UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, the STATE of INDIANA, and the COMMONWEALTH OF MASSACHUSETTS *ex rel.* WENDY WELCH, M.D.,

Plaintiffs,

vs.

CLEANSLATE CENTERS, INC., TOTAL WELLNESS CENTERS, LLC, CLEANSLATE CENTERS, LLC, CLEANSLATE MEDICAL GROUP OF INDIANA, LLC, CLEANSLATE MEDICAL GROUP OF PENNSYLVANIA, LLC, CLEANSLATE MEDICAL GROUP OF CONNECTICUT, LLC, CLEANSLATE MEDICAL GROUP OF ARIZONA, PLLC, CLEANSLATE MEDICAL GROUP OF FLORIDA, PLLC, CLEANSLATE MEDICAL GROUP OF WISCONSIN, S.C., CLEANSLATE MEDICAL GROUP OF TEXAS, PLLC, CLEANSLATE MEDICAL GROUP OF KENTUCKY, PLLC, CLEANSLATE MEDICAL GROUP OF OHIO, LLC ALL DOING BUSINESS AS CLEANSLATE CENTERS; AMANDA LOUISE WILSON, M.D.; and APPLE TREE PARTNERS,

Defendants.

Civil Action No. 17-cv-30038-MGM

JURY TRIAL DEMANDED

FIRST AMENDED COMPLAINT FOR VIOLATIONS OF THE FALSE CLAIMS ACT

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I. INTRODUCTION

1. This is an action to recover damages, civil penalties, and other relief on behalf of the United States, the Commonwealth of Massachusetts, and the State of Indiana (the "States" or "*Qui Tam* States") arising from false and/or fraudulent claims, statements and records, presented to government health care programs, as well as failure to return overpayments, and conspiracy, all in violation of the federal False Claims Act, 31 U.S.C. §§ 3729, *et seq*., and the State False Claims Act statutes identified herein ("State *Qui Tam* statutes" or "State FCAs").[1] In addition, Relator seeks to recover damages for personal claims of retaliation in violation of federal and state statutes, and wrongful termination of employment, breach of contract and other common law state claims.

2. This health care fraud has been and continues to be committed by Defendants through their chain of outpatient addiction treatment centers, at which tens of thousands of patients suffering from opioid addiction seek treatment. Relator estimates that Defendants have defrauded the federal and state governments of over $100 million dollars since at least 2009.

3. Defendants have exploited the national opioid epidemic in a scheme to build and operate a chain of for-profit "addiction-treatment centers" that their own employees described as a "pill mill" where physicians are expected to "rubber stamp" stacks of prescriptions. Defendants' primary focus is distributing buprenorphine-based drugs to as many opioid-addicted patients as possible followed by months and years of automatic and medically unnecessary confirmatory testing, while avoiding the cost of medically necessary oversight, counseling, coordination of care, and individualized treatment. Defendants' own Chief Medical Officer

[1] This complaint incorporates all allegations set forth in the Complaint in Intervention of the Commonwealth of Massachusetts filed in this matter on October 16, 2020.

described results of CleanSlate chart reviews as "an unacceptable deviation from the standard of care" and "and unacceptable risk to the company."

4. At CleanSlate, clinical assessment, diagnosis and treatment are dictated by corporate policies drafted by non-physicians and applied without individualized decision-making by inadequately trained and supervised call center employees, nurse practitioners and physician assistants. Defendants hire part-time, inexperienced, and under-trained physicians whose primary role is to sign prescriptions for opioid medication based on a cursory review of clinical notes for patients with whom they have no valid physician relationship. Indeed, the value these physicians bring to CleanSlate is not their medical judgment at all, but their potential to prescribe buprenorphine prescriptions to the maximum number of patients allowed by law.

5. Further, as part of this scheme, Defendants mandate expensive laboratory tests, including Urine Drug Screens ("UDS") performed at every patient visit, and unnecessary confirmatory tests for every patient prescribed buprenorphine, all funneled to their own clinical laboratory. Often, the results of these CleanSlate tests were not used to inform treatment decisions for patients. In many instances, the test results were never even reviewed by any CleanSlate medical staff, thereby confirming the complete lack of medical necessity. Defendants imposed this wasteful testing regime not only to compensate for the lack of competent medical judgment among its staff, but also because it was a major revenue and profit driver for CleanSlate's national expansion.

6. Defendants' claims to federal and state governments for laboratory testing services performed at CleanSlates' laboratory are false and/or fraudulent because they violate self-referral and kickback prohibitions and are medically unnecessary in violation of core government healthcare rules.

7. Defendants' scheme also involved numerous fraudulent claims for office visits and buprenorphine prescriptions performed and ordered by inadequately supervised Nurse Practitioners and Physician Assistants in violation of state law and DEA regulations.

8. CleanSlate's practices exposed countless patients to serious medical harm. Plaintff-Relator Dr. Wendy Welch's ("Dr. Welch") review of CleanSlate's patient charts identified numerous instances in which patients' tests revealed dangerous combinations of drugs of abuse, indicative of significant relapse, without any change in care, or even any acknowledgment by the supervising CleanSlate medical professionals. Similarly, CleanSlate's charts reveal numerous instances in which practitioners noted that a patient needed a higher level of care than CleanSlate could provide, but those concerns were ignored and the CleanSlate system simply scheduled the patient for the next visit and the next buprenorphine prescription, followed by the next medically unnecessary confirmatory lab test. Relator is also aware of at least one example in which Defendants' reliance on non-medical personnel and corporate policies to supervise high-risk patients led to the abandonment of one such patient who lost their insurance and relapsed. Ultimately and tragically this patient overdosed and died.

9. Beginning in 2016, Defendants escalated the scope of their scheme. Fueled by the flow of venture capital funds from Defendant Apple Tree Partners and the resulting focus on the profits to be made from the opioid epidemic, CleanSlate accelerated its expansion far beyond its ability to provide medically safe care to patients. The acknowledged goal of that "rapid expansion" was to satisfy the Apple Tree Partners' desire to show "ratios that tee us up for future exit" and "tell a story that flows back to P&L." At the direction of Apple Tree Partners, CleanSlate embarked on an aggressive plan to realize "$500 million revenue; $125 million EBITDA; 25% margin; $1B valuation; 50,000 patients; in 3 years." Defendants knew that such

financial results could only be achieved through a system which targeted, and defrauded, government health care programs.

II. JURISDICTION AND VENUE

10. This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1345 and 31 U.S.C. § 3732, which confer jurisdiction over actions brought pursuant to 31 U.S.C. §§ 3729 and 3730. This Court has original and supplemental jurisdiction over the state law claims pursuant to 31 U.S.C. § 3732(b) and 28 U.S.C. § 1367 because this action is brought under state laws for the recovery of funds paid by the *Qui Tam* States and arises from the same transaction or occurrence as the claims brought on behalf of the United States under 31 U.S.C. § 3730. This Court also has original and supplemental jurisdiction over Relator's personal claims for retaliation in violation of federal and state law, breach of Relator's contract, and other claims comprising the same case or controversy pursuant to 28 U.S.C. §§ 3732 and 1367(a).

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

12. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a), 28 U.S.C. § 1391, and 28 U.S.C. § 1395(a), because one or more of the Defendants reside in and/or transact business in this District by, among other things, organizing and operating office based opioid treatment (OBOT) centers that engage in the misconduct alleged herein.

III. PARTIES

13. Plaintiffs the United States of America and the *Qui Tam* States are the real parties in interest with respect to the federal and state False Claims Act *qui tam* claims herein. Plaintiff-Relator Dr. Wendy Welch is pursuing certain causes of action on behalf of the named Plaintiffs the United States and the States on the FCA *qui tam* claims set forth herein pursuant to 31 U.S.C.

§ 3730(b) and comparable provisions of the State FCAs. She is also pursuing personal claims under the anti-retaliation provisions of the False Claims Act, 31 U.S.C. § 3730(h), and state law analogues, as well as other claims related to her employment.

14. Plaintiff-Relator Dr. Wendy Welch is a resident of the State of North Carolina. She began working with CleanSlate as the Eastern Division Medical Director around September 2016, but her official start date was October 31, 2016. Dr. Welch resigned on December 16, 2016 and her last day of employment was January 16, 2017. Dr. Welch is familiar with and has direct, independent, and material knowledge of the Defendants' business operations and the allegations herein.

15. Defendant Total Wellness Centers, LLC ("Total Wellness") is a single member professional limited liability company located in Northampton, Massachusetts. Dr. Maria Russo-Appel serves as its manager. Total Wellness was organized in Massachusetts on October 8, 2009 to provide outpatient substance abuse treatment. Defendant Amanda Wilson served as the single member and sole manager of Total Wellness. Defendants Total Wellness and Amanda Wilson opened and operated a clinical laboratory located in Holyoke, Massachusetts. Since at least May 2012, Total Wellness been doing business as CleanSlate Centers. Total Wellness is the practice and billing entity for all treatment in Massachusetts. Total Wellness also owns the CleanSlate laboratory in Holyoke, MA.

16. Defendant CleanSlate Centers, LLC is a now-canceled professional limited liability company with its headquarters in Florence, Massachusetts. It was organized on June 21, 2010 with Dr. Amanda Wilson as its sole manager, to render "physician supervised medical opioid addiction treatment." On October 10, 2013, the general character of its business was

changed to "provide administrative and management services." On May 31, 2015, its sole manager, Dr. Wilson, executed a certificate of cancellation of CleanSlate Centers, LLC.

17. Defendant CleanSlate Centers, Inc. is a privately held company organized under the laws of the State of Delaware in December 2013. The initial principal place of business for CleanSlate Centers, Inc was located in Northampton, Massachusetts.

18. CleanSlate Centers, Inc. provides management services to the CleanSlate practices. It is the ultimate parent of and wholly controls the state level CleanSlate entities including Total Wellness. These entities are the practicing and billing entities in each of the states in which they are located. They were established as "friendly" professional corporations ("PCs") to attempt to evade corporate practice of medicine restrictions and other legal regulations. Besides Total Wellness, these state level entities include:

a. Defendant CleanSlate Medical Group of Indiana, LLC, d/b/a CleanSlate Centers, is an Indiana limited liability company with its original principal office address in Northampton, Massachusetts. It was organized on February 5, 2016 with Dr. Amanda Wilson as its sole manager. Since at least November 2016, Andrew Mendenhall, M.D., formerly CleanSlate Regional Medical Director for the Northeast Region, has been identified as its President.

b. Defendant CleanSlate Medical Group of Pennsylvania, LLC is a Pennsylvania professional limited liability company with registered agent CT Corporation System of Dauphin County. It was organized on June 1, 2016 by Dr. Amanda Wilson to "provide professional medical services."

c. Defendant CleanSlate Medical Group of Connecticut, LLC is a Connecticut limited liability company with business address in Brentwood, TN. It was organized on November 14, 2016 with Dr. Mendenhall as its sole Member and Manager.

d. Defendant CleanSlate Medical Group of Arizona, PLLC is an Arizona professional limited liability company with registered agent CT Corporation System. It was organized on December 6, 2016 by Dr. Mendenhall. Its Member and manager is Nasser Hajaig, M.D.

e. Defendant CleanSlate Medical Group of Florida, PLLC is a Florida limited liability company with business address in Brentwood, TN. It was organized on February 2, 2017 with Dr. Mendenhall as its Member and Manager.

f. Defendant CleanSlate Medical Group of Wisconsin, S.C., is a Wisconsin service corporation incorporated by Dr. Mendenhall on December 13, 2016, with business address in Brentwood, TN.

g. Defendant CleanSlate Medical Group of Texas, PLLC, is a Texas professional limited liability company with registered agent CT Corporation System. It was organized on January 23, 2017 by Dr. Mendenhall with CleanSlate Medical Group of Indiana, LLC as its sole Member.

h. Defendant CleanSlate Medical Group of Kentucky, PLLC is a Kentucky professional limited liability company with registered agent CT Corporation System. It was organized on February 8, 2017 by Dr. Mendenhall with CleanSlate Medical Group of Indiana, LLC as its sole Member. Its principal office is 12 Cadillac Drive, Suite 380, Brentwood, TN 3702.

i. Defendant CleanSlate Medical Group of Ohio, LLC is an Ohio limited liability company with registered agent CT Corporation System. It was organized on February 8, 2017 by Dr. Mendenhall.

CleanSlate Centers, Inc., CleanSlate Centers, LLC, Total Wellness, each of the above-identified ClanSlate state level entities, and their respective subsidiaries and affiliates, are referred to collectively herein as "CleanSlate" or "CleanSlate Centers."

19. Defendant Amanda Louise Wilson, M.D. ("Dr. Wilson"), of West Springfield, Massachusetts, founded Defendant Total Wellness, LLC in 2009, and was previously the majority share-holder (at least until early 2017) and Chairperson of the Board of Directors of CleanSlate, Inc. Dr. Wilson has been licensed to practice medicine in the Commonwealth of Massachusetts since 2000, and is licensed in Indiana, Connecticut, New Hampshire, Rhode Island, Vermont, Pennsylvania, and Maine.

20. Defendant Apple Tree Partners a/k/a Apple Tree Partners Research, Inc. is a life sciences venture capital firm organized under the laws of the State of Delaware with a principal place of business in New York. In and after 2014, Apple Tree Partners held various interests in CleanSlate based on its purchases of successive series of preferred stock. Apple Tree Partners also controlled a block of seats on CleanSlate's Board of Directors.

21. Apple Tree Partners purchased and held its position in CleanSlate through Apple Tree Partners, IV L.P. and ATP III, GP Ltd. Apple Tree Partners, IV L.P. is a Cayman Islands exempted limited partnership whose principal business is to make, hold and dispose of equity and equity-related investments. ATP III GP, Ltd. is a Cayman Islands exempted company whose principal business is to act as the sole general partner of Apple Tree Partners IV, L.P.. Both Apple Tree Partners IV, L.P. and ATP III GP, Ltd conduct business out of the Apple Tree Partners

offices in New York, New York. Seth L. Harrison, M.D. is the Managing Partner of Apple Tree Partners and the Director of both Apple Tree Partners, IV, L.P. and ATP III GP, Ltd. Seth Harrison also served on the CleanSlate Board of Directors.

22. Apple Tree Partners a/k/a Apple Tree Partners Research, Inc., Apple Tree Partners IV, L.P., and ATP III GP, Ltd. are referred to collectively herein as "Apple Tree Partners" or "ATP."

IV. APPLICABLE FEDERAL AND STATE LAWS AND REGULATIONS

A. Government Health Insurance Programs

23. The Health Insurance for the Aged and Disabled Program, known as Medicare, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395 *et seq*. ("Medicare"), is a health insurance program administered by the United States Government, funded by taxpayer revenue. The United States Department of Health and Human Services ("HHS"), through its Centers for Medicare and Medicaid Services ("CMS"), oversees Medicare.

24. Medicare was designed to be a health insurance program and to provide for payment of, among other things, medical services and equipment to persons over 65 years of age and certain others who qualify under Medicare's terms and conditions. The Medicare program has four parts: Part A, Part B, Part C, and Part D. Medicare Part A, the Basic Plan of Hospital Insurance, covers the cost of inpatient hospital services and post-hospital nursing facility care. *See* 42 U.S.C. §§ 1395c-1395i-4. Medicare Part B, the Voluntary Supplemental Insurance Plan, covers the cost of services performed by physicians and certain other health care providers, such as services provided to Medicare patients by physicians, laboratories, and diagnostic testing facilities. *See* 42 U.S.C. §§ 1395k, 1395l, 1395x(s). Medicare Part C covers certain managed care plans, and Medicare Part D provides subsidized prescription drug coverage for Medicare beneficiaries.

25. The Medicaid program, Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v ("Medicaid"), is a health insurance program administered by the United States Government and the States and is funded jointly by state and federal taxpayer revenue. CMS and HHS oversee Medicaid jointly with agencies in each State. Each named Plaintiff State participates in Medicaid.

26. Medicaid is designed to assist participating States in providing medical and laboratory services, medical equipment, and prescription drugs to needy individuals that qualify for Medicaid. The States and federal government share reimbursement costs. States directly pay providers, and then obtain the federal contribution from accounts drawn on the United States Treasury. 42 C.F.R. §§ 430.0 *et seq*. (1994). Federal funding for the Medicaid Program includes support for Medicare Savings Programs which help qualifying Medicare beneficiaries pay Part A and B premiums, co-payments, co-insurance, and deductibles. The Medicare Savings Programs consist of the Qualified Medicare Beneficiary Program, 42 U.S.C. § 1396d(p)(1), the Specified Low-Income Medicare Beneficiary Program, 42 U.S.C. § 1396a(a)(10)(E)(iii), the Qualifying Individual Program, 42 U.S.C. § 1396a(a)(10)(E)(iv), and the Qualified Disabled and Working Individuals Program, 42 U.S.C. § 1396d(s). Medicaid may serve as the primary insurer, or in some instances as the secondary insurer (*e.g*., with Medicare or private insurance paying primary coverage). Medicaid sets forth minimum requirements for state Medicaid programs to meet to qualify for federal funding and each participating state adopts its own state plan and regulations governing the administration of the state's Medicaid program. For example:

a. the Massachusetts Medicaid program, MassHealth, promulgates regulations that govern a healthcare provider's interactions with the program, *see generally*, 130 C.M.R. § 401.401- 130 C.M.R. § 650.035; and

b. the Indiana Family and Social Services Administration administers the Indiana's Medicaid program, collectively referred to as the Indiana Health Coverage Programs (IHCP), s*ee generally*, Indiana Administrative Code Titles 405, 407.

27. The Civilian Health and Medical Program of the Uniformed Services (now known as "TRICARE"), 10 U.S.C. §§ 1071-1106, provides benefits for health care services furnished by civilian providers, physicians, and suppliers to members of the Uniformed Services and to spouses and children of active duty, retired, and deceased members. TRICARE pays for, among other things, medical devices and surgeries for its beneficiaries.

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

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

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

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

32. Reimbursement practices under all Government Health Care Programs closely align with the rules and regulations governing Medicare reimbursement. The most basic reimbursement requirement is that the service provided must be reasonable and medically necessary. *See*, *e.g.*, 42 U.S.C. § 1395y(a)(1)(A) (Medicare does not cover items or services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."); *id.* at §§ 1396, *et seq*. (Medicaid); §§ 410.50, 411.15(k)(1), 411.406; *Moore ex rel. Moore v. Reese*, 637 F.3d 1220, 1232 (11th Cir. 2011) ("Although the standard of 'medical necessity' is not explicitly denoted in the Medicaid Act, it has become a judicially accepted component of the federal legislative scheme." (citing *Beal v. Doe,* 432 U.S. 438, 444 (1977)); *United States v. Rutgard*, 116 F.3d 1270, 1275-76 (9th Cir. 1997) (holding that TRICARE and the Railroad Retirement Health Insurance Program follow the same rules and regulations as Medicare, citing, *e.g*., 32 C.F.R. § 199.4(a)(1)(i)); *United States ex rel. Riley v. St. Luke's Episcopal Hospital, 355 F.3d 370, 376 n.6* (5th Cir. 2004) (recognizing that CMS 1500 Form carries an express certification and holding that hospital CHAMPUS reimbursement sought on Form 1450 has the same certification as the CMS Form 1500).

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

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

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

35. Under Government Health Care Programs, medical care may in some situations be provided by non-physician providers, including Nurse Practitioners ("NP") and Physician Assistants ("PA) (collectively "mid-level practitioners") if they are appropriately supervised by a physician. The level of supervision depends in part on the applicable billing method. Where mid-level practitioners' services are billed with a physician's name and National Provider Identifier (NPI) number under Medicare's incident-to rules, the services must be directly supervised. *See* 42 C.F.R. §§ 410.26; 410.32. Services billed by a PA must be supervised by a physician responsible for the overall direction of care and for assuring that the services provided are medically appropriate. *See* Medicare Benefit Policy Manual, Ch. 15 § 190. Services billed by a NP must be performed in collaboration with one or more physicians (MD/DO) with medical direction and appropriate supervision as required by the law of the state in which the services are furnished. *Id.* at § 200.

36. Each of the states in which CleanSlate practices, establishes by regulation the required level of supervision for mid-level practitioners. For example:

a. Arizona:

i. A physician is responsible for supervising the PA and ensuring the healthcare tasks the PA performs are within the PA's scope of training and experience and

have been properly delegated by the supervising physician. Ariz. Rev. Stat. § 32.2533(A).

ii. Supervision means a physician's opportunity or ability to provide or exercise direction and control over the services of a PA. Supervision does not require a physician's constant physical presence if the supervising physician is or can be easily in contact with the PA by telecommunication. Ariz. Rev. Stat. § 32.2501(17). If the PA practices in a location where a supervising physician is not routinely present, the PA must meet in person or by telecommunication with a supervising physician at least once a week to ensure ongoing direction and oversight of the PA's work. Ariz. Rev. Stat. § 32.2531(J).

b. Connecticut:

i. Each PA must have a clearly identified supervising physician who maintains the final responsibility for patient care and the PA's performance. Conn. Gen. Stat. § 20-12c(a).

ii. Supervision in relevant settings means the exercise by the supervising physician of oversight, control and direction of the PA's services. Supervision includes, but is not limited to: continuous availability of direct communication either in person or by radio, telephone or telecommunications between the PA and supervising physician; active and continuing overview of the PA's activities to ensure the supervising physician's directions are being implemented and to support the PA in performance of his/her services; personal review by the supervising physician of the PA's services at a facility or practice location where the PA or supervising physician performs services, in accordance with a written delegation agreement,

as described in Conn. Gen. Stat. § 20-12d(a), to ensure patient care; review of the PA's charts and records on a regular basis as necessary to ensure quality patient care and written documentation by the supervising physician of such review at the facility or practice location where the PA or supervising physician performs services; delineation of a predetermined plan for emergency situations; and designation of an alternate licensed physician in the absence of the supervising physician. Conn. Genn. Stat. § 20-12a(7)(B).

iii. NPs are considered advanced practice registered nurses (APRNs). Conn. Gen. Stat. § 20-94a(a). APRN's must collaborate with a physician licensed in Connecticut for the first three years and 2,000 hours of being licensed as an APRN. Conn. Gen. Stat. § 20-87a(2).

iv. "Collaboration" means a mutually agreed upon relationship between the NP and a physician who is educated, trained or has relevant experience that is related to the work of such NP. The collaboration must address a reasonable and appropriate level of consultation and referral, coverage for the patient in the absence of the NP, a method to review patient outcomes, and a method of disclosure of the relationship to the patient. Relative to the exercise of prescriptive authority, the collaboration between the NP and physician must be in writing and must address the level of schedule II and schedule III controlled substances that the NP may prescribe and provide a method to review patient outcomes, including, but not limited to, the review of medical therapeutics, corrective measures, lab tests and other diagnostic procedures that the NP may prescribe, dispense and administer. Conn. Gen. Stat. § 20-87a(2).

c. Florida:

i. A PA performs delegated services by a supervising physician. Fla. Stat. § 458.347(e).

ii. "Supervision" means responsible supervision and control. Except in cases of emergency, supervision requires the easy availability or physical presence of the licensed physician for consultation and direction of the actions of the physician assistant. For the purposes of this definition, the term "easy availability" includes the ability to communicate by way of telecommunication. The boards shall establish rules as to what constitutes responsible supervision of the physician assistant. Fla. Stat. § 458.347(f).

iii. An NP (APRN) must work within the framework of an established protocol that must be maintained on site at the location where the APRN works. Fla. Stat. § 464.012(3).

iv. A physician must maintain supervision for directing the specific course of medical treatment. Fla. Stat. § 464.012(b)(3). If the NP or PA is not in the same office as the supervising physician, the practice location must be within 25 miles of the physician's primary place of practice or in a county that is contiguous to the county of the physician's primary place of practice. The distance between any offices can't exceed 75 miles. Fla. Stat. 458.348(3)(c).

d. Indiana:

i. PAs must practice in collaboration with a licensed physician. Ind. Code § 25-27.5-1-3; Ind. Code § 25-27.5-2-4.7.

ii. Collaboration means overseeing the activities of, and accepting responsibility for, the medical services rendered by a PA and that one (1) of the following conditions is met at all times that services are rendered or tasks are performed by the PA: The collaborating physician or the physician designee is physically present at the location where services are rendered or tasks are performed by the PA. When the collaborating physician or the physician designee is not physically present at the location at which services are rendered or tasks are performed by the PA, the collaborating physician or the physician designee is able to personally ensure proper care of the patient and is: immediately available through the use of telecommunications or other electronic means; and able to see the person within a medically appropriate time frame for consultation, if requested by the patient or the physician assistant. Ind. Code § 25-27.5-2-4.9. A collaborating physician or physician designee must review patient encounters not later than ten business days, and within a reasonable time, as established in the collaborative agreement, after the PA has seen the patient, that is appropriate for the maintenance of quality medical care. *Id*.

iii. NPs are APRN's, Ind. Code § 25-23-1-1(b)(1) and must operate in collaboration with a licensed practitioner as evidenced by a practice agreement, Ind. Code § 25-23-1-19.4(c).

iv. NPs with prescriptive authority must submit proof of collaboration with a licensed practitioner in the form of a written practice agreement that sets forth the manner of how the NP and licensed practitioner will cooperate, coordinate, and consult with each other in the provision of health care to patients. Practice agreements

shall be in writing and shall also set forth provisions for the type of collaboration between the advanced practice nurse and the licensed practitioner and the reasonable and timely review by the licensed practitioner of the prescribing practices of the advanced practice nurse. 848 IAC 5-1-1.

e. Kentucky:

i. A physician is required to provide adequate, active, and continuous supervision of a PA's activities to ensure that the PA is performing as directed. KRS § 311.856(10). A PA shall not practice medicine independently. Each PA must practice under supervision. KRS § 311.858(9).

ii. Supervision means overseeing the activities of and accepting of responsibility for the medical services rendered by a physician assistant. Each team of physicians and physician assistants shall ensure that the delegation of medical tasks is appropriate to the physician assistant's level of training and experience, that the identifications of and access to the supervising physician are clearly defined, and that a process for evaluation of the physician assistant's performance is established. KRS § 311.840(6).

iii. If prescribing non-legend drugs, an NP must have a written collaboration agreement with the physician for 4 years. KRS § 314.042(8)-(9). If an NP is prescribing Schedule II-V controlled substances, he or she must also have written collaboration agreement. KRS 314.042(10).

iv. Collaboration means the relationship between the NP and a physician in the provision of prescription medication, including both autonomous and cooperative

decision-making, with the advanced practice registered nurse and the physician contributing their respective expertise. 201 KAR 20:057(1).

f. Massachusetts:

i. A PA may perform medical services only when such services are rendered under the supervision of a registered physician. MGL 112 § 9E; 243 CMR 2.08(2).

ii. A supervising physician shall afford supervision adequate to assure that: The PA provides medical services in accordance with accepted medical standards. Supervision is adequate under if it permits a physician assistant who encounters a new problem not covered by a written protocol or which exceeds established parameters to initiate a new patient care plan and consult with the supervising physician. 243 CMR 2.08(2); 263 CMR 5.04(3).

iii. NPs are considered APRNs, 244 CMR 4.03, when engaged in prescriptive practice and must do so in accordance with written guidelines mutually developed and agreed upon with the NP and the supervising physician. In all cases, the written guidelines will: Include a defined mechanism for the delegation of supervision to another physician including, but not limited to, duration and scope of the delegation; [d]escribe circumstances where physician consultation or referral is required for the pharmacologic treatment of medical conditions or managing emergencies; Include a defined mechanism and time frame to monitor prescribing practices; [s]pecify that the initial prescription of Schedule II drugs must be reviewed within 96 hours. 244 CMR 4.07(2); 243 CMR 2.10(5).

iv. A supervising physician must review and provide ongoing direction for the NPs prescriptive practice in accordance with written guidelines mutually developed

and agreed upon with the NP pursuant to 244 CMR: Board of Registration in Nursing and 243 CMR 2.10.

g. Ohio:

i. The supervising physician of a PA exercises supervision, control and direction of the PA. A PA may practice in any setting within which the supervising physician has supervision, control, and direction of the PA. R.C. § 4730.21(A).

ii. In supervising a physician assistant, the supervising physician shall be continuously available for direct communication with the PA by either being physically present at the location where the physician assistant is practicing or being readily available to the physician assistant through some means of telecommunication and being in a location that is a distance from the location where the physician assistant is practicing that reasonably allows the physician to assure proper care of patients. The supervising physician shall personally and actively review the physician assistant's professional activities. The supervising physician shall regularly perform any other reviews of the physician assistant that the supervising physician considers necessary. R.C. § 4730.21(A). A PA must practice under on-site supervision of supervising physician for first 500 hours of prescriptive authority, unless exceptions apply (practiced with prescriptive authority in another jurisdiction for more than 1000 hours). R.C. § 4730.44(B).

iii. A nurse practitioner must collaborate with one or more physicians. R.C. § 4723.43(C). There must be a written standard of care arrangement on file with the NP's employer, and the Board of Nursing must have the name and business

address of each collaborating physician. R.C. § 4723.431. The agreement must be reviewed every 2 years. OAC 4723-8-04(7)(a).

iv. Collaboration requires that a physician has entered into a standard care arrangement with the nurse and is continuously available to communicate with the NP either in person or by electronic communication. OAC 4723-8-01(B).

h. Pennsylvania:

i. A PA shall not perform a medical service without the supervision and personal direction of an approved physician. 63 P.S. § 422.13(d).

ii. Supervision means: Oversight and personal direction of, and responsibility for, the medical services rendered by a PA. The constant physical presence of the supervising physician is not required so long as the supervising physician and the PA are, or can be, easily in contact with each other by radio, telephone, or other telecommunications device. An appropriate degree of supervision includes: Active and continuing overview of the PA's activities to determine the physician's directions are being implemented. Immediate availability of the supervising physician to the PA for necessary consultations. Personal and regular review within 10 days by the supervising physician of the patient records upon which entries are made by the PA. 49 Pa. Code § 18.122.

iii. An NP (referred to as Certified Registered Nurse Practitioner) must practice in collaboration with a physician. 49 Pa. Code § 21.251. An NP with prescriptive authority approval may, when acting in collaboration with a physician as set forth in a prescriptive authority collaborative agreement and within the NP's specialty, prescribe and dispense drugs and give written or oral orders for drugs and other

medical therapeutic or corrective measures. 49 Pa. Code § 21.283; 63 P.S. § 218.3.

iv. Collaboration requires immediate availability of a licensed physician to a NP through direct communications or by radio, telephone or telecommunications and a physician available to a NP on a regularly scheduled basis for referrals, review of the standards of medical practice incorporating consultation and chart review, drug and other medical protocols within the practice setting, periodic updating in medical diagnosis and therapeutics and cosigning records when necessary to document accountability by both parties. 49 Pa. Code § 21.251; 63 P.S. § 212(13).

i. Texas:

i. PA supervision must be continuous. 22 TAC § 185.14(a).

ii. Supervision requires a physician overseeing the activities of, and accepting responsibility for, the medical services rendered by a PA. Supervision does not require the constant physical presence of the supervising physician but includes a situation where a supervising physician and the person being supervised are, or can easily be, in contact with one another by radio, telephone, or another telecommunication device." 22 TAC § 185.2(22).

iii. NPs require protocols or other written authorization: jointly developed by the advanced practice nurse and the appropriate physician(s), signed by both the advanced practice nurse and the physician(s), reviewed and re-signed at least annually, maintained in the practice setting of the advanced practice nurse, and made available as necessary to verify authority to provide medical aspects of care. 22 TAC § 221.13.

j. Virginia:

i. A PA must not render independent health care and must perform only those medical care services that are within the scope, practice and proficiency of the supervising physician as prescribed in the PA's practice agreement. 18 VAC 85-50-115(A).

ii. "Supervision" means the supervising physician has on-going, regular communication with the physician assistant on the care and treatment of patients, is easily available, and can be physically present or accessible for consultation with the physician assistant within one hour. 18 VAC 85-50-10.

iii. NPs must practice in collaboration and consultation with a physician and have a written practice agreement. 18 VAC 90-30-120(A). NP's can practice independently if they have worked for 5 years and a total of 9,000 hours. 18 VAC 90-30-86(A).

iv. "Collaboration" means the communication and decision-making process among members of a patient care team related to the treatment and care of a patient and includes (i) communication of data and information about the treatment and care of a patient, including exchange of clinical observations and assessments, and (ii) development of an appropriate plan of care, including decisions regarding the health care provided, accessing and assessment of appropriate additional resources or expertise, and arrangement of appropriate referrals, testing, or studies.

k. Wisconsin:

i. The entire practice of any PA must be under the supervision of one or more licensed physicians. Wis. Adm. Code § Med 8.07(1). PA's can issue written prescription orders for drugs only if the PA has had an initial and at least annual thereafter, review of the PA's prescriptive practices by a physician providing supervision. Such reviews shall be documented in writing, signed by the reviewing physician or podiatrist and by the physician assistant, and made available to the Board for inspection upon reasonable request. Wis. Adm. Code § Med 8.07(2)(i).

ii. Supervision means to coordinate, direct, and inspect the accomplishments of another, or to oversee with powers of direction and decision the implementation of one's own or another's intentions. Wis. Adm. Code § Med 8.02(6). A supervising physician must be available to the PA at all times for consultation either in person or within 15 minutes of contact by telecommunication or other means. Wis. Adm. Code § Med 8.10(2).

iii. NPs are considered APRNs, Wis. Adm. Code § N 8.02, and if they have prescriptive authority they must work in a collaborative relationship with a physician. Wis. Adm. Code § N 8.10(7). They may not prescribe, dispense, or administer any compound designated as a Schedule II controlled substance pursuant to the provisions of s. 961.16 (5). Wis. Adm. Code § N 8.06.

iv. The collaborative relationship is a process where an NP is working with a physician, in each other's presence when necessary, to deliver health care services

within the scope of the practitioner's training, education, and experience. Wis. Admin. Code N § 8.10(7).

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

38. In addition, federal and state law contain specific requirements as to certain types of providers/facilities, *e.g.*, opioid treatment facilities, 42 C.F.R. § 8.12 (regulating traditional Opioid Treatment Programs); Drug Addiction Treatment Act of 2000 (DATA 2000), 21 U.S.C. § 823(g) (permitting physicians to prescribe "certain narcotic drugs for maintenance treatment or detoxification treatment" of individuals with opioid dependence); 42 C.F.R. §§ 8.610, *et seq.* (governing physicians operating OBOT programs with DATA 2000 waivers for between 101 and 275 patients); 105 C.M.R. 164.007(F) (governing OBOT programs with more than 300 patients).

39. Physicians and hospitals enter into Provider Agreements with CMS to establish their eligibility to seek Medicare reimbursements. As part of those agreements, the provider must sign the following certification:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to [me] . . . The Medicare laws, regulations, and program instructions are available through the fee-for-service contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but

> not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier's compliance with all applicable conditions of participation in Medicare.

Form CMS-855I, at 25 (for physicians and non-physician practitioners); *see* CMS-855A, at 48 (similar for institutional providers). The States have similar agreements for their Medicaid programs, *see, e.g.*, MassHealth Provider Contract for Individuals form GEN-15, at 1 (similar to CMS form); MassHealth Provider Contract for Entities form GEN-16, at 2 (similar); 130 C.M.R. § 450.223(A) & (C)(1) (all MassHealth provider contracts implicitly incorporate similar language); IHCP [Indiana] Provider Agreement, at 1 (similar).

40. Claims submitted by health care providers to Government Health Care Programs contain similar representations and certifications. *See, e.g.*, Forms CMS-1500 (paper provider claim form used for Medicare and Medicaid); 837P (electronic version of form 1500); 1450 (UB04 – institutional provider paper claim form used for Medicare and Medicaid); 837I (electronic version of form 1450). When submitting a claim for payment, a provider does so subject to and under the terms of his certification to the United States that the services were delivered in accordance with federal law, including, for example, Government Health Care Program laws and regulations. Government Health Care Programs require compliance with these certifications as a material condition of payment and claims that violate these certifications are false or fraudulent claims under the FCA. CMS, its fiscal agents, and relevant State health agencies will not pay claims for medically unnecessary services or claims for services provided in violation of relevant state or federal laws.

41. When submitting a claim for services under Government Health Care Programs, the provider designates a numeric code assigned to that service or procedures by the American Medical Association. These codes are known as Current Procedural Terminology ("CPT") codes and are used by health care providers to represent which services have been provided and for

which they are seeking reimbursement. In addition, CMS has assigned and published alpha-numeric codes for supplies and services that supplement the CPT codes. This coding system is known as the Healthcare Common Procedure Coding System ("HCPCS"). HCPCS codes are similarly used by health care providers to represent to Government Health Care Programs what services have been provided and for which they are seeking reimbursement.

42. To submit claims to Government Health Care Programs, providers must include a CPT or HCPCS code on the claim that accurately represents the service provided or the procedure performed.

B. The Federal and State False Claims Acts

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

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

b. "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(B).

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

d. "knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government." 31 U.S.C. § 3729(a)(1)(G).

44. The FCA further provides that any person who violates the FCA "is liable to the United States for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 . . . , plus 3 times the amount of

damages which the Government sustains because of the act of that person." 31 U.S.C. § 3729(a)(1). The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, 28 U.S.C. § 2461 note, increased the civil penalty as relevantly follows to between $5,500 and $11,000 for violations occurring on or before November 2, 2015, and to between $11,665 to $23,331 for violations occurring after November 2, 2015. 28 C.F.R. §§ 85.3, 85.5.

45. The FCA provides that "the terms 'knowing' and 'knowingly' – (A) mean that a person, with respect to information – (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information; and (B) require no proof of specific intent to defraud." 31 U.S.C. § 3729(b)(1).

46. The FCA provides that "the term 'claim' – (A) means any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that— (i) is presented to an officer, employee, or agent of the United States; or (ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government— (I) provides or has provided any portion of the money or property requested or demanded; or (II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded." 31 U.S.C. § 3729(b)(2).

47. The FCA provides that "the term 'obligation' means an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment." 31 U.S.C. § 3729(b)(3). Moreover, in the health care context,

such as Medicare and Medicaid, the term "obligation" is further defined as "Any overpayment retained by a person after the deadline for reporting and returning the overpayment," that must be reported "[b]y the later of…60 days after the date on which the overpayment was identified…or the date any corresponding cost report is due, if applicable." 42 U.S.C. § 1128J(d). *See also* 42 U.S.C. § 1320a-7k(d).

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

49. The FCA allows any person having information about an FCA violation to bring an action on behalf of the United States, and to share in any recovery. The FCA requires that the Complaint be filed under seal (without service on the defendants during that time) to allow the government time to conduct its own investigation and to determine whether to join the suit. The person bringing the action is known under the FCA as the "relator."

50. Additionally, many states have passed false claims acts, which in most instances closely track the Federal FCA. The State FCAs apply, *inter alia*, to the state portion of Medicaid losses caused by false or fraudulent Medicaid claims to the jointly federal-state funded Medicaid program and failure to report and return any overpayments therefrom. The Defendants' acts alleged herein also constitute violations of the Indiana Medicaid False Claims and Whistleblower Protection Act, Ind. Code §§ 5-11-5.7, *et seq.*, and the Massachusetts False Claims Act, Mass. Gen. Laws ch. 12 §§ 5A, *et seq*. Each of the statutes listed above contains *qui tam* provisions governing, *inter alia*, a relator's right to claim a share of the State's recovery.

51. The allegations set forth in this Complaint have not been publicly disclosed within the meaning of the FCA, as amended, 31 U.S.C. § 3730(e)(4), or analogous provisions of the

state FCAs. In the alternative, if the Court finds that there was a public disclosure of such allegations, Relator is an "original source" as that term is used in the federal and state FCAs. *Id.*

C. The Federal Stark Statute and State Law Counterparts

52. Section 1877 of the Social Security Act (42 U.S.C. § 1395nn), also known as the physician self-referral law and commonly referred to as the "Stark Law," prohibits physicians from making referrals for designated health services including, *inter alia*, laboratory services, to an entity with which they have a financial relationship. 42 U.S.C. § 1395nn (a)(1)(A). It also prohibits entities from billing Government Health Care Programs for services rendered pursuant to a referral by a physician with whom the laboratory has a prohibited financial relationship. 42 U.S.C. § 1395nn(a)(1)(B). Further, neither Medicare nor Medicaid may pay for any designated health services provided in violation of the Stark Statute. 42 U.S.C. § 1395nn(g)(1); 42 U.S.C. § 1396b(s).

53. If a person collects payments billed in violation of the Stark law, that person must refund those payments on a "timely basis," not to exceed 60 days. *See* 42 U.S.C. § 1395nn(g)(2); 42 C.F.R. §§ 411.353(d); § 1003.101 (defining a "timely basis").

54. The Stark law prohibits referrals to any entity under the referring physician's direct or indirect ownership or investment, whether "through equity, debt, or other means, including interest in an entity that itself holds an ownership or investment interest in the entity performing the designated health service." 42 C.F.R. § 411.354(b). The law likewise prohibits referrals in the case of direct or indirect "compensation arrangements." Direct compensation arrangements exist if there is no intervening person between the referring physician and entity rendering the service. *Id. at* § 411.354 (c). Indirect compensation relationships require: (a) an unbroken chain of ownership or compensation arrangements between the referring physician and the entity; (b) that the referring physicians' compensation varies with volume or value of

referrals; and (c) that the entity knows that the compensation varies with the volume or value of referrals. *Id.* at § 411.354 (c)(2).

55. A "referring physician," includes "a physician . . . who directs another person or entity to make a referral or who controls referrals made by another person or entity." 42 C.F.R. § 411.351. Thus, a physician is prohibited from directing or controlling others to make referrals to an entity with which the physician has a financial relationship. *Id*.; *see also id.* at § 411.353(a) (providing that referrals may be imputed to a directing or controlling physician).

56. The statute's exceptions –also known as safe harbors–identify specific arrangements exempted from its prohibitions. Once the government has demonstrated each element of a violation of the Stark law, the burden shifts to the defendant to establish that defendant's conduct at issue was protected by a safe harbor.

57. Violations of the Stark law may subject the physician and the billing entity to exclusion from participation in Government Health Care Programs and various financial penalties, including: (a) a civil money penalty of up to $15,000 for each service included in a claim for which the entity knew or should have known that the payment should not be made; and (b) an assessment of three times the amount claimed for a service rendered pursuant to a referral the entity knows or should have known was prohibited. *See* 42 U.S.C. §§ 1395nn(g)(3), 1320a-7a(a).

58. Some States have laws comparable to the federal Stark statute. For example, Massachusetts has a similar rule prohibiting self-referral of clinical laboratory services unless the laboratory is owned by a physician or group of physicians and used exclusively for their patients and all testing is performed by or under the direct supervision of said physician or group of physicians. Mass. Gen. Laws ch. IIID § 8A. Indiana law requires any physician referring patients

to a health care entity providing "diagnostic care" with which the physician has a financial relationship to disclose the relationship to the patient in writing and offer to refer the patient elsewhere. *See* Ind. C. § 25-22.5-11-2.

D. The Anti-Kickback Laws of the United States and States

59. The Medicare and Medicaid Fraud and Abuse Statute (the "Anti-Kickback Statute" or "AKS"), prohibits any person or entity from offering, paying, soliciting, or receiving "any remuneration" to induce or reward any person for referring, recommending, or arranging for the purchase of any service or item for which payment may be made under a federally-funded health care program. 42 U.S.C. § 1320a-7b(b). The statute's prohibition applies to both sides of an impermissible kickback relationship (*i.e.*, the giver and the recipient of the kickback).

60. Violations of the federal AKS can subject the perpetrator to liability under the federal FCA, for causing the submission of false or fraudulent claims or for making a false or fraudulent statement or record material to a false or fraudulent claim. *See* 42 U.S.C. §§ 1320a-7b(g) ("a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the FCA].") Accordingly, claims for payment for services that result from kickbacks are false or fraudulent under the FCA.; *see also id.* at (h) (no actual knowledge of this section or specific intent to commit a violation of this section is required).

61. The Anti-Kickback Statute contains safe harbors that exempt certain transactions from its prohibitions. *See* 42 C.F.R. § 1001.952. Under these safe harbors, as in the Anti-Kickback Statute generally, payments may not depend on the "volume or value" of referrals. *See*, *e.g.*, *id*. at § 1001.952(a) (investment interests safe harbor); *id*. at § 1001.952(d) (personal services and management contracts safe harbor.). Once the Government has demonstrated each element of a violation of the Anti-Kickback Statute, the burden shifts to the defendant to

establish that defendant's conduct at issue was protected by such a safe harbor or exception. The Government need not prove as part of its affirmative case that defendant's conduct at issue does not fit within a safe harbor.

62. Violation of the Anti-Kickback Statute subjects the violator to exclusion from participation in federal health care programs, civil monetary penalties, and imprisonment of up to five years per violation. 42 U.S.C. § 1320a-7(b)(7), § 1320a-7a(a)(7).

63. Many of the States also have anti-kickback laws similar to the AKS applicable to medical providers and entities participating in their Medicaid programs. *See, e.g.,* Indiana, Ind. Code § 12–15–24–2; Massachusetts, Mass. Gen. Laws ch. 118E § 41; Pennsylvania, 55 P.A. Code § 1101.75(a)(3).

E. Opioid Treatment Regulations

64. Opioid treatment programs are subject to an overlapping set of federal and state laws and regulations. A provider must comply with all governing requirements in any jurisdiction in which he or she practices.

65. Traditionally, physicians were permitted to use opioid medications to treat opioid addiction only in Opioid Treatment Programs (OTPs) approved and regulated under 42 C.F.R. part 8. These clinics utilize Schedule II opioid medications like methadone which must be dispensed to patients on-site rather than prescribed for use at home.

66. In response to the nation's opioid-addiction crisis, Congress enacted DATA 2000, 21 U.S.C. § 823(g), permitting qualifying physicians to obtain waivers from these rules allowing them to prescribe or dispense Schedule III, IV, and V narcotic medications approved by the Food and Drug Administration ("FDA") for the treatment of opioid addiction in office and other clinical settings (*i.e.* OBOT). The only medications presently approved under this program are formulations of buprenorphine, including those branded as Suboxone and Subutex.

67. To be eligible for a DATA waiver, physicians need not have any prior substance abuse or mental health training. They need only be licensed under state law to prescribe medication (prior to 2017, this excluded mid-level practitioners), registered with the DEA to dispense controlled substances, and qualified to treat opioid addiction by:

a. holding a certification in addiction, addiction psychiatry, or addiction medicine from the American Board of Medical Specialties, the American Society of Addiction Medicine, the American Board of Addiction Medicine, or the American Osteopathic Association;

b. participating as an investigator in clinical trials leading to approval of a drug authorized for waiver under DATA 2000; or

c. completing an eight-hour online or in person course on the treatment of opioid-dependent patients.

68. DATA-waived physicians must also comply with applicable DEA regulations including that the prescription be issued in compliance with state as well as federal law. In addition:

a. "All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address and registration number of the practitioner." 21 C.F.R. § 1306.05(a); and

b. "A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. §1306.04(a). "An order

> purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of [21 U.S.C. § 829]."

69. A qualifying physician may have a maximum of 30 patients in opioid dependence treatment at a time for the first year. One year after the initial notification to the Substance Abuse and Mental Health Services Administration (SAMHSA) is submitted, the physician may submit a second notification to treat up to 100 patients.

70. In 2016, SAMHSA exercised its rulemaking authority to permit eligible practitioners to request waivers to treat up to 275 patients. Practitioners treating between 101 and 275 patients are obligated to comply with additional regulations under 42 CFR §§ 8.610, *et seq.* *See* 81 Fed. Reg. 44,711, 44,711-44,739 (2016). Congress further expanded the DATA waiver program under the Comprehensive Addiction and Recovery Act of 2016 (CARA), and, upon implementation, properly supervised mid-level practitioners authorized under state law to prescribe medication were permitted to participate in the DATA program.

71. DATA 2000 also directed SAMHSA to develop a Treatment Improvement Protocol (TIP) containing best practice guidelines for the treatment and maintenance of opioid-dependent patients. This protocol, TIP 40, *Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction* (2004), emphasizes that MAT must be utilized as part of a comprehensive individualized treatment plan and directs physicians to consider:

a. "the appropriateness of office-based or other opioid agonist treatment," by performing "***a comprehensive patient assessment***" that includes a thorough and comprehensive medical, social, and substance use history, an assessment of the patient's readiness to change, a formal mental status examination

(MSE), and baseline laboratory evaluations. The physician must also make individualized inquiries into the appropriateness of Buprenorphine treatment by evaluating a patient's interest in treatment, expectations of compliance with program, and lack of contraindications; the TIP identifies a list of 18 questions to use in making this individualized determination.

b. the risk of fatalities associated with combining buprenorphine and benzodiazepines and/or other central nervous system depressants (e.g., alcohol). The document emphasizes "the importance for physicians to be ***cautious in prescribing buprenorphine in conjunction with benzodiazepines***, as well as in prescribing buprenorphine to patients who are addicted to ***opioids and also are abusing or are addicted to benzodiazepines***." Use of sedative-hypnotics including benzodiazepines, is described as a "***relative contraindication****"* to OBOT.

c. "***Each patient's history and concerns,***" and provide patient counseling about potential side effects from buprenorphine overdosing (especially in combination with benzodiazepines). Thereafter "***attention must be maintained to the psychosocial and family issues that have been identified during the course of treatment***."

72. In April 2013, the Federation of State Medical Boards, in agreement with SAMHSA, promulgated a Model Policy on DATA 2000 and the Treatment of Opioid Addiction in the Medical Office (this updated a 2002 version). This policy echoed many of the same issues as the SAMHSA TIP:

a. "Physicians are not permitted to delegate the prescribing of buprenorphine to non-physicians."

b. An "***individualized treatment plan is critical to the patient's ultimate success*** in returning to productive functioning," and the "treating physician should balance the risks and benefits of medication-assisted treatment in general – and treatment with buprenorphine in particular – against the risks associated with no treatment or treatment without medication." (emphasis added). The pros and cons of agonist medications "should be thoroughly discussed with the patient in terms of potential risks and benefits as part of the informed consent process."

c. Initial patient assessment should include medical and psychiatric history, a substance abuse history, and an evaluation of family and psychosocial supports, as well as a pregnancy test for all women of childbearing age.

d. "Whenever the best clinical course is not clear, consultation with another practitioner may be helpful. The results of the consultation should be discussed with the patient and any written consultation reports added to the patient's record."

e. Accurate and up-to-date medical records that "clearly reflect the decision-making process that resulted in any given treatment regimen" are required. The chart should also contain the patient history, any laboratory tests ordered, and their results, the treatment plan, authorization for release of information to treatment providers, and documentation of discussions with and consultation reports from other health care providers.

73. The Commonwealth of Massachusetts Board of Registration in Medicine promulgates the "Prescribing Practices Policy and Guidelines" ("Mass. Prescribing Guidelines") to provide physicians with an understanding of their responsibilities and the standards applied by the Commonwealth in reviewing practices. This policy was first issued in 1989 and updated in 2010 and 2015. These Guidelines require that:

a. a valid prescription may only be issued "for a legitimate medical purpose, by a practitioner in the usual course of his or her professional practice." This means that "there must be a physician-patient relationship." This applies as well to electronic prescribing.

b. "the physician establish a proper diagnosis and regimen of treatment," and "on first encounter with a patient, a physician must take and record an appropriate medical history and carry out an appropriate physical or mental status examine and record the results."

c. "Physicians must maintain medical records that are detailed enough in nature that the physician's clinical reasoning is discernible from his or her documentation. Treatment plans should be explicitly recorded."

d. Physicians operating under a DATA 2000 waiver "are not permitted to delegate the prescribing of buprenorphine to non-physicians."

e. Even where non-physicians are permitted to write buprenorphine prescriptions (which would not be true prior to implementation of CARA), "physicians are required to supervise the prescriptive practices." "The supervising physician and [non-physician] must sign mutually developed and agreed-upon guidelines for prescriptive practice" and the physician must offer ongoing

> guidance regarding their adherence. "The written guidelines must be very specific regarding the types of medications to be prescribed, any limitations on prescriptions, and when referral or physician consultation is required." These agreements should only be entered when the physician is "able to provide supervision, practice review, and ongoing direction for the" non-physician.

74. Massachusetts Regulations amended in 2016 apply to facilities that, like CleanSlate, treat more than 300 patients. *See* 105 C.M.R. § 164.007(F). These regulations further emphasize a covered entity's obligation to provide individualized assessment of patient need, take complete and accurate medical histories, and obtain patient consents, *id.* at §§ 164.072, 164.0302; provide, directly or through written contract, minimum services including substance abuse counseling and mental health services, *id.* at § 164.074; and have written policies governing the termination of treatment with adequate assurance that the patients will have the ability to transition to adequate alternate treatment, *id.*

75. The Indiana Standards of Professional and Competent Practice of Medicine, embodied in the Indiana Administrative Code at 844 Ind. Admin. Code 5-4-1, prohibit a physician from prescribing "any controlled substance to a person who the physician has never personally physically examined and diagnosed." 844 Ind. Admin. Code 5-4-1.

76. Pursuant to legislative directive in 2016, the Indiana Division of Mental Health and Addiction developed "Best Practice Guidelines for the Treatment of Opioid Use Disorders." These guidelines similarly emphasize the need for appropriate assessment and diagnosis through use of complete medical history; that the physician confirm any diagnosis before treating a patient; that patients in treatment receive mental health screens each quarter; that physicians

consider suspending OBOT if benzodiazepine use is discovered; and the need for clinical teams to adequately communicate.

F. Urine Drug Testing ("UDT") Regulations

77. While UDT can play an important role in mental health and substance abuse treatment, a physician must make an individualized, patient-specific determination about the use of presumptive and definitive testing. *See* Substance Abuse and Mental Health Services Administration (SAMSHA), TAP 32, *Clinical Drug Testing in Primary Care*, 2012. In clinical settings, confirmation testing is not always necessary; rather, correlation with other evidence is appropriate. For example, if the patient or a family member affirms that drug use occurred, expensive confirmatory drug tests are not usually needed. *Id.*; *see also* Drug Testing: A White Paper of the American Society of Addiction Medicine (2013); Public Policy Statement on Drug Testing as a Component of Addiction Treatment and Monitoring Programs and in Other Clinical Settings, American Society of Addiction Medicine (2010). Because drug testing must be tailored to each patient's medical needs, standard panels of tests and testing at set intervals (such as at every designated office visit), known as blanket or standing orders, are not reasonable and medically necessary. *Id.*

78. "***Tests for illicit drugs*** are not sufficient to diagnose addiction and ***cannot substitute for a clinical interview and medical evaluation of the patient*** . . . Physicians must decide which drug tests are necessary in each clinical setting, including office-based buprenorphine treatment." And "when selecting drug tests, physicians should consider the cost to patients, as ***testing for all possible drugs of abuse can be costly***." SAMSHA, TIP 40, *Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction* (2004).

79. HHS-OIG guidance emphasizes that "claims submitted for services will only be paid if the service is covered, reasonable, and necessary for the beneficiary, given his or her

clinical condition." *See* 63 Fed. Reg. 45077, 45079 (Aug 24, 1998). In particular, "to avoid performing unnecessary reflex tests, labs may want to design their requisition form in such a way which would only allow for the reflex test when necessary. . . . Laboratories may wish to adopt a similar policy for confirmation testing which may be mandatory." *Id.* at 4581. Similarly, the OIG discouraged the use of standing orders, urging that such orders "have a fixed term of validity and must be renewed at their expiration." *Id.*

80. In 2013, the Commonwealth of Massachusetts Office of the Auditor investigated UDT practices on behalf of MassHealth. The Audit found that routine confirmatory tests are not medically necessary, noting that, per SAMHSA guidelines, "confirmatory tests should be ordered only by physicians and ***should not be part of a predesigned laboratory panel of tests***." (emphasis added). The Audit further noted that "Substance abuse treatment specialists we contacted stated that they do not typically order confirmatory tests. They stated that they only need to screen whether an illicit substance is present or not and that this information is provided through the initial drug test. However, in rare instances, ***if the accuracy of the first test is questioned (e.g., if a member strongly disagrees with a positive result***), these specialists indicated that a confirmatory test may be warranted." (emphasis added). With respect to confirmatory testing for buprenorphine and its metabolites, the Audit noted that substance abuse professionals, "***do not confirm positive results for methadone or buprenorphine*** for members who are currently receiving those drugs as part of their treatment," because "positive results of these substances in the primary drug test provide the expected appropriate result." (emphasis added).

81. In February 2013, MassHealth issued Community Health Center Bulletin 74, and Physician Bulletin 94 explaining that "authorized prescribers must review requests for laboratory

tests, which they sign to determine medical necessity," that MassHealth will deny "quantitative drug tests billed on the same [Date of Service] as a drug screen service," and providers "must only perform confirmation tests for positive results from a drug screen service on an as-needed basis only when medically necessary. ***Providers should not bill for quantitative tests in lieu of drug screen services or as a routine supplement to drug screens***." (emphasis added).

82. Governing regulations explicitly forbid routine presumptive and definitive UDT without an individualized assessment of patient need. For example, in 2015, National Government Services, Inc., issued Local Coverage Determination (LCD) ID L36037, governing Medicare coverage for UDT in the region, including Massachusetts. This LCD identified as "non-covered services," UDT performed pursuant to "Blanket Orders"; "routine standing orders for all patients in a physician's practice"; and "reflex definitive [UDT] . . . when presumptive testing is performed at point of care because the clinician may have sufficient information to manage the patient. If the clinician is not satisfied, he/she must determine the clinical appropriateness of and order specific subsequent definitive testing (e.g., the patient admits to using a particular drug, or the IA cut-off is set at such a point that is sufficiently low that the physician is satisfied with the presumptive test result)."

83. Government Health Care Programs contain explicit prohibitions on "unbundling" practices services, in which services that should be billed as one comprehensive rate are instead billed in multiple increments increasing the provider's rate of pay. Medicare Claims Processing Manual, Chapter 12, Section 20.3; 130 C.M.R. § 450.307.

V. FACTS AND ALLEGATIONS

84. Defendants have engaged in ongoing schemes to defraud Government Health Care Programs, most notably Medicaid and Medicare Parts B, C, & D, since at least 2009 when Defendant Total Wellness was founded by Defendant Dr. Wilson. The Plaintiff-Relator Dr. Welch

incorporates herein the facts and allegations contained in the Complaint in Intervention of the Plaintiff Commonwealth of Massachusetts filed in this action on October 16, 2020.

85. In response to the nation's ongoing opioid-addiction crisis, Congress changed restrictions on doctors' ability to prescribe certain approved medications that had been shown effective in treating opioid addiction. These restrictions were intended to allow responsible physicians to utilize medication-assisted treatment ("MAT") as part of a comprehensive approach to treating the disease.

86. Defendants exploited these laws in a scheme to build and operate a chain of for-profit "addiction-treatment centers" whose primary function is to prescribe buprenorphine-based drugs to as many opioid addicted patients as possible while avoiding the cost of medically-necessary oversight, counseling, coordination of care, and individualized treatment. Treating decisions are dictated by corporate policies drafted by non-physicians in cookie-cutter fashion without individualized medical assessments and applied by inadequately trained and supervised mid-level practitioners. To increase patient volume and the resulting profits Defendants hire part-time, untrained physicians whose primary job is to sign prescriptions for opioid medication based on a cursory review of clinical notes for patients with whom they have no valid physician relationship. All of this is designed to reduce costs and increase revenue and profits to Defendants at the expense of patient safety.

87. These CleanSlate clinics submit and cause the submission of false and fraudulent claims for the payment of unnecessary and otherwise prohibited medical services, including buprenorphine prescriptions, office visits, and clinical laboratory tests. In 2016, Defendants dramatically escalated the scope of their scheme. Fueled by the flow of private equity funds and insistence on profits over patients, from Defendant Apple Tree Partners, Defendants embarked on

a plan to realize "$500 million revenue; $125 million EBITDA; 25% margin; $1B valuation; 50,000 patients; in 3 years," far beyond their ability to provide medically safe care to patients in a reckless attempt to provide a substantial payout to CleanSlates' owners and investors.

A. The CleanSlate Model: Treat Very Serious Illnesses With Inadequate, Improperly Trained and Under Supervised Staff

88. In a 2015 article, CleanSlate's founder, Dr. Wilson explained that CleanSlate makes "use of nurse practitioners and build a cost-efficient model that can also provide high-quality care to everybody, regardless of their insurance." *See* Julia Brown, *CleanSlate Capitalizes on Unmet Need for MAT*, Behavioral Healthcare Executive, September 10, 2015. The article recognized that "Physicians usually treat an average of seven to fourteen buprenorphine patients, because such patients are often highly complex and need frequent office visits." CleanSlate, however, utilizes the full 30, 100, or 275 patient capacity of its DATA-waived doctors. Dr. Wilson represented that CleanSlate could accomplish this feat safely because, "On site, we have four to six nurse practitioners; an addiction board certified physician, who supervises the nurse practitioners and sees patients regularly; and part-time doctors who come in and work weekly for a couple of hours." Moreover, "the doctors are willing to have 100 patients because they know they're going to be managed tightly by this team approach, which provides ongoing individualized care."

89. In reality, no such treatment model is practiced at CleanSlate. Rather, to continually reduce costs and increase profits, Defendants permit non-clinical employees and inadequately experienced and trained mid-level practitioners to make crucial treatment decisions, putting supervision in the hands of inexperienced and untrained full and part-time physicians.

90. The Medical Directors (also called Lead Physicians), responsible for supervising staff and seeing patients, are rarely addiction specialists and most CleanSlate centers do not have

a physician on-site full-time. Some centers have ***never*** had an on-site physician. The "part-time doctors" do not come in weekly, "for a couple hours," as Dr. Wilson represented.

91. In fact, many patients have never been seen by any CleanSlate physician, let alone the doctor to whom they are assigned. CleanSlate manages these employees with cookie-cutter policies and lacks training adequate to ensure appropriate patient treatment.

92. Defendants focus solely on providing lucrative UDT, and over-booked 15-minute office visits representing "counseling" but primarily devoted to renewing buprenorphine prescriptions and ordering medically unnecessary laboratory testing.

1. Defendants Place Primary Treating Responsibility with Non-Physicians

93. CleanSlate Center's Clinician Training Manual, authored by non-physicians, including Dr. Wilson's ex-wife and CleanSlate co-founder, makes clear that primary medical responsibility, including initial assignment of patients to physicians, vests with non-clinical personnel, including the "Center Manager."

94. CleanSlate's Clinician Manual dictates the tasks performed (usually by a mid-level practitioner) at a patient's initial visit. Notably, the second instruction after "introduce yourself to pt." is "Establish what type of treatment they are seeking." CleanSlate's electronic medical records system, known as Stratus EMR, provides "visit macros" to script the taking of a patient's history. The macros produce text results approximating the free-text entries that would be recorded in an adequate patient history but lack many elements of appropriate medical care required by regulation. The mid-level practitioners are instructed to "determine if the pt. is a candidate for one of the treatment options offered," and determine when the patient should return to receive "induction" medication –the patient's first buprenorphine dose administered in-office. The mid-level practitioner then enters the buprenorphine prescription's details such as dosing and selects a pharmacy to receive the prescription.

95. The clinical workflow is the same in all centers: the mid-level practitioner determines (1) that a Suboxone regimen is appropriate, and (2) the strength, frequency, and quantity of that prescription. Only ***after*** the mid-level practitioner independently diagnoses the patient and determines the initial dose and frequency of Suboxone, does the system route the unsigned prescriptions to a non-clinician "Practice Administrator," who "assigns" the patient to a physician by deciding which prescribing physician's electronic queue will receive the prescription for signing.

96. These policies relegate a physician's primary role in the process to uncritically signing prescriptions drafted by non-prescribers. The Clinician Manual explains to physicians that "given the sensitive nature of our buprenorphine Rx system and the time sensitive signature requirements on a daily basis, the Center Manager may contact you with issues regarding prescriptions." Similarly, the document informs physicians that at CleanSlate, mid-level practitioners "will be medically managing your patients."

97. Relator Dr. Welch's review of charts and claims, *infra*, likewise confirms that the physician allegedly treating the patient and supervising the mid-level almost never comments on, let alone collaborates with the mid-level practitioner.

98. Thus, patients suffering from opioid addiction are given potentially dangerous narcotic prescriptions without any exercise of independent judgment by licensed medical doctors, who are asked only to review templated electronic clinical notes many hours or the day after the visit occurred and electronically apply their signature and DEA waiver number to the prescription.

99. Furthermore, many clinics operate at or above capacity with little margin to accommodate backlogs of prescriptions requests if a physician calls in sick or leaves

employment. This results in frequent changes in the prescriber of record and calls for "immediate cross-coverage," in which a doctor not assigned to the patient signs a prescription. Practice administrators must identify doctors available to sign these prescriptions in real-time, regardless of whether that physician has any familiarity with the patient's medical history. Unsurprisingly, these situations provide even less patient oversight than the normal process. CleanSlate staff is aware, and Relator's chart reviews reflect, that in 2016, 40-60% of all patient prescriptions at CleanSlate, some 350 instances daily, were signed by someone other than the patient's doctor.

100. CleanSlate's Buprenorphine Manual claims that "[e]very [CleanSlate] patient will have a treatment plan which will be personalized to the needs of the patient." This tracks requirements in governing state and federal rules. However, this claim is not reflected in reality, nearly every patient receives identical treatment, and the primary distinction in treatment plan is the frequency with which a patient visits the center for otherwise indistinguishable care. Indeed, "completing" a treatment plan, is a task that Stratus EMR automates each quarter by providing a series of questions and instructing a mid-level practitioner to "click off appropriate boxes as you receive answers from the patient." The non-physician is then directed to approximate an individualized narrative response (20-character minimum) by drafting "two or three unique sentences about the patient. Example: 'John continues to struggle with cocaine use, though stable off heroin. He will continue on MAT and be seen weekly.'"

101. In an email to the CleanSlate Compliance Officer, Richard Raphael, the Regional Medical Director, Dr. Mendenhall, explained the results of the system: "our charts have generally poor quality treatment plans. Clinicians can click around and bypass the q90 day [quarterly prompt to complete a treatment plan] template that pops- up. Those that do fill out treatment plans are doing a lot of robo-clicking and the data is not very consistent."

102. Similarly, ordinary "maintenance" visits are scripted by the Stratus EMR regardless of patient need. The visits primarily revolve around ensuring that the Suboxone prescriptions are not being diverted and that lucrative UDT is performed. As with initial visits, a mid-level practitioner is prompted to unilaterally determine changes in prescription and notify the Center Manager to identify an available prescriber to sign the "immediate Rx." Relator's review of example charts reflects numerous instances in which the patient notes do not reflect the actual tests or test results and generally appear to be the result of "robo-clicking" rather than responsive to the patient visit.

103. Numerous other elements of CleanSlate's program were designed to avoid individualized patient treatment, automate the process, and maximize the role of inexpensive non-medical staff. For example, while CleanSlate policies identify distinct levels of patient need (labeled Green, Yellow, Orange, and Red 1 & 2), with the Red categories (known as "focused supportive care" or "FSC") reflecting patients at the greatest risk of discharge from OBOT to higher levels of treatment, CleanSlate schedules 15 minutes for each appointment, regardless of patient need or visit complexity. Similarly, while Dr. Welch's review of CleanSlate charts suggests that patients assigned to the Medical Directors sometimes received a greater level of care, CleanSlate makes no effort to match serious cases with Medical Directors.

104. CleanSlate's Call-Center Manual indicates that a provider working a 9-5 shift should see 35 patients (leaving less than 15 minutes per patient on average assuming no lunch) and one working an 11-hour shift should see 50 patients. To further wring efficiencies out of the system, CleanSlate policies call for regularly double-booking sessions and relying on patients' consistently missing appointments. When patients do keep appointments, it puts tremendous strain on the system.

105. CleanSlate employed an in-house call-center to handle scheduling. The Call-Center Manual directs the call-center staff to permit or deny requests to reschedule appointments based solely on the number of prior rescheduling requests and does not require that the patient's clinician be informed of the request. However, these requests often indicate relapse and/or increasing acuity of the disease and failure to inform the patient's clinician jeopardizes patient care.

106. The Call-Center Manual likewise directs the staff to treat loss of insurance as a billing issue and fails to recognize the potentially-serious effects of cutting off treatment. Patient charts likewise reflect threats, apparently by call-center staff, to cut off patients with positive balances. However, it is incredibly dangerous for patients taking Suboxone as treatment for opioid addiction, to simply be cut off from their medicine, particularly without a bridge prescription. It almost inevitably causes patient relapse. As explained below, such policies ultimately had fatal consequences for at least one CleanSlate patient.

107. The CleanSlate treatment model as represented by Dr. Wilson relies on each center having a Medical Director to supervise the patients and non-physician staff, but many of the locations never had such a leader or had one only sporadically, leaving patient management in the hands of unsupervised non-physicians. In 2016, the vast majority of the centers maintained only sporadic physician presence: Plymouth, Massachusetts – 24 hours per week; Worcester, Massachusetts – 16 hours of one doctor and 4 of another (follow up only) per week; Athol, Massachusetts – 19 hours per week; Springfield, Massachusetts – 16 hours per week; West Springfield, Massachusetts – 30 hours of one doctor and 8 of another (no doctor on Mondays) per week; Holyoke, Massachusetts - 30 hours of one doctor and 8 of another per week; Greenfield, Massachusetts – 24 hours (no doctor two days a week) per week; Scranton,

Pennsylvania – 3 hours of one doctor weekly and 3 hours every other week with another and 3 hours every month with a third; Wilkes Barre, Pennsylvania – 4 hours every other week; Merrillville, Indiana -30 hours per week; Tewksbury, Massachusetts – no medical doctor present since inception.

108. A CleanSlate "Key Performance Indicators" presentation for October 2016, identified seventeen centers in operation requiring twenty-five "Physician Leads" (Medical Directors). However, CleanSlate had only filled thirteen of these positions. Moreover, a separate list of twelve of those physicians reflects that seven work fewer than forty hours per week, some as few as twenty-four hours. A late October 2016 list of CleanSlate staffing needs identified as "top" needs, full-time supervising physicians in West Springfield, Springfield, Tewksbury, Quincy, Plymouth, and Worcester.

2. CleanSlate's Cookie Cutter Treatment is Supervised By Inexperienced Doctors

109. CleanSlate's physician job descriptions and marketing materials make clear that Defendants recruit ***any*** doctors who can legally issue buprenorphine prescriptions regardless of whether they have expertise in addiction or behavioral health medicine. As of late October 2016, only five Medical Directors were board certified in addiction and virtually none of the part-time doctors had any relevant experience or training. Indeed, the part-time doctors' specialties are irrelevant to Defendants so long as they may legally write prescriptions. Defendants hire, for example, urologists, anesthesiologists, pediatricians, gynecologists, and family medicine and emergency room doctors, so long as they have DEA registration numbers.

110. DATA-waived doctors are given virtually no regular training or time to provide individualized assessments of their patients. They are expected to serve 30 patients working 3 hours a month (from smart phone, tablet, or computer) and lead two 60-minute Group Sessions.

In reality, the "group sessions" are little more than lectures, precluding individual interaction. They are described in recruiting materials as an opportunity to "meet and know the patients you are prescribing buprenorphine for" and often serve as the only opportunity for physicians to interact with patients, whose notes they have been purportedly reading, signing, and then issuing buprenorphine prescriptions from their homes in the evening. Group notes are templated and copied and pasted across patients' charts, containing no evidence that patients attending the session received any individualized medical attention or appropriate clinical intervention.

111. CleanSlate physicians' lack of medical competence was put in stark relief in late October 2016, when the West Springfield Center Manager, Jonathan Candee, asked the Regional Director of Operations, Michelle L'Italien, how to respond to a mid-level provider's question "What do we do and who do we go to when we notice an issue with what the PT DOC's are doing when they see PT's?" Mr. Candee explained that CleanSlate clinical staff, including Regional Medical Director, Dr. Mendenhall, had previously directed the mid-level practitioners to "educate" the physicians about their mistakes, but the staff felt uncomfortable managing physicians (who were ostensibly supervising them).

112. CleanSlate's reliance on mid-level practitioners to educate physicians was and is misplaced; however, because the vast majority of mid-level practitioners also lack experience with substance abuse or mental health treatment. A December 2016 spreadsheet identified only one mid-level practitioner with non-CleanSlate addiction medicine experience. Defendants posted a job description for a Divisional Medical Director, reporting directly to the CEO, that indicated that substance abuse experience is not a requirement for the number two doctor in the organization, yet the job description specifically stated that the person would serve as an expert consultant to the clinical field.

113. Pursuing the growth demanded to achieve Apple Tree Partner's profitable exit put further and dangerous strain on CleanSlate's ability to adequately train its clinical staff. In 2016, CleanSlate's training team was asked to train six individuals (none of whom had any experience in addiction) in two weeks. The team felt that was insufficient time and risked the safety of CleanSlate patients. CleanSlate management was well aware of these concerns, yet they pushed to open new clinics despite not having enough providers, sometimes opening and operating clinics before identifying a Medical Director.

114. In November 2016, the situation at one center reached a critical level as mid-level practitioners transitioned to other roles. In an email, the Regional Director of Operations, Michelle L'Italien, explained to senior clinical staff the difficulty in "trying to buffer out any negativity and stress that the providers have been coming to us with." She warned that "when I hear the words 'I feel like we were working in a pill mill' from providers it truly has me concerned." And "when I hear today that a patient has overdosed three times in one month and we can't get people in for [] appointments due to [the] reduced schedule or lack of providers [it] truly is heartbreaking." She forwarded the email to CleanSlate CEO Greg Marotta apologizing, but describing the issue as "a good snapshot of some of the daily issues we face of working in silos and not as a collaborative team . . . after 19 years of management, I have never seen such a disconnect and separation between departments and communications." Mr. Marotta forwarded the email to senior staff describing it as "a sad state when one of our managers/leaders feels the need to apologize twice, have [sic] a strong sense of doubt about what we are doing, . . . and has to back pedal on raising a concern. Enough is enough . . . ."

3. Defendants Utilize Blanket Urine Drug Testing to Reduce Costs and Inflate Revenue

115. The primacy of revenue and profit in Defendants scheme is reflected in the constant drive to limit the role of medical professionals in treatment while massively over-relying on laboratory tests. The difference between these two drives is that while physician intervention was expensive for Defendants and reimbursed only through relatively low-paying office visits, laboratory tests were a massive profit center.

116. Unusually, and in violation of self-referral and anti-kickback laws, Defendants owned their own clinical laboratory, Defendant Total Wellness Centers, LLC. Both Defendant Dr. Amanda Wilson and then CFO Patrick Murphy, confirmed to Relator Dr. Welch that part of the reason for owning the testing lab was the enormous revenue it drove to CleanSlate.

117. Defendant Total Wellness Centers, LLC, maintains one CLIA accredited laboratory at 59 Bobala Road, Holyoke, MA 01040 that bills under NPI number 1770020018. The CleanSlate Lab performs two types of urine drug testing.

a. A Urine Drug Screen ("Drug Screen"). This test was also called immunoassay "analyzer" testing. It is a high complexity test that CleanSlate describes as having a "high degree of sensitivity and low rate of false positives/negatives." The tests are billed under HCPCS code G0431 (Drug Screen Single Class) and later G0479 (Drug Test Presump Not OPT) or CPT code 80301 (Drug Test PRSMV Chem Analyzer) for which CleanSlate charged $240 and received approximately $80 in Medicare reimbursement and $50 in state Medicaid reimbursement.

b. LCMS confirmatory testing. LCMS is a high complexity test capable of determining the presence and precise quantity of substances and their

> metabolites. Notably, the CleanSlate laboratory could perform LCMS confirmatory testing only for the presences of Buprenorphine and its metabolite Norbuprenorphine. Confirmatory testing was previously billed under CPT code 80348 (Buprenorphine, Qualitative); 83925 (opiates drug measure) and/or 80102 or G06058 (drug confirmation test). Later, CleanSlate billed these procedures under HCPCS code G0480 (high complexity definitive testing for 1-7 substances).

118. A third form of urine drug testing, "dip testing," is widely used in the industry as it can be performed quickly within a doctor's office. However, that test reimburses very little and CleanSlate performed it rarely, primarily before administering the first dose of buprenorphine and in some other specialized situations.

119. CleanSlate requires that its practitioners *routinely* order urine drug testing from its own lab regardless of medical necessity.

120. CleanSlate's Buprenorphine Manual outlines a blanket or standing order for UDS at every patient visit, referred to as a "Standard Standing Order." This testing is performed every time a patient visits a CleanSlate office – such visits range from multiple times weekly to monthly depending on treatment level. Many of the Charts reviewed by Relator, *infra,* reference tests ordered pursuant to this standing order.

121. As outlined in CleanSlate's Buprenorphine Manual, CleanSlate regularly requires practitioners to order LCMS testing for the presence of buprenorphine and its metabolite norbuprenorphine. Depending on the treatment level of a given patient, confirmatory testing will be performed anywhere from twice weekly to quarterly (as well as in other specified situations, such as suspicion of drug diversion).

122. CleanSlate acknowledges that LCMS testing is not medically necessary, admitting that "CleanSlate has a long history of using quantitative data from the buprenorphine LCMS results to make clinical decisions. ***This interpretation of the results is not based in science***, but anecdotally carries a lot of clinical historical weight throughout the organization." (emphasis added).

123. CleanSlate also performs quarterly Hepatitis B&C testing, a Hepatic Liver function panel, and pregnancy tests.

124. This manner of ordering and billing clinical laboratory tests is extremely unusual. For example, in 2014, nearly all of the top 20 individual (non-independent laboratory) Medicare billers using code 80102 in Massachusetts were affiliated with CleanSlate. Indeed, that year, Dr. Wilson's own Medicare records reflect over 1,000 instances of billing for urine drug tests (her most popular procedures) constituting aggregate charges of over $250,000.

125. The practice is also extremely lucrative for CleanSlate. Internal "Key Performance Indicator" ("KPI") presentations confirmed that CleanSlate keeps a close eye on the revenue stream produced by this scheme. The presentations highlight April 2016 as a month in which government reimbursement policies permitted Defendants to increase their laboratory charges from $40 to $100 for each LCMS test. The July "KPI" presentation noted that Defendants' reimbursement for the test would rise from $33 to $50 on average. CleanSlate expected this change to drive revenue growth.

126. Dr. Wilson had long known of the financial potential of this scheme and informed Relator that utilizing revenue for these tests to grow the business was a core part of her plan for CleanSlate from the beginning.

127. CleanSlate was aware of the incredible expense that the tests represent to Government Health Care Programs. As part of its bundled rate "pitch" to managed Medicaid plans, CleanSlate claimed that because it included one monthly UDT in the bundled rate, insurers would save $14,000 annually.

128. To further simplify its operations, increase volume, and avoid the expense of individualized patient treatment, CleanSlate performs confirmatory tests whenever presumptive testing identifies the presence of substances of abuse in a patient's urine sample. CleanSlate calls theses orders "reflex" testing. Such procedures result in significant medically unnecessary testing. Previously, the tests would each be billed under individual test codes reflecting the substance tested for, and later, all tests would be billed comprehensively under code G0480.

129. CleanSlate utilizes a complex and unusual urine specimen collection procedure in which a medical assistant pipets a small amount of urine from a patient's sample to be sent to CleanSlate's in-house laboratory for UDS testing, saving the remainder to be sent to Quest if needed. This procedure results in Quest receiving a specimen after CleanSlate has performed UDS testing, and avoids requesting additional tests be run on a sample already submitted– a circumstance that would cause the billing to be rejected by Government Health Care Programs "code edits" designed to deter billing for medically unnecessary tests.

130. In 2016, Massachusetts Medicaid Providers including MassHealth began to reject CleanSlate billings for G0479 (presumptive testing) and G0480 (confirmatory testing), when those codes were billed for the same date of service. This was a result of the "code edits" imposed by MassHealth in 2013 to prevent medically unnecessary confirmatory testing. CleanSlate repeatedly sought to evade these code edits. It unsuccessfully attempted to bill the codes separately. It also asked contacts at Quest whether it could apply a different date of service

to the confirmatory testing than used on the presumptive testing. Eventually, MassHealth's third-party customer service provider, Maximus, Inc., suggested that the procedures were duplicative "or at the very least overlapping," and asked why CleanSlate would legitimately bill both. CleanSlate billing personnel, misrepresenting CleanSlate's procedures, claimed that while urine drug screen testing is performed "at every visit," the confirmatory testing was performed "at the discretion of the provider . . . to get more accurate results." In response Maximus asked, "why are you performing a presumptive test every visit without the rendering advisement?" and "why not then only bill the definitive test once the rendering has stated its need?"

131. In mid-November 2016, CFO Patrick Murphy circulated the definitive lab issue among senior management, including CEO Greg Marotta, because of its "significant impact to our revenue stream." In that exchange, Director of Billing, Amy Laroche, acknowledged that CleanSlate received $4.24 Million annually from Medicaid plans (managed Medicaid and MassHealth) for prohibited definitive testing. She also noted that while all managed Medicaid plans stated that they follow MassHealth payment guidelines, only some plans enforced the prohibition on unnecessary definitive testing. The discussion indicated that CleanSlate was still seeking to circumvent MassHealth's payment rules. There was no indication however, of serious consideration to following MassHealth billing rules and/or repaying the prior overpayments.

132. Laboratory results, regardless of the testing lab, are provided to clinicians through the Stratus EMR. However, test results are not delivered to an individual clinician's queue so that they could be viewed promptly by the treating clinician and acted upon in a medically appropriate manner. Such a system is industry standard practice. Instead, results are not seen by the clinician until the patient returns for a follow-up visit, when they auto-populate in the clinical note. This frequently occurs well-after the window for appropriate medical intervention for

relapses in sobriety, dangerous drug interactions, and failure to comply with medication regimens.

133. CleanSlate was Stratus EMR's largest client and purchased the company in late 2016. Stratus EMR regularly customized its software to meet CleanSlate's needs. However, despite internal complaints, CleanSlate management never prioritized lab workflows so clinicians could obtain the results of UDT in time to use them in a medically appropriate manner, *i.e.* for the diagnosis and treatment of the patient. Review of patient charts confirms that the results of UDT was rarely acted upon by CleanSlate staff and often not reviewed at all. In June 2016, Dr. Mendenhall identified this issue and asked the laboratory staff to develop a workflow process to resolve it. By December 2016, there was no temporary or permanent fix in place or under development.

134. CleanSlate management concluded that investing in a proper electronic workflow was unnecessary. However, clinical staff were aware that this process was inadequate. In mid-December 2016, Senior Clinical Director Kathleen Haughton discussed the issue with one of CleanSlate's physicians and noted that "we should not be waiting until the patient shows up to open their record and review the ordered labs – but have the reports sent to us via Stratus to SIGN off—and act upon daily." Even when Relator explained that viewing labs in an individual queue is the industry standard and is the most appropriate way to ensure that lab results can be acted upon, her concerns were dismissed. Instead, Defendants chose to prioritize the integration of billing functions into Stratus EMR to suit their business needs and relegated providing timely lab results to be addressed in the first or second quarter of 2017.

B. CleanSlate's Treatment Model Results in False And Fraudulent Claims

1. Defendants' Referrals of Urine Drug Tests to Their Own Lab Violate Stark and Anti-Kickback Laws and are Therefore False Claims

135. CleanSlate's policies and manuals were drafted by employees of CleanSlate, Inc., an entity then controlled by Dr. Wilson. Moreover, one of the authors of these policies is CleanSlate co-founder and Dr. Wilson's ex-wife. These policies direct the members, employees, and contractors of CleanSlate Centers to refer patients for laboratory work to the CleanSlate Lab.

136. Under the Stark Law, because Dr. Wilson directs and controls these referrals, Dr. Wilson is a "referring physician" for all CleanSlate's laboratory orders, a designated health service. 42 C.F.R. § 411.351.

137. Clinicians at CleanSlate had no discretion as to whether to order urine drug testing and no ability to refer it to a lab other than the CleanSlate Lab. CleanSlate's responses to interrogatories issued by the Commonwealth pursuant to a Civil Investigative Demand admit that Dr. Wilson set this policy, which she confirmed during her testimony. CleanSlate also could not identify a single instance in which a clinician did not follow this policy. In Relator's experience, confirmed by statements of other CleanSlate physicians such as Dr. Edna Markaddy, practitioners did not have control over where the urine was sent for testing.

138. CleanSlate maintains collaboration agreements between mid-level pracitioners and CleanSlate physicians. Those agreements explicitly require the mid-level practitioners to follow the protocols in the Buprenorphine/Suboxone manuals. Those manuals as explained, *supra,* impose routine ordering of UDS and LCMS confirmation.

139. According to CleanSlate's interrogatory responses, the only exception to this policy is for patients with Cigna HealthCare insurance, who have their UDS processed at a Quest Diagnostics laboratory, pursuant to a contractual arrangement between CleanSlate and Cigna.

140. CleanSlate and Dr. Wilson cannot identify a single practitioner at CleanSlate who did not follow this policy. When asked how a physician wanted to send a UDS to another laboratory, such as Quest Diagnostics, Dr. Wilson answered, "the physicians didn't express a desire to do that." Dr. Wilson also never received a request from a clinician to send the norbuprenorphine test to another laboratory once the CleanSlate laboratory had the capacity to do that test. At all times that Dr. Wilson was working at CleanSlate, the CleanSlate laboratory never conducted testing for non-CleanSlate patients.

141. LaRoche testified that even if a practitioner had attempted to order a UDS from a laboratory other than CleanSlate's laboratory, CleanSlate's billing software during her tenure would assume that the UDS had been ordered through CleanSlate's laboratory. The staff at CleanSlate's laboratory would need to inform the Billing Department about such an event, in which case LaRoche said they would have to "void the claim, do a corrective claim, take the money back."

142. Until March 2019, Dr. Wilson was the sole member of Defendant Total Wellness, which owned both the CleanSlate clinics and the laboratory. Dr. Wilson was paid an annual salary by CleanSlate. Dr. Wilson also owned a significant portion of CleanSlate's stock.

143. Dr. Wilson therefore, as a physician, was responsible for referring laboratory tests from a clinic in which she had a financial interest to a laboratory in which she had a financial interest, thereby violating the Stark Law.

144. Dr. Wilson designed the system from the start to increase the revenue stream of CleanSlate Centers. Under the Stark Law, Dr. Wilson, the "referring physician" is in prohibited direct ownership and direct and indirect compensation relationships with Total Wellness Center, LLC, the entity performing the services. No applicable safe harbors protect Dr. Wilson's

relationships, in part because any compensation that she receives from Total Wellness depends on the "volume or value" of referrals. *See, e.g.,* 42 C.F.R. 411.357(p) (pertaining to indirect compensation agreements).

145. Defendants cannot take advantage of the safe harbor exceptions for services furnished "by another physician who is a member of the referring physician's group practice" or under their supervision, or for "in-office ancillary services" because the application of either exception would require that CleanSlate qualify as a "group practice" under 42 C.F.R. § 411.352. *See* 42 C.F.R. § 411.355(a), (b).

146. Under the Stark law a "group practice" must: (a) consist of a single legal entity or multiple, state-specific entities, if the states are contiguous and the entities identical, 42 C.F.R. § 411.352(a); (b) have at least two non-contract physician members of the group who each furnish substantially the full range of patient care services that the physician routinely furnishes including medical care, consultation, diagnosis, and treatment, *id.* at § 411.352(b)-(c); and (c) have no less than 75 percent of the physician-patient encounters of the group practice be conducted by its members, *id.* at § 411.352(h). However, CleanSlate fails several elements of this test.

147. A group practice must consist of a ***single legal entity,*** and CleanSlate comprises several professional LLCs in multiple states. This structure cannot constitute a "group practice" unless "the States in which the group practice is operating are contiguous" and "the legal entities are absolutely identical as to ownership, governance, and operation." 42 C.F.R. § 411.352(a). CleanSlate cannot meet either of these prongs of this test.

148. Furthermore, physician members of the group practice (who cannot be independent contractors under § 3121(d)(2) of the Internal Revenue Code of 1986) "must furnish

substantially the full range of patient care services that the physician routinely furnishes, including medical care, consultation, diagnosis, and treatment, through the joint use of shared office space, facilities, equipment, and personnel." 42 C.F.R. § 411.352(c). The DATA-waived doctors cannot be deemed members of the CleanSlate group practice because they do not see patients one-on-one (or in many cases at all) and therefore do not perform the full range of patient care services through CleanSlate's resources. But, if the DATA doctors are not deemed members of the CleanSlate group practice, then CleanSlate's members would "personally conduct [] less than 75 percent of the physician-patient encounters of the group practice[,]" thereby precluding the "group practice" designation. *Id.* at § 411.352 (h). Moreover, most of CleanSlate's patient services and encounters are performed by nurse practitioners and physician's assistants, as attested to by Dr. Wilson, Dr. Mendenhall, and confirmed by Relator.

149. Even if these referrals were somehow attributed to the individual prescribing physicians and mid-level practitioners, either during Dr. Wilson's tenure or after her exit, they would still violate the Stark Law's "Special Rules on Compensation." This regulation states that "a physician's compensation from a bona fide employer or under a managed care contract or other arrangement for personal services may be conditioned on the physician's referrals to a particular provider" only if the referral requirement "is set out in writing and signed by the parties" and does not apply "if the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgment." 42 C.F.R. § 411.354(d)(4).

150. Here, CleanSlate's referral requirement was not set out in writing signed by the parties and did not contain an exception for the patient's preference or his best interest. Thus, no Stark safe harbor protects this scheme.

151. Defendants have also violated comparable state anti-referral laws. *See* Mass. Gen. Laws ch. IIID § 8A; Ind. Code § 25-22.5-11-3. State-specific exceptions are inapplicable. Massachusetts' exception for clinical laboratories owned by licensed physicians or groups of licensed physicians requires that the "testing is performed by or under the direct supervision of said physician or group of physicians," a requirement that CleanSlate's policies preclude here. Mass. Gen. Laws ch. IIID § 8A; *see* Commonwealth of Massachusetts Complaint in Intervention. Indiana law requires the physician to disclose the financial interest to the patient in writing and permit him or her to be referred elsewhere, a practice not followed by Defendants. Ind. Code § 25-22.5-11-3.

152. Furthermore, the testing revenue that flows from Total Wellness to CleanSlate Centers, Inc., constitutes illegal remuneration under the federal and state anti-kickback laws. This remuneration flows to CleanSlate Centers, Inc., to induce or reward it for ordering or arranging for the members, employees, and contractors of CleanSlate Centers to refer patients to Total Wellness's clinical laboratory. The payments ultimately depend on the "volume or value" of referrals, and accordingly, no anti-kickback law safe harbor permits this activity.

153. These actions violate not only the federal Anti-Kickback statute, but also comparable state laws. *See, e.g.,* Indiana, Ind. Code § 12–15–24–2; Massachusetts, Mass. Gen. Laws ch. 118E, § 41; Pennsylvania, 55 P.A. Code § 1101.75(a)(3).

154. Because of the violations of Stark and the Anti-Kickback laws, each request for reimbursement by Government Health Care Programs of testing performed at the CleanSlate

Centers' laboratory constitutes a false or fraudulent claim. Representative examples are identified *infra.*

2. Defendants' Medically Unnecessary Drug Tests Constitute False Claims

155. In violation of medical necessity rules and Government Health Program regulations, CleanSlate utilizes a standard Standing Order/Blanket Order for UDS and other tests such as liver function, performed at the CleanSlate Lab in connection with each Suboxone maintenance visit, regardless of the individualized needs of the patient.

156. In further violation of medical necessity rules, CleanSlate requires its clinicians to perform routinized LCMS testing for buprenorphine and norbuprenorphine in various circumstances. In each of these cases, no individualized effort is made by CleanSlate to ensure that the confirmatory testing is medically appropriate for that patient or will be used in the diagnosis or treatment of the patient's disease.

157. As noted above, CleanSlate recognizes that LCMS testing to confirm expected findings is not medically necessary, admitting that their use of testing "***is not based in science.***" CleanSlate claims that this testing is utilized to prevent drug diversion, but the governing regulations make clear that use of routine confirmatory testing is medically unnecessary for this purpose. The presence of buprenorphine in presumptive testing is expected in patients to whom it is prescribed, and confirmatory testing provides no further relevant information. *See* Massachusetts Audit Report (noting substance abuse professionals, "***do not confirm positive results for methadone or buprenorphine*** for members who are currently receiving those drugs as part of their treatment" because "positive results of these substances in the primary drug test provide the expected appropriate result." (emphasis added).) The only medical indication for such confirmatory testing is when a patient is suspected of diverting the drug *and* covering the diversion by adulterating a sample with crushed buprenorphine. Such circumstances are

exceedingly rare and are appropriately addressed with simple procedures such as direct observation, which CleanSlate also uses.

158. CleanSlate also orders reflex LCMS tests for unexpected findings as a routine supplement to drug screens. CleanSlate procedures require that when an unexpected substance is identified in analyzer testing, it is automatically sent to an outside laboratory for confirmation, without any attempt to contact the patient to determine whether the presence of those substances needs to be confirmed, or whether the patient admits to their use. CleanSlate further utilizes an unusual specimen collection procedure in which it holds urine samples in its refrigerator to be sent to independent laboratories if needed. This procedure appears designed to circumvent anti-fraud rules that ensure that presumptive and confirmatory testing are not performed on the same date of service and prevents additional tests from being added to a sample after submission to an independent laboratory.

159. Each of these practices results in orders for medically unnecessary laboratory explicitly forbidden under governing regulations. Claims seeking payment for medically unnecessary tests are false or fraudulent under the federal and state false claims acts. In particular:

a. Each of the urine drug screens ordered and performed by CleanSlate under blanket and standing orders constitutes a false or fraudulent claim.

b. Each of the LCMS buprenorphine confirmatory tests ordered and performed by CleanSlate pursuant to its policies that it admits are "not based in science" without individualized determinations of medical necessity, constitutes a false or fraudulent claim.

c. Each LCMS confirmatory tests ordered by Defendants and performed by outside laboratories, such as Quest Diagnostic as part of a routine reflex testing panel without individualized determinations of medical constitutes a false or fraudulent claim.

160. Representative examples of these claims are discussed, *infra.*

3. Urine Drug Tests That Were Not Timely Reviewed or Used in Medical Decision Making Constitute False Or Fraudulent Claims

161. Diagnostic laboratory tests, such as urine drug tests here must be ordered by the treating physician and used "in the management of the [patient's] specific medical problem." 42 C.F.R. § 410.32(a).

162. Medical providers are not permitted to bill the government for medically unnecessary or unreasonable services, which includes services performed for no reason other than obtaining a profit. *See, e.g., Kneepkins,* 115 F. Supp. 2d at 41-42 (services billed to Medicare must be reasonable and medically necessary, and they must be provided economically…procedures chosen solely for defendants' economic gain and that were deleterious and inferior are not "medically necessary."). Health care providers must certify that services or items ordered or provided to patients will be provided "economically and only when, and to the extent, medically necessary" and "will be of a quality which meets professionally recognized standards of health care" and "will be supported by evidence of medical necessity and quality." 42 U.S.C. § 1320c-5(a)(1)-(3).

163. As part of CleanSlate's effort to remove individualized decision-making from its processes, laboratory tests are ordered through and results provided via its EMR, Stratus. CleanSlate was Stratus EMR's largest client and purchased the company in late 2016. Stratus EMR regularly customized the software to meet CleanSlate's needs.

164. The EMR does not automatically provide test results and allow them to be viewed by and acted upon in a medically appropriate manner by the treating clinician. Such a system is industry standard practice. Instead, the Stratus EMR system holds all results until the patient returns for a follow-up visit, and they auto-populate in the clinical note. This frequently occurs well after the window for appropriate medical intervention for relapses in sobriety, dangerous drug interactions, and failure to comply with medication regimens. Review of patient charts confirms that the results of urine drug tests were rarely acted upon by any CleanSlate staff, and certainly not by a physician.

165. For example, one patient was given a Hepatitis C test in 2014, but because he did not return after his first visit, he was never informed of the results until 2016, when he sought to rejoin the program and, for the first time, learned that he had the disease.

166. In fact, the results from the UDS may not have even been provided to the clinicians who were treating particular patients, as LaRoche, CleanSlate's former Director of Billing, testified. LaRoche explained that CleanSlate's EMR software could assign a "lab supervisor" to be a different person than the treating clinician, which would result in the treating clinician not receiving the Urine Drug Screen results. LaRoche stated that she raised this issue but was informed by CleanSlate management that it was not a problem, because CleanSlate clinicians do not really review the results anyway. LaRoche stated that Ellen Alexander, CleanSlate's Regional Vice President of Operations for the Northeast Region, and Maria Russo-Appel, Eastern Division Medical Director, told her, "All they do is go ahead and click right through. They don't look at them." This procedure results in medically unnecessary testing.

167. CleanSlate regularly ordered expensive laboratory procedures, both from its in-house laboratory and Quest Diagnostics, that it did not utilize in the diagnosis or treatment of its

patients. Such orders are medically unnecessary and therefore constitute false or fraudulent claims.

168. Representative examples of these claims are discussed, *infra.*

4. Defendants' Buprenorphine Prescriptions Violate State and Federal Law, Causing False or Fraudulent Claims

169. As noted above, CleanSlate's system delegates prescribing authority to unsupervised mid-level practitioners. In most cases, prescriptions are issued, signed, and filled days, weeks, or months before a patient meets with a licensed physician.

170. These procedures violate the relevant state medical regulations. For example, Massachusetts prohibits delegating buprenorphine prescription authority to non-physicians, and Indiana specifically prohibits issuing prescriptions unless patients are seen face-to-face.

171. Even with the implementation of CARA, mid-level practitioners are only allowed to prescribe these substances in accord with state regulations, the relevant state regulations require adequate supervision and collaboration of mid-level practitioners by licensed physicians, including in many cases written collaboration agreements.

172. DEA regulations prohibit the prescribing of buprenorphine in violation of state requirements.

173. CleanSlate records and chart reviews indicate that no such collaboration cooperation, or supervision is performed. *See infra*. As noted above, all Government Health Care Programs require that adequate documentation exist in the medical records. *See, e.g.*, 42 USC § 1395l(e) (Medicare: adequate documentation exist in the medical records); § 1396(a)(27) (Medicaid);

174. From March 2012, through mid to late 2014, CleanSlate transmitted prescriptions for buprenorphine authorized solely by midlevel practitioners; days later, physicians signed and

backdated the prescriptions, in violation of 21 U.S.C. §§ 829(b) and 842(a)(1), and 21 C.F.R. §§ 1306.03, 1306.05(a), and 1306.04(a). While CleanSlate entered into a settlement of these violations with respect to DEA penalties, it remains liable for causing false claims for the resulting prescriptions under both the Medicare and Medicaid Programs.

175. On November 21, 2016, CleanSlate and Defendant Total Wellness entered into a settlement agreement with the Drug Enforcement Agency ("DEA") and the United States Department of Justice ("DOJ").

176. CleanSlate and Defendant Total Wellness paid a total of $750,000, including $500,000.00 to resolve the backdating of prescriptions allegations, which only covered claims improperly billed to Medicare, not MassHealth, even though these problems were companywide and not specific to Medicare beneficiaries. Dr. Wilson was a signatory to this settlement agreement.

177. As part of the federal investigation and settlement, CleanSlate informed its employees in December 2016 via email, that it addressed the issues by appointing a new management team. It also stated that it began the process of hiring at least one full-time doctor at each of its clinics. CleanSlate also indicated that it implemented a new electronic prescribing system and protocols under which only appropriate clinicians prescribe buprenorphine. CleanSlate also said that it committed to implementing a new system under which only doctors can prescribe buprenorphine electronically to attempt to ensure that a doctor reviews the patient visit information before the prescription is issued.

178. The conduct is outlined in further detail in a December 2016 email to Dr. Mendenhall by one physician, Dr. Paul Gerstein. Dr. Gerstein began working for CleanSlate around April 2014 and said that he signed off on prescriptions for CleanSlate patients that he was

not treating and knew nothing about. He states that he was asked to "rubber stamp" and pre-date those prescriptions.[2]

179. Each of the prescriptions written by Defendants in violation of federal law, and DEA and state regulations and reimbursed by Government Health Care Programs is a false or fraudulent claim caused by Defendants' fraud.

180. Additional examples of false claims are identified *infra*.

5. Defendants' Claims for Treatment by Unsupervised Mid-Level Practitioners Are False and Fraudulent

181. Defendants bill office visits under CPT Evaluation/Management codes for office visits 99203-99215.

182. Prior to CleanSlate's settlement described above, the visits were billed with a physician's NPI's pursuant to Medicare's incident-to rules, despite CleanSlate's lack of direct supervision.

183. Moreover, while CleanSlate now bills these codes with a mid-level practitioner modifier, use of this modifier indicates that the mid-level practitioner is supervised. In fact, they are not. Where the services are billed by a Physician's Assistant, a physician responsible for the overall direction and for assuring that the services provided are medically appropriate must supervise the service. *See* Medicare Benefit Policy Manual, Ch. 15 § 190. Services billed by a Nurse Practitioner must be performed in collaboration with one or more physicians (MD/DO) with medical direction and appropriate supervision as required by the law of the State in which the services are furnished. *Id.* at § 200.

[2] A representative example of false claims submitted pursuant to prescription backdating are included in the Complaint in Intervention filed by the Commonwealth of Massachusetts on October 16, 2020 (Patient G)

184. Review of CleanSlate patient charts makes clear that no such supervision or collaboration is provided.

185. Such misrepresented claims are false or fraudulent claims.

C. Representative Examples of False Claims And Charts

1. Relator's Chart Review Exposes False Claims And Serious Patient Harm

186. In November 2016, auditors from Geisinger Health Plan (GHP) requested full records for four CleanSlate Pennsylvania patients at the Wilkes Barre location. Non-clinical staff was aware of the request for over a week before informing clinical staff. Geisinger offered both commercial plans and managed government Medicaid and Medicare plans. These charts revealed:

a. GHP Patient 1: Under the care of Brenda Goodrich, DO: Initially seen by a PA in mid-December 2015.[3]

   i. Never seen by a physician.

   ii. Patient denied Xanax abuse, but test results dated mid-December, are positive for benzodiazepines. CleanSlate systems identified two simultaneous Xanax prescriptions from different non-CleanSlate providers. PA notes reference positive tests but no action taken by PA.

   iii. Later notes discuss "counseling" patient, but nothing indicates any collaboration or conversation with a physician. PA notes do not document that they called the physician of record to discuss. MD notes are very

[3] Relator's internal communications and notes refer to these patients by initials, DOB, and specific dates of treatment. These details are being withheld to ensure compliance with the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") 45 CFR Section 164.502. Relator will furnish this information in a HIPAA compliant manner to Defendants and this Court upon request.

infrequent and consist of only a line or two, with none of these issues being addressed. PA continued to prescribe Suboxone.

iv. No treatment plan.

v. Continued positive test results for benzodiazepines, including repeated positive test results for clonazepam.

b. GHP Patient 2: First seen in mid-December 2015.

i. Patient is listed as "red" or highest level of care needed.

ii. Patient was first seen by a physician in late June 2016, over seven months later.

iii. Patient has notes reflecting being seen by a physician dated early August 2016, but this was a late entry for a June 2016 cursory group visit.

c. GHP Patient 3: first seen mid-December 2015.

i. Patient tested positive for benzodiazepines repeatedly.

ii. No documentation of physician involvement, with the exception of a few cursory, templated group visit notes that are not customized to the patient.

187. In sum, Relator discovered the following deeply troubling issues:

a. two patients had received multiple months of Suboxone without ever having been seen by a physician;

b. two had no clear documentation of a physician/patient relationship;

c. one patient had been seen only twice by a physician in eleven months of treatment – once reflected by cursory "group visit" notes inserted in the chart over a month after the alleged date of service;

d. another patient's chart reflected benzodiazepine prescriptions from multiple non-CleanSlate doctors and multiple tests reflecting several benzodiazepines. The mid-level practitioner's notes mentioned the positive tests, but not acknowledgement of the patient's benzodiazepine prescriptions or any discussion with the patient's CleanSlate physician or outside physicians. The physician's notes were infrequent and did not address any of the issues.

188. In response, Relator undertook her own review of 20 random Pennsylvania patient charts from the Scranton and Wilkes Barre locations. These charts, like the prior four, showed that in every case, the level of care was well below what would be expected of a physician-led addiction practice. In most cases, no valid doctor-patient relationship was documented and, in many cases, patients had never had a face-to-face encounter with their prescriber. Some particular examples of charts included:

a. PA Patient 1: Initially seen by a mid-level practitioner in early April 2016.[4]

i. In mid-April physician entered note to mid-level: "please give warning to patient that if next urine drug screen positive for cocaine and opiate, I will not sign prescription." Mid-level responded "Prescribing physician concerns noted, but please note that the urine samples of concern were taken during the patient's initial week of treatment. We do not expect them to have 'clean' urines during the first and second visit as they are just starting treatment."

[4] Relator's internal communications and notes refer to these patients by internal record number and dates of treatment. These details are being withheld to ensure compliance with HIPAA. Relator will furnish this information in a HIPAA-compliant manner to Defendants and this Court upon request.

ii. Late May prescribing physician wrote note in chart but did not see the patient.

iii. Early August, mid-level entered a note dated August but labeled "late entry" for a visit that occurred in June.

iv. This patient had never been seen face to face by a physician.

b. PA Patient 2: Seen mid-August 2016 through late November 2016. Had never seen a physician face to face.

c. PA Patient 3: Seen early December 2015 through late November 2016. Had never been seen face to face by a physician

d. PA Patient 4: Initial appointment by mid-level in late December 2015. Mid-January 2016 physician visit. Mid-May cursory physician notes from group session. This is a complex patient with multiple confirmed benzodiazepines in urine. Cursory physician notes that do not address clinical management of the patient. Late October 2015, mid-level recommending home re-induction of buprenorphine without documentation of physician involvement.

e. PA Patient 5: Early October 2016, initial appointment with mid-level. Patient continues to be seen without any physician visit to date. UDS shows positive for opioids, cocaine, and alcohol.

f. PA Patient 6: Mid-August 2016 initial appointment with physician. Next appointment with physician mid-November 2016. Patient continues to test positive for cocaine, benzodiazepines, and alcohol without evidence of action by clinical team beyond canned statements that they have told the patient the combination is dangerous.

g. PA Patient 7: Early February 2016, initial note by physician. Not seen by physician again until early August when patient discusses suicidal thoughts. Not seen by physician again until early November when the physician documents recent suicide attempt by shooting high doses of IV crystal meth. CleanSlate system shows psychiatric medication written by psychiatrist, however CleanSlate clinical notes do not document that any coordination of care occurred.

h. PA Patient 8: Initial visit mid-November 2016 with mid-level. Mid-November UDS show positive for fentanyl with no plan to address. Patient has never seen a physician at CleanSlate.

189. In sum, this review of charts identified:

a. The majority of charts reviewed (17/20) did not have documented evidence that the prescribing physician had a valid doctor/patient relationship with the patient;

b. Nine of the patients had never seen a physician;

c. Five of the patients had been seen in a group setting only, with notes that were not specific to the patient. Group visits for all patients were boilerplate and appeared to be copied and pasted into charts without customization;

d. Three of the patients saw a physician for the first time several weeks after their first prescription;

e. The Stratus EMR tracks compliance with a patients' visits with their prescribing physicians. The programmed standard of compliance was two visits every twelve months. This contradicted Defendants' claims that patients

saw their doctor quarterly; this representation was specifically presented to the DEA/DOJ in the settlement discussed below;

f. All charts, even the few evidencing a physician/patient relationship, showed serious quality issues. These included:

i. A physician note directing a mid-level practitioner to warn a patient that after the next positive UDT for cocaine, the physician would refuse to sign further prescriptions. The mid-level practitioner apparently overruled the physician and wrote in the chart, "we do not expect them to have 'clean' urines during the first and second visit";

ii. Notes for a complex patient with multiple confirmed benzodiazepines in UDT recommending that the patient be permitted to do an "induction" visit at home with no documentation of physician involvement in the decision;

iii. Continual positive tests for cocaine, benzodiazepines, and alcohol with no notes beyond canned statements that the combination is dangerous; and

iv. Physician notes reflecting that a patient discussed suicidal thoughts; the patient was then not seen by the physician for three months when the notes reflected a suicide attempt. The chart showed psychiatric medications written by an outside doctor, but no notes reflecting coordination of care.

190. Less than two weeks later, Relator and the President of Operations for the East Division, Adam McPhee, met with Pat Richardson, a senior executive with a Medicaid plan in Indiana. Ms. Richardson requested that Relator review four Indiana Medicaid charts due to

concern that they indicated a lack of medically necessary individualized care. Review of these charts[5] found the following:

a. Three charts indicated test results conflicting with the monthly reports that CleanSlate had been providing to the insurer. For example, one patient's tests had multiple positive indications of marijuana use and one positive result for amphetamine use, but the monthly reports provided to the insurer reflected negative UDT results;

b. None of the charts showed evidence of a valid doctor-patient relationship;

c. Two patients were prescribed buprenorphine prior to being seen by a physician in direct violation of Indiana law;

d. One patient had never been seen by a physician;

e. One patient's chart reflected persistently positive tests for benzodiazepines with some cursory notes that the issue was discussed with the patient, but nothing indicating consideration of providing the patient with appropriate counseling, elevated care, or consideration of the dangerous interactions between benzodiazepines and buprenorphine;

f. Three patients' UDT reflected marijuana and cocaine use, notes failed to reflect appropriate discussion of issues with patient or attempts to provide adequate individualized treatment.

191. The Relator Dr. Welch reviewed her findings with the Regional Medical Director, Dr. Mendenhall, who confirmed that he had found similar issues in a sample of fifteen

[5] Relator's internal communications and notes refer to these patients by internal record number and dates of treatment. These details are being withheld to ensure compliance with HIPAA. Relator will furnish this information in a HIPAA-compliant manner to Defendants and this Court upon request.

Massachusetts charts[6] in February 2016 and had presented these findings to CleanSlate's CMO, CEO and co-founders. He also confirmed that approximately 50% of the sample he reviewed did not have documented evidence of the required quarterly group visits and that CleanSlate did not have a process in place to ensure that compliance is achieved. Further, Dr. Mendenhall confirmed that the lack of documentation accurately reflected the actual clinical practice at the centers.

192. In sum, Relator's review of over 40 charts consistently revealed the following serious clinical deficiencies:

a. The majority of charts reviewed did not have documented evidence that prescribing physicians had valid doctor/patient relationships with their patients. The charts indicate that physicians sign off on the clinical notes of mid-level practitioners, but there is a consistent lack of documentation that the prescribing physicians meet with patients and participate in the initial assessment, initial treatment planning, and ongoing medical decision making for patients on their panel.

b. The majority of charts reviewed did not have documented evidence that the prescribing physicians had seen patients quarterly in group visits. Stratus EMR indicates whether a patient has been seen quarterly. Despite this customized screen, which highlighted the lack of compliance, the majority of charts did not have documentation reflecting any attempt to contact patients, assess them telephonically, or offer face-to-face group appointments with their prescribing physicians.

[6] Relator's has internal notes describing these records identified by internal record number and dates of treatment. These details are being withheld to ensure compliance with HIPAA. Relator will furnish this information in a HIPAA-compliant manner to Defendants and this Court upon request.

c. Every chart lacked documented evidence that laboratory results, including urine drug testing results, were viewed by clinicians upon receipt of results or utilized to make timely clinical decisions.

d. The majority of the charts indicated some specific UDT result (usually presence of substance of abuse) that should have resulted in individualized notes and some medical discussion or intervention but failed to note a corresponding medical reaction.

e. In the majority of patients with both an opioid use disorder and a co-occurring benzodiazepine use disorder, the charts did not contain documentation of consideration of higher levels of care and did not contain evidence of care coordination with other prescribing physicians in the community.

f. None of the charts documented evidence of collaboration and supervision between the prescribing physician, mid-level practitioner, and center Medical Director.

g. The chart review revealed no instances in which physicians declined to issue prescriptions presented to them. In some rare cases, physicians would note that they would not sign further prescriptions if a patient continued to test positive for substances of abuse. However, the charts lacked documentation that the prescribing physicians took any other actions, such as discussing with other clinical staff appropriate management, attempting to contact patients to re-assess items of concern, considering higher levels of care, or offering immediate or increased group appointments. Further, since a significant number of patient prescriptions are signed by "emergency" prescribers and not

the prescriber of record and lab results are not seen by clinicians until the patient returns for subsequent visits, there is insufficient coordination of care to ensure that the prescribing physician's concerns are addressed.

h. The majority of charts reflect frequent changes in the prescribers of record and numerous instances of prescriptions "authorized" by various prescribers.

i. Most comments in charts appear to be templated macros and do not reflect individualized assessments. This is true even in very serious cases.

193. Relator, along with Regional Medical Director, Dr. Mendenhall, approached Chief Medical Officer, Dr. Clark, and other senior members of CleanSlate for support. Initially Dr. Clark acknowledged the problems. Relator and Dr. Mendenhall drafted a plan of response. This plan included limiting the admission of new patients into existing centers and delaying opening new centers until sufficient staff and policies could ensure patient safety across all centers. Dr. Clark, however, quickly realized the scope of the required remediation, noting that bringing the centers into compliance could take "12 days solid of MD time" assuming each doctor could see three patients per hour. After consideration of the issue by senior executives, the plan was scrapped in favor of continued growth.

2. Additional Representative Examples of False and Fraudulent Claims

194. Relator identified additional representative examples of CleanSlate's false and fraudulent claims to Government Health Care Programs.[7]

195. MA Patient 1 was seen at the Worcester, MA location from at least mid-September 2016 through late October 2017.

[7] Relator has access to certain internal notes and documents that identify patient names/initials dates of birth and dates of service. Relator also has access to corresponding Medicaid payment records for these patients. These details are being withheld to ensure compliance with HIPAA. Relator will furnish this information in a HIPAA-compliant manner to Defendants and this Court upon request.

196. On many occasions, MA Patient 1's clinical notes do not reflect that the providers viewed the results of the internal CleanSlate drug tests or the results of the external confirmatory tests for various drugs of abuse, and the notes also do not reflect that the providers used those results to make timely treatment decisions for the patient. Records indicate that Network Health One Care, an MCE, was billed for and paid claims for this visit and these tests.

197. For example, in late April, MA Patient 1 was seen by PA Angelina Hodgkins. The chart indicates that PA Hodgkins was supervised by both Christopher Kennedy MD who was the suboxone prescriber and Flora Sadri-Azarbayejani, MD, the physician supervising laboratory test requests for the patient. It is not clear why a PA would have separate supervisors for lab test requests and for prescriptions. The chart indicates that a UDS test was ordered by Dr. Sadri-Azarbayejani over two weeks before the visit pursuant to a "standing order." The chart indicates that the UDS returned positive for opiates the day after the visit. The chart also reflects confirmatory LCMS tests were sent to Quest with the same sample date as the patient's visit. This likely reflects that CleanSlate siphoned the patient's urine to hold and send later upon a positive UDS. The patient notes reflect no discussion inquiring about the patient using other drugs. No notes reflect any discussion with the patient upon receiving test results indicating patient is in relapse.

198. The PA notes reflect no discussion with supervising physicians. The PA notes are signed the next day by Dr. Kennedy with a canned statement that "this patient is assigned to my panel of Buprenorphine patients, and I have reviewed the patient's record, and agree with the current assessment and plan as outlined by Angelina Hodgkins." The notes are signed three days later by Dr. Sadri-Azarbayejani with a statement that she ordered the labs entered "today" in the labs section of the Electronic Medical Record.

199. Billing records indicate that Network Health One Care, an MCE, paid claims for an office visit, UDS and LCMS confirmatory tests to CleanSlate and Quest all dated the same as the patient's visit.

200. A week later, MA Patient 1 returned to CleanSlate. On this visit the patient was seen by Marilou Bartus, NP with the same physician supervisors. The notes include no discussion of the positive LCMS for morphine but do reflect that the UDS was positive for opiates and benzodiazepines. Notably the prior UDS was negative for benzodiazepines and the chart reflects the fact that the patient is prescribed Clonazepam, a benzodiazepine, so such results would be expected. The notes do reflect discussing that the patient claimed to have eaten poppy seeds. A patient blaming positive urine tests on "poppy seeds" is a classic deflection by patients suffering from this disease. Nevertheless, the NP notes state that the patient, who appears to be in relapse now, "is in Stabilization Phase; Patient continues to be appropriate for OBOT; Patient is responding to OBOT." None of the notes indicate any discussion about the relapse with the supervising physician. The supervising physician's notes appeared to be canned and state only "I have reviewed the note and/or discussed [the patient] with Marilou Bartus including reviewing the physical exam, treatment plan, addiction history and past medical history and I agree that the patient meets DSM-V criteria for Opioid Addiction, and that they are a good candidate for office based Buprenorphine treatment, with the plan to place the patient on Suboxone 12/3 mg film."

201. The only reaction to the results seems to be the ordering of a large number of additional confirmatory tests including those for Opiates, Oxycodone, Heroin and metabolites, Fentanyl, Benzodiazepines (to confirm presence of prescribed drugs and absence of non-prescribed drugs); Buprenorphine confirmation (inexplicably justified by the positive opiates result); and a poppy seed IGE.

202. Billing records indicate that Network Health Network Health One Care paid claims for UDS and LCMS confirmatory tests to CleanSlate and Quest all dated the same as the patient's visit.

203. MA Patient 2 was seen by CleanSlate at the New Bedford, MA location from at least early March 2014 through early September 2017, representing 53 unique visits and 3 and half years of continuous treatment. The clinical notes and lab results indicate that the patient was in sustained recovery from opioid addiction. Clinical notes contain detailed wrapper counts, which is a way for providers to assess for diversion. There were no notes indicating that the patient had ever attempted to divert suboxone. Despite there being no clinical indication to send urine samples to the CleanSlate lab for Buprenorphine confirmatory testing, on 25 occasions CleanSlate physicians ordered confirmatory tests for this patient. Of note, some of these tests were within days of one another, and the provider appeared to have not reviewed the result from the days prior.

D. Scienter: Defendants Knew About These Serious Deficiencies

1. Defendants Knew That Owning Their Own Lab Implicated Self-Referral Laws

204. Defendants' reliance on this scheme and knowledge of its illegality was confirmed to Relator in a discussion regarding the corporate structure of CleanSlate's laboratories. CleanSlate CFO, Patrick Murphy, explained that the structure implicates self-referral laws because Dr. Wilson owns Defendant Total Wellness Center, LLC, which runs the laboratory. One of the topics of discussion was whether the laboratory tests should be referred to third-party laboratories because of the financial requirements and regulatory implications of expanding laboratory operations to facilitate its growth plans. These concerns were balanced against the enormous revenue Defendants receive from testing.

205. Similarly, in an email dated November 10, 2016 Mr. Murphy discussed the "thinking of ownership" regarding the various state level entities. Mr. Murphy admitted that "Given certain MA referral limitations Amanda as the owner of [Total Wellness] can't own other entities that refer into [Total Wellness]."

2. Defendants Knew that Their Prescriptions And Services Violated Governing Rules and Regulations

206. CleanSlate management was well-aware of the lack of doctor-patient contact as the issue was repeatedly discussed internally. Many at CleanSlate urged management to ensure that patients saw a doctor in person before being prescribed opioids. Chief Medical Officer Dr. Clark, then President-elect of the American Society of Addiction Medicine, was horrified when she reviewed the results of Relator's GHP chart review. She stated that the charts "show care was not delivered in fidelity to our Mission, vision, values - or medico-legal standards of care." She assessed the care described in the charts as "an unacceptable deviation from the standard of care for OBOT, from our treatment program as sold to GHP, and unacceptable risk to the company." And she predicted that "We will and should crash as a company if this is the care we are providing." Dr. Clark also noted that the care reflected in the charts contradicted the representations CleanSlate had made to the DOJ: "in the face of our settlement, this needs to be fixed urgently with every patient's chart documenting that they have seen by a physician ASAP."

207. By early December 2016, however, after speaking with CleanSlate board, Dr. Clark had changed her view and now argued that having a legal prescriber see a patient prior to prescribing was a "platinum level pristine care model" and CleanSlate would do so only in Indiana, Kentucky and Connecticut, where Dr. Clark viewed it as a legal requirement. She described the requirement as "a very high bar" that "must be addressed creatively." In other states, management's professed "goal" was for doctors to see patients face-to-face within 7 to 10

days after starting medication. Even in Kentucky, Dr. Clark suggested that CleanSlate could claim a "critical access issue" justified "less stringent time frames."

208. By mid-December 2016, even this goal was deemed unattainable in the short-term. A list of action items circulated by President of Operations, East Division, Adam McPhee, reflected that "1:1 MD visits" would occur within "10/30 days of treatment" and noted that "Initially, may need to work towards 30 day window due to limited resources." This new crisis also appeared to have displaced complying with CleanSlate's promise to the DEA and DOJ to prioritize hiring full-time physicians at each center; that effort had now fallen to fifth on the action items list.

209. Despite the Massachusetts Prescribing Guidelines forbidding physicians operating under a DATA 2000 waiver from delegating the prescribing of buprenorphine to non-physicians, CleanSlate policies permitted mid-levels to authorize prescriptions for buprenorphine to patients for up to a month before they ever saw a physician face-to-face. Even in Indiana, where CleanSlate acknowledged the legal requirement of face-to-face physician examinations prior to commencing treatment, CleanSlate center staff were unaware of the requirement and patient charts establish that patients regularly received buprenorphine prescriptions before being seen by physicians. As late as December 2016, CleanSlate persisted in scheduling new patient intakes on days in which no doctor was scheduled to work at Indiana clinics.

210. When asked how CleanSlate planned to comply with Indiana's enhanced OBOT regulations, Dr. Clark bragged that Indiana FSSA Secretary John Wernert had privately promised that the requirements would be eliminated at the next legislative session.

211. As late as December, after Relator's chart review assessments had been circulated among CleanSlate staff, monthly reports continued to reflect many Indiana patients testing

positive for substances of abuse, with only cursory notes that a clinician discussed risks of substance abuse with the patient.

212. CleanSlate was aware of the extent to which their practices fell below federal and state legal requirements and acceptable medical practice, and the consequences they would face should the Government Health Care Programs learn the truth. In November 2016, CleanSlate announced a settlement with the DEA and the United States Department of Justice ("DOJ").

213. In particular, the DEA discovered that mid-level practitioners had been utilizing the identifying number of legal prescribers to write apparently valid hard-copy prescriptions that were only later signed and back-dated by the prescriber of record in violation of DEA regulations. But, the DEA was unaware that the prescriptions and treatment plans were the product of mid-level practitioner decision-making without valid doctor-patient relationships or individualized patient assessments and treatment plans in violation of state law. Because the DEA believed the violations consisted solely of a technical back-dating issue, CleanSlate "fixed" the issue by coding Stratus EMR to require a DATA-waived doctor's electronic signature before a prescription could be sent to the pharmacy.

214. Similarly, while the DOJ discovered that unsupervised mid-level practitioner services had been improperly billed under physicians' direct supervision in violation of Medicare incident-to billing rules, CleanSlate represented that the mid-level practitioners were supervised generally by the Medical Director and DATA-waived doctor who operate in a "group practice." CleanSlate hid the fact that that mid-level practitioners made nearly all medical decisions and lacked the supervision required for even direct billing. Defendants also misrepresented that patients were seen quarterly by their physician, when, as noted above, the internal "goal" was

twice a year and even this was regularly missed. This lack of full information necessarily affected the size and scope of DOJ's settlement.

215. CleanSlate deeply misrepresented the state of its clinical practice to the DEA and DOJ. When the part-time doctors at CleanSlate learned of the settlement, they immediately recognized the inadequacy of CleanSlate's settlement. One docåtor noted that the DEA settlement ran to February 2014, but he was instructed to engage in the same activity when he was hired in April of that year. He also noted that CleanSlate had falsely informed him that its illegal process was DEA approved. The doctor was particularly concerned that while CleanSlate negotiated a settlement with the government on its own behalf (that expressly excluded actions by the DEA against individual prescribers), it never informed physicians that they were practicing illegally, preventing them from protecting themselves or complying with the law. Further, the doctor noted that even after he transitioned to electronic prescribing, he was instructed to rubber stamp prescriptions for patients he wasn't treating and knew nothing about – in his mind the equivalent of the prohibited practice minus the backdating.

216. Defendants' actions and policies reflected their knowledge about the DEA's likely response if it knew the extent of their practices. Internally, CEO, Greg Marotta sought to downplay the seriousness of the DEA letters that CleanSlate physicians and mid-level practitioners began to receive, claiming that CleanSlate staff "may continue to receive letters of admonition from the DOJ until CARA is fully implemented. This is standard procedure and has no bearing on your ability to practice or your formal record." In contrast to this nonchalance, the Clinician Manual stressed that "it is ***critical*** that you reach out to your Center Manager **ASAP** if the DEA contacts you for any reason related to your prescribing of buprenorphine."

217. When CleanSlate learned that the DEA wished to speak with a physician, operations and compliance staff would request that the physician meet with them first. In at least one case, operations staff provided a physician with CleanSlate manuals and a list of questions that the DEA "usually ask during the meeting," noting that the DEA "usually concentrate on the induction process" (a procedure that part-time physicians did not have first-hand experience with) and urged the doctor to "read over that section . . . thoroughly, though you should familiarize yourself with the whole manual." The physician was urged to learn how to navigate through the EMR because the DEA would be asking about prescriptions that the physician had signed for individual patients.

218. Massachusetts revised its substance abuse licensing regulations in 2016. CleanSlate staff reviewed the new requirements and created a document identifying and detailing the extent to which CleanSlate's program was deficient with Massachusetts regulations and Commission on Accreditation of Rehabilitation Facilities ("CARF") standards required for board accreditation. CleanSlate internally acknowledged numerous of areas of deficiency, particularly with respect to requirements relating to training, obtaining complete medical histories, and making individualized treatment decisions. In December 2016, Regional Medical Director, Dr. Mendenhall explained that "there is wide variance" between CleanSlate's operations and the requirements for "HR/Training/Supervision policies- that essentially don't exist." Moreover, he noted "substantial variance with our clinical programming and documentation," and "wider variance in terms of the clinical model in MA." Dr. Mendenhall placed the blame squarely on CleanSlate's treatment model, explaining "it simply isn't possible for people seeing 4-5 patients an hour to track some of this data down." He later explained that "ALL of the CARF and for MA-DPH requirements are going to fall on our medical staff to execute and complete, with

essentially no time or support staff (Care Coordinators) . . . The infrastructure has not been built for successful deployment in our high-volume clinical environment."

219. In late December 2016, Massachusetts Department of Public Health ("DPH") inspected the West Springfield center as part of the licensing process and noted numerous deficiencies, including failure to obtain adequate substance abuse histories, inadequate evidence of physician sign-off in charts, failure to follow-up on patient no-shows, use of doctors lacking proof of valid DEA waivers and others practicing with expired DEA waivers. CleanSlate CEO Gregory Marotta asked Compliance Director Richard Raphael to evaluate how CleanSlate was "stacking up." Mr. Raphael explained "it's reasonable to assume the Clinical piece is being neglected (or in "Fair" condition) because of the lack of clinical attention as evidenced by the DPH report," and that "the current state (i.e., pushing out the inspection for CARF, resistance to implementation of standards because of resource issues, etc.) is not going to make CARF and DPH (or [Pennsylvania Centers of Excellence]) standards happen."

220. Likewise, Defendants were aware that the urine drug tests results were not getting to the prescribers in a timely manner and were being ignored. As LaRoche, CleanSlate's former Director of Billing, testified, the EMR system prevented the treating clinician from receiving the Urine Drug Screen results. LaRoche stated that she raised this issue but was informed by CleanSlate management that it was not a problem, because CleanSlate clinicians do not really review the results anyway. LaRoche stated that Ellen Alexander, CleanSlate's Regional Vice President of Operations for the Northeast Region, and Maria Russo-Appel, Eastern Division Medical Director, told her, "All they do is go ahead and click right through. They don't look at them." This procedure results in medically unnecessary testing.

E. Apple Tree Partners Controlled and Directed CleanSlate's False and Fraudulent Practices and Was the Beneficiary of Those Practices

221. In 2014, Apple Tree Partners began to invest in CleanSlate and its for-profit network of addiction-treatment centers and clinical laboratory. According to Defendant Wilson, it was Diane Daych from Apple Tree Partners who first "approached" Wilson. Dr. Wilson testified that Daych and ATP were "very knowledgeable about the opioid disorder space" and "very excited about CleanSlate." In and after 2014, ATP acquired control of CleanSlate through its purchases of successive series of preferred stock.

222. The accompanying investor agreements ensured ATP control over CleanSlate through the power to appoint "Preferred Designees" and "Preferred Independent Directors" to the CleanSlate Board of Directors. Both ATP Venture Partner Diane Daych and ATP Managing Partner Seth Harrison served on the CleanSlate Board of Directors. ATP also exercised its right to appoint a number of "Preferred Independent Directors" to the CleanSlate Board, giving ATP effective control over the corporate governance of CleanSlate. As Dr. Wilson, who was CleanSlate's CEO at the time, testified concerning the role ATP had in creating the Board, "it was through their connections largely that I met most of the board members."

223. As accomplished investors in health care companies, ATP knew when it invested in CleanSlate that health care providers which bill government health care programs are subject to laws and regulations designed to prevent fraud, including the Stark Law and the AKS. When asked to share her recollection of what was discussed during bimonthly meetings of the ATP-controlled Board of Directors, Dr. Wilson testified "we always talked about compliance."

224. Defendant Wilson also testified that ATP's investment in CleanSlate "changed everything in the structure of the company." Wilson testified that, following ATP's investment, she continued to make day-to-day decisions over CleanSlate's operations while matters "of any

magnitude" were made in consultation of the Board. Wilson also acknowledged that ATP's investments were essential to the expansion of CleanSlate, stating "I could only grow maybe two or three [CleanSlate locations] a year" whereas following the ATP investment "we could get to 80."

225. Defendant Wilson recalled that ATP "did their due diligence process" prior investing in CleanSlate. Corporate records reveal ATP was aware that both the U.S. Department of Justice and the U.S. Drug Enforcement Administration were investigating CleanSlate for activities dating back as far as January 1, 2012.

226. By May 2016, as ATP was purchasing another series of CleanSlate preferred stock, the terms of its voting agreement were amended to give ATP even greater control over CleanSlate if certain "Triggering Events" occurred. Those triggering events were expressly defined to include the revocation of Dr. Wilson's medical license or her DEA issued controlled substance certificate, or Dr. Wilson's "felony conviction" in connection with the Department of Justice investigation or the Drug Enforcement Administration investigation.

227. Board records reveal that, in October 2016, the CleanSlate Board of Directors voted to create a sub-committee "to assist with settlement discussions" being conducted on CleanSlate's behalf with the U.S. Department of Justice. That committee was composed of ATP Partner Diane Daych and ATP "Preferred Independent Directors" Gene Fleming and Paul Brown.

228. Weeks later, in November 2016, CleanSlate entered into its Settlement Agreement with the U.S. Department of Justice and the U.S. Drug Enforcement Administration and agreed to pay $750,000 to resolve the investigations into CleanSlate's violation of Medicare and DEA regulations. This settlement provided ATP with an acute warning as to the consequences of failing to follow relevant laws and regulations that apply to providers treating

patients suffering from opioid dependance. The settlement also provided ATP with actual knowledge of CleanSlate's prohibited backdating of prescriptions for MassHealth members. Yet, the ATP controlled CleanSlate Board of Directors made no effort to ensure that CleanSlate repaid any of those overpayments to MassHealth or any MCEs.

229. Settlement of the federal investigations cleared the way for full implementation of the CleanSlate "Rapid Expansion Initiative." That plan had been developed over the course of 2016 during offsite meetings held at ATP's offices in New York City. The Executive Summary of the Initiative stated "Fueled by the national opioid addiction epidemic, we have the opportunity and responsibility to expand our services across the country" and set as a stated objective "Build a $500 million revenue company with a 25% margin, $1B valuation, serving 50,000 patients, in 3 years."

230. To accomplish those aggressive goals the Rapid Expansion Initiative specified, among other actions, leveraging ATP's "relationships" to "enhance [the] tactical pipeline of current opportunity targets." The Initiative also included the objective of identifying "immediate high demand O/P addiction services market" with the corresponding action item to "start with payers, including "Mcaid" and "gov't agencies." Later the Initiative identified, as additional action items, the "Federal 30/100 patient limit and APC prescribing; bupe prescribing regulations [and] federal funding" as well as "State patient/medication limits, bupe practice licensing and medical practice requirement."

231. Consistent with the goals set in the ATP-sponsored Rapid Expansion Initiative, over the course of 2016 CleanSlate issued and circulated regular KPI (Key Performance Indicator) summaries. The KPI summaries included information on the financial performance of

the CleanSlate laboratory and analyzed the laboratory's revenue by the type and billing code of each test that was billed to and paid by Medicaid and Medicare.

232. In October 2016, CleanSlate management provided actual and projected financial summaries to the Board of Directors, but only after the presentation was edited and approved by ATP Partner Diane Daych. The CleanSlate summaries included one slide, titled "Payer Sensitivity – Based on Lives in Target States" which identified close to 100,000 potential "Suboxone patients" of which approximately one quarter were designated as "Mcaid." The same chart included "Estimated Annual Revenue" figures based on the number of patients who could be "converted" to Suboxone and, presumably, placed in the CleanSlate program of unsupervised buprenorphine prescriptions followed by months and years of medically unnecessary confirmatory testing performed at the CleanSlate laboratory.

233. The same October 2016 summaries included a separate slide titled "Patients Needed to Reach $500M Q4'18 Revenue Run Rate." One set of columns on that slide projected that Medicaid and Medicare Fee For Service patients would account for at least 26,000 of the total 44,000 patients needed to reach the stated target.

234. ATP's investments and financial resources were crucial to the implementation of the CleanSlate Rapid Expansion Initiative. It was foreseeable to ATP that the expansion of CleanSlate would result in a steady increase in the submission of false and fraudulent claims to Government Health Care programs.

235. A few weeks after the October 2016 meeting of the CleanSlate board, which was held at ATP's New York City offices, defendant Wilson sent an email to Relator Welch and CleanSlate President of Operations for the East Division, Adam McPhee concerning certain

"modeling" Wilson had conducted in line with "our Rapid Expansion projections." In that email, Wilson confirmed that the end of 2018 was the "Apple Tree expected exit date."

236. According to media reports, in or about December 2017, CleanSlate Director and ATP Partner Diane Daych and CleanSlate Director Paul Brown launched a new growth equity firm called Granite Growth Health Partners. The same media reports stated that Granite Growth Health Partners had "the backing of $45 billion private equity titan HarbourVest Partners."

237. One of the December 2017 media reports on the launch of the Granite Growth equity firm quoted CleanSlate CEO Greg Marotta as stating, "Granite Growth partners appreciate that providers have unique needs and challenges to navigate, particularly in the increasingly complex healthcare environment" and "Even more than strong investors, they are trusted, hands-on advisors who bring an incredible depth of knowledge and experience to their partnership."

238. In or about December 2017, Granite Growth Health Partners bought out ATP's holdings in CleanSlate. Thus, ATP benefitted substantially from CleanSlate's false claims and retained overpayments rendering it liable as a beneficiary under the Massachusetts False Claims Act.

F. Defendants' Conduct Was Material To The Government

239. Defendants' fraudulent schemes alleged herein violated the Stark Law and the AKS and were designed to influence and negate providers' independent medical judgment in a way that is fundamentally at odds with the function of the Medicare and Medicaid systems.

240. Any designated health service provided in violation of the Stark Law, or in violation of the AKS, is not payable under Medicare or Medicaid, including MassHealth and Indiana Medicaid.

241. In its Provider Agreements with CMS, MassHealth, and Indiana Medicaid, CleanSlate falsely promised that it would comply with all applicable fraud, waste and abuse laws, which include the Stark Law, the AKS, and the FCA. CleanSlate's promises to comply with all applicable fraud, waste and abuse laws were material to its continued participation in the Medicare, MassHealth and Indiana Medicaid systems.

242. Defendants knew that compliance with the Stark Law and the AKS was a condition of payment and material requirement for receiving reimbursement from Medicare, Medicaid, MassHealth, and Indiana Medicaid.

243. By letter dated October 9, 2020, MassHealth exercised its authority to suspend payments to CleanSlate Centers, Inc. for laboratory services. MassHealth suspended payment based on a credible allegation of fraud that CleanSlate's laboratory billed MassHealth for urine drug tests that were "medically unnecessary and/or referred to the laboratory by CleanSlate's own clinics, thereby violating state and federal self-referral laws."

244. Likewise, insurers do not pay for medically unnecessary tests. *See United States v. Bertram*, 900 F.3d 743, 749 (6th Cir. 2018), *cert. denied*, 139 S. Ct. 852, 202 L. Ed. 2d 582 (2019). ("The timing of the tests was a material fact because Anthem wouldn't have paid for the tests had it known they weren't needed). This is because "the purpose of urinalysis is to give contemporaneous information about the presence of drugs in the patient's body." For this reason Government Health Care Programs do not knowingly pay for urine drug testing that is not needed or used in treatment.

G. Harm to the Government and Patients

1. Financial Harms to the Government

245. Defendants' use of corporate-wide policies reduces expenses and supports massive revenue growth, thereby enabling Defendant ATP to show "ratios that tee us up for

future exit" and "tell a story that flows back to P&L." Combined with CleanSlate's indifference to rules and regulations governing prescribing, treatment, and supervision, this has resulted in Government Health Care Programs paying tens of millions of dollars for unnecessary, unreasonable, and often harmful medical procedures to a "pill mill." These false claims include, *inter alia*, prescriptions written in the absence of a doctor-patient relationship in violation of DEA and other rules; and mid-level practitioners billing for procedures for which they lacked adequate supervision.

246. Fueled by its profit interest in securing lucrative referrals to its own clinical laboratory, CleanSlate's standing and blanket orders for medically-unnecessary and unreasonable testing resulted in false or fraudulent claims for tens of millions of dollars of tests. Moreover, CleanSlate's systems were unable to timely use any such test results. Since 2009, Government Health Care Programs have reimbursed tens of millions of dollars for these tests.

2. Harm to Patients

247. Beyond the financial fraud inherent in Defendants scheme, their profit-driven inadequate medical treatment has caused serious harm to very sick patients who desperately need competent medical attention. Chart reviews demonstrated the impact of these policies. They indicate a consistent lack of doctor-patient relationships, practitioners failing to recognize or act on the results of the expensive tests they regularly ran, and regular failure to provide physician intervention and to elevate patients to a higher level of treatment when needed.

248. In one case, a CleanSlate patient was given a Hepatitis C test *in 2014*, but because he did not return after his first visit, he was never informed of the results *until 2016*, when he sought to rejoin the program and for the first time, learned that he had the disease. He did know that his girlfriend had tested positive (and had recently given birth to a child) but was uncertain

who had given the disease to whom. These concerns were brought to the attention of CleanSlate management, which ignored them.

249. In one case, CleanSlate had been prescribing Suboxone for two months despite knowing upon intake that a patient was taking oxycodone and Xanax and UDT indicated fentanyl and prescribed benzodiazepines.

250. Other Chart reviews identified pervasive positive UDT without comment or appropriate clinical intervention, unaddressed drug relapses, continued drug abuse without intervention, and failure to see a doctor for over a year of treatment.

251. When CleanSlate Chief Medical Officer Dr. Clark learned of the lapses in care reflected in Relator's chart review she said they "show care was not delivered in fidelity to our Mission, vision, values - or medico-legal standards of care." She assessed the care described in the charts as "an unacceptable deviation from the standard of care for OBOT, from our treatment program as sold to GHP, and unacceptable risk to the company." And predicted that "We will and should crash as a company if this is the care we are providing." Dr. Clark also noted that the care reflected in the charts contradicted the representations CleanSlate had made to the DOJ: "in the face of our settlement, this needs to be fixed urgently with every patient's chart documenting that they have seen by a physician ASAP."

252. In one particularly tragic incident, a patient at the West Springfield, Massachusetts center, a military veteran, who was responding well to OBOT informed the center staff that he had lost his insurance and could not afford to self-pay. While Massachusetts regulations require that OBOT facilities have a written policy ensuring that patient well-being is protected in such situations, and Defendants were aware of the requirement, the interaction was handled on an *ad*

hoc basis by non-clinical staff without consulting the patient's physician, mid-level provider, or any other CleanSlate clinical staff.

253. Had a physician been involved, he or she would likely have known of the importance of providing the patient with a bridge prescription because sudden cessation of Suboxone nearly guarantees patient relapse. Patients in treatment lose their prior tolerance to opioids rendering heroin relapse unexpectedly deadly. Unfortunately, in this case, the patient fatally overdosed leaving a young son without his father.

254. CleanSlate did not automatically inform any clinical staff including Regional Medical Director, Dr. Mendenhall and Chief Medical Officer, Dr. Clark, of such patient deaths. Clinical staff first learned of the event through a later request to deactivate the patient's chart due to his death. When Dr. Mendenhall learned of the incident, he was sufficiently concerned to ask the Center Manager whether there were other recent deaths of which he had not been informed. He was infuriated by the lack of (legally required process) and noted that CleanSlate had "an issue with patient abandonment for a couple of years" and that it "is a primary topic of importance for" Dr. Clark. He informed Dr. Clark of the event, describing it as "the kind of shit we have to get to stop ASAP" and demanded that a "sentinel event report be started." He argued that such issues were fixable, "but not without substantial resources that need to be deployed that will impact the staffing model."

H. Retaliation Against Relator

255. Relator worked for Defendants pursuant to a written contract. The contract contained, in relevant part, a provision guaranteeing certain benefits should Relator resign for good cause and provide sufficient notice.

256. After Relator internally raised concerns regarding the serious operational deficiencies she observed, Relator, along with others, drafted a plan of response, which included

limiting the admission of new patients into existing centers and delaying opening new centers until sufficient staff and policies were secured to ensure patient safety across all centers. Their concerns were rebuffed by CleanSlate management in favor of continued growth. Furthermore, the incident had marked Relator as a troublemaker not aligned with Defendants' plans.

257. Relator was excluded from key meetings where decisions about clinical workflows were discussed. For example, management decided to change the way that buprenorphine/norbuprenorphine confirmations were reported in the electronic health record. Before the fall of 2016, CleanSlate reported buprenorphine/norbuprenorphine results with numerical values. This is the standard way to report the results of confirmatory testing. After Relator raised concerns about the volume of buprenorphine/norbuprenorphine tests, meetings where held without her knowledge or presence, and then an email was sent from Kathleen Haughton, Senior Clinical Director, informing the clinical workforce that CleanSlate would no longer be reporting numerical values, but rather, would report only "positive" or "negative" results.

258. Relator continued to notice that she was being excluded from key meetings where important clinical workflow decisions were being made, even though she was the second highest ranking physician in the organization. Despite expressing these concerns to Greg Marotta and Dr. Clark, she continued to be excluded from important meetings and key discussions.

259. This response led Relator to conclude that she could not successfully continue to work for Defendants. She provided notice of her intent to resign for good cause as required by her contract. CleanSlate was initially willing to provide the contractually required termination benefits, but upon learning that she would not agree to sign a broad release which would waive

her rights to file and recover under any whistleblower law, CleanSlate refused to comply with its contractual requirements.

VI. CLAIMS FOR RELIEF

CLAIMS AGAINST ALL DEFENDANTS

Count One

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

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

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

262. From at least October 2009 to the present, Defendants failed to comply with applicable statutes and regulations prohibiting backdating of prescriptions by physicians, medically unnecessary urine drug testing, including the requirements that such testing be reviewed and used in treatment, mid-level supervision requirements applicable to billing and prescribing and self-referral of urine drug testing to CleanSlate's own laboratory.

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

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

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

266. Additionally, the United States is entitled to the maximum penalty of between $11,665 to $23,331 (or other statutory maximum provided for by law) for each and every violation alleged herein.

Count Two

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

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

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

269. From at least October 2009 to the present, Defendants failed to comply with applicable statutes and regulations prohibiting backdating of prescriptions by physicians, medically unnecessary urine drug testing, including the requirements that such testing be reviewed and used in treatment, mid-level supervision requirements applicable to billing and prescribing and self-referral of urine drug testing to CleanSlate's own laboratory.

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

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

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

273. Additionally, the United States is entitled to the maximum penalty of between $11,665 to $23,331 (or other statutory maximum provided for by law) for each and every violation alleged herein.

Count Three

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

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

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

276. From at least October 2009 to the present, Defendants failed to comply with applicable statutes and regulations prohibiting backdating of prescriptions by physicians, medically unnecessary urine drug testing, including the requirements that such testing be reviewed and used in treatment, mid-level supervision requirements applicable to billing and prescribing and self-referral of urine drug testing to CleanSlate's own laboratory.

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

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

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

280. Additionally, the United States is entitled to the maximum penalty of between $11,665 to $23,331 (or other statutory maximum provided for by law) for each and every violation alleged herein.

Count Four

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

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

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

283. From at least October 2009 to the present, Defendants have conspired to submit false and fraudulent claims for payment and statements and records to Government Health Care Programs through failure to comply with applicable statutes and regulations prohibiting backdating of prescriptions by physicians, medically unnecessary urine drug testing, including the requirements that such testing be reviewed and used in treatment, mid-level supervision requirements applicable to billing and prescribing and self-referral of urine drug testing to CleanSlate's own laboratory.

284. By and through the acts described above, Defendants conspired to commit violations of 31 U.S.C. § 3729(a)(1)(A), (B), and (G). Further to Defendants' conspiracy and fraudulent scheme, despite knowing that tens of millions of dollars in payments from the federal government have been received in violation of the False Claims Act and in violation of the Stark law and Anti-Kickback Statute's prohibitions on receipt of payment for services rendered in

connection with an improper financial arrangement, Defendants have refused and failed to refund these payments and have continued to submit false or fraudulent claims, statements, and records to the United States.

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

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

287. Additionally, the United States is entitled to the maximum penalty of between $11,665 to $23,331 (or other statutory maximum provided for by law) for each and every for each and every violation alleged herein.

Count Five

Indiana Medicaid False Claims Act
Ind. Code §§ 5-11-5.7, *et seq*.

288. Relator incorporates by reference the preceding paragraphs as though fully set forth herein.

289. This is a civil action brought by Relator, on behalf of the State of Indiana, against Defendants under the State of Indiana False Claims and Whistleblower Protection Act, Ind. Code § 5-11-5.7-4(a).

290. By and through the acts described above, Defendants have knowingly made, used, or caused to be made or used a false record or statement material to an obligation to pay money to the State of Indiana and they have concealed and improperly avoided an obligation to pay money to the State of Indiana, including specifically Defendants' obligation to report and repay past overpayments of Medicaid and other government health care program claims for which

Defendants knew they were not entitled to and therefore refunds were properly due and owing to the State of Indiana.

291. The Indiana FCA, Ind. Code § 5-11-5.7-2(a)(l), creates liability for any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." Defendants have violated this provision of the Indiana FCA.

292. The Indiana FCA, Ind. Code § 5-11-5.7-2(a)(2), creates liability for any person who "knowingly makes, uses, or causes to be made or used, a false record or statement that is material to a false or fraudulent claim." Defendants have violated this provision of the Indiana FCA.

293. The Indiana FCA, Ind. Code § 5-11-5.7-2(a)(6)(A)-(B), creates liability for any person who "(A) makes, uses, or causes to be made or used, a false record or statement concerning an obligation to pay or transmit money or property to the state; or (B) conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the state." Defendants have violated this provision of the Indiana FCA.

294. The Indiana FCA, Ind. Code § 5-11-5.5-2(b)(7), creates liability for any person who "conspires with another person to perform an act described in subdivisions (1) through (6)." Defendants have violated this provision of the Indiana FCA.

295. Pursuant to the Indiana FCA, Defendants are thus liable to the State for penalties of at least five thousand dollars $5,000 and up to three (3) times the amount of damages sustained by the state. Ind. Code § 5-11-5.5-2(b).

Count Six

Massachusetts False Claims Act
Mass. Gen. Laws ch. 12, §§ 5A, *et seq*.

296. Relator incorporates by reference the preceding paragraphs as though fully set forth herein.

297. This is a civil action brought by Relator, on behalf of the Commonwealth of Massachusetts, against Defendants under the Massachusetts False Claims Act, Mass. Ann. Laws, ch. 12, § 5C(2).

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

299. The Massachusetts FCA, Mass. Ann. Laws, ch. 12, § 5B(1), creates liability for any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." Defendants have violated this provision of the Massachusetts FCA.

300. The Massachusetts FCA, Mass. Ann. Laws, ch. 12, § 5B(2), creates liability for any person who "knowingly makes, uses or causes to be made or used a false record or statement material to a false or fraudulent claim." Defendants have violated this provision of the Massachusetts FCA.

301. The Massachusetts FCA, Mass. Ann. Laws, ch. 12, § 5B(3), creates liability for any person who "conspires to commit a violation of this subsection." Defendants have violated this provision of the Massachusetts FCA.

302. The Massachusetts FCA, Mass. Ann. Laws, ch. 12, § 5B(9), creates liability for any person who "knowingly makes, uses or causes to be made or used a false record or statement material to an obligation to pay or to transmit money or property to the commonwealth or a political subdivision thereof, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the commonwealth or a political subdivision thereof." Defendants have violated this provision of the Massachusetts FCA.

303. The Massachusetts FCA, Mass. Ann. Laws, ch. 12, § 5B(3), creates liability for any person who "conspires to commit a violation of this subsection." Defendants have violated this provision of the Massachusetts FCA.

304. Pursuant to the Massachusetts FCA, Defendants are thus liable to the Commonwealth for statutorily defined damages sustained because of the acts of Defendants and civil penalties between $11,665 to $23,331 (or other statutory maximum provided for by law) for each and every violation alleged herein. Mass. Ann. Laws, ch. 12, § 5B.

CLAIMS AGAINST DEFENDANTS AMANDA LOUISE WILSON, M.D AND APPLE TREE PARTNERS

Count Seven

Massachusetts False Claims Act Beneficiary Provision
Mass. Gen. Laws ch. 12, §§ 5A, *et seq*.

305. Relator incorporates by reference the preceding paragraphs as though fully set forth herein.

306. This is a civil action brought by Relator, on behalf of the Commonwealth of Massachusetts, against Defendants under the Massachusetts False Claims Act, Mass. Ann. Laws, ch. 12, § 5C(10).

307. By and through the acts described above, Defendants Amanda Louise Wilson, M.D. and Apple Tree Partners have benefitted, through the proceeds of their investments and ownership interest, from CleanSlate Centers' false claims to the Commonwealth and retained overpayments. Defendants have failed to disclose the false claims and overpayments to the Commonwealth within the statutorily defined period.

308. The Massachusetts FCA, Mass. Ann. Laws, ch. 12, § 5B(10), creates liability for any person who

> is a beneficiary of an inadvertent submission of a false claim to the commonwealth or a political subdivision thereof, or is a beneficiary of an overpayment from the commonwealth or a political subdivision thereof, and who subsequently discovers the falsity of the claim or the receipt of overpayment and fails to disclose the false claim or receipt of overpayment to the commonwealth or a political subdivision by the later of: (i) the date which is 60 days after the date on which the false claim or receipt of overpayment was identified; or (ii) the date any corresponding cost report is due, if applicable,

309. Defendants have violated this provision of the Massachusetts FCA.

310. Pursuant to the Massachusetts FCA, Defendants are thus liable to the Commonwealth for statutorily defined damages sustained because of the acts of Defendants and civil penalties between $11,665 to $23,331 (or other statutory maximum provided for by law) for each and every violation alleged herein. Mass. Ann. Laws, ch. 12, § 5B.

CLAIMS ON BEHALF OF THE RELATOR PERSONALLY AGAINST DEFENDANT CLEANSLATE CENTERS

Count Eight

Retaliation in Violation of False Claims Act
31 U.S.C. § 3730(h)

311. Relator realleges and incorporates by reference the allegations of the foregoing paragraphs as though fully set forth herein.

312. Defendants harassed, discriminated against, threatened, and ultimately caused Relator to resign employment because of lawful acts Relator undertook to stop violations of, and a conspiracy to violate, the False Claims Act. Defendants' retaliation also independently violates the FCA, 31 U.S.C. § 3730(h).

313. Defendants' retaliation and discrimination has inflicted damages on Relator including, but not limited to, past and future earnings, lost employment benefits (including health insurance benefits and retirement contributions), job-search expenses, humiliation, mental anguish, and emotional distress, all collectively in an amount to be determined at trial.

314. Defendants' actions were knowing, malicious, willful, and with conscious disregard for Relator's rights under the law. Relator is further entitled to exemplary and punitive damages in an amount to be determined at trial.

Count Nine

Breach of Contract and Implied Covenant of Good Faith and Fair Dealing

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

316. Relator worked for Defendants pursuant to a written contract. The contract contained, in relevant part, a provision guaranteeing certain benefits should Relator resign for

good cause and provide sufficient notice. That contract was also subject to an implied covenant of good faith and fair dealing, including a covenant not to discriminate against or discharge Relator for refusal to participate in or comply with a conspiracy to defraud the federal government and States.

317. CleanSlate breached that contract and its corresponding implied covenant of good faith and fair dealing by retaliating against Relator for refusing to engage in CleanSlate's scheme to increase revenue at further risk to patient sales and for taking lawful acts to prevent violations of the federal FCA state law.

318. CleanSlate further breached the contract by refusing to provide the contractually required termination benefits upon receiving timely notice that Relator was terminating the contract for good cause.

319. As a result of Defendant's breach of contract and the implied covenant of good faith and fair dealing, Relator has suffered damages including, but not limited to, her good cause termination benefits, lost past and future earnings, lost employment benefits (e.g., health insurance benefits, and retirement contributions), job-search expenses, humiliation, embarrassment, mental anguish, and emotional distress—in an amount to be determined specifically at trial.

320. Defendants' conduct was performed knowingly, maliciously, oppressively, and with conscious disregard for both Relator's rights and state and federal law. Relator is entitled to exemplary and punitive damages against Defendant in an amount to be determined at trial.

VII. PRAYERS FOR RELIEF

WHEREFORE, Relator prays for judgment against Defendants as follows:

A. That Defendants are enjoined from violating the federal False Claims Act, 31 U.S.C. §§ 3729, *et seq.*, and the State of Indiana and the Commonwealth of Massachusetts FCAs;

B. That judgment be entered against Defendants and in favor of the United States and the Relator in an amount equal to three times the amount of damages caused by Defendants' misconduct, as well as a civil penalty for each FCA violation in the maximum statutory amount;

C. That judgment be entered against Defendants and in favor of the *Qui Tam* States and the Relator in the amount of the damages sustained by the *Qui Tam* States multiplied as provided for in the State FCAs, plus civil penalties in the ranges provided by the State FCAs;

D. That Defendants be ordered to disgorge all sums by which they have been enriched unjustly by their wrongful conduct;

E. That judgment be granted for Relator against Defendants for all costs, including, but not limited to, court costs, litigation costs, expert fees, and all attorneys' fees permitted under 31 U.S.C. § 3730(d), and comparable provisions of the State FCAs;

F. That Relator be awarded the maximum amount permitted under 31 U.S.C. § 3730(d), and comparable provisions of the State FCAs;

G. That Relator be awarded all available damages, prejudgment interest, fees and costs pursuant to Relator's personal claims for retaliation and wrongful termination and breach of contract and covenants of employment under the federal FCA, 31 U.S.C. § 3730(h), and common law, including, without limitation, two times back pay plus interest (and prejudgment interest), reinstatement or in lieu thereof front pay, and compensation for any special damages and/or exemplary or punitive damages, and litigation costs, and attorneys' fees; and

H. That the Court award such other relief as the Court deems proper.

JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38, Plaintiff-Relator requests a jury trial.

October 16, 2020

Respectfully submitted,

/s/ *Suzanne E. Durrell*

Suzanne E. Durrell (BBO #139280)
Email: suzanne@thomasdurrell.com
David W.S. Lieberman (BBO #673803)
Email: david@thomasdurrell.com
WHISTLEBLOWER LAW COLLABORATIVE LLC
20 Park Plaza, Suite 438
Boston, MA 02116-4334
Tel: (617) 366-2800
Fax: (888) 676-7420

Counsel for Plaintiff-Relator

Jeanne E. Helton, Esq.
(904) 359-7761
Email: jhelton@smithhulsey.com
James H. Post, Esq.
(904) 359-7700
Email: jpost@smithhulsey.com
SMITH HULSEY & BUSEY
225 Water Street, Suite 1800
Jacksonville, Florida 32202

Of Counsel