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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. YINA ELIZABETH CRUZ, Defendant.	NO. CR24-00090 VC VIOLATIONS; 18 U.S.C. § 371 – Conspiracy; 18 U.S.C. §§ 981, 982, 21 U.S.C. § 853, 26 U.S.C. § 2461 – Criminal Forfeiture SAN FRANCISCO VENUE

INFORMATION

The Attorney for the United States charges:

GENERAL ALLEGATIONS

At all times relevant to this Information, unless otherwise specified:

The Medicare and Medicaid Programs

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.

2. The Medicaid Program ("Medicaid") was a federal and state funded health insurance program designed to provide medical assistance to persons whose income and resources were insufficient to meet the costs of necessary care and services.

3. Medicare and Medicaid were each a "health care benefit program," as defined by Title 18, United States Code, Section 24(b), and a "Federal health care program," as defined by Title 42, United States Code, Section 1320a-7b(f).

4. Individuals who qualified for Medicare benefits were commonly referred to as "beneficiaries." Individuals who qualified for Medicaid benefits were commonly referred to as "recipients" (hereafter, "beneficiaries" and "recipients" will be collectively referred to as "beneficiaries"). Each Medicare beneficiary was given a unique Medicare identification number.

5. Medicare covered different types of benefits, which were separated into different program "parts." Medicare Part B covered, among other things, items and services supplied and provided by physicians, nurse practitioners, and other qualified health care providers, including office visits, that were medically necessary and ordered by licensed medical doctors or other qualified health care providers. Medicare Part D covered prescription drugs.

6. Health care benefit programs typically required providers to enroll in the programs in order to submit claims for items and services. Specifically, as part of the Medicare and Medicaid enrollment processes, providers, including nurse practitioners, submitted enrollment applications. Once applications were approved, providers received a provider number. Providers that received a provider number were able to file claims to obtain reimbursement for benefits, items, and services provided to beneficiaries.

7. Medicare and Medicaid paid for items and services only if they were medically reasonable and necessary, eligible for reimbursement, and provided as represented. Medicare and Medicaid did not pay for items and services that were procured through the payment of illegal kickbacks and bribes.

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Medicare and Medicaid Prescription Drug Plans

8. To receive Part D benefits, a beneficiary enrolled in a Medicare drug plan. Medicare drug plans were operated by private health care insurance companies approved by Medicare and referred to as drug plan "sponsors." A beneficiary in a Medicare drug plan could fill a prescription at a pharmacy and use his or her plan to pay for some or all of the prescription.

9. Medicare's drug plans were administered by pharmacy benefit managers ("PBMs"), which adjudicated and processed payment for prescription drug claims submitted by eligible pharmacies. PBMs also audited participating pharmacies to ensure compliance with their rules and regulations.

10. A pharmacy could participate in Medicare Part D by entering into a provider agreement with a Part D drug plan or with a PBM. Pharmacies entered into contractual agreements with PBMs either directly or indirectly. If indirectly, providers first contracted with pharmacy network groups, which then contracted with PBMs on behalf of providers. By contracting with drug plans or PBMs, directly or indirectly, pharmacies agreed to comply with all applicable laws, rules, and regulations, including all applicable federal and state laws.

11. Medicaid also provided coverage to its recipients for prescription drugs. Medicaid beneficiaries could obtain their prescription drug benefits from pharmacies either through "fee-for-service" enrollment or through "Medicaid Managed Care Plans," which were administered by private insurance companies that were paid by Medicaid. A beneficiary in a Medicaid drug plan could fill a prescription at a pharmacy and use his or her plan to pay for some or all of the prescription.

12. Upon receiving prescriptions, pharmacies submitted claims for reimbursement to Medicare, PBMs, or Medicaid for the prescription drugs dispensed to beneficiaries. Medicare, PBMs, and Medicaid reimbursed pharmacies at specified rates, minus any copayments to be paid by beneficiaries.

13. Pharmacies were permitted to submit claims for reimbursement to Medicare and Medicaid only for prescription drugs that were dispensed upon a valid prescription, medically necessary, and eligible for reimbursement.

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14. Medicare and Medicaid drug plans were each a "health care benefit program," as defined by Title 18, United States Code, Section 24(b), and a "Federal health care program," as defined by Title 42, United States Code, Section 1320a-7b(f).

The Controlled Substances Act

15. The Controlled Substances Act ("CSA"), Title 21, United States Code, Section 801 *et seq*., and its implementing regulations governed the manufacture, distribution, and dispensation of controlled substances in the United States. With limited exceptions for medical professionals, the CSA made it unlawful for any person to knowingly or intentionally manufacture, distribute, or dispense a controlled substance or conspire to do so.

16. The CSA and its implementing regulations set forth which drugs and other substances were defined by law as "controlled substances," and assigned those controlled substances to one of five schedules (Schedule I, II, III, IV, or V) depending on their potential for abuse, likelihood of physical or psychological dependency, accepted medical use, and accepted safety for use under medical supervision.

17. A controlled substance assigned to Schedule II had a high potential for abuse, was highly addictive, and had a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions. Abuse of a Schedule II controlled substance could have led to severe psychological and/or physical dependence.

18. Pursuant to the CSA and its implementing regulations, Amphetamine-Dextroamphetamine was classified as a Schedule II controlled substance. Amphetamine-Dextroamphetamine was sold generically and under a variety of brand names, including Adderall. Other stimulants, including lisdexamfetamine (sometimes sold under the brand name Vyvanse) and methylphenidate (sometimes sold under the brand name Ritalin), also were classified as Schedule II controlled substances.

19. Medical practitioners, such as nurse practitioners and physicians, who were authorized to prescribe controlled substances by the jurisdiction in which they were licensed to practice medicine, were authorized under the CSA to prescribe, or otherwise distribute, controlled substances, if they were registered with the Attorney General of the United States. 21 U.S.C. § 822(b); 21 C.F.R. § 1306.03. Medical practitioners were required to register with the Drug Enforcement Administration ("DEA") in

order to prescribe controlled substances. Upon application by the practitioner, the DEA assigned a unique registration number to each qualifying medical practitioner. The DEA was responsible for enforcement of controlled substance laws in the United States.

20. The CSA required all practitioners to be registered in the state in which the patients to which they were prescribing controlled substances were located, regardless of whether the prescribing was taking place via telemedicine. The CSA provided that every person who dispensed, or who proposed to dispense, any controlled substance shall obtain from DEA a registration issued in accordance with DEA rules and regulations. 21 U.S.C. § 822(a)(2). Under the CSA, such dispensing included prescribing and administering controlled substances. § 802(10). DEA was permitted to only register a person to dispense a controlled substance if that person was permitted to do so by the jurisdiction in which his or her patients were located. § 802(21), 823(f). Thus, unless an applicable exception applied, DEA regulations required a practitioner to obtain a separate DEA registration in each state in which a patient to whom he or she prescribed a controlled substance was located when the prescription was made, regardless of whether the prescription was made via telemedicine.

21. Title 21 of the Code of Federal Regulations, Section 1306.04, which governed the issuance of prescriptions for controlled substances, provided that a prescription for a controlled substance must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of their professional practice. It provided that, to be effective, a prescription for a controlled substance:

> must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is on the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

22. Pursuant to their corresponding responsibility, pharmacies adopted policies to ensure that controlled substance prescriptions were issued for a legitimate medical purpose in the usual course of

professional practice. In order to exercise their corresponding responsibility, pharmacists reviewed relevant information about the prescription, including documentation and evidence provided by the practitioner regarding whether the prescription was issued for a legitimate medical purpose in the usual course of professional practice. Pharmacies in the ordinary course relied on information transmitted by the practitioner.

The Ryan-Haight Act

23. The Ryan Haight Online Pharmacy Consumer Protection Act of 2008 was enacted to stem the increase in the use of controlled substances purchased on the internet. The Act mandated, with limited exceptions, that the dispensing of a controlled substances by means of the internet be predicated on a valid prescription issued by a practitioner who has conducted at least one in-person medical evaluation of the patient. The Act was codified in Title 21 of the United States Code.

24. Title 21, United States Code, Section 841(h) provided that it was unlawful to "knowingly or intentionally— write[ ] a prescription for a controlled substance for the purpose of delivery, distribution, or dispensation by means of the Internet in violation of [Title 21, United States Code,] [S]ection 829(e) …."

25. Title 21, United States Code, Section 829(e)(1) provided that, "[n]o controlled substance that is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act may be delivered, distributed, or dispensed by means of the Internet without a valid prescription."

26. Title 21, United States Code, Section 829(e)(2)(A) provided that in order for a prescription to be valid it had to be "be issued for a legitimate medical purpose in the usual course of practice by— (i) a practitioner who has conducted at least 1 in-person medical evaluation of the patient; or (ii) a covering practitioner."

27. Title 21, United States Code, Section 829(e)(2)(B)(i) provided that an "in-person medical evaluation" was "a medical evaluation that is conducted with the patient in the physical presence of the practitioner, without regard to whether portions of the evaluation are conducted by other health professionals."

28. Title 21, United States Code, Sections 829(e)(3) and 802(54) provided that the requirement of conducting at least one in-person medical evaluation did not apply in certain

circumstances involving "the practice of telemedicine" where the Secretary of [HHS] has declared "a public health emergency" and it "involve[d] patients located in such areas, and such controlled substances, as the Secretary, with the concurrence of the Attorney General, designate[d]." 21 U.S.C. § 802(54)(D).

29. Title 21, United States Code, Section 802(54) provided that "[t]he term 'practice of telemedicine' means, for purposes of this subchapter, the practice of medicine in accordance with applicable Federal and State laws by a practitioner (other than a pharmacist) who is at a location remote from the patient and is communicating with the patient, or health care professional who is treating the patient, using a telecommunications system referred to in [S]ection 1395m(m) of [T]itle 42 …."

30. Title 42, United States Code, Section 1395m(m)(1) and implementing regulations, including Title 42, Code of Federal Regulations, Section 410.78, provided that "interactive telecommunications system means … multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner," and that "the term 'telecommunications system' include[d] store-and-forward technologies that provide for asynchronous transmission of health care information" only in "telemedicine demonstration program conducted in Alaska and Hawaii."

31. On or about January 31, 2020, the Secretary of HHS declared a national public emergency under Title 42, United States Code, Section 247d as a result of the spread of the novel coronavirus COVID-19 within the United States.

32. In response to the COVID-19 Public Health Emergency as declared by the Secretary, pursuant to the authority under Section 319 of the Public Health Service Act (42 U.S.C. § 247), the DEA granted temporary exceptions to the Ryan Haight Act and DEA's implementing regulations under Title 21, United States Code, Section 802(54)(D), thereby allowing the prescribing of controlled medications via telemedicine encounters—even when the prescribing practitioner had not conducted an in-person medical evaluation of the patient—in certain circumstances in order to prevent lapses in care.

33. These emergency flexibilities involving telemedicine allowed, during the pendency of the COVID-19 Public Health Emergency, the prescribing of controlled substances without first conducting an in-person examination only if all of the following conditions were met: the prescription was issued

for a legitimate medical purpose by a practitioner acting in the usual course of professional practice; telemedicine communication was conducted using an audio-visual, real-time, two-way interactive communication system; and the practitioner was acting in accordance with applicable federal and state laws. The principal purpose of these policies was to limit the spread of COVID-19 by enabling patient access to medically necessary controlled substances through telemedicine, without otherwise altering the existing legal prohibitions on writing prescriptions that contravene federal or state laws.

The Defendant

34. Defendant Yina Cruz was a nurse practitioner who maintained a DEA registration number and was authorized to prescribe controlled substances in the States of New York and New Jersey.

35. Cruz was, from in or around March 2021 to in or around January 2023, an independent contractor for Done Health P.C. (together with its affiliated company, Done Global, Inc. ("Done")).

36. Done was a self-proclaimed "digital health company" that operated on a subscription-based model where individuals ("Done members") paid a monthly fee to Done. Done advertised that it provided online diagnosis, treatment, and refills of medication for attention deficit hyperactivity disorder ("ADHD"). Done's principal place of business was within the Northern District of California.

COUNT ONE: (18 U.S.C. § 371 – Conspiracy)

37. All previous paragraphs of this Information are realleged and incorporated by reference as though fully set forth herein.

38. From in or around March 2021, and continuing through in or around January 2023, in San Francisco, in the Northern District of California, and elsewhere, the defendant,

YINA ELIZABETH CRUZ,

knowingly and intentionally conspired and agreed with Done and others, known and unknown to the Attorney for the United States, to:

a) defraud the United States by impairing, impeding, obstructing, and defeating through deceit, craft, trickery, and dishonest means, the lawful government functions of CMS and HHS, an agency and a department of the United States; and

b) violate Title 21, United States Code, Sections 841(a)(1) and (b)(1)(C) by knowingly and

intentionally distributing and dispensing, not for a legitimate medical purpose in the usual course of professional practice, mixtures and substances containing detectable amounts of a Schedule II controlled substance, namely Amphetamine-Dextroamphetamine.

Purpose of the Conspiracy

39. It was the purpose of the conspiracy for Cruz, Done, and others to unlawfully enrich themselves by: (a) issuing prescriptions to Done members for Adderall that were not for a legitimate medical purpose in the usual course of professional practice; (b) enabling Done members to obtain Adderall and other stimulants from pharmacies by, among others, providing prescriptions, transmitting health care insurance information to pharmacies, and causing pharmacies to submit false and fraudulent claims for reimbursement to health care insurance plans; (c) concealing and disguising the unlawful prescription of Adderall, the submission of false and fraudulent claims to Medicare and Medicaid, and the receipt and transfer of the proceeds of the conspiracy; and (d) diverting proceeds of the conspiracy for their personal use and benefit, for the use and benefit of others, and to further the fraud.

Manner and Means of the Conspiracy

40. The dishonest and deceitful manner and means by which Cruz, Done, and others sought to accomplish the purpose and object of the conspiracy included, among other things, the following:

41. Cruz submitted and caused the submission of enrollment documents to Medicare and Medicaid, in which she certified that she would comply with all Medicare and Medicaid rules and regulations and program instructions, and would not knowingly cause to be presented a false and fraudulent claim for payment by Medicare and Medicaid. Despite this certification, Cruz caused to be presented false and fraudulent claims for payment by Medicare and Medicaid as described below.

42. Done acquired thousands of members by advertising that members could obtain easy access to prescriptions for Adderall and other stimulants in exchange for payment of a monthly subscription fee to Done.

43. Cruz and others agreed with Done to work as independent contractors for Done and were paid to diagnose Done members with ADHD and issue prescriptions for Adderall and other stimulants regardless of whether the prescriptions were for a legitimate medical purpose in the usual course of professional practice, in order to increase subscription revenue for Done and its co-conspirators.

44. Owners and operators of Done paid and caused payments to be made to Cruz to sign prescriptions and cause pharmacies to dispense prescriptions that were not for a legitimate medical purpose in the usual course of professional practice, medically unnecessary, and ineligible for reimbursement from Medicare and Medicaid.

45. Cruz and others were provided access by Done to Medicare and Medicaid beneficiary information and other confidential patient information for thousands of Done members in order for Cruz and others to write prescriptions for Adderall and other stimulants.

46. In the course and scope of her work for Done, and for the benefit of herself and Done, Cruz and others ordered Adderall and other stimulants for Done members, including Medicare and Medicaid beneficiaries, with whom she lacked a pre-existing practitioner-patient relationship, without an examination, and sometimes based solely on a short video or audio communication and limited patient intake documents, or without any video or audio communication at all. Cruz and others agreed with Done and others to provide few, if any, medical treatment options besides prescribing Adderall and other stimulants.

47. In the course and scope of her work for Done, and for the benefit of herself and Done, Cruz and others signed orders for Adderall and other stimulants for Done members, including Medicare and Medicaid beneficiaries, regardless of whether the Done member (a) met the Diagnostic and Statistical Manual of Mental Disorders (DSM)-V criteria for diagnosing ADHD; (b) posed a risk of diversion; and/or (c) was provided dosages, directions, combinations, or quantities of medications beyond those normally prescribed.

48. Cruz agreed with Done and others that, after an initial consultation with a Done member, Cruz would be paid solely based on "patient load" (the number of patients to whom Cruz wrote prescriptions each month) and would not be paid for any patient consultation, time, or medical services that she provided to Done members.

49. After an initial consultation with a Done member, Cruz and others signed additional monthly prescriptions for Schedule II controlled substances, including Adderall and other stimulants, that were not for a legitimate medical purpose in the usual course of professional practice for Done members, including Medicare and Medicaid beneficiaries (a) without an in-person examination and

without seeing, speaking to, and/or otherwise engaging in audio or video communication with Done members; and (b) without determining the Done members' medical need for the prescriptions. In some instances, Done paid Cruz and others to write prescriptions for Done members whom Cruz had never seen or had any prior telemedicine consultation with, including for Done members in states where Cruz was not licensed to write controlled substance prescriptions under state and federal law.

50. Neither Cruz nor Done billed Medicare and Medicaid or other insurance payors for telemedicine consultations with Done members. Instead, Done solicited monthly subscription fees from Done members in exchange for prescriptions that were signed by Cruz and others, and dispensed at pharmacies. Done created a platform whereby Done members paid a monthly subscription fee in exchange for easy access to prescriptions for Adderall and other stimulants.

51. In order to cause pharmacies to dispense Adderall and other stimulants that were not for a legitimate medical purpose in the usual course of professional practice for Done members, and obstruct, interfere with, and deprive pharmacies of their ability to exercise their corresponding responsibility to ensure that dispensed medications were only for a legitimate medial purpose in the usual course of professional practice, Cruz, Done, and others, among other things, (a) collected insurance information from Done members; (b) transmitted Done members' insurance information to pharmacies for the purpose of causing the pharmacies to bill the Done members' insurance for dispensing Adderall and other stimulants; (c) made or caused to be made false and fraudulent representations to pharmacies in order to cause them to dispense Adderall and other stimulants to Done members; and (d) submitted and caused the submission of false and fraudulent documents to Medicare and Medicaid and other insurance payors, in order to induce them to pay for the Adderall and other stimulants that pharmacies dispensed to Done members.

52. Prescriptions issued by Cruz for Done were transmitted to pharmacies to dispense Adderall and other stimulants. The pharmacies submitted and caused the submission of false and fraudulent claims to Medicare and Medicaid based on the prescriptions signed by Cruz. Medicare and Medicaid paid these false and fraudulent claims, resulting in the pharmacies dispensing Adderall and other stimulants to Done members.

53. Cruz and others falsified, fabricated, altered, and caused the falsification, fabrication, and

alteration of patient files, prescriptions, pre-authorizations, and other records, all to support prescriptions that were not for a legitimate medical purpose in the usual course of professional practice, and the submission of claims to Medicare and Medicaid that were medically unnecessary, ineligible for reimbursement, and not provided as represented.

54. Cruz and others concealed and disguised the conspiracy by preparing and causing to be prepared false and fraudulent documentation and submitting and causing the submission of false and fraudulent documents, that falsely made it appear that the prescriptions written by Cruz for Done members were for a legitimate medical purpose in the usual course of professional practice.

55. Cruz and others caused the submission of false and fraudulent claims to Medicare and Medicaid for prescriptions that were medically unnecessary, ineligible for Medicare and Medicaid reimbursement, and not provided as represented.

Overt Acts

56. In furtherance of the conspiracy, and to accomplish its objects and purpose, at least one of the co-conspirators committed and caused to be committed, in the Northern District of California and elsewhere, at least one of the following overt acts, among others:

57. On or about March 19, 2021, Cruz signed an independent contractor agreement with Done, which was signed on Done's behalf by an executive of Done.

58. On or about August 4, 2021, Cruz wrote two prescriptions for Adderall for Patient No. 1, who paid monthly subscription fees to Done.

59. On or about August 4, 2021, Cruz, Done, and others caused the transmission of the Adderall prescriptions for Patient No. 1 to Pharmacy No. 1.

60. On or about August 4 and August 5, 2021, Cruz caused the submission of false and fraudulent claims by Pharmacy No. 1 to Medicaid, in the approximate amounts of $204.81 and $235.91, respectively, for the prescription written by Cruz for Patient No. 1. Medicaid paid these claims and Adderall was dispensed to Patient No. 1.

All in violation of Title 18, United States Code, Section 371.

FORFEITURE ALLEGATION: (18 U.S.C. §§ 981, 982; 21 U.S.C. § 853; 26 U.S.C. § 2461)

61. The allegations contained in this Information are re-alleged and incorporated by reference for the purpose of alleging forfeiture pursuant to Title 18, United States Code, Sections 981(a)(1)(C) and 982(a)(7); Title 21, United States Code, Section 853; and Title 26, United States Code, Section 2461(c).

62. Upon conviction for the offense set forth in this Information, the defendant,

YINA ELIZABETH CRUZ,

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 $70,798.65.

63. 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.

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All pursuant to Title 18, United States Code, Sections 981(a)(1)(C) and 982(a)(7); Title 21, United States Code, Section 853; Title 26, United States Code, Section 2461(c), and Federal Rule of Criminal Procedure 32.2.

DATED: February 12, 2024

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