UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

UNITED STATES OF AMERICA

v. CASE NO. 8:20-cr-195-T-35AAS
18 U.S.C. § 1349

MICHAEL NOLAN

INFORMATION

The United States Attorney charges:

COUNT ONE
(Conspiracy to Commit Health Care Fraud)

A. Introduction

At times material to this Information:

The Medicare Program

1. The Medicare Program ("Medicare") was a federal health care benefit program that provided items and services to individuals who were (a) age 65 or older, (b) had certain disabilities, or (c) had end-stage renal disease. Individuals who received Medicare benefits were called "beneficiaries."

2. Medicare was administered by the Centers for Medicare and Medicaid Services ("CMS"), which was an agency of the United States Department of Health and Human Services ("HHS").

3. To help administer Medicare, CMS contracted with private insurance companies called "Medicare Administrative Contractors" or "MACs." MACs performed many functions, such as processing Medicare claims or enrolling suppliers into the Medicare program. In performing such functions, MACs were assigned to particular geographical "jurisdictions."

4. Medicare was made up of several component "parts" that covered different items and services. Medicare Part A, for example, covered inpatient hospital stays. Medicare Part B covered, among other items and services, outpatient care and supplies—including, pertinently, orthotic devices.

Durable Medical Equipment ("DME")

5. Orthotic devices included items such as knee braces, back braces, shoulder braces, wrist braces, and other braces. Such orthotic devices were referred to as "durable medical equipment" or "DME." Under Medicare Part B, as detailed later, beneficiaries could only receive Medicare-covered DME (such as braces) from "suppliers" that were enrolled in Medicare.

6. Medicare claims for DME were processed by two MACs: (i) CGS Administrators, LLC ("CGS"), and (ii) Noridian Healthcare Solutions ("Noridian"). Together, CGS and Noridian are referred to herein as the "DME MACs."

Medicare Part B Enrollment: The Form CMS-855S

7. A different MAC, Palmetto GBA, LLC ("Palmetto"), handled the enrollment of DME suppliers into Medicare. Palmetto was the single entity responsible for, among other duties, issuing or revoking Medicare supplier billing privileges for DME suppliers. Palmetto was also referred to as the National Supplier Clearinghouse ("NSC") MAC for DME suppliers.

8. To enroll in Medicare Part B, DME suppliers were required to submit a completed enrollment application—meaning the "Form CMS-855S"—to Medicare. The Form CMS-855S listed many standards necessary to obtain and to retain Medicare billing privileges as a DME supplier.

9. Pursuant to those standards, DME suppliers were required to provide complete and accurate information on the Form CMS-855S and, further, report any changes to such information to the NSC MAC within 30 days. The standards for DME suppliers also included the following requirements:

a. an authorized individual (one whose signature is binding) must sign the application for billing privileges;

b. DME suppliers were prohibited from direct solicitation to Medicare beneficiaries;

c. DME suppliers had to fill orders from their own inventory or, otherwise, were to contract with another company for the purchase of items to fill orders;

d. DME suppliers had to maintain a staffed physical facility accessible to the public at least thirty hours per week, with visibly posted hours of operation;

e. DME suppliers must disclose any person having ownership, financial or control interest in the supplier;

f. DME suppliers must not convey or reassign a supplier number; and

g. DME suppliers must be accredited by an accreditation organization to receive a supplier billing number.

Owners and Managers of DME Suppliers

10. The Form CMS-855S required applicants to disclose to Medicare any individual or organization with an ownership interest, a financial interest, or managing control of a DME supplier. This included (i) anyone with 5% or more of an ownership stake, either direct or indirect, in the DME supplier; (ii) anyone with a partnership interest in the DME supplier, regardless of the percentage of ownership, (iii) any organizations with "managing control" over the DME supplier, as well as (iv) any and all "managing employees."

11. "Managing employee" was defined on the Form CMS-855S (and elsewhere) as any general manager, business manager, administrator, director, or other individual who exercised operational or managerial control over, or who, directly or indirectly, conducted the day-to-day operations of the DME supplier. This included anyone under contract or through some other

arrangement, whether or not the individual was a "W-2 employee" of the DME supplier.

12. The Form CMS-855S also called for extensive information regarding those who owned, managed, and/or controlled (financially or otherwise) the DME supplier. This information included the mandatory disclosure of "Adverse Legal Actions," which was defined to include, among other things, any federal or state felony conviction within 10 years.

Certification by Authorized Official

13. Finally, the Form CMS-855S required the signature of an "authorized official." The act of signing, or authorizing such signing, bound the DME supplier and official(s) to abide by all "laws, regulations, and program instructions" for Medicare. It also bound and certified the DME supplier and official(s) to the following terms, among others:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to me or to the organization listed in Section 1B of this application. The Medicare laws, regulations, and program instructions are available through the fee-for-service contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations and program instructions[,] including, but not limited to, the Federal Anti-Kickback Statute, 42 U.S.C. section 1320a–7b(b)[.]
>
> ***
>
> I 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.

On-Site "BOC" and Medicare Inspections

14. To enroll in Medicare, DME suppliers were required to complete an accreditation process by an organization approved by CMS. One CMS-approved organization that could perform such accreditation was known as the Board of Certification/Accreditation or the "BOC." The BOC had a set of standards that DME suppliers had to meet for accreditation, which were tested at on-site inspections and random re-inspections.

15. The NSC MAC also conducted surprise on-site inspections for Medicare enrollment, which helped verify the information disclosed in the Form CMS-855S and supporting documents. DME supplier responses to the NSC MAC's on-site inspections were recorded, in part, on a Site Investigation for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics and Supplies, Form CMS-R-263. An authorized site inspector would interview staff seeking, among other information, a complete list of all owners and managers (as defined previously) and, further, whether they or any of their relatives owned other medical entities.

16. The NSC MAC inspection also involved a review of any on-site DME inventory. DME suppliers that did not maintain their own inventory

could be asked to produce a contract with a third-party vendor, such as a DME "drop-shipping" company.

17. Further, the NSC MAC inspection inquired about marketing efforts including, pertinently, direct solicitation or the utilization of any third party to solicit beneficiaries' referrals via telephone.

18. Finally, all Medicare-enrolled DME suppliers were subject to random re-inspections. During a re-inspection, an inspector could make the same inquiries noted above, request supporting documentation, and seek follow up information from the DME supplier. Failure to comply could result in the suspension or revocation of Medicare billing privileges.

DME Suppliers' Unique Identification Numbers: NPIs and PTANs

19. To bill Medicare, the DME supplier required two unique identification numbers: (i) a "National Provider Identifier" or "NPI," and (ii) a "Provider Transaction Access Number" or "PTAN." To issue NPIs, CMS developed the National Plan and Provider Enumeration System, which assigned NPIs to providers, including DME suppliers.

20. For PTANs, the NSC MAC was the entity responsible for issuing such identifiers to DME suppliers, but only after approving their Forms CMS-855S, meaning the Medicare enrollment application. With both the PTAN

and the NPI, DME suppliers could submit claims and receive payments from Medicare for braces and other equipment.

DME Claims Submission under Medicare Part B

21. Claims for DME supplies could be submitted for payment to the MAC through an "Electronic Data Interchange ("EDI") system. EDI was a computer-to-computer electronic exchange of business documents using a standard format. Pertinently, EDI allowed a DME supplier the ability to transmit Electronic Media Claims ("EMC") to a Medicare in a compliant format. Medicare, in turn, required that a DME supplier complete a Common Electronic Data Interchange ("CEDI") agreement for EDI services with the DME MACs. The CEDI agreement, in electing to submit Medicare claims electronically, required the DME supplier to agree to several terms and conditions. Such terms and conditions included the following requirements:

a. that it will be responsible for all Medicare claims submitted to CMS or a designated CMS contractor by itself, its employees, or its agents;

b. that it will submit claims only on behalf of those Medicare beneficiaries who have given their written authorization to do so, and to certify that required beneficiary signatures, or legally authorized signatures on behalf of beneficiaries, are on file;

c. that it will submit claims that are accurate, complete, and truthful;

d. that it will affix the CMS-assigned unique identifier number (submitter ID) of the provider on each claim electronically transmitted to the A/B MAC, CEDI, or other contractor if designated by CMS;

e. that the CMS-assigned unique identifier number (submitter identifier) or NPI constitutes the provider's legal electronic signature and constitutes an assurance by the provider that services were performed as billed; and

f. that it will acknowledge that all claims will be paid from Federal funds, that the submission of such claims is a claim for payment under the Medicare program, and that anyone who misrepresents or falsifies or causes to be misrepresented or falsified any record or other information relating to that claim that is required pursuant to this agreement may, upon conviction, be subject to a fine and/or imprisonment under applicable Federal law.

22. Both methods of filing claims required the submission of certain information relating to a specific patient or beneficiary. The information necessary for a DME claim included:

a. the type of service provided, identified by an "HCPCS" code (meaning "Healthcare Common Procedure Coding System");

b. the date of service or supply;

c. the referring physician's NPI;

d. the charge for such services;

e. patient's diagnosis;

f. the NPI and PTAN for the DME entity seeking reimbursement; and

g. certification by the DME provider that the supplies are medically necessary.

23. Further, before submitting a claim for an orthotic brace to the DME MAC, a supplier was required to have on file the following:

a. written documentation of a verbal order or a preliminary written order from a treating physician;

b. a detailed written order from the treating physician;

c. information from the treating physician concerning the beneficiary's diagnosis;

d. any information required for the use of specific modifiers;

e. a beneficiary's written assignment of benefits; and

f. proof of delivery of the orthotic brace to the beneficiary.

24. Finally, under Medicare Part B, providers were not permitted to routinely waive copayments, which were the portion of the cost of an item paid by a beneficiary.

Cancer-Genetic Testing

25. Cancer genetic testing ("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 had cancer at the time of the test.

26. 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. Except for certain exceptions, Medicare did not cover "examinations performed for a purpose other than treatment or diagnosis of a specific illness, symptoms, complaint or injury." 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."

27. 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. 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 a physician treating the beneficiary are not reasonable and necessary.

28. 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.

Telemedicine Services for Medicare Beneficiaries

29. Telemedicine was a means of connecting patients to providers via a telecommunication technology, such as video-conferencing. Telemedicine companies hired physicians and other providers to furnish telemedicine services to individuals. Telemedicine companies typically paid "treating providers" a fee to consult with patients. In order to generate revenue, telemedicine companies typically either billed the Medicare program or other health insurance program, or offered a membership program to patients.

30. Some telemedicine companies offered membership programs to patients who signed a contract for telemedicine services, paid a set dollar amount per month, and paid a fee each time the patient had a telemedicine encounter with one of its providers.

31. Medicare Part B covered expenses for specified telehealth services if certain requirements were met. These requirements included, among others: (a) that the beneficiary was typically located in a rural area (meaning, outside a "Metropolitan Statistical Area" or in a rural health professional shortage area); (b) that the services were delivered via an interactive audio- and video-telecommunications system; and (c) that the

beneficiary was at a practitioner's office or a specified medical facility—not at home—during the telehealth service furnished by a remote practitioner.

CHAMPVA

32. The Civilian Health and Medical Program of the Department of Veterans Affairs ("CHAMPVA") was a federal health benefit program. CHAMPVA was a comprehensive health care program in which the VA shared the cost of covered health care services and supplies with eligible beneficiaries. The eligible categories for CHAMPVA beneficiaries were the spouses or children of veterans who had been rated permanently and totally disabled for a service-connected disability and the surviving spouse or child of a veteran who died from a VA-rated service-connected disability. In general, the CHAMPVA program covered most health care services and supplies that were medically and psychologically necessary. CHAMPVA was always the secondary payer to Medicare and reimbursed beneficiaries for costs that Medicare did not cover. Health care claims must have first been sent to Medicare for processing. Medicare electronically forwarded claims to CHAMPVA after Medicare had processed them. For Medicare supplemental plans, CHAMPVA processed the remaining portion of the claim after receiving Medicare's explanation of benefits.

The Conspirators and Their Enterprises

The REMN Faction

33. In or about October 2016, MICHAEL NOLAN and R.E. established REMN Management LLC ("REMN") in Tampa, Florida, which is within the Middle District of Florida. Together, NOLAN, R.E., and other conspirators associated with REMN are referred to as the REMN Faction. REMN was a purported "marketing" company serving the CGx-testing and DME industries.

34. In or about April 2018, the REMN Faction conspirators formed a purported telemedicine company called Comprehensive Telcare, LLC ("CompTel"), which was also in the Middle District of Florida. CompTel's telemedicine services were integrated with REMN's purported marketing operations. The REMN Faction conspirators also offered CompTel's services to third parties, including Patsy Truglia, for a per-claim fee. The REMN Faction conspirators dissolved both REMN and CompTel in or around March 2019.

35. Within days of dissolving REMN and CompTel, the REMN Faction conspirators began operating Allure Health Management LLC, which offered the same telemedicine services that CompTel had.

36. The REMN Faction also controlled, owned, held financial interests in, and/or managed multiple DME supply companies—hereinafter, collectively, the "DME Fronts"—including, but not limited to SunRay Medical, Inc. (1265900690/7730250001), JAM Medical (1164990594/7730230001), and A Step Above Medical, Inc. ("A Step Above") (1891270526/7724560001).

The Regency Faction

37. Regency, Inc. ("Regency") was a DME billing and consulting company in Largo, Florida. Regency was owned and operated by K.W., who resided in Pinellas County, Florida. K.W. and others, including S.P. and M.K., at Regency are collectively referred to as the Regency Faction.

38. Regency's consulting services included, among other things, the creation and sale of "turn-key" DME supply companies to clients. As part of this service, Regency generally assisted clients with the accreditation and Medicare-enrollment processes. The REMN Faction conspirators and others used these services to establish DME Fronts.

CGx Marketers

39. Archer Diagnostics, LLC ("Archer"), a South Carolina limited liability company with its principal place of business at 300B American Legion Road, Greer, South Carolina, was a purported marketing company that

identified and solicited beneficiaries to receive CGx testing and provided CGx tests to laboratories.

40. Mark Allen ("Allen"), a resident of South Carolina, owned, operated, and/or controlled Archer.

41. JL Management, LLC ("JL"), a Wyoming limited liability company registered with an address at 30 N. Gould Street, Sheridan Wyoming, was a purported medical billing company. Allen and R.E. owned, operated, and/or controlled JL.

CGx Laboratories

42. Acadian Diagnostic Laboratories, LLC ("Acadian") was a Louisiana limited liability company with its principal place of business at 11842 Justice Avenue, Baton Rouge, Louisiana, within the Middle District of Louisiana. Acadian was a laboratory that purported to provide diagnostic laboratory services, including CGx testing.

43. Laboratory A, a Louisiana limited liability company, purported to provide diagnostic laboratory services, including CGx testing.

B. The Conspiracy

44. Beginning in or about October 2016, and continuing until in or about April 2019, in the Middle District of Florida and elsewhere, the defendant,

MICHAEL NOLAN,

did knowingly and willfully combine, conspire, confederate, and agree with R.E., P.S., K.W., Patsy Truglia, Ruth Fernandez, Mark Allen, and others to commit health care fraud, in violation of 18 U.S.C. § 1347.

C. Manner and Means of the Conspiracy

45. The manner and means by which the defendants and their conspirators sought to accomplish the objects of the conspiracy included, among others, the following:

a. It was part of the conspiracy that the REMN Faction conspirators would and did run a telemarketing operation through REMN and other entities targeting the Medicare-aged population to generate orders for DME braces and CGx-testing.

b. It was further a part of the conspiracy that, to target Medicare beneficiaries, the REMN Faction conspirators would and did obtain personally identifying information or "PII"—such as names, dates of birth,

and/or Medicare ID numbers—for the Medicare-aged population, including by purchasing PII from known "lead generators."

c. It was further a part of the conspiracy that call-center representatives would and did call, or purport to call, Medicare beneficiaries to inquire about, among other information, the beneficiaries' Medicare eligibility, their health status, and whether they wanted DME braces or CGx testing.

d. It was further a part of the conspiracy that call-center representatives would and did make written electronic records of the calls, and purported calls, to Medicare beneficiaries to build orders for DME braces and/or CGx testing.

e. It was further a part of the conspiracy that, through automation and other electronic means, the REMN Faction conspirators would and did cause the transmission of Medicare beneficiaries' orders for DME braces and/or CGx testing to medical practitioners associated with telemedicine companies, including CompTel.

f. It was further a part of the conspiracy that the REMN Faction conspirators would and did offer and pay illegal bribes to medical practitioners to sign and to prescribe the orders for DME braces and/or CGx testing under the guise of "telemedicine," regardless of medical necessity.

g. It was further a part of the conspiracy that, often, the medical practitioners associated with telemedicine companies would and did sign the DME brace and/or CGx-testing orders without ever contacting the Medicare beneficiaries, rather than using the required interactive audio- and video-telecommunications system for a compliant telehealth consultation.

h. It was further a part of the conspiracy that the REMN Faction conspirators would and did electronically transmit, or caused the transmission of, signed DME or CGx-testing orders, which were secured through illegal bribes, to other conspirators, including Truglia, Fernandez, Allen, and others.

i. It was further a part of the conspiracy that the REMN Faction conspirators, the Regency Faction conspirators, and others would and did acquire and create DME Fronts for the purpose of submitting illegal claims for DME braces to Medicare.

j. It was further a part of the conspiracy that the REMN Faction conspirators, the Regency Faction conspirators, and others would and did conceal from Medicare and others, that NOLAN held financial interests in the DME Fronts. The methods of concealment included, among others, the use of straw owners for Medicare enrollment applications (*i.e.*, Forms CMS-855S), corporate records, and other documents.

k. It was further a part of the conspiracy that the REMN Faction conspirators would and did sell and offer to sell orders for DME braces and CGx-testing to other conspirators, including Truglia, R.D., and others.

l. It was further a part of the conspiracy that one or more of the REMN Faction conspirators and Allen caused signed orders for CGx tests and CGx samples to be transmitted to Acadian, Laboratory A, and other testing laboratories, where the samples were tested and claims for reimbursement were submitted to Medicare.

m. It was further a part of the conspiracy that Acadian, Laboratory A, and other testing laboratories paid bribes and kickbacks to Allen and one or more of the REMN Faction conspirators, through REMN and JL, in exchange for the referral of CGx samples.

n. It was further a part of the conspiracy that the REMN Faction conspirators would and did facilitate submission of approximately $25 million of illegal DME claims to Medicare through DME fronts controlled and/or managed by Truglia, Fernandez, and others, resulting in payments of approximately $10 million.

o. It was further a part of the conspiracy that the REMN Faction conspirators would and did facilitate the submission of over

approximately $109 million of illegal CGx claims to Medicare through Acadian and Laboratory A, resulting in payments of over approximately $19 million; and

p. It was further part of the conspiracy that the conspirators would and did participate in meetings, perform various acts, and make statements to accomplish the object of and to conceal the conspiracy.

All in violation of 18 U.S.C. § 1349.

FORFEITURE

1. The allegations contained in Count One of this Information are realleged and incorporated by reference for the purpose of alleging forfeitures pursuant to the provisions of 18 U.S.C. § 982(a)(7).

2. Upon conviction of the violation alleged in Count One, the defendant shall forfeit to the United States of America, pursuant to 18 U.S.C. § 982(a)(7), any and all property, real or personal, which constitutes or is derived, directly or indirectly, from proceeds traceable to the commission of the offense.

3. The property to be forfeited includes, but is not limited to, a judgment in the amount of approximately $2.1 million, which represents the amount of proceeds obtained by the defendant as a result of the commission of the offenses.

4. If any of the property described above, as a result of any act or omission of the defendant:

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

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

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

d. has been substantially diminished in value; or

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

the United States of America shall be entitled to forfeiture of substitute property under the provisions of 21 U.S.C. § 853(p), as incorporated by 18 U.S.C. § 982(b)(1).

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