IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

vs.

MICHAEL SAYEGH,

Defendant.

Case No. 2:21-cr-172

Judge Morrison

21 U.S.C. § 846
21 U.S.C. § 841(a)(1)
18 U.S.C. § 1349
18 U.S.C. § 1347
18 U.S.C. § 2

FORFEITURE ALLEGATIONS

INDICTMENT

The GRAND JURY charges:

At times material to this Indictment:

GENERAL ALLEGATIONS

The Defendants, Related Individuals, and Entities

1. Defendant MICHAEL SAYEGH ("SAYEGH") was a licensed medical doctor in Ohio, credentialed under State Medical Board of Ohio License Number # 35.085692. SAYEGH was registered with federal and state authorities in Ohio to prescribe Schedule II – V controlled substances. SAYEGH was enrolled with the Medicare program as a Medicare provider since approximately 2007. SAYEGH was also enrolled with the Ohio Medicaid program as a Medicaid provider since approximately 2004.

2. The Pain Management Clinic, LLC ("TPMC") was a purported medical practice that operated out of two locations: 1175 South 13th Street, Cambridge, Ohio 43725, and 7335 East Livingston Avenue, Reynoldsburg, Ohio 43068. SAYEGH owned and operated TPMC and, as part of the operation of his business, personally prescribed controlled substances,

including highly addictive opioids, through these facilities. As the owner and operator of TPMC, SAYEGH also entered into agreements with Medicare and the Ohio Medicaid Program, among other insurance plans, to provide reimbursement for certain services provided at TPMC.

3. SAYEGH employed multiple individuals, including other medical practitioners who were registered with federal and state authorities to prescribe controlled substances, at TPMC during times relevant to the Indictment.

The Controlled Substances Act and Code of Federal Regulations

4. The Controlled Substances Act ("CSA"), Title 21, United States Code, Section 801, *et.seq.* and Title 21, Code of Federal Regulations, Section 1306.04 governed the manufacture, distribution, and dispensation of controlled substances in the United States. The CSA and the Code of Federal Regulations (CFR) contained definitions relevant to this Indictment, some of which are set forth below.

5. The term "controlled substance" meant a drug or other substance, or immediate precursor, included in Schedule I, II, III, IV and V, as designated by Title 21, United States Code, Section 802(c)(6), and the CFR. The designation "Schedule II" meant the drug or other substance had a high potential for abuse; the drug had a currently accepted medical use with severe restrictions; and abuse of the drug or other substance may have led to severe psychological or physical dependence. The designation "Schedule IV" meant the drug or other substance had a low potential for abuse relative to substances that were listed as Schedule III. However, concurrent use of some Schedule II (such as opioids) and Schedule IV controlled substances (such as benzodiazepines) greatly increased a patient's risk of overdose and death.

6. Methadone and oxycodone were Schedule II controlled substances.

7. The term "dispense" meant to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance. The term "distribute" meant to deliver (other than by administering or dispensing) a controlled substance.

8. The Drug Enforcement Administration (DEA) issued registration numbers to qualifying practitioners, who thereby became authorized to dispense Schedule II, III, IV, and V controlled substances. To issue a prescription for a controlled substance, a doctor must have had a DEA registration number for each location in which they were dispensing medicine, and for each state where the doctor was prescribing controlled substances.

9. The term "dosage" was the amount, frequency, and number of doses of medication authorized by a practitioner with a valid DEA registration number. The term "prescription" meant an order for medication which was dispensed to or for an ultimate user but does not include an order for medication which is dispensed for immediate administration to the ultimate user.

10. Title 21, Code of Federal Regulations, Section 1306.04 provided that "[a]ll prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address and registration number of the practitioner."

11. Under the CSA and CFR, a prescription for a controlled substance was unlawful unless issued for a legitimate medical purpose by a registered practitioner acting in the usual

course of professional practice.

The Medicare Program

12. The Medicare program ("Medicare") was a federal health care program, affecting commerce, that provided benefits to persons who were 65 years of age or older or disabled.

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

14. Medicare was administered by the United States Department of Health and Human Services, through its agency, the Centers for Medicare and Medicaid Services ("CMS").

15. Individuals who qualified for Medicare benefits were commonly referred to as "beneficiaries." Each beneficiary was given a unique Medicare identification number.

16. Medicare covered different types of benefits and was separated into different program "parts." Among other things, Medicare Part B covered outpatient physician services such as office visits and laboratory services, including urine drug testing ("UDT").

17. As part of the Medicare enrollment process, health care providers, including clinics and physicians (collectively, "providers"), submitted enrollment applications to Medicare. To participate in Medicare, including Medicare Part B, providers were required to certify that they would comply with all Medicare-related laws, rules, and regulations, including, among others, the Federal anti-kickback statute. If Medicare approved a provider's application, Medicare assigned the provider a Medicare provider number. A provider with a Medicare provider number could submit claims to Medicare to obtain reimbursement for medically necessary items and services rendered to beneficiaries. Medicare providers were given access to Medicare manuals and service bulletins describing procedures, rules, and regulations.

18. When seeking reimbursement from Medicare, providers certified that: (1) the contents of the claim forms were true, correct, and complete; (2) the claim forms were prepared in compliance with the laws and regulations governing Medicare; and (3) the services purportedly provided, as set forth in the claim forms, were medically necessary.

19. Medicare reimbursed claims submitted by providers if the services and items provided were medically necessary for the diagnoses and treatment of beneficiaries. Conversely, Medicare did not cover and would not reimburse claims for services and items that were not medically necessary.

20. Medicare, by and through its fiscal intermediaries, ultimately reimbursed claims submitted by providers, including TPMC for laboratory services and UDT, in the Southern District of Ohio.

The Ohio Medicaid Program

21. Medicaid, established by Congress in 1965, was a federal and state funded health care program providing benefits to individuals and families who met specified financial and other eligibility requirements, and certain other individuals who lacked adequate resources to pay for medical care. CMS was responsible for overseeing the Medicaid program in participating states, including Ohio. Individuals receiving Medicaid benefits were referred to as Medicaid "members."

22. The Ohio Medicaid Program ("Ohio Medicaid") was a "health care benefit program" as defined by Title 18, United States Code, Section 24(b).

23. "The Ohio Department of Medicaid ("ODM") administered Ohio Medicaid in the State of Ohio. ODM received, reviewed, and paid Ohio Medicaid claims submitted by providers."

24. Providers meeting certain criteria could enroll in and obtain Ohio Medicaid provider numbers. Upon Medicaid enrollment, providers were permitted to provide medical services and items to members, and subsequently submit claims, either electronically or in hardcopy, to Ohio Medicaid, through fiscal intermediaries, seeking reimbursement for the cost of services and items provided.

25. When seeking reimbursement from Ohio Medicaid, providers certified that: (1) the contents of the claim forms were true, correct, and complete; (2) the claim forms were prepared in compliance with the laws and regulations governing Medicaid; and (3) the services purportedly provided, as set forth in the claim forms, were medically necessary.

26. Ohio Medicaid reimbursed claims submitted by providers if the services and items provided were medically necessary for the diagnoses and treatment of members. Conversely, Medicaid did not cover and would not reimburse claims for services and items that were not medically necessary.

27. Ohio Medicaid, through ODM and through its fiscal intermediaries, ultimately reimbursed claims submitted by service providers, including TPMC, for laboratory services and UDT in the Southern District of Ohio.

UDT Health Care Claims

28. At all time periods relevant to the Indictment, UDT was a reimbursable service under both Medicare and Ohio Medicaid. In order to be reimbursed, UDT must be reasonable

and necessary to help the physician monitor for medication adherence, diversion, efficacy, side effects, and patient safety in general.

29. UDT was divided into two categories: qualitative (also known as presumptive) testing and quantitative (also known as definitive) testing. Qualitative testing identified which substances, if any, were present in the provided specimen. Quantitative testing identified how much of a particular substance was present in the provided specimen.

30. Qualitative testing was performed in a variety of ways, including utilizing devices that were capable of being read by direct optical observation, such as "cups" that reacted to the specimen and identified which drugs, if any, were present ("optical devices"), as well as by more complex testing performed by instrument chemistry analyzers. Quantitative testing was performed by higher complexity instrument chemistry analyzers.

31. Medicare and Ohio Medicaid considered qualitative testing to be medically necessary, and appropriately reimbursable, in the treatment of chronic pain patients, provided the presumptive testing was used in the diagnosis and treatment of members and the need for the testing was substantiated by documentation in the patient's medical record. Conversely, Medicaid specifically excluded from coverage, and did not consider medically necessary, "blanket orders" or routine quantitative testing of substances without individualized decision making relating to the patient.

32. Medicare and Ohio Medicaid considered quantitative testing to be medically necessary, and appropriately reimbursable, in the treatment of chronic pain patients in certain limited circumstances, including when members had a specific and documented need for quantitative testing. Conversely, Medicare and Ohio Medicaid specifically excluded from

coverage, and did not consider medically necessary, "blanket orders" or routine quantitative testing of substances without individualized decision making relating to the patient.

The Illegal Controlled Substance Distribution and Fraudulent UDT Scheme

Overview and Purpose of the Scheme

33. From at least January 2015 through at least March 2020, SAYEGH and others known and unknown to the Grand Jury engaged in a scheme to prescribe opioids and other controlled substances to TPMC patients who should not have received such substances. SAYEGH illegally issued these prescriptions himself and with the assistance of others. SAYEGH and others wrote such illegal prescriptions, in part, because each patient they kept at TPMC, through the distribution of opioids, represented another opportunity to bill for medically unnecessary but lucratively reimbursed UDT. The more procedures SAYEGH and others were able to bill, the more money TPMC would receive in reimbursement from Medicare, Ohio Medicaid, and other health care benefit programs, and the more money SAYEGH would ultimately receive in compensation as the owner and operator of TPMC.

Manner and Means

34. SAYEGH and others known and unknown to the Grand Jury, through TPMC, provided physician services to beneficiaries, members, and other patients, including purported pain management services by, among other methods, prescribing controlled substances.

35. TPMC had purported policies relating to the clinical importance of UDT. Specifically, TPMC's policy was that if a patient fails to abide by the terms of a pain contract or "fails" a urine toxicology test, the patient would be discharged from TPMC's care and referred to an alcohol and drug rehabilitation program. Patients signed written agreements to submit to

UDT when requested by a provider at TPMC to determine compliance with the patient's pain control medicine. As part of that agreement, patients acknowledge that TPMC prescribers will stop prescribing pain control medicines or change the patient's treatment plan if the patient exhibits any additional problem as a result of prescribed treatment or any other addictive substances such as cocaine or non-medical marijuana. TPMC documentation confirms that the reason for UDT is to rule out and discharge noncompliant patients and to prevent overdose and serious complications for patients on opioid treatment.

36. Despite these purported policies, SAYEGH and others continued to prescribe controlled substances to TPMC patients who engaged in aberrant behavior. SAYEGH and others also prescribed controlled substances to patients who presented in other ways that would have alerted a medical professional that it was outside the usual course of professional practice and without a legitimate medical purpose to prescribe the types, combinations, and dosages of controlled substances that the patients were prescribed at TPMC.

37. The dangerous prescribing of controlled substances, including opioids, was in part driven by SAYEGH'S desire and intent to perform and bill for UDT for TPMC patients, including those insured by Medicare and Ohio Medicaid. These tests were lucratively reimbursed by Medicare, Ohio Medicaid, and other health care benefit programs.

38. To that end, SAYEGH directed TPMC employees to obtain urine specimens from patients ("provided specimens") during office visits.

39. At all times relevant to the Indictment, SAYEGH leased laboratory equipment from Company 1 in order to directly perform qualitative and quantitative UDT for TPMC

patients. This allowed SAYEGH, and others he employed at TPMC, to bill Medicare and Ohio Medicaid, among other insurance programs, directly for UDT performed for TPMC patients.

40. SAYEGH directed employees of TPMC to perform both qualitative and quantitative testing on the provided specimens, irrespective of any identified individualized need, and concealed the existence of this blanket order from Medicare and Ohio Medicaid, among other health care benefit programs.

41. SAYEGH further directed employees of TPMC to perform both qualitative and quantitative testing on the provided specimens despite the fact that he received delayed results for both tests. Therefore, TPMC staff already received the results of the quantitative testing by the next time the patient would be seen at the practice, which invalidated any clinical meaning or medical use for the qualitative tests.

42. At SAYEGH'S direction, TPMC employees submitted false and fraudulent claims to Medicare and Ohio Medicaid for qualitative testing, representing that these tests were medically necessary for the diagnosis and treatment of patients, when there was no medical necessity for the qualitative tests and these tests were performed for the purpose of maximizing subsequent reimbursements from Medicare and Ohio Medicaid, among other health care benefit programs. SAYEGH also ordered TPMC employees to submit false and fraudulent claims to Medicare and Ohio Medicaid for qualitative and quantitative testing on dates when TPMC's laboratory equipment was inoperable and required maintenance.

COUNT ONE

CONSPIRACY TO UNLAWFULLY DISTRIBUTE CONTROLLED SUBSTANCES

[21 U.S.C. § 846]

THE GRAND JURY CHARGES THAT:

43. Paragraphs 1 through 42 of the Indictment are realleged and incorporated by reference as though fully set forth herein.

44. From at least in or around January 2015, and continuing through at least in or around March 2020, in the Southern District of Ohio, and elsewhere, the defendant MICHAEL SAYEGH knowingly and intentionally combined, conspired, confederated, and agreed with other persons known and unknown to the Grand Jury to unlawfully distribute and dispense controlled substances, including but not limited to methadone and oxycodone, outside the usual course of professional practice and without a legitimate medical purpose.

In violation of 21 U.S.C. § 846.

COUNTS TWO THROUGH SEVEN

UNLAWFUL DISTRIBUTION AND DISPENSING OF CONTROLLED SUBSTANCES

[21 U.S.C. § 841(a)(1)]

THE GRAND JURY CHARGES THAT:

45. Paragraphs 1 through 42 of the Indictment are realleged and incorporated by reference as though fully set forth herein.

46. On or about the dates set forth below, in the Southern District of Ohio, and elsewhere, the defendant MICHAEL SAYEGH, aiding and abetting, and aided and abetted by, others known and unknown to the Grand Jury, did knowingly, intentionally, and unlawfully dispense and distribute, and cause to be dispensed and distributed, outside the usual course of professional practice and not for a legitimate medical purpose, the controlled substances listed below, each of which constitutes a separate count of this Indictment:

Count	Patient	Approximate Date of Written Prescription	Controlled Substance(s)
2	R.D.	8/17/2017	Methadone

Count	Patient	Approximate Date of Written Prescription	Controlled Substance(s)
3	R.D.	8/17/2017	Oxycodone
4	A.M.	3/1/2019	Methadone
5	A.M.	3/1/2019	Oxycodone
6	B.T.	6/19/2019	Methadone
7	B.T.	6/19/2019	Oxycodone

Each in violation of 21 U.S.C. §§ 841(a)(1), 841(b)(1)(C), and 18 U.S.C. § 2.

COUNT EIGHT

CONSPIRACY TO COMMIT HEALTH CARE FRAUD

[18 U.S.C. § 1349]

THE GRAND JURY FURTHER CHARGES THAT:

47. Paragraphs 1 through 42 of the Indictment are realleged and incorporated by reference as though fully set forth herein.

48. From at least on or about January 1, 2015, and continuing through at least in or around March 2020, in the Southern District of Ohio and elsewhere, the defendant MICHAEL SAYEGH did knowingly and willfully combine, conspire, confederate, and agree with others known and unknown to the Grand Jury to knowingly and willfully execute a scheme and artifice to defraud health care benefit programs affecting commerce, as defined in Title 18, United States Code, Section 24(b), that is, Medicare and Ohio Medicaid, 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 programs, 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

49. Paragraph 33 of the Indictment is realleged and incorporated by reference as a description of the purpose of the conspiracy to commit health care fraud.

Manner and Means

50. Paragraphs 34 through 42 of the Indictment are realleged and incorporated by reference as a description of the manner and means of the conspiracy to commit health care fraud.

In violation of 18 U.S.C. § 1349.

COUNTS NINE AND TEN

HEALTH CARE FRAUD

[18 U.S.C. §§ 1347 and 2]

THE GRAND JURY FURTHER CHARGES THAT:

51. Paragraphs 1 through 42 of the Indictment are realleged and incorporated by reference as though fully set forth herein.

52. From at least on or about January 1, 2015, and continuing through at least in or around March 2020, in the Southern District of Ohio, and elsewhere, the defendant, MICHAEL SAYEGH, aiding and abetting, and aided and abetted by, others known and unknown to the Grand Jury, did knowingly and willfully execute, and attempt to execute, a scheme and artifice to defraud health care benefit programs affecting commerce, as defined in Title 18, United States Code, Section 24(b), that is, Medicare and Ohio Medicaid, 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 programs, in connection with the delivery of and payment for health care benefits, items, and services, which scheme is further

described below.

Purpose of the Scheme and Artifice

53. It was the purpose of the scheme and artifice for SAYEGH and his co-conspirators to unlawfully enrich themselves by (1) submitting and causing the submission of false and fraudulent claims to Medicare and Ohio Medicaid for qualitative UDT that was medically unnecessary and not clinically meaningful in the course of treatment to patients of TPMC; (2) concealing the submission of these false and fraudulent claims; and (3) diverting the fraud proceeds for their use and benefit and for the use and benefit of others.

The Scheme and Artifice

54. The Grand Jury realleges and incorporates by reference Paragraphs 34 through 42 of this Indictment as a description of the scheme and artifice.

Acts in Execution of the Scheme and Artifice

55. On or about the dates specified below, in the Southern District of Ohio, and elsewhere, MICHAEL SAYEGH, aiding and abetting, and aided and abetted by, others known and unknown to the Grand Jury, did knowingly and willfully execute, and attempt to execute, the above-described scheme and artifice to defraud health care benefit programs affecting commerce, as defined in Title 18, United States Code, Section 24(b), that is, Medicare and Ohio Medicaid, 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 programs, as follows:

Count	Beneficiary	Type of Claim	Payer Source	Approximate Date of Service Allegedly Performed	Approximate Amount Paid
9	R.D.	Qualitative UDT	Ohio Medicaid	7/25/2017	$11.79
10	M.M.	Qualitative UDT	Medicare	10/3/2019	$63.36

Each in violation of 18 U.S.C. §§ 1347 and 2.

FORFEITURE ALLEGATIONS

The GRAND JURY further alleges:

56. The allegations contained in paragraphs 1 through 55, and specifically Counts 1 through 10, are incorporated here for the purpose of alleging forfeiture pursuant to the provisions of Title 18, United States Code, Section 982 and Title 21, United States Code, Section 853.

57. Upon conviction of a violation of Title 21, United States Code, Section 846, as alleged in Count 1, or one or more violations of Title 21, United States Code, Section 841, as alleged in Counts 2 through 7 of this Indictment, the defendant, MICHAEL SAYEGH, shall forfeit to the United States of America any property constituting, or derived from, any proceeds obtained, directly or indirectly, as the result of such offenses and any property used, or intended to be used, in any manner or part, to commit, or to facilitate the commission of, the offenses.

58. Upon conviction of a violation of Title 18, United States Code, Section 1349, as set forth in Count 8, or one or more violations of Title 18, United States Code, Section 1347, as set forth in Counts 9 and 10 of this Indictment, the defendant, MICHAEL SAYEGH, shall forfeit to the United States of America, pursuant to Title 18, United States Code, Section 982(a)(7) and Title 18, United States Code, 981(a)(1)(C), any property, real or personal, that constitutes or is derived, directly or indirectly, from gross proceeds traceable to the commission of the offenses.

59. If any of the property described above as being 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 that cannot be subdivided without difficulty;

the defendant shall forfeit to the United States any other property of the defendant, up to the value of the property described above, pursuant to Title 21, United States Code, Section 853(p), Title 18, United States Code, Section 982(b)(1), Title 18, United States Code, Section 981(a)(1)(C) and Title 28, United States Code, Section 2461(c).

All pursuant to Title 21, United States Code, Section 853(a), Title 18, United States Code, Section 982(a)(7), Title 18, United States Code, Section 981(a)(1)(C), and Title 28, United States Code, Section 2461(c).

A TRUE BILL:

s/ Foreperson
FOREPERSON

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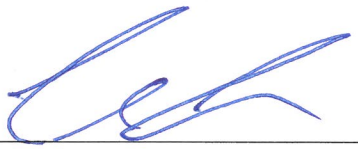

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