

per capita income compared to the national average. *Id.* § 1396d(b). The remainder of the Medicaid budget is funded by the state.

3. MassHealth, through its providers, provides treatment and medications to help individuals recover from substance use disorders, including opioid use disorder. Opioids are a class of drugs that include heroin, fentanyl, and oxycodone. Opioid use disorder is defined by the American Society of Addiction Medicine (“ASAM”) as a chronic, relapsing brain disease that causes significant impairment or distress.

4. Those services include coverage for prescription medications, treatment programs, and counseling. MassHealth pays for Office-Based Opioid Treatment (“OBOT”), which are programs that provide medically-monitored treatment to individuals who are addicted to opioids in a primary care setting.

5. Defendants own and operate many OBOT centers in Massachusetts and around the country, where individuals receive medication-assisted treatment for substance use disorders. Defendants primarily treat opioid addiction, but also treat alcohol addiction. Defendants have provided substance use treatment to more than 27,000 individuals in its Massachusetts locations, with many of those individuals receiving MassHealth coverage.

6. Defendants also own and operate an independent clinical laboratory in Holyoke, Massachusetts, where Defendants perform tests of clinical specimens for patients who have been seen at their OBOT centers.

7. When patients first come to Defendants’ OBOT centers to receive treatment, they are typically seen by a midlevel clinician (nurse practitioner or physician assistant). As part of this initial visit, the patient submits to an immunoassay urine drug screen (“UDS”), a lower-complexity test that is used to detect the presence of certain substances in the patient’s urine. As

a matter of Defendants' company policy, a UDS is collected and performed at every subsequent visit the patient has at Defendants' OBOT centers.

8. In addition to the UDS, Defendants also order several types of more complex urine drug tests, commonly referred to as "quantitative tests," which can identify not just the presence, but the amount/quantity of a particular drug in the patient's urine. These tests are ordered under a variety of circumstances, including when the patient exhibits drug-seeking or drug-influenced behaviors during the visit, when certain substances are identified in the UDS after the visit, and/or when called for by company policies dictating intervals at which complex urine drug tests should be ordered.

9. Defendants sometimes: (1) simultaneously order UDS and quantitative tests during a visit, resulting in duplicative testing; (2) order quantitative tests reflexively whenever a substance appears in a UDS, regardless of the patient's statements regarding use of the substance and/or whether the UDS reflects the expected result; (3) order quantitative tests to confirm the presence or absence of the metabolite of buprenorphine, norbuprenorphine (known as "norbuprenorphine LCMS tests")² even if the patient has not demonstrated any potential for drug diversion or if the patient has not been prescribed buprenorphine; and (4) do not check the results of the UDS unless the patient returns to CleanSlate. These situations result in medically unnecessary tests ordered and/or billed by CleanSlate, thereby resulting in submission of false claims.

10. Defendants' clinicians do not have discretion as to: (1) whether to order a UDS; or (2) which laboratory to refer a UDS or norbuprenorphine LCMS test to be conducted. Defendants require, as a matter of company policy, that a UDS be ordered at every visit and that

² LCMS is an acronym referring to "liquid chromatography-mass spectrometry."

all UDS and norbuprenorphine LCMS tests be performed at Defendants' own laboratory.

11. Defendants' company policy, which directs clinicians to refer patients' UDS and norbuprenorphine LCMS tests to its clinical laboratory, in which they have (or had) an ownership interest, violates federal and state laws prohibiting self-referral of laboratory testing, thereby resulting in submission of false claims.

12. During the relevant time period, Defendants also engaged in practices that led to backdating of prescriptions by physicians. After patients had already picked up prescriptions that were sent to pharmacies by midlevel clinicians, CleanSlate physicians later reviewed the notes from the patient visits and backdated the prescriptions to the office visit dates. CleanSlate has already resolved with Medicare, but not MassHealth, for causing the submission of false claims based on these invalid prescriptions.

13. As a result of the ordering of medically unnecessary urine drug testing, the self-referral of testing to a laboratory they own (or owned), and the backdating of prescriptions by physicians, Defendants submitted or caused to be submitted claims for services in violation of regulations to MassHealth, as well as to various managed care entities ("MCEs"), entities under contract with MassHealth to administer the payment of benefits for MassHealth beneficiaries. Defendants knew or should have known of these violations, yet billed MassHealth and MCEs as if the services had been provided in full compliance with state and federal laws and MassHealth regulations.

14. The Commonwealth now files this action under the Massachusetts False Claims Act, Mass. Gen. Laws c. 12, §§ 5A *et seq.*; Mass. Gen. Laws c. 111D, §§ 8A and 8(17); Mass. Gen. Laws c. 118E, §§ 40 and 44; 130 C.M.R. §§ 450.237, 450.260(A), and 450.260(I); and the common law to recover damages and civil penalties from Defendants for losses suffered by the

MassHealth program.

JURISDICTION AND VENUE

15. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1345, 1367(a), and under 31 U.S.C. § 3732(b), which provides this court with jurisdiction over state law claims arising from the same transactions or occurrences as an action brought under the federal False Claims Act.

16. The Court may exercise personal jurisdiction over Defendants under 31 U.S.C. § 3732(a) because Defendants operate and/or have operated treatment centers and an independent clinical laboratory throughout the Commonwealth and therefore transact business in the District of Massachusetts.

17. Venue is proper in this District under 31 U.S.C. § 3732 and 28 U.S.C. § 1391(b)&(c) because Defendants regularly conduct and/or conducted business within the District of Massachusetts, maintained employees and offices in this District, and, as a result of the statutory violations alleged herein, submitted false claims and/or caused false claims to be submitted in this District.

PARTIES

18. Plaintiff the Commonwealth of Massachusetts is a sovereign state and body politic duly organized by law and is represented by the Attorney General of the Commonwealth, who brings this action in the public interest and on behalf of the Commonwealth and its citizens and taxpayers.

19. Plaintiff-Relator Dr. Wendy Welch (“Relator”) 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.

20. Defendant Total Wellness Centers, LLC (“Total Wellness”) is a single member professional limited liability company with headquarters at 244 Main Street Annex, Northampton, MA 01060. Defendant Total Wellness was organized in Massachusetts on October 8, 2009 by Dr. Amanda Wilson and Dr. Omar Faruk to provide “outpatient substance abuse treatment.” Defendant Total Wellness’s sole member was Dr. Amanda Wilson until March 2019. Since at least May 2012, Total Wellness has been doing business as CleanSlate. Defendant Total Wellness entered into a management services agreement with Defendant CleanSlate Centers, Inc. in January 2014; prior to that, it was the original CleanSlate entity. Defendant Total Wellness also owns the clinical laboratory in Holyoke. The Holyoke laboratory is an operating division of Defendant Total Wellness, not a separate legal entity.

21. Defendant CleanSlate Centers, Inc. is a Delaware corporation incorporated on December 24, 2013 with its principal place of business in Tennessee. Defendant CleanSlate Centers, Inc.’s principal place of business was formerly Northampton, MA. Defendant CleanSlate Centers, Inc. provides management services to professional entities in several states which furnish medical services under the CleanSlate name.

22. Defendant CleanSlate Centers, LLC was a Massachusetts limited liability company that was organized in Massachusetts on June 21, 2010. Its general character of business was amended to state that it provided “administrative and management services.” Dr. Amanda Wilson was the registered agent and sole corporate officer when it dissolved on September 16, 2015. Defendant CleanSlate Centers, LLC was located at 46 Sovereign Way, Florence, MA 01602.

23. Defendant Amanda Louise Wilson, M.D. (“Dr. Wilson”) is a resident of

Washington. Defendant Dr. Wilson has been licensed to practice medicine in Massachusetts since 2000. Defendant Dr. Wilson founded Total Wellness in 2009 and was the sole limited liability company member and manager until March 2019. She served as President, Director, and Chairwoman of CleanSlate's Board of Directors when it incorporated and, at least until early 2017, was its largest non-institutional shareholder.

STATUTORY AND REGULATORY FRAMEWORK

I. PROHIBITIONS OF SELF-REFERRAL

24. Section 1877 of the Social Security Act (42 U.S.C. § 1395nn), also known as the federal physician self-referral law (and commonly referred to as the "Stark Law"), prohibits physicians from referring Medicare or Medicaid patients for designated health services to an entity with which the physician has a financial relationship. 42 C.F.R. § 411.350; 42 U.S.C. § 1395nn(a). Clinical laboratory services are considered "designated health services." 42 C.F.R. § 411.351. The clinical laboratory is also prohibited from submitting claims to Medicare or Medicaid for services resulting from the prohibited referral. 42 U.S.C. § 1395nn(a)(1)(B).

25. A referring physician is defined as a "physician who makes a referral . . . or 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. Midlevel clinicians (nurse practitioners and physician assistants) are not considered physicians. Pursuant to 42 C.F.R. § 411.353(a), "a referral made by a physician's group practice, its members, or its staff may be imputed to the physician, if the physician directs the group practice, its members, or its staff to make the referral or if the physician controls referrals made by his or her group practice, its members, or its staff."

26. Any designated health service provided in violation of the Stark Law is not payable under Medicaid. 42 U.S.C. § 1395nn(g)(1); 42 U.S.C. § 1396b(s).

27. There are several exceptions to the Stark Law, which are outlined at 42 U.S.C. § 1395nn and Sections 411.355-357 of the Medicare Regulations. *See* 42 C.F.R. §§ 411.355-357.

28. The first relevant exception, the group practice exception, permits referral of designated health services provided personally by (or under the personal supervision of) another physician in the same group practice. 42 U.S.C. § 1395nn(b)(1). To qualify as a group practice, a practice must meet several conditions, including that: (1) it must be a single legal entity, 42 C.F.R. § 411.352(a); (2) it must have at least two physicians who are “members” of the group, 42 C.F.R. § 411.352(b); (3) those physician members must furnish substantially the full range of patient care services furnished by the main physician, 42 C.F.R. § 411.352(c); (4) those physician members must furnish 75% of the total patient care services provided, 42 C.F.R. § 411.352(d)(1); and (5) those physician members must conduct 75% of all patient care encounters, 42 C.F.R. § 411.352(h).

29. The second relevant exception is the *bona fide* employment exception. Under this exception, any amount paid by an employer to the referring provider of the designated health services who has a *bona fide* employment relationship with the employer does not implicate the Stark Law if the following conditions are met: (1) the employment is for identifiable services; (2) the amount of remuneration under the employment is consistent with fair market value of services and is not determined in a manner that takes into account the volume or value of any referrals by the referring physician; and (3) the amount is commercially reasonable even if no referrals were made to the employer. 42 U.S.C. § 1395nn(e)(2); 42 C.F.R. § 411.357(c). Additionally, the referral requirement itself must (1) be set out in writing signed by the parties; and (2) contain an exception if the patient expresses a preference for a different provider or the referral is not in the patient’s best medical interests. 42 C.F.R. § 411.354(d)(4)(iv).

30. Massachusetts law also prohibits a person or company from “knowingly refer[ring], request[ing], order[ing] or send[ing] any specimen derived from the human body for examination to a clinical laboratory in which the person or company, or any of its owners, directors, partners, employees or family members thereof have a direct or indirect ownership interest.” Mass. Gen. Laws c. 111D, § 8A.

31. Similarly, Mass. Gen. Laws c. 111D, § 8(17) prohibits a laboratory from “knowingly solicit[ing], accept[ing], or test[ing] any specimen . . . that is received from, ordered, requested, or referred by any such person, company, or other individual with an ownership interest.”

32. These provisions exempt conduct by “(i) a clinical laboratory owned by a licensed physician or group of licensed physicians used exclusively in connection with the diagnosis and treatment of the physician’s or group of physicians’ own patients and where all testing is performed by or under the direct supervision of the physician or group of physicians; (ii) a hospital or clinic licensed under [Mass. Gen. Laws c. 111, § 51] used exclusively in connection with the diagnosis or treatment of the hospital’s or clinic’s own patients; or (iii) any case exempted under [the Stark Law], or specifically permitted by regulations or rules of the United States Secretary of Health and Human Services, the federal Centers for Medicare or Medicaid Services, the executive office of health and human services or the executive office for administration and finance.” *Id.*; *see also* Mass. Gen. Laws c. 111D, § 8A.

II. DEPARTMENT OF PUBLIC HEALTH SUBSTANCE USE DISORDER TREATMENT CENTER LICENSURE REGULATIONS

33. OBOT centers are licensed by the Department of Public Health’s (“DPH”) Bureau of Substance Addiction Services (“BSAS”). BSAS issues licenses to providers that substantially comply with the regulations specified in 105 C.M.R. § 164.012(I), including certain regulations

at 105 C.M.R. §§ 164.300 *et seq.*

34. Under Department of Public Health regulations, substance use disorder is defined as “the range of conditions associated with alcohol, tobacco, and other drug use, including substance dependence, abuse, and withdrawal.” 105 C.M.R. § 164.006.

35. Substance use disorder treatment is “an evidence-based practice intended to assess status, reduce symptoms, or mitigate the effects of substance misuse, substance use disorders, or co-occurring disorders; reduce risk of relapse and associated harm; or restore or establish well-being for individuals and families.” *Id.* Services may include a variety of services, such as “care coordination, case management, medical, pharmacological, psychological, psycho-educational, rehabilitative, or social services and therapies.” *Id.* A substance use disorder treatment program is “an organized system of services containing a mission, philosophy, and model of substance use disorder treatment.” *Id.*

36. OBOT is defined as “treatment of opioid dependence with an [Food and Drug Administration]-approved narcotic medication used for detoxification or maintenance by a qualified health care professional who is registered with the U.S. Department of Justice Drug Enforcement Agency, as required by 21 U.S.C. § 823(g) (known as DATA 2000), in a health care professional’s office setting or in a primary care center.” *Id.*

37. An opioid treatment program is a Substance Abuse and Mental Health Service Administration (“SAMHSA”)-certified program that “engages in supervised assessment and treatment, using approved medication, of individuals who are addicted to opioids.” *Id.* SAMHSA is an agency within the United States Department of Health and Human Services that is focused on improving behavioral health and reducing the impact of substance use disorder and mental illness. *See* <https://www.samhsa.gov/about-us>.

38. Medication-assisted treatment is defined as “use of a medication approved by the federal Food and Drug Administration (FDA), in combination with counseling and behavioral therapies, for the treatment of an opioid related substance use disorder.” *Id.*

III. MASSHEALTH REGULATIONS

39. As a MassHealth provider, CleanSlate must also comply with MassHealth regulations. CleanSlate entered into a provider contract with MassHealth, which Dr. Wilson signed, which requires it to comply with all state and federal laws, regulations, and rules applicable to participation in MassHealth.

40. The regulations governing independent clinical laboratory services are set forth at 130 C.M.R. §§ 401.000 *et seq.*

41. The administrative and billing regulations governing all providers who participate in MassHealth are set forth at 130 C.M.R. §§ 450.000 *et seq.*

A. MassHealth Independent Clinical Laboratory Regulations

42. A clinical laboratory is defined in 130 C.M.R. § 401.402 as “a laboratory that conducts microbiological, serological, chemical, hematological, biophysical, radiobioassay, cytological, immunohematological, immunological, pathological, or other examinations of materials derived from the human body, to provide information for the assessment of a medical condition or for the diagnosis, prevention, or treatment of any disease.” An independent clinical laboratory is defined in 130 C.M.R. § 401.402 as “a freestanding clinical laboratory that is not affiliated with a hospital.”

43. An authorized prescriber is “authorized under state law to prescribe drugs . . . and to order the test under [Mass Gen. Laws] c. 111D and for the sole purpose of ordering medically necessary drug screen services. . .” 130 C.M.R. § 401.402.

44. A standing order is “a request by an authorized prescriber for an independent clinical laboratory to repeat one or more tests over a specified period of time.” 130 C.M.R. § 401.402. Standing orders are “not permissible unless such repeated tests are medically necessary” and part of the patient’s treatment plan. 130 C.M.R. § 401.416(B). An authorized prescriber may request an independent clinical laboratory to perform tests on a single date or issue a standing order. *Id.* Standing orders may not surpass 180 days in length unless it is a standing order request for substance use disorder testing, which may not surpass 30 days in length. *Id.*

45. MassHealth only pays for independent clinical laboratory services that are “medically necessary for the diagnosis, treatment, and prevention of disease, and for the maintenance of health of the MassHealth members.” 130 C.M.R. § 401.410.

46. “The independent clinical laboratory may not bill for a service unless it has received a written request to perform that specific service from an authorized prescriber who is treating the member and will use the test for the purpose of diagnosis, treatment, or an otherwise medically necessary reason.” 130 C.M.R. § 401.416(A).

47. MassHealth does not pay for a test of an individual drug if that drug was already included in a test for a panel of drugs that has been performed by that laboratory or requested by another authorized provider. 130 C.M.R. § 401.420.

B. MassHealth All Provider Regulations

48. In addition to the specific regulations governing specific provider types, all MassHealth providers are subject to the “all provider” regulations at 130 C.M.R. §§ 450.000 *et seq.*

49. These “all provider” regulations state, in relevant part, that every provider under contract with MassHealth agrees to comply with all laws, rules, and regulations governing

MassHealth. 130 C.M.R. § 450.223(C)(1).

50. MassHealth regulations define a “member” as “a person determined by the MassHealth agency to be eligible for MassHealth.” *Id.* § 450.101. The regulations do not distinguish between those members receiving benefits through MassHealth fee-for-service (“FFS”), or through one of MassHealth’s contracting entities, such as its MCEs. Thus, claims submitted by providers with respect to services to members through any of these mechanisms must comply with MassHealth regulations.

51. MassHealth does not pay “a provider for services that are not medically necessary,” as reflected in “MassHealth . . . medical necessity and coverage guidelines.” 130 C.M.R. § 450.204.

52. The regulations also state that every provider under contract with MassHealth certifies when submitting a claim for payment that “the information submitted in, with, or in support of the claim is true, accurate, and complete.” *Id.* § 450.223(C)(2)(e).

53. The MassHealth regulations governing overpayments state, “A provider must report in writing and return any overpayments to the MassHealth agency within 60 days of the provider identifying such overpayment or, for payments subject to reconciliation based on a cost report, by the date any corresponding cost report is due, whichever is later.” *Id.* § 450.235(B).

54. A provider is liable to the MassHealth agency for the full amount of any overpayments, or other monies owed under 130 C.M.R. §§ 450.000 *et seq.*, including but not limited to 130 C.M.R. § 450.235(B), or under any other applicable law or regulation. *Id.* § 450.260(A).

C. MassHealth Provider Bulletins

55. MassHealth issues provider bulletins as needed to communicate procedures,

reminders, and other information to MassHealth providers.

56. MassHealth has made clear that quantitative drug tests are not medically necessary when “billed on the same [date of service] as a drug screen service” and has informed providers that it will deny claims accordingly. MassHealth Physician Bulletin 94 (Feb. 2013), *available at* <http://www.mass.gov/eohhs/docs/masshealth/bull-2013/phy-94.pdf>; *see also* MassHealth Independent Clinical Laboratory Bulletin 9 (Feb. 2013), *available at* <https://www.mass.gov/doc/independent-clinical-laboratory-bulletin-9-drug-screenquantitative-drug-test-claim-edit-drug/download>.

57. MassHealth has also stated that “[p]roviders should not bill for quantitative tests in lieu of drug screen services or as a routine supplement to drug screens.” MassHealth Physician Bulletin 94 (Feb. 2013), *available at* <http://www.mass.gov/eohhs/docs/masshealth/bull-2013/phy-94.pdf>.

IV. ADDITIONAL REQUIREMENTS

A. Drug Addiction Treatment Act of 2000

58. The Drug Addiction Treatment Act of 2000, P.L. 106-310, 114 Stat. 1101 (“DATA”), part of the Children’s Health Act of 2000, allows doctors who meet certain qualifications to treat opioid dependency with narcotic medications approved by the FDA in settings other than opioid treatment programs.

59. DATA allows qualified doctors to obtain a waiver from separate registration requirements to treat opioid dependency with Schedule III, IV, and V medications or combinations of such medications that have been approved by the FDA.

60. Since buprenorphine is the only FDA-approved narcotic medication in Schedules III, IV, or V, this Act effectively governs the prescription of buprenorphine.

B. Comprehensive Addiction and Recovery Act of 2016

61. The Comprehensive Addiction and Recovery Act of 2016, P.L. 114-198, 130 Stat. 695 (“CARA”), which was signed on July 22, 2016, allows midlevel clinicians (nurse practitioners and physician assistants) to prescribe buprenorphine for addiction treatment purposes.

62. These midlevel clinicians must still: (a) meet certain training requirements; (b) be licensed under state law to prescribe Schedule III, IV, or V controlled substances for the treatment of pain; and (c) be supervised by or work in collaboration with a DATA-waived physician if state law requires them to prescribe controlled substances for addiction treatment in collaboration with or under the supervision of a physician. 21 U.S.C. § 823(g)(2)(G)(iv).

63. Prior to the enactment of CARA, midlevel clinicians at CleanSlate could complete patient evaluations and physical examinations and order laboratory testing. But midlevel clinicians were limited from issuing prescriptions for medication-assisted treatment, principally buprenorphine. Accordingly, midlevel clinicians were responsible for gathering information from the patient and reviewing it with a physician, who was responsible for signing any prescription. After the enactment of CARA, midlevel clinicians can prescribe buprenorphine directly to patients, as long as they comply with the requirements set forth above.

C. Prescribing Regulations

64. MassHealth only pays for prescriptions “if the pharmacy has in its possession a prescription that meets all requirements for a legal prescription under all applicable federal and state laws and regulations.” 130 C.M.R. § 406.411(A).

65. The U.S. Drug Enforcement Administration (“DEA”) has issued regulations governing prescriptions. According to these regulations, “[a] prescription for a controlled

substance may be issued only by an individual practitioner who is . . . authorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession.” 21 C.F.R. § 1306.03(a).

66. Moreover the DEA requires that “[a]ll 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).

V. BACKGROUND ON MEDICATION-ASSISTED TREATMENT

67. Medication-assisted treatment is the use of medications in combination with counseling and behavioral therapies to treat opioid use disorders and to help people sustain recovery.

68. There are three drugs approved by the FDA for the treatment of opioid dependence: (1) buprenorphine; (2) naltrexone; and (3) methadone.

69. Suboxone is an FDA-approved buprenorphine drug. Suboxone consists of a combination of buprenorphine and naloxone. Suboxone is a 40% agonist (as a result of buprenorphine) and 60% antagonist (as a result of naloxone). Roughly 95% of Clean Slate’s patients are prescribed Suboxone.

70. Vivitrol is an FDA-approved naltrexone drug. Vivitrol is solely an antagonist. Approximately 5% of Clean Slate’s patients are prescribed Vivitrol. It is primarily used to treat patients who were recently incarcerated, weaned off buprenorphine, or who do not want to receive an agonist drug. Vivitrol patients are dosed via a monthly injection.

71. Methadone is an agonist only. It relieves opioid cravings but requires daily dosing at a clinic, which may impede a patient’s ability to perform normal functions. Clean Slate does

not administer methadone.

MASSHEALTH CLAIMS SUBMISSION AND BILLING

I. MASSHEALTH REVENUE STREAMS

72. There are two streams of payment at issue in this action and that will be relevant to determining the total damage amount. These are payments to the Defendants through MassHealth FFS and various MCEs.

73. MassHealth beneficiaries enrolled in an MCE plan must enroll in one of the MCEs approved by MassHealth. The MCE is responsible for delivering and paying for the members’ health care services. MassHealth pays for the services provided to MassHealth members enrolled in an MCE on a capitated basis from Medicaid funds MassHealth receives from the United States and the Commonwealth. Each MCE contracts with providers within its network. The CleanSlate entities that are the subject of this action were paid by the following MCEs³:

AllWays Health Partners
Boston Medical Center Health Plan
Commonwealth Care Alliance
Fallon
Health New England
Network Health Plan
Senior Whole Health
Tufts Health Plan

74. Massachusetts regulations do not distinguish among MassHealth beneficiaries who receive MassHealth benefits via FFS and MassHealth beneficiaries who receive benefits via MCEs. All of these MassHealth beneficiaries are MassHealth members under 130 C.M.R. § 450.101, and their benefits are paid for using funds that have been provided by the United States

³ The Massachusetts Behavioral Health Partnership, Partners HealthCare Choice, and United HealthCare have paid claims to CleanSlate, but have not paid any claims relevant to this action.

and the Commonwealth through MassHealth. Consequently, payment for these services, whether the claims are submitted to MassHealth directly or through one of the MCEs, comes from the MassHealth.

II. CLAIMS SUBMISSION

75. Providers, such as CleanSlate, contract with MassHealth and MCEs to provide substance use disorder treatment in an office-based setting to MassHealth members and laboratory testing of MassHealth members' specimens.

76. All claims submitted by providers on behalf of any MassHealth beneficiary, regardless of whether that beneficiary receives care on a FFS basis or through an MCE, must comply with MassHealth and DPH regulations, including those set forth in 130 C.M.R. §§ 401.000 *et seq.* and §§ 450.000 *et seq.*

77. Every provider that submits claims to MassHealth certifies when submitting a claim for payment that "the information submitted in, with, or in support of the claim is true, accurate, and complete." 130 C.M.R. § 450.223(C)(2)(e). Therefore, providers impliedly certify that they are complying with applicable regulations when submitting claims for payment.

78. Similarly, pursuant to CleanSlate's provider agreements with MassHealth and the various MCEs, providers must comply with all federal and state laws and regulations, including the Stark Law, Massachusetts laws prohibiting self-referrals, and the Massachusetts False Claims Act. An MCE cannot change MassHealth's conditions of payment for MassHealth providers. MCE contracts do not alter the expectations of MassHealth regarding regulatory compliance.

79. Under the Massachusetts False Claims Act, a "claim" is "made to a contractor, subcontractor, grantee or other person, if the money or property is to be spent or used on behalf of or to advance a program or interest of the commonwealth or political subdivision thereof and

if the commonwealth or any political subdivision thereof: (i) provides or has provided any portion of the money or property which is requested or demanded; or (ii) will reimburse directly or indirectly such contractor, subcontractor, grantee or other person for any portion of the money or property which is requested or demanded.” Mass. Gen. Laws c. 12, § 5A.

80. A request for payment made by a provider to an MCE on behalf of a MassHealth member is a “claim” for the purposes of Mass. Gen. Laws c. 12, §§ 5B and 5C. Presenting a false or fraudulent request or demand for payment to an MCE for services provided to a MassHealth member is therefore a “false claim” for the purposes of Mass. Gen. Laws c. 12, §§ 5B and 5C.

81. The Current Procedural Terminology (“CPT”) coding system, developed by the American Medical Association, is designed to provide information about services provided for financial and administrative purposes. CPT codes identify, for the payer, the services for which the provider seeks reimbursement. MassHealth, along with the MCEs, uses the CPT coding system for services performed by clinicians and laboratories.

82. MassHealth has identified the list of payable CPT codes that correspond to billable laboratory services. *See* MassHealth Independent Clinical Laboratory Bulletin 52 (July 2020), *available at* <https://www.mass.gov/doc/lab-52-diagnostic-tests-for-covid-19-0/download>.

83. Claims submitted to MassHealth and MCEs are submitted in batches and either approved or denied based on applicable system edits. A system edit may automatically deny a claim if a required field is not filled out—for example, the name of the member who received the services. Additionally, claims or providers may be flagged for further review for high utilization of certain CPT codes or other anomalies. Usually, though, claims are batched for submission and are then approved or denied by a computer algorithm that allows or denies such claims based on the system edits that have been programmed into the system.

84. In short, MassHealth providers bill largely on the honor system. If MassHealth or the Massachusetts Attorney General’s Office later learn that claims should not have been paid—whether due to fraud or for any other reason—they must use other methods to recoup these claims, which have already been paid to the provider.

85. The Massachusetts Attorney General’s Office has access to claims data submitted by CleanSlate through the Medicaid Management Information System (“MMIS”). This database allows investigators to export and review reports of claims information based on the billing and servicing provider ID.

FACTUAL ALLEGATIONS

86. At all relevant times, Defendants were required to comply with the statutory and regulatory requirements enumerated in this Complaint, but Defendants were in violation of those requirements. This noncompliance resulted in the knowing submission of false claims to MassHealth and MCEs.

I. CLEANSLATE OPERATIONS

87. Defendants own and/or operate a number of OBOT centers, throughout the Commonwealth of Massachusetts. According to CleanSlate’s website, centers are currently at the following Massachusetts locations:

- a. 201 South Main Street, Suite 3, Athol, MA 01331
- b. 82 Paris Street, 3rd Floor, Boston, MA 02128
- c. 342 Gifford Street, Unit 3C, Falmouth, MA 02540
- d. 1 Arch Place, 3rd Floor, Greenfield, MA 01301
- e. 306 Race Street, 2nd Floor, Holyoke, MA 01040
- f. 68 Camp Street, Unit 1, Hyannis, MA 02601

- g. 360 Merrimack Street, Building 9, Entrance G, 3rd Floor, Lawrence, MA 01843
- h. 165 Mill Street, 2nd Floor, Leominster, MA 01453
- i. 280 Union Street, Suite 302, Lynn, MA 01901
- j. 92 Grape Street, New Bedford, MA 02740
- k. 77 Hospital Avenue, Suite 107, North Adams, MA 01247
- l. 53 Eagle Street, 4th Floor, Pittsfield, MA 01201
- m. 46 Obery Street, Plymouth, MA 02360
- n. 1985 Main Street, Suite E, Springfield, MA 01103
- o. 170 Main Street, Units G4-G8, Tewksbury, MA 01876
- p. 83 South Street, Suite 3, Ware, MA 01082
- q. 40 Church Avenue, Suite 202, Wareham, MA 02571
- r. 900 Memorial Avenue, West Springfield, MA 01089
- s. 411 Chandler Street, Worcester, MA 01602

See <https://www.cleanslatecenters.com/location/massachusetts>. Collectively, these entities are referred to as “CleanSlate OBOT centers.”

88. Defendant Total Wellness also owns one CLIA-accredited,⁴ certified independent laboratory, located at 59 Bobala Road, Holyoke, MA 01040 (CLIA number 22D1105941). The Holyoke laboratory principally performs two types of urine drug tests: (1) a UDS; and (2) a norbuprenorphine LCMS test.

89. At all relevant times, Defendant Total Wellness has been a MassHealth provider,

⁴ CLIA refers to the Clinical Laboratory Improvement Amendments. The Centers for Medicare & Medicaid Services (“CMS”) regulates all laboratory testing (except research) performed on humans in the U.S. through CLIA. *See* <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA>.

operating using the name “CleanSlate Centers.” It operates and bills under MassHealth provider identification (“ID”) number 110083630. Each CleanSlate OBOT center, in addition to the laboratory, is designated by a letter code in addition to a MassHealth provider ID, as follows:

Provider Name and Location	Provider ID and Service Location
CleanSlate Centers, 59 Bobala Road, Holyoke, MA 01040 (<i>Inactive</i>)	110083630A
CleanSlate Centers, 1 Arch Place, Fl 3, Greenfield, MA 01301	110083630B
CleanSlate Centers, 92 Grape St, New Bedford, MA 02740	110083630C
CleanSlate Centers, 306 Race St, Fl 2, Holyoke, MA 01040	110083630D
CleanSlate Centers, 1681 Washington St, Braintree, MA 02184 (<i>Inactive</i>)	110083630E
CleanSlate Centers, 1985 Main St, Ste E, Springfield, MA 01103	110083630F
CleanSlate Centers, 411 Chandler St, Worcester, MA 01602	110083630G
CleanSlate Centers, 244 Main St Annex, Northampton, MA 0160 (<i>Inactive</i>)	110083630H
CleanSlate Centers, 53 Eagle St, Ste 4, Pittsfield, MA 01201	110083630I
CleanSlate Centers, 83 South St, Ste 3, Ware, MA 01082	110083630J
CleanSlate Centers, 1495 Hancock St, Quincy, MA 02169	110083630K
CleanSlate Centers, 170 Main St, Unit G4-G8, Tewksbury, MA 01876	110083630L
CleanSlate Centers, 900 Memorial Ave, W Springfield, MA 01089	110083630M
CleanSlate Centers, 201 S Main St, Ste 3, Athol, MA 012331	110083630N
CleanSlate Centers, 46 Obery St, Plymouth, MA 02360	110083630O
CleanSlate Centers, 82 Paris St, Fl 3, Boston, MA 02128	110083630P
CleanSlate Centers, 360 Merrimack St, Lawrence, MA 01843	110083630Q
CleanSlate Centers, 280 Union St, Ste 302, Lynn, MA 01901	110083630R
CleanSlate Centers, 165 Mill St, #2, Leominster, MA 01453	110083630S
CleanSlate Centers, 7 Hospital Ave, Ste 107, North Adams, MA 01247	110083630T
CleanSlate Centers, 68 Camp St, Hyannis, MA 02601	110083630U
CleanSlate Centers, 342 Gifford St, Unit C, Falmouth, MA 02540	110083630V
CleanSlate Centers, 40 Church Ave, Ste 202, Wareham, MA 02571	110083630W
CleanSlate Centers, 320 Bolton St, Ste1 103 MMC, Marlborough, MA 01752	110083630X
CleanSlate Centers, 59 Bobala Rd, Holyoke, MA 01040	110083630Y

90. Each OBOT center bills under National Provider Identifier (“NPI”) number 1770816506.

91. The Holyoke laboratory is registered with MassHealth as a “Certified Independent Laboratory” provider and bills under NPI number 1770020018.

III. CLEANSLATE'S CLAIMS

92. A substantial portion of Defendants' Massachusetts patients are MassHealth members.

93. Defendants frequently billed and were paid the following codes for laboratory services during the relevant time period:⁵

- a. 80076: Hepatic Function Panel
- b. 80307: Drug Test PRSMV Chem Analyzer
- c. 86803: Hepatitis C Antibody
- d. 87340: Hepatitis B Surface AG IA
- e. 87389: HIV-1 AG w/ HIV-1 & HIV-2 AB
- f. G0431: Drug Screen Single Class
- g. G0479: Drug Test Presump Not OPT
- h. G0480: Drug Test Def 1-7 Classes
- i. G6058: Drug Confirmation

94. Defendants frequently billed and were paid the following codes for evaluation and management services during the relevant time period:

- a. 99202 – 99205: Office/Outpatient Visit New
- b. 99212 – 99215: Office/Outpatient Visit EST

95. Defendants received payment from MassHealth and MCEs for laboratory procedure codes in the following amounts:

- a. MassHealth FFS: \$8,427,797.92
- b. AllWays Health Partners: \$24,555.90

⁵ This list is not exhaustive, but representative of the types of services and codes billed to MassHealth. A full list of codes billed and used in the calculation of damages can be found in the summary chart included as Exhibit 1.

- c. Boston Medical Center Health Plan: \$10,788,339.20
- d. Commonwealth Care Alliance: \$977,681.64
- e. Fallon: \$1,163,712.63
- f. Health New England: \$3,316,767.97
- g. Network Health Plan: \$232,781.32
- h. Senior Whole Health: \$6,342.06
- i. Tufts Health Plan: \$99,225.77

96. Defendants received payment from MassHealth and MCEs for evaluation and management codes in the following amounts:

- a. MassHealth FFS: \$10,802,177.04
- b. AllWays Health Partners: \$8,594.21
- c. Boston Medical Center Health Plan: \$11,830,213.05
- d. Commonwealth Care Alliance: \$1,321,780.55
- e. Fallon: \$1,629,121.64
- f. Health New England: \$3,881,427.73
- g. Network Health Plan: \$23,917.93
- h. Senior Whole Health: \$5,955.56
- i. Tufts Health Plan: \$2,718.56

97. In sum, CleanSlate has been paid more than \$25 million from MassHealth and MCEs for laboratory and more than \$29 million for evaluation and management services, a total of more than \$54 million, during the relevant period.

98. CleanSlate's Code of Conduct, set forth at Exhibit 2, states that CleanSlate must comply with applicable federal and state laws, rules, and regulations, and payer policies. It also

states that it will refund overpayments made by a federal or other healthcare program in accordance with applicable laws and policies.

99. CleanSlate's MassHealth provider contract, an iteration of which is set forth at Exhibit 3, which was signed by Dr. Wilson, similarly requires it to comply with all federal and state laws, rules, and regulations governing its participation in the MassHealth program.

100. Defendants initially utilized Advanced M.D. as a billing software, but that system was integrated into an electronic medical records ("EMR") software company called Stratus EMR. CleanSlate was Stratus EMR's largest client. CleanSlate purchased Stratus EMR in late 2016.

101. The former Director of Billing at CleanSlate, Amy LaRoche, testified pursuant to a Civil Investigative Demand on December 12, 2019 and described the process for billing at CleanSlate. LaRoche stated that, after a clinician sees a patient, a note from the service is generated in CleanSlate's billing software. CleanSlate billing staff would typically manually select the codes corresponding to the patient notes. The codes are then sent from the EMR to CleanSlate's clearinghouse, which either accepts or rejects the claim. If the claim is accepted, it is sent to the payer to initiate a payment or denial. Once CleanSlate receives the payment or a denial, it is posted in the system. If the claim is denied, CleanSlate follows up with the insurance company.

102. A copy of CleanSlate's Billing Department manual is attached as Exhibit 4.

IV. THE FORMATION OF CLEANSLATE

103. Dr. Wilson testified pursuant to a Civil Investigative Demand on January 28, 2020. Dr. Wilson testified that she initially formed and financed CleanSlate in 2009.

104. Dr. Wilson stated that she began by opening CleanSlate treatment centers in West

Springfield and Greenfield. She first employed a nurse practitioner, a physician assistant, two front desk staff, and one or two doctors. Dr. Wilson's initial business partner, Dr. Omar Faruk, left the company after about twelve weeks.

105. Dr. Wilson stated that she opened new and bigger office locations as CleanSlate's patient population rapidly expanded. Dr. Wilson also worked to expand the business by educating providers and presenting to community offices.

106. Dr. Wilson testified that she faced challenges in hiring doctors because of the lack of addiction medicine doctors in the country. Dr. Wilson stated that, when she brought on new doctors, she provided a lot of mentorship and coaching about CleanSlate's treatment model. She described her mentorship as "A lot of being in the clinic with them. A lot of cases that we would co-manage." Dr. Wilson described the initial onboarding process by saying, "Potential clinicians were brought to the West Springfield office, and education month-long intensive program was built for them. They stayed there. They had 20 or 30 people in the room at each visit, or each education grouping. So we were doing mini residency."

107. In her role as CleanSlate's Chief Executive Officer ("CEO"), Dr. Wilson engaged in research, worked in the field, and conducted trainings and community engagement. Dr. Wilson was in charge of all hiring for a period of time and led the trainings of clinicians.

108. Dr. Wilson testified that, in 2010 and 2011, she made the final decision to open CleanSlate's clinical laboratory. When the laboratory opened, it only could perform UDS, though it eventually began conducting norbuprenorphine LCMS tests around 2014.

109. Dr. Wilson testified that the reason she decided to open the laboratory was that tests CleanSlate had previously been using to measure substances in patients' urine were yielding false negatives and false positives, so she decided that CleanSlate needed to use an immunoassay

analyzer for drug screens to increase testing quality. However, Dr. Wilson also confirmed during her testimony that the laboratory was profitable for CleanSlate.

110. The laboratory began receiving referrals for testing from CleanSlate OBOT centers and began running UDS on June 1, 2011. Once the laboratory opened, Dr. Wilson testified that it processed all UDS for CleanSlate. Dr. Wilson also testified that the laboratory processed all norbuprenorphine LCMS testing for CleanSlate once it acquired that capability. Dr. Wilson was unaware of any instance in which doctors or midlevel clinicians sought to, or did, send UDS or norbuprenorphine LCMS tests to a laboratory other than CleanSlate's laboratory.

V. CLEANSLATE'S EVOLVING CORPORATE STRUCTURE

111. Dr. Wilson testified that, around 2014, CleanSlate began to develop a corporate structure and executive-level managers after it was approached for investment by Apple Tree Partners. Apple Tree Partners is a venture capital firm that invests in pharmaceuticals, biotechnology, medical technology, and healthcare services. Dr. Wilson stated that the Apple Tree Partners's investment allowed CleanSlate to drastically expand its business.

112. Around that same time, CleanSlate created a Board of Directors. Even after the inception of the Board of Directors, Dr. Wilson stated that she continued to make day-to-day decisions. Dr. Wilson acted as both CEO and Chairwoman of CleanSlate's Board of Directors until 2016, at which time she stepped down as CEO and remained Chairwoman of the Board of Directors. Dr. Wilson did not step down from the Board of Directors until early 2018. Dr. Wilson ceased serving as Defendant Total Wellness's sole member around March 2019.

113. CleanSlate continued to open additional OBOT centers after the Apple Tree Partners investment. However, Dr. Wilson stated that it was her decision to expand in new areas and open new clinics.

114. Dr. Wilson also stated that, even after the investment, she had the final call on setting up CleanSlate company policies and making staffing decisions. As Apple Tree Partners's investment grew, Dr. Wilson stated that her responsibilities evolved constantly, but she continued to be involved in clinical recruitment and building the business.

115. CleanSlate also began opening clinics in states other than Massachusetts. CleanSlate originally opened a clinic in Connecticut, then began opening in Pennsylvania around 2014. The Connecticut and Pennsylvania entities were originally incorporated within Defendant Total Wellness, but later, all CleanSlate entities that opened and operated in states outside of Massachusetts were organized as separate limited liability companies.

116. Those separate limited liability companies have a management services agreement with Defendant CleanSlate Centers, Inc. Defendant CleanSlate Centers, Inc. has a contractual management relationship with Defendant Total Wellness, CleanSlate Medical Group of Pennsylvania, LLC, CleanSlate Medical Group of Indiana, LLC, CleanSlate Medical Group of Connecticut, and other professional entities operating under the CleanSlate name (collectively, the "Professional Entities"). A chart reflecting the relationship between these Professional Entities as of August 2017 is attached as Exhibit 5.

117. Each of the Professional Entities owns and operates a physician practice in the applicable states. Defendant CleanSlate Centers, Inc. generally holds the non-professional assets related to the physician practice of each Professional Entity, such as space, equipment leases, and commercial vendor contracts. Defendant CleanSlate Centers, Inc. provides all non-professional business, administrative, and back-office services to each physician practice and employs back-office employees in exchange for a management fee, pursuant to a Business Support Services Agreement with each Professional Entity. The Business Support Services Agreement between

Defendants Total Wellness and Defendant CleanSlate Centers, Inc. is attached as Exhibit 6.

118. Defendant CleanSlate Centers, Inc. and each Professional Entity are also parties to a Deficit Funding Loan Agreement, an example of which is attached as Exhibit 7, that governs the terms and conditions of any loans made from Defendant CleanSlate Centers, Inc. to a Professional Entity.

119. As the company continued to grow, Dr. Wilson hired additional employees to fill senior management roles. Around January 2016, Dr. Wilson hired a Regional Medical Director, Andrew Mendenhall, M.D. (“Dr. Mendenhall”), to oversee the OBOT centers. Dr. Mendenhall testified pursuant to a Civil Investigative Demand on December 18, 2019. Dr. Mendenhall testified that, as Regional Medical Director, he oversaw all the clinician providers, including the physicians (full-time and part-time) and midlevel clinicians. However, Dr. Mendenhall still reported to Dr. Wilson.

120. Later in 2016 or early in 2017, Dr. Mendenhall became the sole limited liability company member and manager of several of the Professional Entities, including Pennsylvania and Indiana. Dr. Mendenhall testified that he was set up to be the member for several CleanSlate Professional Entities to meet compliance requirements for certain states and the organization. Dr. Mendenhall eventually transferred his interests in some of the Professional Entities.

121. Dr. Wilson testified that Greg Marotta was hired in 2015 as the Chief Operating Officer (“COO”), with the expectation that he would eventually transition to CEO. Dr. Wilson testified that Greg Marotta had the experience to scale CleanSlate’s business, whereas Dr. Wilson’s skillset was geared towards entrepreneurial thinking.

122. Marotta assumed the role of CEO around the summer of 2016. At that time, Dr. Wilson testified that she and Marotta worked collaboratively to make decisions at CleanSlate,

but she transitioned more responsibility to Marotta as he became more comfortable.

123. CleanSlate also hired for other positions over time, including a Director of Compliance, Richard Raphael, and Eastern Division Medical Director, Dr. Welch. Before Raphael was hired, CleanSlate's core team was responsible for compliance-related activities, which included Dr. Wilson. An organizational chart reflecting CleanSlate's corporate reporting structure as of January 2017, which Dr. Welch prepared, is included as Exhibit 8.

VI. CLEANSLATE'S TREATMENT MODEL

124. Dr. Wilson, Dr. Mendenhall, and Dr. Welch described how CleanSlate's treatment model works. Dr. Welch explained that patients initially call the CleanSlate call center to schedule an appointment. A call center employee will determine whether the patient is an appropriate candidate for CleanSlate's treatment model, and if so, will schedule an initial appointment at one of CleanSlate's OBOT centers. Dr. Mendenhall confirmed that patients can call the call center, but also added that some patients arrive as walk-ins.

125. When a CleanSlate patient first arrives to a CleanSlate OBOT center, the patient is greeted by administrative staff and fills out initial paperwork.

126. According to Dr. Mendenhall, the patient is then greeted by a medical assistant and asked to provide a urine sample. The medical assistant collects a urine sample and checks vital signs before a patient is seen by a clinician. The medical assistant may initiate a urinalysis using a "dipstick" test, which changes color if abnormal substances are detected.

127. Dr. Mendenhall and Dr. Welch stated that the patient would then be examined by a clinician, typically a nurse practitioner or physician assistant. Dr. Wilson confirmed that, as CleanSlate grew, the proportion of patients seen by midlevel clinicians increased. The clinician performs a comprehensive physical examination to evaluate whether the patient has withdrawal

symptoms of substance abuse. The patient provides information about past medical, surgical, social, and drug use history. The clinician then evaluates whether the patient is an appropriate candidate for CleanSlate's treatment model, and if so, schedules a follow-up appointment. The patient is also typically issued a prescription for Suboxone.

128. Dr. Mendenhall testified that, pre-CARA, the nurse practitioner or physician assistant would recommend the issuance of a prescription for Suboxone, but because midlevel providers could not prescribe independently, the prescription would be approved and signed by a physician via the EMR. Since the implementation of CARA, midlevel providers have been able to independently issue prescriptions.

129. Dr. Welch explained that CleanSlate referred to the physicians who sign prescriptions electronically, but do not see patients individually or in person, as "DATA doctors."

130. According to Dr. Wilson and Dr. Mendenhall, the patient is then scheduled for a follow-up appointment. For example, the patient may return for Suboxone induction, bringing an unopened prescription to the office after abstaining for 24 hours, or return for a visit a few weeks later.

131. CleanSlate patients are placed in one of several color-coded "stages" of treatment as part of this process, which is reflected in the treatment matrix attached as Exhibit 9 and CleanSlate's buprenorphine protocol manual attached as Exhibit 10.

132. CleanSlate generally had four color-coded treatment stages, which Dr. Wilson testified she "invented":

- a. Orange = This category referred to patients' initial phase, after having begun treatment at CleanSlate. This category can also refer to a patients'

stabilization phase. Patients in this category were seen weekly.

- b. Green = This category referred to patients who had generally been with CleanSlate for some time, usually nine to twelve months, and had been stable in taking medications. They would be seen monthly.
- c. Yellow = This category referred to patients who were “slightly strugglers who are on their way, but not quite 100 percent,” according to Dr. Wilson. These patients were seen twice a month at CleanSlate OBOT centers.
- d. Red = This category referred to patients who required focused, supportive care. They would be seen twice per week.

133. These categories of treatment are also discussed in videos made available by CleanSlate online, including at https://www.youtube.com/watch?v=py5YSZ393G4&list=PL7CvGzQSxnawB1wua5rjfvRm5IPX_AskA&index=2.

134. Dr. Wilson testified that new clinicians at CleanSlate, many of whom did not have experience in addiction medicine, were trained on this treatment model during a “mini residency.” Dr. Mendenhall testified that new clinicians would be provided a copy of the manual at Exhibit 10 and would be subject to “consistent clinical review.” Dr. Wilson also confirmed that this manual was “part of the foundational teachings as we went through different aspects of treatment.” Dr. Welch recalled that clinician training at CleanSlate generally lasted six weeks and included online training and in-person training at CleanSlate’s headquarters in Northampton, MA. Dr. Welch also confirmed that many of CleanSlate’s new hires had no experience in addiction medicine, which made them less likely to question CleanSlate’s procedures.

VII. CLEANSLATE’S TESTING POLICY

135. The matrix at Exhibit 9 and the manual at Exhibit 10 also describe CleanSlate's policy for urine drug testing of patients in each phase of treatment. Dr. Wilson and Dr. Mendenhall confirmed these practices and described each test.

136. At each patient visit, regardless of stage, CleanSlate performs a UDS, a lower-complexity test which is used to detect the presence of certain substances in the patient's urine. These UDS are performed exclusively at CleanSlate's own laboratory. As described by doctors who worked at CleanSlate who were interviewed by the Commonwealth and in CleanSlate's "Clinician Training Manual," included as Exhibit 11, these UDS were often ordered by clinicians via a standing order, which would facilitate collection and testing for a UDS every time a patient visited CleanSlate.

137. Indeed, one physician who worked at CleanSlate, Dr. Edna Markaddy, told the Commonwealth in an interview that she did not even recall signing off on UDS, but that she assumed that it was done via standing order.

138. According to Dr. Welch, CleanSlate's EMR software does not generate a notification to clinicians when a patient's UDS comes back. Dr. Welch explained that, at other treatment facilities she has worked, the EMR creates a "queue" of new results for a clinician to check once the results become available, but that was not the case at CleanSlate.

139. As a result, Dr. Welch stated that patients' UDS results were typically not reviewed unless the patient attended another visit at CleanSlate. Dr. Welch communicated her concern about this lack of test result review to Dr. Mendenhall via email in December 2016, as reflected in Exhibit 12. Dr. Welch also attempted to resolve this issue in December 2016 with Paul Chabot, Chief Information Officer, as reflected in Exhibit 13.

140. For example, Dr. Welch recalls a CleanSlate patient who 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.

141. 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 UDS results. LaRoche stated that she raised this issue after insurer Blue Cross Blue Shield identified concerns about this practice in an audit, which are reflected in the redacted audit results attached as Exhibit 14. LaRoche stated that she was informed by CleanSlate management that it was not a problem, because CleanSlate clinicians do not really review UDS results anyway. LaRoche stated that Ellen Alexander, CleanSlate's Regional Vice President of Operations for the Northeast Region, and Dr. Maria Russo-Appel, then Eastern Division Medical Director, told her, "All they do is go ahead and click right through. They don't look at them." This procedure resulted in medically unnecessary testing.

142. In addition to UDS, CleanSlate routinely orders higher-complexity quantitative tests to be performed at another clinical laboratory, Quest Diagnostics, which, according to Dr. Wilson, "is an absolute measure in nanograms per millimeter of the exact substance in the fluid sample provided."

143. CleanSlate ordered quantitative tests in a variety of circumstances. First, when the patient's UDS yields an unexpected result, the clinician may order a specific quantitative test. An unexpected result may occur if a patient tests positive for an illicit drug or negative for a prescribed drug. According to Dr. Welch, if the UDS comes back with an unexpected result, the

EMR automatically orders a quantitative test for that substance. Because these confirmatory tests are ordered automatically regardless of whether the clinician has had a conversation with the patient about the results, which, according to Dr. Welch, could obviate the need for further testing, this procedure resulted in medically unnecessary testing.

144. Dr. Welch's assessment is corroborated by Dr. Wilson's own testimony, as she described the need for confirmatory testing "[i]f someone comes in with an unexpected result, then let's really focus on, you know, opioids and oxy. And should you feel the patient is not being truthful, that's a circumstance where you would order an automated, like, a test that would come as a result of that first assessment." Similarly, CleanSlate's "Clinical Training Manual," included as Exhibit 11, notes that "We order reflex testing at every visit to definitively test for results that will change our Treatment Plan. For example, a positive OPI or OXY or a negative BUP."

145. Occasionally, CleanSlate ordered quantitative testing even though the only positive result in the UDS was for buprenorphine, which is the expected result for a patient taking Suboxone because the drug contains buprenorphine. This procedure resulted in medically unnecessary testing.

146. For example, in the case of Patient A, whose redacted patient records are attached as Exhibit 15 and Exhibit 16, the clinician at CleanSlate ordered a quantitative test at Quest Diagnostics's laboratory during Patient A's April 13, 2015 visit. Patient A's UDS during his previous visit, which was obtained on March 30, 2015 and reviewed by the clinician during the April 13, 2015 visit, was positive for buprenorphine and no other substances, rendering the quantitative test medically unnecessary. CleanSlate still billed \$240.00 to Commonwealth Care Alliance, an MCE, for Procedure Code G0431 (Drug Screen Single Class) for date of service

April 13, 2015 and was paid \$79.49. Quest Diagnostics also billed \$132.08 to Commonwealth Care Alliance for Procedure Code G6056 (Assay of Opiates) for date of service April 13, 2015 and was paid a total of \$52.96.

147. Second, CleanSlate also ordered confirmatory testing at the same time as the UDS, based on the patient's behavior during the visit. Dr. Welch stated that this scenario could occur when a patient reveals in the visit that she had taken a substance but did not know which one or how much. As a result, the clinician might order a quantitative test on the spot, even though a UDS was also ordered pursuant to a standing order. This procedure resulted in medically unnecessary testing, because CleanSlate was ordering duplicative tests of differing levels of complexity.

148. For example, in the case of Patient B, whose redacted patient records are attached as Exhibit 17, the practitioner at CleanSlate ordered a quantitative test at Quest Diagnostics during a visit on May 15, 2015. Pursuant to a standing order signed a few weeks earlier, a UDS at CleanSlate's laboratory was also ordered. The results from the more complex quantitative test actually came back before the less complex UDS, but CleanSlate still billed \$240.00 to Commonwealth Care Alliance for Procedure Code G0431 (Drug Screen Single Class) for the UDS and was paid \$79.49. Quest Diagnostics billed \$214.01 to Commonwealth Care Alliance for Procedure Codes G0434 (Drug Screen Multi Drug Class) and G6056 (Assay of Opiates) and was paid a total of \$68.86.

149. CleanSlate's laboratory also performs LCMS testing for norbuprenorphine, the metabolite of buprenorphine. According to Dr. Wilson, this test is used to detect diversion because it can identify whether the buprenorphine has been absorbed into the blood stream of the patient.

150. Unlike other quantitative tests, the LCMS tests for norbuprenorphine are not case-specific, and instead are required to be performed at regular intervals based on CleanSlate's protocols in the manual at Exhibit 10. This test is to be performed twice per month on Category Red patients, once per month on Category Orange patients, and once every three months on Category Yellow and Category Green Patients.

151. According to Dr. Welch, the LCMS testing for norbuprenorphine was performed by CleanSlate even when there was no evidence or concern about the patient's diversion of Suboxone and/or no negative results on the UDS for the presence of buprenorphine. Dr. Welch believes that there is "no clinical justification" for this practice, particularly in light of representations made to her by Eltahir Elbakri, who ran CleanSlate's laboratory, that only 1% of samples test negative for norbuprenorphine. Elbakri's representations are reflected in a November 2016 email chain with Dr. Welch included as Exhibit 18. This protocol resulted in medically unnecessary testing.

152. For example, in the case of Patient C, whose redacted patient records are attached as Exhibit 19, there were no documented concerns about the patient during his January 21, 2015 visit. Patient C was described as "well-appearing, comfortable . . . pupils appear normal . . . awake, alert, oriented . . . engaged during the visit." The most recent UDS was also reviewed by the CleanSlate clinician during the visit and was found to be "appropriate." Nevertheless, per protocol, CleanSlate ordered both a UDS and a norbuprenorphine LCMS test for Patient C. CleanSlate billed \$240 to Commonwealth Care Alliance for Procedure Code G0431 (Drug Screen Single Class) and was paid \$78.22. CleanSlate also billed \$40 to Commonwealth Care Alliance for Procedure Code 83925 (Opiates), which likely reflects the norbuprenorphine LCMS test performed at CleanSlate's laboratory, and was paid \$26.54.

153. In fact, on occasion, CleanSlate ordered a norbuprenorphine LCMS test to be performed at CleanSlate's own laboratory for patients who were not even receiving Suboxone treatment, rendering such a test completely unnecessary. For example, Patient D, whose redacted patient records are attached as Exhibit 20, was being treated with Vivitrol, not Suboxone. Patient D's UDS results had previously shown negative results for buprenorphine. Nevertheless, during a visit on August 22, 2017, CleanSlate ordered a norbuprenorphine LCMS test for Patient D to detect the presence of the metabolite of buprenorphine, even though Patient D had not been prescribed buprenorphine.

154. CleanSlate patients are also subject to several other types of testing, including a liver function test and random urine drug tests. Patients in most categories receive at least some of those tests every month, but the types and frequencies of tests are administered according to the patient's treatment category.

155. CleanSlate's overall testing program could result in a patient, in just one month, receiving a UDS at every visit, quantitative testing at some visits, an additional LCMS test for norbuprenorphine even without concerns about diversion, a liver function test, and a random urine drug screen. The overlapping utility of these tests results in duplicative, medically unnecessary testing.

VIII. CLEANSLATE'S REFERRAL OF TESTS TO A LABORATORY IT OWNS

156. Almost exclusively, the UDS and norbuprenorphine LCMS tests CleanSlate orders are performed by its own laboratory. The UDS are ordered at every visit, regardless of patient treatment category. Dr. Wilson made the decision to set this policy, by her own admission.

157. Clinicians at CleanSlate had no discretion as to whether to order these UDS

and/or where the tests would be performed, which was set by company policy established by Dr. Wilson. CleanSlate's responses to interrogatories issued by the Commonwealth pursuant to a Civil Investigative Demand and set forth at Exhibit 21 indicate that Dr. Wilson established this policy. Dr. Markaddy confirmed that she did not have control over where the urine was sent for testing.

158. According to CleanSlate's interrogatory responses at Exhibit 21, 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.

159. CleanSlate and Dr. Wilson cannot identify a single clinician at CleanSlate who did not follow this policy. When asked how a physician who wanted to send a UDS to another laboratory, such as Quest Diagnostics, could do that, 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 LCMS 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.

160. 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 an external referral, in which case LaRoche said they would have to "void the claim, do a corrective claim, take the money back."

161. Until March 2019, Dr. Wilson was the sole member of Defendant Total Wellness,

which owned both the CleanSlate OBOT clinics and the laboratory. Dr. Wilson was paid an annual salary by CleanSlate and was the largest non-institutional shareholder at CleanSlate for most of the relevant time period.

162. 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.

163. No relevant exception to the Stark Law applies here. CleanSlate does not qualify as a group practice because, at a minimum: (1) 75% of the services are not provided by the physician members of the group practice, as required by 42 C.F.R. § 411.352(d)(1); and (2) 75% of the patient encounters are not performed by physician members of the group practice, as required by 42 C.F.R. § 411.352(h). Most of CleanSlate's patient services and encounters are performed by nurse practitioners and physician assistants, as attested to by Dr. Wilson, Dr. Mendenhall, and Dr. Welch.

164. CleanSlate also does not qualify for the *bona fide* employment exception, which is not implicated because the physicians, nurse practitioners, and physician assistants at CleanSlate are not the "referring provider" for purposes of evaluating the exception. Dr. Wilson, in setting the policy that UDS should be ordered at every visit and conducted by CleanSlate's own laboratory, is the person 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. The fact that clinicians have no control over where to send referrals is supported by the fact that CleanSlate corporate agreements with insurance companies, not individual clinicians, decide where tests should be sent.

165. Dr. Wilson herself does not qualify for the *bona fide* employment exception

because she was not an employee, but rather was the sole member of the LLC.

166. As a result, all UDS and norbuprenorphine LCMS tests referred by CleanSlate to its own laboratory violate the Stark Law.

167. This practice also violates Massachusetts self-referral provisions, which prohibit a person or company from referring a specimen to a laboratory in which it (or its owners or directors) have an ownership interest. Mass. Gen. Laws c. 111D, § 8A. Here, the “person” making the referral is Dr. Wilson and the “company” making the referral is CleanSlate. No relevant exception applies.

168. One example of CleanSlate self-referral of urine drug testing is for Patient E. CleanSlate billed MassHealth for \$343.29 for Procedure Code G0431 (Drug Screen Single Class), which was referred and performed via CleanSlate’s own laboratory in Holyoke on January 20, 2015. MassHealth paid CleanSlate \$48.78 for the claim. CleanSlate also billed MassHealth for \$40.00 for Procedure Code G6058 (Drug Confirmation), which presumably reflects a norbuprenorphine LCMS test that was referred and performed via CleanSlate’s own laboratory in Holyoke on January 20, 2015. MassHealth paid CleanSlate \$13.53 for that claim.

169. Another example of CleanSlate’s self-referral of urine drug testing is for Patient F. CleanSlate billed Fallon, one of MassHealth’s MCEs, for \$120.00 for Procedure Code G0480 (Drug Test Def 1-7 Classes), which was referred and performed via CleanSlate’s own laboratory in Holyoke on August 21, 2018. Fallon paid CleanSlate \$59.69 for the claim.

IX. CLEANSLATE’S PRIOR NONCOMPLIANCE

170. On November 21, 2016, CleanSlate and Defendant Total Wellness entered into a settlement agreement with the DEA and the United States Department of Justice, which is attached as Exhibit 22.

171. According to the settlement agreement, from March 28, 2012 through February 18, 2014, Defendant Total Wellness (and from January 1, 2014 through February 18, 2014, CleanSlate) sent patient buprenorphine prescriptions to pharmacies to be filled, even though only midlevel clinicians had authorized the prescriptions. After the patients picked up their prescriptions from the pharmacies, CleanSlate part-time doctors reviewed the notes from the patient visits and backdated the prescriptions to the visit dates.

172. CleanSlate and Defendant Total Wellness paid \$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.

173. The conduct is outlined in further detail in a December 2016 email to Dr. Mendenhall by CleanSlate physician, Dr. Paul Gerstein, included as Exhibit 23. 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 stated that he was asked to “rubber stamp” and pre-date those prescriptions. These concerns led Dr. Gerstein to request a leave of absence from CleanSlate.

174. One example of Dr. Gerstein’s concerns is exemplified by a patient visit that occurred on December 11, 2015, as reflected in the redacted patient records for Patient G, attached as Exhibit 24. On that date, Patient G was seen by Physician Assistant Erin Cooley, who issued a prescription for buprenorphine. Although the listed prescriber was Dr. Gerstein and the prescription date was December 11, 2015, that patient’s record and visit were not reviewed by Dr. Gerstein until the next day, as reflected in Exhibit 24. MassHealth paid Rite Aid Pharmacy \$21.35 for this prescription.

175. As part of the federal investigation and settlement, CleanSlate informed its employees in December 2016 via email, included as Exhibit 25, 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.

176. This settlement demonstrates that Defendants had actual and constructive knowledge of their backdating of prescriptions for MassHealth members. Yet, to date, CleanSlate has not repaid any overpayments to MassHealth or MCEs stemming from this noncompliance.

**X. DEFENDANTS' KNOWLEDGE OF MEDICAL NECESSITY
NONCOMPLIANCE**

177. CleanSlate had actual and constructive knowledge of issues associated with the medical necessity of its urine drug testing program.

178. Dr. Mark Jankowske, a physician who worked at CleanSlate from early 2015 through June 2017, said that he reported concerns to Ellen Alexander, CleanSlate's Vice President of Operations for the Northeast Region. Dr. Jankowske reported that he was concerned about the number of quantitative tests CleanSlate was ordering, including the norbuprenorphine LCMS test that was exclusively performed at CleanSlate's laboratory. Alexander explained to him, similar to how Dr. Wilson testified, that the norbuprenorphine LCMS test was necessary to prevent diversion.

179. In October 2016, CleanSlate also had communications with MassHealth's

customer service subcontractor, MAXIMUS, which raised concerns about CleanSlate's testing protocols, as reflected in the email included as Exhibit 26. In that conversation, MAXIMUS asked why CleanSlate was billing for both a UDS and norbuprenorphine LCMS test during the same visit. LaRoche sought guidance from Dr. Mendenhall, who responded by explaining that it is CleanSlate's "protocol" to seek a UDS at every visit and to also conduct routine norbuprenorphine LCMS testing. Notably, Dr. Mendenhall also commented that the UDS is collected as a "standing protocol."

180. Similarly, in November 2016, as reflected in the emails included as Exhibit 27, Chief Financial Officer ("CFO") Patrick Murphy raised concerns to a variety of CleanSlate employees, including CEO Greg Marotta and Dr. Welch, about MassHealth's denial of claims when CleanSlate submits a claim for a UDS and norbuprenorphine LCMS test on the same date of service. Murphy noted that not being paid for both tests will have "a significant impact to our revenue stream" and suggested a review to both the "underlying workflow and billing process." LaRoche noted as well that, if MassHealth and MCEs continue to deny claims on that basis, CleanSlate would face yearly gross losses of more than \$4 million.

181. Dr. Welch recalls attending a meeting with at least LaRoche, Murphy, and Raphael in which the issue of CleanSlate's billing for UDS and quantitative tests performed at its laboratory on the same date of service was raised. Dr. Welch recalled that Murphy suggested that CleanSlate decided to continue with its practice because the laboratory was "a substantial revenue source."

182. Raphael, CleanSlate's former Compliance Officer, recalled that LaRoche had also raised concerns about compliance with medical necessity requirements associated with CleanSlate's drug testing policies. Raphael lamented that the executive team at CleanSlate was

not communicative with individuals responsible for compliance, which ultimately led him to leave his role as Compliance Officer. Raphael also stated that he would raise concerns with CleanSlate's executive team about certain compliance issues, but nothing would be done to address those concerns.

183. LaRoche similarly stated that she had raised concerns about CleanSlate's billing for urine drug tests and whether insurance payers would cover those tests. LaRoche stated that senior leadership at CleanSlate understood that payers would not necessarily pay for all the tests CleanSlate was ordering, but the policy was to bill for those tests and see what happens. LaRoche added that she suggested "building a report to track the number of tests for each individual before we even consider billing. . . And we did a mock up report of that at some point in time, and we started to track all of that. And we were told not to. We just should bill it out and we'll deal with it after the fact." She believed that conversation was with Murphy.

184. LaRoche remembered that she drafted a memorandum, which raised the issue of inappropriate billing for UDS and the lack of collaboration in the record between the treating clinician and the assigned "lab supervisor," to whom the UDS results were sent. LaRoche stated that she sent this memorandum directly to Neil Kunkel, CleanSlate's Chief Legal and Compliance Officer, as well as to Murphy and Raphael. LaRoche was laid off from CleanSlate "[s]hortly after I sent that memo when Pat Murphy said you should have never sent that memo."

185. Dr. Welch also expressed concerns about the medical necessity of the norbuprenorphine LCMS tests run at CleanSlate's laboratory in a series of emails to CleanSlate's senior management in November and December 2016, included as Exhibit 28, stating that "Our lab director told me that he is processing 3000 bup/norbup confirmations per month. I have asked for clarification from him and from Andy, as it appears that there might be an opportunity to look

at the clinical circumstances for sending these for confirmation.” CleanSlate’s Chief Medical Officer, Dr. Kelly Clark, responded that “We should take this opportunity to ensure we are performing the correct testing from a clinical standpoint and in compliance with ASAM guidelines. As Wendy notes, it would appear we may be running too many assays unnecessarily as it stands.”

186. Dr. Welch, in her resignation letter directed to Marotta, attached as Exhibit 29, also expressed her concerns about the medical necessity of the norbuprenorphine LCMS tests run at CleanSlate’s laboratory, stating “When I expressed concerns to both you and the CFO that we are sending 3000 urine samples per month to our lab for definitive confirmations for norbuprenorphine, and that my initial review of monthly patient volume, clinical workflows, and chart documentation did not appear to validate medical necessity for this volume of testing, my concerns were dismissed.”

187. These conversations demonstrate that Defendants had actual and/or constructive knowledge of their noncompliance with medical necessity requirements for laboratory testing. Yet, to date, CleanSlate has not repaid any overpayments to MassHealth or MCEs stemming from this noncompliance.

XI. DEFENDANTS’ KNOWLEDGE OF SELF-REFERRAL NONCOMPLIANCE

188. CleanSlate had actual and constructive knowledge of its violation of self-referral laws through its company policy of referring UDS and norbuprenorphine LCMS tests to its Holyoke laboratory.

189. Dr. Wilson testified that, early on at CleanSlate, she personally reviewed the requirements for complying with MassHealth regulations. As CleanSlate grew, she was a member of the CleanSlate compliance committee, which worked collaboratively to identify and

address potential compliance issues, and to raise those issues to the Board of Directors.

190. Dr. Wilson stated that, in the course of the compliance committee discussions but prior to Raphael joining CleanSlate as the Compliance Officer, the Stark Law and/or the federal Anti-Kickback Statute was discussed. Dr. Wilson said that she was aware of the Stark Law because it was discussed when CleanSlate was in the process of developing the laboratory. Dr. Wilson testified that she discussed these issues with counsel, and CleanSlate has stated that the counsel for purposes of evaluating whether the laboratory arrangement complied with the Stark Law was Bulkley, Richardson & Gelinas, LLP.

191. Raphael recalled that, in his role as Compliance Officer, he created policies governing CleanSlate's compliance with a variety of legal requirements, including the Stark Law and Anti-Kickback Statute. That policy is included as Exhibit 30. Raphael added that he coordinated trainings for employees at CleanSlate on these policies using software from Thomson Reuters. Raphael stated that, at some point in 2018, Marotta and Murphy instructed him to stop creating compliance policies.

192. Dr. Welch recalled a meeting in which she, Raphael, Murphy, and Adam McPhee (President of Operations for CleanSlate's East Division) discussed the future of CleanSlate's laboratory. At the meeting, Murphy raised whether CleanSlate should sell its laboratory to focus on the core business of providing patient care. Dr. Welch recalled the attendees of the meeting discussing how the laboratory falls under the Defendant Total Wellness umbrella and that this practice implicates self-referral laws, which was "more of a risk" for CleanSlate. Murphy suggested that the laboratory should not be sold because it was a positive revenue stream for CleanSlate. Dr. Welch's notes from the meeting are included as Exhibit 31.

193. Dr. Welch also recalled Murphy stating incorrectly that CleanSlate avoids self-

referral laws by operating as a “group practice” and intended to operate using this model in other states, incorporating laboratories under a “group practice” owned by a physician as the sole member of the LLC. Dr. Welch recalled Murphy informing her that the lawyers had approved this arrangement, even though CleanSlate’s senior management, including Dr. Wilson (who hired most of the initial employees), knew that CleanSlate’s patient encounters and visits were primarily handled by midlevel clinicians.

194. Dr. Welch was asked to serve as the member of certain LLCs in other states by Murphy and Marotta and declined to do so out of concern for her own liability. Dr. Welch documented those concerns in her resignation letter, included as Exhibit 29.

195. Dr. Welch also recalled a one-on-one conversation she had with Dr. Wilson in November 2016, in which Dr. Wilson informed her that the laboratory was a critical part of CleanSlate’s business model because, in part, it was a substantial revenue source.

196. These conversations demonstrate that Defendants had actual and constructive knowledge of their noncompliance with applicable self-referral laws. Yet, to date, CleanSlate has not repaid any overpayments to MassHealth or MCEs stemming from this noncompliance.

197. Once this case was unsealed and the Commonwealth informed the Court that it intended to intervene in this matter, MassHealth imposed a payment suspension on CleanSlate’s fee-for-service claims for laboratory services.

CAUSES OF ACTION

Defendant Total Wellness – Count One **(Self-Referral of Specimen of Human Body to a Laboratory, MASS. GEN. LAWS c. 111D, § 8A)**

198. Plaintiff Commonwealth of Massachusetts incorporates by reference the allegations contained in paragraphs 1-197 of this Complaint as if fully alleged herein.

199. From at least July 2014 to the present, Defendant Total Wellness knowingly referred specimens from the human body, which had been obtained at clinics wholly owned by Defendant Total Wellness, to a clinical laboratory also wholly owned by Defendant Total Wellness, in violation of Mass. Gen. Laws c. 111D, § 8A.

200. These self-referrals do not qualify for any available exception under Mass. Gen. Laws c. 111D, § 8A because: (1) the physicians who have been the sole member of Defendant Total Wellness from July 2014 to the present, Dr. Amanda Wilson and Dr. Andrew Mendenhall, do not treat patients at Defendant Total Wellness and/or do not exercise direct supervision over the treatment of patients at Defendant Total Wellness; (2) Defendant Total Wellness is not a hospital or clinic licensed under Mass. Gen. Laws c. 111, § 51; and (3) Defendant Total Wellness is not otherwise exempted under 42 U.S.C. § 1395nn(b)-(d) or specifically permitted by rules or regulations of the United States Department of Health and Human Services (“HHS”), CMS, the Massachusetts Executive Office of Health and Human Services (“EOHHS”), or the Massachusetts Executive Office for Administration and Finance (“A&F”).

201. By virtue of Defendant Total Wellness’s self-referrals of specimens from the human body to its own clinical laboratory, Plaintiff Commonwealth of Massachusetts has suffered actual damages and is entitled to recover treble damages plus civil monetary penalties.

Defendant Total Wellness – Count Two
(Acceptance and Testing of Self-Referred Specimen of Human Body by a Laboratory,
MASS. GEN. LAWS c. 111D, § 8(17))

202. Plaintiff Commonwealth of Massachusetts incorporates by reference the allegations contained in paragraphs 1-201 of this Complaint as if fully alleged herein.

203. From at least July 2014 to the present, Defendant Total Wellness’s clinical laboratory knowingly accepted and tested specimens from the human body, which had been

referred by clinics wholly owned by Defendant Total Wellness, in violation of Mass. Gen. Laws c. 111D, § 8(17).

204. These self-referrals do not qualify for any available exception under Mass. Gen. Laws c. 111D, § 8(17) because: (1) the physicians who have been the sole member of Defendant Total Wellness from July 2014 to the present, Dr. Amanda Wilson and Dr. Andrew Mendenhall, do not treat patients at Defendant Total Wellness and/or do not exercise direct supervision over the treatment of patients at Defendant Total Wellness; (2) Defendant Total Wellness is not a hospital or clinic licensed under Mass. Gen. Laws c. 111, § 51; and (3) Defendant Total Wellness is not otherwise exempted under 42 U.S.C. § 1395nn(b)-(d) or specifically permitted by rules or regulations of HHS, CMS, EOHHS, or A&F.

205. By virtue of Defendant Total Wellness's acceptance and testing of self-referrals of specimens from the human body, Plaintiff Commonwealth of Massachusetts has suffered actual damages and is entitled to recover treble damages plus civil monetary penalties.

Defendant Total Wellness – Count Three
(False Claims in Violation of Massachusetts False Claims Act, MASS. GEN. LAWS c. 12, § 5B(a)(1))

206. Plaintiff Commonwealth of Massachusetts incorporates by reference the allegations contained in paragraphs 1-205 of this Complaint as if fully alleged herein.

207. From at least April 5, 2011 to the present, Defendant Total Wellness failed to comply with applicable statutes and regulations prohibiting backdating of prescriptions by physicians, medically unnecessary urine drug testing, and self-referral of urine drug testing to Defendant Total Wellness's own laboratory, including 42 U.S.C. § 1395nn, Mass. Gen. Laws c. 111D, § 8(17), Mass. Gen. Laws c. 111D, § 8A, 130 C.M.R. § 450.204, and 130 C.M.R. § 406.411(A). MassHealth was unaware of the noncompliance.

208. As a result of the noncompliance, from at least April 5, 2011 to the present, Defendant Total Wellness, either with actual knowledge or deliberate ignorance of or reckless disregard for the truth, submitted or caused to be submitted false claims for services to the MassHealth program in violation of Mass. Gen. Laws c. 12, § 5B(a)(1).

209. These claims were false inasmuch as they were for services not eligible for reimbursement because Defendant Total Wellness misrepresented compliance with applicable statutes and regulations that are conditions of payment. These misrepresentations were material as that term is defined in the Massachusetts False Claims Act and interpreted by the courts.

210. By virtue of the false or fraudulent claims that Defendant Total Wellness knowingly submitted and caused to be submitted, Plaintiff Commonwealth of Massachusetts has suffered actual damages and is entitled to recover treble damages plus civil monetary penalties.

Defendant Total Wellness – Count Four
(Reverse False Claims in Violation of Massachusetts False Claims Act, MASS. GEN. LAWS c. 12, § 5B(a)(10))

211. Plaintiff Commonwealth of Massachusetts incorporates by reference the allegations contained in paragraphs 1-210 of this Complaint as if fully alleged herein.

212. From at least April 5, 2011 to the present, Defendant Total Wellness failed to comply with applicable statutes and regulations prohibiting backdating of prescriptions by physicians, medically unnecessary urine drug testing, and self-referral of urine drug testing to Defendant Total Wellness's own laboratory, including 42 U.S.C. § 1395nn, Mass. Gen. Laws c. 111D, § 8(17), Mass. Gen. Laws c. 111D, § 8A, 130 C.M.R. § 450.204, and 130 C.M.R. § 406.411(A). MassHealth was unaware of the noncompliance.

213. As a result of Defendant Total Wellness's material misrepresentations of compliance, from at least April 5, 2011 to the present, Defendant Total Wellness received money

to which it was not entitled, and which it has retained.

214. Throughout the relevant time period, Defendant Total Wellness knew or should have known that it had misrepresented compliance with applicable statutes and regulations and was in receipt of money that should not have been paid. At the very least, Defendant Total Wellness knew or should have known that it had misrepresented compliance with statutes and applicable regulations and was in receipt of money that should not have been paid by November 2016, at which point CleanSlate employees were discussing the medical necessity of its testing policies and the federal settlement that did not return money to MassHealth and/or MCEs for backdating of prescriptions.

215. These sums of money therefore constituted overpayments. Defendant Total Wellness has not repaid to MassHealth and/or MCEs any overpayments it obtained by submitting claims and receiving money to which it was not entitled.

216. Defendant Total Wellness is therefore the beneficiary of overpayments from the Commonwealth, having subsequently discovered the receipt of overpayments. Defendant Total Wellness has failed to disclose to the Commonwealth the false claims and/or receipt of overpayments, in violation of Mass. Gen. Laws c. 12, § 5B(a)(10).

217. By virtue of the knowing and improper retention of overpayments, Plaintiff Commonwealth of Massachusetts has suffered actual damages and is entitled to recover treble damages plus civil monetary penalties.

Defendant Total Wellness – Count Five
(False Statements in Violation of MASS. GEN. LAWS c. 118E, §§ 40(1), 44)

218. Plaintiff Commonwealth of Massachusetts incorporates by reference the allegations contained in paragraphs 1-217 of this Complaint as if fully alleged herein.

219. From at least April 5, 2011 to the present, Defendant Total Wellness failed to

comply with applicable statutes and regulations prohibiting backdating of prescriptions by physicians, medically unnecessary urine drug testing, and self-referral of urine drug testing to Defendant Total Wellness's own laboratory, including 42 U.S.C. § 1395nn, Mass. Gen. Laws c. 111D, § 8(17), Mass. Gen. Laws c. 111D, § 8A, 130 C.M.R. § 450.204, and 130 C.M.R. § 406.411(A). MassHealth was unaware of the noncompliance.

220. As a result of this noncompliance, Defendant Total Wellness, either with actual knowledge or in willful blindness, knowingly and willfully made or caused to be made false claims for services to the MassHealth program, which constitute false statements or representations in violation of Mass. Gen. Laws c. 118E, § 40(1).

221. These claims were false because they were for services that were not eligible for reimbursement because Defendant Total Wellness misrepresented compliance with applicable statutes and regulations that are conditions of payment. These misrepresentations were material to payment.

222. By virtue of the false or fraudulent claims that Defendant Total Wellness submitted or caused to be submitted, Plaintiff Commonwealth of Massachusetts has suffered actual damages and is entitled to recover treble damages plus the costs of investigation and litigation, in accordance with Mass. Gen. Laws c. 118E, § 44.

Defendant Total Wellness – Count Six
(Reverse False Statements in Violation of MASS. GEN. LAWS c. 118E, §§ 40(3), 44)

223. Plaintiff Commonwealth of Massachusetts incorporates by reference the allegations contained in paragraphs 1-222 of this Complaint as if fully alleged herein.

224. From at least April 5, 2011 to the present, Defendant Total Wellness failed to comply with applicable statutes and regulations prohibiting backdating of prescriptions by physicians, medically unnecessary urine drug testing, and self-referral of urine drug testing to

Defendant Total Wellness's own laboratory, including 42 U.S.C. § 1395nn, Mass. Gen. Laws c. 111D, § 8(17), Mass. Gen. Laws c. 111D, § 8A, 130 C.M.R. § 450.204, and 130 C.M.R. § 406.411(A).

225. As a result of this noncompliance, Defendant Total Wellness, either with actual knowledge or in willful blindness, received benefits to which it was not entitled, and which it has retained, in violation of Mass. Gen. Laws c. 118E, § 40(3).

226. Defendant Total Wellness knew or should have known that it had failed to comply with applicable statutes and regulations prohibiting backdating of prescriptions by physicians, medically unnecessary urine drug testing, and self-referral of urine drug testing to Defendant Total Wellness's own laboratory, and that it was in receipt of money that should not have been paid. At the very least, Defendant Total Wellness knew or should have known that it had failed to comply with applicable statutes and regulations and was in receipt of money that should not have been paid by November 2016, at which point CleanSlate employees were discussing the medical necessity of its testing policies and the federal settlement that did not return money to MassHealth and/or MCEs for backdating of prescriptions.

227. Defendant Total Wellness concealed or failed to disclose to the Commonwealth the false claims and/or receipt of overpayments in order to retain those overpayments.

228. By virtue of the knowing and improper retention of overpayments, the Commonwealth has suffered actual damages and is entitled to recover treble damages plus the costs of investigation and litigation, in accordance with Mass. Gen. Laws c. 118E, § 44.

Defendant Total Wellness – Count Seven
(Recovery of Overpayment, 130 C.M.R. §§ 450.237, 450.260(A), 450.260(I))

229. Plaintiff Commonwealth of Massachusetts incorporates by reference the allegations contained in paragraphs 1-228 of this Complaint as if fully alleged herein.

230. From at least April 5, 2011 to the present, Defendant Total Wellness failed to comply with applicable statutes and regulations, including 42 U.S.C. § 1395nn, Mass. Gen. Laws c. 111D, § 8(17), Mass. Gen. Laws c. 111D, § 8A, 130 C.M.R. § 450.204, and 130 C.M.R. § 406.411(A), prohibiting backdating of prescriptions by physicians, medically unnecessary urine drug testing, and self-referral of urine drug testing to Defendant Total Wellness's own laboratory. Defendant Total Wellness submitted claims for services while Defendant Total Wellness was not in compliance with those applicable statutes and regulations. MassHealth paid for those claims.

231. By virtue of Defendant Total Wellness's submission of claims to MassHealth and/or MCEs while in violation of applicable statutes and regulations, MassHealth made overpayments to Defendant Total Wellness.

232. Defendant Total Wellness is liable to repay to the Commonwealth of Massachusetts the amount received from these overpayments in an amount to be determined at trial.

Defendant Total Wellness – Count Eight
(Unjust Enrichment)

233. Plaintiff Commonwealth of Massachusetts incorporates by reference the allegations contained in paragraphs 1-232 of this Complaint as if fully alleged herein.

234. If Defendant Total Wellness had not impliedly misrepresented compliance with applicable statutes and regulations, MassHealth and/or MCEs would not have paid for the claims submitted for services. By retaining monies received from its submissions of claims that were reimbursed by MassHealth and/or MCEs, Defendant Total Wellness has retained money that is the property of the Commonwealth of Massachusetts and to which Defendant Total Wellness is not entitled.

235. It is unfair and inequitable for Defendant Total Wellness to retain revenue from payments from MassHealth and/or MCEs that Defendant Total Wellness obtained by violating applicable statutes, regulations, and provider contracts.

236. As a consequence of the acts set forth above, Defendant Total Wellness has been unjustly enriched and is liable to pay such amounts, which are to be determined at trial, to Plaintiff Commonwealth of Massachusetts.

Defendant Total Wellness – Count Nine
(Breach of Contract)

237. Plaintiff Commonwealth of Massachusetts incorporates by reference the allegations contained in paragraphs 1-236 of this Complaint as if fully alleged herein.

238. Defendant Total Wellness breached its MassHealth provider contract from at least April 5, 2011 to the present by submitting illegitimate claims for payment to MassHealth and/or MCEs for services provided that did not comply with applicable statutes and regulations prohibiting backdating of prescriptions by physicians, medically unnecessary urine drug testing, and self-referral of urine drug testing to Defendant Total Wellness's own laboratory, including 42 U.S.C. § 1395nn, Mass. Gen. Laws c. 111D, § 8(17), Mass. Gen. Laws c. 111D, § 8A, 130 C.M.R. § 450.204, and 130 C.M.R. § 406.411(A).

239. From at least April 5, 2011 to the present, Defendant Total Wellness breached its MassHealth provider contract by failing to comply with all state and federal laws, regulations, and rules applicable to participation in the MassHealth program and submitting claims for payment that were based on claims for services not in compliance with all state and federal laws, regulations, and rules applicable to MassHealth.

240. Each illegitimate claim submitted by Defendant Total Wellness that was not in compliance with MassHealth rules and regulations constitutes a breach of Defendant Total

Wellness's provider contract.

241. As a result of Defendant Total Wellness's breach of its provider contract, the Commonwealth has been damaged.

Defendants CleanSlate Centers – Count Ten
(False Claims in Violation of Massachusetts False Claims Act, MASS. GEN. LAWS c. 12, § 5B(a)(1))

242. Plaintiff Commonwealth of Massachusetts incorporates by reference the allegations contained in paragraphs 1-241 of this Complaint as if fully alleged herein.

243. From at least April 5, 2011 to the present, Defendant Total Wellness failed to comply with applicable statutes and regulations prohibiting backdating of prescriptions by physicians, medically unnecessary urine drug testing, and self-referral of urine drug testing to Defendant Total Wellness's own laboratory, including 42 U.S.C. § 1395nn, Mass. Gen. Laws c. 111D, § 8(17), Mass. Gen. Laws c. 111D, § 8A, 130 C.M.R. § 450.204, and 130 C.M.R. § 406.411(A).

244. By virtue of their management and financial relationship with Defendant Total Wellness, from at least April 5, 2011 to the present, Defendants CleanSlate Centers, either with actual knowledge or deliberate ignorance of or reckless regard for the truth, caused false claims to be submitted for services to the MassHealth program in violation of Mass. Gen. Laws c. 12, § 5B(a)(1).

245. These claims were false inasmuch as they were for services not eligible for reimbursement because Defendant Total Wellness misrepresented compliance with applicable statutes and regulations that are conditions of payment. These misrepresentations were material as that term is defined in the Massachusetts False Claims Act and interpreted by the courts.

246. By virtue of the false or fraudulent claims that Defendants CleanSlate Centers

knowingly caused to be submitted, Plaintiff Commonwealth of Massachusetts has suffered actual damages and is entitled to recover treble damages plus civil monetary penalties.

Defendants CleanSlate Centers – Count Eleven
(Reverse False Claims in Violation of Massachusetts False Claims Act, MASS. GEN. LAWS c. 12, § 5B(a)(10))

247. Plaintiff Commonwealth of Massachusetts incorporates by reference the allegations contained in paragraphs 1-246 of this Complaint as if fully alleged herein.

248. From at least April 5, 2011 to the present, Defendant Total Wellness failed to comply with applicable statutes and regulations prohibiting backdating of prescriptions by physicians, medically unnecessary urine drug testing, and self-referral of urine drug testing to Defendant Total Wellness's own laboratory, including 42 U.S.C. § 1395nn, Mass. Gen. Laws c. 111D, § 8(17), Mass. Gen. Laws c. 111D, § 8A, 130 C.M.R. § 450.204, and 130 C.M.R. § 406.411(A).

249. As a result of Defendant Total Wellness's material misrepresentations of compliance and by virtue of their management and financial relationship with Defendant Total Wellness, from at least April 5, 2011 to the present, Defendants CleanSlate Centers received money to which they were not entitled, and which they have retained.

250. Defendants CleanSlate Centers knew or should have known that Defendant Total Wellness had misrepresented compliance with applicable statutes and regulations and that Defendants CleanSlate Centers, through Defendant Total Wellness, were in receipt of money that should not have been paid. At the very least, Defendants CleanSlate Centers knew or should have known that Defendant Total Wellness had misrepresented compliance with applicable statutes and regulations and they were in receipt of money that should not have been paid by November 2016, at which point CleanSlate employees were discussing the medical necessity of

its testing policies and the federal settlement that did not return money to MassHealth and/or MCEs for backdating of prescriptions.

251. These sums of money therefore constituted overpayments. Defendants CleanSlate Centers have not repaid to MassHealth and/or MCEs any overpayments they obtained by causing the submission of claims and receiving money to which they were not entitled.

252. Defendants CleanSlate Centers are therefore beneficiaries of overpayments from the Commonwealth, having subsequently discovered the receipt of overpayments. Defendants CleanSlate Centers have failed to disclose to the Commonwealth the false claims and/or receipt of overpayments, in violation of Mass. Gen. Laws c. 12, § 5B(a)(10).

253. By virtue of the knowing and improper retention of overpayments, Plaintiff Commonwealth of Massachusetts has suffered actual damages and is entitled to recover treble damages plus civil monetary penalties.

Defendants CleanSlate Centers – Count Twelve
(False Statements in Violation of MASS. GEN. LAWS c. 118E, §§ 40(1), 44)

254. Plaintiff Commonwealth of Massachusetts incorporates by reference the allegations contained in paragraphs 1-253 of this Complaint as if fully alleged herein.

255. From at least April 5, 2011 to the present, Defendant Total Wellness failed to comply with applicable statutes and regulations prohibiting backdating of prescriptions by physicians, medically unnecessary urine drug testing, and self-referral of urine drug testing to Defendant Total Wellness's own laboratory, including 42 U.S.C. § 1395nn, Mass. Gen. Laws c. 111D, § 8(17), Mass. Gen. Laws c. 111D, § 8A, 130 C.M.R. § 450.204, and 130 C.M.R. § 406.411(A).

256. By virtue of their management and financial relationship with Defendant Total Wellness, from at least April 5, 2011 to the present, Defendants CleanSlate Centers knowingly

and willfully caused false claims to be made for services to the MassHealth program, which constitute false statements or representations in violation of Mass. Gen. Laws c. 118E, § 40(1).

257. These claims were false because they were for services that were not eligible for reimbursement because Defendant Total Wellness misrepresented compliance with applicable statutes and regulations that are conditions of payment. These misrepresentations were material to payment.

258. By virtue of the false or fraudulent claims that Defendants CleanSlate Centers caused to be submitted, Plaintiff Commonwealth of Massachusetts has suffered actual damages and is entitled to recover treble damages plus the costs of investigation and litigation, in accordance with Mass. Gen. Laws c. 118E, § 44.

Defendants CleanSlate Centers – Count Thirteen
(Reverse False Statements in Violation of MASS. GEN. LAWS c. 118E, §§ 40(3), 44)

259. Plaintiff Commonwealth of Massachusetts incorporates by reference the allegations contained in paragraphs 1-258 of this Complaint as if fully alleged herein.

260. From at least April 5, 2011 to the present, Defendant Total Wellness failed to comply with applicable statutes and regulations prohibiting backdating of prescriptions by physicians, medically unnecessary urine drug testing, and self-referral of urine drug testing to Defendant Total Wellness's own laboratory, including 42 U.S.C. § 1395nn, Mass. Gen. Laws c. 111D, § 8(17), Mass. Gen. Laws c. 111D, § 8A, 130 C.M.R. § 450.204, and 130 C.M.R. § 406.411(A).

261. As a result of Defendant Total Wellness's material misrepresentations of compliance and by virtue of their management and financial relationship with Defendant Total Wellness, from at least April 5, 2011 to the present, Defendants CleanSlate Centers received benefits to which they were not entitled, and which they have retained, in violation of Mass. Gen.

Laws c. 118E, § 40(3).

262. By virtue of their management and financial relationship with Defendant Total Wellness, from at least April 5, 2011 to the present, Defendants CleanSlate Centers knew or should have known that Defendant Total Wellness had failed to comply with applicable statutes and regulations prohibiting backdating of prescriptions by physicians, medically unnecessary urine drug testing, and self-referral of urine drug testing to Defendant Total Wellness's own laboratory, and that they were in receipt of money that should not have been paid. At the very least, Defendants CleanSlate Centers knew or should have known that Defendant Total Wellness had failed to comply with applicable statutes and regulations and that they were in receipt of money that should not have been paid by November 2016, at which point CleanSlate employees were discussing the medical necessity of its testing policies and the federal settlement that did not return money to MassHealth and/or MCEs for backdating of prescriptions.

263. Defendants CleanSlate Centers concealed or failed to disclose to the Commonwealth the false claims and/or receipt of overpayments in order to retain those overpayments.

264. By virtue of the knowing and improper retention of overpayments, the Commonwealth has suffered actual damages and is entitled to recover treble damages plus the costs of investigation and litigation, in accordance with Mass. Gen. Laws c. 118E, § 44.

Defendants CleanSlate Centers – Count Fourteen
(Unjust Enrichment)

265. Plaintiff Commonwealth of Massachusetts incorporates by reference the allegations contained in paragraphs 1-264 of this Complaint as if fully alleged herein.

266. If Defendant Total Wellness had not impliedly misrepresented compliance with applicable state laws and regulations, MassHealth and/or MCEs would not have paid for the

claims submitted for services. When Defendant Total Wellness was enriched, by virtue of their management and financial relationship with Defendant Total Wellness, Defendants CleanSlate Centers were enriched.

267. By retaining monies received from the submissions of false claims that were reimbursed by MassHealth and/or MCEs, Defendants CleanSlate Centers have retained money that is the property of the Commonwealth of Massachusetts and to which Defendants CleanSlate Centers are not entitled.

268. It is unfair and inequitable for Defendants CleanSlate Centers to retain revenue from payments from MassHealth and/or MCEs that Defendants CleanSlate Centers obtained by violating federal and state laws.

269. As a consequence of the acts set forth above, Defendants CleanSlate Centers have been unjustly enriched and are liable to pay such amounts, which are to be determined at trial, to Plaintiff Commonwealth of Massachusetts.

Defendant Dr. Amanda Wilson – Count Fifteen
(Self-Referral of Specimen of Human Body to a Laboratory, MASS. GEN. LAWS c. 111D, § 8A)

270. Plaintiff Commonwealth of Massachusetts incorporates by reference the allegations contained in paragraphs 1-269 of this Complaint as if fully alleged herein.

271. From at least July 2014 to March 2019, Defendant Dr. Wilson knowingly referred and/or requested referrals of specimens from the human body, which had been obtained at clinics wholly owned by Defendant Total Wellness, of which she was the only member, to a clinical laboratory also wholly owned by Defendant Total Wellness, in violation of Mass. Gen. Laws c. 111D, § 8A.

272. These self-referrals do not qualify for any available exception under Mass. Gen.

Laws c. 111D, § 8A because: (1) Dr. Wilson did not treat patients at Defendant Total Wellness and/or did not exercise direct supervision over the treatment of patients at Defendant Total Wellness; (2) Defendant Total Wellness is not a hospital or clinic licensed under Mass. Gen. Laws c. 111, § 51; and (3) Defendant Total Wellness is not otherwise exempted under 42 U.S.C. § 1395nn(b)-(d) or specifically permitted by rules or regulations of the HHS, CMS, EOHHS, or A&F.

273. By virtue of Defendant Dr. Wilson's self-referrals of specimens from the human body to a clinical laboratory she owned, Plaintiff Commonwealth of Massachusetts has suffered actual damages and is entitled to recover treble damages plus civil monetary penalties.

Defendant Dr. Amanda Wilson – Count Sixteen
(False Claims in Violation of Massachusetts False Claims Act, MASS. GEN. LAWS c. 12, § 5B(a)(1))

274. Plaintiff Commonwealth of Massachusetts incorporates by reference the allegations contained in paragraphs 1-273 of this Complaint as if fully alleged herein.

275. From at least April 5, 2011 to the present, Defendant Total Wellness failed to comply with applicable statutes and regulations prohibiting backdating of prescriptions by physicians, medically unnecessary urine drug testing, and self-referral of urine drug testing to Defendant Total Wellness's own laboratory, including 42 U.S.C. § 1395nn, Mass. Gen. Laws c. 111D, § 8(17), Mass. Gen. Laws c. 111D, § 8A, 130 C.M.R. § 450.204, and 130 C.M.R. § 406.411(A). MassHealth was unaware of the noncompliance.

276. As a result of the noncompliance, from at least April 5, 2011 to March 2019, Defendant Dr. Wilson, either with actual knowledge or deliberate ignorance of or reckless disregard for the truth, in her role as CEO, Chairwoman of the Board, and sole member of Defendant Total Wellness, caused false claims to be submitted for services to the MassHealth

program in violation of Mass. Gen. Laws c. 12, § 5B(a)(1).

277. These claims were false inasmuch as they were for services not eligible for reimbursement because Defendant Total Wellness misrepresented compliance with applicable statutes and regulations that are conditions of payment. These misrepresentations were material as that term is defined in the Massachusetts False Claims Act and interpreted by the courts.

278. By virtue of the false or fraudulent claims that Dr. Wilson knowingly caused to be submitted, Plaintiff Commonwealth of Massachusetts has suffered actual damages and is entitled to recover treble damages plus civil monetary penalties.

Defendant Dr. Amanda Wilson – Count Seventeen
(Reverse False Claims in Violation of Massachusetts False Claims Act, MASS. GEN. LAWS c. 12, § 5B(a)(10))

279. Plaintiff Commonwealth of Massachusetts incorporates by reference the allegations contained in paragraphs 1-278 of this Complaint as if fully alleged herein.

280. From at least April 5, 2011 to the present, Defendant Total Wellness failed to comply with applicable statutes and regulations prohibiting backdating of prescriptions by physicians, medically unnecessary urine drug testing, and self-referral of urine drug testing to Defendant Total Wellness's own laboratory, including 42 U.S.C. § 1395nn, Mass. Gen. Laws c. 111D, § 8(17), Mass. Gen. Laws c. 111D, § 8A, 130 C.M.R. § 450.204, and 130 C.M.R. § 406.411(A).

281. As a result of Defendant Total Wellness's material misrepresentations of compliance and in her roles as CEO, Chairwoman of the Board, and sole member of Defendant Total Wellness, from at least April 5, 2011 to the present, Defendant Dr. Wilson received money to which she was not entitled, and which she has retained.

282. Defendant Dr. Wilson knew or should have known that Defendant Total Wellness

had misrepresented compliance with applicable statutes and regulations and that she, through Defendant Total Wellness, was in receipt of money that should not have been paid. At the very least, Defendant Dr. Wilson knew or should have known that Defendant Total Wellness had failed to comply with applicable statutes and regulations and that she was in receipt of money that should not have been paid by November 2016, at which point CleanSlate employees were discussing the medical necessity of its testing policies and the federal settlement that did not return money to MassHealth and/or MCEs for backdating of prescriptions.

283. These sums of money therefore constituted overpayments. Defendant Dr. Wilson has not repaid to MassHealth and/or MCEs any overpayments she obtained by causing submission of claims and receiving money to which she was not entitled.

284. Dr. Wilson is therefore a beneficiary of overpayments from the Commonwealth, having subsequently discovered the receipt of overpayments. She has failed to disclose to the Commonwealth the false claims and/or receipt of overpayments, in violation of Mass. Gen. Laws c. 12, § 5B(a)(10).

285. By virtue of the knowing and improper retention of overpayments, Plaintiff Commonwealth of Massachusetts has suffered actual damages and is entitled to recover treble damages plus civil monetary penalties.

Defendant Dr. Amanda Wilson – Count Eighteen
(False Statements in Violation of MASS. GEN. LAWS c. 118E, §§ 40(1), 44)

286. Plaintiff Commonwealth of Massachusetts incorporates by reference the allegations contained in paragraphs 1-285 of this Complaint as if fully alleged herein.

287. From at least April 5, 2011 to the present, Defendant Total Wellness failed to comply with applicable statutes and regulations prohibiting backdating of prescriptions by physicians, medically unnecessary urine drug testing, and self-referral of urine drug testing to

Defendant Total Wellness's own laboratory, including 42 U.S.C. § 1395nn, Mass. Gen. Laws c. 111D, § 8(17), Mass. Gen. Laws c. 111D, § 8A, 130 C.M.R. § 450.204, and 130 C.M.R. § 406.411(A).

288. By virtue of in her roles as CEO, Chairwoman of the Board, and sole member of Defendant Total Wellness, from at least April 5, 2011 to the present, Dr. Wilson knowingly and willfully caused false claims to be made for services to the MassHealth program, which constitute false statements or representations in violation of Mass. Gen. Laws c. 118E, § 40(1).

289. These claims were false because they were for services that were not eligible for reimbursement because Defendant Total Wellness misrepresented compliance with applicable statutes and regulations that are conditions of payment. These misrepresentations were material to payment.

290. By virtue of the false or fraudulent claims that Dr. Wilson caused to be submitted, Plaintiff Commonwealth of Massachusetts has suffered actual damages and is entitled to recover treble damages plus the costs of investigation and litigation, in accordance with Mass. Gen. Laws c. 118E, § 44.

Defendant Dr. Amanda Wilson – Count Nineteen
(Reverse False Statements in Violation of MASS. GEN. LAWS c. 118E, §§ 40(3), 44)

291. Plaintiff Commonwealth of Massachusetts incorporates by reference the allegations contained in paragraphs 1-290 of this Complaint as if fully alleged herein.

292. From at least April 5, 2011 to the present, Defendant Total Wellness failed to comply with applicable statutes and regulations prohibiting backdating of prescriptions by physicians, medically unnecessary urine drug testing, and self-referral of urine drug testing to Defendant Total Wellness's own laboratory, including 42 U.S.C. § 1395nn, Mass. Gen. Laws c. 111D, § 8(17), Mass. Gen. Laws c. 111D, § 8A, 130 C.M.R. § 450.204, and 130 C.M.R. §

406.411(A).

293. As a result of Defendant Total Wellness's material misrepresentations of compliance and in her role as CEO, Chairwoman of the Board, and sole member of Defendant Total Wellness, from at least April 5, 2011 to the present, Dr. Wilson received benefits to which she was not entitled, and which she has retained, in violation of Mass. Gen. Laws c. 118E, § 40(3).

294. In her roles as CEO, Chairwoman of the Board, and sole member of Defendant Total Wellness, from at least April 5, 2011 to March 2019, Dr. Wilson knew or should have known that Defendant Total Wellness had failed to comply with applicable statutes and regulations prohibiting backdating of prescriptions by physicians, medically unnecessary urine drug testing, and self-referral of urine drug testing to Defendant Total Wellness's own laboratory, and that she was in receipt of money that should not have been paid. At the very least, Defendant Dr. Wilson knew or should have known that Defendant Total Wellness had failed to comply with applicable statutes and regulations and that she was in receipt of money that should not have been paid by November 2016, at which point CleanSlate employees were actively discussing the medical necessity of its testing policies and the federal settlement that did not return money to MassHealth and/or MCEs for backdating of prescriptions.

295. Dr. Wilson concealed or failed to disclose to the Commonwealth the false claims and/or receipt of overpayments in order to retain those overpayments.

296. By virtue of the knowing and improper retention of overpayments, the Commonwealth has suffered actual damages and is entitled to recover treble damages plus the costs of investigation and litigation, in accordance with Mass. Gen. Laws c. 118E, § 44.

Defendant Dr. Amanda Wilson – Count Twenty
(Unjust Enrichment)

297. Plaintiff Commonwealth of Massachusetts incorporates by reference the allegations contained in paragraphs 1-296 of this Complaint as if fully alleged herein.

298. If Defendant Total Wellness had not impliedly misrepresented compliance with applicable state laws and regulations, MassHealth and/or MCEs would not have paid for the claims submitted for services. When Defendant Total Wellness was enriched, in her roles as CEO, Chairwoman of the Board, and sole member of Defendant Total Wellness, Dr. Wilson was enriched.

299. By retaining monies received from the submissions of false claims that were reimbursed by MassHealth and/or MCEs, Dr. Wilson has retained money that is the property of the Commonwealth of Massachusetts and to which she is not entitled.

300. It is unfair and inequitable for Dr. Wilson to retain revenue from payments from MassHealth and/or MCEs that Dr. Wilson obtained by violating federal and state laws.

301. As a consequence of the acts set forth above, Dr. Wilson has been unjustly enriched and is liable to pay such amounts, which are to be determined at trial, to Plaintiff Commonwealth of Massachusetts.

JURY DEMAND

302. The Commonwealth demands trial by jury in this action of all issues so triable.

PRAYERS FOR RELIEF

WHEREFORE, the Commonwealth demands and prays that after trial on the merits, judgment be entered in its favor as follows:

Defendant Total Wellness

- a. Counts One and Two – for the amount of the Commonwealth’s damages, trebled as required by law, plus the costs of investigation and litigation, including the costs of experts, and civil penalties as required by Mass.

Gen. Laws c. 111D, § 13(b), together with such other relief as may be just and proper;

- b. Counts Three and Four – for the amount of the Commonwealth’s damages, trebled as required by law, plus the costs of investigation and litigation, including the costs of experts, and civil penalties as required by Mass. Gen. Laws c. 12, § 5B, together with such other relief as may be just and proper;
- c. Counts Five and Six – for the amount of the Commonwealth’s damages, trebled as required by law, plus the costs of investigation and litigation, together with such other relief as may be just and proper;
- d. Count Seven – for the amount of the Commonwealth’s damages, as is proved at trial, and costs;
- e. Count Eight – for the amount of the Commonwealth’s damages, as is proved at trial, interest, and costs; and
- f. Count Nine – for the amount of the Commonwealth’s damages, as is proved at trial, and interest at the statutory rate of 12% pursuant to Mass. Gen. Laws c. 231, § 6C, from the date of each breach of contract, together with such other relief as may be just and proper.

Defendants CleanSlate Centers

- a. Counts Ten and Eleven – for the amount of the Commonwealth’s damages, trebled as required by law, plus the costs of investigation and litigation, including the costs of experts, and civil penalties as required by Mass. Gen. Laws c. 12, § 5B, together with such other relief as may be just and proper;
- b. Count Twelve and Thirteen – for the amount of the Commonwealth’s damages, trebled as required by law, plus the costs of investigation and litigation, together with such other relief as may be just and proper; and
- c. Count Fourteen – for the amount of the Commonwealth’s damages, as is proved at trial, interest, and costs.

Defendant Dr. Amanda Wilson

- a. Count Fifteen – for the amount of the Commonwealth’s damages, trebled as required by law, plus the costs of investigation and litigation, including the costs of experts, and civil penalties as required by Mass. Gen. Laws c. 111D, § 13(b), together with such other relief as may be just and proper;
- b. Counts Sixteen and Seventeen – for the amount of the Commonwealth’s damages, trebled as required by law, plus the costs of investigation and

litigation, including the costs of experts, and civil penalties as required by Mass. Gen. Laws c. 12, § 5B, together with such other relief as may be just and proper;

- c. Counts Eighteen and Nineteen – for the amount of the Commonwealth’s damages, trebled as required by law, plus the costs of investigation and litigation, together with such other relief as may be just and proper;
- d. Count Twenty – for the amount of the Commonwealth’s damages, as is proved at trial, interest, and costs; and

Respectfully submitted,

COMMONWEALTH OF MASSACHUSETTS

By its attorney,
MAURA HEALEY
Attorney General

Dated: October 16, 2020

By: /s/ Kevin Lownds
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CERTIFICATE OF SERVICE

I hereby certify that this document with any attachments filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF).

Dated: October 16, 2020

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