IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

UNITED STATES OF AMERICA *ex rel.* [UNDER SEAL]

Plaintiffs,

v.

[UNDER SEAL]

Defendants.

Case No.

_____

Complaint for Violations of the Federal False Claims Act, 31 U.S.C. §§ 3729 *et seq*., the Georgia False Medicaid Claims Act, O.C.G.A. §§ 49-4-168 *et seq*.; the Colorado Medicaid False Claims Act, Colo. Rev. Stat. §§ 25.5-4-303.5 *et seq*.; the Indiana Medicaid False Claims and Whistleblower Protection Act, Ind. Code §§ 5-11-5.7-1 *et seq*.; and the District of Columbia False Claims Act, D.C. Code § 2-381.01 *et seq*.

FILED UNDER SEAL pursuant to 31 U.S.C. § 3730(b)(2)

Jury Trial Demanded

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

UNITED STATES OF AMERICA and THE STATES OF GEORGIA, COLORADO, INDIANA, & DISTRICT OF COLUMBIA *ex rel*. JONI DONNELL

Plaintiffs,

v.

OXY-GEN LABORATORY, LLC
5680 Oakbrook Parkway, Suite 100
Norcross, Georgia 30093

Registered Agent:

Jean-Francoise Toure
2610 Trees of Avalon Pkwy
McDonough, Georgia 30253

and

JEAN-FRANCOISE TOURE
2610 Trees of Avalon Pkwy
McDonough, Georgia 30253

and

FAFA MIDJOLA
407 Grenier Terrace
Lawrenceville, Georgia 30045

Defendants.

Case No.

Complaint for Violations of the Federal False Claims Act, 31 U.S.C. §§ 3729 *et seq*., the Georgia False Medicaid Claims Act, O.C.G.A. §§ 49-4-168 *et seq*.; the Colorado Medicaid False Claims Act, Colo. Rev. Stat. §§ 25.5-4-303.5 *et seq*.; the Indiana Medicaid False Claims and Whistleblower Protection Act, Ind. Code §§ 5-11-5.7-1 *et seq*.; and the District of Columbia False Claims Act, D.C. Code § 2-381.01 *et seq*.

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INTRODUCTION

1. *Qui tam* relator Joni Donnell ("Donnell" or "Relator"), by her attorneys, individually, and on behalf of the United States of America and the States of Georgia, Colorado, Indiana, and the District of Columbia, files this Complaint against Defendants Oxy-Gen Laboratory, LLC ("Oxy-Gen"), Jean-Francois Toure ("Toure"), and Fafa Midjola ("Midjola") (collectively, "Defendants") to recover damages, penalties, and attorneys' fees for violations of the federal False Claims Act, 31 U.S.C. §§ 3729 *et seq.* ("FCA" or "False Claims Act"), and analogous state false claims laws.

2. Defendants' violations of the federal and state False Claims Acts arise from false claims Oxy-Gen submitted, and continues to submit, at the direction and under the supervision of Toure and Midjola, to Medicare, TRICARE, and various State Medicaid programs, for genetic tests, which: (1) are not medically necessary; (2) are not ordered by a treating physician; (3) are not provided as billed; and (4) are induced by offers of remuneration in violation of the Anti-Kickback statute.

JURISDICTION AND VENUE

3. This Court has subject matter jurisdiction over this action under 28 U.S.C. § 1331, 28 U.S.C. § 1367, and 31 U.S.C. § 3732(a)-(b).

4. This Court has personal jurisdiction over Defendants pursuant to 31 U.S.C. § 3732(a) because Oxy-Gen is headquartered in this judicial district and Toure resides in this judicial district.

5. Venue is proper in this Court under 28 U.S.C. § 1391(c) and 31 U.S.C. § 3732(a) because Oxy-Gen is headquartered in Georgia, the complained-of illegal acts occurred within this judicial district, and Toure resides in this judicial district.

THE PARTIES

6. Relator Donnell is a citizen of the United States and a resident of Loganville, Georgia. Relator Donnell worked at Oxy-Gen from February 2018 through August 2019.

7. Relator Donnell brings this action for violations of the False Claims Act on behalf of herself and the United States of America, seeking recovery for damages to federally funded health insurance programs, including, but not limited to, Medicare, Medicaid, and TRICARE.

8. Relator Donnell brings this action on behalf of the States of Georgia, Colorado, Indiana, and the District of Columbia (collectively, the "State Plaintiffs") to recover damages to each state's Medicaid Program for violations of the following state false claims laws that are modeled after the federal False

Claims Act: the Georgia False Medicaid Claims Act ("Georgia FMCA"), O.C.G.A. §§ 49-4-168 *et seq*.; the Colorado Medicaid False Claims Act ("Colorado MFCA"), Colo. Rev. Stat. §§ 25.5-4-303.5 *et seq*.; the Indiana Medicaid False Claims and Whistleblower Protection Act ("Indiana MCWPA"), Ind. Code §§ 5-11-5.7-1 *et seq*.; and the District of Columbia False Claims Act ("D.C. FCA"), D.C. Code § 2-381.01 *et seq*.

9. Other states to which Oxy-Gen billed for lab tests, such as Wisconsin, do not have their own False Claims Acts. In those instances, Relator Donnell brings this action on behalf of the United States to recover the federal portion of Oxy-Gen's reimbursement.

10. Defendant Oxy-Gen is a limited liability company located in Norcross, Georgia. Oxy-Gen's Georgia entity control number is 16091394. Oxy-Gen's NPI number is 1730628439.

11. Defendant Toure is a resident of McDonough, Georgia, and is the founder, owner, and manager of Oxy-Gen.

12. Defendant Midjola is a resident of Lawrenceville, Georgia, and is the billing manager of Oxy-Gen.

THE LAW

I. The False Claims Act

13. During all times relevant to the facts of this case, the federal False Claims Act provided in pertinent part that:

> [A]ny person who (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; . . . or (G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government, is liable to the United States Government for a civil penalty of not less than $5,500.00 and not more than $10,000.00, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 Note; Public Law 104-410),[1] plus three times the amount of damages which the Government sustains because of the act of that person.
>
> * * * *
>
> (b) . . . For purposes of this section (1) the terms "knowing" and "knowingly" (A) mean that a person, with respect to information (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information; and (B) require no proof of specific intent to defraud; (2) the term "claim" (A) means any request or demand, whether under contract or otherwise, for money or property and whether or not the United States has title to

[1] Civil penalties increase to up to $21,563 per false claim for claims submitted to the Government after November 2, 2016 and including treble damages. 28 C.F.R. § 85.5.

> the money or property, that (i) is presented to an officer, employee, or agent of the United States; or (ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government (I) provides or has provided any portion of the money or property requested or demanded; or (II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded; . . . (3) the term "obligation" means an established duty, whether or not fixed, arising from an expressed or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment; and (4) the term "material" means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.

31 U.S.C. § 3729 (2009).

II. The State False Claims Acts

14. Each of the State Plaintiffs has a state False Claims Act that is modeled after the federal False Claims Act, 31 U.S.C. §§ 3729-33: Georgia FMCA, O.C.G.A. §§49-4-168 *et seq.*; the Colorado MFCA, Colo. Rev. Stat. §§ 25.5-4-303.5 *et seq.*; the Indiana MCWPA, Ind. Code §§ 5-11-5.7-1 *et seq.*; and the D.C. FCA, D.C. Code § 2-381.02 *et seq*.

15. The core provisions of the Georgia FMCA are typical of these state False Claims Acts. The Georgia FMCA provides that any person who:

> (A) Knowingly presents or causes to be presented to the Georgia Medicaid program a false or fraudulent claim for payment or

approval;

(B) Knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim;

* * * *

(7) Knowingly makes, uses, or causes to be made or used a false record or statement material to an obligation to pay or transmit property or money to the Georgia Medicaid program, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit property or money to the Georgia Medicaid program,

shall be liable to the State of Georgia for a civil penalty consistent with the civil penalties provision of the federal False Claims Act, 31 U.S.C. 3729(a), as adjusted by the federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461; Public law 101-410), and as further amended by the federal Civil Penalties Inflation Adjustment Improvements Act of 2015 (Sec. 701 of Public Law 114-74), plus three times the amount of damages which the Georgia Medicaid program sustains because of the act of such person.

O.C.G.A. § 49-4-168.l(a)(l)–(3) (2018).

16. Under O.C.G.A. § 49-4-168(2), "knowing" and "knowingly" require no proof of specific intent to defraud, and instead, mean that a person, with respect to information:

i. Has actual knowledge of the information;

ii. Acts in deliberate ignorance of the truth or falsity of the

information; or

iii. Acts in reckless disregard of the truth or falsity of the information.

17. The Georgia FMCA defines "material" as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." O.C.G.A. § 49-4-168(3).

18. The statute defines "claim" to include claims submitted to Medicaid and the Medicaid managed care programs:

> any request or demand, whether under a contract or otherwise, for money, property, or services, which is made to the Georgia Medicaid program, or to any officer, employee, fiscal intermediary, grantee or contractor of the Georgia Medicaid program, or to other persons or entities if it results in payments by the Georgia Medicaid program, if the Georgia Medicaid program provides or will provide any portion of the money or property requested or demanded, or if the Georgia Medicaid program will reimburse the contractor, grantee, or other recipient for any portion of the money or property requested or demanded. A claim includes a request or demand made orally, in writing, electronically, or magnetically. Each claim may be treated as a separate claim.

O.C.G.A. § 49-4-168(1).

19. Similarly, the Colorado MFCA provides that "any person who:

a) Knowingly presents or causes to be presented a false or fraudulent claim for payment or approval;

> b) Knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim;
>
> * * * *
>
> f) Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the state in connection with the "Colorado Medical Assistance Act", or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the state in connection with the "Colorado Medical Assistance Act",
>
> shall be liable to the state for a civil penalty of not less than five thousand five hundred dollars and not more than eleven thousand dollars; except that these upper and lower limits on liability shall automatically increase to equal the civil penalty allowed under the federal "False Claims Act", 31 U.S.C. sec. 3729, et seq., if and as the penalties in such federal act may be adjusted for inflation as described in said act in accordance with the federal "Civil Penalties Inflation Adjustment Act of 1990", Pub. L. No. 101-410, plus three times the amount of damages that the state sustains because of the act of that person[.]"

Co. Rev. Stat. § 25.5-4-305 (2016).

20. Under Co. Rev. Stat. § 25.5-4-304(3)(a), "knowing" and "knowingly" require no proof of specific intent to defraud.

21. The Colorado MFCA defines "material" as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." Co. Rev. Stat. § 25.5-4-304(4).

22. The statute defines "claim" as follows:

> any request or demand for money or property, whether under a contract or otherwise, and regardless of whether the state has title to the money or property, under the "Colorado Medical Assistance Act" that is presented to an officer, employee, or agent of the state; or made to a contractor, grantee, or other recipient if the money or property is to be spent or used on the state's behalf or to advance a program or interest of the state and if the state provides or has provided any portion of the money or property requested or demanded; or will reimburse the contractor, grantee, or other recipient for any portion of the money or property that is requested or demanded.

Co. Rev. Stat. § 25.5-4-304(1)(a).

23. Similarly, the Indiana MCWPA provides that any person who:

> 1) Knowingly presents or causes to be presented a false or fraudulent claim for payment or approval;
>
> 2) Knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim;
>
> * * * *
>
> 6) (A) Knowingly makes, uses, or causes to be made or used, a false record or statement concerning an

> obligation to pay or transmit money or property to the state,
>
> Is . . . liable to the state for a civil penalty of at least five thousand five hundred dollars ($5,500) and not more than eleven thousand dollars ($11,000), as adjusted by the federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note, Public Law 101-410), and for up to three (3) times the amount of damages sustained by the state. In addition, a person who violates this section is liable to the state for the costs of a civil action brought to recover a penalty or damages.

Ind. Code 5-11-5.7-2.

24. Under Ind. Code 5-11-5.7-1(b)(4), "knowing" and "knowingly" require no proof of specific intent to defraud, and instead, mean that a person, with respect to information:

i. Has actual knowledge of the information;

ii. Acts in deliberate ignorance of the truth or falsity of the information; or

iii. Acts in reckless disregard of the truth or falsity of the information.

25. The Indiana MFCA defines "material" as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." Ind. Code 5-11-5.7-1(b)(5).

26. The statute defines "claim" to include claims submitted to Medicaid and the Medicaid managed care programs:

> any request or demand for money or property, whether under a contract or otherwise, and whether or not the state has title to the money or property, that is presented to an officer, employee, or agent of the state; or is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the state's behalf or to advance a state program or interest, and if the state provides or has provided any part of the money or property that is requested or demanded; or will reimburse the contractor, grantee, or other recipient for any part of the money or property that is requested or demanded.

Ind. Code 5-11-5.7-1(b)(1).

27. Similarly, the D.C. FCA provides that any person who:

> 1) Knowingly presents or causes to be presented a false or fraudulent claim for payment or approval;
>
> 2) Knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim;
>
> * * * *
>
> 6) Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the District, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the District;

> shall be liable to the District for 3 times the amount of damages which the District sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the District for the costs of a civil action brought to recover penalties or damages, and shall be liable to the District for a civil penalty of not less than $5,500, and not more than $11,000, for each false or fraudulent claim.

D.C. Code § 2–381.02.

28. D.C. Code § 2–381.01(7), "knowing" and "knowingly" require no proof of specific intent to defraud, and instead, mean that a person, with respect to information:

i. Has actual knowledge of the information;

ii. Acts in deliberate ignorance of the truth or falsity of the information; or

iii. Acts in reckless disregard of the truth or falsity of the information.

29. The D.C. FCA defines "material" as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." D.C. Code § 2–381.01(8).

30. The statute defines "claim" to include claims submitted to Medicaid and the Medicaid managed care programs:

> Any request or demand, whether under a contract or otherwise, for money or property, and whether or not the District has title to the money or property, that is presented to an officer, employee, or agent of the District; or is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the District's behalf or to advance a District program or interest, and if the District provides or has provided any portion of the money or property requested or demanded; or will reimburse the contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded.

D.C. Code § 2–381.01(1).

31. The State Plaintiffs also have a variety of statutes that allow them to recover monies their Medicaid programs paid for goods or services that were tainted by kickbacks or violated other state Medicaid regulations that are material to payment.

III. The Anti-Kickback Statute and State Prohibitions on Kickbacks

32. The federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2) ("AKS"), prohibits offering to pay or paying any remuneration "to any person to induce such person to purchase . . . any good . . . service, or item for which payment may be made in whole or in part under a Federal healthcare program."

33. Underscoring the breadth of the statutory definition, the HHS OIG Anti-Kickback Provisions, 56 Fed. Reg. 35952, 35958 (1991), broadly define the

term "remuneration" as "anything of value in any form or manner whatsoever." *See* HHS-OIG Anti-Kickback Provisions, 56 Fed. Reg. 35952, 35958 (1991); *accord United States ex rel. Fry v. The Health All. of Greater Cincinnati*, 2008 U.S. Dist. LEXIS 102411, at *17 (S.D. Ohio Dec. 18, 2008).

34. Violation of the Anti-Kickback Statute is a felony punishable by fines and imprisonment and can result in exclusion from participation in federal health care programs. *See* 42 U.S.C. § 1320a-7b(b).

35. In March 2010, the Patient Protection and Affordable Care Act modified the language of the Anti-Kickback Statute to provide that claims submitted in violation of the statute automatically constitute false claims for purposes of the False Claims Act. The new language specifically provides that "a claim that includes items or services resulting from a violation of the Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of [the False Claims Act]." 42 U.S.C. § 1320a-7b(g).

36. According to the legislative history of the Patient Protection and Affordable Care Act, this amendment to the Anti-Kickback Statute was intended to clarify "that all claims resulting from illegal kickbacks are considered false claims for the purpose of civil actions under the False Claims Act, even when the claims

are not submitted directly by the wrongdoers themselves." 155 Cong. Rec. S10852, S10854 (Oct. 28, 2009).

37. Even prior to the 2010 Amendment, Courts had long held that compliance with the Anti-Kickback Statute was a condition of payment under federal health care programs and is material to the Government's decision to pay claims. *See Guilfoile v. Shields,* 913 F.3d 178, n. 12 (1st Cir. 2019)

38. The State Plaintiffs have similar anti-kickback statutes and requirements that apply to their Medicaid programs. Compliance with these statutes and requirements are conditions of payment under the Medicaid programs in the State Plaintiffs, and the State Plaintiffs will not pay for Medicaid claims tainted by kickbacks. These statutes and requirements include: Georgia Department of Community Health (DCH), Part I Policies and Procedures for Medicaid/PeachCare for Kids, Section 106(E); Colo. Rev. Stat. §§ 24-31-809; Ind. Code §12-15-24-2; and D.C. Code § 4-802(c)-(d).

IV. Federally Funded Health Care Programs and Regulations

A. Medicare

39. In 1965, Congress enacted Title XVIII of the Social Security Act under 42 U.S.C. § 1395 *et seq.* ("The Medicare Program" or "Medicare")

authorizing the federal government to pay for the cost of certain medical services for persons aged 65 and older.

40. The United States, through the Department of Health and Human Services ("HHS"), administers the Medicare Program. Part B of the Medicare Program is a federally subsidized health insurance system for disabled persons, blind persons, or persons who are 65 or older. Eligible persons aged 65 and older may enroll in Part B of the Medicare Program to obtain benefits in return for payments of monthly premiums as established by HHS. Part B covers, in general, 80% of reasonably charged services and items other than hospital expenses, and 100% of clinical diagnostic services.

41. HHS has delegated the administration of the Medicare Part B Program to the Centers for Medicare and Medicaid Services ("CMS").

42. Medicare reimbursement to providers of medical services is accomplished through private insurance carriers ("carriers"), as provided by 42 U.S.C. § 1395u. The carrier, on behalf of the Medicare Program, reviews and approves claims submitted for reimbursement by Medicare providers.

43. Before participating in the Medicare Program, providers such as Oxy-Gen are required to certify compliance with Medicare's rules and regulations.

Thereafter, each time the provider submits a claim for payment, it is required to recertify its continued compliance.

44. To participate in the Medicare program as a new enrollee, clinical laboratories such as Oxy-Gen must submit a Medicare Enrollment Application, Form CMS-855B, in order to bill or receive funds from Medicare. *See* CMS-855B, Medicare Enrollment Application for Clinics, Group Practices, and Certain Other Suppliers. These entities must also complete Form CMS-855B to change information or to reactivate, revalidate, and/or terminate Medicare enrollment. Enrolled providers of medical services to Medicare beneficiaries are eligible for government reimbursement for covered medical services and must agree to abide by the rules, regulations, policies, and procedures governing claims for payment in order to receive such reimbursement.

45. As part of the enrollment application process, an authorized official with legal authority to enroll the provider in the Medicare Program and "to commit the organization to fully abide by the statutes, regulations, and program instructions of the Medicare program" must execute a Certification Statement, which "binds the [provider] to all of the requirements listed in the Certification

Statement and acknowledges that the [provider] may be denied entry to or revoked from the Medicare program if any requirements are not met." *Id.*

46. The enrollment application sets forth the following, *inter alia*, "additional requirements that the [provider] must meet and maintain in order to bill the Medicare [P]rogram" and which the provider must certify and attest to having read and understood:

> I have read and understand the Penalties for Falsifying Information, as printed in this application. I understand that any deliberate omission, misrepresentation, or falsification of any information contained in this application or contained in any communication supplying information to Medicare, or any deliberate alteration of any text on this application form, may be punished by criminal, civil, or administrative penalties including, but not limited to, the denial or revocation of Medicare billing privileges, and/or the imposition of fines, civil damages, and/or imprisonment.
>
> * * *
>
> I agree to abide by the Medicare laws, regulations and program instructions that apply to this supplier. The Medicare laws, regulations, and program instructions are available through the Medicare contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier's

> compliance with all applicable conditions of participation in Medicare.
>
> I agree that any existing or future overpayment made to the supplier by the Medicare program may be recouped by Medicare through the withholding of future payments.
>
> I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity.

See CMS Form 855-B, Medicare Enrollment Application.

47. Accordingly, Defendants have a duty to be knowledgeable of the statutes, regulations, and guidelines regarding coverage for Medicare services.

48. Absent certain exceptions that are inapplicable here, Medicare does not reimburse, and providers agree not to submit claims, for services that are not medically necessary, not appropriately administered, or not properly documented. Medicare requires, as a condition of payment, that services be "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A). Providers who wish to participate in the Medicare Program must ensure that their services are provided "economically and only when, and to the extent, medically necessary." 42 U.S.C. § 1320c-5(A)(1).

49. In short, in order for Defendants to be properly reimbursed by the Medicare Program, CMS requires that Defendants perform medically necessary services and appropriately document the justification and administration of those services.

50. The carrier makes payment on claims, which appear to be eligible for reimbursement under Medicare Part B, on behalf of the United States. *See* 42 U.S.C. § 1395u(a). HHS, through CMS, has issued the Medicare Carriers Manual ("Manual"), which is a guideline and explanation of the Medicare statute and its regulations.

51. Before accepting Medicare assignments, Defendants, and all providers who submit claims for services provided to Medicare beneficiaries, must certify that they will operate in accordance with the requirements established by the Secretary of HHS.

52. In addition to the initial and ongoing certifications, each time a provider submits a claim, electronically or otherwise, the submission must state, in boldface type, immediately preceding the provider's signature:

(1) "This is to certify that the foregoing information is true, accurate, and complete."

> (2) "I understand that payment of this claim will be from Federal and State funds, and that any falsification, or concealment of a material fact, may be prosecuted under Federal and State laws."

42 C.F.R. § 455.18(a).

53. For each individual claim for payment, providers such as Oxy-Gen must submit a CMS Form 1500 (or its electronic equivalent, known as the 837P format), which requires the provider to certify that:

> 1) the information on this form is true, accurate and complete; 2) I have familiarized myself with all applicable laws, regulations, and program instructions . . . ; 3) I have provided or will provide sufficient information required to allow the [G]overnment to make an informed eligibility and payment decision; 4) this claim . . . complies with all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment . . . ; [and] 5) the services on this form were medically necessary . . . .

CMS-1500; *see* 42 C.F.R. § 424.32.

54. When filing the electronic equivalent of the CMS-1500, a provider also certifies that:

> The services shown on this form were medically indicated and necessary for the health of the patient and were personally furnished by me or were furnished incident to my professional service by my employee under my immediate personal supervision, except as otherwise expressly permitted by Medicare or CHAMPUS regulations.

55. Because it is not feasible for the Medicare Program, or its contractors, to review medical records corresponding to each of the millions of claims for payment it receives from providers, the Program relies on providers to comply with Medicare requirements and relies on providers to submit truthful and accurate certifications and claims. Generally, once a provider submits a CMS Form 1500, or the electronic equivalent, to Medicare, the claim is paid directly to the provider, in reliance on the foregoing certifications, without any review of supporting documentation, including medical records.

56. Federal law prohibits providers from making "any false statement or representation of a material fact in any application for any . . . payment under a federal healthcare program." 42 U.S.C. § 1320a-7b(a)(1). Similarly, federal law requires providers who discover material omissions or errors in claims submitted to Medicare, Medicaid or other federal health care programs to disclose those omissions or errors to the government. *See* 42 U.S.C. § 1320a-7b(a)(3).

57. At all times herein, Defendants had knowledge of their legal obligation to stay abreast of the public policies expressed in the laws and regulations mentioned and that they must comply with all applicable Federal laws in order to receive Medicare reimbursement for the services performed.

B. TRICARE

58. TRICARE, formerly known as the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), is a federal health care program established by the Department of Defense ("DOD"). *See* 10 U.S.C. §§ 1071-1110.

59. TRICARE provides health care benefits for approximately 9 million active duty military personnel and their families, as well as retired service members and their dependents.

60. TRICARE is managed by the Defense Health Agency ("DHA").

61. The regulations governing claims submission, review, and payment for TRICARE are set forth in 32 C.F.R. § 199 *et seq.*

62. TRICARE allows for reimbursement of laboratory and pathological services only to the extent that the services are related to a specific illness or injury or a definitive set of symptoms. *See* 32 C.F.R. § 199.4(g)(2); *see also* TRICARE Policy Manual 6010.60-M, Chapter 6, Section 3.1 (excluding from coverage any genetic testing "that is not medically necessary and does not influence the beneficiary's medical management . . . .").

C. Administration

63. The Medicare program is administered by private healthcare insurers known as Medicare Administrative Contractors ("MACs").

64. MACs are awarded geographic jurisdiction to process Medicare claims for beneficiaries.

65. MACs are also responsible for establishing local coverage determinations ("LCDs").

66. An LCD is a decision made by a MAC on whether a particular service or item is reasonable and necessary, and therefore covered by Medicare within the specific region that the MAC oversees.

67. CMS is responsible for publishing National Coverage Determinations ("NCDs"). An NCD is a decision made by CMS on whether a particular service or item is reasonable and necessary, and therefore covered by Medicare anywhere in the United States.

V. State Funded Health Care Programs and Regulations

A. Medicaid

68. In 1965, Congress enacted Title XIX of the Social Security Act under 42 U.S.C. § 1396 *et seq*. ("The Medicaid Program" or "Medicaid"). Under the

program, the federal government provides matching funds to states to enable them to provide medical assistance to residents who meet certain eligibility requirements. The objective is to help states provide medical assistance to residents whose incomes and resources are insufficient to meet the costs of necessary medical services.

69. Medicaid serves as the nation's primary source of health insurance coverage for low-income populations, providing coverage to over sixty-five million people. All states, the District of Columbia, and the U.S. territories have Medicaid programs.

70. States that participate in the Medicaid Program administer their own Medicaid program. *See* 42 U.S.C. § 1396a. The states establish eligibility standards, the scope and types of services covered, and the rate of payment.

71. State administrators must comply with federal Medicaid laws, which have certain requirements for service delivery, quality, funding, and eligibility.

72. The United States, through CMS, monitors the state-run Medicaid programs.

73. The federal government pays a share of each state's Medicaid expenditures. The federal medical assistance percentage ("FMAP") calculation

determines the amount of federal reimbursement for each state's Medicaid expenditures. FMAP is calculated using the per capita income amounts of the state relative to total U.S. per capita income.

74. The FMAP formula is designed so that the federal government pays a larger portion of Medicaid costs in states with lower per capita incomes relative to the national average.

75. The Patient Protection and Affordable Care Act extended Medicaid eligibility to all adults under the age of 65 with incomes below 138% of the federal poverty level.

76. The Supreme Court's ruling in *National Federation of Independent Business v. Sebelius* effectively made the expansion optional for states. *See* 567 U.S. 519 (2012).

77. As of 2019, 36 states and the District of Columbia have chosen to adopt the adult expansion.

78. Medicaid's Children's Health Insurance Program ("CHIP") extends medical coverage to eligible children.

79. As of 2018, approximately 9.6 million children are enrolled in CHIP.

i. State of Georgia

80. The Georgia Medicaid program has enrolled nearly 2 million individuals in Medicaid and CHIP.

81. The State of Georgia has not adopted expansion to adults.

82. The State of Georgia has an FMAP of 67.3%.

ii. State of Colorado

83. The Colorado Medicaid program is known as Health First Colorado.

84. Health First Colorado has enrolled nearly 1.3 million individuals in Medicaid and CHIP.

85. Health First Colorado has adopted expansion to adults.

86. The State of Colorado has an FMAP of 50%.

iii. State of Indiana

87. The Indiana Medicaid program has enrolled nearly 1.5 million individuals in Medicaid and CHIP.

88. The Indiana Medicaid program has adopted expansion to adults.

89. The State of Indiana has an FMAP of 65.83%.

iv. District of Columbia

90. The District of Columbia Medicaid program has enrolled approximately 250,000 individuals in Medicaid and CHIP.

91. The District of Columbia Medicaid program has adopted expansion to adults.

92. District of Columbia has an FMAP of 70.00%.

B. Selected Medicaid Regulations and Requirement

93. In each of the State Plaintiffs, health care providers must enroll in the state's Medicaid program in order to be paid for providing goods and services to Medicaid recipients. Each of the State Plaintiffs requires independent laboratories to enroll as providers in order to be able to submit claims for payment from Medicaid.

94. As part of their Medicaid provider enrollment process, each of the State Plaintiffs requires providers to certify or agree that they will comply with state and federal laws that relate to the provision of goods and services under the Medicaid program. In addition, some of the Plaintiff States require providers to

subsequently certify that they will comply with state and federal laws relating to the provision of goods and services under the Medicaid program.

95. For example, all Georgia Medicaid providers that submit claims electronically must complete an Electronic Funds Transfer Agreement and agree to the following:

> Legal Compliance. Provider shall abide by all federal and state laws governing the Medicaid program.
>
> * * * *
>
> Provider further acknowledges and agrees that only Payees who have agreed in writing to: 1) comply with all Department policies regarding the payment of medical assistance; and 2) be subject to the recoupment policies outlined in the Provider's Statement of Participation and as set forth in the Power of Attorney for Electronic Claims Submission, shall be deemed acceptable Payees.
>
> * * * *
>
> Provider certifies by such acceptance [of funds] that Provider presented the claims for the services . . . and that the services were rendered by or under the supervision of Provider. Provider understands that payment will be from federal and state funds and that any falsification, or concealment of a material fact, may be prosecuted under federal and state laws.

Georgia Department of Community Health Electronic Funds Transfer Agreement.

96. Providers such as Oxy-Gen were required to enroll in the Georgia

Medicaid program and enter into a provider agreement called a "Statement of Participation." Included among the express certifications of the Statement of Participation are:

> Provider shall comply with all of the Department's requirements applicable to the category(ies) of service in which Provider participates under this Statement of Participation, including Part I, Part II, and the applicable Part III manuals.
>
> * * * *
>
> Claims Submissions: Certification of Claims. Provider shall submit claims for Covered Services rendered to eligible Medicaid recipients in the form and format designated by the Department. For each claim submitted by or on behalf of Provider, Provider shall certify each claim for truth, accuracy and completeness . . . .
>
> * * * *
>
> Provider shall maintain in an orderly manner and ensure the confidentiality of all original source documents, medical records, identifying recipient data, and any copies thereof, as may be necessary to fully substantiate the nature and extent of all services provided.
>
> * * * *
>
> Provider shall render Covered Services, as defined in the Department's Policies and Procedures manuals, to eligible Medicaid recipients that are medically necessary as defined by the Department, within the parameters permitted by Provider's license or certification, and within the category(ies) of services indicated in the Provider Enrollment documents. By submitting claims for reimbursement, Provider certifies that Covered Services were rendered in the amount, duration, scope and frequency indicated on the claims.

* * * *

> Payment shall be made in conformity with the provisions of the Medicaid program, applicable federal and state laws, rules and regulations promulgated by the U.S. Department of Health and Human Services and the State of Georgia, and the Department's Policies and Procedures manuals in effect on the date the service was rendered. . . . Provider agrees that the Department shall not reimburse any claim, or portion thereof, for services rendered . . . for which federal financial participation is not available.

* * * *

> Provider acknowledges that payment of claims submitted by or on behalf of Provider will be from federal and state funds, and the Department may withhold, recoup, or recover payments as a result of Provider's failure to abide by the Department's requirements.

Department of Community Health Division of Medical Assistance, Statement of Participation, DMA-002 (Rev. 04/03).

97. The State Plaintiffs also establish regulations and policies governing the materials conditions of payment for their Medicaid programs.

98. Similar to the Medicare regulations, the State Plaintiffs require providers to perform only those services that are medically necessary. For example, in Georgia, providers such as Oxy-Gen must "[b]ill the [Georgia Medicaid Program] for only those covered services that are medically necessary and within

accepted professional standards of practice." Georgia Department of Community Health (DCH), Part I Policies and Procedures for Medicaid/PeachCare for Kids, Section 106(K).

99. The State Plaintiffs place additional requirements on each type of provider. For example, independent laboratories such as Oxy-Gen are prohibited from billing for laboratory services that are not ordered by a qualified medical professional. For example, in Georgia, independent laboratories must "[a]gree to bill only for laboratory services requested by an Attending or Consulting Physician, Physician Assistant, Advanced Nurse Practitioner, Nurse Midwife and Podiatrist. Georgia Department of Community Health (DCH), Part II Policies and Procedures for Independent Laboratories, Section 601.7.

VI. Reimbursement Background

100. The American Medical Association ("AMA") has assigned codes to medical procedures for use in billing submissions to CMS or private insurance.

101. The AMA has three levels of codes: Level I codes consist of the Current Procedural Terminology ("CPT") codes; Level II codes consist of the alphanumeric Healthcare Common Procedure Coding System ("HCPCS") codes and primarily include non-physician products, supplies, and procedures not

included in the CPT database; Level III codes consist of HCPCS local codes, which were developed by state Medicaid and Medicare agencies as well private insurers for use in specific jurisdictions.

102. A CPT code is a medical code used to report medical, surgical, and diagnostic procedures to health insurance companies, including CMS.

103. CPT and HCPCS codes work hand-in-hand to describe all patient interactions.

104. CMS developed the National Correct Coding Initiative ("NCCI") to help ensure correct coding methods are followed and to avoid inappropriate payment for claims.

105. According to the NCCI Policy Manual, providers are required to report procedures using the most comprehensive CPT code that describes the services performed. The use of multiple CPT codes when a more comprehensive CPT code is appropriate is known as "unbundling."

106. The NCCI Procedure-to-Procedure ("PTP") edit tables define the circumstances when two CPT codes should not be reported together.

107. Each edit table contains a list of edit pairs, which are pairs of HCPCS/CPT codes that should generally not be reported together. Each edit pair has a column one and column two HCPCS/CPT code.

108. If a provider reports the two codes of an edit pair, the column two code is denied, and the column one code is eligible for payment.

109. However, if it is clinically appropriate to utilize an NCCI-associated modifier, both the column one and column two codes are eligible for payment.

110. The PTP edit tables indicate whether an edit pair may be used together via a modifier. Where an edit pair is assigned a modifier indicator of "0" in the modifier column of the PTP edit table, a modifier may never be used. However, where an edit pair is assigned a modifier indicator of "1" in the modifier column of the PTP edit table, the use of a modifier may be appropriate, but only in certain circumstances.

111. CMS defines a number of modifiers that may be used under appropriate circumstances to include both CPT codes from an edit pair on a claim for reimbursement.

112. Modifier 59 is to be used for distinct procedural services. Under certain circumstances, it may be necessary to perform two independent services

that use CPT codes from an edit pair. In order to use modifier 59, a provider must include documentation to indicate that the procedure was for a different session, different procedure or surgery, different site or organ system, separate incision/excision, separate lesion, or separate injury not ordinarily encountered or performed on the same day by the same individual.

113. Modifier 91 is to be used for repeat laboratory procedural services performed on the same day to obtain subsequent reportable test values. A provider should only use modifier 91 to indicate the completion of subsequent, repeat lab tests for the same beneficiary on the same day in order to obtain new test data.

114. When used appropriately for medically necessary procedures, modifiers 59 and 91 prevent denials of Medicare, TRICARE, or Medicaid claims when CPT codes are billed in an edit pair.

VII. Genetic Testing and Reimbursement

115. Genetic testing covers a broad category of medical procedures that involve examining the body's DNA, which carries genetic information.

116. Genetic testing utilizes laboratory methods to analyze genes, which are a portion of one's hereditary DNA code that contributes to, among other things, an individual's phenotypic traits. Genetic tests can be used to identify health risks,

such as a patient's risk for certain types of cancers as the result of DNA mutations. One method of conducting genetic testing is to obtain a DNA sample from a patient using a cheek (buccal) swab that is sufficient to obtain a genetic profile. The DNA swab is then submitted to a clinical laboratory, such as Oxy-Gen, for analysis, and the results are sent back to the health care provider that deemed the testing to be medically reasonable and necessary.

117. Pharmacogenomic testing ("PGx") is used to determine how different individuals will react to a particular treatment or medication. PGx is used to explain why drugs work in some patients but not in others.

118. Cancer genomic testing ("CGx") testing is used to determine whether a patient is a carrier of certain types of hereditary cancer cells.

119. The Medicare Part B Program excludes from coverage diagnostic tests, which include genetic tests, "that are not reasonable and necessary . . . [f]or the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 C.F.R. § 411.15(k)(1). In order to be considered "reasonable and necessary," Medicare rules require that genetic testing "must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and

who uses the results in the management of the beneficiary's specific medical problem." 42 C.F.R. § 410.32(a). "Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary."[2] *Id.*

120. Furthermore, genetic tests for *screening* and *prevention* purposes, which are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury, are not covered by Medicare except as explicitly authorized by statute. In fact, Medicare only explicitly authorizes one genetic test to *preventatively* screen for cancer: Medicare covers a fecal DNA colorectal cancer test in accordance with National Coverage Determination 210.3. *See* 42 C.F.R. § 410.37.

121. As of June 2019, the MAC for Medicare Parts A and B for Georgia is Palmetto GBA.

122. As of June 2019, the MAC for Medicare Parts A and B for Indiana is WPS.

123. In 2011, Palmetto GBA established the Molecular Diagnostic Program ("MolDX") to administer coverage, coding, and pricing standards and

[2] Non-physician practitioners, such as clinical nurse specialists or physicians assistants, may also order genetic tests but are subject to the same requirement as physicians: they must consult or treat the beneficiary for a specific medical problem and use the test results to manage the beneficiary's specific medical problem. *See* 42 C.F.R. § 410.32(a)(2).

requirements for molecular diagnostic tests and other molecular pathology services.

124. WPS has also adopted MolDX.

125. Local Coverage Determinations for Palmetto GBA and WPS regarding genetic testing state that MolDX will review all new test/assay clinical information to determine if a test meets Medicare's reasonable and necessary requirement. MolDX will only cover and reimburse tests that demonstrate analytical and clinical validity, and clinical utility at a level that meets Medicare reasonable and necessary requirement. *See, e.g.*, LCD L3024, L35025, L36813.

126. As of June 2019, the MAC for Medicare Parts A and B for Colorado and the District of Columbia is Novitas.

127. LCDs for Novitas regarding genetic testing state that it is not appropriate to bill for services that are not covered as if they are covered.

128. For example, the LCD for the BRCA1 and BRCA2 genes state that coverage by Medicare is not appropriate where a patient has no personal history of breast, ovarian, fallopian tube, primary peritoneal, pancreatic or prostate cancer. *See, e.g.*, L36715. In order to receive reimbursement from Medicare, the entity submitting the claim (i.e., the lab) must maintain documentation from the ordering

physician indicating the medical necessity of the genetic testing. *See* 42 C.F.R. § 410.32(d)(2).

129. The United States, through the Department of Justice, "is committed to ensuring that laboratory tests, including drug and genetic tests, are ordered based on each patient's medical needs and not just to increase physician and laboratory profits" and "will not tolerate practices such as the ordering of excessive, non-patient specific tests and the provision of inducements to physicians that lead to unnecessary costs being imposed upon our nation's health care programs." Press Release, U.S. Dep't of Justice, *Millennium Health Agrees To Pay $256 Million To Resolve Allegations Of Unnecessary Drug And Genetic Testing And Illegal Remuneration To Physicians* (October 19, 2015), https://www.justice.gov/opa/pr/millennium-health-agrees-pay-256-million-resolve-allegations-unnecessary-drug-and-genetic (last visited Apr. 2, 2020).

130. The United Sates, through the Department of Justice, has brought both civil and criminal claims against entities and providers who violated the above outlined requirements for laboratory testing. *See id;* Criminal Complaint, Dkt. No. 1, *United States of America v. Matthew S. Ellis*, No. 2:19-mj-06194-SCM (D.N.J.).

VIII. Factual Allegations

131. Oxy-Gen, which was founded on September 27, 2016 by Toure, operates a clinical laboratory located in Lilburn, Georgia. Oxy-Gen was located at 331 Arcado Rd., Lilburn, GA 30047 through May 2019 at which point operations moved to 5680 Oakbrook Parkway, #100, Norcross, GA 30093.

132. Toure oversees all of Oxy-Gen's staff and operations.

133. Midjola is Oxy-Gen's billing manager and handles all billing issues in-house.

134. Oxy-Gen has approximately 10 employees.

135. Oxy-Gen's testing laboratories are located on-site and are operated by Oxy-Gen employees. Toure, Sally LNU, and Kathy LNU conducted the laboratory tests during Donnell's employment at Oxy-Gen.

136. Oxy-Gen was enrolled in the Medicare, TRICARE, and Medicaid Programs and certified that it would abide by the rules, regulations, policies, and procedures governing claims for payment in order to receive reimbursement.

Billing for Services that Were Not Ordered by a Treating Physician

137. Medicare, Medicaid, and TRICARE beneficiaries, receptive to marketing ploys that combine serious claims about cancer with free screening

offers to detect the disease, are asked to fill out a questionnaire requesting their medical background and that of their family and to provide an oral buccal swab that is submitted for Oxy-Gen's genetic testing.

138. Many of Oxy-Gen's customers do not meet the eligibility criteria for Medicare and Medicaid coverage for genetic testing; however, Oxy-Gen creates, or causes to be created, false records indicating medical necessity.

139. Oxy-Gen's lab orders are based upon fraudulent referrals from physicians who falsely represent the patient's medical necessity for genetic testing.

140. Many of Oxy-Gen's customers never see or speak with the referring physician, and the lab orders upon which Oxy-Gen performs its genetic testing are signed by a telemedicine physician who neither "furnishes a consultation or treats a beneficiary for a specific medical problem" nor "uses the results in the management of the beneficiary's specific medical problem." 42 C.F.R. § 410.32(a).

141. Many patients were never seen by the referring clinic identified on the genetic testing lab requisition, which was confirmed by Jonise Armour, a former employee in Oxy-Gen's billing department who frequently called the clinics for additional information.

142. As further indication of its fraudulent practices, some referrals from Oxy-Gen's distributors would contain customer photographs taken in the customer's living room or in front of the customer's home, which was clearly visible in the background.

143. Oxy-Gen falsifies claims for genetic testing by attaching false requisitions to show that patients were referred by physicians for genetic testing.

144. In fact, prior to July 2019, one of Oxy-Gen's ordering physicians was Matthew Ellis, a physician licensed in the State of Florida who served as the director of Ark Laboratory Network, LLC and as the Chief Medical Officer for Privy Health, Inc. In or around July 2019, Dr. Ellis was charged with conspiracy to commit health care fraud for ordering genetic tests for patients he never saw or treated. According to the criminal complaint issued by the United States District Court for the District of New Jersey, distributors obtained DNA swabs without the involvement of Dr. Ellis or any other health care professional fulfilling the role of a treating provider (and before Dr. Ellis or any other health care professional ever considered whether such tests were medically necessary). The distributors sent the DNA swabs to a clinical laboratory to undergo genetic testing, pursuant to Dr. Ellis' signed order, with the intent that the laboratory would bill Medicare for such

testing without any health care professional examining or even speaking with the patients. Ark Laboratory Network, LLC and Privy Health, Inc. partnered to illegally acquire DNA samples and Medicare information from hundreds of patients nationwide.

145. As an example, Oxy-Gen performed a breast and ovarian cancer test panel and a colorectal cancer test panel on a buccal swab from a 32-year-old Medicaid beneficiary in Indiana, Patient 2,[3] based upon a lab order electronically signed by Dr. Ellis, who is not licensed to practice medicine in Indiana. Patient 2's buccal swab was collected by Privy Health, Inc. technician Richard Baki on December 22, 2018, and her Oxy-Gen lab order listed the "specific ICD-10 Codes to determine medical necessity for Cancer Predisposition testing" as: Z80.41, C56.1, C56.2, Z15.01, Z15.02, Z15.04, Z84.81, R53.82, R52, R10.9, R19.4. Dr. Ellis did not see or speak with Patient 2 before her DNA swab was collected, tested, or billed.

146. Upon information and belief, Casey LNU and Ed LNU, who worked for two of Oxy-Gen's distributors, also worked with Dr. Ellis.

[3] The names of these patients discussed in this Complaint are known to Relator and will be confidentially provided upon request to Defendants, the United States, or the Court.

147. When Relator Donnell learned that Dr. Ellis was improperly signing referrals for laboratory tests performed by Oxy-Gen, she emailed and spoke with Defendants Toure and Midjola about her concerns that Oxy-Gen was billing for laboratory tests referred by doctors who did not see or treat the patient and were not licensed to practice medicine where the patient was located.

148. In response, Defendant Midjola told Relator Donnell that she simply "did what the boss told [her] to do," referring to Defendant Toure.

149. Defendant Toure ignored Relator Donnell whenever she brought up her concerns about Dr. Ellis and the other improper physician referrals.

150. Oxy-Gen knowingly submitted false claims based on tests fraudulently ordered by Dr. Ellis and Privy Health, Inc. and/or recklessly disregarded or deliberately ignored relevant federal regulations based on this improper relationship.

151. Oxy-Gen had a duty to return any overpayments to relevant federal and state health care programs resulting from the submission of false claims pertaining to Dr. Ellis' fraudulent lab orders. By failing to return these overpayments, Oxy-Gen committed a separate, additional violation of the federal and state False Claims Acts.

152. Oxy-Gen continues to submit false claims for genetic tests that are referred through multiple fraudulent sources falsely indicating medical necessity, which is required by 42 C.F.R. 410.32(d)(3)(iii).

Billing for Services that Are Not Medically Necessary

153. Oxy-Gen markets and performs clinical laboratory genetic testing, including PGx and CGx screening tests.

154. According to its website, Oxy-Gen's PGx "testing profile provides information on the connection between a patient's unique genetic makeup and their response to certain medications . . . [and shifts] the emphasis in medicine from reaction to prevention . . . [to] detect disease at an earlier stage, identify effective medications, reduce adverse drug reactions and minimize health costs." *See* https://www.oxy-genlab.com/oxypharmacogenomics/ (last visited Mar. 24, 2020).

155. Furthermore, Oxy-Gen's CGx testing "analyzes mutations in a patient's DNA known to be associated with an increased risk of hereditary cancer . . . [and] provide[s] a comprehensive report indicating a patient's potential susceptibility to various hereditary cancers." *See* https://www.oxy-genlab.com/services/ (last visited Mar. 24, 2020).

156. In addition to performing tests based on referrals by doctors who have never seen or treated the patient, Oxy-Gen's billing manager, Defendant Midjola, subjectively matched customers' questionnaire responses regarding medical histories to CPT codes billed to Government payors.

157. These genetic tests performed by Oxy-Gen were not ordered by the customer's treating medical provider and were *per se* not medically necessary for the customer.

158. At times, customers called to complain that they never received their test results. Because the tests are not ordered by a treating physician, the customers do not have a physician to review and interpret their test results.

159. Oxy-Gen performs and submits payment claims for tests based on its determination of reimbursement by Government payors.

Billing for Services Not Provided as Claimed

160. Oxy-Gen often conducts a full sequence analysis procedure when testing for certain genes. The full sequence analysis procedure allows variations in the protein-region of any gene to be identified, rather than in only a select few genes.

161. When a CPT code for a full sequence analysis procedure is used on a claim for reimbursement, NCCI's PTP edit tables generally prevent reimbursements for CPT codes assigned to gene testing for the known familial variants analysis procedure.

162. For some gene testing, the PTP edit tables indicate that the use of a modifier to bill for both the full sequence analysis procedure and the known familial variants analysis procedure is never appropriate for the same patient on the same day. For such edit pairs, PTP edit tables assign the edit pair a modifier indicator of "0", which indicates a modifier may never be used.

163. For example, the PTP edit table assigns the edit pair of CPT codes 81201 and 81202 a modifier indicator of "0." CPT code 81201 is assigned to the full sequence analysis procedure for the gene APC. CPT code 81202 is assigned to the known familial variants analysis procedure for the same gene. According to the PTP edit table, this edit pair is assigned a modifier indicator of "0" because these procedures are mutually exclusive.

164. Oxy-Gen uses modifier 59 to bill for CPT code 81201 along with CPT code 81202 on claims for reimbursement. Because the use of modifier 59 to bill for both procedures when testing for the gene APC is never appropriate according to

the PTP edit table, Oxy-Gen's claims for reimbursement are false as billed for services that are not medically necessary and are not provided as claimed.

165. For example, on April 17, 2019, Oxy-Gen billed for services provided to Patient 3, using CPT Code 81202 and charged $1,270.00 for the procedure. Oxy-Gen then billed for services provided to Patient 3 using CPT code 81202 on the same date and charged $570.00 for the procedure. Both of these claims were paid in full.

166. Additionally, according to the PTP edit table, the edit pair of CPT codes 81321 and 81322 should never be billed together. CPT code 81321 is assigned to the full sequence analysis procedure for the gene SNRPN/UBE3A. CPT code 81322 is assigned to the known familial variants analysis procedure for the same gene. As above, these procedures are assigned a modifier indicator of "0" because the procedures are mutually exclusive.

167. Oxy-Gen also uses modifier 59 to bill for CPT code 81321 along with CPT code 81322 on claims for reimbursement. Because the use of modifier 59 to bill for both procedures when testing for the gene SNRPN/UBE3A is never appropriate according to the PTP edit table, Oxy-Gen's claims for reimbursement

are false as billed for services that are not medically necessary and are not provided as claimed.

168. For example, on May 3, 2019, Oxy-Gen billed for services provided to Patient 4, a 56-year-old Medicaid beneficiary in Colorado, using CPT Code 81321 and charged $1,244.26 for the procedure. Oxy-Gen then billed Colorado Medicaid for services provided to Patient 4 using CPT code 81322 on the same date and charged $79.27 for the procedure. Both claims were paid in full.

169. For other edit pairs related to genetic testing, the PTP edit tables indicate that the use of a modifier to bill for both the full sequence analysis procedure and the known familial variants analysis procedure is appropriate in some circumstances. For such edit pairs, PTP edit tables assign the edit pair a modifier indicator of "1," which indicates the use of a modifier may be appropriate, but only in certain circumstances. A modifier should only be used for these edit pairs where a procedure is medically necessary and where the modifier is used in accordance with CMS regulations.

170. Oxy-Gen uses modifier 59 to bill the following edit pairs on the same claim for reimbursement: CPT code 81292 and CPT code 81293; CPT code 81295

and CPT code 81296; CPT code 81298 and CPT code 81299; and CPT code 81317 and CPT code 81318.

171. For example, on April 14, 2019, Oxy-Gen billed for services provided to Patient 5, a 36-year-old Medicaid beneficiary located in Colorado, using CPT Code 81292 and charged $1130.66 for the procedure. Oxy-Gen then billed Colorado Medicaid for services provided to Patient 5 using CPT code 81293 on the same date and charged $662.00 for the procedure. Colorado Medicaid adjusted the amount, but ultimately paid Oxy-Gen $1,124.36 for the first claim and $69.07 for the second claim.

172. According to the PTP edit tables, these edit pairs are generally not permitted to be billed together because in each case, the column 1 CPT code describes a "more extensive procedure" than the column 2 CPT code.

173. While these edit pairs are assigned a modifier indicator of "1," the use of modifier 59 should not be used for these edit pairs unless a distinct procedure is performed. In order to perform a distinct procedure, providers must provide documentation indicating the procedure is medically necessary.

174. Once Oxy-Gen receives a sample in the mail from the marketing representatives, the sample is tested at the on-site labs by Defendant Toure and two

other Oxy-Gen employees, Kathy LNU and Sallie LNU. Defendant Midjola *then* submits a claim for reimbursement via CollaborateMD billing software *before* lab results are even received or reported. Consequently, Oxy-Gen cannot know whether the known familial variants analysis procedure is medically necessary *before* performing tests on these genes.

175. In addition to using modifier 59 to bill for procedures not performed as claimed, Oxy-Gen also uses modifier 91 for certain edit pairs.

176. The use of modifier 91 is appropriate only where a laboratory procedure is performed multiple times on the same patient on the same day to obtain subsequent reportable test values.

177. Because Oxy-Gen submits its claims for reimbursement *before* receiving the laboratory report, Oxy-Gen fraudulently bills for repeat and additional testing through the use of modifier 91 without determining the medical necessity of the repeat or additional testing.

178. Oxy-Gen uses modifier 91 to fraudulently bill additional, multiple CPT codes on its claims for reimbursement, despite performing the procedure only once.

179. For example, on June 3, 2019, Oxy-Gen billed $503.52 for services provided to a 56-year-old Medicaid beneficiary in Colorado, Patient 6, using CPT Code 81405. Oxy-Gen then billed Colorado Medicaid for services provided to Patient 6 using the same CPT Code on the same date via the use of Modifier 91 and charged $503.52 for the second procedure even though the testing procedure was performed only one time on Patient 6. However, by using Modifier 91, Oxy-Gen billed for the procedure as if it had been completed more than once.

180. Further, even when Oxy-Gen performs multiple testing procedures on the same patient on the same day, CMS policy prohibits separate payment for duplicate genetic testing or testing for the same analyte by more than one methodology, therefore Oxy-Gen's use of modifier 91 remains unlawful.

Referrals in Exchange for Remuneration in Violation of the Anti-Kickback Statute

181. Oxy-Gen submits claims to federal and state health care payors that are tainted by kickbacks provided to distributors and customers in the form of monetary gift cards.

182. Oxy-Gen receives the majority of its business from distributors who work with marketing companies to obtain samples.

183. The marketing companies from whom Oxy-Gen receives the majority of its business engage in a variety of marketing practices, including telemedicine. The vast majority of these marketing salespeople have no medical background and little or no training in genetics.

184. Oxy-Gen employed a full-time sales representative, Crystal McDonald from October 2017 through December 31, 2018. McDonald marketed Oxy-Gen's services mainly to medical offices, which made up a small minority of Oxy-Gen's business.

185. At the time McDonald worked for Oxy-Gen, Oxy-Gen had no large medical accounts such as hospitals or area physicians' groups.

186. Other than McDonald, Oxy-Gen mainly worked with third-party distributors who worked with a group of marketing companies that practice telemedicine, one of which was True Blue Health.

187. Oxy-Gen paid these distributors a flat rate for each specimen that the distributor brought to Oxy-Gen.

188. Many of the distributors came to work with Oxy-Gen through Ryad LNU, Toure's silent partner who left Oxy-Gen in or around May 2018 to open another, similar, laboratory testing business.

189. On numerous occasions, Relator Donnell spoke with Casey LNU and Ed LNU, who worked for two of the distributors Oxy-Gen used to solicit customers.

190. Oxy-Gen's distributors market to customers at health events and health fairs and through telephone cold calls, Facebook ads, and door-to-door sales.

191. Oxy-Gen's distributors incentivize customers to provide samples for genetic testing by offering $50.00 gift cards in exchange for their DNA samples and insurance information.

192. Pursuant to 42 U.S.C. § 1320a–7a(a)(5), it is a violation of law to offer or provide anything of value to a beneficiary in order to influence the beneficiary to order or receive any item or service that is reimbursed by Medicare or Medicaid.

193. Oxy-Gen's knowing and willful payment of remuneration to customers in the form of monetary gift cards in order to induce them to undergo genetic testing violates the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2).

194. For example, in August 2018, a 68-year-old beneficiary, Patient 1, called Oxy-Gen to dispute a $10.00 copay for which she was billed. On the same call, Patient 1 stated that she was paid $50.00 to participate in the research.

195. On numerous occasions, Relator Donnell told Defendants Toure and Midjola that providing Oxy-Gen customers with kickbacks in the form of gift cards was illegal.

196. Despite initially denying the practice, Defendants Toure and Midjola could no longer deny that distributors were paying Oxy-Gen customers gift cards in exchange for samples after Relator Donnell repeatedly advised them of specific Oxy-Gen customers confirming the kickback scheme.

197. In response, Defendant Midjola told Relator Donnell that she simply "did what the boss told [her] to do," indicating that the kickbacks were at Defendant Toure's instruction.

198. Defendant Toure continued to ignore Relator Donnell whenever she brought up her concerns about the kickbacks.

199. Relator Donnell also raised concerns about the kickbacks to Ed LNU, who worked for one of Oxy-Gen's distributors. In response Ed LNU told Relator Donnell that Defendant Toure approved of the marketing and that Relator Donnell,

who was a "GED graduate[,] could not tell a B.S. of Science what to do," referencing Defendant Toure.

200. Marketing and telemedicine agents for Oxy-Gen's distributors promise monetary incentives to potential patients in exchange for their DNA samples.

201. Oxy-Gen submits or causes to be submitted the resulting claims for reimbursement to Government payors despite the provision of these kickbacks to their patients.

202. Such claims are, as a matter of law, *per se* false or fraudulent. *See* 42 U.S.C. § 1320a-7b(g).

Fraudulent Inducement to Enter Government Contracts

203. Oxy-Gen fraudulently induced the Government to enter into a specific Provider Enrollment Agreement to reimburse Oxy-Gen for laboratory services provided to Government beneficiaries by affirmatively committing "to fully abide by the statutes, regulations, and program instructions of the Medicare [P]rogram" or be "denied entry to or revoked from the Medicare [P]rogram . . ." if any requirements are not met. CMS-855B, Medicare Enrollment Application for Clinics, Group Practices, and Certain Other Suppliers.

204. Oxy-Gen also fraudulently induced the Government to enter into a specific Provider Enrollment Agreement to reimburse Oxy-Gen for laboratory services provided to Government beneficiaries by "agree[ing] to abide by the Medicare laws, regulations and program instructions that apply to [Oxy-Gen]" and by certifying its "understand[ing] that payment of a claim by Medicare is conditioned [not only] upon the claim and the underlying transaction complying with such laws, regulations, and program instructions . . . [but also] on [Oxy-Gen's] compliance with all applicable conditions of participation in Medicare. Id.

205. Additionally, Oxy-Gen fraudulently induced the Government to enter into a specific Provider Enrollment Agreement to reimburse Oxy-Gen for laboratory services provided to Government beneficiaries by agreeing "that any existing or future overpayment made to [Oxy-Gen] by the Medicare program may be recouped by Medicare through the withholding of future payments."

206. Oxy-Gen's prospective promises and certifications to comply with the statutes, regulations, and program instructions of the Medicare Program, which were specifically made at the time of enrollment by Oxy-Gen's corporate officer, were false when made, and the Government would not have entered into a Provider

Enrollment Agreement with Oxy-Gen to pay claims associated with its contracted services had it known of Oxy-Gen's unwillingness to comply with such rules.

207. Furthermore, in order to bill or receive funds from Medicare, CMS requires Oxy-Gen (upon the submission of each claim for payment on CMS Form 1500) to certify that it has "provided or will provide sufficient information required to allow the [G]overnment to make an informed eligibility and payment decision;" that the "claim . . . complies with all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment;" and that "the services . . . were medically necessary." By making these certifications on each CMS Form 1500 submitted and providing misleadingly incomplete information regarding its noncompliance with the statutes, regulations, and program instructions of the Medicare Program, Oxy-Gen fraudulently induced the Government to enter contracts to pay claims that it otherwise would not have paid. Specifically, Oxy-Gen's false certification of compliance with the Anti-Kickback statute and Medicare regulations enacted to ensure the medical necessity of lab tests, which were material to the Government's decision to reimburse Oxy-Gen for laboratory services provided to Government beneficiaries, was misleadingly incomplete such that it amounted to fraud.

208. The original fraud that influenced the Government's decision to enter into a Provider Enrollment Agreement or pay a claim submitted on a CMS Form 1500 "pressed ever to the ultimate goal—payment of government money to persons who had caused it to be defrauded." *Marsteller for the use and Benefit of United States v. Tilton*, 880 F.3d 1302, 1314 (11th Cir. 2018). Oxy-Gen's false and fraudulent statements and omissions, which were material to the Government's decision to pay and had a natural tendency to influence the payment of money, were designed and offered to induce the Government to enter contracts in reliance thereof and to pay Oxy-Gen for laboratory services.

209. Oxy-Gen's omission of critical qualifying information and material facts regarding its compliance with regulations, which were designed to ensure the medical necessity of laboratory services, was an actionable misrepresentation intended to induce the Government to pay money it otherwise would not have paid and resulted in false claims (representative examples of which are provided in paragraphs 145, 165, 168, 171, 179, 194 above) being submitted to and paid by Medicare, Medicaid, and other Government payors.

210. Oxy-Gen knowingly and fraudulently retained each payment that was improperly received from Medicare, Medicaid, and other Government payors

based upon its misrepresentations, false statements, and certifications to induce such payment.

Oxy-Gen Knew or Should Have Known its Conduct was Fraudulent

211. Defendants had actual knowledge of, recklessly disregarded, or acted with deliberate indifference as to Medicare, TRICARE, and Medicaid requirements and the submission of false claims for payment to federal and state health care payors.

212. At all times in his role as manager of Oxy-Gen, Defendant Toure had actual knowledge of, recklessly disregarded, or acted with deliberate indifference as to Oxy-Gen's improper and fraudulent solicitation of patients and billing procedures.

213. All of Oxy-Gen's claims for reimbursement are submitted in-house by Defendant Midjola.

214. At all times in her role as billing manager at Oxy-Gen, Defendant Midjola had actual knowledge of, recklessly disregarded, or acted with deliberate indifference as to Oxy-Gen's improper and fraudulent billing procedures.

215. In fact, Medicare representatives informed Oxy-Gen of certain improper billing procedures, and on one occasion, Defendant Midjola responded: "Why would I downcode and get paid less?"

216. Relator Donnell informed Defendants Toure and Midjola on numerous occasions that Oxy-Gen's solicitation of patients and billing procedures were improper.

217. For example, in late 2018, Relator Donnell spoke with Defendant Toure about Oxy-Gen's improper use of modifiers, but Defendant Toure ignored Relator Donnell's concerns and continued to fraudulently use the modifiers.

218. On another occasion, Relator Donnell sent an email to Defendant Toure about Dr. Ellis, the physician who ordered test services for Indiana patients despite not being licensed in Indiana. After receiving no response, Relator Donnell spoke directly with Toure about Dr. Ellis, but Defendant Toure again ignored Relator Donnell's concerns.

219. Finally, when Relator Donnell spoke with Defendant Midjola about Oxy-Gen's improper billing practices, Defendant Midjola responded: "Why would I downcode and get paid less?"

220. By devising and implementing the above fraudulent practices and instructing Oxy-Gen's employees to effectuate such practices, Defendant Toure knowingly caused Oxy-Gen to present the above false claims to Government payors and to make false records and statements material to such claims.

221. Alternatively, Defendant Toure deliberately ignored and/or recklessly disregarded the falsity of the information Oxy-Gen submitted to Government payors to obtain reimbursement for exorbitant amounts and, likewise, deliberately ignored or recklessly disregarded the fraudulent practices of Oxy-Gen's employees.

Materiality of Oxy-Gen's Fraudulent Conduct

222. The provision of medically necessary laboratory tests is the essential service that forms the heart of the bargain upon which the Government pays for Oxy-Gen's lab services.

223. The systemic fraudulent conduct described herein precluded Oxy-Gen's ability to provide tests that were medically necessary, a service at the heart of its bargain with the Government, and Oxy-Gen's false certification to the contrary was clearly material to the Government's decision to pay claims.

224. Furthermore, Oxy-Gen's compliance with the regulations described herein was material to the Government's decision to pay claims because the regulations relate specifically to ensuring medical necessity, and Medicare, Medicaid, and other Government payors would not have paid claims premised upon tests that Oxy-Gen could not have ensured were medically necessary.

225. Based upon Oxy-Gen's inability to ensure the medical necessity of its tests, Medicare, Medicaid, and other Government payors would not have paid claims for lab tests that Oxy-Gen could not truthfully certify were "reasonable and necessary for the diagnosis and treatment of illness . . . or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A).

226. Oxy-Gen's compliance with the regulations cited herein was a precondition to receiving reimbursement from Medicare, TRICARE, Medicaid, and all other Government payors, and Oxy-Gen's noncompliance with the regulations as described herein resulted in Oxy-Gen's presentation of false claims to Medicare, Medicaid, and all other Government payors.

227. As an example that Oxy-Gen knew compliance with the regulations cited herein was material to the Government's decision to pay and was a precondition to receiving Government reimbursement, one of Oxy-Gen's ordering

physicians, Dr. Ellis, was charged with conspiracy to commit health care fraud for ordering genetic tests for patients he never saw or treated.

228. Additionally, Oxy-Gen's compliance with the Anti-Kickback Statute is material to the Government's decision to pay claims submitted as a result of the illegal kickback. Anti-kickback violations are inherently material, and the Government would not have paid claims Oxy-Gen submitted for lab tests procured through illegal referrals, which were based upon Oxy-Gen's payment of remuneration to distributors and patients.

COUNT I
Violation of the False Claims Act
31 U.S.C. § 3729(a)(1)(A)

229. Relator Donnell incorporates herein by reference and re-alleges the allegations set forth in Paragraphs 1 - 228.

230. The False Claims Act imposes liability on any person who knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval. *See* 31 U.S.C. § 3729(a)(1)(A).

231. Defendants knowingly present or cause to be presented to the United States false claims in order to obtain payment or approval under federally funded programs.

232. The United States, unaware of the falsity of the claims made by Defendants, and in reliance on the accuracy thereof, pay Defendants for such false claims.

233. By reasons of the acts and conduct of Defendants in violation of 31 U.S.C. § 3729(a)(1)(A), the United States has suffered actual damages.

234. By virtue of these false claims, Defendants are jointly and severally liable to the United States for incurred damages resulting from such false claims, trebled, plus civil penalties for each violation of the Act.

COUNT II
Violation of the False Claims Act
31 U.S.C. § 3729(a)(1)(B)

235. Relator Donnell incorporates herein by reference and re-alleges the allegations set forth in Paragraphs 1 - 228.

236. The False Claims Act imposes liability on any person who knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim. *See* 31 U.S.C. § 3729(a)(1)(B).

237. Defendants submitted false records or statements to the United States, which were material to their false and fraudulent claims, by expressly and impliedly certifying their compliance (or failing to disclose their noncompliance)

with all relevant federal regulations authorizing such payments when submitting claims for payment (i.e., through CMS Form 1500 and CMS Form 855B).

238. Defendants also submitted false records or statements to the United States, which were material to their false and fraudulent claims, by knowingly misrepresenting that Defendants were entitled to payment and approval for lab services that were not rendered in compliance with all relevant federal regulations (i.e., through CMS Form 1500 and CMS Form 855B) and were based upon fraudulent lab orders.

239. The United States relied on these falsified records when it paid Defendant's claims.

240. By reasons of the acts and conduct of Defendants in violation of 31 U.S.C. § 3729(a)(1)(B), the United States has suffered actual damages.

241. By virtue of these false claims, Defendants are jointly and severally liable to the United States for incurred damages resulting from such false claims, trebled, plus civil penalties for each violation of the Act.

COUNT III
Violation of the Anti-Kickback Statute
42 U.S.C. § 1320a-7b(b)

242. Relator Donnell incorporates herein by reference and re-alleges the allegations set forth in Paragraphs 1 - 228.

243. The Anti-Kickback Statute prohibits offering, paying, soliciting, or receiving anything of value to induce rewards, referrals, or general federal health care business, including Medicare and Medicaid. *See* 42 U.S.C. § 1320a-7b(b).

244. Defendants knowingly performed genetic testing on samples received from customers who were offered kickbacks for providing the samples.

245. The result of Defendants' actions has led the Government to pay for items that resulted from prohibited activities under the Anti-Kickback Statute in order to generate financial compensation for Defendants at the expense of the Government.

246. By reasons of the acts and conduct of Defendants in violation of 42 U.S.C. § 1320a-7b(b), the United States has suffered actual damages.

COUNT IV
Violation of the Colorado Medicaid False Claims Act
Colo. Rev. Stat. § 25.5-4-305(1)(a)

247. Relator Donnell incorporates herein by reference and re-alleges the allegations set forth in Paragraphs 1 - 228.

248. The Colorado Medicaid False Claims Act imposes liability on any person who knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval. *See* Colo. Rev. Stat. § 25.5-4-305(1)(a).

249. Defendants knowingly present or cause to be presented to the State of Colorado false claims in order to obtain payment or approval under the Colorado Medicaid Program.

250. The State of Colorado, unaware of the falsity of the claims made by Defendants, and in reliance on the accuracy thereof, pay Defendants for such false claims.

251. By reasons of the acts and conduct of Defendants in violation of Colo. Rev. Stat. § 25.5-4-305(1)(a), the State of Colorado has suffered actual damages.

252. By virtue of these false claims, Defendants are jointly and severally liable to the State of Colorado for incurred damages resulting from such false

claims, up to an amount equal to the civil penalty allowed under the Federal False Claims Act. *See* Colo. Rev. Stat. § 25.5-4-305(1).

COUNT V
Violation of the Colorado Medicaid False Claims Act
Colo. Rev. Stat. § 25.5-4-305(1)(b)

253. Relator Donnell incorporates herein by reference and re-alleges the allegations set forth in Paragraphs 1 - 228.

254. The Colorado Medicaid False Claims Act imposes liability on any person who knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim. *See* Colo. Rev. Stat. § 25.5-4-305(1)(b).

255. Defendants submitted false records or statements to the State of Colorado, which were material to their false and fraudulent claims, by expressly and impliedly certifying their compliance (or failing to disclose their noncompliance) with all relevant regulations authorizing such payments when submitting claims for payment.

256. Defendants also submitted false records or statements to the State of Colorado, which were material to their false and fraudulent claims, by knowingly misrepresenting that Defendants were entitled to payment and approval for lab

services that were not rendered in compliance with all relevant regulations and were based upon fraudulent lab orders.

257. The State of Colorado relies on these falsified records when it pays Defendants' claims.

258. By reasons of the acts and conduct of Defendants in violation of Colo. Rev. Stat. § 25.5-4-305(1)(b), the State of Colorado has suffered actual damages.

259. By virtue of these false claims, Defendants are jointly and severally liable to the State of Colorado for incurred damages resulting from such false claims, up to an amount equal to the civil penalty allowed under the Federal False Claims Act. *See* Colo. Rev. Stat. § 25.5-4-305(1).

COUNT VI
Violation of the Georgia False Medicaid Claims Act
O.C.G.A. § 49-4-168.1(a)(1)

260. Relator Donnell incorporates herein by reference and re-alleges the allegations set forth in Paragraphs 1 - 228.

261. The Georgia False Medicaid Claims Act imposes liability on any person who knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval. *See* O.C.G.A. § 49-4-168.1(a)(1).

262. Defendants knowingly present or cause to be presented to the State of Georgia false claims in order to obtain payment or approval under the Georgia Medicaid Program.

263. The State of Georgia, unaware of the falsity of the claims made by Defendants and in reliance on the accuracy thereof, pay Defendants for such false claims.

264. By reasons of the acts and conduct of Defendants in violation of O.C.G.A. § 49-4-168.1(a)(1), the State of Georgia has suffered actual damages.

265. By virtue of these false claims, Defendants are jointly and severally liable to the State of Georgia for penalties consistent with the civil penalties provision of the Federal False Claims Act. *See* O.C.G.A. § 49-4-168.1(a).

COUNT VII
Violation of the Georgia Medicaid False Claims Act
O.C.G.A. § 49-4-168.1(a)(2)

266. Relator Donnell incorporates herein by reference and re-alleges the allegations set forth in Paragraphs 1 - 228.

267. The Georgia False Medicaid Claims Act imposes liability on any person who knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim. *See* O.C.G.A. § 49-4-168.1(a)(2).

268. Defendants submitted false records or statements to the State of Georgia, which were material to their false and fraudulent claims, by expressly and impliedly certifying their compliance (or failing to disclose their noncompliance) with all relevant regulations authorizing such payments when submitting claims for payment.

269. Defendants also submitted false records or statements to the State of Georgia, which were material to their false and fraudulent claims, by knowingly misrepresenting that Defendants were entitled to payment and approval for lab services that were not rendered in compliance with all relevant regulations and were based upon fraudulent lab orders.

270. The State of Georgia relies on these falsified records when it pays Defendants' claims.

271. By reasons of the acts and conduct of Defendants in violation of O.C.G.A. § 49-4-168.1(a)(2), the State of Georgia has suffered actual damages.

272. By virtue of these false claims, Defendants are jointly and severally liable to the State of Georgia for penalties consistent with the civil penalties provision of the Federal False Claims Act. *See* O.C.G.A. § 49-4-168.1(a).

COUNT VIII
Violations of the Indiana False Claims and Whistleblower Protection Act
IND. CODE § 5-11-5.7-2(a)(1)

273. Relator Donnell incorporates herein by reference and re-alleges the allegations set forth in Paragraphs 1 - 228.

274. Ind. Code § 5-11-5.7-2(a)(1) imposes liability on a person knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval.

275. Defendants knowingly present or cause to be presented to the state of Indiana, false claims, in order to obtain payment or approval under the Indiana Medicaid program.

276. Defendants knowingly made or caused to be made, false records or statements material to the false and fraudulent claims when they used referrals that were fraudulently completed to indicate medical necessity.

277. Indiana, unaware of the falsity of the claims made by Defendants, and in reliance on the accuracy thereof, pay Defendants for such false claims.

278. By reasons of the acts and conduct of Defendants in violation of Ind. Code § 5-11-5.7-(2)(a)(1), the State of Indiana has suffered actual damages.

279. By virtue of these false claims, Defendants are jointly and severally liable to the State of Indiana for penalties consistent with the Indiana Medicaid False Claims and Whistleblower Protection Act, including a penalty of at least $5,500.00, and for up to three times the amount of damages sustained by the state. Ind. Code § 5-11-5.7(a).

COUNT IX
Violations of the Indiana False Claims and Whistleblower Protection Act
Ind. Code § 5-11-5.7-2(a)(2)

280. Relator Donnell incorporates herein by reference and re-alleges the allegations set forth in Paragraphs 1 - 228.

281. Ind. Code § 5-11-5.7-2(a)(2) imposes liability on a person who knowingly makes, uses, or causes to be made or used, a false record or statement that is material to a false or fraudulent claim.

282. Defendants submitted false records or statements to the State of Indiana, which were material to their false claims, by expressly and impliedly certifying their compliance (or failing to disclose their noncompliance) with all relevant regulations authorizing such payments when submitting claims for payment.

283. Defendants also submitted false records or statements to the State of Indiana, which were material to their false claims, by knowingly misrepresenting that Defendants were entitled to payment and approval for lab services that were not rendered in compliance with all relevant regulations and were based upon fraudulent lab orders.

284. The State of Indiana relies on these falsified records when it pays Defendants' claims.

285. By reasons of the acts and conduct of Defendants in violation of Ind. Code § 5-11-5.7-2(a)(2), the State of Indiana has suffered actual damages.

286. By virtue of these false claims, Defendants are jointly and severally liable to the State of Indiana for penalties consistent with the Indiana Medicaid False Claims and Whistleblower Protection Act, including a penalty of at least $5,500.00, and for up to three times the amount of damages sustained by the state. Ind. Code § 5-11-5.7(a).

COUNT X
Violations of the District of Columbia False Claims Act
D.C. Code. § 2-381-.02

287. Relator Donnell incorporates herein by reference and re-alleges the allegations set forth in Paragraphs 1 - 228.

288. D.C. Code. § 2-381-.02(a)(1) imposes liability on a person who knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval.

289. Defendants knowingly present or cause to be presented to the District of Columbia, false claims, in order to obtain payment or approval under the District of Columbia Medicaid program.

290. The District of Columbia, unaware of the falsity of the claims made by Defendants, and in reliance on the accuracy thereof, pay Defendants for such false claims.

291. By reasons of the acts and conduct of Defendants in violation of D.C. Code. § 2-381-.02(a)(1), the District of Columbia has suffered actual damages.

292. By virtue of these false claims, Defendants are jointly and severally liable to the District of Columbia for penalties consistent with the District of Columbia False Claims Act, including a penalty of at least $5,500.00, and for up to three times the amount of damages sustained by the state. D.C. Code. § 2-381-.02(a).

COUNT XI
Violations of the District of Columbia False Claims Act
D.C. Code. § 2-381-.02

293. Relator Donnell incorporates herein by reference and re-alleges the allegations set forth in Paragraphs 1 - 228.

294. D.C. Code. § 2-381-.02(a)(2) imposes liability on a person who knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.

295. Defendants submitted false records or statements to the District of Columbia, which were material to their false claims, by expressly and impliedly certifying their compliance (or failing to disclose their noncompliance) with all relevant regulations authorizing such payments when submitting claims for payment.

296. Defendants also submitted false records or statements to the District of Columbia, which were material to their false claims for medical assistance, by knowingly misrepresenting that Defendants were entitled to payment and approval for lab services that were not rendered in compliance with all relevant regulations and were based upon fraudulent lab orders.

297. The District of Columbia relies on these falsified records when it pays Defendants' claims.

298. By reasons of the acts and conduct of Defendants in violation D.C. Code. § 2-381-.02(a)(2), the District of Columbia has suffered actual damages.

299. By virtue of these false claims, Defendants are jointly and severally liable to the District of Columbia for penalties consistent with the District of Columbia False Claims Act, including a penalty of at least $5,500.00, and for up to three times the amount of damages sustained by the state. D.C. Code. § 2-381-.02(a).

PRAYER FOR RELIEF

WHEREFORE, Relator Donnell, acting on behalf of herself, the United States of America, and the State Plaintiffs, demands and prays that judgment be entered against Defendants for violations of the federal and state False Claims Acts as follows:

(a) In favor of the United States and the State Plaintiffs against Defendants for treble the amount of damages to the federal and state health care programs from the submission of false claims, plus the maximum civil penalties for

each violation of the Federal False Claims Act and for each violation of the applicable analogous state False Claims Act;

(b) In favor of Relator Donnell for the maximum amount pursuant to 31 U.S.C. § 3730(d) and analogous state False Claims Act provision to include reasonable expenses, attorney's fees, and costs incurred by Relator Donnell;

(c) For all costs of the civil action;

(d) In favor of Relator Donnell, the United States, and the State Plaintiffs for further relief as this Court deems to be just and equitable; and

(e) Such other relief as this Court deems appropriate.

JURY DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relator Donnell hereby demands a jury trial.

Respectfully Submitted,

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