UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

22-20317-CR-BLOOM/OTAZO-REYES

Case No. _____

18 U.S.C. § 1349
18 U.S.C. § 981(a)(1)(C)
18 U.S.C. § 982(a)(7)

UNITED STATES OF AMERICA

v.

OMAR SALEH,

Defendant.

_____/

INFORMATION

The United States Attorney charges that:

GENERAL ALLEGATIONS

At all times material to this Information:

The Medicare Program

1. 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. The benefits available under Medicare were governed by federal statutes and regulations. The United States Department of Health and Human Services ("HHS"), through its agency, the Centers for Medicare and Medicaid Services ("CMS"), oversaw and administered Medicare. Individuals who received benefits under Medicare were commonly referred to as Medicare "beneficiaries."

2. Medicare was a "health care benefit program," as defined by Title 18, United States Code, Section 24(b).

3. Medicare was subdivided into multiple program "parts." Medicare Part A covered health services provided by hospitals, skilled nursing facilities, hospices, and home health agencies. Medicare Part B covered, among other things, medical services provided by physicians, medical clinics, laboratories, and other qualified health care providers, such as office visits, minor surgical procedures, and laboratory testing, that were medically necessary and ordered by licensed medical doctors or other qualified health care providers. Medicare Part C, also known as the "Medicare Advantage" Program, provided Medicare beneficiaries with the option to receive their Medicare benefits through private managed health care plans, including health maintenance organizations and preferred provider organizations. Health care providers, whether under Medicare Part A, B, or C, that provided and supplied items and services to Medicare beneficiaries, were referred to as "providers."

Part B Coverage and Regulations

4. CMS acted through fiscal agents called Medicare administrative contractors ("MACs"), which were statutory agents for CMS for Medicare Part B. The MACs were private entities that reviewed claims and made payments to providers for services rendered to beneficiaries. The MACs were responsible for processing Medicare claims arising within their assigned geographical area, including determining whether the claim was for a covered service.

5. To receive Medicare reimbursement, providers had to make appropriate application to the MAC and execute a written provider agreement. The Medicare provider enrollment application, CMS Form 855, was required to be signed by an authorized representative of the provider. CMS Form 855 contained a certification that stated:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to [the provider]. The Medicare laws, regulations, and program instructions are available through the [MAC]. 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…).

6. CMS Form 855 contained additional certifications that the provider "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."

7. Payments under Medicare Part B were often made directly to the provider rather than to the patient or beneficiary. For this to occur, the beneficiary would assign the right of payment to the provider. Once such an assignment took place, the provider would assume the responsibility for submitting claims to, and receiving payments from, Medicare.

8. A Medicare claim was required to contain certain important information, including: (a) the beneficiary's name and Health Insurance Claim Number ("HICN") or Medicare Beneficiary Identifier ("MBI"); (b) a description of the health care benefit, item, or service that was provided or supplied to the beneficiary; (c) the billing codes for the benefit, item, or service; (d) the date upon which the benefit, item, or service was provided or supplied to the beneficiary; and (e) the name of the referring physician or other provider, as well as a unique identifying number, known either as the Unique Physician Identification Number ("UPIN") or National Provider Identifier ("NPI"). The claim form could be submitted in hard copy or electronically.

9. Medicare Part B paid for claims 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 to Medicare. Medicare would not pay for items or services, including laboratory tests, that were procured through kickbacks and bribes.

Genetic Testing

10. Various forms of genetic testing existed using DNA sequencing to detect mutations in genes that could indicate a higher risk of developing certain diseases or health conditions in the future, including certain types of cancers (known as cancer genetic or "CGx" testing), cardiovascular disease (known as "cardio genetic testing"), diabetes, obesity, Parkinson's disease, Alzheimer's disease, and dementia. Pharmacogenetic tests ("PGx" tests) were laboratory tests that used DNA sequencing to assess how the body's genetic makeup would affect the response to certain medications.

11. Except for certain statutory exceptions, Medicare did not cover laboratory 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 "[e]xaminations performed for a purpose other than treatment or diagnosis of a specific illness, symptom, complaint or injury." 42 C.F.R. § 411.15(a)(1).

12. If laboratory 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 410.32(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" and "[t]ests not ordered by the physician who is treating the beneficiary are not reasonable and necessary." *Id.*

13. To conduct genetic testing, a laboratory must have obtained 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 genetic sample was then submitted to the laboratory to conduct a genetic test.

14. DNA samples were submitted along with requisitions that identified, among other things, the patient, the patient's insurance, and the specific test to be performed, such as a comprehensive panel of genes to test for risks of multiple cancers. In order for laboratories to have submitted claims to Medicare for genetic tests, the requisitions had to be approved by a physician or other authorized medical professional who attested to the medical necessity of the test. Such requisitions were known as "doctors' orders."

Telemedicine

15. Telemedicine provided a means of connecting patients to doctors by using telecommunications technology, such as the internet or a telephone, to interact with a patient. Telemedicine companies provided telemedicine services, or telehealth services, to individuals by hiring doctors and other health care providers.

16. Medicare Part B covered expenses for specific telehealth services if certain requirements were met. These requirements included that: (a) the beneficiary was located in a rural or health professional shortage area; (b) services were delivered via an interactive audio and video telecommunications system; and (c) the beneficiary was in a practitioner's office or a specified medical facility—not at a beneficiary's home—during the telehealth service with a remote practitioner. In or around March 2020, in response to the COVID-19 pandemic and in order to enable access to care during the public health emergency, some of these requirements were amended temporarily to, among other things, cover telehealth services for certain office and

hospital visits, even if the beneficiary was not located in a rural area or a health professional shortage area and even if the telehealth services were furnished to beneficiaries in their home. However, all telehealth services were still required to be reasonable and necessary, provided as represented, eligible for reimbursement, and not procured through the payment of kickbacks and bribes.

The Defendant, Related Companies, and a Related Individual

17. Defendant **OMAR SALEH**, a resident of Naples, Florida, was a medical doctor licensed to work in multiple states, including Florida, and enrolled as a Medicare provider.

18. Panda Conservation Group, LLC ("Panda") was a Texas company that owned multiple laboratories engaging in CGx and Cardio genetic testing, including Amerihealth Laboratory, LLC ("Amerihealth") and MP3 Labs, Inc. ("MP3") (hereinafter "the Laboratories"). To market its services, Panda used a call center operating under the name "Health Awareness Project," or "HAP," located in Fort Lauderdale, Florida.

19. Michael Stein, a resident of Palm Beach County, through his companies 1523 Holdings LLC ("1523 Holdings"), d/b/a Inwerx, and Growthlogix, LLC ("Growthlogix"), d/b/a Digital Mayo, LLC, arranged for telemedicine providers to refer Medicare beneficiaries to the Laboratories for genetic testing.

CONSPIRACY TO COMMIT HEALTH CARE FRAUD
(18 U.S.C. § 1349)

From in or around April 2020, and continuing through in or around October 2020, in Miami-Dade County, in the Southern District of Florida, and elsewhere, the defendant,

OMAR SALEH,

did knowingly and willfully, that is, with intent to further the object of the conspiracy, combine, conspire, confederate, and agree with others known and unknown to the United States Attorney,

including Michael Stein, 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, in violation of Title 18, United States Code, Section 1347.

Purpose of the Conspiracy

20. It was a purpose of the conspiracy for **OMAR SALEH** and his co-conspirators to unlawfully enrich themselves by, among other things: (a) soliciting and receiving kickbacks and bribes in exchange for signing doctors' orders for genetic testing that was medically unnecessary, ineligible for reimbursement, and not provided as represented; (b) submitting and causing the submission of false and fraudulent claims to Medicare for genetic tests; (c) concealing and causing the concealment of false and fraudulent claims; and (d) diverting the fraud proceeds for their personal use and benefit, the use and benefit of others, and to further the fraud.

Manner and Means of the Conspiracy

The manner and means by which defendant and his co-conspirators sought to accomplish the object and purpose of the conspiracy included, among other things, the following:

21. **OMAR SALEH** falsely certified to Medicare that he would comply with all Medicare rules and regulations and federal laws, including the Federal Anti-Kickback Statute, the requirement not to knowingly present or cause to be presented a false and fraudulent claim for payment by Medicare, and the requirement not to submit claims with deliberate ignorance or reckless disregard of their truth or falsity.

22. Co-conspirators obtained access to thousands of Medicare beneficiaries' insurance information and DNA material by causing them to be targeted with deceptive marketing campaigns, including online advertising and telemarketing, that promoted genetic testing.

23. **OMAR SALEH** solicited and received kickbacks and bribes from Michael Stein in exchange for agreeing to refer medically unnecessary doctor's orders for genetic testing to the Laboratories. The kickbacks involved beneficiary referrals and the opportunity to bill Medicare for telemedicine visits under the more flexible telehealth rules CMS put in place during the COVID-19 pandemic.

24. **OMAR SALEH** had no prior relationship with the Panda-referred beneficiaries, was not treating the beneficiaries for any medical condition, and did not use the test results in the treatment of the beneficiaries. Despite this, **SALEH** falsely certified in the doctors' orders he signed that he was "the patient's treating physician and this order is based upon Medicare's requirement that the testing is not ordered for the purposes of screening but for the diagnosis and treatment of the patient's individual medical condition." **SALEH** and his co-conspirators knew this was false.

25. During the COVID-19 public health emergency, **OMAR SALEH** caused the submission of an amount in excess of approximately $2.6 million in false and fraudulent claims to Medicare for genetic tests that were (a) procured through illegal kickbacks and bribes, (b) medically unnecessary, (c) ineligible for reimbursement, and (d) not provided as represented. Medicare paid the Laboratories in excess of approximately $1.6 million for these claims.

26. **OMAR SALEH**'s co-conspirators used the fraud proceeds derived from the Laboratories to benefit themselves and others, and to further the conspiracy.

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

FORFEITURE ALLEGATIONS

1. The allegations of this Information are hereby re-alleged and by this reference fully incorporated herein for the purpose of alleging forfeiture to the United States of America of certain property in which the defendant, **OMAR SALEH**, has an interest.

2. Upon conviction of a violation of Title 18, United States Code, Section 1349, as alleged in this Information, the defendant 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, pursuant to Title 18, United States Code, Sections 981(a)(1)(C) and 982(a)(7).

3. If any of the property described above, 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 party;

c. has been placed beyond the jurisdiction of the court;

d. has been substantially diminished in value; or

e. has been co-mingled with other property which cannot be divided without difficulty,

the United States of America shall be entitled to forfeiture of substitute property pursuant to Title 21, United States Code, Section 853(p), as incorporated by Title 18, United States Code, Section 982(b)(1).

All pursuant to Title 18, United States Code, Sections 982(a)(7) and 981(a)(1)(C), as incorporated by Title 28, United States Code, Section 2461(c), and the procedures set forth in Title 21, United States Code, Section 853, made applicable by Title 18, United States Code, Section 982(b)(1).

JUAN ANTONIO GONZALEZ
UNITED STATES ATTORNEY
SOUTHERN DISTRICT OF FLORIDA

LORINDA I. LARYEA
ACTING CHIEF
CRIMINAL DIVISION, FRAUD SECTION
U.S. DEPARTMENT OF JUSTICE

LIGIA MARKMAN
TRIAL ATTORNEY
CRIMINAL DIVISION, FRAUD SECTION
U.S. DEPARTMENT OF JUSTICE

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

UNITED STATES OF AMERICA

v.

OMAR SALEH,

_____/
Defendant.

CASE NO.:

CERTIFICATE OF TRIAL ATTORNEY*

Superseding Case Information:

New Defendant(s) (Yes or No)
Number of New Defendants
Total number of New Counts

Court Division (select one)
☑ Miami ☐ Key West ☐ FTP
☐ FTL ☐ WPB

I do hereby certify that:

1. I have carefully considered the allegations of the indictment, the number of defendants, the number of probable witnesses and the legal complexities of the Indictment/Information attached hereto.

2. I am aware that the information supplied on this statement will be relied upon by the Judges of this Court in setting their calendars and scheduling criminal trials under the mandate of the Speedy Trial Act, Title 28 U.S.C. §3161.

3. Interpreter: (Yes or No) No
List language and/or dialect:

4. This case will take 0 days for the parties to try.

5. Please check appropriate category and type of offense listed below:

(Check only one)		(Check only one)	
I	☑ 0 to 5 days	☐	Petty
II	☐ 6 to 10 days	☐	Minor
III	☐ 11 to 20 days	☐	Misdemeanor
IV	☐ 21 to 60 days	☑	Felony
V	☐ 61 days and over		

6. Has this case been previously filed in this District Court? (Yes or No) No
If yes, Judge Case No.
7. Has a complaint been filed in this matter? (Yes or No) No
If yes, Magistrate Case No.
8. Does this case relate to a previously filed matter in this District Court? (Yes or No) Yes
If yes, Judge Altonaga Case No. 21-CR-20321
9. Defendant(s) in federal custody as of
10. Defendant(s) in state custody as of
11. Rule 20 from the District of
12. Is this a potential death penalty case? (Yes or No) No
13. Does this case originate from a matter pending in the Northern Region of the U.S. Attorney's Office prior to August 8, 2014 (Mag. Judge Shaniek Maynard? (Yes or No) No
14. Does this case originate from a matter pending in the Central Region of the U.S. Attorney's Office prior to October 3, 2019 (Mag. Judge Jared Strauss? (Yes or No) No

By: _____

LIGIA MARKMAN
DOJ Trial Attorney
Court ID No. A5502656

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

PENALTY SHEET

Defendant's Name: OMAR SALEH

Case No:

Count #: 1

Title 18, United States Code, Section 1349

Conpiracy to Commit Health Care Fraud

*** Max. Term of Imprisonment: 10 years**
*** Mandatory Min. Term of Imprisonment (if applicable): N/A**
*** Max. Supervised Release: 3 years**
*** Max. Fine: $250,000 or twice the gross gain or loss from the offense**

***Refers only to possible term of incarceration, supervised release and fines. It does not include restitution, special assessments, parole terms, or forfeitures that may be applicable.**

AO 455 (Rev. 01/09) Waiver of an Indictment

UNITED STATES DISTRICT COURT

for the

Southern District of Florida

United States of America)
v.) Case No.
)
Omar Saleh,)
Defendant)

WAIVER OF AN INDICTMENT

I understand that I have been accused of one or more offenses punishable by imprisonment for more than one year. I was advised in open court of my rights and the nature of the proposed charges against me.

After receiving this advice, I waive my right to prosecution by indictment and consent to prosecution by information.

Date: _____

_____
Defendant's signature

_____
Signature of defendant's attorney

ERIC CRUZ, ESQ.
Printed name of defendant's attorney

_____
Judge's signature

_____
Judge's printed name and title