AUSA: Regina R. McCullough Telephone: (313) 226-9618

AO 91 (Rev. 11/11) Criminal Complaint Special Agent: Steven Warren Telephone: (313) 392-8020

UNITED STATES DISTRICT COURT

for the

Eastern District of Michigan

United States of America

v.

DR. CHARLES DONALD MOK II

Case No. 2:20-mj-30163
Judge: Unassigned,
Filed: 04-24-2020

CRIMINAL COMPLAINT

I, the complainant in this case, state that the following is true to the best of my knowledge and belief.

On or about the date(s) of January 1, 2018 to Present in the county of Macomb in the Eastern District of Michigan, the defendant(s) violated:

Code Section	*Offense Description*
Title 18 U.S.C. § 1347	Health Care Fraud
Title 18 U.S.C. § 1349	Conspiracy to Commit Health Care Fraud

This criminal complaint is based on these facts:

SEE ATTACHED AFFIDAVIT.

☐ Continued on the attached sheet.

Complainant's signature

Steven Warren, Special Agent

Printed name and title

Sworn to before me and signed in my presence and/or by reliable electronic means.

Judge's signature

Date: April 24, 2020

City and state: ~~XXXXXXXX~~ Bay City, Michigan

HON. Patricia T. Morris, United States Magistrate Judge

Printed name and title

APPLICATION IN SUPPORT OF A CRIMINAL COMPLAINT

This is an application for a criminal complaint and summons pursuant to Rule 4(a) of the Federal Rules of Criminal Procedure charging defendant CHARLES MOK with the offense of violating 18 U.S.C. § 1347, health care fraud, and 18 U.S.C . § 1349, health care fraud conspiracy.

INTRODUCTION AND AGENT BACKGROUND

1. I am a Special Agent employed by the United States Department of Health and Human Services ("HHS"), Office of Inspector General ("OIG"), Office of Investigations. I have been so employed since July 2010 and am currently assigned to the Detroit Field Office of HHS-OIG. I am an investigative or law enforcement officer of the United States within the meaning of 18 U.S.C. § 2510(7), in that I am empowered by law to conduct investigations and to make arrests for federal felony offenses.

2. Since becoming a Special Agent with HHS-OIG, my duties and responsibilities have included conducting investigations, audits, and inspections in connection with the administration and enforcement of laws, regulations, orders, contracts, and programs in which HHS is, or may be, a party of interest. I also perform other duties on behalf of the Secretary of HHS. My chief responsibility is the investigation of fraud involving Federal Health Care Programs. As a Special Agent with HHS-OIG, I have received basic criminal investigator training as well

as specialized training in the investigation of fraud and financial crimes. Previously, I was employed as a Special Agent with the Ohio Attorney General's Office, Medicaid Fraud Control Unit for approximately two years.

3. Over approximately the last twelve years, my primary responsibility has been the investigation of criminal fraud against the federally-funded health care programs commonly known as Medicare and Medicaid. These investigations have included individuals, organizations, and businesses that have violated federal laws, including, but not limited to, Title 18, United States Code, Section 1347 (Health Care Fraud), Title 18, United States Code, Section 287 (False, Fictitious, or Fraudulent Claims), Title 18, United States Code, Section 1349 (Conspiracy to Commit Health Care Fraud). In connection with investigating these offenses, I have participated in the execution of search warrants for documents and other evidence in cases involving violations of these offenses.

4. I have knowledge of the facts set forth in this affidavit as a result of my participation in the investigation, as well as information provided to me by other law enforcement agencies, including the Federal Bureau of Investigation ("FBI"). Information pertinent to this investigation was also provided CoventBridge Group (formerly NCI AdvanceMed), the current unified program integrity contractor in Michigan for HHS responsible for performing investigations

and audits designed to protect the Medicare program ("Medicare") from fraud, waste, and abuse. This affidavit is intended to show merely that there is sufficient probable cause for the requested warrant and does not set forth all of my knowledge about this matter.

THE MEDICARE PROGRAM

1. Generally

5. The Medicare Program ("Medicare") is a federally funded health care program providing benefits to persons who are over the age of sixty-five or disabled. Medicare is administered by the Centers for Medicare and Medicaid Services ("CMS"), a federal agency within the HHS. Individuals who receive Medicare benefits are referred to as Medicare "beneficiaries."

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

7. Medicare has four parts: hospital insurance (Part A), medical insurance (Part B), Medicare Advantage (Part C), and prescription drug benefits (Part D).

8. This investigation involves an outpatient clinic providing varicose vein treatment, among other services, including high-dose intravenous ("IV") vitamin C infusions during the COVID-19 pandemic. Services provided at an outpatient clinic, if deemed reasonable and necessary, are covered by Medicare Part B.

9. Medicare Part B claims are processed and paid by private insurance organizations, known as fiscal intermediaries and carries, respectively, who contract with CMS to administer their specific part of Medicare Program.

10. By becoming a participating provider in Medicare, enrolled providers agree to abide by the policies and procedures, rules, and regulations governing reimbursement. To receive Medicare funds, enrolled providers, together with their authorized agents, employees, and contractors, are required to abide by all provisions of the Social Security Act, the regulations promulgated under the Act, and applicable policies, procedures, rules, and regulations issued by CMS and its authorized agents and contractors. Health care providers are given and provided with online access to Medicare manuals and services bulletins describing proper billing procedures and billing rules and regulations.

11. When a provider enrolls in Medicare, Medicare requires the provider to certify that they provider understands that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with the laws, regulations, and program instructions applicable to Medicare. A provider also must certify that the provider will not submit false or fraudulent claims. Medicare would not pay claims for services that were not medically necessary and were not provided as represented to Medicare.

2. Varicose Vein Treatment

12. Medicare relies on Medicare Administrative Contractors ("MACs") to process claims for Medicare Fee-For-Service ("FFS") beneficiaries. MACs are multi-state, regional contractors responsible for administering both Medicare Part A and Medicare Part B claims. The MAC responsible for the State of Michigan is Wisconsin Physician Service Insurance Corporation ("WPSIC").

13. MACs issue Local Coverage Determinations ("LCDs") on whether a service or item is reasonable and necessary, and therefore covered by Medicare within the specific region that the MAC oversees.

14. WPSIC issued LCD L34536[1] as it relates to varicose vein treatment(s) for the State of Michigan.

15. Historically, varicose veins have been treated by conservative measures such as exercise, periodic leg elevation, weight loss, compressive therapy and avoidance of prolonged immobility. When conservative measures are unsuccessful, and symptoms persist, the next step has been sclerotherapy or surgical ligation with or without stripping. Sclerotherapy involves the injection of a sclerosing solution into the varicose vein(s).

[1] https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=34536&ver=30&articleId=56914&CoverageSelection=Local&ArticleType=All&PolicyType=Final&s=South+Carolina&CptHcpcsCode=93971&bc=gAAAABAAQAAA&

16. More recently, endoluminal radiofrequency ablation (“ERFA") and endoluminal laser ablation have been developed as alternatives to sclerotherapy and surgical intervention. These procedures as designed to damage the intimal wall of the vein resulting in fibrosis and subsequent ablation of the lumen of a segment of the vessel.

17. Doppler ultrasound or duplex studies are often used to map the anatomy of the venous system prior to the procedure. Medicare will cover one ultrasound or duplex scan prior to the procedure to determine the extent and configuration of the varicosities when it is medically necessary. The Current Procedural Terminology codes for radiofrequency and laser include the intra-operative ultrasound service in the valuation and ultrasound may not be billed separately with these procedures.

18. Indications for surgical treatment and sclerotherapy include:

- A 3-month trial of conservative therapy such as exercise, periodic leg elevation, weight loss, compressive therapy, and avoidance of prolonged immobility where appropriate, has failed, AND
- The patient is symptomatic and has one, or more, of the following:

- Pain, aching, cramping, burning, itching and/or swelling during activity or after prolonged standing severe enough to impair mobility
- Recurrent episodes of superficial phlebitis
- Non-healing skin ulceration
- Bleeding from a varicosity
- Stasis dermatitis
- Refractory dependent edema

19. In addition to the factors in the paragraph above, the patient's anatomy and clinical condition are amenable to the ERFA or laser ablation including ALL of the following:

- Absence of aneurysm in the target segment.
- Maximum vein diameter of 20 mm for ERFA or 30 mm for laser ablation.
- Absence of thrombosis or vein tortuosity, which would impair catheter advancement.
- The absence of significant peripheral arterial diseases.

20. Limitations for ERFA and laser ablation include:

- ERFA and laser ablation are covered only for the treatment of symptomatic varicosities of the lesser or greater saphenous veins and their tributaries which have failed 3 months of conservative measures, by any technique, will be considered cosmetic and therefore not covered.
- Intra-operative ultrasound guidance is not separately payable with ERFA, laser ablation.
- The treatment of asymptomatic varicose veins, or symptomatic varicose veins without a 3-month trial of conservative measures, by any technique, will be considered cosmetic, and therefore not covered unless there is associated bleeding.
- Coverage is only for devices specifically Food and Drug Administration ("FDA")-approved for these procedures.
- One pre-operative Doppler ultrasound studies will be allowed if medically necessary.
- Post-procedure Doppler ultrasound studies will be allowed if medically necessary.

21. The stab phlebectomy of the same vein performed on the same day as endovenous radiofrequency or laser ablation may be covered if the criteria for reasonable and necessary as described in this LCD are met.

22. If sclerotherapy is used with endovenous ablation, it may be covered if the criteria for reasonable and necessary as described in this LCD are met.

23. The treatment of asymptomatic veins with endoluminal ablation or sclerotherapy is not considered medically reasonable and necessary. If it is determined on review that the varicose veins were asymptomatic, the claim will be denied as a noncovered (cosmetic) procedure.

24. The following are documentation requirements that must be met for the service to be reimbursed by Medicare:

- Each claim must be submitted with a diagnosis code(s) that reflects the condition of the patient and indicates the reason(s) for which the service was performed.
- The patient's medical record must contain a history and physical examination supporting the diagnosis of symptomatic varicose veins, and the failure of an adequate (at least 3 months) trial of conservative management.

- This documentation must be made available to Medicare upon request.
- When the documentation does not meet the criteria for the service rendered or the documentation does not establish the medical necessity for the services such services will be denied as not reasonable and necessary under Section 1862(a)(1) of the Social Security Act.

25. The table below shows the 2019 Michigan reimbursement rates for the different varicose vein treatment codes.

Table[2]

CODE	DESCRIPTION	NON-FACILITY PRICE	FACILITY PRICE
36465	Injection of non-compounded foam sclerosant with ultrasound compression maneuver to guide dispersion of the injectate, inclusive of all imaging guidance and monitoring; single incompetent extremity truncal vein (e.g., great saphenous vein, accessory saphenous vein)	$1,568.27	$135.79
36466	Injection of non-compounded foam sclerosant with ultrasound compression maneuver to guide dispersion of the injectate, inclusive of all imaging guidance and monitoring; multiple incompetent truncal vein (e.g., great saphenous vein, accessory saphenous vein), same leg	$1,651.30	$172.84
36470	Injection of sclerosant; single incompetent vein (other than telangiectasia)	$111.48	$43.40
36471	Injection of sclerosant; multiple incompetent veins (other than telangiectasia), same leg	$202.14	$85.94

3. High-Dose Intravenous Vitamin C Infusion

26. Vitamin C is a nutrient that is found in various fruits and vegetables. vitamin C is an antioxidant and helps prevent damage to cells caused by free radicals. It also works with enzymes to play a key role in making collagen. vitamin C is also called L-ascorbic acid or ascorbate.

27. High-dose vitamin C may be taken by mouth or given by an IV infusion (through the vein into the bloodstream). When taken by IV infusion, vitamin C can reach higher levels in the blood than when the same amount is taken by mouth.

[2] Centers for Medicare and Medicaid, Physician Fee Schedule (April 21, 2020) https://www.cms.gov/apps/physician-fee-schedule/search/search-criteria.aspx

28. In general, high-dose vitamin C given by IV has caused very few side effects in clinical trials. However, IV vitamin C may cause serious side effects in patients with kidney disease, G6DP deficiency, or hemochromatosis.

29. Generally, drugs and biologicals are covered by Medicare only if all of the following requirements are met:

- They meet the definition of drugs or biologicals
- They are of the type that are not usually self-administered
- They meet all the general requirements for coverage of items as incident to a physician's service
- They are reasonable and necessary for the diagnosis or treatment of the illness or injury for which they are administered according to accepted standards of medical practice
- They are not excluded as noncovered immunizations
- They have not bee determined by the FDA to be less than effective

30. Use of the drug or biological must be safe and effective and otherwise reasonable and necessary. Drugs or biologicals approved for marketing by the FDA are considered safe and effective for purposes of this requirement when used for indications specified on the labeling. Therefore, Medicare may pay for the use of an FDA approved drug or biological, if:

- It was injected on or after the date of FDA approval
- It is reasonable and necessary for the individual patient; and
- All other applicable coverage requirements are met

31. Determinations as to whether a medication is reasonable and necessary for an individual patient should be made on the same basis as all other such determinations (i.e. with the advice of medical consultants and with reference to accepted standards of medical practice and the medical circumstances of the individual case). The following guidelines identify three categories in which medications would not be reasonable and necessary according to the accepted standards of medical practice:

- Not for a Particular Illness; medications given for a purpose other than the treatment of a particular condition, illness, or injury are not covered (except for immunizations)
- Charges for Medications; vitamins given simply for the general good and welfare of the patient and not as accepted therapies for a particular illness are excluded from coverage
- Excessive Medications; medications administered for treatment of a disease and which exceed the frequency or duration of injections indicated by accepted standards of medical practice are not covered

32. If a medication is determined not to be reasonable and necessary for diagnosis or treatment of an illness or injury according to the above guidelines, the MAC excludes the entire charge (i.e. for both the medication and its administration). Also, the MAC excludes from payment any charges for other services (such as office visits) which were primarily for the purpose of administering a noncovered injection.

33. Medicare does not cover preventative care for immune booster and thus any vitamin C infusion for a Medicare beneficiary as a prophylaxis (i.e. immune boosting) is not a covered service.

34. The table below shows the 2019 Michigan reimbursement rates for the codes related to infusion therapy.

CODE	DESCRIPTION	NON-FACILITY PRICE	FACILITY PRICE
99201		$44.30	$26.75
99202		$74.21	$50.36
99203		$105.66	$75.85
99204	Office or other outpatient visit for the evaluation and	$161.19	$128.40
99205	management of a new patient	$202.98	$167.54
99211		$21.76	$9.17
99212		$43.61	$25.39
99213		$72.30	$50.77
99214	Office or other outpatient visit for the evaluation and	$106.08	$78.26
99215	management of an established patient	$142.49	$110.36
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug)	$67.66	$67.66
86769	Antibody; severe acute respiratory syndrome coronavirus 2(SARS-CoV-2) (Coronavirus disease [COVID-19])	Fee Schedule is Not Available	Fee Schedule is Not Available

J7050	Infusion; normal saline solution, 250 cc	Fee Schedule is Not Available	Fee Schedule is Not Available
J3490	Unclassified drugs	Fee Schedule is Not Available	Fee Schedule is Not Available

THE DEFENDANT AND HIS PRACTICE

35. The Defendant, CHARLES MOK, is a Doctor of Osteopathy and received his degree from the Chicago College of Osteopathic Medicine in Illinois in 1989. MOK was first licensed in the State of Michigan on or around June 23, 1990. MOK also maintains professional licenses in at least ten other states; Florida, South Carolina, Georgia, Wisconsin, Indiana, Nebraska, North Carolina, Ohio, Mississippi, and Tennessee.

36. Allure Medical Spa, PLLC (ALLURE) was founded in 2014 by MOK. ALLURE is organized under the laws of the State of Michigan. Its principal place of business is at 8180 26 Mile Road, Shelby Township. MI 48316. ALLURE operates twenty-six outpatient clinics specializing in varicose vein treatments in eight different states with at least six clinics within the State of Michigan.

37. ALLURE utilizes a "flat leadership" model with no C-suite, no managers, and no explicit hierarchy. There is an executive team, known as a "Strategic Counsel," comprised of MOK and several upper management employees.

38. ALLURE is not an enrolled Medicare provider and bills for services its providers render under VEIN CENTER AT ALLURE MEDICAL SPA, PLLC ("VEIN CENTER") using National Provider Identifier ("NPI") 1457302051. VEIN CENTER's principle place of business is at the ALLURE location in Shelby Township. ALLURE and VEIN CENTER are two separate entities and there is no management services organizations (MSOs) agreement in place.

39. Medicare records indicate VEIN CENTER has been an enrolled provider with Medicare dating back to at least November 1, 2017, and as such, has certified to Medicare that it would comply with all Medicare rules and regulations, including that it would not knowingly present or cause to be presented a false and fraudulent claim for payment by Medicare.

40. According to the enrollment record, VEIN CENTER's principal practice location is at the Shelby Township ALLURE location.

INVESTIGATIVE BACKGROUND

41. In April 2020, HHS-OIG and the FBI initiated an investigation into ALLURE in connection with allegations of health care fraud related to varicose vein treatments.

42. A cooperating witness, ("CW-1"), is an employee at ALLURE. As part of CW-1's job responsibilities, CW-1 is known to have direct access to MOK,

to other key employees, as well as to records, files, and materials maintained at ALLURE. CW-1 has corroborated CW-1's access to ALLURE personnel and information by providing documents, communications, and by conducting consensually recorded voice calls.

CW-1 reported that ALLURE engaged in a continuing scheme to defraud the United States through the submission of false and fraudulent claims to Medicare for payment for services in its clinics treating varicose veins. Claims were false and fraudulent because they were for services that were unreasonable, unnecessary, or that simply did not occur as ALLURE reported to have occurred. Specifically, these schemes included:

- Upcoding of Varithena Treatments: ALLURE treats tributary (branch) veins with Varithena injections but bills Medicare as if its providers had treated the patients' greater saphenous veins ("GSV") veins with Varithena injections. The proper codes for treatment of the tributary veins with Varithena injections are CPT code(s) 36470 and 36471. The CPT code(s) for treatment of the GSV with Varithena injections are 36465 and 36466. CPT code(s) 36465 and 36466 have much higher reimbursement rates then CPT code(s) 36470 and 36471. As such, ALLURE upcodes the visits and improperly bills CPT code(s)

36465 and 36466 for Varithena injections into the tributary veins in order to increase reimbursements.

- Providing Excessive, Medically Unnecessary Treatments: Records show that ALLURE patients receive up to 19 Varithena injections per leg and/or up to 12 ablations per leg, beyond what is medically necessary to treat their conditions. Medicare regulations state that "Medicare would not expect to see . . . more than three sclerotherapy sessions [such as Varithena injections] for each leg." Industry standard is less than two ablations per person. ALLURE is providing excessive and medically unnecessary treatments in order to increase profits.

43. The allegations relating to Varithena date back to 2018, when ALLURE first started using Varithena injections to treat varicose veins.

44. CW-1 also informed law enforcement that, beginning on April 14, 2020, ALLURE began offering high-dose IV vitamin C infusions to patients at risk of contracting COVID-19 and those who have already tested positive for COVID-19. The roll-out of these procedures was marketed through a video offering a treatment which MOK said was being used in hospitals across the country to treat

the most advanced COVID-19 related disease for individuals who tested positive for COVID-19. In multiple launch videos, MOK states that ALLURE is offering these infusions because vitamin C reduces the duration and severity of symptoms of COVID-19. In other statements, he recognizes that vitamin C has not been approved by the FDA or any other agency or recognized medical association to treat COVID-19.

45. CW-1 received communications via electronic mail indicating that ALLURE will bill insurance companies, including Medicare, for treatments related to the IV vitamin C infusion to include an CPT code(s) related to office visits for new and established patients, infusion with saline and vitamin C, and antibody testing.

46. On April 20, 2020, CW-1 provided law enforcement with information from internal records readily available to CW-1 showing that ALLURE has submitted at least 98 claims to insurance companies, including Medicare, related to infusion therapy services as it relates to COVID-19 treatment.

PROBABLE CAUSE

47. Probable cause that MOK violated 18 U.S.C. §1347 is established from Medicare data, statements, records, and information from employees of ALLURE (including CW-1), statements from medical experts, and medical review of patient records.

48. This evidence demonstrates that prior to and continuing during the COVID-19 pandemic, MOK engaged in a scheme to defraud the United States through the submission of false and fraudulent claims to Medicare for payment related to the treatment of varicose veins.

49. The evidence will further demonstrate that MOK used the COVID-19 pandemic as an opportunity to bill insurers for Vitamin-C infusions fraudulently represented as COVID-19 treatments and preventative measures. In addition to billing for fraudulent medical treatments at ALLURE, MOK failed to observe appropriate protocols at the clinic minimize the spread of the virus.

A. MEDICARE DATA

50. Medicare claims data demonstrates that from January 1, 2018 until April 7, 2020, ALLURE billed approximately 27,580 claims for services rendered by its providers to approximately 3,131 Medicare beneficiaries. These services include treatments related varicose veins and dermatologic conditions which led to

approximately $41.4 million in billings to Medicare resulting in approximately $12.5 million paid to ALLURE.

51. During the same time frame, ALLURE has billed approximately 409 claims for CPT code 36465 totaling approximately $1.3 million of which $450,000 was paid. ALLURE has billed approximately 5,395 claims for CPT code 36466 totaling approximately $19.7 million of which $5.9 million was paid.

52. According to a peer comparison of Medicare data for the 2nd half of 2019, ALLURE was paid approximately $3.1 million, more than five times as much as the next highest practice in the nation, which was paid approximately $588,000 for CPT Code 36466.

53. ALLURE is not only a reimbursement outlier; it is an outlier on the intensity of its use of CPT Code 36466 when compared to other, similar codes. CW-1 alleges that ALLURE should be billing its services under CPT code(s) 36470 and 36471 instead of under CPT code(s) 36465 and 36466. A distribution of these four CPT codes across all practices in the United States shows that ALLURE is an extreme outlier on CPT code 36466 in that approximately 88% of its total claims for these four codes are CPT code 36466, while the national average is approximately 11%; approximately 82% of its Medicare beneficiaries are being billed for this code while the national average is approximately 11% and

Medicare beneficiaries are on average getting 3.67 of these procedures while the national average is two.

54. MOK himself has been identified as an extreme outlier for Michigan-based physicians. His billing records place him in the 99.9th percentile in the country in billings for potentially cosmetic procedures.

55. As was noted above, internal records readily available to CW-1 show that ALLURE has submitted at least 98 claims to insurance companies, including Medicare, related to Vitamin-C infusion therapy services offered to patients as purported COVID-19 treatment and preventative care.

B. EMPLOYEE STATEMENTS

CW-1

Vericose Vein Treatments

56. CW-1 reports that MOK and other practitioners at ALLURE treat varicose veins, which are twisted, swollen veins, often appearing blue or dark purple. Varicose veins are caused by venous insufficiency as a result of valve reflux (incompetence). As such, varicose veins are also known as incompetent veins. Any superficial vein may become varicosed, but the veins most commonly affected are those in the legs. Superficial veins in the legs include the truncal

veins; the GSV, the small saphenous vein ("SSV") and their tributary and accessory veins, and the accessory saphenous veins ("ASV").

57. The GSV is the major superficial vein of the medial leg and thigh. It is the longest vein in the human body, extending from the top of the foot to the upper thigh and groin. The SSV is a superficial, subcutaneous vein of the lower leg.

58. Tributary veins and ASVs differ in terms of the structure of their wall and their topography. Tributaries have a fragile wall, frequently associated with a tortuous, varicose appearance, with thin-walled ectatic zones interrupted by thick-walled zones. In contrast, ASVs possess a more solid, reinforced media and can consequently be considered to have a "saphenous" type of wall. Topographically, ASVs remain relatively linear and run close to the main saphenous trunk while tributaries are often situated at a distance from saphenous trunks and may travel around the thigh, corresponding to a scarf distribution. Accordingly, treatment of the tributaries and the ASVs is billed differently.

59. Perforator (branch) veins connect the superficial venous system with the deep venous system.

60. According to CW-1, MOK and other practitioners at ALLURE treat perforator (branch) veins with Varithena injections but bill Medicare as if its

providers treated the patients' truncal veins with Varithena injections in order to maximize reimbursements.

61. Treatment of varicose veins includes compression therapy, ablation and sclerotherapy. According to the treatment plan section of the ALLURE patient visit notes, ALLURE's general practice is to first ablate the GSV, SSV or ASV using either / both radiofrequency ablation ("RFA") and laser ablation ("EVLA"). This procedure "injures" the vein walls causing the veins to close and eventually turn into scar tissue. It is impractical to ablate tributary veins due to their thin walls and spiral shape. As such, if the patient continues to experience symptoms, which is common, ALLURE then treats the varicosed tributary veins (referred internally at ALLURE as "varicosities") with sclerotherapy, the injection of foam. Since around spring of 2018, ALLURE has been treating the tributary veins primarily with Varithena injections. In the past, ALLURE used sodium tetradecyl sulphate ("STS") injection to treat the tributaries.

62. Varithena is FDA-approved for treatment of incompetent GSVs, ASVs and tributaries above and below the knee. Varithena is not FDA-approved for the treatment of the SSV. ALLURE primarily treats the veins above the knee with Varithena but also treats veins below the knee as well on a routine basis. The billing code(s) for treatment of the veins with Varithena are CPT code(s) 36465

(single incompetent truncal vein) and 36466 (multiple incompetent truncal veins in the same leg). The definitions of CPT code(s) 36465 and 36466 define truncal veins as the GSVs and the ASVs. Tributary veins are excluded from the two definitions. The proper billing code(s) for treatment of other incompetent veins, such as tributary veins, with Varithena injections are CPT code(s) 36470 and 36471. CPT code(s) 36465 and 36466 have a much higher reimbursement rates than CPT code(s) 36470 and 36471. As such, ALLURE upcodes the visits and bills Medicare CPT code(s) 36465 and 36466 for Varinthea injections into the tributary veins in order to increase reimbursements.

63. Ablations and Varinthea injections are mutually exclusive treatments. Once a vein is ablated, it is closed. As such, there is no need to treat it with Varintena injections. This means that ALLURE did not and could not have treated the GSV, ASVs, or SSVs with Varithena injections following an RFA and/or an EVLA ablation. The Ultrasound Order section in the patients' medical record clearly states the GSVs were already ablated before the start of the patient's Varithena injections. As such, Varithena injections following ablations of the GSVs, SSVs, and ASVs (when applicable) were performed on the tributary veins. Accordingly, the vast majority of Varithena claims following ablation of the GSV should have been billed as CPT code(s) 36470 or 36471.

64. ALLURE is documenting the treatments in the patient's medical record in a very generalized fashion stating something to the effect of "ultrasound guided injections on non-compounded microfoam therapy for the right great saphenous, small right saphenous, right varicose and/or enlarged branches and due to vein morphology and distal disease." The "and/or" statement is overly inclusive and suggests that the GSV and SSV were also injected in addition to the tributaries. However, this is not correct, and cannot be, because the GSV was already ablated and closed, and Varithena is not FDA-approved for treating the SSV. As such, according to CW-1, the documentation is false.

65. CW-1 has direct knowledge of thousands of Medicare claims for beneficiaries who received Varithena injections after ablations and whose Varithena injections were improperly billed as CPT code(s) 36465 and 36466. Many of the beneficiaries were billed for several Varithena injections.

66. MOK has attempted to justify billing Medicare CPT code(s) 36465 and 36466 when injecting tributaries in several communications with CW-1. MOK argues that, if ALLURE providers inject the tributaries with Varithena, some of the foam will make its way into the truncal veins that were already ablated and this justifies billing Medicare for the higher reimbursable CPT code(s). MOK's explanation directly contradicts LCD 34536, which governs the provisions of

Medicare services for varicose vein treatment in Michigan. The code definitions specifically state that CPT code(s) 36465 and 36466 are only for injecting truncal veins. The CPT code(s) are based on which vein is injected, not which veins the foam might eventually seep into. Moreover, ALLURE had already ablated the truncal veins so no Varithena foam could make its way to any of the tributaries because they were already closed. MOK'S justification for this billing practice is thus directly belied by the rules governing reimbursement for the relevant codes, leading CW-1 to believe it disingenuous.

67. In videos created by MOK and distributed and/or available to ALLURE staff including CW-1, MOK references his personal review of Medicare regulations and makes clear that he is against making any changes to how ALLURE bills for Varithena. According to CW-1, he is resolute on this point despite having heard concerns from fellow practitioners and other ALLURE employees about the propriety of this billing practice. MOK acknowledges that truncal veins and tributary veins are different veins and that CPT code(s) differentiate between the two. Despite this, MOK explores various theories to justify classifying both under the umbrella of truncal veins because otherwise, if ALLURE were billing correctly, it would receive significantly less reimbursement per Varithena injection. This would affect ALLURE's overall profits.

68. ALLURE also renders medically unnecessary Varithena injections and ablations to Medicare beneficiaries in order to maximize its profits. Internal ALLURE records readily available to CW-1 show that some ALLURE patients receive up to 19 Varithena injections per leg and/or up to 12 ablations per leg, well beyond what is medically necessary to treat their conditions.

69. According to Medicare regulations, Medicare would not expect to see more than three sclerotherapy sessions, which includes Varithena injections, for each leg.

2. PRACTICES DURING THE COVID-19 PANDEMIC

70. In March of 2020, Governor Gretchen Whitmer, issued an Executive Order placing temporary restrictions on non-essential medical and dental procedures. Governor Whitmer ordered that "all hospitals, freestanding surgical outpatient facilities, and dental facilities, and all state-operated outpatient facilities. . . must implement a plan to temporarily postpone, until the termination of the state of emergency under section 3 of Executive Order 2020-4, all non-essential procedures…for purpose of this order, 'non-essential procedures' means a medical or dental procedure that is not necessary to address a medical emergency or to preserve the health and safety of a patient, as determined by a licensed medical provider."

71. Despite the Executive Order, MOK has directed ALLURE and its staff to continue performing elective, non-essential medical procedures and to keep its clinics open.

72. ALLURE providers and staff are continuing to perform vein ablations, Varithena vein injections, and even cosmetic procedures on hundreds of patients. MOK interprets the Executive Order and Directive as not applying to ALLURE because he categorizes ALLURE's procedures as essential rather than elective. MOK told ALLURE staff if ALLURE does not treat patients now, the patients will develop complications and seek help at hospitals, which will drain hospital resources. MOK seeks to capitalize on the fact that ALLURE's competitors have closed their offices and see this as an opportunity to steal competitors' patients. In ordering ALLURE's operations to continue, MOK and ALLURE is subjecting ALLURE's patients to COVID-19 and risk increasing the spread of the virus.

73. On March 20, 2020, when MOK was alerted of the State of Michigan Order, CW-1 participated in a video conference with MOK and several other ALLURE staff members. It was suggested to MOK that ALLURE's vein procedures are non-essential and that the Executive Order applies to ALLURE. MOK was further advised that ALLURE's competitors in Michigan were closing

their vein practices in Michigan. MOK responded saying the other practices were "cowards" and the COVID-19 pandemic is an "opportunity to capture the market."

74. MOK followed-up the meeting by publishing a video for ALLURE staff and then subsequently uploading the video to his YouTube channel[3] explaining why ALLURE was staying open and operating despite the Executive Order. In the video, MOK states ALLURE is "doing everything that can be done to limit exposure," including self-screenings of employees for COVID-19 symptoms and asking employees to leave if they have a cough or temperature. MOK further states that he is "doing things based on science and data, and not on "hype" because "the worst-case scenario [that Michigan is preparing for] will not occur." MOK adds: "We don't have to one-up the Governor. . . We don't have to take it a step further and say were not gonna close our business down because this virus is expected to be here until December. . . because that is way past an over-abundance of caution. . . I'm trying to avoid doing, making errors that we have control over. Now if the governor comes in and says we have to close down medical practices, that's what it is. . . we have to do it." However, when the Governor issued another Executive Order requiring that all activities that are not

[3] https://www.youtube.com/watch?v=VHXjEIynrI8&feature=youtu.be

necessary to sustain or protect life be suspended and all non-essential personnel stay home, MOK again refused to comply.

75. ALLURE's management has expressed concern that ALLURE remains open. On March 23, 2020, a Regional Director ("EMPLOYEE-1") sent CW-1 a text message stating, "I can't help but feel we are manipulating the governors [sic] message. Realistically how many times over the past year has a vein patient ended up in a hospital. I'm not feeling good about the decision."

76. On March 23, 2020, one of ALLURE's Directors ("EMPLOYEE-2") sent CW-1 a text message stating the following, "Omg [Oh my God]. He [MOK] wants cosmetic patients to stay on. He just flipped on me." CW-1 replied, "What? I thought he was canceling cosmetic patients." EMPLOYEE-2 responded, "Me too. . . he just said no and he doesn't know where that's coming from and he want [sic] a zoom meeting with us. . .to get on the same page because we're ruining the business."

77. CW-1 has observed that MOK has been facing pushback from ALLURE's providers and management team for his decision to keep ALLURE open and operating. In response, MOK published another video on his YouTube

channel on March 24, 2020[4] threatening providers with malpractice lawsuits if they don't continue treating patients.

78. Based on CW-1's medical training and experience working at ALLURE, patients that visit ALLURE do not go to the hospital after an ablation. MOK is manipulating the Executive Order to fit his narrative, which is to do everything to keep the business running, even if this puts ALLURE's staff and patient's lives at risk. If MOK's priority was patient care, ALLURE would not be screening and treating new patients during this time but would instead focus on scanning established patients who had an ablation to ensure they do not develop a DVT. However, even providing these scans to established patients is not an essential service necessary to sustain or protect life since according to CW-1 and EMPLOYEE-1 indicated less than 1% of ALLURE patients have developed a DVT from an ablation. As such, prior to the COVID-19 pandemic, ALLURE did not routinely scan patients for a DVT after an ablation procedure but is asking patients to come in for this scan while a statewide emergency Executive Order is in effect. This scenario is easily accomplished by ALLURE providers whom are available on-call for emergencies.

[4] https://www.youtube.com/watch?v=pzeBsCimUNc&feature=youtu.be

79. In a March 24, 2020 text message to CW-1, MOK wrote, "We've had massive breakthroughs Added 38 new patient screens today which is very high for a Tuesday. Our culture and core values are the most alive and well in our history and our goal to restore wages is the most safe it's been. We are still at risk. But our amazing ladies and gentlemen have stepped up. It almost feels like WW2 where people pulled together to save our world as we know it. . . Today. [sic] We added 28 mapping Did you look at the video from today? I think we need to send it to all vein practices to save healthcare I'm leery to as it is a strategy. But want to as we need to save healthcare". MOK later stated, "I'd like to send to every Doc. Need to do a call. If we don't act more lives are lost. Not related to us. Our mission is to save healthcare I need freedom to do it."

80. Internal ALLURE records readily available to CW-1 show that between March 24, 2020 and April 14, 2020, ALLURE has treated approximately 950 patients, in-person at its clinics, including the Subject Premises. The clinics' waiting rooms were full of patients sitting next to each other and not adhering to the six-foot social distancing recommendation by the Centers for Disease Control ("CDC"). Employees are working without proper PPE and are in close contact with each other and patients during examinations and treatments. The majority of

ALLURE's patient census are patients over 50 years of age and have other health problems.

81. CW-1 is aware of five employees that have tested positive for COVID-19 yet continued to work and treat patients at ALLURE. At least one employee, a nurse practitioner (EMPLOYEE-3), continued to work knowing s/he had tested positive for COVID-19. Another employee, a physician (EMPLOYEE-4), came back to work after self-isolating for nine days between March 21, 2020 and March 30, 2020. On April 5, 2020, CW-1 was informed that both EMPLOYEE-3 and EMPLOYEE-4 tested positive for COVID-19.

82. EMPLOYEE-3 exhibited COVID-19 symptoms on March 24, 2020 and subsequently took leave from ALLURE. Per human resources ("HR") notes readily available to CW-1, EMPLOYEE-3 returned to work on March 30, 2020 but according to other internal ALLURE records readily available to CW-1, the records suggest EMPLOYEE-3 returned to work on April 9, 2020. Those same records show that between March 16, 2020 and April 18, 2020, EMPLOYEE-3 treated 131 patients at ALLURE. On April 17, 2020, EMPLOYEE-3 reported to CW-1 that s/he was administered a nasal swab test which indicted s/he was still positive for COVID-19 and s/he remained symptomatic. Despite EMPLOYEE-3's

concern, MOK assigned EMPLOYEE-3 to treat COVID-19 patients because s/he had already contracted the virus.

83. EMPLOYEE-4 returned to work at ALLURE on March 30, 2020 upon becoming asymptomatic for COVID-19. On March 30, 2020, EMPLOYEE-4 tested positive for COVID-19. Despite testing positive, EMPLOYEE-3 and EMPLOYEE-4 continue to work at ALLURE treating patients.

84. Internal ALLURE records readily available to CW-1 show that between March 16, 2020 and March 20, 2020, before self-isolating, EMPLOYEE-4 treated 40 patients. From March 30, 2020 to April 8, 2020, EMPLOYEE-4 treated 69 patients. Most of the patients treated by EMPLOYEE-4 are over the age of 50 and many are in their 60s, 70s, and some patients are in their 80s. The numbers continue to grow as EMPLOYEE-4 is continuing to work at ALLURE.

85. MOK advised EMPLOYEE-4 and others within management including CW-1 that none of the staff EMPLOYEE-4 has worked with, and continues to work with, need to be informed of the positive COVID-19 results. MOK indicated he did not want to alert the staff who work with EMPLOYEE-4 or the patients treated by EMPLOYEE-4 to self-quarantine themselves because he does not think it is warranted.

86. A physician assistant (EMPLOYEE-5) tested positive for COVID-19 based on a test administered at ALLURE. EMPLOYEE-5 began exhibiting COVID-19 symptoms on or around March 16, 2020 but did not take leave from work until March 26, 2020. Internal ALLURE records readily available to CW-1 show that between March 16, 2020 and March 20, 2020, before self-isolating, EMPLOYEE-5 treated 33 patients.

87. A registered vascular technician (EMPLOYEE-6) worked directly with EMPLOYEE-5 between March 16, 2020 and March 20, 2020 and ultimately tested positive for COVID-19. EMPLOYEE-6 took leave from ALLURE on March 25, 2020 and returned to work on April 9, 2020 after being cleared by the ALLURE COVID-19 Director.

88. Based on HR records readily available to CW-1, six other employees exhibited COVID-19 symptoms but were never tested. These employees continued to work a portion or all the time it was suspected they had contracted COVID-19.

INTRAVENOUS INFUSION OF VITAMIN C

89. On April 12, 2020, ALLURE started offering high-dose IV infusions of vitamin C for patients who are at risk of contracting COVID-19, and who have already tested positive for COVID-19. MOK categorizes "at risk" patients as those

individuals who are essential workers and on the frontline of the COVID-19 pandemic, such as nurses and firefighters, and also those individuals who have an immunodeficiency. MOK further represented that the IV infusions will be covered by the patient's medical insurance.

90. MOK presented the idea for IV infusions to ALLURE's management team in-person and by video he sent on April 10, 2020. In the video, MOK acknowledges that vitamin C is not FDA-approved for treating COVID-19, and states that ALLURE will not advertise it this way. On April 11, 2020, MOK published a video on his YouTube channel[5] advertising the vitamin C IV infusion therapy. In the video, MOK states that "IV vitamin C is being used in hospitals across the country to treat the most advanced disease associated with COVID-19, called Severe Acute Respiratory Syndrome Coronavirus 2 or SARIS-2." MOK further states, "It is also being used to reduce the duration and severity of illness in more moderate forms of COVID-19… it is becoming standard of care to use high-dose vitamin C for the sickest patients." MOK's stated goal in using IV vitamin C is to keep people from even going to the hospital.

91. In a separate YouTube post reviewed by federal law enforcement, MOK praised the benefits of vitamin C infusion as a treatment for COVID-19 by

[5] https://www.youtube.com/watch?v=RKXSeHiXJRc

stating that such infusions will "reduce the severity of symptoms, duration of illness, and therefore the ***contagiousness***." According to the FDA, there are no drugs, therapeutics, or vaccines yet approved to specifically treat, cure, or prevent COVID-19.

92. ALLURE began rendering infusions as a billable service in Michigan on April 14, 2020. All medical records relating to the IV vitamin C infusions are being documented on a single piece of paper, inconsistent with ALLURE's regular practice of using an electronic medical record.

93. ALLURE staff have expressed concern to CW-1 indicating that they are concerned about providing Vitamin-C infusions to patients who have contracted COVID-19 patients or are at a high risk of doing so. MOK stated that sick patients will be seen on designated days and only in the surgery center. During an April 15, 2020 management meeting, MOK said that those offices that refuse to provide this service (IV vitamin C infusion) would be fired and they would have to be shut down. MOK said, "If you won't treat COVID patients in the fear that they would expose vein patients you need to shut down!" In response to the pushback from ALLURE's staff and providers, MOK told non-management staff and providers during a later meeting on April 15, 2020 that the Government is telling him to render vitamin C infusions and this is why ALLURE's offices are open.

EMPLOYEE-2

94. On April 19, 2020, EMPLOYEE-2 was interviewed by law enforcement regarding current practices at ALLURE.

95. As a result of the COVID-19 pandemic, ALLURE's primary medical focus of venous procedures has dropped off. As a result, ALLURE began a campaign to bring patients back in for follow-up care related possible post-operative blood clots. This type of follow-up care was not something typical of ALLURE prior to the COVID-19 pandemic. The campaign was implemented by MOK.

C. OTHER WITNESS STATEMENTS

Physician-1

96. On April 19, 2020, PHYSICIAN-1 was interviewed by law enforcement regarding the use of IV vitamin C infusion as it relates to COVID-19 treatment. PHYSICIAN-1 is a board certified internist that has been treating COVID-19 patients at a local hospital system.

97. According to PHYSICIAN-1, vitamin C is well-absorbed orally and there is not an advantage receiving vitamin C intravenously as opposed to orally. There is no indication in the medical literature to suggest IV over oral is

recommended except for a patient having difficulty taking a pill or one needing parenteral nutrition.

98. PHYSICIAN-1 indicated that too much vitamin C can cause the vitamin to turn into oxalate which can cause kidney stones. High-dose IV infusion of vitamin C would show up in a patient's urine and PHYSICIAN-1 once again opined that such high levels could cause kidney stones in a patient.

99. According to PHYSICIAN-1, there is no indication vitamin C shortens the length or severity of a virus including COVID-19. There is no specific available evidence indicating vitamin C is a beneficial treatment for COVID-19. Vitamin C is not an anti-viral medication, is not a treatment nor a prevention for COVID-19 and will not boost the immune system to specifically protect against COVID-19.

100. PHYSICIAN-1 reviewed an article written by MOK titled *Dosing & Safety of High Dose Intravenous Vitamin C*. At the time of the review, PHYSICIAN-1 was provided with the article but not the identity of the author. PHYSICIAN-1 opined the article was not consistent with sound medical practice. PHYSICIAN-1 noted that author was utilizing IV infusion therapy of Vitamin C even for patients whose profiles indicated that Vitamin-C would likely trigger side effects. The author speaks of IV vitamin C infusion being a treatment for cancer

but PHYSICIAN-1 stated that practice has been abandoned. The piece contains no discussion of vitamin C being used as an effective treatment against viruses, including COVID-19.

Physician-2

101. On April 20, 2020, PHYSICIAN-2, a vascular surgeon at a local hospital, was interviewed by law enforcement regarding CPT code(s) 36465 and 36466. CPT code(s) 36465 and 36466 are specific to the billing of ablations related to the truncal veins and cannot be billed when the ablation is being done to the tributary veins.

102. According to PHYSICIAN-2, a Varithena injection can be used to ablate, like an ERFA, but a Varithena injection and ERFA cannot be done on the same patient because they accomplish the same task. Once an ablation is done on a patient there is no need for additional treatments including a Varithena injection.

103. Most insurance companies, including Medicare, require conservative treatment and this is the standard of care within the industry. If every patient receives intervention treatment, PHYSICIAN-2 maintains that such a physician would be outside the "curve" of standard medical practice.

104. On April 22, 2020, PHYSICIAN-2 had the opportunity to review three medical records from ALLURE patients. PHYSICIAN-2 reported as follows.

105. **Patient SR:** The patient was initially seen on or about June 24, 2019. It appears that the patient was to have some type of free screening. However, there was a note to the effect that the patient was billed for a duplex study and an office visit. The patient was again seen on July 8, 2019 at which time a radiofrequency ablation was performed of the right great saphenous vein. The patient was again seen on July 9, 2019 at which time a radiofrequency ablation of the left great saphenous vein was performed. I was unable to find any notes that specifically addressed the patient's response to these treatments. On July 18, 2019 the patient reportedly underwent Verithena injection of an accessory saphenous vein in the right leg. However, I was unable to verify the presence of an accessory vein on the initial duplex study report. This was billed with the code 36466. If there was an injection of an accessory saphenous vein, it should have been billed with 36465 which is a single truncal vein. On July 22, 2019 the patient underwent Varithena injection of the left small saphenous vein. This again is a single trunk, but was billed under 36466. On July 25, 2019 a venous duplex evaluation revealed no evidence of deep vein thrombosis and ablation of both the right and left great saphenous veins and small saphenous veins. Reportedly on the same day, the patient underwent Varithena injection of the great saphenous vein and a saphenous vein tributary. However, as noted according to the duplex, the great saphenous vein

was already ablated. The patient went on to have what appear to be 6 more Varithena injections of the right great saphenous vein. The patient also underwent multiple Verithena injections of the left great saphenous vein. In addition, the patient underwent multiple radiofrequency ablations of isolated perforator veins. In most of these cases, the code for the Varithena injections used was 36466. However, in none of these cases were two truncal veins identified as being injected. Furthermore, even if indicated, many of these procedures could have been combined at a single sitting. In my opinion, there is evidence of improper billing, as well as treatment that clearly falls outside the standard of care. (emphasis added).

106. **Patients RL and BM:** PHYSICIAN-2 further opined that he saw this same pattern of improper billing and treatment outside the standard of care in the patient files of RL and BM.

Registered Nurse-1 and Physician 3

107. On April 20, 2020, REGISTERED NURSE-1 and PHYSICIAN-3 were interviewed by law enforcement regarding the use of IV vitamin C infusion as it relates to the billing to Medicare for COVID-19 treatment. REGISTERED NURSE-1 and PHYSICIAN-3 are employees of CoventBridge Group, which is

responsible for detecting fraud and abuse in Medicare claims for the region including Michigan.

108. REGISTERED NURSE-1 indicated any claim submitted to Medicare for a COVID-19 related treatment must contain the proper International Statistical Classification of Diseases and Related Health Problem (ICD)-10 code for COVID-19.

109. REGISTERED NURSE-1 and PHYSICIAN-3 indicated that IV vitamin C infusion must be reasonable and necessary and accepted standard of practice for Medicare to pay any claim as it relates to COVID-19 treatment. There are current studies ongoing with relation to the "sickest of the sick" receiving high doses over multiple days in a critical care unit but the results are inconclusive. The studies (and their eventual results) will not apply to the regular "walking around" patient population. Since the studies are currently in the trial level, its treatment is not considered standard of practice and thus would not be an approved claim by Medicare.

110. Additionally, Medicare does not cover preventative care as it relates to IV vitamin C infusion therapy to prevent COVID-19 and thus would not be an approved claim.

CONCLUSION

111. Based on the forgoing, there is probable cause to believe that CHARLES MOK has committed the crime of health care fraud in violation of 18 U.S.C. § 1347, and has conspired with others to commit health care fraud in violation of 18 U.S.C § 1349.