

2022R00557/RV

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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

JUL 19 2022

AT 8:30 _____ M
WILLIAM T. WALSH
CLERK

UNITED STATES OF AMERICA	:	Hon. Michael A. Shipp
	:	
	:	Crim. No. 22-485 (MAS)
v.	:	
	:	18 U.S.C. § 1349
	:	
VINIT PATEL	:	

INFORMATION

The defendant having waived in open court prosecution by indictment, the United States Attorney for the District of New Jersey charges:

(Conspiracy to Commit Health Care Fraud)

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

The Defendant

a. Defendant VINIT PATEL was a licensed medical doctor, resident of Alabama, and enrolled Medicare provider.

The Laboratories

b. Express Diagnostics, LLC (“Express Diagnostics”) was a New Jersey limited liability company located in East Brunswick, New Jersey, that purported to serve as a diagnostic testing laboratory.

c. BioConfirm Laboratory USA, LLC and BioConfirm Laboratories, LLC (collectively, “BioConfirm”) were Georgia limited liability companies located in Doraville, Georgia, that together purported to serve as a diagnostic testing laboratory.

d. Performance Laboratories, LLC (“Performance”) was an Oklahoma limited liability company located in Oklahoma City, Oklahoma, that purported to serve as a diagnostic testing laboratory.

e. Clio Laboratories, LLC (“Clio”) was a Florida and Georgia limited liability company located in Lawrenceville, Georgia, that purported to serve as a diagnostic testing laboratory.

f. Express Diagnostics, BioConfirm, Performance, and Clio are collectively referred to as the “Laboratories.”

g. The Laboratories were enrolled Medicare providers and submitted claims to Medicare for payment.

The Medicare Program

h. The Medicare Program (“Medicare”) was a federally-funded program that provided free or below-cost health care benefits to certain individuals, primarily the elderly, blind, and disabled. Medicare was administered by the Centers for Medicare and Medicaid Services (“CMS”), a federal agency within the U.S. Department of Health and Human Services (“HHS”). Individuals who received Medicare benefits were referred to as Medicare “beneficiaries.”

i. Medicare was divided into multiple parts with separate coverages: Part A covered hospital inpatient care; Part B covered physicians’ services and outpatient care; Part C covered Medicare Advantage Plans; and Part D covered prescription drugs.

j. Medicare was a “Federal health care program,” as defined in Title 42, United States Code, Section 1320a-7b(f), and a “health care benefit program,” as defined in Title 18, United States Code, Section 24(b).

k. Medicare paid claims for items and services only if the items or services were medically reasonable, medically necessary for the treatment or diagnosis of the patient’s illness or injury, documented, and actually provided as represented.

l. Medicare would not pay for items or services that were procured through kickbacks and bribes.

Genetic Testing

m. Genetic tests were laboratory tests designed to identify specific inherited mutations in a patient’s genes.

n. Genetic tests related to a patient’s hereditary predisposition to cancer were commonly referred to as “CGx” tests. These tests used DNA sequencing to detect mutations in genes that could indicate a higher risk of developing certain types of cancers in the future. CGx testing was not a method of diagnosing whether an individual presently had cancer.

o. In order to have a genetic test performed, an individual provided a saliva sample that contained their DNA material. The sample was then transmitted to a laboratory for testing.

p. Medicare did not cover diagnostic testing that was not “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). Except for certain statutory exceptions, Medicare did not cover “[e]xaminations performed for a purpose other than treatment or diagnosis of a specific illness, symptoms, complaint, or injury.” 42 U.S.C. § 411.15(a)(1). Among the statutory exceptions Medicare covered were cancer screening tests such as “screening mammography, colorectal cancer screening tests, screening pelvic exams, [and] prostate cancer screening tests.” *Id.*

q. If diagnostic testing was necessary for the diagnosis or treatment of illness or injury, or to improve the functioning of a malformed body member, Medicare imposed additional regulations before covering the testing. Title 42, Code of Federal Regulations, Section 410.32(a) provided that “all diagnostic x-rays tests, diagnostic laboratory tests, and other diagnostic tests must be ordered by the physician who is treating the beneficiary, that is, a 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. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary.”

The Conspiracy

2. From in or around October 2017, and continuing through in or around April 2019, in the District of New Jersey and elsewhere, defendant

VINIT PATEL

did knowingly and intentionally conspire and agree with others known and unknown, to knowingly and willfully execute a scheme and artifice to defraud a health care benefit program affecting commerce, as defined in Title 18, United

States Code, Section 24(b), that is, Medicare, and to obtain, by means of materially false and fraudulent pretenses, representations, and promises, money and property owned by, and under the custody and control of said health care benefit program, in connection with the delivery of and payment for health care benefits, items, and services, contrary to Title 18, United States Code, Section 1347.

Goal of the Conspiracy

3. It was the goal of the conspiracy for defendant VINIT PATEL and his co-conspirators to unlawfully enrich themselves by, among other things: (a) submitting and causing the submission of false and fraudulent claims to Medicare for genetic tests that were ordered and referred through illegal kickbacks and bribes; (b) submitting and causing the submission of false and fraudulent claims to Medicare for genetic tests that were medically unnecessary, ineligible for reimbursement, and not provided as represented; (c) concealing the submission of false and fraudulent claims to Medicare and the receipt and transfer of the proceeds of the fraud; and (d) diverting proceeds of the fraud for the personal use and benefit of defendant VINIT PATEL and his co-conspirators.

Manner and Means of the Conspiracy

4. The manner and means by which defendant VINIT PATEL and his co-conspirators sought to accomplish the goal of the conspiracy included, among other things, the following:

a. Defendant VINIT PATEL caused to be submitted a Medicare enrollment application in which he certified that he would abide by all applicable

Medicare laws, regulations, and program instructions, including the Federal Anti-Kickback Statute, and that he would not knowingly present or cause to be presented false or fraudulent claims to Medicare.

b. Defendant VINIT PATEL agreed to and did solicit and receive cash kickbacks and bribes from a co-conspirator in exchange for approving genetic tests that the Laboratories and other purported diagnostic testing laboratories billed to Medicare.

c. Defendant VINIT PATEL's co-conspirators solicited Medicare beneficiaries to provide their personal identifying information and a genetic sample. Defendant VINIT PATEL's co-conspirators filled out genetic testing laboratory requisition forms with the beneficiaries' personal identifying information and false information about the beneficiaries' medical history.

d. Defendant VINIT PATEL agreed to and did sign these genetic testing laboratory requisition forms, along with letters of medical necessity, falsely certifying that the tests were medically necessary and would determine the Medicare beneficiaries' medical management and treatment decisions, among other things. These affirmations were false and fraudulent because the tests were not medically necessary and defendant VINIT PATEL was not treating the beneficiaries or managing their care. Defendant VINIT PATEL had no interaction with the Medicare beneficiaries for whom he ordered genetic tests.

e. Defendant VINIT PATEL's co-conspirators referred the genetic testing laboratory requisition forms to the Laboratories and other purported diagnostic testing laboratories in exchange for kickbacks and bribes.

f. Defendant VINIT PATEL and others, through the Laboratories and other purported diagnostic testing laboratories, submitted and caused the submission of approximately \$3.4 million in false and fraudulent claims to Medicare for genetic tests that were procured by the payment of kickbacks and bribes, medically unnecessary, ineligible for reimbursement, and not provided as represented.

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

FORFEITURE ALLEGATIONS
18 U.S.C. § 982(a)(7)

1. The allegations contained in this Information are re-alleged here for the purpose of alleging forfeiture against defendant VINIT PATEL.

2. Pursuant to Title 18, United States Code, Section 982(a)(7), upon being convicted of the crime charged in this Information, defendant VINIT PATEL shall forfeit to the United States any property, real or personal, that constitutes or is derived, directly or indirectly, from gross proceeds traceable to the commission of the offense.

Substitute Assets Provision

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

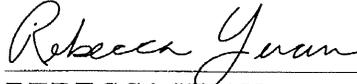
- a. cannot be located upon the exercise of due diligence;
- b. has been transferred or sold to, or deposited with, a third person;
- c. has been placed beyond the jurisdiction of the Court;
- d. has been substantially diminished in value; or
- e. has been commingled with other property which cannot be subdivided without difficulty;

it is the intent of the United States, pursuant to Title 21, United States Code, Section 853(p), as incorporated by Title 18, United States Code, Section 982(b), to seek forfeiture of any other property of defendant VINIT PATEL up to the value of the forfeitable property described above.



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