MHS/2022R00918

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA	:	Hon.
	:	
v.	:	Criminal No.
	:	
KEATON LANGSTON	:	18 U.S.C. § 1349

I N F O R M A T I O N

The defendant having waived in open court prosecution by Indictment, the Attorney for the United States for the District of New Jersey, acting under authority conferred by 28 U.S.C. § 515, charges:

COUNT ONE
(Conspiracy to Commit Health Care Fraud)

1. Unless otherwise indicated, at all times relevant to this Information:

Background on the Medicare Program and Genetic Testing

a. Medicare was a federally-funded program established to provide medical insurance benefits for individuals age 65 and older and certain disabled individuals who qualified under the Social Security Act. Individuals who receive benefits under Medicare were referred to as "Medicare beneficiaries."

b. Medicare was administered by the Center for Medicare and Medicaid Services ("CMS"), a federal agency under the United States Department of Health and Human Services.

c. Medicare was divided into four parts, which helped cover specific services: Part A (hospital insurance), Part B (medical insurance), Part C (Medicare Advantage), and Part D (prescription drug coverage).

d. Medicare Part B covered non-institutional care that included physician services and supplies, such as durable medical equipment ("DME") and genetic cancer screening ("CGX") tests that were needed to diagnose or treat medical conditions and that met accepted standards of medical practice.

e. Medicare was a "health care benefit program," as defined by 18 U.S.C. § 24(b), and a "Federal health care program," as defined by 42 U.S.C. § 1320a-7b(f), that affected commerce.

DME

f. In order for a supplier of DME services to bill Medicare Part B, that supplier had to enroll with Medicare as a Durable Medical Equipment, Prosthetics, Orthotics, and Supplies ("DMEPOS") supplier by completing a Form CMS-855S.

g. As provided in the Form CMS-855S, to enroll as a DMEPOS supplier, every DMEPOS supplier had to meet certain standards to obtain and retain billing privileges to Medicare, such as, but not limited to, the following: (1) provide complete and accurate information on the Form CMS-855S, with any changes to the information on the form reported within 30 days; (2) disclose persons and organizations with ownership interests or managing control; (3) abide by applicable Medicare laws, regulations and program instructions, such as, but not limited to, the Federal Anti-Kickback Statute ("AKS") (42 U.S.C. § 1320a-7b(b)); (4) acknowledge that the payment of a claim by Medicare was conditioned upon the claim and the underlying transaction complying with such laws, regulations and program instructions; and (5) refrain from knowingly

presenting or causing to be presented a false or fraudulent claim for payment by Medicare and submitting claims with deliberate ignorance or reckless disregard of their truth or falsity.

CGX Tests

h. Genetic tests were laboratory tests designed to identify specific inherited mutations in a patient's genes. These genetic variations affected a patient's risk of developing certain diseases or how the patient responded to medications. CGX Tests were genetic tests related to a patient's hereditary predisposition for cancer.

i. To conduct a genetic test, a laboratory must obtain a DNA sample from the patient. Such samples were typically obtained from the patient's saliva by using a cheek (buccal) swab to collect sufficient cells to provide a genetic profile. The DNA sample was then submitted to the laboratory for analysis, such as CGX Tests.

j. If the patient had insurance, the laboratory would typically submit a claim for reimbursement for the test to the patient's insurance carrier. The claims for payment for CGX Tests sometimes exceeded $10,000, while reimbursement rates for CGX Tests sometimes exceeded approximately $8,000 per test.

k. Medicare excluded from coverage diagnostic 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). To be considered "reasonable and necessary," Medicare

rules required that genetic testing "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." *Id.*

l. In order for a healthcare provider to bill Medicare for services rendered, it had to enroll with Medicare as a Medicare provider or "Supplier." For example, in order to bill Medicare for a CGX Test, a clinical laboratory was first required to complete and submit a Form CMS-855B, the Medicare Enrollment Application for "Clinics/Group Practices and Certain Other Suppliers."

m. As provided in the Form CMS-855B, in order to enroll with Medicare, a supplier of healthcare services such as a clinical laboratory had to, among other things, certify the following: (1) the supplier understood that any deliberate omission, misrepresentation, or falsification of any information on the Form CMS-855B could be punished by criminal, civil, or administrative penalties; (2) the supplier agreed to abide by applicable Medicare laws, regulations, and program instructions, such as, but not limited to, the AKS; (4) the supplier understood that payment of a claim by Medicare was conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions; and (5) the supplier had to refrain from knowingly presenting or causing to be presented a false or fraudulent claim for

payment by Medicare and submitting claims with deliberate ignorance or reckless disregard of their truth or falsity.

Compounded Drugs

n. In general, "compounding" was a practice in which a licensed pharmacist, or a licensed physician, combined, mixed, or altered ingredients of a drug to create a medication tailored to the needs of an individual patient. Pharmacies engaged in the practice of compounding were referred to as "compounding pharmacies."

o. Compounded drugs were not approved by the Food and Drug Administration ("FDA"); that is, the FDA did not verify the safety, potency, effectiveness, or manufacturing quality of compounded drugs.

p. Generally, compounded drugs were prescribed by a physician when an FDA-approved drug did not meet the health needs of a particular patient. For example, if a patient was allergic to a specific ingredient in an FDA-approved medication, such as a dye or preservative, a compounded drug could be prepared excluding the substance that triggered the allergic reaction. Compounded drugs also could be prescribed when a patient could not consume a medication by traditional means, such as an elderly patient or child who could not swallow an FDA-approved pill and needed the drug in a liquid form that was not otherwise available.

q. Medicare-authorized suppliers of healthcare services, such as clinical laboratories, DMEPOS suppliers, and pharmacies, could only submit claims to Medicare for reasonable and medically necessary services. Medicare

would not reimburse claims for services that it knew were neither reasonable nor medically necessary. Likewise, Medicare would not reimburse claims for services that it knew were procured through kickbacks or bribes. Such claims were deemed false and fraudulent because they violated Medicare laws, regulations, and program instructions, as well as violated federal criminal law. For example, where a CGX Test, a DME order, or a prescription for a compounded drug was procured through the payment of a kickback in violation of the AKS, a claim to Medicare for reimbursement for that test, order, or prescription was fraudulent. By implementing these restrictions, Medicare aimed to preserve its resources, which were largely funded by United States taxpayers, for those elderly and other qualifying beneficiaries who had a need for genuine medical services.

TRICARE

r. TRICARE was a health care program of the United States Department of Defense ("DoD") Military Health System that provided coverage for DoD beneficiaries worldwide, including active-duty service members, National Guard and Reserve members, retirees, their families, and survivors. The Defense Health Agency, an agency of the DoD, was the military entity responsible for overseeing and administering the TRICARE program.

s. TRICARE was a "health care benefit program," as defined by Title 18, United States Code, § 24(b), and a "Federal health care program," as defined by Title 42, United States Code, § 1320a-7b(f), that affected commerce.

CHAMPVA

t. The Civilian Health and Medical Program of the Department of Veterans Affairs ("CHAMPVA") was a federal health care benefit program within the Department of Veterans Affairs ("VA"). CHAMPVA was a comprehensive health care program in which the VA shared the cost of covered health care services and supplies with eligible beneficiaries. The eligible categories for CHAMPVA beneficiaries were the spouses or children of veterans who had been rated permanently and totally disabled for a service-connected disability and the surviving spouse or child of a veteran who died from a VA-rated service-connected disability.

u. In general, the CHAMPVA program covered most health care services and supplies that were medically and psychologically necessary. CHAMPVA was always the secondary payer to Medicare and reimbursed beneficiaries for costs that Medicare did not cover. Health care claims had to have first been sent to Medicare for processing. Medicare electronically forwarded claims to CHAMPVA after Medicare had processed them.

v. CHAMPVA was a "health care benefit program," as defined by Title 18, United States Code, § 24(b), and a "Federal health care program," as defined by Title 42, United States Code, § 1320a-7b(f), that affected commerce.

Relevant Individuals and Entities

w. Defendant KEATON LANGSTON ("defendant LANGSTON") was a resident of Mississippi. Defendant LANGSTON and other individuals owned, operated, and had financial interests in a clinical laboratory (the "Subject

Laboratory"), pharmacies (collectively, the "Subject Pharmacies"), and durable medical equipment ("DME") supply companies (collectively, the "Subject DME Companies") located in the United States.

The Subject Laboratory

x. DANIEL HURT, a co-conspirator not charged in this Information, was a resident of Florida.

y. Defendant LANGSTON, HURT, and other individuals owned, operated, and had financial interests in the Subject Laboratory, which conducted or arranged for a variety of medical tests.

z. Defendant LANGSTON, HURT, and others enrolled the Subject Laboratory as a Medicare supplier and were approved to bill Medicare for medically necessary CGX Tests. Pursuant to the requirements described above, the Subject Laboratory was responsible for acknowledging that any claims made to Medicare complied with the relevant laws, regulations, and program instructions.

The Subject DME Companies

aa. AARON WILLIAMSKY ("WILLIAMSKY") and NADIA LEVIT ("LEVIT"), co-conspirators not charged in this Information, were each residents of New Jersey who owned, operated, and/or had financial or controlling interests with others in numerous DME supply companies located in New Jersey and elsewhere (the "WILLIAMSKY/LEVIT DME Companies"), including the Subject

DME Companies. The WILLIAMSKY/LEVIT DME Companies primarily supplied DME such as knee, ankle, back, wrist, and shoulder braces.

bb. DOMENIC J. GATTO, JR. ("GATTO"), a co-conspirator not charged in this Information, was a resident of Florida.

cc. BRIAN HERBSTMAN ("HERBSTMAN"), a co-conspirator not charged in this Information, was a resident of New Jersey.

dd. DME Company-1 and DME Company-2, two of the Subject DME Companies, were DME supply companies located in New Jersey and Florida, respectively. Defendant LANGSTON—together with WILLIAMSKY, LEVIT, HERBSTMAN, and GATTO—owned DME Company-1 and DME Company-2. DME Company-1 and DME Company-2 were registered DMEPOS suppliers with Medicare. Defendant LANGSTON and his co-conspirators concealed their affiliation with DME Companies-1 and -2 by failing to disclose themselves as owners to Medicare.

The Subject Pharmacies

ee. Defendant LANGSTON and other individuals owned, operated, and had financial interests in the Subject Pharmacies, which conducted or arranged for a variety compounded medications.

ff. CHRISTOPHER CIRRI ("CIRRI") and NICHOLAS DEFONTE ("DEFONTE"), co-conspirators not charged in this Information, jointly owned, operated, and had a financial interest in various entities located in New Jersey (the "CIRRI/DEFONTE Supply Companies") through which defendant CIRRI and

DEFONTE obtained doctors' orders for DME ("DME Orders") and prescriptions for compounded medications ("Compound Orders").

The Conspiracy

2. From at least as early as April 2017 through in or around November 2021, in the District of New Jersey, and elsewhere, the defendant,

KEATON LANGSTON,

did knowingly and intentionally conspire and agree with others to knowingly and willfully execute, and attempt to execute, a scheme and artifice to defraud a health care benefit program and to obtain, by means of false and fraudulent pretenses, representations, and promises, any of the money owned by, and under the custody and control of, a health care benefit program, as defined by 18 U.S.C. § 24(b), in connection with the delivery of or payment for health care benefits, items and services, contrary to Title 18, United States Code, Section 1347.

Goal of the Conspiracy

3. The goal of the conspiracy was for defendant LANGSTON and others to profit by submitting or causing the submission of false and fraudulent claims for DME Orders, Compound Orders, and CGX Tests to federal and private health care benefit programs.

Manner and Means of the Conspiracy

4. The manner and means by which defendant LANGSTON and others sought to accomplish the goal of the conspiracy included, among other things, the following:

The Subject Laboratory

a. Defendant LANGSTON, HURT, and others (through the Subject Laboratory) entered into kickback agreements with individuals who operated entities that targeted Medicare beneficiaries for CGX Tests (the "CGX Suppliers"). Under these agreements, defendant LANGSTON, HURT, and others paid kickbacks to the CGX Suppliers for each Medicare beneficiary the Suppliers referred to defendant LANGSTON and others if the beneficiaries ultimately received CGX Tests from the Subject Laboratory, without regard for medical necessity. The Subject Laboratory submitted claims for payment to Medicare for these CGX Tests. Medicare reimbursed the Subject Laboratory without knowing that the services were not medically necessary or were procured through the payment of kickbacks.

b. Generally speaking, in order to generate referrals and orders for CGX Tests, CGX Suppliers used a variety of methods, including making cold calls, using targeted Internet advertisements, and making in-person solicitations for various medical services to elderly Medicare beneficiaries across the United States, including New Jersey. Through the CGX Suppliers, targeted beneficiaries were questioned to determine whether they met certain eligibility requirements for the relevant test. Once the Suppliers identified an eligible beneficiary, the Suppliers worked with a network of telemedicine health care providers to generate prescriptions for CGX Tests. In general, those health care providers were not treating the beneficiaries for any symptoms or conditions, but instead

intended to provide those pre-screened beneficiaries with prescriptions for CGX Tests regardless of medical necessity.

c. Once the CGX Suppliers obtained prescriptions, the CGX Suppliers sent testing kits to the beneficiaries. Beneficiaries then completed the buccal swab or other testing mechanism contained in the kit and returned it to the CGX Suppliers or the Subject Laboratory. Defendant LANGSTON knew that the CGX Suppliers were not treating beneficiaries for a specific medical problem or using the CGX Test results in the management of the beneficiary's specific medical problem.

d. Ultimately, defendant LANGSTON (through the Subject Laboratory) electronically submitted or caused the electronic submission of fraudulent claims to Medicare and other health care benefit programs for payment for each of the CGX Tests.

e. Defendant LANGSTON (through the Subject Laboratory) paid kickbacks to CGX Suppliers for each CGX Test that was billed to Medicare and other health care benefit programs.

f. To conceal the payments of bribes in exchange for referral of patients for CGX Tests that were not medically necessary, defendant LANGSTON, HURT, and others (through the Subject Laboratory) and the CGX Suppliers entered into sham contracts in order to make it appear that the Suppliers were engaged in, and being paid for, legitimate marketing and referral services for the Subject Laboratory (the "CGX Agreements"). The CGX Agreements provided, among other things, that the Subject Laboratory would pay the CGX Suppliers

based on the hours and expenses incurred or on a flat-rate basis. In reality, defendant LANGSTON and the CGX Suppliers understood that payments were on a per-test basis.

The Subject Pharmacies and the Subject DME Companies

g. As they did with the Subject Laboratory, Defendant LANGSTON and his co-conspirators also entered into kickback agreements with suppliers (the "RX Order Suppliers") who could regularly provide the Subject Pharmacies and the Subject DME Companies with DME Orders and Compound Orders (collectively, "RX Orders"). Defendant LANGSTON and his co-conspirators used the Subject Pharmacies and Subject DME Companies to bill federal and private health care benefit programs for RX Orders without regard for medical necessity. The process involved multiple layers of kickbacks, intermediaries, and unlawful conduct, as set forth below.

h. Generally, RX Order Suppliers (including CIRRI and DEFONTE) generated RX Orders in the same manner as the CGX Suppliers generated referrals and orders for CGX Tests. RX Order Suppliers (including CIRRI and DEFONTE) first identified qualified beneficiaries located in New Jersey and elsewhere through the use of marketing call centers under their direction. Once beneficiaries were identified by the marketers, RX Order Suppliers (including CIRRI and DEFONTE) utilized the services of telemedicine companies

to secure RX Orders, regardless of whether the prescriptions were medically justified for the beneficiaries.

i. After obtaining RX Orders, RX Order Suppliers (including CIRRI and DEFONTE) transmitted and caused to be transmitted the RX Orders to providers for processing, including the Subject DME Companies and the Subject Pharmacies, who in turn billed Medicare, TRICARE, CHAMPVA, and other federal and private health care benefit programs. Defendant LANGSTON and his co-conspirators paid kickbacks to the RX Order Suppliers (including CIRRI and DEFONTE) for each RX Order that resulted in reimbursement from a paying health care benefit program.

j. Beginning at least as early as April 2017, CIRRI and DEFONTE (through the CIRRI/DEFONTE Supply Companies) agreed with defendant LANGSTON to provide Compound Orders to the Subject Pharmacies in exchange for kickbacks from defendant LANGSTON and his co-conspirators for each Compound Order that resulted in a reimbursement from a federal or private health care benefit program. Defendant LANGSTON and his co-conspirators thereafter paid kickbacks to CIRRI and DEFONTE for each Compound Order that resulted in reimbursement from a paying health care benefit program.

k. In or around April 2017, defendant LANGSTON and GATTO agreed that RX Order Suppliers associated with GATTO would provide Compound Orders to one of defendant LANGSTON's Subject Pharmacies in exchange for kickbacks of a portion of the reimbursement from Medicare and

other health care benefit programs. In exchange for brokering the arrangement between LANGSTON and the RX Order Suppliers, defendant LANGSTON agreed to provide GATTO a kickback for each Compound Order provided by the RX Order Suppliers to the Subject Pharmacies that was subsequently reimbursed by a federal or private health care benefit program.

l. Beginning in or around January 2018, defendant LANGSTON, GATTO, HERBSTMAN, WILLIAMSKY, and others agreed that WILLIAMSKY would arrange for the RX Order Suppliers he used in connection with the WILLIAMSKY/LEVIT DME Companies to provide Compound Orders to the Subject Pharmacies in exchange for kickbacks of a portion of the reimbursement from Medicare and other health care benefit programs. In exchange for their brokering of the kickback relationship between the RX Order Suppliers and the Subject Pharmacies, defendant LANGSTON agreed to provide WILLIAMSKY and GATTO a kickback for each Compound Order provided by the RX Order Suppliers to the Subject Pharmacies that was subsequently reimbursed by a federal or private health care benefit program.

m. Beginning in or around March 2018, defendant LANGSTON, GATTO, HERBSTMAN, WILLIAMSKY, LEVIT, CIRRI, and DEFONTE agreed that CIRRI and DEFONTE would provide DME Orders to the Subject DME Companies in return for approximately $265 in kickbacks for each DME Order procured. In exchange for their brokering of the kickback relationship between CIRRI and DEFONTE (through the CIRRI/DEFONTE Supply Companies) and WILLIAMSKY and LEVIT, CIRRI and DEFONTE agreed to pay defendant LANGSTON, GATTO,

and HERBSTMAN a kickback of approximately $30 (and later, $10) for each DME Order that CIRRI and DEFONTE provided to the WILLIAMSKY/LEVIT DME Companies (including the Subject DME Companies). Defendant LANGSTON and his co-conspirators thereafter received kickbacks from CIRRI and DEFONTE for DME Orders that CIRRI and DEFONTE provided to the WILLIAMSKY/LEVIT DME Companies (including the Subject DME Companies).

n. Beginning in or around April 2018, defendant LANGSTON, GATTO, HERBSTMAN, CIRRI, and DEFONTE agreed that WILLIAMSKY would provide CIRRI and DEFONTE with information about the Medicare beneficiaries for whom the WILLIAMSKY/LEVIT DME Companies had previously provided DME. CIRRI and DEFONTE would use the information to generate Compound Orders in the manner described above and then provide those Compound Orders to the Subject Pharmacies in exchange for kickbacks of a portion of the reimbursement from Medicare and other health care benefit programs. In exchange for his role in brokering the kickback relationship between CIRRI and DEFONTE and the Subject Pharmacies, defendant LANGSTON agreed to provide GATTO kickbacks for the Compound Orders provided by CIRRI and DEFONTE to the Subject Pharmacies. GATTO, in turn, would pay kickbacks to HERBSTMAN. CIRRI and DEFONTE similarly agreed to provide WILLIAMSKY kickbacks for his role in facilitating the agreement.

* * * *

o. Defendant LANGSTON and his co-conspirators knew that the claims to Medicare and other federal and private health care benefit programs

for each of the CGX Tests and RX Orders were fraudulent because they were (i) procured through the payment of kickbacks and bribes and therefore not eligible for federal reimbursement; (ii) medically unnecessary; and/or (ii) approved by providers not treating the beneficiary.

p. As a result of defendant LANGSTON's participation in the health care fraud scheme, from at least as early as in or around April 2017 through in or around November 2021, Medicare and other health care benefit programs paid the Subject Laboratory, the Subject DME Companies, and the Subject Pharmacies at least approximately $51,166,032 for CGX Tests and RX Orders that were the product of the illicit scheme. Defendant LANGSTON received at least approximately $10,038,295 from these reimbursements.

All in violation of Title 18, United States Code, Section 1349.

FORFEITURE ALLEGATIONS

1. Upon conviction of the offense alleged in this Information, defendant LANGSTON shall forfeit to the United States, pursuant to 18 U.S.C. § 982(a)(7), all property, real or personal, that constitutes or is derived, directly and indirectly, from gross proceeds traceable to the commission of the offense (as defined in 18 U.S.C. § 24) alleged in this Information, which was at least approximately $10,038,295.

SUBSTITUTE ASSETS PROVISION
(Applicable to All Forfeiture Allegations)

2. If any of the above-described forfeitable property, as a result of any act or omission of the defendant:

(a) cannot be located upon the exercise of due diligence;

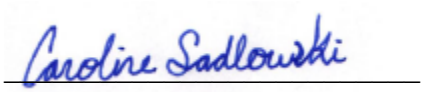
(b) has been transferred or sold to, or deposited with, a third person;

(c) has been placed beyond the jurisdiction of the Court;

(d) has been substantially diminished in value; or

(e) has been commingled with other property which cannot be subdivided without difficulty;

the United States shall be entitled to forfeiture of substitute property, pursuant to 21 U.S.C. § 853(p), as incorporated by 18 U.S.C. § 982(b).



CAROLINE SADLOWSKI
Attorney for the United States,
Acting Under Authority Conferred
By 28 U.S.C. § 515

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INFORMATION FOR

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CAROLINE SADLOWSKI
ATTORNEY FOR THE UNITED STATES
ACTING UNDER AUTHORITY CONFERRED
BY 28 U.S.C. § 515
NEWARK, NEW JERSEY

MATTHEW SPECHT
ASSISTANT U.S. ATTORNEY
(973) 353-6061