties under the federal False Claims Act, 31 U.S.C. § 3729, *et seq.*, and North Carolina False Claims Act, N.C.G.S. § 1-605, *et seq.*, against Defendants Preferred Pain Management & Spine Care, P.A., a North Carolina

Professional Association with its principal place of business located in Winston-Salem, Forsyth County, North Carolina and locations in Greensboro, Guilford County, North Carolina; Dr. David Spivey, individually; and Mrs. Sherry Spivey, individually.

2. Relator's allegations relate to illicit Medicare and Medicaid fraud. Defendants ordered unnecessary confirmatory tests of urine and were reimbursed for these tests by the federal government. In fact, Defendants went so far as to take the highly unusual step of purchasing the expensive testing equipment to conduct all of its testing in-house, rather than send its samples to a commercial laboratory. Defendants' fraud was so blatant that they developed a requisition form for urine tests with a box labeled "ALL DRUGS and METABOLITES MEDICARE ONLY." Defendants then instructed its employees to check that box for Medicare patients, meaning that they would test for up to 35 drugs when only a small handful were medically necessary. Moreover, that small handful should have been determined on a patient-by-patient basis, but Defendants strongly resisted this approach.

3. Defendants know, and at all relevant times knew, that these tests are unnecessary and that Medicare and, to a lesser extent, Medicaid should not be reimbursing them. Yet, they nonetheless engaged in this practice and, upon information and belief, continue to do so today. Indeed, it has been extremely lucrative for Defendants. Upon information and belief, to date, Defendants have defrauded the federal government out of millions of dollars between late 2013 and the present.

4. What's more, Defendants illegally retaliated against Relator for complaining about and otherwise opposing the alleged Medicare and Medicaid fraud. Defendants first demoted Relator

for her complaints and, when she would not relent, Defendants terminated Relator's employment.

II. JURISDICTION

5. This action arises under the False Claims Act, 31 U.S.C. §3729, *et seq*.

6. This action arises under the laws of the United States, and jurisdiction over this action is otherwise conferred upon this Court by 31 U.S.C. §3730(a), 31 U.S.C. §3730(b), 31 U.S.C. §3732(a), 31 U.S.C. § 3732(b), and 28 U.S.C. §1331.

7. Venue is proper in this district pursuant to 31 U.S.C. §3732(a), which provides that "any action under §3730 may be brought in any judicial district in which the Defendant or, in the case of multiple Defendants, any one Defendant can be found, resides, transacts business, or in which any act proscribed by §3729 occurred." At all material times to the subject of this action, Defendants resided and regularly conducted business within North Carolina, within this judicial district. Furthermore, acts proscribed by §3729, and giving rise to this action, occurred within this judicial district.

8. Pursuant to 31 U.S.C. §§ 3729, *et seq.* and N.C.G.S. § 1-605, *et. seq.*, and before filing this civil action for false claims, Relator Rebecca Kovalich voluntarily provided to the United States Government and the State of North Carolina a Confidential Pre-Filing Disclosure Statement. The United States Attorney General received the Disclosure Statement on December 11, 2017; the United States Attorney for the Middle District of North Carolina received the Disclosure Statement on December 8, 2017; and the Attorney General for the State of North Carolina received the Disclosure Statement on December 14, 2017.

9. Venue also lies under 28 U.S.C. § 1391(b) and (c) because Defendants transact business within this district and the facts forming the basis of this Complaint occurred within this district.

10. There are no bars to recovery under 31 U.S.C. §3730(e) or N.C.G.S. §1-611. Substantially the same allegations as those alleged in this suite have not been publicly disclosed in a federal criminal, civil, or administrative hearing in which the Government or its agents were a party, or in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation, or from the news media. Alternatively, Relator Kovalich is an original source as defined in 31 U.S.C. §3730(e). Relator Kovalich has knowledge that is independent of and materially adds to any publicly disclosed allegations or transactions. Further, this action is not based upon the public disclosure of allegations or transactions in criminal, civil, or administrative hearing at the State or Federal level, or in a congressional, legislative, administrative, General Accounting Office, or State Auditor's report, hearing, audit, or investigation, or from the news media. In the alternative, Relator Kovalich is an original source as defined in N.C.G.S. §1-611(d). Relator Kovalich has direct and independent knowledge of the information on which the allegations are based.

III. PARTIES

11. Relator Kovalich is an individual who resides in Charleston County, South Carolina. She also resides part-time in Forsyth County, North Carolina. She is a citizen of the United States.

12. Defendant Preferred Pain Management & Spine Care, P.A. ("PPM" or "Defendant PPM") is a North Carolina Professional Association with its principal place of business located

in Winston-Salem, Forsyth County, North Carolina and locations in Greensboro, Guilford County, North Carolina. It conducts business in North Carolina on a daily basis.

13. Defendant Dr. David Spivey ("Dr. Spivey") resides in Forsyth County, North Carolina. He owns and operates PPM from its Winston-Salem location.

14. Defendant Mrs. Sherry Spivey ("Mrs. Spivey") resides in Forsyth County, North Carolina. She partly owns and manages PPM from its Winston-Salem location.

II. FACTUAL ALLEGATIONS

A. Urine Testing and Its Profitability.

15. Drug testing plays an important role in pain treatment. Monitoring a patient's medication use is important to ensure that he or she is adhering to his or her treatment plan. Moreover, behavioral observations routinely do not provide a full picture. Urine is often the preferred biologic specimen for testing. It is easy to collect and store and is relatively cost-effective to test. (Ex. A.) https://www.ncmedboard.org/images/uploads/other_pdfs/Policy_for_the_Use_of_Opiates_for_the_Treatment_of_Pain_June_4_2014.pdf

16. Indeed, the abuse of opioids to treat pain, which many refer to as an "epidemic" heightens the importance of such testing. "In North Carolina, six-hundred and seventy three North Carolinians were reported to have died in 2012 from unintentional poisoning by opioids other than opium and heroin (12). Extrapolating data from the 2011 and 2012 National Survey on Drug Use and Health suggests that as many as 70% of these opiate related deaths are associated with a prescription medication shared by or stolen from the individual for whom the drug was

prescribed." (Ex. A.) https://www.ncmedboard.org/images/uploads/other_pdfs/Policy_for_the_Use_of_Opiates_for_the_Treatment_of_Pain_June_4_2014.pdf

17. Urine Drug Testing ("UDT") detects parent drugs and/or their metabolites. It demonstrates recent use of prescription medications, unprescribed drugs, and illicit substances. (Ex. B.) http://eo2.commpartners.com/users/ama/downloads/udt5_Copy.pdf

18. There are two main types of UDT: (1) immunoassay drug testing—either laboratory based or at point-of-care ("POC"); and (2) laboratory-based specific drug identification, including liquid chromatography/mass spectrometry ("LCMS"). These types are commonly used in conjunction with one another. Liquid chromatography is used to separate the different components in a specimen and mass spectrometry is used to specifically identify the components of the specimen. (Ex. B.) http://eo2.commpartners.com/users/ama/downloads/udt5_Copy.pdf

19. The first type, which comes first, is often referred to as a "screen." It typically looks for oxycodone, methamphetamine, amphetamines, opiates, cocaine metabolite, benzodiazepines, THC (often), methadone, ethyl alcohol, buprenorphine, and barbiturates. This, referred to as an "11 panel screening test," determines the presence of these various drugs in the urine and can, depending on the type of screening, give some details about concentration levels.

20. There are three common situations when LCMS is necessary: "(1) to specifically identify the drug; for example, that morphine is the opiate causing the positive immunoassay response; (2) to identify drugs not otherwise included in other testing methods; and (3) when results are disputed by the patient (ie, contested)." (Ex. B.) http://eo2.commpartners.com/users/ama/downloads/udt5_Copy.pdf

21. False positives are possible in screens and concentration accuracy is less than perfect for small amounts of drugs. Thus, the standard of care is to perform confirmatory testing for the specific drugs that receive positive results in the initial screen. Most labs are not equipped to perform confirmatory drug testing. As a result, they typically send such confirmatory drug testing to commercial labs. Confirmatory testing provides the concentration of the drugs found in the screening, and false positive or negative results are rare.

22. Urine Drug Testing ("UDT") is big business in the United States. Laboratories around the country regularly perform drug tests to uncover whether a patient is taking drugs that could interfere with medical treatment. It is similarly common to subject patients to drug tests to make sure that they are complying with drug prescriptions set forth by physicians.

23. The equipment required to adequately perform drug testing is sophisticated and complex. This means that the equipment is often quite expensive and requires significant upfront investment. This is why most providers send their drug testing to commercial laboratories, who have already invested in the proper equipment, to carry out the testing.

24. The cost of performing an individual drug test is low. Thus, increasing the volume of these inexpensive tests also increases the amount of money coming in. For laboratories with the expensive equipment already in tow, UDT can be extremely profitable. A multitude of tests can be run on a single urine sample.

25. Medicare reimbursed at around $130 for an 11 panel screen in 2014 and 2015 and, as of 2016, it reimburses at around $80 per panel screen. Dr. Spivey was incredibly in-tune with these Medicare rates. In fact, he paid a substantial fee to be a member in a physicians group that pooled its money for lawyers and lobbyists to keep Medicare reimbursement rates high. (Ex. C.)

26. Medicare reimbursed up to around $570 for a full panel of confirmatory tests in 2014 and 2015. In or around early 2016, Medicare switched to a tiered reimbursement system: $80 for 1–7 drugs tested, $123 for 8–14, $166 for 15–21, and $215 for 22 or more. (Ex. D.)

27. Medicare switched to the tiered system in response to rampant billing abuse by providers throughout the country.

28. Many patients do not test positive for the presence of most drugs, unless the physician has prescribed them, on the initial screen. The standard of care should be to only run second tests on patients who return a positive on drugs not prescribed by that physician or negative for drugs prescribed. This is efficient and the costs remain low.

29. Performing all confirmatory tests for patients is medically unnecessary. Again, the initial screening accurately detects the *presence* of drugs (some systems roughly detect concentration, as well)—the confirmatory test is used to detect *concentration*. Testing for a drug, and getting reimbursed for it, that providers already know is not there, and was not prescribed, is medically unnecessary.

B. Federal Reimbursement.

30. Through Medicare, the United States Government reimburses a significant percentage of the country's UDT. Medicare Plan B covers medically necessary UDT, which means it is paid by the federal government. (Ex. E.) https://www.medicare.gov/what-medicare-covers/part-b/what-medicare-part-b-covers.html

31. Medicare covers individuals over age 65 and those who are permanently disabled for Social Security Act purposes. The latter is most relevant in this case. Those disabled by chronic pain undergo UDT regularly and Medicare covers much of this testing.

32. Medicare limits reimbursement to that "reasonable and necessary for diagnosis or treatment of illness or injury." 42 U.S.C. § 1395(a)(1)(A). Put another way, Medicare is forbidden from paying for unnecessary urine testing.

33. The Office of the Inspector General of the Department of Health and Human Services ("OIG") has set forth guidelines for combatting unnecessary urine testing. (Ex. F.) It provides recommendations to laboratories to prevent them from violating Medicare fraud rules.

34. It specifies: "claims submitted for services will only be paid if the service is covered, reasonable, and necessary for the beneficiary, given his or her clinical condition." It continues, "Laboratories should take all reasonable steps to ensure that it is not submitting claims for services that are not covered, reasonable and necessary."

35. It also states, "Medicare may deny payment for a test that the physician believes is appropriate, but which does not meet the Medicare coverage criteria (e.g., done for screening purposes) or where documentation in the entire patient record, including that maintained in the physician's records, does not support that the tests were reasonable and necessary for a given patient."

36. Put generally, the Guidance encourages individualized assessments for each lab test ordered. It discourages standing orders and customized profiles.

37. Standing orders, which amount to blanket procedures, are discouraged because they are not usually acceptable documentation of what tests are reasonable and necessary. They run counter to the encouraged individual assessment approach.

38. Likewise, though the term is slightly misleading, custom profiles often lead to significant issues. They amount to a set of lab tests to be run each time a specific physician

submits a sample unless he or she expressly orders otherwise. Again, the Guidance strongly discourages this because it regularly leads to medically unnecessary tests and Medicare fraud.

C. Dr. Spivey and Mrs. Spivey Ready PPM to Be a Urine Testing, Money-Making Machine.

39. Dr. Spivey has a checkered past. On September 4, 2015, Dr. Spivey entered into a Consent Order with the North Carolina Medical Board in which Dr. Spivey agreed to "refrain from the use or possession of alcohol and all other mind- or mood-altering substances and all controlled substances including but not limited to, sedatives, stimulants, and pain medication." The Consent Order states that "Dr. Spivey has a history of substance abuse." It also explains that he "entered in-patient treatment for twenty-eight (28) days of inpatient relapse prevention training." The Consent Order also references opioid use. (Ex. G.) https:// wwwapps.ncmedboard.org/repository//0/0/4/9/77eea888-86f4-4c8f-8cf3-d9dd2a092bef.pdf

40. In 2009, PPM encountered problems with LabCorp, the company to which they sent urine samples for analysis. LabCorp's turnaround was too slow. Hence, Dr. Spivey decided to invest in his own analyzer machine to test urine samples. This machine cost PPM about $45,000.

41. Mrs. Spivey soon called Relator, complaining that she and her husband were going broke. PPM was hemorrhaging money into the reagents for the new machine, yet it was not working properly and generating revenue at the rate that Dr. Spivey had been promised by the equipment salesman.

42. Dr. Spivey also called Relator and asked her to find a way to send the machine back to the seller. Relator reviewed the agreement and told him that would not be possible.

43. But Relator called in support to get the analyzer running successfully. They fixed the machine.

44. With the analyzer issue fixed, PPM profits began to steadily increase. At Dr. Spivey's request, Relator began overseeing the lab in or around February 2009 and on or around May 29, 2009, she hired Medical Technician Susan Freaney.

45. The analyzer's success was short-lived. PPM began experiencing problems with the machine again. At the same time, reagents for the Biolis analyzer purchased from Carolina Liquid Chemistries were becoming more and more expensive. In or around January 2012, Relator contacted Select Lab Partners, with which she had a business relationship, and Select Lab Partners recommended the IR 500 which was a more dependable chemistry analyzer and required less expensive reagents. Dr. Spivey traded in the Biolis for the IR 500.

46. The IR 500 is an immunoassay screening analyzer. An immunoassay screening analyzer, unlike dipstick test cups, can measure concentration. That is, where the dipstick cup method can only detect whether a drug is present but not the amount, the IR 500 can detect the drug and provide data on its concentration in the sample. Since the IR 500 came into the picture, this reality has not changed at PPM. Even the initial UDT screening stage could detect drug concentration but at a higher threshold than the LCMS. http://slplabs.com/lab-management/toxicology/

47. Select Lab Partners also provided reagents at less cost to Dr Spivey, and the business began to be more profitable.

D. Defendants Massively Defraud the Federal Government and Illegally Fire Relator.

1. Defendants Acquire a Liquid Chromatography-Mass Spectrometry Machine in Order to Conduct All of Its UDT In-House.

48. In or around December 2012, Dr. Spivey asked Relator to purchase a Liquid Chromatography-Mass Spectrometry ("LCMS") machine to confirm the samples from the IR 500. This would mean that PPM could conduct all of its testing in-house.

49. Relator contacted Select Lab Partners to negotiate directly with Dr. Spivey to purchase a LCMS. She also encouraged him to interview other equipment vendors such as Sherry Gregory, a LCMS representative employed with Thermo Fisher Scientific to get the best application for his laboratory. Dr. Spivey chose to purchase the LCMS from Shimadzu offered by Select Lab Partners as it was less expensive and more appropriate for his volume of tests. The analyzer was purchased December 2012, but delivered January 2013. The LCMS was certified and running by mid-2013.

50. The specific model that Defendants obtained was the Shimadzu LCMS-8030. (Ex. H.) https://www.shimadzu.eu/sites/default/files/LCWT11.pdf

2. Defendants Use Requisition Forms Specifically Designed to Facilitate Medicare Fraud.

51. At the time (mid-2013), PPM used a requisition form for its providers that simply listed the drugs to be tested, *i.e.*, it did not group drugs into categories that could all be ordered with one stroke of the pen. (Ex. I.)

52. PPM's "providers" refers to all physicians, physician assistants, and nurse practitioners employed by or otherwise working for PPM.

53. However, by around early 2014, Dr. Spivey wanted to make it easier for his providers to order more tests. He specifically asked Relator to develop a new requisition form and provide

a breakdown on what he could bill Medicare using that form. (Ex. J.) Relator worked with then Billing Manager Annette Hempstead to create an updated laboratory requisition form to make group test ordering easier for Dr. Spivey and PPM's providers.

54. The majority of PPM's patients were Medicare patients, which drove Dr. Spivey to create a new laboratory requisition form to see the cash breakdown by test. Relator handed him the new form with her hand-written notes, showing that PPM would be reimbursed $129.92 for the screening and $570.02 for confirmation testing if PPM tested for every single available drug. (Ex. C.) Dr. Spivey was thrilled with this report.

55. The new LCMS machine produced at least $4,000,000 in revenue in 2014. Roughly 60% of PPM's patients are Medicare patients.

56. In the past, Dr. Spivey and PPM made the majority of their money from spinal cord stimulators. However, on or around January 1, 2014, Medicare cut PPM's reimbursement for spinal cord stimulators by approximately 80 percent. Dr. Spivey and PPM had seen this coming, and the LCMS machine made up for Dr. Spivey's losses—and then some. Defendants' sudden obsession with UDT was no accident.

57. With the new form and machinery, Dr. Spivey and PPM were set to make money off of Medicare hand over fist. Dr. Spivey mandated that providers order all confirmatory tests in addition to the initial screening tests. This meant that by early 2014 at the latest, PPM and Dr. Spivey were ordering medically unnecessary tests and causing the federal government, through Medicare, to needlessly reimburse Dr. Spivey and PPM for unnecessary confirmatory urine tests.

58. But the fraud was about to get even more blatant. By mid-2014, Dr. Spivey became unhappy with the new form. It clearly stated that "all tests could be ordered individually." (Ex.

J.) Relator took extra precaution to include this language because she viewed a blanket order of all tests for Medicare patients as fraudulent. Dr. Spivey, on the other hand, insisted on only one selection box for Medicare patients that would direct his providers to order all available tests.

59. Relator viewed this as fraudulent and she advised Dr. Spivey that it could get him into trouble as he did not have medical justifications to perform these tests. In April 2016, Relator showed Dr. Spivey the newly proposed ICD 10 codes. Dr. Spivey told Relator that her duties were not in billing; it was now Ms. Frey who was in charge of in-house billing. To get around Relator, Dr. Spivey instructed his employee physicians and PAs to order a panel of tests rather than select them individually.

60. Then, in or around April 2015, Dr. Spivey got his wish when he asked Ms. Frey to change the lab requisition form to say "ALL DRUGS and METABOLITES MEDICARE ONLY." (Ex. K.) This went into effect in or around that time. There was literally a separate box for Medicare patients and checking it meant running every single test, which by necessity included a vast majority that were medically unnecessary.

61. In late 2015, it appeared that Dr. Spivey and PPM's fraud was set to suffer a major blow. In or around September 2015, Medicare sent physicians an updated confirmatory drug testing fee schedule for UDT, which included a tiered system. (Ex. L.) Specifically, Medicare proposed a reimbursement rate of $61.45 for 1–7 drug, $78.66 for 8–14 drugs, $127.82 for 15–34 drugs, and $167.14 for 35 or more drugs. Medicare took this action because of fraud and over-billing like that alleged here.

62. This caused Dr. Spivey to panic. Before, he could bill for every drug and make, roughly, $700 per patient (Ex. J.). Under the proposed schedule, the most he could make in 2016

would be $167.14 per patient on confirmatory testing, and his requisition form didn't even have 35 tests at the time, so it would be $127.82. (Exs. L & D.)

63. In response, in mid-October 2015, Defendants quickly added two new drugs to the confirmation tests, K-2 and bath salts, to get to the maximum tests that the LCMS analyzer could perform. (Ex. K.)

64. What's more, PPM and Dr. Spivey began an intense lobbying effort to combat this new Medicare proposal. Dr. Spivey and other providers efforts were somewhat successful—Medicare kept the tiers but adopted the following reimbursements: $80 for 1–7 drugs, $123 for 8–14, $166 for 15–21, and $215.08 for 22 or more. (Ex. D.) With this tiered system official for 2016, Dr. Spivey would have to take steps to drastically increase volume to maintain the same income from Medicare fraud.

3. Defendants Take Drastic Steps to Protect Their Fraudulent Medicare Schemes.

65. On October 1, 2015, Defendants fired Physician Discoveries, their external medical billing service, and purchased billing software. They brought billing in-house and appointed Brandi Frey to oversee all medical billing, including laboratory billing. Dr. Spivey gave the billing service 90 days notice.

66. The Medicare issue was simmering behind the scenes. Providers (PPM's other doctors, PAs, and NPs) were complaining about the Medicare practices in that the laboratory requisition forms allowed individual test selection for commercial insurances but this option was not afforded to Medicare patients. Laboratory requisition forms for Medicare patients only allowed one selection and defaulted to the maximum number of tests.

67. As of January 1, 2016, with Physician Discoveries out of the picture, PPM, through Mrs. Spivey, severely limited any involvement of Relator in the laboratory outside of direct operations. She refused to train Relator (and others) on PPM's new billing system. Defendants removed Relator from laboratory billing involvement because of her complaints about Medicare fraud and her resistance to the fraud-facilitating requisition forms.

68. Then, at around the same time, PPM fired Susan Sanders, who was also involved in billing and had many years of billing experience. Again, Mrs. Spivey was the figurehead who was apparently behind this decision.

69. Mrs. Spivey's influence at PPM started increasing significantly, beginning in early 2015 and consistently escalated after that. PPM, through Mrs. Spivey, put code locks on the billing department doors to physically keep Relator and others who might resist the fraud out of the room.

70. Ms. Frey, and her closely held staff of three, were the only employees given access to the billing department.

71. In Q1 2016, Ms. Frey told Relator that Dr. Spivey was instructing her to over-bill all patients, hitting Medicare patients the hardest. She showed Relator an example by giving her a lab requisition from Anne Thomas, PA who only indicated one confirmatory test code. Dr. Spivey told Ms. Frey to bill all available tests instead, over-riding Thomas' original order. Ms. Frey voiced her concerns to Relator. She said that she could lose her billing certification for billing the unnecessary additional tests. However, Dr. Spivey was Ms. Frey's direct supervisor and boss and she was left with no choice. Relator informed Ms. Frey to bill only what was

indicated by the provider on the laboratory requisition form regardless of any verbal changes on which Dr. Spivey insisted without consulting the originating provider.

72. Because PPM literally locked Relator out of the billing department, Ms. Frey had to meet with Relator in the break room.

73. In or around April 2016, during a meeting, Ms. Frey, with Relator present, again voiced her concerns about the additional unnecessary lab billing to Mary Benton, the contracted acting office manager. Ms. Frey expressed fear for her job if she confronted Dr. Spivey directly regarding billing more tests than the initiating provider indicated.

74. Relator then confronted Dr. Spivey and showed him new International Statistical Classification of Diseases and Related Health Problems "ICD" codes; the ICD-10. This confrontation also occurred in or around April 2016.

75. The ICD-10 specifies that, in order to run all of the confirmatory tests, Dr. Spivey would need proper medical documentation to support the additional tests.

76. Relator told him that he could not order all of the tests when his providers were only selecting a few specific tests. Dr. Spivey became enraged. He shouted, "You have nothing to do with billing! That is Brandi's responsibility." Relator was, at this point and by Dr. Spivey's own declaration, doing more than simply carrying out the day-to-day lab duties of her job. Relator tried to explain that this could be interpreted as Medicare fraud. Dr. Spivey refused to listen.

77. There can be no doubt whatsoever that, by this point in April 2016, Relator had engaged in protected activity under Section 3730(h) of the False Claims Act.

78. On June 9, 2016, Defendants terminated Relator's employment. They replaced Relator with Gretchen Hawks, MT, who, upon information and belief, had not complained about fraud on the federal government.

79. This termination was not motivated by legitimate, non-retaliatory reasons. Dr. Spivey was openly angered by Relator's complaints that he was engaging in fraud on the federal government by over-billing Medicare and Medicaid patients. Defendants took any billing involvement away from Relator after she warned them that they could get into serious trouble. She complained again after this, very near in time to her termination. This motivated PPM's decision to fire Relator.

E. <u>Defendants' Fraud Was, and Continues to Be, Substantial.</u>

80. Dr. Spivey and PPM were indeed making money hand-over-fist by defrauding the federal government.

81. In many ways, the fraud at hand here, though not identical, is similar to that outlined in United States of America *ex rel. Mark McGuire, Plaintiff-Relator v. Millennium Laboratories, Inc., Defendant*, Case Number 1:12-cv-10132-NMG. (Ex. M.)

82. Although PPM and Dr. Spivey did not use dipstick test cups like those at issue in *Millennium Laboratories*, they still double dipped on negative initial screenings. In other words, Defendants sent negative tests from the IR 500 to the LC-MS machine and were reimbursed for the medically unnecessary confirmatory tests.

83. In *Millenium*, the Defendant directed clients to order 10 confirmatory tests even if the screen was negative. Here, by late 2015, Defendants were ordering up to 35 (the maximum number the LCMS was validated to perform) confirmatory tests on negative screens. That

number was slightly lower in 2014 and the first part of 2015, but Defendants were reimbursed more per patient in 2014 and early 2015 because Medicare had not yet implement its tiered system and instead reimbursed on a per drug-tested-for basis.

84. Medicare's 2016 switch to the tiered system strongly incentivized Defendants to increase the volume of fraudulent activity to maintain the same level of fraudulent Medicare income. This is exactly what happened.

85. To date, through the fraudulent Medicare practices alleged above, Defendants have defrauded the federal government out of millions of dollars. (Exs. N, O, & P.) The attached documents, Exhibits N, O, and P, show a detailed break-down of PPM's revenue in 2013, 2014, and 2015. They specifically include LCMS and related net income. Relator was terminated in 2016 and is not in possession of a revenue breakdown for that year. However, upon information and belief, it would show much of the same. Discovery will reveal the true extent of Defendants' Medicare fraud, but the information available reveals that it was substantial.

86. Defendants' practices began in or around the third quart of 2013 (i.e., between October and December 2013) (Ex. Q), and, upon information and belief, continues through to today. (Ex. R.)

87. In fact, PPM and Dr. Spivey's new lab manager, Ms. Hawks told Relator, in or around September 2016, that Defendants are currently ordering "the full Monty" on *every* patient that walks in the door. Linda Jones, MT, Compliance Director, Select Lab Partners, contacted Relator with concerns that the lab had been ordered by Dr. Spivey to override his employee providers' single test orders and process the maximum number of tests that the LCMS was capable of performing. Relator told Ms. Jones to speak directly to PPM's new lab manager and advise her to

perform only the tests indicated on the laboratory requisition form initiated by the originating provider. Furthermore, Relator also informed Ms. Jones to relay to PPM's lab manager that, should Dr. Spivey want more tests performed on another provider's requisition form, then Dr. Spivey would need to personally sign the requisition. Without question, this involved a significant number of Medicare and, upon information and belief, Medicaid patients.

88. Defendants' fraud—that which is outlined in this Complaint—was certainly still occurring at the time of Relator's termination on or around June 9, 2016. Upon information and belief, Defendants' only substantial change vis-a-vis the fraud at issue is that Defendants are currently committing fraud for medically unnecessary urine testing for every single patient, regardless of whether he or she is covered by Medicare or private insurance.

89. Also, a July 24, 2017, Comparative Billing Report outlines the substantial over-billing. (Ex. S.)

V. ACTIONABLE CONDUCT

A. The Federal False Claims Act.

90. This is an action to recover damages and civil penalties on behalf of the United States and Relator Kovalich arising from the false and/or fraudulent claims, statements, and acts of Defendants made and caused to be made in violation of the False Claims Act (FCA), 31 U.S.C. §§3729–3732.

91. Based on the relevant FCA provisions, Relator Kovalich, on behalf of the United States Government, seeks through this action to recover damages and civil penalties arising from Defendants' submission and/or causation of the submission of false claims to the federal government.

92. For violations occurring prior to November 2, 2015, the FCA provided that any person who:

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

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

. . .

is liable to the government for a civil penalty of not less than $5,500 and not more than $11,000 for each such claim plus three times the amount of damages sustained by the Government because of the false or fraudulent claim.

31 U.S.C. §3729(a)(1) (2011).

93. For violations occurring after November 2, 2015, the FCA provides that any person who:

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

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

. . .

is liable to the government for a civil penalty of not less than $10,781 and not more than $21,563 for each such claim plus three times the amount of damages sustained by the Government because of the false or fraudulent claim.

31 U.S.C. §3729(a)(1).

94. Any person who violates the FCA is liable for three times the amount of damages that the government sustains because of the act of that person.

95. The FCA defines "claim" as:

> A. mean[ing] 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. providers 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) (2011).

96. The FCA allows any person having knowledge of a false or fraudulent claim against the Government to bring an action in Federal District Court of themselves and of the United States Government and to share in any recovery as authorized by 31 U.S.C. §3730 (2011).

B. <u>The North Carolina False Claims Act.</u>

97. This is an action to recover damages and civil penalties on behalf of the State of North Carolina and Relator Kovalich arising from the false and/or fraudulent claims, statements,

and acts of Defendants made and caused to be made in violation of the North Carolina False Claims Act, N.C.G.S. §§51-1-605-617.

98. Based on the relevant provision of the North Carolina False Claims Act, Relator Kovalich, on behalf of the State of North Carolina, seeks through this action to recover damages and civil penalties arising from Defendants' submission and/or causation of the submission of false claims to the North Carolina state government.

99. The North Carolina False Claims Act provides in relevant part:

Any person who commits any of the following acts shall be liable to the State for three times the amount of damages that the State sustains because of the act of that person. A person who commits any of the following acts also shall be liable to the State for the costs of a civil action brought to recover any of those penalties or damages and shall be liable to the State for a civil penalty of not less than five thousand five hundred dollars ($5,500) and not more than eleven thousand dollars ($11,000) for each violations:

(1) Knowingly presents or causes to be presented a false or fraudulent claim for payment or approval.

(2) Knowingly makes, uses, or causes to be made or used, a false record or statement to a false or fraudulent claim.

N.C.G.S. §51-1-607(a).

C. Defendants Submitted False and/or Fraudulent Claims for Payment or Approval.

100. Defendants submitted and/or caused the submission of false and/or fraudulent claims for payments to government programs such as Medicare, Medicaid, and TRICARE. Those false

and/or fraudulent claims for payment include, but are not limited to, claims for medically unnecessary UDT.

101. Every claim and request by Defendants for payment under the Medicaid, Medicare, and/or TRICARE programs for payments based on medically unnecessary UDT, as described above, constitutes a separate violation of the Federal False Claims Act.

102. As a result of Defendants' submission of false and/or fraudulent claims for payment, Defendants have received significant sums of money to which they are not legitimately entitled. The United States and the State of North Carolina have suffered substantial damages as a result.

D. Defendants Made, Used, and/or Caused to be Made or Used, False Records and/or Statements Material to False or Fraudulent Claims.

103. Defendants made, used, and/or caused to be made or used, false records and/or statements material to false or fraudulent claims in order to be reimbursed by government programs such as Medicare, Medicaid, and TRICARE.

104. As a result of Defendants submission of false and/or fraudulent claims for payment, Defendants have received significant sums of money to which they are not legitimately entitled. The United States and the State of North Carolina have suffered substantial damages as a result.

E. Defendants Conspired to Do That Listed Above.

105. In performing the acts described above, Defendants individually by and through their own acts, or through the acts of their agents, servants, officers, and employees, knowingly conspired to present or make, use, and/or cause to be made or used, false records or statements material to false or fraudulent claims paid or approved by Medicare, Medicaid, and TRICARE.

106. As a result of Defendants conspiracy, Defendants have received significant sums of money to which they are not legitimately entitled. The United States and the State of North Carolina have suffered substantial damages as a result.

F. Defendants Retaliated Against Relator Kovalich in Violation of 31 U.S.C. §3730(h).

107. Relator Kovalich was discharged for, potentially among other reasons, engaging in protected activity under 31 U.S.C. §3730(h). As a consequence of Defendants' violations of §3730(h), Relator Kovalich has been damaged substantially in amounts to be proven by the evidence.

FIRST CLAIM FOR RELIEF
(FALSE CLAIMS—31 U.S.C. §3729(a)(1)(A))

108.The allegations of all paragraphs in this Complaint are incorporated by reference.

109. In performing the acts described above, Defendants individually by and through their own acts, or through the acts of their agents, servants, officers, and employees, knowingly presented, and/or caused to be presented, to an officer or employee of the United States Government, false or fraudulent claims for payments or approval under Medicare, Medicaid, and TRICARE, in violation of 31 U.S.C. §3729(a)(1)(A).

110. As a result of the Defendants' fraudulent conduct, the United States government has been damaged in amounts to be determined at trial.

111. Additionally, the United States is entitled to penalties of up to $11,000 for reach and every violation of 31 U.S.C. §3729(a)(1)(A) by the Defendants that were committed before November 2, 2015.

112. Additionally, the United States is entitled to penalties of up to $21,563 for reach and every violation of 31 U.S.C. §3729(a)(1)(A) by the Defendants that were committed after November 2, 2015.

SECOND CLAIM FOR RELIEF
(FALSE STATEMENTS—31 U.S.C. §3729(a)(1)(B))

113. The allegations of all paragraphs in this Complaint are incorporated by reference.

114. In performing the acts described above, Defendants individually by and through their own acts, or through the acts of their agents, servants, officers, and employees, knowingly made, used, and/or caused to be made or used, false records or statements material to false or fraudulent claims paid or approved by Medicare, Medicaid, and TRICARE, in violation of 31 U.S.C. §3729(a)(1)(B).

115. As a result of the Defendants' fraudulent conduct, the United States government has been damaged in amounts to be determined at trial.

116. Additionally, the United States is entitled to penalties of up to $11,000 for reach and every violation of 31 U.S.C. §3729(a)(1)(B) by the Defendants that were committed before November 2, 2015.

117. Additionally, the United States is entitled to penalties of up to $21,563 for reach and every violation of 31 U.S.C. §3729(a)(1)(B) by the Defendants that were committed after November 2, 2015.

THIRD CLAIM FOR RELIEF
(CONSPIRACY—31 U.S.C. §3729(a)(1)(C))

118. The allegations of all paragraphs in this Complaint are incorporated by reference.

119. In performing the acts described above, Defendants individually by and through their own acts, or through the acts of their agents, servants, officers, and employees, knowingly conspired to present or make, use, and/or cause to be made or used, false records or statements material to false or fraudulent claims paid or approved by Medicare, Medicaid, and TRICARE, in violation of 31 U.S.C. §3729(a)(1)(C).

120. As a result of the Defendants' fraudulent conduct, the United States government has been damaged in amounts to be determined at trial.

121. Additionally, the United States is entitled to penalties of up to $11,000 for reach and every violation of 31 U.S.C. §3729(a)(1)(C) by the Defendants that were committed before November 2, 2015.

122. Additionally, the United States is entitled to penalties of up to $21,563 for reach and every violation of 31 U.S.C. §3729(a)(1)(C) by the Defendants that were committed after November 2, 2015.

FOURTH CLAIM FOR RELIEF
(FALSE CLAIMS—N.C.G.S. §1-607(a)(1))

123. The allegations of all paragraphs in this Complaint are incorporated by reference.

124. In performing the acts described above, Defendants individually by and through their own acts, or through the acts of their agents, servants, officers, and employees, knowingly presented, and/or caused to be presented, false or fraudulent claims for payments or approval under the North Carolina Medicaid program and/or other state health care programs, in violation of N.C.G.S. §1-607(a)(1).

125. As a result of the Defendants' fraudulent conduct, the the State of North Carolina has been damaged in amounts to be determined at trial.

126. Additionally, the State of North Carolina is entitled to penalties of up to $11,000 for reach and every violation of N.C.G.S. §1-607(a)(1) by the Defendants that were committed before November 2, 2015.

127. Additionally, the State of North Carolin is entitled to penalties of up to $21,563 for reach and every violation of N.C.G.S. §1-607(a)(1)) by the Defendants that were committed after November 2, 2015.

FIFTH CLAIM FOR RELIEF
(FALSE STATEMENTS—N.C.G.S. §1-607(a)(2))

128. The allegations of all paragraphs in this Complaint are incorporated by reference.

129. In performing the acts described above, Defendants individually by and through their own acts, or through the acts of their agents, servants, officers, and employees, knowingly made, used, and/or caused to be made or used, false records or statements material to a false or fraudulent under the North Carolina Medicaid program and/or other state health care programs, in violation of N.C.G.S. §1-607(a)(2).

130. As a result of the Defendants' fraudulent conduct, the the State of North Carolina has been damaged in amounts to be determined at trial.

131. Additionally, the State of North Carolina is entitled to penalties of up to $11,000 for reach and every violation of N.C.G.S. §1-607(a)(2) by the Defendants that were committed before November 2, 2015.

132. Additionally, the State of North Carolina is entitled to penalties of up to $21,563 for reach and every violation of N.C.G.S. §1-607(a)(2) by the Defendants that were committed after November 2, 2015.

SIXTH CLAIM FOR RELIEF
(CONSPIRACY—N.C.G.S. §1-607(a)(3))

133. The allegations of all paragraphs in this Complaint are incorporated by reference.

134. In performing the acts described above, Defendants individually by and through their own acts, or through the acts of their agents, servants, officers, and employees, knowingly conspired to present or make, use, and/or cause to be made or used, false records or statements material to false or fraudulent claims under the North Carolina Medicaid program and/or other state health care programs, in violation of N.C.G.S. §1-607(a)(3).

135. Additionally, the State of North Carolina is entitled to penalties of up to $11,000 for reach and every violation of N.C.G.S. §1-607(a)(3) by the Defendants that were committed before November 2, 2015.

136. Additionally, the State of North Carolin is entitled to penalties of up to $21,563 for reach and every violation of N.C.G.S. §1-607(a)(3) by the Defendants that were committed after November 2, 2015.

SEVENTH CLAIM FOR RELIEF
(RETALIATION—31 U.S.C. §3730(h))

137. The allegations of all paragraphs in this Complaint are incorporated by reference.

138. In performing the acts described above, Defendants individually by and through their own acts, or through the acts of its agents, servants, officers, and employees, unlawfully retaliated against Relator Kovalich in violation of 31 U.S.C. §3730(h).

139. Specifically, Defendants demoted and then terminated Relator Kovalich for engaging in protected activity pursuant to 31 U.S.C. §3730(h). As a result of Defendants' unlawful retaliation, Relator Kovalich has suffered damages in amounts to be determined at trial.

PRAYER FOR RELIEF

WHEREFORE, Relator Kovalich, on behalf of herself, the United States Government, and the State of North Carolina, prays as follows:

1. That for violations of the Federal False Claims Act, 31 U.S.C. §3729, *et seq.*, this Court enter Judgment against Defendants in an amount equal to three times the amount of damages the United States Government has sustained because of Defendants' actions, plus a civil penalty of $11,000 for each action in violation of 31 U.S.C. §3729 committed before November 2, 2015, and a civil penalty of $21,563 for each violation of 31 U.S.C. §3729 committed after November 2, 2015;

2. That for violations of the North Carolina False Claims Act, N.C.G.S. §1-605, *et seq.*, this Court enter Judgment against Defendants in an amount equal to three times the amount of damages the State of North Carolina has sustained because of Defendants' actions, plus a civil penalty of $11,000 for each action in violation of N.C.G.S. §1-607(a) committed before November 2, 2015, and a civil penalty of $21,563 for each violation of N.C.G.S. §1-607(a) committed after November 2, 2015;

3. That Relator Kovalich be awarded the maximum amount allowed pursuant to 31 U.S.C. §3730(d) and N.C.G.S. §1-610, including the costs and expenses of this action and reasonable attorneys' fees;

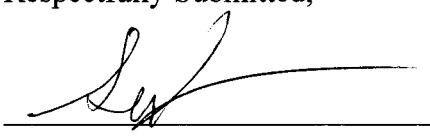
4. That Relator Kovalich be awarded all relief to which she is entitled pursuant to 31 U.S.C. §3730(h);

5. That a trial by jury be held on all issues; and

6. That the United States Government, the State of North Carolina, and Relator Kovalich receive all relief, both in law and equity, to which they reasonably be entitled.

This the 22nd day of January, 2018.

Respectfully Submitted,



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