IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

UNITED STATES *ex rel.* REBECCA KOVALICH, Plaintiff, v. PREFERRED PAIN MANAGEMENT & SPINE CARE, P.A. and DR. DAVID SPIVEY, Defendants.	)	**Civil Action No.: 1:18CV44** **JURY TRIAL DEMANDED**

THE UNITED STATES' COMPLAINT IN INTERVENTION

For its Complaint in Intervention, the United States, by and through Matthew G.T. Martin, the United States Attorney for the Middle District of North Carolina, alleges as follows:

INTRODUCTION

1. The United States brings this action against Defendants pursuant to the False Claims Act ("FCA"), 31 U.S.C. §§ 3729 *et seq.*, seeking treble damages and civil penalties, and under common law and equitable theories of recovery.

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

Winston-Salem, North Carolina. Defendant David Spivey, M.D. ("Dr. Spivey") is board-certified in anesthesiology and pain medicine. He is the president and owner of PPM.

3. As described below, PPM, through Dr. Spivey, designed and executed a scheme to maximize profits from urine drug testing ("UDT") by performing excessive amounts of UDT for essentially all patients (including those covered by Medicare, Medicaid and other federal health care programs) regardless of whether the UDT was reasonable and necessary for the diagnosis or treatment of any individual patient.

4. As PPM and Dr. Spivey were aware, Medicare only covers tests that are reasonable and necessary for the treatment or diagnosis of an individual patient's illness or injury, based on his or her medical condition. 42 U.S.C. § 1395y(a)(1)(A). The need for each test, for each patient, must be individually assessed and documented in the patient's medical chart. 42 C.F.R. § 410.32(a), (d)(2). Many patients, including those with chronic pain, do not need extensive laboratory-based UDT.

5. At Dr. Spivey's direction, PPM's in-house laboratory nonetheless performed extensive and expensive UDT for all of PPM's patients, regardless of whether the treating provider desired or ordered such testing. Contrary to industry standards, PPM simultaneously ordered both initial "screening" tests and confirmatory tests—even though the screening tests were not available at the time of the patient visits or otherwise used to determine whether confirmation testing was necessary at all. PPM then billed Medicare and other federal health care programs for both screening and confirmatory tests for

numerous drugs or drug classes per urine sample, including tests for drugs that patients were not suspected of taking, and for unnecessary confirmation of expected results.

6. Through these and other practices, from at least June 2013 through at least the end of 2016 ("the relevant time period"), Defendants knowingly submitted and caused to be submitted more than $1.5 million in false claims to federal health care programs, by billing or causing to be billed to federal health care programs claims for UDT that were not medically reasonable and necessary, in violation of the FCA.

JURISDICTION

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1345.

8. This Court may exercise personal jurisdiction over Defendants under 31 U.S.C. § 3732(a) because each Defendant resides and/or transacts business in the Middle District of North Carolina.

9. Venue is proper in this District under 31 U.S.C. § 3732 and 28 U.S.C. § 1391(b), because Defendants transact business in this District, and a substantial part of the events giving rise to this action occurred in this District.

PARTIES

10. The United States brings this action on behalf of the Department of Health and Human Services ("HHS"), which, through the Centers for Medicare and Medicaid Services ("CMS"), administers Medicare and Medicaid; on behalf of the Office of Personnel Management ("OPM"), which funds and oversees the Federal Employees Health

Benefit Program ("FEHBP") and on behalf of the Department of Veterans Affairs ("VA"), which administers the Civilian Health and Medical Program of the VA ("CHAMPVA") and the VA's Fee Basis Program.

11. Relator Rebecca Kovalich is a resident of Charleston County, South Carolina, who also resides part-time in Forsyth County, North Carolina. From around April 2014 through June 9, 2016, Ms. Kovalich was employed as PPM's Lab Administrator. Before that time, Ms. Kovalich performed contract work for PPM relating to laboratory operations.

12. Defendant Dr. Spivey is a resident of Forsyth County, North Carolina, and a physician licensed to practice medicine in North Carolina. During the relevant time period, he was PPM's owner, CEO, and President. He was previously subject to public discipline from the North Carolina Medical Board, pursuant to the terms of a September 2015 Consent Order.

13. Defendant PPM is a Professional Association authorized and existing under the laws of the State of North Carolina, with its principal place of business in Winston-Salem, North Carolina.

14. During the relevant time period, PPM participated in and submitted claims for reimbursements to federal health care programs, including Medicare, Medicaid, FEHBP, and VA programs. Upon information and belief, around 50-60% of PPM's patients during the relevant time period were Medicare beneficiaries.

LEGAL AND REGULATORY BACKGROUND

I. The False Claims Act

15. The FCA provides, in pertinent part, that any person who:

> (a)(1)(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (a)(1)(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; [or]
>
> (a)(1)(C) conspires to commit a violation of subparagraph (A) [or] (B) …

is liable to the United States for three times the amount of damages which the Government sustains, plus a civil penalty per violation. 31 U.S.C. § 3729(a). For violations occurring between September 28, 1999 and November 1, 2015, the civil penalty amounts range from a minimum of $5,500 to a maximum of $11,000. *See* 28 C.F.R. § 85.3; 64 Fed. Reg. 47099, *47103 (1999). For violations occurring on or after November 2, 2015, the civil penalty amounts range from a minimum of $11,181 to a maximum of $22,363. 28 C.F.R. § 85.5.

16. For purposes of the FCA,

> 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).

17. The FCA defines "material" to mean "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).

II. The Medicare Program

18. In 1965, Congress enacted Title XVIII of the Social Security Act, known as the Medicare program, to pay for the costs of certain health care services. *See* 42 U.S.C. §§ 1395, *et seq*. HHS is responsible for administering and supervising the Medicare program. CMS is the HHS component that is directly responsible for administering the Medicare program.

19. Entitlement to Medicare is based on age, disability, or affliction with end-stage renal disease. 42 U.S.C. §§ 426, 426-1, 426A. Individuals who are insured under Medicare are referred to as Medicare "beneficiaries."

20. The Medicare program consists of four parts: A, B, C, and D. Part B covers outpatient care, including physician services and ancillary services, such as clinical laboratory services, furnished by physicians and other providers and suppliers.[1] 42 U.S.C. § 1395k.

A. The Medicare Part B Program

21. Medicare Part B only covers services, including diagnostic laboratory services, which are reasonable and necessary for the diagnosis or treatment of an illness or injury. *See* 42 U.S.C. § 1395y(a)(1)(A) ("[N]o payment may be made under [Medicare] part A or part B . . . for any expenses incurred for items or services . . . which . . . are not

[1] In the relevant regulations, physicians and other practitioners are generally referred to as "suppliers" in the Medicare program, rather than "providers." *See* 42 C.F.R. § 400.202. This Complaint nonetheless uses the common term "provider" to refer to individual practitioners.

reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member[.]"); 42 C.F.R. § 411.15(k)(1).

22. The Secretary of HHS ("Secretary") is responsible for specifying services covered under the "reasonable and necessary" standard and has wide discretion in selecting the means for doing so. *See* 42 U.S.C. § 1395ff(a). Typically, the Secretary acts through formal regulations and sub-regulatory guidance.

23. The Secretary provides guidance to eligible providers pursuant to a series of Manuals, published by CMS, which are available to the public on the Internet. *See generally*, CMS Internet-Only Manuals (IOMs), *available at* https://www.cms.gov/regulations-and-guidance/guidance/manuals/internet-only-manuals-ioms.html (last visited October 14, 2019) (hereinafter "CMS Manuals").

24. At all times relevant to this complaint, CMS contracted with private contractors, referred to as Medicare Administrative Contractors ("MACs"), to act as agents in reviewing and paying claims submitted by health care providers. 42 U.S.C. §§ 1395h, 1395u; 42 C.F.R. §§ 421.3, 421.100, 421.104. MACs generally act on behalf of CMS to process and pay Part B claims and perform administrative functions on a regional level.

25. During the relevant time period of this Complaint, Palmetto GBA was the MAC responsible for processing Medicare Part B claims in North Carolina.

26. Medicare MACs also issue Local Coverage Determinations ("LCD"s") which identify, for their jurisdiction, procedures and services that will be covered as medically reasonable and necessary, and therefore eligible for payment under Medicare.

The LCDs specify under what clinical circumstances an item or service is considered to be reasonable and necessary.

27. Medicare regulations require providers and suppliers to certify that they meet, and will continue to meet, the requirements of the Medicare statute and regulations. 42 C.F.R. § 424.516(a)(1).

28. To participate in the Medicare program as a new enrollee, group practices and clinical laboratories must submit a Medicare Enrollment Application, Form CMS-855B. These entities must also complete Form CMS-855B to change information or to reactivate, revalidate, and/or terminate Medicare enrollment.

29. Form CMS 855-B requires, among other things, signatories to certify:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to this supplier . . . . 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 supplier's compliance with all applicable conditions of participation in Medicare. * * * I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and I will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity.

See https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/cms855b.pdf (last visited October 14, 2019).

30. An authorized official must sign the "Certification Section" in Section 15 of Form CMS-855B, which "legally and financially binds [the] supplier to all of the laws, regulations, and program instructions of the Medicare program." *Id.*

31. The National Provider Identifier ("NPI") is a standard and unique health identifier for health care providers. All providers and practitioners must have an assigned NPI number prior to enrolling in Medicare.

32. Typically, physicians are compensated for the services they provide Medicare patients on a fee-for-service basis as determined by Medicare's fee schedule. 42 U.S.C. § 1395w-4. To obtain compensation, physicians must deliver a compensable service and certify that the service was medically necessary for the health of the patient.

33. The Medicare statute requires that each request for payment or bill submitted for an item or service payable under Medicare Part B include the name and NPI for the referring physician. 42 U.S.C. § 1395l(q)(1).

34. To obtain Medicare reimbursement for certain outpatient items or services, providers and suppliers submit a claim form known as the CMS 1500 form ("CMS 1500") or its electronic equivalent, known as the 837P format. Among the information the provider or supplier includes on a CMS 1500 or through the 837P format are certain five-digit codes, including Current Procedural Terminology Codes ("CPT codes") and Healthcare Common Procedure Coding System ("HCPCS") Level II codes, that identify the services rendered and for which reimbursement is sought, and the NPI of the "rendering provider" and the "referring provider or other source." Each code corresponds to a specific service.

35. When submitting claims to Medicare on the CMS 1500, providers certify, inter alia, that (a) the services rendered are medically indicated and necessary for the health of the patient; (b) the information on the claim form is "true, accurate, and complete"; and

(c) the provider understands that "payment and satisfaction of this claim will be from Federal and State funds, and that any false claims, statements, or documents, or concealment of material fact, may be prosecuted under applicable Federal and State laws." After a February 2012 revision to the CMS 1500, providers further certify that their claims comply "with all applicable Medicare . . . laws, regulations, and program instructions for payment including but not limited to the Federal anti-kickback statute and Physician Self-Referral law (commonly known as the Stark Law)." CMS 1500 also requires providers to acknowledge that: "Any person who knowingly files a statement of claim containing any misrepresentation or any false, incomplete or misleading information may be guilty of a criminal act punishable under law and may be subject to civil penalties."

36. Similarly, when enrolling to submit claims electronically, providers certify that they will submit claims that are "accurate, complete, and truthful." https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS10164B.pdf (last visited October 14, 2019).

37. Health care providers are prohibited from knowingly presenting or causing to be presented claims for items or services that the person knew or should have known were not medically necessary, or knew or should have known were false or fraudulent. 42 U.S.C. §§ 1320a-7a(a)(1), 1320a-7(b)(7) (permitting exclusion of providers for the foregoing violations).

38. A provider has a duty to familiarize itself with the statutes, regulations, and guidelines regarding coverage for the Medicare services it provides. *Heckler v. Cmty. Health Servs. of Crawford Cty., Inc.*, 467 U.S. 51, 64 (1984).

39. Because it is not feasible for the Medicare program, or its contractors, to review medical records corresponding to each of the millions of claims for payment it receives from providers, the program relies on providers to comply with Medicare requirements and relies on providers to submit truthful and accurate certifications and claims.

40. Generally, once a provider submits a CMS 1500, or the electronic equivalent, to the Medicare program, the claim is paid directly to the provider, in reliance on the foregoing certifications, without any review of supporting documentation, including medical records.

41. During the relevant time period, Defendants billed Medicare under Part B for medical services including, but not limited to, clinical laboratory services furnished by physicians and other providers, by submitting claims for reimbursement on the CMS 1500 or its electronic equivalent to Palmetto GBA.

III. The North Carolina Medicaid Program

42. The North Carolina Medicaid Program is authorized by Title XIX of the Social Security Act. 42 U.S.C. §§ 1396 *et seq.* Medicaid is a joint federal-state program that provides health care benefits, including laboratory services coverage, for certain

groups including the poor and disabled. Each state must have a single state agency to administer the Medicaid program. 42 U.S.C. § 1396a.

43. The North Carolina Department of Health and Human Services, Division of Medical Assistance ("NCDMA") administers the Medicaid program in North Carolina and receives, processes and pays claims for services under the Medicaid program. HHS periodically reimburses NCDMA for the federal share of all qualified Medicaid claims and ensures that the state complies with minimum standards in the administration of the program.

44. Providers bill Medicaid for services provided to Medicaid beneficiaries by submitting claim forms electronically to NCDMA through its fiscal agent. NCDMA's fiscal agent was HP Enterprise Services until 2013, when NCDMA began using Computer Sciences Corporation, which later became CSRA Inc. Since April 2018, following an acquisition, CSRA has been known as GDIT.

45. A Medicaid provider must sign a Provider Agreement to participate in Medicaid. In so doing, the provider agrees to learn and adhere to Medicaid program policies, along with other federal and state regulations and Medicaid billing instructions. The provider also acknowledges that Medicaid payment is conditioned upon compliance with Medicaid laws, regulations, and program instructions.

46. Medicaid requires compliance with applicable statutes, regulations, and guidelines, as a precondition of government payment or reimbursement.

47. North Carolina state Medicaid providers may only submit claims for reimbursement that are medically necessary and accurately billed to Medicaid.

48. As with the Medicare program, a Medicaid provider must submit an equivalent version of the CMS 1500 for claims for reimbursement.

49. Medicaid requires compliance with the terms of the claim form as a precondition of government payment.

50. As a condition of payment, the Medicaid provider furnishes and certifies to certain information on the Medicaid claims form or submission, including the identity of the patient, the provider number, the procedure for which the provider is billing, the identity of the providers who are billing and rendering the service, and the value billed for the services provided.

51. NCDMA issues Medicaid policies, bulletins, and other materials to provide guidance to providers regarding which services are reimbursable by Medicaid and how to bill those services. *See* 42 C.F.R. § 431.18.

52. Because it is not feasible for the Medicaid program, or its contractors, to review medical records corresponding to each of the claims for payment it receives from providers, the program relies on providers to comply with Medicaid requirements and relies on providers to submit truthful and accurate certifications and claims.

53. During the relevant time period, Defendants billed Medicaid for medical services including, but not limited to, clinical laboratory services furnished by physicians

and other providers, by submitting claims for reimbursement to NCDMA through its fiscal agent.

IV. FEHBP

54. Congress established the FEHBP to provide health benefits to civilian federal employees. *See generally* 5 U.S.C. § 8901 *et seq.* The FEHBP is administered by OPM, which, in turn, contracts with various health insurance carriers to provide services to FEHBP members and their families. *See id.* §§ 8902, 8909(a). The OPM makes payments to the insurance carriers for services rendered to FEHPB members using funds from the Employee Benefits Fund, which the United States Treasury holds and invests. *Id.* § 8909.

55. As a condition of funding, the FEHBP requires that covered services be medically necessary to prevent, diagnose, or treat an illness, disease, injury or condition.

56. During the relevant time period, Dr. Spivey and PPM submitted claims to health insurance carriers in the FEHBP program for reimbursement for services rendered to federal government employees and their families.

V. VA Health Benefits

57. In addition to services provided at VA facilities, the VA also operates programs through which it reimburses medical treatment for eligible beneficiaries. During the relevant time period, Defendants participated in these programs.

58. CHAMPVA, the Civilian Health and Medical Program of the VA, is a comprehensive health care program in which VA shares the cost of covered health care services and supplies with eligible beneficiaries. One of the eligible categories for

CHAMPVA is the spouse or child of a veteran who has been rated permanently and totally disabled for a service-connected disability. CHAMPVA is a secondary payer to Medicare and reimburses beneficiaries for costs not covered by Medicare.

59. CHAMPVA conditions payment for medical services and supplies on the requirement that they "are medically necessary and appropriate for the treatment," and specifically excludes services and supplies that "are not medically … necessary for the diagnosis or treatment of a covered condition." 38 C.F.R. § 17.272(a); *see also* § 17.272(a)(1) (excluding from coverage "[s]ervices, procedures or supplies for which the beneficiary has no legal obligation to pay).

60. The CHAMPVA Policy Manual (03.01.01) requires that all claims from providers must be submitted on a standard billing form, and specifically lists the CMS-1500 as an acceptable paper format.

61. The CHAMPVA Policy Manual (03.05.12) provides for reimbursement of laboratory services, defined as "services necessary for, and rendered in connection with…. diagnosis in the treatment of an illness or injury."

62. CHAMPVA reimburses the lower of the CHAMPVA Maximum Allowable Charge ("CMAC"), the VA prevailing charge, and the billed charge.

63. The Fee Basis VA Program allows veterans to be seen by a community provider, for health care provided outside the VA. *See* 38 C.F.R. § 17.93. When VA facilities cannot provide all of the necessary medical care and services required by its patients due to geographic inaccessibility, medical urgency, or when it is economically

advantageous to obtain care through the community, the VA may authorize payment for medical care in private sector facilities. Outpatient providers submit bills for service to the authorizing VA facility. The VA facility reviews the bills and transmits payment messages to the VA's Central Fee payment center at the Austin Information Technology Center (AITC).

VI. Urine Drug Testing

A. Regulatory Requirements for Laboratory Test Services

64. Laboratory services must meet all applicable requirements of the Clinical Laboratory Improvement Amendments of 1988 ("CLIA"), 42 U.S.C. § 263a, as set forth at 42 C.F.R. Part 493.

65. "Clinical laboratory services involve the . . . examination of materials derived from the human body for the diagnosis, prevention, or treatment of a disease or assessment of a medical condition." Medicare Benefit Policy Manual ("MBPM"), Pub. 100-02, Ch. 15, § 80.1 (issued 11/19/07), available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf (last visited October 11, 2019).

66. Medicare regulations establish that (1) laboratory tests must be ordered by the physician treating the patient for the treatment of a specific illness or injury; (2) laboratory test orders that are not individualized to patient need (or for which the need is not documented in the patient chart) are not covered services; and (3) claims for such

laboratory services that do not meet these requirements are ineligible for payment and must be denied. *See* 42 C.F.R. § 410.32.

67. Pursuant to 42 C.F.R. § 410.32(a), all diagnostic tests "must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary." (Emphasis added). The MPBM's "Requirements for Ordering and Following Orders for Diagnostic Tests" define an "order" as "a communication from the treating physician/practitioner requesting that a diagnostic test be performed for a beneficiary . . . . [T]he physician must clearly document, in the medical record his or her intent that the test be performed." MPBM, Ch. 15, § 80.6.1 (issued 8/29/08).

68. To assess whether those services are reasonable and necessary and whether reimbursement is appropriate, Medicare requires proper and complete documentation of the services rendered to beneficiaries. In particular, the Medicare statute provides that:

> No payment shall be made to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person under this part for the period with respect to which the amounts are being paid or for any prior period.

42 U.S.C. § 1395l(e). As described above, the North Carolina Medicaid program imposes similar requirements.

69. Medicare regulations expressly state that a laboratory's claim for a service will be denied if there is not sufficient documentation in the patient's medical record to establish that the service was reasonable and necessary. 42 C.F.R. § 410.32(d)(3).

70. The Department of Health and Human Services, Office of Inspector General ("HHS-OIG") also published Compliance Program Guidance for Clinical Laboratories in the Federal Register. 63 Fed. Reg. 45076 (Aug. 24, 1998), available at https://www.oig.hhs.gov/authorities/docs/cpglab.pdf (last visited Oct. 16, 2019). Among other things, the HHS-OIG guidance clarifies that laboratory order forms should emphasize the need for a justification and assessment of each test ordered: "Medicare may deny payment for a test . . . which does not meet the Medicare coverage criteria (e.g., done for screening purposes) or where documentation in the entire patient record . . . does not support that the rests were reasonable or necessary for a given patient." *Id.* at 45079.

B. Types of Urine Drug Tests

71. Drug testing is used to determine the presence or absence of drugs or metabolites, *i.e.*, a byproduct of a drug after it is metabolized by the body. Drug testing can be "qualitative" (to determine the presence or absence of a drug or metabolite) or "quantitative" (to provide a numerical concentration of a drug or metabolite). Different testing methodologies have different capabilities and limitations.

72. Drug testing is performed in a number of contexts. In the clinical pain management context—particularly in the case of management through long-term opioid

use—drug testing can be used to monitor whether patients are taking prescribed drugs and adhering to treatment, or are taking or abusing drugs not prescribed.

73. Urine is commonly used for drug testing and is the medium for testing that was used during the relevant time period by PPM.

74. Urine drug testing ("UDT") can be accomplished in two phases: first, presumptive testing (sometimes referred to as "screening" testing, which is usually qualitative) and, when necessary, definitive testing (sometimes referred to as "confirmatory" testing). The initial presumptive test gives a positive result when the presence of a drug or metabolite in the urine exceeds a given concentration and a negative result when the drug or metabolite is below this concentration.

75. There are two primary methods of performing presumptive tests. These tests can be performed using a point of care ("POC") testing cup or test strips that are dipped into a urine sample. POC testing cups and test strips are relatively inexpensive and typically feature a panel of 11 or 12 treated strips, one for each drug or drug class being tested. When the strips are dipped into the urine specimen, a change in color signifies the presence or absence of the specific drug or drug class for which each strip tests. Using POC cups or strips, a provider can receive almost immediate results for the substances tested in his or her own office. Alternatively, presumptive tests can be performed by an immunoassay analyzer, a device found in laboratories and in some physicians' offices, which rapidly determines the presence or absence of the tested drugs. Immunoassay tests are generally reimbursed at higher levels than POC test cups and strips.

76. Under CLIA, CMS oversees all laboratory testing services. UDT performed using POC test cups and test strips is generally "CLIA-waived." CLIA-waived tests are categorized as simple laboratory examinations and procedures that have an insignificant risk of an erroneous result or pose no risk of harm to the patient if the test is performed incorrectly. 43 C.F.R. § 493.15(b). To perform CLIA-waived tests, physicians need to enroll in CLIA and obtain a waiver. 42 C.F.R. § 493.35. To operate an immunoassay analyzer, however, physician practices and laboratories are generally required to obtain a CLIA certification to perform moderate or high complexity laboratory tests. 42 C.F.R. §§ 493.20, 493.25.

77. During the relevant time period, PPM owned an immunoassay analyzer and performed its own presumptive testing using that equipment. PPM operated under CLIA certification number 34D2054245.

78. Presumptive UDT can be useful in making point of care decisions when the patient is present, if the results are available at the time of the patient visit. It can also be used to inform the need for further confirmatory testing, for instance, to rule out a false positive or to determine the concentration of a particular drug.

79. Definitive or confirmatory UDT is generally conducted in laboratories that can perform mass spectrometry and either gas or liquid chromatography. These testing methodologies can provide quantitative results, identifying the concentration of a drug or metabolite in a sample. The equipment required to perform definitive UDT is more sophisticated, and expensive, than the equipment for presumptive or screening tests, and

therefore, most treating providers are not equipped to perform definitive testing themselves. Instead, treating providers typically refer definitive drug testing to independent laboratories.

80. As discussed below, however, beginning around June 2013, PPM began performing its own definitive UDT, using mass spectrometry and liquid chromatography ("LCMS"). PPM's LCMS machine enabled it to test urine specimens for numerous drugs and metabolites during a single run of a sample.

81. The clinical value of definitive UDT depends in part on whether the presumptive test result is expected or unexpected, as well as the patient's history of drug abuse, history of medication adherence and compliance, clinical presentation, and/or medical history.

82. However, "[c]hromatography generally is reserved for confirmatory or definitive testing when the initial [screening] results are unexpected." Raouf et al., *A Practical Guide to Urine Drug Monitoring.* FEDERAL PRACTITIONER, April 2018, at 41. For example, if a patient is prescribed a certain drug, a positive presumptive test result for that class of drug would be expected. If the test result is negative for that class of drug, however, and the patient insists that she is taking her medication as prescribed, a definitive laboratory test to "confirm" this unexpected negative result may be reasonable and necessary.

83. Similarly, if a patient's presumptive test yielded a positive result for a non-prescribed or illicit drug, then definitive UDT to evaluate this unexpected positive result

may, under certain circumstances and depending on individual patient factors, be reasonable and necessary.

84. In some instances, definitive UDT of an expected presumptive test result or for a substance not available on a presumptive test may also be medically reasonable and necessary. For example, aberrant patient behavior, a patient's unexpected clinical presentation, and/or a patient's particular history of drug abuse may justify specific definitive UDT. The reasonableness and necessity of such tests, however, depends on the presentation and provider assessment of each individual patient and that patient's individual circumstances. If a presumptive test is negative for an illicit drug or a drug not prescribed, and there is nothing in the patient's presentation or drug abuse history to indicate abuse of that drug, then routine definitive UDT for that drug is not reasonable and necessary for the treatment and diagnosis of that patient, and therefore not covered by federal health care programs.

85. In all situations, definitive UDT should be used only to the limited extent it is necessary for an individual patient, based on that individual's presumptive test results and other factors specific to that individual. Frequency of definitive UDT should also be based on an assessment of individual patient risk. Widespread definitive UDT should not be ordered as a matter of course.

C. Guidelines on Urine Drug Testing

86. Several organizations have published guidelines regarding UDT in the clinical setting, including UDT for chronic pain patients prescribed opioids.

87. None of these guidelines recommended the routine use of quantitative testing to "confirm" expected negative immunoassay results.

88. Instead, when these guidelines addressed the need for confirmatory testing, they generally recommended a UDT protocol whereby an immunoassay test is administered first and then only *unexpected* results are referred for confirmatory testing via a quantitative method such as LCMS.

89. For example, the Washington State Agency Medical Directors' Group Interagency Guideline on Opioid Dosing for Chronic Non-Cancer Pain ("Washington State Guidelines"), as updated in 2010, states that the purpose of the immunoassay test is to provide rapid results that should help avoid further, unnecessary laboratory confirmation testing of expected results by "guid[ing] appropriate utilization of confirmatory testing." Washington State Agency Medical Directors' Group, *Interagency Guideline on Opioid Dosing for Chronic Non-cancer Pain*, 2010 update, available at http://agencymeddirectors.wa.gov/files/opioidgdline.pdf (last visited Oct. 16, 2019).

90. The 2010 Washington State Guidelines recommended confirmation testing only for positive results: "When the immunoassay result is unexpected and the patient does not acknowledge or credibly explain the result, a confirmatory test . . . should be ordered." *Id.* Similar recommendations were made by other authoritative entities, including the American Society of Interventional Pain Physicians ("ASIPP"). *See* Manchikanti *et al.*, PAIN PHYSICIAN 2012; 15:S67-S116, ISSN 1533-3159, "ASIPP Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain" (recommending baseline

screening at initial visit and then adherence monitoring with "confirmation for accuracy with chromatography in select cases") (emphasis added).

91. Dr. Spivey is, and, upon information and belief, was during the relevant time period, a member of ASIPP. The "Pain Physician" journal, cited in the preceding and following paragraphs, is the official publication of ASIPP.

92. ASIPP published in 2011, and reprinted in 2012, a diagram charting "algorithmic steps in urine drug testing in chronic pain." *Id.* at S92. The diagram recommends baseline testing at the point of care, using an immunoassay test. *If* there is an inappropriate or unexplained result, confirmatory testing is warranted for that result. If results are appropriate, no confirmatory testing is needed, and the algorithm suggests a *random* point of care (i.e., immunoassay screening) test in 1-3 months. And if the results of that test are appropriate, the algorithm suggests follow-up screening in 6-12 months. In short, confirmatory testing is recommended only for unexplained results. *See generally id.*

93. "[I]t would be abusive to an economically strained health care system to routinely screen every patient at every visit." Owen *et al. Urine drug testing: current recommendations and best practices*. PAIN PHYSICIAN, 2012;15:ES126, available at https://www.painphysicianjournal.com/current/pdf?article=MTcxMA%3D%3D&journal=68 (last visited Oct. 16, 2019).

94. In 2015, the Department of Justice resolved a FCA case against Millennium Laboratories, due to Millennium's widespread inappropriate use of UDT, including inappropriate standing orders or recommended "panels" for medically unnecessary

confirmation testing. The settlement was widely reported in national media and industry news sources.

D. Medicare and Medicaid Coverage of UDT

95. Local Coverage Determinations ("LCDs") are determinations issued by MACs "respecting whether or not a particular item or service is covered" by the MAC. 42 U.S.C. § 1395ff(f)(2)(B). At various points during the relevant time period, Palmetto GBA issued LCDs regarding UDT. These LCDs were made available to all providers within Palmetto GBA's jurisdiction. In general, these LCDs provided guidance regarding the appropriate indications for and expected frequency of presumptive and definitive UDT in order to be covered by Medicare. As part of that guidance, the LCDs indicated that the use of routine standing orders for UDT is not reasonable and necessary.

96. For example, LCD L35105 took effect in Medicare Jurisdiction M, which includes North Carolina, on December 15, 2014, and was in effect until September 30, 2015.[2] The LCD provided that presumptive UDT "may be ordered when it is necessary to rapidly obtain and integrate results into clinical assessment and treatment decisions." The LCD also specified that definitive UDT is reasonable and necessary under certain circumstances, but that the rationale for ordering definitive UDT must be documented in the patient's record. The LCD makes clear that "the same physician-defined profile [of definitive testing] is not reasonable and necessary for every patient in a physician's

[2] As discussed below, LCD L35724 took effect on October 1, 2015, to reflect a switch from the ICD-9 to ICD-10 diagnosis codes.

practice. Definitive UDT orders should be individualized based on clinical history and risk assessment, and must be documented in the medical record."

97. LCD L35105 includes specific guidance for UDT in pain management practice. In particular, medical necessity "must be based on patient-specific elements identified during the clinical assessment, and documented by the clinician." At a minimum, the documentation must include a risk assessment plan. And frequency of testing after an initial baseline visit "must be based on individual patient needs substantiated by documentation in the patient's medical record." Frequency of testing "must be based on a complete clinical assessment of the individual's risk potential for abuse and diversion using a validated risk assessment interview or questionnaire and should include the patient's response to prescribed medications and the side effects of medications."

98. The LCD also notes that UDT should be performed at random, rather than regular intervals, at a frequency ranging from once per year to 1-3 times every 3 months, based on patient risk profile. In short, monthly definitive testing is only appropriate for high risk patients, if the particular patient's risk profile and screening results support such frequency of testing, and only if the testing is tailored to that specific patient's history and presentation.

99. LCD L35105 is clear that "Blanket Orders"—defined as "an identical order for all patients in a clinician's practice without individualized decision-making at every visit"—are "non-covered services." The LCD also lists other non-covered services:

a. "Routine standing orders for all patients in a physician's practice are not reasonable and necessary."

b. "Confirmation/definitive identification of a presumptive UDT negative result is not reasonable and necessary except when a patient on a prescribed medication should have had a presumptive positive result."

100. LCD L35105's non-covered services were consistent with ASIPP's existing 2011 and 2012 industry guidelines, as discussed above.

101. On October 1, 2015, the existing LCD was updated to reflect new diagnosis and billing codes, and the new LCD L35724 took effect in Medicare Jurisdiction M, which includes North Carolina. LCD L35724 continued the coverage guidance from L 35105 regarding presumptive and definitive UDT and required that the following elements, at a minimum, be used to determine medical necessity: (1) the patient's history, physical examination, and previous laboratory findings; (2) the patient's current treatment plan; (3) the patient's prescribed medication(s); and (4) and the patient's risk assessment plan. This LCD also stated that definitive UDT orders "should be individualized based on clinical history and risk assessment, and must be documented in the medical record." The LCD also indicated that the use of routine standing orders for all patients in a provider's practice is not reasonable and necessary, and that "blanket orders"—*i.e.*, identical orders for all patients in a practice without individualized decision making at every visit—were not covered services.

102. Relating to Medicaid coverage, in May 2016, NCDMA issued a Special Bulletin to providers regarding Urine Drug Screening. The Bulletin provided that "Definitive drug testing must **only** be performed in the presence of an unanticipated result on a presumptive drug screen, and only for the drug class(es) that produced the unanticipated result."

103. To prevent abuse, North Carolina Medicaid issued Clinical Coverage Policy No.1S-8, reiterating that medical necessity for drug testing "must be beneficiary-specific and based on elements identified during clinical assessment," which must be documented in the patient's medical record. The Policy officially became effective on January 1, 2017, but Medicaid began reimbursing for new UDT codes (corresponding to the below Medicare codes) in January 2016.

104. Under Policy No. 1S-8, much like the LCDs issued by Palmetto, the risk profile of a beneficiary must be based on a validated risk assessment interview or questionnaire. In the case of a low-risk chronic pain patient, random presumptive and definitive testing should not exceed 1-2 times **per year**, and only "prescribed medications, non-prescribed medications that may pose a safety risk if taken concomitantly with prescribed medication(s), and illicit substances based on beneficiary history, clinical presentation, and community usage." In the case of a moderate-risk patient, random presumptive and definitive testing should only occur 2-4 times per year, and only for "prescribed medications, non-prescribed medications that may pose a safety risk if taken concomitantly with prescribed medication(s), and illicit substances based on beneficiary

history, clinical presentation, and community usage." And lastly, in the case of a high-risk beneficiary, random presumptive and definitive testing should only occur 1-3 times every 90 days, and only for "prescribed medications, non-prescribed medications that may pose a safety risk if taken concomitantly with prescribed medication(s), and illicit substances based on beneficiary history, clinical presentation, and community usage."

105. Defendants had knowledge of these LCDs, including through active participation in industry groups that lobbied for favorable reimbursement rates, but nevertheless continued to refer orders for, or perform, unreasonable and unnecessary UDT that was billed to Medicare, Medicaid, FEBHP and the VA, as described below.

E. Reimbursements for Laboratory Tests

106. Different types of urine drug tests have different costs.

107. During the relevant time period, Medicare generally reimbursed presumptive UDT based on the methodology (analyzer versus POC test cup or strip) used by the physician practice or the complexity of the test under CLIA. During the relevant time period, POC tests were reimbursed by Medicare at a rate of $12-25 and analyzer tests were reimbursed by Medicare at a rate of $65-$100. Most frequently, Defendants billed for an immunoassay screen, using code G0431 (until the code was deleted in 2016), which was reimbursed between $95-100. Beginning in January 2016, code G0431 was replaced with G0479, which was reimbursed by Medicare at a rate of $79.25.

108. Prior to January 1, 2016, definitive UDT was generally billed using individual CPT codes for each and every drug or drug class tested. These tests were reimbursed at around $15-$50 for each individual definitive or confirmatory test.

109. In response to concerns regarding the potential for overpayment when billing for each individual drug test, CMS announced in 2015 that it would revise the way that it reimbursed definitive UDT under the Medicare program

110. In or around late spring in 2015, Palmetto GBA announced that, in anticipation of upcoming changes to Medicare reimbursement of definitive UDT, all definitive UDT should be billed under a single code (84999), with a text string indicating the number of specific tests billed. The tests would be reimbursed in "tiers," with maximum reimbursement of $250.

111. Effective January 1, 2016, CMS implemented its changes to UDT reimbursement rates. See Calendar Year (CY) 2016 Clinical Laboratory Fee Schedule (CLFS) Final Determinations, available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/Archive-Test-Codes-and-Payment-Determinations-files-.zip (last viewed October 11, 2019). In particular, rather than continuing to permit providers to bill for each and every individual definitive drug test, CMS created four CPT codes for definitive UDT: G0480, G0481, G0482, and G0483. Only one of these four definitive UDT codes may be billed per patient per day. *Id.* The following table defines these codes and their corresponding 2016 Medicare reimbursement amount:

Definitive UDT Code	Definition	2016 Medicare Reimbursement
G0480	Definitive drug testing for 1-7 drug classes, including metabolites.	$79.94
G0481	Definitive drug testing for 8-14 drug classes, including metabolites.	$122.99
G0482	Definitive drug testing for 15-21 drug classes, including metabolites.	$166.03
G0483	Definitive drug testing for 22 or more drug classes, including	$215.23

See id.; 2016 Clinical Diagnostic Laboratory Fee Schedule, available at https://www.cms.gov/apps/ama/license.asp?file=/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/16CLAB.zip (last visited October 11, 2019). Medicaid began using these codes in 2016 as well, with slightly different reimbursement rates.

DEFENDANTS' FRAUDULENT SCHEME

112. As detailed below, under the direction and control of Dr. Spivey, PPM routinely ordered excessive UDT for all patients (including Medicare, Medicaid, FEHBP and VA beneficiaries), regardless of individual patient assessment or need. Defendants also submitted, or caused the submission of, medically unnecessary UDT claims to federal health care programs. Defendants submitted, or caused the submission of, these claims with knowledge that they were medically unnecessary—or at least in reckless disregard of that fact.

113. During the relevant time period, Dr. Spivey participated in the IPPAT Coalition, Inc., an industry group representing pain management physicians that monitored Medicare coverage determinations and lobbied for favorable laboratory testing reimbursement rates. As a result, he was highly attuned to reimbursement requirements and rates during the relevant time period.

114. In addition to Dr. Spivey, PPM also employed other physicians, physician assistants ("PAs"), and nurse practitioners ("NPs") during the relevant time period. Dr. Spivey supervised some PAs and NPs, but generally only saw patients for complex procedures, rather than routine management. He nonetheless controlled all of PPM's policies with respect to frequency of UDT and type of UDT ordered.

115. During routine office visits with providers—as often as every month—PPM patients were asked to provide a urine sample for testing.

116. PPM's practices with respect to UDT changed dramatically in summer 2013.

117. Prior to June 2013, PPM performed only point-of-care presumptive (or screening) UDT at its facilities. If a test yielded a positive result for a specific substance, PPM would send the sample to Quest Diagnostics, Incorporated for definitive (or confirmatory) testing. However, when PPM sent a sample to Quest, it only requested and received confirmation testing for the specific substance or substances that were flagged on the screening test.

118. Consistent with this practice, PPM's patient notes from this time simply order "a quantitative 11-panel drug test," without reference to automatic confirmation testing.

119. In early 2013, however, PPM purchased its own Liquid Chromatography-Mass Spectrometry ("LCMS") machine. Once the machine was operational and certified, in or around June 2013, PPM began performing its own confirmation testing using the (expensive) in-house LCMS machine.

120. Once PPM had the ability to perform—and bill for—confirmation UDT in-house, its UDT practices changed, at Dr. Spivey's direction. PPM performed presumptive screening tests, alcohol tests, and excessive confirmatory testing for all patients, at every or nearly every pain management visit, without regard to individual risk, patient history, or medical necessity.

121. PPM ordered the screening tests and confirmatory tests at the same time, and on the same form. The results for the screening tests were not available before confirmatory tests were ordered. PPM's providers therefore could not have used presumptive tests to inform the need for confirmatory testing. In addition, the results of the presumptive screening tests were not available before patients left the office, and patients were given prescriptions before the screening results were available. PPM thus did not alter patient care based on the initial screening results. As a result, the screening tests were not medically reasonable and necessary for diagnosis or treatment.

122. PPM also routinely ordered testing for alcohol use as part of the initial screening on a monthly basis regardless of individualized patient risk or need. The alcohol test was part of PPM's immunoassay screening panel. However, from at least June 2013 until Medicare changed the relevant billing codes, PPM billed Medicare for both the G0431 code (screen for multiple drug classes by immunoassay "per patient encounter") and the 82055 code (alcohol test) separately, effectively seeking reimbursement twice for the same test and sample.

123. PPM used a paper requisition form, or "LCMS Confirmation Lab Sheet," for its UDT ordering. Until PPM started doing its own confirmation testing, it used a requisition form that allowed a provider to select each drug individually to be tested. No "panels" were listed on this sheet. At Dr. Spivey's direction, in July 2013, PPM prepared a new form that encouraged providers to select a large subgroup of tests in a "panel," such as a "drugs of abuse panel." This requisition form was implemented and in use around early 2014.

124. Despite this apparent discretion for individual providers, PPM's LCMS was configured to test only for all available substances, and was not ever configured on a patient-by-patient basis to test for individual drugs or metabolites, or any specific subgroup of drugs or metabolites.

125. As a result, regardless of how any particular requisition form was completed—and even if the treating provider originally selected only one or two specific panels or substances for testing—PPM performed confirmatory tests for all available

substances. This was true even for substances that were at low risk for abuse by pain management patients, such as PCP. As explained in more detail below, PPM billed for between 7-14 individual confirmation tests per patient through April 2015, then sought reimbursement at the highest available "tier" (i.e., for the largest number of tests) thereafter.

126. Patients were tested uniformly regardless of whether they were high-risk or not, and regardless of whether their prior tests were consistent with clinical expectations.

127. As just one example, and as detailed with respect to specific patients below, from approximately June 2013 through May 2017, PPM received payment from Medicare alone in excess of $66,528.24 for UDT involving phencyclidine ("PCP") (CPT Code 83992). PCP is not a commonly abused drug, yet PPM routinely tested all patients for PCP use, including patients in their 70s and 80s who were unlikely to be using PCP. PPM then billed Medicare for these medically unnecessary tests. *See generally* Weaver & Mathews. "Doctors cash in on drug tests for seniors, and Medicare pays the bill." THE WALL STREET JOURNAL. Nov. 10, 2014, *available at*: https://www.wsj.com/articles/doctors-cash-in-on-drug-tests-for-seniors-and-medicare-pays-the-bill-1415676782 (last accessed Oct. 7, 2019).

128. By 2014, other individual providers at PPM had no control over whether their patients received confirmation testing at all, how often they were tested, nor which substances were included in confirmation testing. Dr. Spivey directed that testing be performed at every visit, and for a full panel of tests. These policies were conveyed through

word of mouth or at staff meetings. And as explained above, even if a provider did not select every test on the requisition form, PPM tested for all available substances.

129. Around the middle of 2015, Dr. Spivey attended a Palmetto GBA meeting, and learned about Medicare's changes to a tiered reimbursement model, limiting the ceiling on UDT reimbursement and profitability. He was upset about this change. As a result, Dr. Spivey began exploring ways to perform even more UDT, and also pressured other PPM providers to increase their utilization of additional procedures, such as epidural injections.

130. As explained above, around this time, Palmetto directed Medicare providers to start billing confirmatory UDT under the 84999 code, using different "tiers" depending on how many tests were ordered, in anticipation of the transition to new tiered codes in 2016. The reimbursement rates ranged from $186-$250, depending on the number of tests ordered.

131. PPM thus changed its requisition form again, in or around late spring to summer 2015, this time adding a check box for "ALL DRUGS AND METABOLITES....MEDICARE ONLY," and referencing the 84999 code. This check box did not offer treating providers an option to select any specific individual confirmatory tests. Instead, PPM continued to perform all available tests for all patients, and consistently billed for the highest possible reimbursement. PPM had no Medicare claims reimbursed at the $186 tier. Of 1655 paid claims, 1202 were reimbursed at $245, and 361 were reimbursed at $230.50. In short, PPM was billing at or near the maximum number of confirmatory tests for all of its patients, without regard to medical necessity.

132. Once the new Medicare tired pricing for confirmatory testing took effect, PPM again consistently, and almost exclusively, billed for the highest possible number of tests. From January 1, 2016 through May 24, 2017, PPM billed just two claims for the "1-7 [drug] classes" code (G0480), zero claims for the "8-14 classes" code (G0481), zero claims for the "15-21 classes" code (G0482), and two hundred and eleven claims for the "22+ classes" code (G0483).

A. Illustrations - Individual Patient Testing and Billing

133. Patient S.M. provides an illustration of the changes in PPM's testing and billing practices once PPM began performing its own confirmation testing.

134. Patient S.M. visited PPM on March 5, 2013. No UDT screen was ordered on that date. The notes from the visit indicate that the last screen was on January 31, 2013 and was appropriate. Patient S.M. visited PPM again on April 2, 2013. A screen was ordered on this date. It was positive only for benzodiazepines and oxycodone. PPM sent the sample to Quest for confirmation only of benzodiazepines and opiates.

135. Patient S.M. visited PPM again on April 30, 2013. No screen was ordered at that time. Patient S.M. then visited PPM on May 28, 2013. PPM performed a screen, which showed positive results only for oxycodone. PPM sent the sample to Quest for confirmation only of opiates.

136. After PPM began its in-house confirmation testing, patient S.M. began receiving drastically more screening and confirmation testing.

137. Between August 2013 and November 2015, S.M. visited PPM twenty-four times. The only visit at which no UDT was performed was a single visit on July 22, 2014. At every other visit, PPM performed both screening and multiple unnecessary confirmation tests, contrary to its previous practice with this patient.

138. For a date of service on August 1, 2013, PPM performed and billed—in addition to a drug screen, ethanol assay, creatinine assay, and Ph assay—twelve separate confirmatory tests, for PCP, methadone, two separate amphetamine tests, cocaine, and other drugs. Medicare reimbursed $433.33 for the tests on this date. Defendants knew that these claims for UDT were not reasonable and necessary and were false.

139. For S.M.'s next visit on October 8, 2013, PPM performed and billed—in addition to a drug screen, ethanol assay, creatinine assay, and Ph assay—ten separate confirmatory tests, for PCP, barbiturates, cocaine, and amphetamines, among other substances. Medicare reimbursed $485.78 for this unnecessary UDT. Defendants knew that these claims for UDT were not reasonable and necessary and were false.

140. For S.M.'s next visit on December 4, 2013, PPM performed and billed—in addition to a drug screen, ethanol assay, creatinine assay, and Ph assay—ten separate confirmatory tests, for PCP, barbiturates, cocaine, and amphetamines, among other substances. Medicare reimbursed $485.78 for this unnecessary UDT. Defendants knew that these claims for UDT were not reasonable and necessary and were false.

141. For S.M.'s next visit on January 28, 2014, PPM performed and billed—in addition to a drug screen, ethanol assay, creatinine assay, and Ph assay—ten separate

confirmatory tests, for PCP, barbiturates, cocaine, and amphetamines, among other substances. Medicare reimbursed $482.15 for this unnecessary UDT. Defendants knew that these claims for UDT were not reasonable and necessary and were false.

142. S.M. visited PPM again on February 25, 2014, March 25, 2014, April 24, 2014, May 22, 2014, June 24, 2014, September 25, 2014, October 22, 2014, November 19, 2014, December 22, 2014, January 12, 2015, February 16, 2015, March 16, 2015, April 15, 2015, May 13, 2015, June 30, 2015, July 28, 2015, September 9, 2015, September 30, 2015, and November 25, 2015.

143. Each time, PPM performed and billed for multiple medically unnecessary confirmation tests, just as on prior visits. Prior to April 2015, PPM billed these confirmation tests individually. Beginning in April 2015, PPM began billing S.M.'s confirmation tests under the 84999 code, seeking maximum reimbursement based on a high number of tests performed. Medicare reimbursed $8,095.88 for medically unnecessary UDT resulting from S.M.'s visits between February 2014 and November 2015. Defendants knew that these claims for UDT were not reasonable and necessary and were false.

144. Patient T.A. provides an illustration of Dr. Spivey's blanket order overriding the treating provider's decision.

145. Patient T.A. visited PPM on May 28, 2014, and provided a specimen for testing. The attending Physician Assistant indicated on the requisition form that, in addition to the presumptive screening test, the patient should be tested for six individual drugs from the "drugs of abuse" panel, excluding MDMA, heroin, and PCP. Similarly,

rather than selecting a full "analgesic" panel, the provider selected only certain drugs to be tested for confirmation.

146. Despite these limited selections by the provider, PPM's lab nonetheless tested for all available substances, rather than only those individual tests selected in the requisition form. PPM also tested for, and billed for, a definitive PCP test, even though the treating provider did not order that test. Medicare reimbursed $19.65 for the PCP test performed on this date. Defendants knew that this claim for UDT was not reasonable and necessary and was false.

147. Patient D.E. provides an example of overutilization and unnecessary confirmatory testing, including a blanket order overriding the treating provider's selected tests.

148. Patient D.E. was seen at PPM on March 9, 2015. A UDT sample was collected on that date. Patient records from the visit indicate that "no aberrant behaviors [were] detected," and that prior drug test results were negative for illicit drugs. The provider completed a requisition form requesting a screening test, a "drugs of abuse" panel, and an opiate panel.

149. PPM performed both a presumptive screening test and a confirmatory drug test, for all available drugs, including substances that had not been selected on the requisition form. The screening results were not available until March 10, 2015, after D.E.'s visit. The screening test results were consistent with the medication prescribed, and no other drugs were indicated. Because PPM ordered the screening and confirmatory tests

simultaneously, however, these results had no impact on which confirmatory testing PPM performed. Because the screening results were not available at the time of the patient's appointment, the results had no impact on patient care on that date, nor did the results impact whether D.E. received a prescription on that day. Medicaid reimbursed $483.78 for those tests. Defendants knew that these claims for UDT were not reasonable and necessary and were false.

150. Patient D.E. was also seen at PPM on April 18, 2015, May 11, 2015, and June 8, 2015. On each occasion, a sample was collected. On each occasion, patient records from the visit indicate that no aberrant behaviors were detected, and previous test results from prior visits were consistent with the prescribed medication regime. On each occasion, the provider ordered both screening and confirmatory tests, and only selected the "drugs of abuse" and "opiate" panels. And on each occasion, PPM nonetheless tested for the full available panel of drugs. Medicaid reimbursed UDT claims totaling $464.60 for the April 18, 2015 visit, $483.78 for the May 11, 2015 visit, and $343.33 for the June 8, 2015 visit. Defendants knew that these claims for UDT were not reasonable and necessary and were false.

151. Patient L.D. provides an example of UDT overutilization, particularly in the case of a low-risk patient.

152. Patient L.D. had a claims history with PPM dating back to at least 2012. PPM's testing practices with respect to patient L.D. prior to use of its LCMD machine in summer 2013 illustrate the change in testing and billing as of that time.

153. Between January 2012 and May 2013, patient L.D. visited PPM approximately seventeen times, for back pain treatments and long-term medication management. PPM billed presumptive drug screens for only four of those visits.

154. Between September 2013 and October 2015, however, patient L.D. had twenty-one visits, all with both screening and confirmation drug testing. During that time period, Medicare reimbursed $9,060.11 for UDT claims for patient L.D.[3] Defendants knew that these claims for UDT were not reasonable and necessary and were false.

155. L.D.'s patient records from between December 30, 2014 and March 23, 2015 note that each most recent prior screen was appropriate for prescribed medications and negative for illicit substances. Yet she was tested for all available substances, including drugs of abuse, with confirmation, at those visits and each visit afterwards.

156. L.D. was between 82-84 years old during visits to PPM. PPM nonetheless billed for confirmatory PCP tests for patient L.D. on September 10, 2013, November 5, 2013, February 25, 2014, March 25, 2014, May 20, 2014, June 18, 2014, July 16, 2014, August 12, 2014, September 10, 2014, November 6, 2014, December 4, 2014, December 30, 2014, February 20, 2015, and March 23, 2015. Medicare reimbursed PPM $275.30 for PCP tests alone during that time period, along with additional reimbursement for medically

[3] By contrast, PPM only earned $653.14 in reimbursement for outpatient evaluation and management for those twenty-one visits.

unnecessary drug confirmation tests for cocaine and amphetamines.[4] Defendants knew that these claims for UDT were not reasonable and necessary and were false.

157. Patient O.G. provides another example of medically unnecessary confirmation testing, particularly with respect to illicit drugs. The billing records from O.G.'s treatment also reflect the contrast between PPM's practices before and after summer 2013.

158. Patient O.G. was treated at PPM between 2012 and 2015, and was between 76-79 years old during this time period.

159. Between January 2012 and June 2013, patient O.G. visited PPM twenty times, and PPM billed for presumptive screening ten times. Between July 2013 and December 2015, however, Patient O.G. visited PPM twenty-three times, and PPM conducted and billed both presumptive and confirmatory testing (including PCP testing) nineteen times.

160. O.G.'s patient records from between December 2013 and April 2015 indicate no inconsistent results, no use of illicit drugs, and no aberrant behavior. The records document no concern regarding medication management or other risk assessment indicating that any UDT was necessary, let alone simultaneous presumptive and definitive tests at nearly every visit. For visits between July 2013 and December 2015, Medicare

[4] As explained above, beginning around May 2015, PPM began using a different CPT code—84999—for definitive testing for Medicare patients. PPM continued to perform medically unnecessary UDT as to patient L.D. after that date, but PCP confirmation testing was not separately billed after that date.

reimbursed PPM $12,315.81 for UDT for patient O.G. Defendants knew that these claims for UDT were not reasonable and necessary and were false.

161. Patient L.M. provides an example of overutilization and unnecessary confirmatory testing.

162. Patient L.M. visited PPM on April 9, 2015, May 7, 2015, June 4, 2015, and June 29, 2015. At each visit, his treating provider noted that the prior UDT was appropriate for prescribed drugs, and that the test showed no use of illicit drugs. The notes from each visit also indicate that no aberrant behaviors were detected. Yet at each visit, PPM performed screening tests and confirmatory testing, for all available substances. Medicare reimbursed PPM $481.64 for UDT for the April 9, 2015 visit, $353.66 for the May 7, 2015 visit, $353.65 for the June 4, 2015 visit, and $353.65 for the June 29, 2015 visit. Defendants knew that these claims for UDT were not reasonable and necessary and were false.

FIRST CAUSE OF ACTION
Against PPM and Spivey
False Claims Act: Presenting and Causing False Claims – Medically Unnecessary and Unreasonable UDT Furnished by PPM (31 U.S.C. § 3729(a)(1)(A))

163. The United States re-alleges and incorporates by reference all Paragraphs of this Complaint set out above as if fully set forth here.

164. During the relevant time period, PPM and Spivey knowingly presented and/or caused to be presented materially false and fraudulent claims for payment or approval to the Medicare, Medicaid, FEHBP, and VA programs for medically unnecessary and unreasonable UDT performed at PPM's in house laboratory.

165. The defendants presented or caused to be presented such claims with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

166. The United States sustained damages because of this wrongful conduct.

SECOND CAUSE OF ACTION
Against PPM and Spivey
False Claims Act: False Statements Material to False Claims – Medically Unnecessary and Unreasonable UDT Furnished by PPM (31 U.S.C. § 3729(a)(1)(B))

167. The United States re-alleges and incorporates by reference all Paragraphs of this Complaint set out above as if fully set forth here.

168. During the relevant time period, PPM and Spivey knowingly made, used, and caused to be made or used false records or statements material to false or fraudulent claims submitted to the United States, and payment of those false or fraudulent claims by the United States was a reasonable and foreseeable consequence of the defendants' statements and actions.

169. These false records and statements included false certifications on provider enrollment forms and false and misleading representations on claim forms that claims for payment for UDT furnished by PPM that were billed to Medicare, Medicaid, FEHBP, and the VA were medically necessary and reasonable, when, in fact, that UDT was medically unnecessary and unreasonable.

170. The Defendants made or used, or caused to be made or used, such false records or statements with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

171. The United States sustained damages because of this wrongful conduct.

THIRD CAUSE OF ACTION
Against PPM
Payment by Mistake – Medically Unreasonable and Unnecessary Services

172. The United States re-alleges and incorporates by reference all Paragraphs of this Complaint set out above as if fully set forth here.

173. This is a claim for the recovery of monies paid by the United States during the relevant time period to Defendant PPM as a result of mistaken understandings of fact.

174. The United States paid PPM for UDT that did not comply with the requirements of Medicare, Medicaid, FEHBP, and the VA programs. The United States made these payments without knowledge of material facts and under the mistaken belief that PPM was entitled to receive payment for such claims when it was not. The United States' mistaken beliefs were material to its decision to pay PPM for such claims. Accordingly, PPM is liable to make restitution to the United States of the amounts of the payments made in error to PPM by the United States.

FOURTH CAUSE OF ACTION
Against PPM and Spivey
Unjust Enrichment

175. The United States re-alleges and incorporates by reference all Paragraphs of this Complaint set out above as if fully set forth here.

176. This is a claim for the recovery of monies by which Defendants have been unjustly enriched during the relevant time period at the expense of the United States.

177. By directly or indirectly obtaining government funds to which they were not entitled, the defendants each were unjustly enriched, and are liable to account for and pay as restitution such amounts, or the proceeds therefrom, which are to be determined at trial, to the United States.

PRAYER FOR RELIEF

The United States demands and prays that judgment be entered in its favor against Defendants as follows:

A. On Counts I and II under the False Claims Act, for the amount of the United States' damages, trebled as required by law, plus costs of investigation and prosecution, and such civil penalties for each false claim as are authorized by law, together with such further relief as may be just and proper.

B. On Count III for payment by mistake, against Defendant PPM, for the damages sustained and/or amounts by which PPM was paid by mistake or by which PPM retained illegally obtained monies, plus interest, costs, and expenses, and for all such further relief as may be just and proper.

C. On Count IV for unjust enrichment, for the damages sustained and/or amounts by which Defendants were unjustly enriched or by which Defendants retained illegally obtained monies, plus interest, costs, and expenses, and for all such further relief as may be just and proper.

D. Pre- and post-judgment interest, costs, and such other relief as the Court may deem appropriate.

DEMAND FOR JURY TRIAL

The United States demands a jury trial in this case.

Dated: October 18, 2019

Respectfully submitted,

MATTHEW G.T. MARTIN
United States Attorney

/s/ Cassie Crawford
Cassie L. Crawford
Assistant U.S. Attorney
NCSB #45396
United States Attorney's Office
101 South Edgeworth Street, 4th Floor
Greensboro, NC 27401
336-333-5351
cassie.crawford@usdoj.gov

CERTIFICATE OF SERVICE

I hereby certify that on October 18, 2019, the foregoing was served by electronic mail pursuant to Local Rule 5.3(c)(3) upon the following:

Michael Berger
Special Assistant U.S. Attorney
N.C. Assistant Attorney General
MBerger@ncdoj.gov

Sean F. Herrmann
Herrmann & Murphy, PLLC
Attorney for Relator
sean@herrmannmurphy.com

Rule 4 service of this Complaint and Summons upon Defendants will follow.

/s/ Cassie Crawford
Cassie Crawford
Assistant U.S. Attorney
NCSB #45396
United States Attorney's Office
101 South Edgeworth Street, 4th Floor
Greensboro, NC 27401
336-333-5351
cassie.crawford@usdoj.gov