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United States Attorney

FILED
JUN 09 2020
SUSAN Y. SOONG
CLERK, U.S. DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. JULIE TAGUCHI, Defendant.	CR 20 00229 EJD CASE NO. VIOLATION[S]: 18 U.S.C. § 1349 - Conspiracy to Commit Health Care Fraud – 1 count Notice of forfeiture SAN JOSE VENUE

NC

INFORMATION

The United States Attorney charges:

COUNT ONE

(Conspiracy to Commit Health Care Fraud)

At all times material to this Information:

The Medicare Program

1. Medicare was a federally-funded health care program that provides benefits to persons who are at least 65 years old or disabled. Medicare was administered by the Centers for Medicare and Medicaid Services ("CMS"), a federal agency under the United States Department of Health and Human Services ("HHS"). Individuals who received benefits under Medicare are referred to as Medicare "beneficiaries."

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Medicare was divided into multiple parts: Part A covered hospital inpatient care, Part B covered physicians' services and outpatient care, Part C was Medicare Advantage Plans, and Part D covered prescription drugs.

2. 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).

3. Medicare programs covering different types of benefits were separated into different program "parts." Medicare Part B was a medical insurance program that covers non-institutional care that includes, among other things, medical testing by clinical laboratories, where those services are reasonable and necessary to diagnose or treat medical conditions and that meet accepted standards of medical practice.

4. CMS regulates all laboratory testing (except research) performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments (CLIA). All clinical laboratories must be properly certified by CLIA to receive Medicare or Medicaid payments. Upon certification, the medical provider, such as a clinical laboratory, was able to provide for a Medicare Provider Identification Number ("PIN") for billing purposes. A health care provider who was assigned a Medicare PIN and provided services to beneficiaries was able to submit claims for reimbursement to the Medicare contractor/carrier that included the PIN assigned to that medical provider.

5. Medicare Part B covered medical testing by clinical laboratories. Some examples of medical tests that fell within the purview of Medicare Part B included:

a. Allergy testing: Allergy referred to conditions in which immune responses to environmental antigens cause tissue inflammation and organ dysfunction. Allergy testing was performed to determine immunologic sensitivity or reaction to antigens for the purpose of identifying the cause of the allergic state.

b. COVID-19 testing: COVID-19 testing assessed whether an individual had the novel coronavirus disease 2019, commonly referred to as "COVID-19."

6. 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." Title 42, United States Code, Section 1395y(a)(1)(A). 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." Title 42, United States Code, Section 1395y(a)(1)(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." Title 42, Code of Federal Regulations, Section 411.15(a)(1).

7. If diagnostic testing were 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." "Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary." *Id.*

8. Medicare, through its contractors, set forth rules and regulations regarding the circumstances in which allergy testing was reasonable and necessary. Allergy testing can be conducted "in vivo", which correlates the performance and evaluation of selective cutaneous and mucous membrane tests (commonly referred to as "skin tests") with the patient's history, physical examination, and other observations. Allergy hypersensitivity may also be tested "in vitro" (commonly referred to as "blood tests") by measurement of allergen-specific serum IgE. Percutaneous skin testing remains the test of

choice in most clinical situations where immediate hypersensitivity reactions are suspected. Overall, skin testing is quick, safe, and cost-effective.

9. Under certain limited conditions, in vitro testing was covered by Medicare Part B. Quantitative (measuring the amount of sensitivity) in vitro allergen specific IgE testing was covered under conditions where skin testing is not possible or is not reliable. Examples of indications for in vitro testing include patients with severe dermatographism, ichthyosis or generalized eczema.

10. It would not be expected that all patients would receive the same tests or the same number of sensitivity tests. The number of tests performed must be judicious and related to the history, physical findings, and clinical judgment specific to each individual.

11. Payments under the Medicare program were often made directly to a provider of the goods and services, such as a clinical laboratory. This payment occurred when the provider submitted the claim to Medicare for payment. A Medicare claim was required to set forth, among other things, the name and identification of the physician or other health care provider who had ordered the services. Providers could only submit claims to Medicare for testing that was ordered by the health care provider listed on the claim. To be reimbursed from Medicare for laboratory testing, including allergy and COVID-19 testing, the testing had to be reasonable, medically necessary, documented, and actually provided as represented to Medicare.

The Defendant and Related Individuals and Entities

12. Defendant JULIE TAGUCHI was a physician who was licensed in the State of California and the laboratory director of Arrayit Corporation ("Arrayit").

13. Arrayit was a Nevada corporation based in the Northern District of California. Arrayit describes itself as "a world leader in microarray technology empowering researchers and doctors in the life sciences, wellness and healthcare testing markets." Arrayit was a participating provider in the Medicare program and submitted claims to Medicare.

14. Mark Schena was a 57-year-old scientist who described himself as the "Father of Microarray Technology," and serves as Arrayit's President.

15. "CEO 1" was the chief executive officer of Arrayit.

The Health Care Fraud Conspiracy

16. From at least in or around July 2018 to in or around April 2020, in the Northern District of California and elsewhere, the defendant,

JULIE TAGUCHI,

did willfully that is, with the intent to further the objects of the conspiracy, and knowingly combine, conspire, confederate, and agree with each other and with Mark Schena, CEO 1, and others known and unknown to the United States Attorney to commit certain offenses against the United States, namely: 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

17. It was a purpose of the conspiracy for Defendant TAGUCHI and her co-conspirators to unlawfully enrich themselves by: (a) submitting or causing the submission of false and fraudulent claims to Medicare for services that were (i) procured by the payment of kickbacks and bribes; (ii) medically unnecessary; (iii) not eligible for Medjicare reimbursement; and/or (iv) not provided as represented; (b) concealing the submission of false and fraudulent claims to Medicare and the receipt and transfer of the proceeds from the fraud; and (c) diverting proceeds of the fraud for the personal use and benefit of Defendant TAGUCHI and her co-conspirators, and to further the conspiracy.

Manner and Means

18. The manner and means by which Defendant TAGUCHI and her co-conspirators sought to accomplish the object and purpose of the conspiracy included, among other things, the following:

19. It was part of the conspiracy that Mark Schena, CEO 1, and others would apply for and maintain various laboratory certifications from state and federal agencies, including from the Centers for Medicare & Medicaid Services Clinical Laboratory Improvement Amendments (CLIA), that allowed Arrayit to conduct testing and submit claims to Medicare and other insurance plans.

20. It was further part of the conspiracy that Defendant TAGUCHI, Mark Schena, CEO 1, and others would submit or cause the submission of false and fraudulent attestations and other documents to state and federal regulators, including CLIA, that falsely certified that Defendant TAGUCHI possessed the appropriate qualifications to serve as laboratory director of Arrayit and did in fact conduct testing and carry out other responsibilities as Arrayit's laboratory director.

21. It was further part of the conspiracy that Defendant TAGUCHI provided her national provider number to Mark Schena and others, which was used to submit false and fraudulent claims for allergy testing on behalf of Arrayit for patients who Defendant TAGUCHI never saw or treated.

22. It was further part of the conspiracy that Defendant TAGUCHI solicited and received kickbacks and bribes from CEO 1 and others in exchange for allowing her national provider number to be used by Arrayit to submit false and fraudulent claims for allergy testing for patients who Defendant TAGUCHI never saw or treated.

23. It was further part of the conspiracy that as the effects of the COVID-19 pandemic began to be felt in the United States and many beneficiaries faced difficulty obtaining access to COVID-19 testing, Mark Schena, CEO 1, and others used the pandemic as an opportunity to expand the pre-existing allergy kickback and health care fraud conspiracy by offering COVID-19 testing and bundling the COVID-19 test with Arrayit's more expensive allergy testing, which does not identify or treat

COVID-19.

24. It was further part of the conspiracy that Defendant TAGUCHI ordered and caused others to order the bundled Arrayit COVID-19 and allergy test, despite knowing that the allergy test was medically unnecessary and the COVID-19 test returned "false positive" results, whereby it indicated that a patient was positive for antibodies for COVID-19, when in reality the positive results were due to past or present infection with non-COVID-19 coronavirus strains.

25. It was further part of the conspiracy that Defendant TAGUCHI, Mark Schena, CEO 1, and others concealed and disguised the scheme by entering into sham contracts and agreements that disguised the kickbacks and bribes as payments for laboratory director or other legitimate services.

26. It was further part of the conspiracy that Defendant TAGUCHI, together with others, submitted or caused the submission of approximately $248,784.16 in false and fraudulent claims that were procured through the payment of kickbacks and bribes, medically unnecessary, ineligible for Medicare reimbursement, and/or not provided as represented.

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

NOTICE OF FORFEITURE

THE UNITED STATES ATTORNEY FURTHER CHARGES THAT:

1. As a result of the violation of Title 18, United States Code, Section 1349, set forth in this Information, the defendant,

JULIE TAGUCHI,

shall forfeit to the United States of America any property, real or personal, that constitutes, or is derived, directly or indirectly, from the gross proceeds traceable to the commission of the offense, including, but not limited to, the sum of $10,039.20.

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2. If any of the property subject to forfeiture, 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 commingled with other property which cannot be divided without difficulty;

it is the intent of the United States, pursuant to Title 18, United States Code, Section 982(b), incorporating Title 21, United States Code, Section 853(p), to seek forfeiture of any other property of the defendant up to the value of the property subject to forfeiture.

All pursuant to Title 18, United States Code, Section 982(a)(7).

DAVID L. ANDERSON
United States Attorney
Northern District of California

ROBERT ZINK
Chief, Fraud Section
U.S. Department of Justice

Jacob Foster

DATED: June 9, 2020

JACOB FOSTER
JUSTIN WEITZ
Assistant Chiefs
Criminal Division, Fraud Section
U.S. Department of Justice

William Frentzen

DATED: June 9, 2020

WILLIAM FRENTZEN
Chief, Corporate Fraud Strike Force
U.S. Attorney's Office for the
Northern District of California

DEFENDANT INFORMATION RELATIVE TO A CRIMINAL ACTION - IN U.S. DISTRICT COURT

BY: ☐ COMPLAINT ☒ INFORMATION ☐ INDICTMENT ☐ SUPERSEDING

Name of District Court, and/or Judge/Magistrate Location
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION

FILED
JUN 09 2020
SUSAN Y. SOONG
CLERK, U.S. DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE

OFFENSE CHARGED

COUNT ONE: Conspiracy to Commit Health Care Fraud, 18 U.S.C. § 1349

☐ Petty
☐ Minor
☐ Misde-meanor
☒ Felony

PENALTY: COUNT ONE: not more than 10 years and $250,000 fine or two times the gain or loss, not more than 3 years supervised release, $100 special assessment.

DEFENDANT - U.S

JULIE TAGUCHI

DISTRICT COURT NUMBER

CR 20 00229 EJD NC

PROCEEDING

Name of Complainant Agency, or Person (& Title, if any)

United States Postal Inspection Service

☐ person is awaiting trial in another Federal or State Court, give name of court

☐ this person/proceeding is transferred from another district per (circle one) FRCrp 20, 21, or 40. Show District

☐ this is a reprosecution of charges previously dismissed which were dismissed on motion of:
☐ U.S. ATTORNEY ☐ DEFENSE } SHOW DOCKET NO.

☐ this prosecution relates to a pending case involving this same defendant

☐ prior proceedings or appearance(s) before U.S. Magistrate regarding this defendant were recorded under } MAGISTRATE CASE NO.

Name and Office of Person Furnishing Information on this form: David L. Anderson
☒ U.S. Attorney ☐ Other U.S. Agency

Name of Assistant U.S. Attorney (if assigned): William Frentzen

DEFENDANT

IS *NOT* IN CUSTODY

1) ☒ Has not been arrested, pending outcome this proceeding. If not detained give date any prior summons was served on above charges

2) ☐ Is a Fugitive

3) ☐ Is on Bail or Release from (show District)

IS IN CUSTODY

4) ☐ On this charge

5) ☐ On another conviction } ☐ Federal ☐ State

6) ☐ Awaiting trial on other charges

If answer to (6) is "Yes", show name of institution

Has detainer been filed? ☐ Yes ☐ No } If "Yes" give date filed

DATE OF ARREST Month/Day/Year

Or... if Arresting Agency & Warrant were not

DATE TRANSFERRED TO U.S. CUSTODY Month/Day/Year

☐ This report amends AO 257 previously submitted

ADDITIONAL INFORMATION OR COMMENTS

PROCESS:

☐ SUMMONS ☒ NO PROCESS* ☐ WARRANT

Bail Amount:

If Summons, complete following:
☐ Arraignment ☐ Initial Appearance

Defendant Address:

Date/Time: Before Judge:

Comments:

** Where defendant previously apprehended on complaint, no new summons or warrant needed, since Magistrate has scheduled arraignment*

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

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NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE

CRIMINAL COVER SHEET

Instructions: *Effective November 1, 2016, this Criminal Cover Sheet must be completed and submitted along with the Defendant Information Form, for each new criminal case.*

CASE NAME:
USA v. JULIE TAGUCHI

CASE NUMBER: CR 20 00229 EJD NC

Is This Case Under Seal?	Yes	No ✓	
Total Number of Defendants:	1 ✓	2-7	8 or more
Does this case involve ONLY charges under 8 U.S.C. § 1325 and/or 1326?	Yes	No ✓	
Venue (Per Crim. L.R. 18-1):	SF	OAK	SJ ✓
Is this a potential high-cost case?	Yes	No ✓	
Is any defendant charged with a death-penalty-eligible crime?	Yes	No ✓	
Is this a RICO Act gang case?	Yes	No ✓	

Assigned AUSA (Lead Attorney): William Frentzen

Date Submitted: 6/9/2020

Comments:

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