FILED
U.S. DISTRICT COURT
MIDDLE DISTRICT OF TENN.

JUL 11 2022

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DEPUTY CLERK

UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

UNITED STATES OF AMERICA	)	
	)	No. 3:22-00232
v.	)	
	)	18 U.S.C. § 2
	)	18 U.S.C. § 1349
JOHN R. MANNING	)	18 U.S.C. § 1347

INDICTMENT

THE GRAND JURY CHARGES:

At all times material to this Indictment:

Introduction

1. Defendant **JOHN R. MANNING**, a resident of Ashland City, Tennessee, was a licensed physician who signed prescriptions and other Medicare-required documents for certain tests, medications, and medical devices.

2. **JOHN R. MANNING** worked for various telemedicine companies that arranged for physicians and other medical professionals to prescribe a variety of durable medical equipment, topical creams, and Cancer Genomic ("CGx") testing for Medicare beneficiaries.

The Medicare Program

3. The Medicare Program ("Medicare") was a federal health care program providing benefits to individuals who were the age of 65, or older, or disabled. The benefits available under Medicare were governed by federal statutes and regulations. Individuals who received benefits under Medicare were commonly referred to as Medicare "beneficiaries."

4. Medicare was 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).

5. Medicare covered, among other things, medical services provided by physicians, medical clinics, laboratories, and other qualified health care providers (collectively, "providers"), and office services and outpatient care—including the ordering of durable medical equipment, prosthetics, orthotics, and supplies ("DME")—that were medically necessary and ordered by licensed medical doctors or other qualified health care providers.

6. Providers that provided services to Medicare beneficiaries were able to apply for and obtain a "provider number." A provider that received a Medicare provider number was able to file claims with Medicare to obtain reimbursement for services provided to beneficiaries.

7. To receive Medicare reimbursement, providers had to apply and execute a written provider agreement, known as CMS Form 855. The Medicare application was required to be signed by the provider or an authorized representative of the provider. The application contained certifications that the provider agreed to abide by the Medicare laws and regulations, including the Federal Anti-Kickback Statute, and 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."

8. Medicare Part D provided prescription drug benefits and helped Medicare beneficiaries pay for prescription drugs. Typically, a Medicare beneficiary enrolled in a Medicare Part D plan would fill their prescription at a pharmacy utilizing their Medicare Part D plan coverage to pay for the prescription. The pharmacy would then submit the prescription claim for

reimbursement to the Medicare Part D beneficiary's plan for payment under the beneficiary's Health Insurance Claim Number and/or Medicare Plan identification number.

9. Medicare required of its providers, among other things, that all drugs prescribed or issued be medically necessary, that is, "reasonable and necessary" for the diagnosis and treatment of an illness or injury. Medicare claim forms, for example, required the provider who made a claim for services to certify that the services were "medically indicated and necessary for the health of the patient."

10. For a drug to have been covered and reimbursable under Medicare, the drug must have been prescribed by a physician who was treating the beneficiary within the scope of the physician's license, must have been required to diagnose or treat the beneficiary's medical condition, and must have been safe and effective.

Telemedicine

11. Telemedicine provided a means of connecting patients to doctors by using telecommunications technology to interact with a patient.

12. Legitimate telemedicine companies provided telemedicine services to individuals by hiring doctors and other health care providers. Legitimate telemedicine companies typically paid doctors a fee to conduct consultations with patients. In order to generate revenue, legitimate telemedicine companies typically either billed insurance or received payment from patients who utilized the services of the telemedicine company.

13. During the timeframe of the conspiracy described below, Medicare covered expenses for specified telemedicine services if certain requirements were met. These requirements included, but were not limited to: (a) the beneficiary was located in a rural or health professional shortage area; (b) services were delivered via a two-way, real-time interactive audio and video

telecommunications system; and (c) the beneficiary was at a practitioner's office or a specified medical facility—not at a beneficiary's home—during the telemedicine consultation with a remote practitioner.

Durable Medical Equipment

14. Medicare covered a beneficiary's access to DME, such as off-the-shelf ("OTS") ankle braces, knee braces, back braces, elbow braces, wrist braces, and hand braces (collectively, "braces"). OTS braces required minimal self-adjustment for appropriate use and did not require expertise in trimming, bending, molding, assembling, or customizing to fit the individual.

15. A claim for DME submitted to Medicare qualified for reimbursement only if it was medically necessary for the treatment of the beneficiary's illness or injury and prescribed by a licensed physician.

16. For certain DME products, Medicare promulgated additional requirements that a DME order must meet for an order to be considered "reasonable and necessary." For example, for OTS knee braces billed to Medicare under the Healthcare Common Procedures Coding System ("HCPCS") Codes L1833 and L1851, an order would be deemed "not reasonable and necessary" and reimbursement would be denied unless the ordering/referring physician documented the beneficiary's knee instability by examination of the member and objective description of joint laxity.

Topical Creams

17. Topical creams and ointments were covered by certain beneficiaries' Medicare Part D plans.

18. Fluocinonide was a topical dermatological cream used to help relieve the redness, itching, swelling, and other discomfort caused by skin conditions. Fluocinonide was in a class of medications called corticosteroids.

19. Calcipotriene was a topical dermatological cream used to treat plaque psoriasis. Calcipotriene was in a class of medications called synthetic vitamin D_3 derivatives.

Cancer Genomic Tests

20. Genetic tests related to a patient's hereditary predisposition to cancer were commonly referred to as CGx tests. CGx testing used DNA sequencing to detect mutations in genes that could indicate a higher risk of developing certain types of cancers in the future. CGx testing was not a method of diagnosing whether an individual presently had cancer.

21. Medicare did not cover diagnostic testing that was "not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(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." 42 C.F.R. § 411.15(a)(1). Among the statutory exceptions Medicare covered were cancer screening tests such as "screening mammography, colorectal cancer screening tests, screening pelvic exams, [and] prostate cancer screening tests." *Id.*

22. If diagnostic testing was necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, Medicare imposed additional requirements before covering the testing. Title 42, Code of Federal Regulations, Section 410.32(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.*

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

COUNT ONE
(Conspiracy to Commit Health Care Fraud)

THE GRAND JURY FURTHER CHARGES:

24. Paragraphs 1 through 23 are re-alleged and incorporated by reference as though fully set forth herein.

The Conspiracy

25. From in or around June 2016, and continuing through in or around April 2019, the exact dates being unknown to the Grand Jury, in the Middle District of Tennessee and elsewhere, **JOHN R. MANNING** did knowingly and willfully combine, conspire, confederate, and agree with persons known and unknown to the Grand Jury, 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, or services, in violation of Title 18, United States Code, Section 1347.

The Purpose of the Conspiracy

26. The purpose of the conspiracy was for **JOHN R. MANNING** and his co-conspirators to unlawfully enrich themselves by, among other things: (a) paying and receiving kickbacks and bribes in exchange for signed doctors' orders and prescriptions for DME, topical creams, and CGx testing, that were not legitimately prescribed, not needed, not used, or induced through unlawful kickbacks and bribes; and (b) submitting and causing the submission of false and fraudulent claims to Medicare for DME, topical creams, and CGx testing that were not medically necessary and not eligible for reimbursement.

The Manner and Means of the Conspiracy

27. The manner and means by which **JOHN R. MANNING** and his co-conspirators sought to accomplish the purpose of the conspiracy included, among other things, the following:

a. **JOHN R. MANNING** falsely certified to Medicare that he would abide by all Medicare rules and regulations and federal laws, including that he would not knowingly present or cause to be presented a false and fraudulent claim for payment by Medicare and that he would comply with the Federal Anti-Kickback Statute.

b. **JOHN R. MANNING** worked for multiple telemedicine companies and signed doctors' orders and prescriptions for DME, topical creams, and CGx testing that were used to submit false and fraudulent claims to Medicare.

c. **JOHN R. MANNING** electronically signed doctors' orders and prescriptions for DME, topical creams, and CGx testing for Medicare beneficiaries based on only a brief telephonic conversation, or often no conversation at all, and without establishing a doctor-patient relationship, without seeing or physically examining the beneficiaries, and without regard for medical necessity.

d. In signing the doctors' orders and prescriptions for DME, **JOHN R. MANNING** falsely certified that he completed a consultation and that the treatment he ordered or prescribed was medically necessary.

e. In signing doctors' orders and prescriptions for topical creams, **JOHN R. MANNING** falsely certified that the prescriptions were written based on a valid patient/doctor relationship in the normal course of his practice.

f. In signing doctors' orders for CGx testing, **JOHN R. MANNING** falsely certified that the testing was medically necessary for the diagnosis or detection of a disease, illness, impairment, syndrome, or disorder and that the results would be used in the medical management and treatment decisions for the patient.

g. Telemedicine companies paid **JOHN R. MANNING** a fee per "visit," constituting illegal kickbacks and bribes in exchange for signing doctors' orders and prescriptions.

28. **JOHN R. MANNING** and his co-conspirators caused the submission of false and fraudulent claims to Medicare in excess of approximately $41 million for DME, topical creams, and CGx that were not legitimately ordered or prescribed, not medically necessary, not used, and induced through unlawful kickbacks and bribes.

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

COUNTS TWO AND THREE
(Health Care Fraud)

THE GRAND JURY FURTHER CHARGES:

29. Paragraphs 1 through 23 and 26 through 28 are re-alleged and incorporated by reference as though fully set forth herein.

30. On or about the dates specified below, in the Middle District of Tennessee and elsewhere, **JOHN R. MANNING** did knowingly and willfully execute, and attempt to execute, a scheme and artifice to defraud Medicare, a health care benefit program affecting commerce as defined in 18 U.S.C. § 24(b), 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, Medicare, in connection with the delivery of, and payment for, health care benefits, items, and services, by causing the submission of false and fraudulent claims to Medicare for DME that was, among other things, not legitimately prescribed, not medically necessary, not used, or induced through unlawful kickbacks, with each claim forming a separate count as outlined in the below table:

Count	Medicare Beneficiary	Approx. Date	Claim No.	Approx. Total Amount Billed	Description of Devices Billed; HCPCS Code
2	H.C.	07/06/2018	118190709015000	$853.91	Left knee orthosis (L1851); Addition to lower extremity orthosis, suspension sleeve (L2397)

Count	Medicare Beneficiary	Approx. Date	Claim No.	Approx. Total Amount Billed	Description of Devices Billed; HCPCS Code
3	J.M.	02/27/2019	119060702906000	$1,068.35	Right knee orthosis (L1851); Addition to lower extremity orthosis, suspension sleeve (L2397)

Each in violation of Title 18, United States Code, Sections 1347 and 2.

COUNTS FOUR THROUGH SEVEN
(Health Care Fraud)

THE GRAND JURY FURTHER CHARGES:

31. Paragraphs 1 through 23 and 26 through 28 are re-alleged and incorporated by reference as though fully set forth herein.

32. On or about the dates specified below, in the Middle District of Tennessee and elsewhere, **JOHN R. MANNING** did knowingly and willfully execute, and attempt to execute, a scheme and artifice to defraud Medicare, a health care benefit program affecting commerce as defined in 18 U.S.C. § 24(b), 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, Medicare, in connection with the delivery of, and payment for, health care benefits, items, and services, by causing the submission of, false and fraudulent claims to Medicare for topical creams that were, among other things, not legitimately prescribed, not medically necessary, not used, or induced through unlawful kickbacks, with each claim forming a separate count as outlined in the below table:

Count	Medicare Beneficiary	Approx. Date	Claim No.	Approx. Total Amount Paid	Description of Cream Billed; NDC Code
4	I.T.	04/11/2019	191014990321044999	$186.85	Fluocinonide cream (51672138603)
5	I.T.	04/11/2019	191014990551054997	$669.01	Calcipotriene cream (00781711783)
6	B.P.	01/29/2019	19429950104100005361817O5	$312.50	Fluocinonide cream (51672138603)
7	B.P.	04/12/2019	195023760481 0000537459337	$263.30	Calcipotriene cream (00781711783)

Each in violation of Title 18, United States Code, Sections 1347 and 2.

COUNTS EIGHT AND NINE
(Health Care Fraud)

THE GRAND JURY FURTHER CHARGES:

33. Paragraphs 1 through 23 and 26 through 28 are re-alleged and incorporated by reference as though fully set forth herein.

34. On or about the dates specified below, in the Middle District of Tennessee and elsewhere, **JOHN R. MANNING** did knowingly and willfully execute, and attempt to execute, a scheme and artifice to defraud Medicare, a health care benefit program affecting commerce as defined in 18 U.S.C. § 24(b), 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, Medicare, in connection with the delivery of, and payment for, health care benefits, items, and services, by causing the submission of, false and fraudulent claims to Medicare for CGx testing that was, among other things, not legitimately ordered or prescribed, not medically necessary, not

used, or induced through unlawful kickbacks, with each claim forming a separate count as outlined in the below table:

Count	Medicare Beneficiary	Approx. Date	Claim No.	Approx. Total Amount Billed	CPT Code
8	N.W.	07/30/2018	911118285025290	$21,948.20	81162 81201 81292 81295 81298 81317 81321 81403 81404 81405 81406 81408
9	Y.M.	01/17/2019	531819050127470	$20,282.94	81162 81201 81292 81295 81298 81317 81321 81403 81404 81405 81406 81408

Each in violation of Title 18, United States Code, Sections 1347 and 2.

FORFEITURE ALLEGATION

THE GRAND JURY FURTHER CHARGES:

35. The allegations contained in the Indictment are re-alleged and incorporated by reference as if fully set forth in support of this forfeiture allegation.

36. Pursuant to 18 U.S.C. § 981(a)(1)(C) and 28 U.S.C. § 2461(c), upon conviction of Count One in the Indictment, **JOHN R. MANNING** shall forfeit to the United States of America, any property, real or personal, which constitutes or is derived from proceeds traceable to the violation. The property to be forfeited includes a money judgment in an amount representing the value of any property, real or personal, which constitutes or is derived from proceeds traceable to the violation.

37. Pursuant to 18 U.S.C. § 982(a)(7), upon conviction of Counts Two through Nine, **JOHN R. MANNING** shall forfeit to the United States, any property, real or personal, which constitutes or is derived, directly or indirectly, from gross proceeds traceable to the commission of the offense. The property to be forfeited includes a money judgment in an amount representing the value of any property, real or personal, which constitutes or is derived, directly or indirectly, from gross proceeds traceable to the commission of the offense.

38. Pursuant to 21 U.S.C. § 853(p), as incorporated by 28 U.S.C. § 2461(c), if any of the property described above, as a result of any act or omission of a defendant:

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

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

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

d. has been substantially diminished in value; or

e. has been commingled with other property which cannot be divided without difficulty,

the United States intends to seek forfeiture of any other property of the defendant up to the value of the forfeitable property described above.

A TRUE BILL

[redacted]

FOREPERSON

MARK H. WILDASIN
UNITED STATES ATTORNEY

ROBERT S. LEVINE
ASSISTANT UNITED STATES ATTORNEY

LORINDA I. LARYEA
ACTING CHIEF, FRAUD SECTION, CRIMINAL DIVISION

LESLIE FISHER
TRIAL ATTORNEY, FRAUD SECTION, CRIMINAL DIVISION