UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

UNITED STATES OF AMERICA

v.

CASE NO. 8:26-cr-221-MSS-TGW
18 U.S.C. § 371

LEO CORRIGAN

INFORMATION

The United States Attorney charges:

Introduction

At all times material to this Information:

The Defendant and Related Entities

1. Defendant Leo Corrigan resided in the Middle District of Florida.

2. Mainstream Diagnostic Laboratory, LLC was a Florida corporation and enrolled Medicare provider. The defendant had control over Mainstream Diagnostic Laboratory, LLC.

3. JNL Investments, LLC was a Florida corporation. The defendant was the owner and operator of JNL Investments, LLC.

4. Ready Med, LLC was a Florida corporation. The defendant was the owner and operator of Ready Med, LLC.

5. Laboratory 1 was a Colorado corporation and enrolled Medicare provider, and was a call center targeting the Medicare population to generate leads

and obtain personal information ("PII"), including Health Insurance Claim Numbers ("HICNs") and Medicare Beneficiary Identifiers ("MBIs").

6. Laboratory 2 was a Florida corporation and enrolled Medicare provider.

7. Laboratory 3 was an Arizona corporation and enrolled Medicare provider.

8. Marketing Company 1 was in San Salvador, El Salvador.

The Medicare Program

9. The Medicare program ("Medicare") was a federal health care program that provided medical benefits, items, and services to beneficiaries:

a. age 65 or older,

b. under age 65 with certain disabilities, and

c. of all ages with end-stage renal disease (permanent kidney failure requiring dialysis or a kidney transplant).

10. The Centers for Medicare and Medicaid Services ("CMS") was an agency of the U.S. Department of Health and Human Services ("HHS") and was the federal governmental body responsible for the administration of Medicare.

11. Medicare included coverage under component parts. Medicare Part A was a hospital insurance program that covered beneficiaries for, among other types of care, inpatient care in hospitals and other facilities. Medicare Part B was a medical insurance program that covered doctors' services, outpatient care,

diagnostic testing, and some other medical items and services not covered under Part A.

12. Laboratories, pharmacies, physicians, nurse practitioners, and other health care providers that furnished items and services to Medicare beneficiaries were referred to as Medicare "providers." To participate in Medicare, providers were required to submit a Medicare enrollment application, which required providers to certify that they would abide by Medicare laws, regulations, and program instructions, including the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b). If Medicare approved a provider's application, Medicare assigned the provider a Medicare "provider number." A health care provider with a Medicare provider number could file claims with Medicare to obtain reimbursement for medically necessary items and services rendered to beneficiaries.

13. Medicare claims were required to be properly documented in accordance with Medicare rules and regulations. To receive payment from Medicare, providers submitted or caused the submission of claims to CMS that were required to set forth, among other information, the Medicare beneficiary's name and unique Medicare beneficiary identification number, the item or service provided to the beneficiary, the date the item or service was provided, and the cost of the item or service, and the name and unique physician identification number of the physician who prescribed or ordered the item or service.

14. Medicare reimbursed laboratories, pharmacies, and other health care providers for medically necessary items and services rendered to beneficiaries.

Medicare would not reimburse providers for claims for testing, items or services that were procured in violation of the Federal Anti-Kickback Statute, including the provision prohibiting the purchase, sale, and distribution of Medicare beneficiary identification numbers.

Medicare Beneficiary Identification Numbers

15. Each Medicare beneficiary was identified with a unique beneficiary identification number. These beneficiary identification numbers were used to determine a beneficiary's eligibility for Medicare benefits and to submit claims to Medicare seeking reimbursement for covered benefits, items, and services. HICNs and MBIs were two types of Medicare beneficiary identification numbers.

16. HICNs were typically comprised of the beneficiary's social security number and often included one or more additional letters. In 2015, Congress passed the Medicare Access and CHIP Reauthorization Act ("MACRA"), which mandated that CMS phase out the use of social security numbers in the assignment of Medicare beneficiary identification numbers.

17. Following the passage of MACRA, CMS began to assign Medicare beneficiaries MBIs, which were comprised of a unique series of eleven randomly generated numbers and letters. MBIs, like HICNs, were used to identify qualifying beneficiaries in all Medicare transactions such as billing and claim submissions. One purpose of using this randomly generated series of numbers and letters was to improve patient identity protection and prevent identity theft. According to CMS, personal identity theft affected a large and growing number of senior citizens. CMS

implemented the new MBIs in an effort to combat identity theft and safeguard taxpayer dollars.

Over-the-Counter COVID-19 Tests

18. Starting on April 4, 2022, and continuing through the duration of the COVID-19 public health emergency, Medicare covered and paid for over-the-counter COVID-19 tests at no cost to beneficiaries with Medicare Part B and those with Medicare Advantage plans. This program was intended to ensure Medicare beneficiaries had access to COVID-19 tests they needed to stay safe and healthy during the COVID-19 pandemic. Eligible providers capable of providing ambulatory health care services were permitted to distribute to Medicare beneficiaries over-the counter COVID-19 tests that were approved, authorized, or cleared by the U. S. Food and Drug Administration.

19. Medicare would not pay for more than eight over-the-counter COVID19 tests, per calendar month, per Medicare beneficiary. Providers could distribute over-the-counter COVID-19 tests only to Medicare beneficiaries who requested them. Providers were required to keep documentation showing a Medicare beneficiary's request for the tests.

20. Medicare did not cover over-the-counter COVID-19 tests billed by durable medical equipment suppliers or providers who distributed over-the-counter COVID-19 tests to Medicare beneficiaries during an inpatient stay at a hospital or skilled nursing facility.

Cancer Genomic Tests

21. Cancer genomic ("CGx") testing 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.

22. 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)(l)(A). Except for certain statutory exceptions, Medicare did not cover "examinations performed for a purpose other than treatment or diagnosis of a specific illness, symptoms, complaint or injury." 42 C.F.R. § 411.l5(a)(l). 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.*

23. 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 requirements before covering the testing. Title 42, Code of Federal Regulations, Section 410.2(a) provided, "All diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests 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." "Tests not

ordered by the physician who is treating the beneficiary are not reasonable and necessary." *Id.*

24. Because CGx testing did not diagnose cancer, Medicare only covered such tests in limited circumstances, such as when a beneficiary had cancer and the beneficiary's treating physician deemed such testing necessary for the beneficiary's treatment of that cancer. Medicare did not cover CGx testing for beneficiaries who did not have cancer or lacked symptoms of cancer.

COUNT ONE
(Conspiracy to Purchase, Sell, and Distribute Medicare Beneficiary Identification Numbers)

A. Introduction

25. The United States Attorney realleges and incorporates the paragraphs 1, 2, and 9 through 20 of the Introduction to this Information as if fully set forth herein.

B. The Conspiracy

26. From in or around February 2022, and continuing through in or around July 2023, in the Middle District of Florida and elsewhere, the defendant,

LEO CORRIGAN,

did knowingly and willfully combine, conspire, confederate, and agree with others, known and unknown to the United States Attorney, to:

a. defraud the United States out of money and property and by impeding, impairing, obstructing, and defeating the lawful function of HHS, through its agency CMS, in the administration of Medicare, by deceit, craft, and trickery; and

b. purchase, sell, and distribute, and arrange for the purchase, sale, and distribution, of Medicare beneficiary identification numbers, that is, HICNs and MBIs, in violation of 42 U.S.C. § 1320a7b(b)(4).

C. Manner and Means

27. The manner and means by which the defendant and his coconspirators sought to accomplish the purposes of the conspiracy included, among others, the following:

a. It was part of the conspiracy that a coconspirator would and did own and operate Mainstream Diagnostic Laboratory, LLC.

b. It was further part of the conspiracy that LEO CORRIGAN would and did maintain control over Mainstream Diagnostic Laboratory, LLC, and that the conspirators would and did conceal LEO CORRIGAN's interest in the entity;

c. It was further part of the conspiracy that a coconspirator would and did purchase Mainstream Diagnostic Laboratory, LLC, as an enrolled Medicare provider. As part of the change of ownership enrollment application, the coconspirator would and did falsely certify, among other things, that Mainstream Diagnostic Laboratory, LLC would abide by Medicare laws, regulations, and program instructions, including the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b).

d. It was further part of the conspiracy that conspirators would and did fail to disclose LEO CORRIGAN on the Medicare enrollment application for Mainstream Diagnostic Laboratory, LLC, notwithstanding that the enrollment application required disclosure of, among other things, all individuals who have a five percent or greater direct or indirect ownership interest in the applicant and all managing employees of the applicant. "Managing employee" was defined as a general manager, business manager, administrator, director, or other individual who exercised operational or managerial control over, or who directly conducted, the day-to-day operations of the supplier, either under contract or through some other arrangement, regardless of whether the individual was a W-2 employee of the supplier.

e. It was further part of the conspiracy that conspirators would and did pay Marketing Company 1 approximately $210,000 in exchange for Medicare beneficiary identification numbers, including HICNs and MBIs, and other information, for thousands of Medicare beneficiaries throughout the United States.

f. It was further part of the conspiracy that conspirators would and did cause over-the-counter COVID-19 tests to be shipped to those Medicare beneficiaries whose Medicare beneficiary identification numbers had been purchased, regardless of whether the Medicare beneficiaries had requested or needed the tests.

g. It was further part of the conspiracy that conspirators would and did cause Mainstream Diagnostic Laboratory, LLC to submit more than $7.5 million in false and fraudulent claims to Medicare for over-the-counter COVID-19 tests that were medically unnecessary and ineligible for reimbursement, and they would and did cause Medicare to pay more than $3.2 million based on those claims.

h. It was further part of the conspiracy that a coconspirator would and did cause a portion of the Medicare reimbursement payments to be transferred to LEO CORRIGAN and that the coconspirator retained a portion of the Medicare reimbursement payments for his own use.

D. Overt Act

28. LEO CORRIGAN and coconspirators committed various overt acts in furtherance of the conspiracy, and to effect the objects thereof, in the Middle District of Florida and elsewhere. In furtherance of the conspiracy, and to accomplish its object and purpose, at least one coconspirator committed and caused to be committed, in the Middle District of Florida, at least one overt act:

a. On or about February 10, 2023, LEO CORRIGAN sent or caused to be sent an ACH payment to Marketing Company 1 in the amount of $30,000 in exchange for Medicare beneficiary information.

All in violation of 18 U.S.C. § 371.

COUNT TWO
(Conspiracy to Solicit and Receive Remuneration)

A. Introduction

29. The United States Attorney realleges and incorporates the paragraphs 1, 3 through 17, and 21 through 24 of the Information to this Indictment as if fully set forth herein.

B. The Conspiracy

30. From in or around March 2020, and continuing through in or around May 2022, in the Middle District of Florida and elsewhere, the defendant,

LEO CORRIGAN,

did knowingly and willfully combine, conspire, confederate, and agree with others, known and unknown to the United States Attorney, to:

a. defraud the United States out of money and property and by impeding, impairing, obstructing, and defeating the lawful function of HHS, through its agency CMS, in the administration of Medicare, by deceit, craft, and trickery; and

b. knowingly and willfully solicit and receive remuneration (including kickbacks and bribes) directly and indirectly, overtly and covertly, in cash and in kind, in return for ordering, and arranging for and recommending ordering any service and item for which payment may be made in whole and in part under a Federal health care program in return for ordering medical services and items to be provided to Medicare beneficiaries.

C. Manner and Means

31. The manner and means by which the defendant and his coconspirators sought to accomplish the purposes of the conspiracy included, among others, the following:

a. It was part of the conspiracy that LEO CORRIGAN would and did own and operate JNL Investments, LLC and Ready Med, LLC.

b. It was further part of the conspiracy that LEO CORRIGAN and his coconspirators would and did obtain access to the PII and purported personal health information of hundreds of Medicare beneficiaries.

c. It was further part of the conspiracy that LEO CORRIGAN and his coconspirators would and did provide the Medicare beneficiaries' PII and purported personal health information to medical providers that had no relationship to the Medicare beneficiaries to sign orders for genetic testing and other items and services that could be billed to Medicare.

d. It was further part of the conspiracy that LEO CORRIGAN and his coconspirators would and did transfer orders for genetic testing and other items and services for Medicare beneficiaries to entities owned by their client coconspirators—including Laboratories 1, 2, and 3—in exchange for payments in the form of kickbacks and bribes, understanding that the orders would be used to support false and fraudulent claims submitted to Medicare.

e. It was further part of the conspiracy that LEO CORRIGAN would and did receive, via check, wire, and/or ACH, at least $1,790,845 in illegal kickbacks and bribes.

f. It was further part of the conspiracy that the conspirators who owned and operated the laboratories would and did use the orders obtained through bribes and kickbacks to support false and fraudulent claims to Medicare.

g. It was further part of the conspiracy that LEO CORRIGAN and his coconspirators would and did disguise and conceal the nature and source of the kickbacks and bribes by, among other conduct, entering into sham contracts that hid the true nature of the payments.

h. It was further part of the conspiracy that LEO CORRIGAN and his coconspirators would and did facilitate the submission of false and fraudulent claims to Medicare resulting in payments of at least $4,267,646.74 for genetic testing services that were ineligible for Medicare reimbursement because they were procured through the payment of illegal kickbacks and bribes, medically unnecessary, and/or not provided as represented.

i. It was further part of the conspiracy that conspirators would and did participate in meetings, perform various acts, and make statements to accomplish the objects of the conspiracy and to conceal the conspiracy.

D. Overt Act

32. LEO CORRIGAN and coconspirators committed various overt acts in furtherance of the conspiracy, and to effect the objects thereof, in the Middle District

of Florida and elsewhere. For example, on or about the dates set forth below, each of which constitutes a separate overt act, LEO CORRIGAN and his coconspirators from Laboratory 1 caused the following wire transfers of funds, which constituted kickbacks and bribes for genetic testing swabs and signed requisition forms:

Overt Act	Date	Kickback Amount
a.	7/13/2020	$38,500.00
b.	7/24/2020	$100,000.00
c.	8/7/2020	$75,500.00
d.	8/21/2020	$16,400.00
e.	9/8/2020	$35,000.00
f.	9/18/2020	$11,840.00
g.	10/2/2020	$10,545.00
h.	10/19/2020	$22,570.00
i.	10/30/2020	$22,570.00
j.	11/16/2020	$22,570.00
k.	11/30/2020	$22,570.00
l.	12/16/2020	$22,570.00
m.	12/30/2020	$22,570.00
n.	1/15/2021	$22,570.00
o.	2/16/2021	$22,570.00
p.	3/5/2021	$8,000.00

All in violation of 18 U.S.C. § 371.

FORFEITURE

1. The allegations contained in Counts One and Two are incorporated by reference for the purpose of alleging forfeitures pursuant to 18 U.S.C. § 982(a)(7).

2. Upon conviction of a conspiracy to violate 42 U.S.C. § 1320a-7b(b), in violation of 18 U.S.C. § 371, the defendant shall forfeit to the United States, pursuant to 18 U.S.C. § 982(a)(7), any property, real or personal, which constitutes or is derived, directly or indirectly, from gross proceeds traceable to the offense.

3. The property to be forfeited includes, but is not limited to, an order of forfeiture in the approximate amount of $2,464,754.04, which is the amount the defendant obtained as a result of the commission of the offense.

4. If any of the property described above, as a result of any act or omission of the defendants:

a. cannot be located upon the exercise of due diligence;

b. has been transferred or sold to, or deposited with, a third party;

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 divided 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)(1).

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for

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