

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF KENTUCKY
NORTHERN DIVISION
ASHLAND**

Civil Case No. _____

United States of America,

Plaintiff,

v.

**Rose O. Uradu, M.D.
a/k/a Onyinyechi Rose Uradu; and
Ultimate Care Medical Services, LLC
d/b/a Ultimate Treatment Center,**

Defendants.

COMPLAINT

Plaintiff, the United States of America, by and through its undersigned counsel, alleges as follows:

INTRODUCTION

1. The United States of America (“United States” or the “Government”) brings this action against Ultimate Care Medical Services, LLC (“Ultimate Treatment Center”), a substance abuse treatment center, and its owner and operator, Dr. Rose O. Uradu (“Dr. Uradu”; with Ultimate Treatment Center, “Defendants”).

2. The United States seeks civil penalties under the Controlled Substances Act, 21 U.S.C. § 801 *et seq.*, and its implementing regulations, 21 C.F.R. § 1300 *et seq.*, on two bases: First, Dr. Uradu issued buprenorphine prescriptions to twice as many patients as is permitted by law. *See* 21 U.S.C. § 842(a)(1). Second, Ultimate Treatment Center failed to maintain complete and accurate records of the clinic’s methadone and buprenorphine inventories, as

reflected by shortages of both controlled substances. *See* 21 U.S.C. § 827(a)(3). This failure to comply with the Controlled Substances Act's record-keeping requirements created the potential for the unlawful diversion of these drugs.

3. The United States also seeks to recover treble damages and civil penalties under the False Claims Act, 31 U.S.C. § 3729 *et seq.*, on two bases: First, during the period January 2013 to September 2014, Ultimate Treatment Center, at the direction of Dr. Uradu, systematically defrauded the Medicare and Kentucky Medicaid programs by submitting false claims for evaluation and management services that were not actually provided to patients. Second, during the period July 2013 to December 2014, Ultimate Treatment Center, at the direction of Dr. Uradu, defrauded the Medicare and Kentucky Medicaid programs by submitting false claims for quantitative urine drug tests that were not actually performed. The false or fraudulent claims Ultimate Treatment Center submitted, and that Dr. Uradu caused it to submit, have resulted in losses to the Medicare and Kentucky Medicaid programs in excess of \$1 million.

JURISDICTION AND VENUE

4. This action arises under the Controlled Substances Act, 21 U.S.C. § 801 *et seq.*, and the False Claims Act, 31 U.S.C. § 3729 *et seq.* The Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1345 because the United States, as plaintiff, brings suit under these federal statutes.

5. The Court may exercise supplemental jurisdiction over the common law and equitable causes of action pursuant to 28 U.S.C. § 1367(a).

6. The Court may exercise personal jurisdiction over Defendants pursuant to 31 U.S.C. § 3732(a) because at all relevant times Defendants transacted business within the Eastern District of Kentucky.

7. Venue is proper in the Eastern District of Kentucky pursuant to 28 U.S.C. §§ 1391(b) and (c), as well as 31 U.S.C. § 3732(a) and 21 U.S.C. § 843(f)(2). The

Defendants can be found, reside, and transact business within this District, and the acts proscribed by the False Claims Act and Controlled Substances Act occurred within this District.

PARTIES

8. Plaintiff, the United States of America, brings this suit on its own behalf and on behalf of the United States Drug Enforcement Administration (“DEA”). DEA is the Department of Justice component agency primarily responsible for administering the Controlled Substances Act and investigating Controlled Substances Act violations. This suit is also brought on behalf of the United States Department of Health & Human Services and its operating division, the Centers for Medicare & Medicaid Services.

9. Defendant Ultimate Care Medical Services, LLC is a limited liability company organized and registered in Kentucky, and doing business as Ultimate Treatment Center. Its principal place of business is in Ashland, Boyd County, Kentucky. Ultimate Treatment Center operates a clinic that provides substance abuse treatment services to individuals, including Medicare and Medicaid beneficiaries. Ultimate Treatment Center is a registered Narcotic Treatment Program, holding DEA Registration Number RU0381789, for the purpose of possessing, dispensing, and administering controlled substances for addiction treatment. As a registrant under the Controlled Substances Act, Ultimate Treatment Center must keep complete and accurate records of all such controlled substances.

10. Defendant Rose O. Uradu, M.D., also known as Onyinyechi Rose Uradu, is an individual who resides in Greenup County, Kentucky. Dr. Uradu is a physician who specializes in family medicine and addiction treatment. Dr. Uradu is the owner of Ultimate Treatment Center. She is also the director of the clinic. In this role, Dr. Uradu participated in and supervised the clinic’s daily operations, and directed the billing of Ultimate Treatment Center’s claims to federal health insurance programs. At all relevant times, the actions of

Ultimate Treatment Center occurred at the direction and with the approval and consent of Dr. Uradu.

11. Dr. Uradu works as a physician at Ultimate Treatment Center, treating patients for substance abuse using controlled substances to manage their symptoms. Dr. Uradu has held two separate DEA registrations in her capacity as a registrant practitioner: DEA issued Dr. Uradu Registration Number BU9806083 on June 15, 2006 and FU3559676 on November 2, 2012.

DEFENDANTS' CONTROLLED SUBSTANCES ACT VIOLATIONS

12. The Controlled Substances Act ("CSA") was enacted in 1970 to deter "[t]he illegal importation, manufacture, distribution, and possession and improper use of controlled substances[, which] have a substantial and detrimental effect on the health and general welfare of the American people." 21 U.S.C. § 801(2). The CSA authorizes the DEA to regulate controlled substances and to register handlers of controlled substances, thereby creating a "closed" system of drug distribution. This closed system tracks controlled substances from manufacture to delivery to ensure that they are not illegally diverted for improper uses, thereby "provid[ing] the legitimate drug industry with a unified approach to narcotic and dangerous drug control." H.R. Rep. No. 91-1444, 91st Cong., 2d Sess. (1970), *reprinted in* 1970 U.S.C.A.A.N. 4566, 4571-72.

13. Under the CSA, a provider registered with the DEA may "dispense" a controlled substance, which means to deliver the controlled substance to the ultimate user, including by prescribing or administering the controlled substance. 21 U.S.C. § 802(10).

14. Under the CSA, a registered provider may "administer" a controlled substance, which means to apply directly (by injection, ingestion, or other means) a controlled substance to the body of a patient. 21 U.S.C. § 802(2).

15. Ultimate Treatment Center dispensed and administered methadone for the treatment of its patients. Methadone is a Schedule II controlled substance regulated under

the CSA. Methadone is used medically in treating opiate addiction, but also carries a street value and has a potential for abuse by recreational users. Abuse of methadone can cause serious trauma and even death; thus, its diversion from legitimate medical uses poses a significant public health risk.

16. Dr. Uradu wrote prescriptions for buprenorphine in her treatment of patients. Buprenorphine is a Schedule III controlled substance regulated under the CSA. It is marketed in two formulations under the brand names Suboxone and Subutex. Buprenorphine is used medically in treating opioid addiction. But, like methadone, buprenorphine carries a street value and has a potential for abuse by recreational users.

17. As providers who dispense and administer controlled substances, Defendants are required to operate in strict accordance with the provisions of the CSA and its implementing regulations, 21 C.F.R. § 1300 *et seq.* (the “CSA Regulations”). These statutory and regulatory obligations are designed to ensure that controlled substances are not taken outside the legitimate chain of distribution and illegally diverted.

I. Dr. Uradu Issued Invalid Prescriptions To Patients In Excess Of Her DATA Waiver Patient Limit

A. DATA-Waiver Privileges

18. Under the Drug Addiction Treatment Act of 2000 (“DATA”), qualified physicians may prescribe or dispense buprenorphine to treat opioid addiction in the office setting.

19. DATA also waives certain DEA registration requirements for physicians treating drug dependency with buprenorphine. DEA-registered physicians who apply and are qualified pursuant to DATA are issued a waiver, and then are authorized to prescribe and dispense buprenorphine for maintenance and detoxification treatment (“DATA-Waiver Privileges”).

20. In order to receive DATA-Waiver Privileges, the physician must submit to the Substance Abuse and Mental Health Services Administration (“SAMHSA”) a notification of her intent to prescribe or dispense buprenorphine for substance abuse treatment. The physician must also certify that she will not provide buprenorphine to more than the authorized number of patients at any one time. *See* 21 C.F.R. § 1301.28(b)(1).

21. During the relevant period, DATA-waived physicians were only permitted to treat 30 patients or 100 patients at any one time, depending on the authorization they received. *See* 21 U.S.C. §§ 823(g)(2)(B)(iii)(I) & (II); 21 C.F.R. § 1301.28(b)(1)(iii).

22. Under the CSA, DEA is authorized to conduct periodic audits and inspections of registrants to ensure compliance with DATA and its implementing regulations. 21 U.S.C. § 822(f).

B. Dr. Uradu Exceeded Her DATA-Waiver Patient Limit

23. On or about August 12, 2008, Dr. Uradu first received her DATA-Waiver Privileges for 30 patients under her Registration Number BU9806083.

24. On or about September 10, 2009, Dr. Uradu submitted SAMHSA Form 167, providing notice of her intent and need to use approved narcotics for substance abuse treatment for 100 patients. *See* Exhibit 1: SAMHSA Notification. On Section 10 of this form, Dr. Uradu specifically certified her “maximum patient load.” That is, she certified that she “will not exceed 100 patients for maintenance and detoxification at one time.”

25. Thereafter, effective on or about November 20, 2009, Dr. Uradu’s DEA Registration Number BU9806083 was authorized to treat no more than 100 patients with buprenorphine drug products (such as Suboxone and Subutex) for substance abuse maintenance or detoxification treatment.

26. However, in 2014, Dr. Uradu repeatedly treated more patients than allowed under her registration.

27. In October 2014, DEA conducted an audit of Dr. Uradu's prescriptions for buprenorphine drug products, including Suboxone and Subutex. As part of this audit, DEA analyzed prescriptions for buprenorphine drug products issued by Dr. Uradu during the period July 1, 2014 through October 7, 2014, and filled at McMeans Pharmacy in Ashland, Kentucky, and at CVS Pharmacy in Portsmouth, Ohio.

28. DEA's audit determined that Dr. Uradu exceeded her DATA-Waiver patient limit in each month audited. Specifically:

- a. In July 2014, Dr. Uradu faxed or called in prescriptions for buprenorphine drug products for 210 unique patients, putting her 110 patients over her limit.
- b. In August 2014, Dr. Uradu faxed or called in prescriptions for buprenorphine drug products for 266 unique patients, putting her 166 patients over her limit.
- c. In September 2014, Dr. Uradu faxed or called in prescriptions for buprenorphine drug products for 294 unique patients, putting her 194 patients over her limit.

C. Dr. Uradu's Prescriptions For Patients Over Her Limit Are Unlawful

29. Each prescription for buprenorphine drug products that Dr. Uradu issued over her 100-patient limit is unlawful and a violation of the CSA. 21 U.S.C. § 842(a)(1).

30. Section 842(a)(1) of the CSA makes it unlawful for any physician to dispense a controlled substance in violation of 21 U.S.C. § 829. *See* 21 U.S.C. § 842.

31. The rules governing the dispensing of controlled substances are set forth generally in Section 829 of the CSA and more specifically in Part 1306 of the CSA Regulations. *See* 21 C.F.R. § 1306.01.

32. Under Part 1306.04(c) of the CSA Regulations, a physician may not issue a prescription "for 'detoxification treatment' or 'maintenance treatment,' unless . . . the

practitioner is in compliance with the requirements of [21 C.F.R.] § 1301.28.”
See 21 C.F.R. § 1306.04(c).

33. Under 21 C.F.R. § 1301.28, DATA-waived physicians may not write prescriptions that exceed their applicable patient limit. In line with this regulation, Dr. Uradu specifically certified that she would “not exceed 100 patients for maintenance or detoxification treatment at one time” when she applied for her DATA waiver. *See* Exhibit 1: SAMHSA Notification.

34. Accordingly, every prescription Dr. Uradu issued to a patient over her applicable DATA waiver limit is an invalid prescription under 21 U.S.C. § 829. *See* 21 U.S.C. § 829; 21 C.F.R. § 1306.04(a).

35. Thus, under Section 842(a)(1) of the CSA, each of the 470 prescriptions Dr. Uradu wrote over the DATA waiver limit between July and September 2014 is unlawful.

36. Dr. Uradu is liable to the United States for civil penalties for these 470 unlawful prescriptions. *See* 21 U.S.C. § 842(c)(1)(A). Specifically, for each violation, Dr. Uradu is “subject to a civil penalty of not more than \$25,000.” *Id.*

II. Defendants Failed To Maintain Accurate Records Of Controlled Substances

37. A “closed” system for drug distribution requires that each registrant maintain accounting and security systems so that no controlled drugs are lost, stolen, or inappropriately dispensed to abusers or street dealers through false or inappropriate prescriptions or diversions. This can only be accomplished through complete compliance with the CSA and the CSA Regulations.

38. Specifically, under the CSA, a provider who dispenses controlled substances must maintain “a complete and accurate record” of each controlled substance received, sold, delivered, or otherwise disposed. 21 C.F.R. § 1304.21(a); *see also* 21 U.S.C. § 827(a)(3). Such records must be maintained and be available for inspection and copying by authorized officials for at least two years. 21 U.S.C. § 827(b).

39. Refusing or negligently failing to make or keep required records is unlawful and a violation of the CSA. 21 U.S.C. § 842(a)(5). The United States is entitled to recover civil penalties of up to \$10,000 for each recordkeeping violation. 21 U.S.C. § 842(c)(1)(B).

40. On May 9, 2017, DEA conducted a record-keeping accountability audit of methadone and buprenorphine drug products at Ultimate Treatment Center. This audit was part of an In-Depth Regulatory Investigation of Ultimate Treatment Center pursuant to an Administrative Inspection Warrant.

41. DEA's audit examined Ultimate Treatment Center's records for methadone and buprenorphine for the period January 1, 2017 to April 28, 2017.

42. Based on documentation that Ultimate Treatment Center provided to DEA, and the accountability audit conducted on-site by DEA, DEA found that Ultimate Treatment Center did not maintain complete and accurate records of its methadone inventory.

43. Specifically, according to Ultimate Treatment Center's records, Ultimate Treatment Center had a beginning inventory of 2,685,639 mg of methadone 10 mg/ml oral solution, and received 6,000,000 mg during the audit period, for a total of 8,685,639 mg. According to Ultimate Treatment Center's records, Ultimate Treatment Center dispensed 5,765,295 mg during the audit period.

44. Based on these records, Ultimate Treatment Center should have had a closing inventory of 2,920,344 mg of methadone. But, the closing inventory listed on Ultimate Treatment Center's records was only 2,461,900 mg. Thus, Ultimate Treatment Center's records did not account for 458,444 mg of methadone. This shortage is the equivalent of approximately forty-five 1-liter bottles of methadone 10 mg/ml oral solution.

45. DEA's accountability audit also revealed that Ultimate Treatment Center failed to maintain complete and accurate records of its buprenorphine inventory.

46. Specifically, according to Ultimate Treatment Center's records, Ultimate Treatment Center had a beginning inventory of 1,015 buprenorphine 8 mg/2 mg tablets, and

received 9,600 tablets during the audit period, for a total of 10,615 tablets. According to Ultimate Treatment Center's records, it dispensed 7,514.5 tablets during the audit period.

47. Based on these records, Ultimate Treatment Center should have had a closing inventory of 3,100.5 tablets. But, the closing inventory listed on Ultimate Treatment Center's records was only 2,436.5 tablets. Thus, Ultimate Treatment Center's records did not account for 664 8 mg/2 mg tablets of buprenorphine, which is the equivalent of 22 bottles of buprenorphine 8 mg/2mg tablets.

48. Accordingly, for methadone and buprenorphine, Ultimate Treatment Center negligently failed to maintain complete and accurate records between January 1, 2017 and April 28, 2017. Ultimate Treatment Center is liable to the United States for civil penalties for these record-keeping violations. 21 U.S.C. § 842(a)(5); 21 U.S.C. § 842(c)(1)(B).

DEFENDANTS' FALSE CLAIMS ACT VIOLATIONS

I. The False Claims Act

49. The False Claims Act ("FCA") prohibits knowingly presenting, or causing to be presented, to the Government a false or fraudulent claim for payment or approval. 31 U.S.C. § 3729(a)(1)(A). The FCA further prohibits knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim. 31 U.S.C. § 3729(a)(1)(B).

50. Under the FCA, "knowingly" means that with respect to information, a person (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. 31 U.S.C. § 3729(b)(1). The FCA does not require that the defendant have the specific intent to defraud the federal government. 31 U.S.C. § 3729(b)(1)(B).

51. For each violation of the FCA, a defendant is liable to the United States for civil penalties of not less than \$5,000 and not more than \$10,000 per false claim, as adjusted for

inflation, and three times the amount of damages that the Government sustained as a result of the defendant's actions. 31 U.S.C. § 3729(a)(1).

II. Government Healthcare Programs

A. The Medicare Part B Program

52. The United States, through its Department of Health & Human Services ("HHS"), administers the Supplementary Medical Insurance Program for the Aged and Disabled established by Part B, Title XVIII, of the Social Security Act, 42 U.S.C. §§ 1395j-1395w-4 (the "Medicare Part B Program"). HHS has delegated the administration of the Medicare Part B Program to its component agency, the Centers for Medicare & Medicaid Services ("CMS").

53. The Medicare Part B Program is a federally subsidized health insurance program for persons who are 65 years of age or older, and for those who are disabled. Eligible individuals may enroll in the Medicare Part B Program to obtain benefits in return for payments of monthly premiums as established by HHS.

54. The Medicare Part B Program is funded by contributions from the federal treasury, and by insurance premiums paid by enrolled beneficiaries.

55. The Medicare Part B Program pays for medical and other health services provided to enrolled beneficiaries by physicians and healthcare entities.

56. Physicians and healthcare entities who are participating providers in the Medicare Part B Program may seek reimbursement from Medicare Part B for services rendered to enrolled beneficiaries, provided that the services are rendered in compliance with the laws, rules, regulations, policies, and procedures governing reimbursement.

57. The Medicare Part B Program only pays for services that are reasonable and necessary for the diagnosis or treatment of illness or injury. 42 U.S.C. § 1395y(a)(1)(A). Medicare Part B does not pay for routine visits performed without relationship to the

treatment or diagnosis for a specific illness, symptom, complaint, or injury. *See* Medicare Benefit Policy Manual, Chapter 16, Section 90.

58. At all times relevant, Ultimate Treatment Center and Dr. Uradu were enrolled in the Medicare Part B Program.

B. The Kentucky Medicaid Program

59. HHS, through CMS, also administers the Medicaid program, created under Title XIX of the Social Security Act, 42 U.S.C. § 1396, *et seq.*, to provide federally-subsidized health insurance to indigent persons whose incomes are insufficient to meet the costs of necessary healthcare. In Kentucky, the Medicaid program was established pursuant to KRS Chapter 205 and administrative regulations set forth in 907 KAR Chapter 1. The Kentucky Cabinet for Health and Family Services, Department for Medicaid Services, administers the Medicaid program in Kentucky (“the Kentucky Medicaid Program”) (with the Medicare Part B Program, the “Government Healthcare Programs”).

60. Funding for Medicaid is shared between the federal Government and those states participating in the Medicaid program. Approximately 70% of each dollar spent by the Kentucky Medicaid Program is contributed by the federal Government pursuant to Title XIX of the Social Security Act.

61. The Kentucky Medicaid Program pays for medical and other health services provided to enrolled beneficiaries by physicians and healthcare entities.

62. Physicians or healthcare entities who are participating providers in the Kentucky Medicaid Program may seek reimbursement for services rendered to enrolled beneficiaries, provided that the services are rendered in compliance with the laws, rules, regulations, policies, and procedures governing reimbursement.

63. The Kentucky Medicaid Program only pays for services that are medically necessary. 907 KAR 3:005, Section 3.

64. At all times relevant, Ultimate Treatment Center and Dr. Uradu were enrolled in the Kentucky Medicaid Program.

C. Claim Submission Process

65. During the relevant period, Defendants were permitted to submit claims for payment to the Medicare Part B Program and the Kentucky Medicaid Program.

66. Throughout the relevant period, Ultimate Treatment Center submitted claims to the Medicare Part B Program through a Medicare Administrative Contractor (or “MAC”), which contracted with CMS to process and pay claims for Medicare Part B services. The MAC with responsibility for processing and paying Ultimate Treatment Center’s claims to Medicare Part B was CGS Administrators, LLC (“CGS”).

67. Throughout the relevant period, Ultimate Treatment Center submitted claims to the Kentucky Medicaid Program through the Department for Medicaid Services or its contractors, including managed care organizations.

68. Ultimate Treatment Center submitted claims to the Government Healthcare Programs using a standardized paper claim form known as the CMS-1500.

69. At the time each claim form was submitted, Ultimate Treatment Center made certain certifications:

a. For Medicare claims, that the services for which Ultimate Treatment Center sought payment were “personally furnished by me” and were “medically indicated and necessary for the health of the patient.”

b. For Medicaid claims, that the services for which Ultimate Treatment Center sought payment “were medically indicated and necessary to the health of the patient.” It also certified that all information provided “is true, accurate, and complete,” and acknowledged that it understood “that payment and satisfaction of this claim will be from Federal and State funds, and that any false claim, statements, or documents, or concealment of a material fact, may be prosecuted under applicable Federal or State laws.”

70. As an alternative to use of the paper CMS-1500 claim forms, Ultimate Treatment Center submitted claims to Medicare electronically after submitting an Electronic Data Interchange Enrollment Form to CGS. By signing this Enrollment Agreement, Ultimate Treatment Center agreed that it will “submit claims that are accurate, complete, and truthful;” “that services were performed as billed;” and that “all claims will be paid from Federal funds, that the submission of such claim is a claim for payment under the Medicare program.” Dr. Uradu executed this Electronic Data Interchange Enrollment Agreement on behalf of Ultimate Treatment Center.

71. As an alternative to use of the paper CMS-1500 claim forms, Ultimate Treatment Center submitted claims to the Kentucky Medicaid Program electronically after signing an addendum to its provider agreement called a MAP-380 form. Dr. Uradu executed the MAP-380 form on behalf of Ultimate Treatment Center. Ultimate Treatment Center acknowledged that its signature on the MAP-380 form “constitutes compliance with the following certification required of each individual claim transmitted by electronic media”:

This is to certify that the transmitted information is true, accurate, and complete I understand that payment and satisfaction of these claims will be from Federal and State funds and that any false claims, statements, or documents or concealment of a material fact, may b[e] prosecuted under applicable Federal and State Law.

72. At all times relevant, Ultimate Treatment Center submitted claims to the Government Healthcare Programs for reimbursement. Ultimate Treatment Center received reimbursement from the Programs based on these claims.

73. Ultimate Treatment Center’s claims were submitted to Government Healthcare Programs at Dr. Uradu’s direction.

74. At all times relevant, Dr. Uradu received financial benefit as a result of Ultimate Treatment Center billing those claims to the Government Healthcare Programs.

D. Coding Criteria

75. Healthcare providers use a uniform system of coding to report the services and procedures furnished to patients. The Physicians Current Procedural Terminology (“CPT”) code set is a medical code set maintained by the American Medical Association. CPT codes identify services and procedures rendered to patients during encounters with healthcare providers.

76. Healthcare providers use the CPT code set when billing the Government Healthcare Programs for most services. Each CPT code is assigned an allowable charge by the payor, which is then published in the payor’s fee schedule.

77. Healthcare providers must use the appropriate CPT code on claims in order to receive reimbursement from the Government Healthcare Programs. In order to bill any code, the services rendered must meet the definition of that code. It is the provider’s responsibility to ensure that the codes selected reflect the services furnished.

78. Evaluation and management (“E&M”) services refer to certain services furnished by physicians and certain non-physician practitioners, including nurse practitioners, clinical nurse specialists, and physician assistants.

79. The CPT codes to bill for E&M services are organized into various categories and levels. In general, the more complex the visit, the higher the level of code the physician or non-physician practitioner may bill within the appropriate category.

80. There are three key components to E&M services: (1) patient history; (2) examination; and (3) medical decision-making, which refers to the complexity of establishing a diagnosis or selecting a treatment option. These components must be provided, and also documented in the patient’s medical record, for the E&M service to be covered by the Government Healthcare Programs.

81. Medicare’s Claims Processing Manual states that, “Medical necessity of a service is the overarching criterion for payment in addition to the individual requirements of

a CPT code. It would not be medically necessary or appropriate to bill a higher level of evaluation and management service when a lower level of service is warranted.” Chapter 12, Section 30.6.1 (Selection of Level of Evaluation and Management Service).

82. At all relevant times, Ultimate Treatment Center employees (typically non-physician practitioners) administered methadone to beneficiaries of the Government Healthcare Programs. Ultimate Treatment Center would bill the Government Healthcare Programs for E&M services relating to these visits. In most instances, Ultimate Treatment Center billed the Government Healthcare Programs using CPT code 99212 when administering methadone to established patients.

83. CPT code 99212 is used to describe services provided in the office setting for the evaluation and management of an established patient. Proper use of this code requires at least two of the three following components be performed by the practitioner: (1) a problem-focused history; (2) a problem-focused examination; and (3) straightforward medical decision-making. The American Medical Association guidelines for this code indicate that practitioners typically spend ten minutes face-to-face with the patient.

III. Defendants Submitted False Claims And Created False Records For E&M Services Not Performed

A. False Claims For E&M Services Not Performed

84. Between January 2013 and September 2014, Defendants improperly billed the Government Healthcare Programs for E&M services when no such services were actually provided.

85. At all relevant times, Ultimate Treatment Center administered methadone to its patients for substance abuse treatment. Many patients received methadone doses daily.

86. Ultimate Treatment Center administered methadone to patients at a dosing window. After checking in at Ultimate Treatment Center’s reception desk, the patient would approach the dosing window and an Ultimate Treatment Center nurse would confirm the

patient's identity and verify the patient's appropriate dose. The dosing nurse would then administer the patient's methadone dose, and observe the patient taking the dose. After the dose was administered, the patient would leave the clinic.

87. During these methadone administration visits, the patient would not typically see a physician or a non-physician practitioner for an examination, counseling, or other treatment.

88. During these methadone administration visits, the dosing nurse would not take or review the patient's medical history. The dosing nurse would not conduct a physical examination or take the patient's vital signs. The dosing nurse would not exercise medical decision-making about the patient's diagnosis or future treatment.

89. To document the methadone administration visit, the dosing nurse would use the "Methasoft" software program. The Methasoft program would automatically record the date, time, and dose for the patient encounter in the "dosing log." This was the only documentation prepared for the encounter. The dosing nurse would not document a patient history, subjective or objective observations of the patient, or a plan for treatment.

90. During the relevant period, Ultimate Treatment Center typically administered methadone doses to 250-300 patients during an eight-hour period. Accordingly, on average, dosing nurses spent less than two minutes administering methadone doses to each individual patient.

91. Even though the dosing nurse did not take a patient history, perform an examination, or exercise medical decision-making, Ultimate Treatment Center billed the Government Healthcare Programs for E&M services using CPT code 99212 for these daily methadone administration encounters.

92. The methadone administration encounters were billed as E&M services at Dr. Uradu's direction.

93. Ultimate Treatment Center and Dr. Uradu were aware of the specific requirements for billing E&M services, including that such services required performance of a patient history, an examination, and medical decision-making.

94. For example, in January 2013, the billing company used by Ultimate Treatment Center provided Dr. Uradu with written definitions of the CPT codes for certain E&M services, and asked her which code to use for the daily methadone administration. Dr. Uradu responded to “use whichever one they [insurers] approve,” and that Ultimate Treatment Center “will put a note everyday,” indicating that records would be created for each date of service.

B. False Medical Records Documenting E&M Services

95. Ultimate Treatment Center used an electronic medical records system that permitted its practitioners to clone medical notes. This ability to easily clone notes enabled Ultimate Treatment Center to create the illusion that its practitioners were performing E&M services at dosing visits when, in fact, they were not.

96. In order to justify billing an E&M code for a patient’s dosing visit, Ultimate Treatment Center falsely documented E&M services by copying notes from one visit to the next, over and over again.

97. The resulting records are identical in nearly every respect—from the history of present illness, to the observations of the patient, to the patient’s treatment plan. These cloned records documenting daily E&M visits continue for days, weeks, and even months in a row.

98. The dosing nurses who actually saw the patients did not create these records. The dosing nurses used the Methasoft program to document only the patient’s methadone dose; they did not document a patient history, subjective or objective observations of the patient, or a plan for treatment.

i. Example Patient B.J.

99. By way of representative example, Patient B.J. was a patient at Ultimate Treatment Center during the relevant period. From July 31, 2013 to July 29, 2014, B.J. visited Ultimate Treatment Center almost daily for methadone administration. Ultimate Treatment Center billed Medicare for these visits as E&M services, using CPT Code 99212. These claims are itemized in Exhibit 2, attached hereto.

100. But, as described above, the methadone dosing visits did not feature the key components of E&M services—a patient history, an examination, or medical decision-making.

101. Additionally, Ultimate Treatment Center’s medical records for these dates of service are cloned, and falsely document E&M services that were not actually provided.

102. For example, B.J.’s medical records for purported E&M visits during the period July 31, 2013 to October 30, 2013 are identical, reporting the same symptoms and observations, and providing the same narrative descriptions.

a. On each of these 92 dates of service, the medical records list B.J.’s chief complaint as, “I cannot manage my addiction by myself. I get very antsy and restless towards end of day.”

b. On each of these 92 dates of service, the medical records reflect that B.J. reported that he was “anxious and afraid of relapsing,” “[h]as been avoiding known triggers,” and is experiencing constipation as a side effect of the medication.

c. On each of these 92 dates of service, the medical records state that B.J.’s medical, social, and family histories were “reviewed.”

d. On each of these 92 dates of service, the medical records document a review of systems, including an examination for track marks and objective notes regarding B.J.’s alertness, mood, speech, gait, and clinical withdrawal signs. The notes for each date of service are the same.

e. The medical records for each of these dates of service list the procedure performed as “99212” and “10 min[utes].”

103. This cloned language persists throughout Ultimate Treatment Center’s medical records for B.J. For example, B.J.’s medical record for July 29, 2014—nearly a year later—states that B.J. is still antsy and restless toward the end of day and still experiencing constipation.

104. Further, on each of the claims in Exhibit 2, Dr. Uradu is listed as the physician who performed the E&M service. But, Dr. Uradu did not provide this service to B.J. on each of these dates.

105. Ultimate Treatment Center created these false records to justify its claims to Medicare for E&M services that were not performed.

106. The claims listed in Exhibit 2 were false or fraudulent because the services for which payment was sought were not actually performed, and because the underlying medical records were falsified.

107. Ultimate Treatment Center and Dr. Uradu knew, recklessly disregarded, or deliberately ignored the fact that E&M services had not been provided to B.J., as falsely claimed on each of the claims listed in Exhibit 2.

108. Medicare paid Ultimate Treatment Center approximately \$8,777.80 for the claims listed in Exhibit 2. Medicare would not have paid these claims if it had known of the claims’ false and fraudulent nature, or the underlying false medical records.

ii. Example Patient R.R.

109. As another representative example, Patient R.R. was a patient at Ultimate Treatment Center during the relevant period. From January 18, 2014 to September 19, 2014, R.R. visited Ultimate Treatment Center 272 times for methadone administration. Ultimate Treatment Center billed Medicare for these visits as E&M services, using CPT Code 99212. These claims are itemized in Exhibit 3, attached hereto.

110. But, as described above, the methadone dosing visits did not feature the key components of E&M services—a patient history, an examination, or medical decision-making.

111. As with Patient B.J., Ultimate Treatment Center created cloned medical records to falsely document E&M services that were not actually performed.

112. For example, R.R.'s medical records for purported E&M visits during the period January 20, 2014 through September 19, 2014 are nearly identical, reporting the same symptoms and observations and providing the same narrative descriptions.

113. For example, R.R.'s medical record for January 20, 2014 documents the following:

a. The History of Present Illness section states, "Pre-dosing review of this patient with chronic opioid addiction that is being managed with daily medication, [sic] Today Patient reports doing well. cravings [sic] and withdrawals much better."

b. The record notes that to maintain his sobriety, R.R. "Stayed at home and tried to manage his cravings as best as can [sic]."

c. The record states that a "New Lab Test" has been performed, without listing its results.

d. The record lists R.R.'s chief complaint as "I cannot manage my addiction by myself" and has a statement of medical necessity indicating that R.R. has a "High diversion risk in patient self administering at home."

114. R.R.'s medical records for the subsequent 8 months are nearly all identical to the January 20, 2014 record, with the same punctuation and capitalization errors, the same methadone dosage, and the same warning of the diversion risk posed by R.R. self-administering methadone at home.

115. This pattern of cloned records continues even after R.R. failed his drug test.

116. For example, on April 24, 2014, R.R.'s drug screen results show a positive result for opiates. But, R.R.'s medical records after this date contain the same cloned language as before. The records do not document any discussion with R.R. regarding his failed drug test, or any recommended changes in dosage or therapy. Indeed, the records do not even acknowledge the positive test result for opiates. It appears that Ultimate Treatment Center's providers did not use the results of the urine drug tests in R.R.'s treatment.

117. Additionally, Ultimate Treatment Center created medical records for E&M services on dates when R.R. was not physically present at the clinic.

118. For example, Ultimate Treatment Center's dosing log for R.R. indicates that on January 20, 2014, R.R. received a dose of methadone at the clinic and was given two doses to take at home on January 21 and 22, 2014.

119. Ultimate Treatment Center provided this home dosing despite noting a "High diversion risk in patient [R.R.] self administering at home" in its cloned records.

120. Despite having provided R.R. with a home dose for January 21 and 22, 2014, Ultimate Treatment Center nonetheless created the same cloned records as it had for dates when R.R. received methadone dosing at the clinic. Ultimate Treatment Center submitted to Medicare claims for payment for E&M services purportedly provided on these dates.

121. This is not an isolated occurrence. On numerous dates of service, Ultimate Treatment Center documented and billed Medicare for E&M office visits on dates when R.R. was not present for methadone dosing.

122. Further, on each of the claims in Exhibit 3, Dr. Uradu is listed as the physician who performed the E&M service. But, Dr. Uradu did not provide this service to R.R. on each of these dates.

123. Ultimate Treatment Center created these false records to justify its claims to Medicare for E&M services that were not performed.

124. The claims listed in Exhibit 3 were false or fraudulent because the services for which payment was sought were not actually performed, and because the underlying medical records were falsified.

125. Ultimate Treatment Center and Dr. Uradu knew, recklessly disregarded, or deliberately ignored the fact that an E&M service had not been provided to R.R., as falsely claimed on each of the claims listed in Exhibit 3.

126. Medicare paid Ultimate Treatment Center approximately \$7,038.36 for the claims listed in Exhibit 3. Medicare would not have paid these claims if it had known of the claims' false and fraudulent nature, or the underlying false medical records.

iii. Example Patient R.D.

127. As another representative example, Patient R.D. was a patient at Ultimate Treatment Center during the relevant period. From January 13, 2014 to September 19, 2014, R.D. visited Ultimate Treatment Center 213 times for methadone administration. Ultimate Treatment Center billed Medicare for these visits as E&M services, using CPT Code 99212. These claims are itemized in Exhibit 4, attached hereto.

128. But, as described above, the methadone dosing visits did not feature the key components of E&M services—a patient history, an examination, or medical decision-making.

129. Additionally, like with Patients B.J. and R.R., Ultimate Treatment Center created cloned medical records for these dates of service to falsely document E&M services that were not actually performed.

130. For example, R.D.'s medical records for purported E&M visits during the period January 13, 2014 to September 8, 2014 are nearly identical, reporting the same symptoms and observations, and providing the same narrative descriptions.

131. As an example, R.D.'s medical records from April 17, 2014 through April 22, 2014—all identical—document the following:

a. The records list R.D.'s chief complaint as, "I cannot manage my addiction by myself," and the medical necessity statement as, "High diversion risk in patient self administering at home."

b. The History of Present Illness section states, "Pre-dosing review of this patient with chronic opioid addiction that is being managed with daily medication, [sic] Today Patient reports; [sic] Withdrawal is much improved. Craving is much.less. [sic]"

c. The records note that to help maintain his sobriety, R.D.: "Stayed at home and tried to manage his cravings as best as can [sic]." (Notably, this is the same language used in the cloned records for patient R.R., *supra*.)

132. R.D.'s medical records for the subsequent five months are nearly all identical to these April 17-22, 2014 records, repeating the same typographical and grammatical errors.

133. Further, on each of the claims in Exhibit 4, Dr. Uradu is listed as the physician who performed the E&M service. But, Dr. Uradu did not provide this service to R.D. on each of these dates.

134. Ultimate Treatment Center created these false records to justify its claims to Medicare for E&M services that were not performed.

135. The claims listed in Exhibit 4 were false or fraudulent because the services for which payment was sought were not actually performed, and because the underlying medical records were falsified.

136. Ultimate Treatment Center and Dr. Uradu knew, recklessly disregarded, or deliberately ignored the fact that an E&M service had not been provided to R.D., as falsely claimed on each of the claims listed in Exhibit 4.

137. Medicare paid Ultimate Treatment Center approximately \$6,328.35 for the claims identified in Exhibit 4. Medicare would not have paid these claims if it had known of the claims' false and fraudulent nature, or the underlying false medical records.

138. The claims described above and identified in Exhibits 2-4 are representative examples only. Ultimate Treatment Center and Dr. Uradu knowingly submitted, or caused to be submitted, numerous other false claims for E&M services to the Government Healthcare Programs.

139. Ultimate Treatment Center and Dr. Uradu both benefitted financially from these false claims for E&M services.

IV. Defendants Submitted False Claims For Urine Drug Tests

A. Types Of Urine Drug Tests

140. Urine drug testing is used to determine the presence or absence of drugs or metabolites, also known as “analytes,” in a patient’s system. In the clinical healthcare context, drug testing can be used to monitor whether patients are taking prescribed drugs, or are taking or abusing drugs not prescribed.

141. Drug testing can be “qualitative,” “quantitative,” or “semi-quantitative.”

142. Qualitative testing indicates the presence or absence of an analyte (*e.g.*, a “positive” or “negative” result). It can be performed at a physician’s office using an enzyme immunoassay analyzer machine. To operate an analyzer, physician practices are generally required to obtain a CLIA certification¹ to perform moderate- or high- complexity laboratory tests. During the relevant period, qualitative tests were billed based on the complexity of the test under CLIA (*e.g.*, billing code G0434 for moderate complexity tests). Qualitative tests may not be billed using the billing codes for quantitative tests.

143. Quantitative testing is more precise, and provides a numerical concentration of an analyte. In order to be classified as quantitative, a single number must result from the test. Quantitative testing is not usually performed at a physician’s office, but at a clinical

¹ CLIA stands for the Clinical Laboratory Improvement Amendments of 1988, as set forth at 42 C.F.R. Part 493. Laboratory services, including urine drug testing, must meet all applicable requirements of CLIA.

laboratory using more precise methodologies, such as gas chromatography with mass spectrometry and liquid chromatography with mass spectrometry. During the relevant period, quantitative tests were billed using CPT codes assigned for quantitative tests of each drug or class and, in some cases, multiple units of those CPT codes. Quantitative tests are generally reimbursed by Government Healthcare Programs at a higher rate than qualitative tests.

144. Semi-quantitative testing is an alternative to qualitative drug testing. It indicates the presence of an analyte and provides a numerical range for the concentration of that analyte – not a single number as with quantitative testing. Semi-quantitative testing can be performed at a physician’s office using an enzyme immunoassay analyzer machine. Semi-quantitative tests may not be billed using the billing codes for quantitative tests.

B. Ultimate Treatment Center Billed For Quantitative Drug Testing That It Did Not Perform

145. At all times relevant, Ultimate Treatment Center performed urine drug testing.

146. Ultimate Treatment Center utilized an analyzer manufactured by Roche called the Cobas Integra 400. The Cobas Integra 400 is categorized as a moderate complexity test under CLIA. The Cobas Integra 400 used by Ultimate Treatment Center produces qualitative and semi-quantitative results.

147. Ultimate Treatment Center’s patient records for urine drug testing report qualitative and semi-quantitative results.

148. Nonetheless, Ultimate Treatment Center billed the Government Healthcare Programs using the CPT codes for quantitative drug tests.

149. Specifically, during the period July 2013 to December 2014, Ultimate Treatment Center routinely billed the Government Healthcare Programs using the following CPT codes, which are for quantitative tests:

CPT Code	Description
80154	Benzodiazepines
80299	Quantitation, Drug, Not Elsewhere Specified
82145	Amphetamine or Methamphetamine
82205	Barbiturate, Not Elsewhere Specified
82520	Cocaine Or Metabolite
83840	Methadone
83925	Opiate(s), Drug and Metabolites, Each Procedure

150. During the relevant period, Ultimate Treatment Center billed these CPT codes in combination for patients on a regular basis, often multiple times per month. As part of this panel of testing, Ultimate Treatment Center billed two units of CPT code 83925 (opiates), reflecting that it performed that quantitative test two times per patient encounter.

151. By way of representative example, Patient B.J. was a patient at Ultimate Treatment Center during the relevant period. Patient B.J. received regular urine drug testing, which Ultimate Treatment Center billed to Medicare. For example, for date of service August 15, 2013, Ultimate Treatment Center submitted claims to Medicare for quantitative testing using CPT codes 80154, 80299, 82145, 82205, 82520, 83840, and 83925 (twice). Medicare paid Ultimate Treatment Center \$169.29 for these tests.

152. Ultimate Treatment Center billed the same panel of quantitative tests for B.J. on dates of service October 7, 2013, October 18, 2013, and October 21, 2013. Medicare paid Ultimate Treatment Center \$169.29 for the tests on each of these dates of service.

153. The claims for quantitative drug tests billed by Ultimate Treatment Center to Medicare for B.J. are itemized in Exhibit 5, attached hereto.

154. As another representative example, Patient R.R. was a patient at Ultimate Treatment Center during the relevant period. Patient R.R. received regular urine drug

testing, which Ultimate Treatment Center billed to Medicare. For example, for date of service September 29, 2014, Ultimate Treatment Center submitted claims to Medicare for quantitative testing using CPT codes 80154, 80299, 82145, 82205, 82520, 83840, and 83925 (twice). Medicare paid Ultimate Treatment Center \$168.01 for these tests.

155. Ultimate Treatment Center billed the same panel of quantitative tests for R.R. on dates of service October 6, 2014, November 10, 2014, and December 8, 2014. Medicare paid Ultimate Treatment Center \$168.01 for the tests on each of these dates of service.

156. The claims for quantitative drug tests billed by Ultimate Treatment Center to Medicare for R.R. are itemized in Exhibit 6, attached hereto.

157. The representative claims identified above and in Exhibits 5 and 6 were false or fraudulent because the services for which payment was sought—quantitative drug testing—were not actually performed. Rather, Ultimate Treatment Center performed qualitative or semi-quantitative drug testing.

158. Ultimate Treatment Center and Dr. Uradu knew, recklessly disregarded, or deliberately ignored the fact that Ultimate Treatment Center performed only qualitative or semi-quantitative testing, and not quantitative testing as falsely claimed on the claims listed in Exhibits 5 and 6.

159. Medicare would not have paid these claims if it had known of the claims' false or fraudulent nature.

160. The claims specifically identified above are representative examples only. Ultimate Treatment Center and Dr. Uradu knowingly submitted, or caused to be submitted, numerous other false claims to the Government Healthcare Programs for quantitative urine drug testing.

161. Ultimate Treatment Center and Dr. Uradu both benefitted financially from these false claims for quantitative testing.

COUNT 1
CONTROLLED SUBSTANCES ACT
UNLAWFUL PRESCRIPTIONS ISSUED IN EXCESS OF DATA WAIVER LIMIT
21 U.S.C. § 842(a)(1)

162. The United States incorporates by reference all paragraphs of this Complaint set out above as if fully set forth herein.

163. During the period July 1, 2014 through September 30, 2014, Dr. Uradu issued at least 470 prescriptions for buprenorphine drug products to patients over her DATA Waiver limit.

164. Each of these prescriptions is invalid under 21 U.S.C. § 829, and constitutes a violation of 21 U.S.C. § 842(a)(1).

165. The United States is entitled to civil penalties in an amount not to exceed \$25,000 for each violation. 21 U.S.C. § 842(c)(1)(A).

COUNT 2
CONTROLLED SUBSTANCES ACT
FAILURE TO MAKE AND MAINTAIN COMPLETE AND ACCURATE
RECORDS OF METHADONE
21 U.S.C. § 842(a)(5)

166. The United States incorporates by reference all paragraphs of this Complaint set out above as if fully set forth herein.

167. The DEA's audit revealed that Ultimate Treatment Center's records did not account for a shortage of 458,444 mg of methadone. In this regard, Ultimate Treatment Center failed to maintain complete and accurate records for each controlled substance received, dispensed, or disposed by Ultimate Treatment Center as required by 21 U.S.C. § 827(a) and 21 C.F.R. § 1304.21(a).

168. Pursuant to 21 U.S.C. § 842(a)(5), it is unlawful for any person to refuse or negligently fail to make, keep, or furnish any records or information required to be kept under the CSA. Ultimate Treatment Center has violated 21 U.S.C. § 842(a)(5) by refusing or

negligently failing to make, keep, and furnish complete and accurate records of Ultimate Treatment Center's receipt, dispensation, and disposition of methadone pursuant to 21 U.S.C. § 827(a) and in accordance with applicable regulations.

169. Pursuant to 21 U.S.C. § 842(c)(1)(B), the United States is entitled to civil penalties in an amount not to exceed \$10,000 for each violation of 21 U.S.C. § 842(a)(5).

COUNT 3
CONTROLLED SUBSTANCES ACT
FAILURE TO MAKE AND MAINTAIN COMPLETE AND ACCURATE
RECORDS OF BUPRENORPHINE
21 U.S.C. § 842(a)(5)

170. The United States incorporates by reference all paragraphs of this Complaint set out above as if fully set forth herein.

171. The DEA's audit revealed that Ultimate Treatment Center's records did not account for a shortage of 664 8 mg/2 mg tablets of buprenorphine. In this regard, Ultimate Treatment Center failed to maintain complete and accurate records for each controlled substance received, dispensed, or disposed by Ultimate Treatment Center as required by 21 U.S.C. § 827(a) and 21 C.F.R. § 1304.21(a).

172. Pursuant to 21 U.S.C. § 842(a)(5), it is unlawful for any person to refuse or negligently fail to make, keep, or furnish any records or information required to be kept under the CSA. Ultimate Treatment Center has violated 21 U.S.C. § 842(a)(5) by refusing or negligently failing to make, keep, and furnish complete and accurate records of Ultimate Treatment Center's receipt, dispensation, and disposition of buprenorphine pursuant to 21 U.S.C. § 827(a) and in accordance with applicable regulations.

173. Pursuant to 21 U.S.C. § 842(c)(1)(B), the United States is entitled to civil penalties in an amount not to exceed \$10,000 for each violation of 21 U.S.C. § 842(a)(5).

COUNT 4
FALSE CLAIMS ACT
FALSE CLAIMS FOR E&M SERVICES NOT PERFORMED
31 U.S.C. § 3729(a)(1)(A)

174. The United States incorporates by reference all paragraphs of this Complaint set out above as if fully set forth herein.

175. Ultimate Treatment Center knowingly presented, directly or indirectly, false or fraudulent claims for payment to the United States, including claims for E&M services billed to the Government Healthcare Programs. The claims were false or fraudulent because they sought payment for E&M services that were not performed.

176. Dr. Uradu knowingly caused to be presented, directly or indirectly, false or fraudulent claims for payment to the United States, including claims for E&M services billed to the Government Healthcare Programs. The claims were false or fraudulent because they sought payment for E&M services that were not performed.

177. If the Government Healthcare Programs had known the claims were false or fraudulent, the Government Healthcare Programs would not have paid the claims.

178. As a result of the false or fraudulent claims presented, or caused to be presented, by the Defendants, the United States suffered damages in an amount to be determined at trial.

COUNT 5
FALSE CLAIMS ACT
CREATION AND USE OF FALSE RECORDS OR STATEMENTS
31 U.S.C. § 3729(a)(1)(B)

179. The United States incorporates by reference all paragraphs of this Complaint set out above as if fully set forth herein.

180. The Defendants knowingly made, used, or caused to be made or used, false records or statements regarding the health care and condition of patients in the form of false medical records. These records or statements were material to claims for payment submitted

to the Government Healthcare Programs. If the Government Healthcare Programs had known that the claims Ultimate Treatment Center submitted for payment contained or were based upon these false records or statements, the Government Healthcare Programs would not have paid the claims.

181. As a result of the false records or statements made, used, or caused to be made or used by the Defendants, the United States suffered damages in an amount to be determined at trial.

COUNT 6
FALSE CLAIMS ACT
FALSE CLAIMS FOR QUANTITATIVE DRUG TESTS NOT PERFORMED
31 U.S.C. § 3729(a)(1)(A)

182. The United States incorporates by reference all paragraphs of this Complaint set out above as if fully set forth herein.

183. Ultimate Treatment Center knowingly presented, directly or indirectly, false or fraudulent claims for payment to the United States, including claims for quantitative drug tests billed to the Government Healthcare Programs. The claims were false or fraudulent because they sought payment for quantitative drug tests that were not performed.

184. Dr. Uradu knowingly caused to be presented, directly or indirectly, false or fraudulent claims for payment to the United States, including claims for quantitative drug tests billed to the Government Healthcare Programs. The claims were false or fraudulent because they sought payment for quantitative drug tests that were not performed.

185. If the Government Healthcare Programs had known the claims were false or fraudulent, the Government Healthcare Programs would not have paid the claims.

186. As a result of the false or fraudulent claims presented, or caused to be presented, by the Defendants, the United States suffered damages in an amount to be determined at trial.

COUNT 7
UNJUST ENRICHMENT

187. The United States incorporates by reference all paragraphs of this Complaint set out above as if fully set forth herein.

188. Directly or indirectly, the Defendants received and retained the benefit of federal monies paid from the Government Healthcare Programs and intended to compensate Ultimate Treatment Center for E&M services and quantitative drug tests that it performed.

189. The E&M services for which the Government Healthcare Programs paid Ultimate Treatment Center were not actually performed by Ultimate Treatment Center.

190. The quantitative drug tests for which the Government Healthcare Programs paid Ultimate Treatment Center were not actually performed by Ultimate Treatment Center.

191. Directly or indirectly, the Defendants have been unjustly enriched with federal monies from the Government Healthcare Programs, in an amount to be determined at trial, which they should not in equity and good conscience be permitted to retain.

COUNT 8
PAYMENT BY MISTAKE

192. The United States incorporates by reference all paragraphs of this Complaint set out above as if fully set forth herein.

193. This is a claim for recovery of monies paid by the United States to Ultimate Treatment Center as a result of mistaken understandings of fact. Dr. Uradu received and retained the benefit of some of these monies.

194. The false claims that the Defendants submitted or caused to be submitted to the United States were paid by the United States based upon mistaken or erroneous understandings of material fact.

195. The United States, acting in reasonable reliance on the truthfulness of the claims and the truthfulness of the Defendants, paid Ultimate Treatment Center certain sums

of money to which Ultimate Treatment Center was not entitled, some of which was diverted to the personal use of Dr. Uradu. In particular, the United States relied upon the Defendants' representation that the claims sought payment for E&M services and quantitative drug tests performed by Ultimate Treatment Center, when in fact the services were not performed. The Defendants are thus liable to account for and to pay such amounts, which are to be determined at trial, to the United States.

PRAYER FOR RELIEF

WHEREFORE, the United States of America requests that judgment be entered in its favor and against Defendants as follows:

1. On Counts 1, 2, and 3, judgment against Defendants for the maximum statutory penalties for each of the violations set forth herein pursuant to the Controlled Substances Act.
2. On Counts 4, 5, and 6 under the False Claims Act, for the amount of the United States' damages, trebled as required by law, and such civil penalties as are required by law.
3. On Counts 7 and 8, for unjust enrichment and payment by mistake, for the amounts mistakenly paid to Defendants or by which the Defendants were unjustly enriched.
4. With respect to each Count, interest, attorney's fees, and costs as allowed by law, and any and all further relief as the Court deems just and proper.

JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38, the United States demands a trial by jury on all issues raised in its Complaint.

Respectfully submitted,

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