IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF VIRGINIA RICHMOND DIVISION

UNITED STATES OF AMERICA

v.

JAWAD BHATTI,

Defendant.

Case No. 3:25-cr-99

Adulterated and Misbranded Device
21 U.S.C. §§ 331(c), 333(a)(2)
(Counts One through Three)

Misbranded Drug
21 U.S.C. §§ 331(k), 333(a)(2)
(Count Four)

Health Care Fraud
18 U.S.C. §§ 1347 and 2
(Counts Five through Ten)

False Statements Related to Health Care Matters
18 U.S.C. § 1035(a)(2)
(Counts Eleven through Fourteen)

Health Care Fraud
18 U.S.C. §§ 1347 and 2
(Counts Fifteen through Twenty)

False Statements Related to Health Care Matters
18 U.S.C. § 1035(a)(2)
(Counts Twenty-One through Twenty-Six)

Forfeiture Allegation

INDICTMENT

June 2025 Term – At Richmond, Virginia

THE GRAND JURY CHARGES THAT:

GENERAL ALLEGATIONS

At all times relevant to the Indictment:

1. The Medicaid program was established by Title 19, Social Security Act of 1965, to

provide medical assistance to indigent persons. The United States Department of Health and Human Services and the Commonwealth of Virginia, through the Commonwealth's Department of Medical Assistance Services, administer and supervise the administration of the Medicaid program in Virginia, which is called the Virginia Medical Assistance Program (Medicaid). The federal and state governments jointly provide funding for Medicaid.

2. The Medicare Program (Medicare) is a federal health insurance program, affecting commerce, that provides benefits to persons who are 65 years of age and older or disabled. Medicare is administered by the United States Department of Health and Human Services through its agency, the Centers for Medicare and Medicaid Services (CMS).

3. Medicaid and Medicare are both "health care benefit programs" as defined in 18 U.S.C. § 24(b).

4. Individuals who qualify for Medicare or Medicaid benefits are commonly referred to as "beneficiaries." Each beneficiary is given a unique identification number.

5. As part of the Medicare enrollment process, health care providers who provide items or services to beneficiaries submit enrollment applications to Medicare. The Medicare provider enrollment application, CMS Form 855B requires a provider, or an authorized representative of the provider, to certify that the provider will comply with all Medicare-related laws, rules, and regulations, including 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."

6. As part of the Medicaid enrollment process, providers submit enrollment applications to Medicaid. The Virginia Medical Assistance Program Provider Enrollment Application requires a provider, or an authorized representative of the provider, to certify that the

provider will comply with all Medicaid-related laws, rules, and regulations, including that the provider is responsible for reading and adhering to the policies and regulations explained in this manual and for ensuring that all employees do likewise. The provider also certifies by his or her personal signature or the signature of an authorized agent on each invoice that all information provided to the Commonwealth's Department of Medical Assistance Services is true, accurate, and complete. Satisfaction and payment of any claim will be from federal and state funds, and any provider who submits false claims, statements, or documents may be prosecuted under applicable federal or state laws.

7. If Medicare or Medicaid approve a provider's application, these government programs assign the provider a provider number. A provider with a provider number can submit claims to obtain reimbursement for actually rendered and medically necessary items and services. Providers are given access to manuals and service bulletins describing Medicare and Medicaid procedures, rules, and regulations.

8. When seeking reimbursement from Medicare or Medicaid for qualifying services rendered by the provider to a Medicare or Medicaid recipient, providers submit the cost of the service provided, together with the appropriate procedure code, as set forth in the Current Procedural Terminology (CPT) Manual or the Healthcare Common Procedure Coding System.

9. Medicare includes coverage under component parts. Medicare Part B covers, among other things, medical items and services that are reasonable and medically necessary.

The Defendant and Healing Hands of Virginia

10. The defendant, JAWAD BHATTI, for the entire relevant period has solely owned and operated Healing Hands of Virginia, a pain management clinic based in Richmond, Virginia, which is in the Eastern District of Virginia.

SCHEME AND ARTIFICE RELATED TO OZONE GAS

11. Federal regulations define ozone as "a toxic gas that with no known useful medical application in specific, adjunctive, or preventive therapy." 21 C.F.R. § 801.415. Ozone is not approved by the Food and Drug Administration to diagnose, cure, mitigate, prevent, or treat disease or to affect the structure or any function of the body and it is therefore illegal to use it in that manner. Additionally, devices that produce ozone gas are also subject to regulation by the Food and Drug Administration.

A. Federal Regulation of Devices and Drugs

12. The United States Food and Drug Administration (FDA) is the federal agency charged with responsibility for protecting the health and safety of the American public by enforcing the Federal Food, Drug, and Cosmetic Act (FDCA).

13. The FDCA's purposes include ensuring that medical products, including devices and drugs, sold for consumption by or for administration to humans, or for other use by or on humans, are safe, effective, and bear labeling containing accurate and certain required information, as well as adequate directions for their safe use. FDA's responsibilities under the FDCA include regulating the manufacture, labeling, and distribution of all drugs and medical devices shipped or received in interstate commerce. Federal regulations define interstate commerce as commerce between any state or territory and any place outside thereof. 21 U.S.C. § 321(b).

1. Devices

14. The FDCA defines a "device" as (in relevant part) "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man

or other animals, or . . . intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes." 21 U.S.C. § 321(h).

15. The "intended use" of an article is defined as the objective intent of the persons legally responsible for the labeling of that article. This objective intent might, for example, be shown by the labeling claims, advertising matter, or oral or written statements made by such persons or their representatives. 21 C.F.R. § 801.4.

16. Under the FDCA, the term "label" means a display of written, printed, or graphic matter upon the immediate container of any article. 21 U.S.C. § 321(k). The term "labeling" is broader, and includes all labels, as well as other printed or graphic matter placed upon or accompanying any article or any of its containers or wrappers. 21 U.S.C. § 321(m).

17. Devices introduced into commercial distribution in the United States after May 28, 1976 cannot legally be marketed in the United States until the manufacturer submits a pre-market approval application to FDA, and FDA approves that application. FDA will not grant pre-market approval unless the information in the pre-market approval application provides FDA with reasonable assurance that the device is safe and effective when used according to its labeling.

18. Manufacturers of medical devices, including foreign establishments that manufacture, prepare, propagate, or process a medical device that is imported or offered for import into the United States, must register with FDA. 21 U.S.C. § 360(i).

19. Under the FDCA, a device is misbranded if, among other things:

a. It is manufactured in a facility that is not registered with FDA; 21 U.S.C. § 352(o); or

b. The notice or other information respecting the device was not provided as required under section 510(k) of the FDCA. 21 U.S.C §§ 360(k); 352(o).

20. A device is "adulterated" if, among other things, the device is a medical device pursuant to 21 U.S.C. § 360c(f) that was required under 21 U.S.C. § 360e(a) to have an approved pre-market application for approval, and does not have such an approval in effect. 21 U.S.C. § 351(f).

2. Drugs

21. The FDCA defines a "drug" to include (1) articles intended to diagnose, cure, mitigate, prevent, or treat disease in man or other animals; or (2) articles intended to affect the structure or any function of the body of man or other animals; or (3) articles used as components of the above. 21 U.S.C. § 321(g)(1)(B), (C), (D).

22. Under the FDCA, the "intended use" of an article means the objective intent of the persons legally responsible for the labeling of that article. This objective intent might, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. 21 C.F.R § 201.128.

23. Some drugs are "new drugs," which are defined as any drug whose composition is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as being safe and effective for use under the conditions prescribed, recommended, and suggested in the drug's labeling. 21 U.S.C. § 321(p). New drugs require FDA approval before they may be marketed. 21 U.S.C. § 355(a); 21 U.S.C. § 331(d). If there is no new drug application, an investigational new drug application must be in effect before the drug may be distributed for research purposes. 21 U.S.C. § 355(i); 21 C.F.R. pt. 312.

24. To obtain FDA approval of a new drug application, the drug's sponsor must

demonstrate, to FDA's satisfaction, that the drug is both safe and effective for each of its claimed uses. 21 U.S.C. § 355(b). To that end, a sponsor of a new drug must submit: (1) full reports of investigations to establish that the drug is safe and effective; (2) a full list of the drug's components; (3) a full statement of the drug's composition; (4) a full description of the methods, facilities, and controls used to manufacture, process, and pack the drug; (5) samples of the drug and its components; and (6) samples of the proposed labeling for the drug.

25. Some drugs are also "prescription drugs," which are defined as those drugs that, because of their toxicity and other potential harmful effects, or the methods of their use, or the collateral measures necessary to their use, are not safe for use except under the supervision of a practitioner licensed by law to administer such drugs. 21 U.S.C. § 353(b)(1)(A). Prescription drugs have additional regulatory requirements, including that at all times prior to dispensing their label bear at a minimum the symbol "Rx only." 21 U.S.C. § 353(b)(4)(A).

26. Under the FDCA, all drugs also must bear labeling that contains adequate directions for use. 21 U.S.C. § 352(f). "Adequate directions for use" are directions sufficient for a layperson to safely use the drug for the purposes for which it is intended. 21 C.F.R. § 201.5. Directions under which a layperson can safely use a prescription drug cannot be written because such drugs can, by definition, only be used safely at the direction, and under the supervision of, a licensed practitioner so they must qualify for an exemption to this requirement. The exemption, set out in 21 C.F.R. § 201.100 requires that *all* its conditions be met, including that its labeling bear the symbol "Rx only" and, if it is a new drug, that it bear FDA-approved labeling. 21 C.F.R. § 201.100(b)(1), 201.100(c)(2).

B. Prohibited Acts

27. Under 21 U.S.C. § 331(c), the receipt in interstate commerce of any adulterated or

misbranded device or drug, and the delivery or proffered delivery thereof for pay or other otherwise after that receipt, is prohibited. 21 U.S.C. § 331(c).

28. Under 21 U.S.C. § 331(k), it is prohibited to do any act with respect to a drug or device that causes it to become misbranded after it moves in interstate commerce and while it is held for sale. 21 U.S.C. § 331(k).

C. Medical Devices at Issue

29. The Zotzmann + Stahl[1] OZON 2000 ozone machine was manufactured by Zotzmann & Stahl GmbH + Co. KG Medizin- Ozontechnik in Germany. The OZON 2000 was marketed as a "field tested hyperbaric ozone therapy device for all kinds of ozone therapy."

30. The OZON 2000 and any Zotzmann product is not cleared or approved in the United States for any indication, including ozone therapy.

31. The Herrman Hyper Medozon is an ozone machine manufactured by Herrmann Apparatebau GmbH (HAB), a German company. The Hyper Medozon machine is marketed as a "reliable system for normobaric ozone-oxygen-therapy" that "covers [the] full spectrum of ozone-oxygen-therapy."

32. The Herrman Hyper Medozon and any HAB product is not cleared or approved in the United States for any indication, including the advertised "ozone-oxygen therapy."

33. The HOCATT ozone machine, an acronym for Hyperthermic Ozone Carbonic Acid Transdermal Technology, is made by Signature Health Limited, which is based in Hong Kong, and is an ozone bath or spa, wherein the user enters the machine's opened chamber and then the doors are closed on the user's body with the user's head remaining outside the chamber. The

1 At the time BHATTI purchased the machine, the company was known as Zotzmann + Stahl but is now known as Zotzmann & Hese KG (hereafter Zotzmann).

machine's now-closed chamber, with the user's body sealed inside, fills with ozone gas. The HOCATT manufacturer claims that the HOCATT detoxifies the entire body, improves circulation, reduces stress, and reduces stretch marks, cellulite, scars, and wrinkles.

34. The HOCATT ozone machine is not cleared or approved in the United States for any indication, including the usage advertised by its manufacturer. In fact, its manufacturer expressly disclaims any medical or curative claims or any FDA approval: "The HOCATT . . . device [is] not designed to diagnose, treat, mitigate, cure, or prevent any disease or medical condition." The manufacturer continues to warn that testimonials do not "reflect or represent Signature Health Limited's product claims," and that "[t]hese statements have not been evaluated by the Food and Drug Administration (FDA). Signature Health Limited's products have not been assessed or approved by FDA or NDF, and we do not make any claims regarding their use to diagnose, treat, cure, or prevent any disease or medical condition." *Id.*

35. Because FDA has determined that "ozone is a toxic gas with no known useful medical application in specific, adjunctive, or preventive therapy," FDA has not approved or cleared any ozone devices to treat any medical conditions. 21 C.F.R. § 801.415.

36. The OZON 2000, the Hyper Medozon, and the HOCATT are unapproved medical devices that are misbranded because none of the manufacturers of the aforementioned devices provided notice or other information respecting the devices as required under section 510(k) of the FDCA, and none of the devices were manufactured in facilities that were registered with FDA in accordance with section 510. The devices are adulterated because they have no approved pre-market application from FDA.

37. Accordingly, the importation of the devices into the United States violates 21 U.S.C. § 331(a), and a practitioner cannot receive the devices in interstate commerce, or use or proffer to

use the unapproved devices on patients under the FDCA. 21 U.S.C. § 331(c).

D. BHATTI's Use of the Ozone Devices

38. In or about August 2019 and as late as December 2019, BHATTI purchased and received in interstate commerce an OZON 2000 machine from the German manufacturer Zotzmann. The OZON 2000 device manufactured ozone gas from medical grade oxygen. Zotzmann is not registered with FDA and therefore could not legally distribute medical devices in the United States. Zotzmann represents that ozone "significantly improves the blood circulation and improves blood lipid parameters" and is used to treat vascular disorders, vertigo, asthma, and other immuno-diseases. Because Zotzmann represents that the OZON 2000 machine can treat these disparate illnesses, the company is engaged in manufacturing, advertising, and distributing these machines as medical devices. 21 U.S.C. § 321(h). Zotzmann also did not notify FDA that the OZON 2000 was being introduced into interstate commerce and the OZON 2000 was not the subject of an FDA-approved premarket application. BHATTI maintained this OZON 2000 machine in his practice.

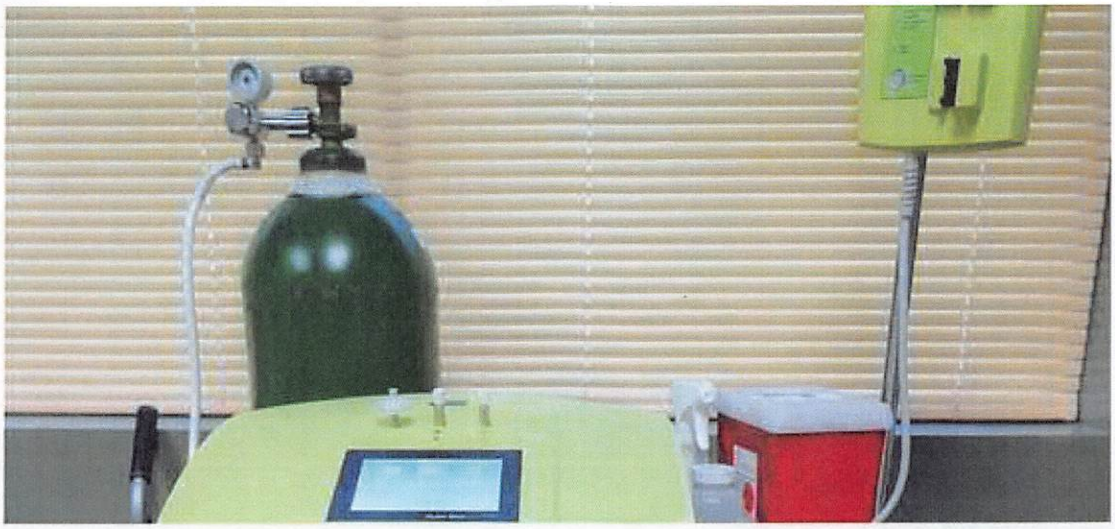
39. On or about July 19, 2019, BHATTI purchased and received in interstate commerce a Hyper Medozon machine from the German manufacturer Herrmann Apparatebau GmbH (HAB). HAB refers in its promotional materials to the Hyper Medozon machine as "medically certified" and represents that medical ozone has "strong bactericidal, virucidal, fungicidal and antiparasitic effect[s]." HAB also advertises the use of the Hyper Medozon machine to extract patients' blood from their body, infuse it with ozone gas, and return the blood to the body. Because HAB represents that the Hyper Medozon machine has medical applications and advertises its medical use on patients, the company is engaged in manufacturing, advertising, and distributing these machines as medical devices. HAB was not registered with FDA as a device manufacturer, nor did it notify FDA the Hyper Medozon device was being introduced into interstate commerce. The

Hyper Medozon device was not the subject of an FDA-approved premarket application. BHATTI maintained this Hyper Medozon machine in his practice.

40. In or about October 2019, BHATTI purchased and received in interstate commerce a HOCATT ozone machine from Signature Health Limited, which is headquartered in Hong Kong. The HOCATT manufacturer claims that the HOCATT detoxifies the entire body, improves circulation, reduces stress, and reduces stretch marks, cellulite, scars, and wrinkles. Because Signature Health Limited represents that the HOCATT machine has medical applications and advertises its medical use on patients, the company is engaged in manufacturing, advertising, and distributing these machines as medical devices. Signature Health Limited was not registered with FDA as a device manufacturer, not did it notify FDA that the HOCATT device was being introduced into interstate commerce. The HOCATT device also was not the subject of an FDA-approved premarket application. BHATTI maintained this HOCATT machine in his practice.

41. Beginning as early as July 2019 and continuing until as late as sometime in 2023, BHATTI used the OZON 2000, the Hyper Medozon, and the HOCATT machines at his medical practice to create ozone gas from medical grade oxygen and administered that ozone to patients, employees, and friends and family. BHATTI administered ozone to these individuals both as a discrete substance and mixed with other substances, such as lidocaine—a local anesthetic that is FDA-approved.

42. BHATTI displayed pictures of his ozone machines on his practice's public-facing website, and there also promoted ozone therapy. Of the four substantive tabs on BHATTI's website, two were related to ozone: one described "ozone injection;" the other, "HOCATT," the ozone immersion device. On the "ozone injection" tab, BHATTI displayed a picture of the green-colored Hyper Medozon ozone machine, and listed the benefits of ozone injections. BHATTI



OZONE AND LIDOCAINE MIX INJECTION

Benefits of Ozone

- Helps with infected wounds
- Repairs circulatory disorders
- Helps alieve geriatric disorders
- Improves macular degeneration
- Helps fight viral diseases
- Reduces pain and helps repair rheumatism and arthritis
- Fights cancer
- Treats SARS
- AIDS Treatment

represented to the public, on his practice's website, that the benefits of an ozone and lidocaine injection included: "helps with infected wounds, repairs circulatory disorders, helps alieve [sic] geriatric disorders, improves macular degeneration, helps fight viral diseases, reduces pain and helps repair rheumatism and arthritis, fights cancer, treats SARS, and AIDS treatment."

43. Another image displayed on the ozone injection tab of BHATTI's website represented that "most importantly ozone is your best friend if you have lower back pain. When injected into a herniated disc ozone will shrink swollen disc and allows pinched nerves to relax again. Making sciatica a thing of the past. Let the front desk know if you need an ozone injection

on your next visit."

44. The "HOCATT" tab of BHATTI's practice's website displayed a picture of the HOCATT ozone machine, and represented that the health benefits of using the HOCATT ozone machine include: "improve energy, improve mental acuity, improve sexual stamina, promote deep relaxation, manage stress, weight management, develop endurance, better concentration, improve strength."

HOCATT

The Cutting Edge of Medicine

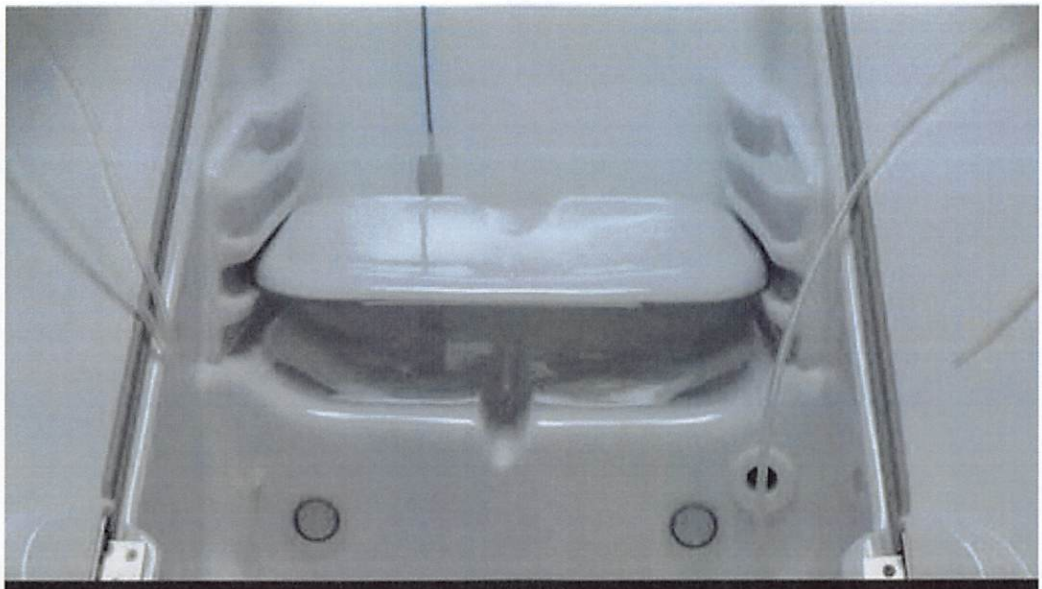
- Improve Energy
- Improve Mental Acuity
- Improve Sexual Stamina
- Promote Deep Relaxation
- Manage Stress
- Weight Mangament
- Develop Endurance
- Better Concentration
- Improve Strength

45. The HOCATT tab of BHATTI's website also displayed the claim that the HOCATT machine was the "cutting edge of medicine," with medical benefits ranging from strengthening the immune system to preventing cancer:

> HOCATT is an ozone incubator, it's a 150k dollar machine that no one practice has within 2 hours of Healing Hands of Virginia. **This investment was for the patients, truly helping patients become pain-free is my life's purpose that's why I didn't hesitate to make the investment**. (emphasis added). . . .
>
> There is another really important function for oxygen which is the ability to get rid of free radicals. Free radicals are unpaired electrons, they are at the heart of many diseases, causing aging in our bodies and is linked to cancer. There was no solution to free radicals until now. Ozone is three oxygen molecules and oxygen loves unpaired electrons (free radicals) it takes those electrons and forms water H2O in the body. It is absolutely the best solution to free radical. The benefits of ozone in the body are countless, some examples include strengthening the immune system, stimulating white blood cells, preventing infections and immune system deficiencies by destroying fungi, bacteria, and viruses. It also helps counteract cell mutations, therefore preventing cancer.

HEALING HANDS OF VIRGINIA

Home ANS Test Ozone injection HOCATT ECP Treatment Book an Appointment



HOCATT

The Cutting Edge of Medicine

HOCATT is an Ozone incubator, it's a 150k dollar machine that no one practice has within 2 hours of Healing Hands of Virginia. This investment was for the patients, truly helping patients become pain-free is my life's purpose that's why I didn't hesitate to make this investment. This machine floods the body with CO2 to dilate the pores in your skin, after 5 minutes it releases ozone (O3) and floods your entire body with oxygen. Ozone is the cutting edge of Medicine.

It's important to know that our nerves need nourishment, we enjoy food while nerves enjoy oxygen. When our nerves don't get the nourishment they need they start to die, which causes pain in our bodies. HOCATT nourishes all of our your nerves with oxygen so you will feel fantastic after each session.

There is another really important function for oxygen which is the ability to get rid of free radicals. Free radicals are unpaired electrons, they are at the heart of many diseases, causing aging in our bodies and is linked to cancer. There was no solution to free radicals until now. Ozone is three oxygen molecules and oxygen loves unpaired electrons (free radicals) it takes those electrons and forms water H2O in the body. It is absolutely the best solution to free radical. The benefits of ozone in the body are countless, some examples include strengthening the immune system, stimulating white blood cells, preventing infections and immune system deficiencies by destroying fungi, bacteria, and viruses. It also helps to counteract cell mutations, therefore preventing cancer.

46. BHATTI made these statements about the medical nature and purposes of the ozone machines that he had purchased and maintained at his practice, and emphasized the purported health benefits his patients would receive from such ozone treatments, to advertise to patients and potential patients BHATTI's intent and willingness to employ these ozone machines to deliver

ozone treatments unapproved by FDA and barred by the FDCA.

47. The statements about the health benefits and treatment purposes of the HOCATT ozone machine on BHATTI's website stand in stark contrast to the warning BHATTI received from the HOCATT manufacturer when BHATTI purchased the HOCATT machine: "BY PURCHASING THE HOCATT OR HUGO, I UNDERSTAND THIS IS NOT A MEDICAL DEVICE, AND I WILL NOT REPRESENT IT AS A MEDICAL DEVICE, NOR STATE THAT BY USING THE HOCATT OR HUGO TREATS OR CURES ANY DISEASE, AND THE HOCATT IS NOT A THERAPY. I AGREE NOT TO STATE THIS ONLINE OR ON MY WEBSITE." Despite receiving and accepting this explicit warning of the HOCATT machine's nature, BHATTI utilized his practice's public-facing website to relay to patients and the public the precise medical claims the device's manufacturer expressly disclaimed.

48. Consistent with his website's advertised ozone treatment services, BHATTI did in fact both administer injections containing ozone and sold or offered access to the HOCATT machine to his patients and other individuals.

49. As advertised in their manufacturers' promotional materials, the OZON 2000 and the Hyper Medozon ozone machines are typically used to extract a patient's blood, infuse the extracted blood with ozone gas, and pump the blood back into the patient's body. BHATTI, in contrast, favored directly injecting ozone, using large syringes, directly into his patient's body. In 2019, BHATTI attended a training about ozone therapy in Michigan, and explained to other attendees that his (BHATTI's) practice included directly injecting ozone into his patients. When used in this way, the ozone is a new drug and would require FDA-approval. It was also a prescription drug that requires, among other things, that its label bear the symbol "Rx Only."

50. When BHATTI injected ozone into his patients, many of those patients reported

experiencing extreme pain at the injection sites (to include the patients' necks, backs, shoulders, scalps, and toes) and throughout their bodies, such that their injuries constituted substantial bodily injury. Some of BHATTI's patients stated that the pain from the ozone injections was the worst pain they had ever experienced. Several of BHATTI's patients sought medical attention at emergency rooms after receiving these FDA-unapproved ozone injections. The patients' health complaints included seizures, vomiting, migraines, nausea, temporary loss of ability to walk, fainting, swelling, chest tightness, numbness, weakness, and temporary loss of vision.

51. One of BHATTI's longtime employees reported to law enforcement that a significant number of BHATTI's patients received an ozone shot at least once after BHATTI started incorporating ozone injections into his pain management practice.

52. Ozone injections were not the only injections performed at BHATTI's practice. It was BHATTI's common practice to employ a nurse practitioner to see additional patients. The nurse practitioners BHATTI hired did not perform ozone injections, but instead performed injections containing lidocaine, a short-term anesthetic, and other FDA-approved medicines and anesthetics. Patients could easily differentiate between the shots with smaller syringes and smaller doses they received from the nurse practitioners at BHATTI's practice and the more painful shots with larger syringes and larger doses they received from BHATTI personally. Some of BHATTI's patients shifted their care from BHATTI to the nurse practitioners to avoid the painful shots BHATTI administered.

53. At least two of BHATTI's employees received ozone injections from BHATTI themselves, and both reported that the ozone injections were both ineffective and extremely painful. One of these two employees was often tasked with holding patients' hands while BHATTI completed ozone injections to comfort and reassure the patient during the painful procedure. A

third employee witnessed BHATTI administer ozone injections to at least two patients in late September or early October of 2020.

54. BHATTI's patients and employees reported that BHATTI often injected patients with ozone without those patients' informed knowledge and consent, meaning that BHATTI did not tell these individuals what he was injecting into their bodies. BHATTI variously told some patients generally that the ozone injections (without naming or identifying the substance) was a new therapy and/or that it would alleviate their pain. In one instance, BHATTI told a patient that he wanted to try a new treatment that would help the circulation of her red blood cells and assist her immune system. In some cases, BHATTI told patients that if they refused to receive BHATTI's planned and proffered ozone injections, BHATTI would withhold their necessary pain medications or terminate them as patients from his practice.

55. BHATTI was aware that the use of ozone for medical purposes was not approved by FDA. This lack of FDA approval for the medical use of ozone was discussed at the ozone training in Michigan in 2019, and BHATTI acknowledged to at least one employee in 2020 that BHATTI knew ozone lacked FDA approval, but that BHATTI had found ozone therapy "effective" in his practice and this was why he continued to employ an FDA-unapproved practice.

56. BHATTI did not mention ozone in the medical records he created that documented patients' office visits and the interventions they received, to include the treatments in the HOCATT machine, despite abundant evidence of BHATTI administering ozone treatments as a regular part of his medical practice. These material omissions and misrepresentations further demonstrate that BHATTI intentionally falsified medical records to cover up his extensive use of ozone therapies. BHATTI's willful misrepresentations in his medical records and his billings reduced or eliminated the ability of government health care programs and FDA to police BHATTI's unlawful use of

unapproved and dangerous ozone therapies.

57. BHATTI stopped administering ozone injections to patients after law enforcement executed a search warrant at BHATTI's practice on or about October 8, 2020, but even after the execution of the search warrant, employees reported that BHATTI still used all three ozone devices periodically on himself and for friends and family until at least sometime in 2023.

58. Following his purchase of the HOCATT device in or about October 2019, BHATTI directed his staff to have patients book ozone treatments in the HOCATT machine. BHATTI directed his staff that they were not to bill the HOCATT treatments to insurance companies, but should instead only accept cash from the recipients. At least five of BHATTI's employees observed individuals enter BHATTI's practice to use the HOCATT device, and some of those employees assisted with setting up the HOCATT treatments. BHATTI's employees heard him extol the purported health benefits of the HOCATT machine to his pain management patients, telling those patients that the ozone machine would help with their chronic pain.

COUNTS 1 - 3
(Misbranded and Adulterated Device)

59. The allegations in paragraphs 1 through 58 of this Indictment are re-alleged and incorporated as though set forth in full here.

60. On or about July 2019 to in or about 2023, in the Eastern District of Virginia, the defendant, JAWAD BHATTI, with intent to defraud and mislead, received in interstate commerce devices that were adulterated within the meaning of 21 U.S.C. § 351(f)(1), in that they lacked an FDA-approved premarket application, and were misbranded, within the meaning of 21 U.S.C. §§ 352(o), 360(i), 360(k), and 21 C.F.R. § 807.81, because they lacked the required premarket notification and were manufactured in an unregistered facility, and BHATTI offered and provided medical treatments on such devices for pay or otherwise. The devices in question are described

below, each being a separate count:

Count	Description of Device
1	OZON 2000 ozone machine from the German manufacturer Zotzmann
2	Hyper Medozon ozone machine from the German manufacturer Herrmann Apparatebau GmbH
3	HOCATT ozone machine from the Hong Kong manufacturer Signature Health Limited

(All in violation of Title 21, United States Code, Sections 331(c) and 333(a)(2))

COUNT 4
(Misbranded Drug)

61. The allegations in paragraphs 1 through 58 of this Indictment are re-alleged and incorporated as though set forth in full here.

62. In or about July 2019 to in or about 2023, in the Eastern District of Virginia, the defendant, JAWAD BHATTI, with the intent to defraud and mislead, did and caused various acts, with respect to a drug, while such drug was held for sale after components of the drug were shipped in interstate commerce, and where the acts resulted in the drug being misbranded, as defined at 21 U.S.C. § 353(b)(4)(A), specifically, JAWAD BHATTI, the defendant, offered for sale the following drug, which did not have a label that bears, at a minimum, the symbol "Rx only."

Count	Description of Drug
4	Ozone plus lidocaine injection

(All in violation of Title 21, United States Code, Sections 331(k) and 333(a)(2)).

COUNTS 5 - 10
(Health Care Fraud)

63. The allegations in paragraphs 1 through 58 of this Indictment are re-alleged and incorporated as though set forth in full here.

64. From in or about January 2014, through in or about October 2024, in the Eastern District of Virginia and within the jurisdiction of this court, the defendant, JAWAD BHATTI, did knowingly and willfully execute and attempt to execute a scheme and artifice to commit health care fraud, that is, to devise a scheme or artifice to defraud a health care benefit program and to obtain, by means of false and fraudulent pretenses, representations, and promises, any of the money owned by, and under the custody and control of, Medicaid and Medicare, health care benefit programs as defined by Title 18, United States Code, Section 24(b), in connection with the delivery of and payment for health care benefits, items, and services, in violation of Title 18, United States Code, Section 1347.

65. The purpose of BHATTI's scheme and artifice to defraud was to obtain health care benefits payments from Medicaid and Medicare to which BHATTI was not entitled by submitting and causing to be submitted false and fraudulent billing claims to Medicaid and Medicare related to BHATTI's administration of ozone gas and BHATTI's deliberate mis-billing of those FDA-unapproved treatments as instead FDA-approved nerve block treatments.

The Scheme and Artifice

66. As described above, BHATTI concealed his use of ozone for medical treatment purposes by omitting any reference to ozone in the medical records BHATTI created that documented his patients' office visits and the interventions BHATTI administered. BHATTI intentionally falsified his patients' medical records to cover up and conceal his extensive use of ozone therapies, which BHATTI knew and understood were not approved by FDA and which—

because such ozone treatments did not comply with community standards of medical practice—were not approved for reimbursement from Medicaid or Medicare. BHATTI's willful misrepresentations in his medical records and his billings reduced or eliminated the ability of government health care programs and FDA to detect BHATTI's unlawful use of unapproved and dangerous ozone therapies.

67. Because ozone therapy and ozone injections are not approved by FDA, there is no established CPT code through which a provider could charge these unapproved therapies to insurance companies, to include government health care programs. BHATTI accordingly used a variety of false billing codes to bill ozone injections and mislead government health care programs about the true (and non-reimbursable) treatments he was administering to his patients.

68. BHATTI generally instructed his employees and his third-party billing company to bill instances of BHATTI's ozone injections as nerve blocks. BHATTI knew and understood that these representations were false for multiple reasons: first, because ozone injections are not nerve blocks, and second, because Bhatti's practice did not properly perform (the separate treatment) of nerve blocks at all. To be reimbursable by Medicaid or Medicare, nerve blocks injections are required to be accompanied by a separate long-lasting steroid. BHATTI did not perform such appropriate nerve block treatments in the course of his practice, a fact confirmed by both BHATTI's employees and BHATTI's medication purchase orders, which reflect that BHATTI's practice did not order or stock anything approaching the quantity of steroids required to bill the massive quantity of nerve blocks for which BHATTI billed.

69. BHATTI also falsely indicated in his practice's medical records that his practice did in fact utilize such a long-lasting steroid. For example, in October 2017, an employee from BHATTI's external billing company emailed one of BHATTI's employees, asking if BHATTI

intended to add a billing code modifier to indicate that BHATTI had used a long-lasting steroid called Kenalog, because BHATTI stated in his medical records that he had used this steroid for an injection. BHATTI's employee informed the billing company that BHATTI then used only lidocaine in his injections, and thus did not use Kenalog as his medical records falsely claimed.

70. The scope of BHATTI's fraudulent nerve block billing included BHATTI's practice of misrepresenting his administration of ozone treatments as "nerve block" treatments, but also included BHATTI's practice of utilizing the "nerve block" CPT billing code for other (non-nerve block) treatments and injections.

71. On or about the dates noted below, in the Eastern District of Virginia, for the purpose of executing the above-described scheme and artifice to defraud, JAWAD BHATTI, aided and abetted by others, knowingly submitted, and caused to be submitted, the following false claims to Medicaid or Medicare, each of which falsely and fraudulently represented that services had actually been rendered consistent with Medicaid or Medicare requirements, when in truth and fact, as BHATTI well knew, the services had not been rendered in compliance with Medicaid or Medicare requirements, each such false claim constituting a separate count of the Indictment:

Count	Date (On or About)	Code Billed	Description of Execution
5	March 4, 2020	64450	BHATTI billed Medicare for conducting a nerve block on Patient 1, representing that he had injected Patient 1 with the steroids Kenalog and Marcaine, when in truth and fact this treatment was not a nerve block because BHATTI's practice lacked the steroids required to conduct a reimbursable nerve block.
6	September 17, 2020	64450	BHATTI billed Medicare for conducting a nerve block on Patient 1, but this injection was not a nerve block because BHATTI's practice lacked the steroids required to conduct a reimbursable nerve block.

7	January 20, 2020	64445	BHATTI billed Medicare for conducting a nerve block on Patient 2, representing that he had injected Patient 2 with steroids Kenalog and Marcaine, but this injection was not a nerve block because BHATTI's practice lacked the steroids required to conduct a reimbursable nerve block.
8	September 21, 2020	64450	BHATTI billed Medicare for conducting a nerve block on Patient 2, but this injection was not a nerve block because BHATTI's practice lacked the steroids required to conduct a reimbursable nerve block.
9	January 15, 2020	64445	BHATTI billed Medicaid for conducting a nerve block on Patient 3, representing that he had injected Patient 3 with the steroids Kenalog and Marcaine, but this injection was not a nerve block because BHATTI's practice lacked the steroids required to conduct a reimbursable nerve block.
10	April 29, 2020	64445	BHATTI billed Medicaid for conducting a nerve block on Patient 3, representing that he had injected Patient 3 with the steroids Kenalog and Marcaine, but this injection was not a nerve block because BHATTI's practice lacked the steroids required to conduct a reimbursable nerve block.

72. In total, BHATTI through his pain management practice, submitted $1,941,204.32 in fraudulent nerve block billing to Medicare and Medicaid, and these government healthcare programs paid BHATTI a total of $465,352.54 to which he was not legitimately entitled.

(In violation of Title 18, United States Code, Sections 1347 and 2).

COUNTS 11 - 14

(False Statements Related to Health Care Matters)

73. The allegations in paragraphs 1 through 72 of this Indictment are re-alleged and incorporated as though set forth in full here.

74. On or about the dates noted below, in the Eastern District of Virginia, the defendant, JAWAD BHATTI, knowingly and willfully made materially false, fictitious, and fraudulent statements and representations, as set forth below, in connection with the delivery of and payment

for health care benefits, items, and services involving Medicaid and Medicare, health care benefit programs as defined in 18 U.S.C. § 24(b), each such instance constituting a separate count of the Indictment.

Count	Date (On or About)	Description of Execution
11	March 4, 2020	BHATTI falsely stated in his medical records that he injected Patient 1 with the steroids Kenalog and Marcaine, but this injection did not consist of those steroids because BHATTI's practice lacked the steroids Kenalog and Marcaine.
12	January 20, 2020	BHATTI falsely stated in his medical records that he injected Patient 2 with the steroids Kenalog and Marcaine, but this injection did not consist of those steroids because BHATTI's practice lacked the steroids Kenalog and Marcaine.
13	January 15, 2020	BHATTI falsely stated in his medical records that he injected Patient 3 with the steroids Kenalog and Marcaine, but this injection did not consist of those steroids because BHATTI's practice lacked the steroids Kenalog and Marcaine.
14	April 29, 2020	BHATTI falsely stated in his medical records that he injected Patient 3 with the steroids Kenalog and Marcaine, but this injection did not consist of those steroids because BHATTI's practice lacked the steroids Kenalog and Marcaine.

(In violation of Title 18, United States Code, Section 1035(a)(2)).

SCHEME AND ARTIFICE RELATED TO RADIOLOGICAL INSERTION OF NEEDLES

75. Medicare and Medicaid allow clinicians, subject to certain requirements, to bill for using radiological means to guide the insertion of a needle, such as for an injection. Radiological guidance is helpful, for example, when a clinician is performing an injection in or near the spine or another sensitive location where proper needle placement is important. Use of radiological guidance to insert the needle also helps ensure that the medication reaches the proper location, such as the source of inflammation.

76. A common type of radiology used for needle insertions is ultrasound. Ultrasound technology uses sound waves at high frequencies to visualize internal organs. The sound waves used in ultrasound technology penetrate and are reflected back to the ultrasound equipment by various internal organs at different speeds, which allows the creation of a visual representation of the body's interior displayed on a nearby monitor. A special gel is applied to the patient's skin and to the ultrasound device to better transmit the sound waves through the patient's body.

77. The CPT code for radiologically guided insertion of a needle is 76942. This code requires that radiology is actually used to guide the insertion of the needle. As the name of the billing code indicates, the procedure requires the use of radiology to guide the *insertion* of the needle, and Medicaid and Medicare will not reimburse a provider if, for example, the radiological guidance is used after the needle is inserted into the recipient's body, or if the needle has already been removed from the recipient's body. Thus, code 76942 cannot properly be billed after the provider's insertion of the needle into the recipient, even if the provider desires to ensure the injection has in fact occurred at the right location or to check for post-injection consequences.

COUNTS 15 - 20
(Health Care Fraud)

78. The allegations in paragraphs 1 through 10 and 75 through 77 of this Indictment are re-alleged and incorporated as though set forth in full here.

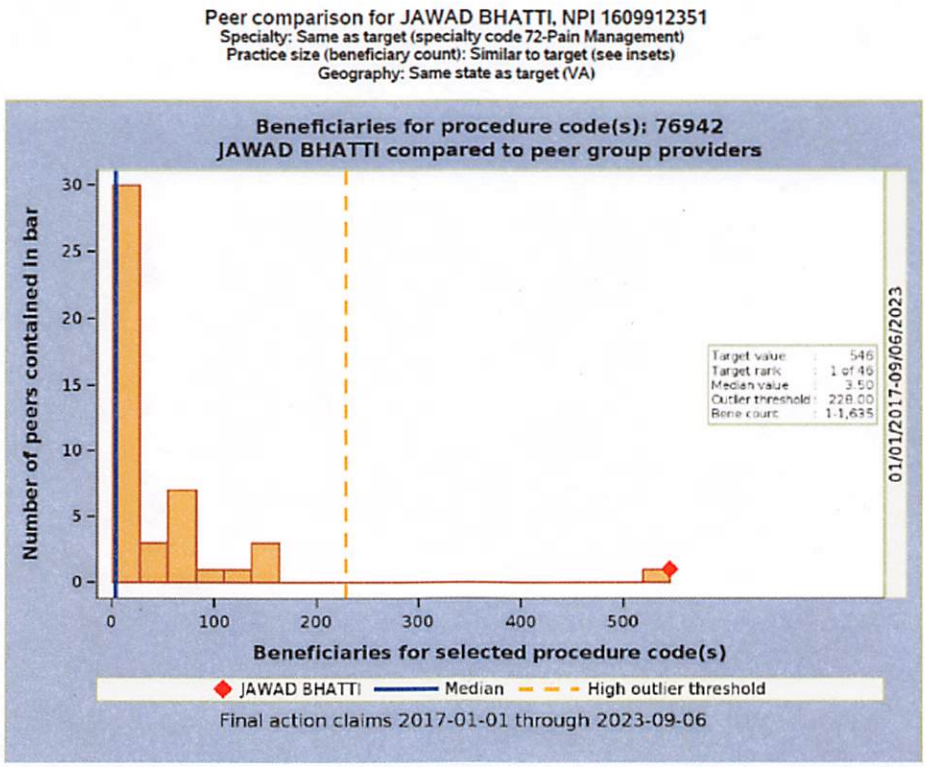
79. From at least in or about January 2014, through at least in or about January 2024, in the Eastern District of Virginia and within the jurisdiction of this court, the defendant, JAWAD BHATTI, did knowingly and willfully execute and attempt to execute a scheme and artifice to commit health care fraud, that is, to devise a scheme or artifice to defraud a health care benefit program and to obtain, by means of false and fraudulent pretenses, representations, and promises, any of the money owned by, and under the custody and control of Medicaid and Medicare, health

care benefit programs as defined by Title 18, United States Code, Section 24(b), in connection with the delivery of and payment for health care benefits, items, and services, in violation of Title 18, United States Code, Section 1347.

80. The purpose of BHATTI's scheme and artifice to defraud was to obtain health care benefits payments from Medicaid and Medicare to which BHATTI was not entitled by submitting and causing to be submitted false and fraudulent billing claims to Medicaid and Medicare related to radiological insertion of needles.

The Scheme and Artifice

81. BHATTI was the most prolific biller of code 76942 in Virginia from 2017 to 2023. As demonstrated below, nearly all of BHATTI's peers—that is, other Virginia physicians with pain management practices—billed code 76942 for less than 100 beneficiaries, and none of his peers billed the code for more than 200 beneficiaries. BHATTI billed this code for more than 500 beneficiaries, more than tripling the count of the next closest pain management doctor.



82. Humana, a Virginia Medicaid contractor, has a Special Investigations Unit dedicated to detecting and preventing fraud, waste, and abuse. In May 2022, this unit conducted an audit of BHATTI's use of code 76942 that covered the period from May 2021 to April 2022. Humana's audit revealed BHATTI billed code 76942 at a 100% error rate, meaning that none of his billing was accurate for the audited sample.

83. BHATTI used identical language in nearly every patient record to describe his supposed process of using ultrasound to guide the injection and to justify his excessive use of this billing code. He described his process as using the ultrasound to guide the injection, evidenced by BHATTI claiming that he used ultrasound to identify parts of the body before performing the injection and using the ultrasound to guide the needle insertion: "Using ultrasound guidance anatomical structures were identified. After the idenification [sic] needle was introduced using ultrasound Sterile precautions were observed Image was recorded on the chart." BHATTI's claims in his medical records about his practice of radiological guidance are contradicted, however, by his patients and employees.

84. BHATTI's employees and patients reported that BHATTI seldom used radiological equipment during the course of his injections, and in those rare instances when BHATTI did utilize radiological guidance, BHATTI typically used the ultrasound only *after* the injection was completed. In other words, BHATTI's normal practice was not to use the ultrasound to guide the injection, as required by Medicaid and Medicare for code 76942.

85. One of BHATTI's long-time employees, a nurse practitioner, explained that BHATTI's practice was to perform an injection, and only then apply the ultrasound gel to the ultrasound equipment and using that equipment to take a picture of the injection site for what BHATTI described as insurance or record purposes. BHATTI did not use the ultrasound machine

to guide the insertion of the needle. The nurse practitioner stated that a post-injection ultrasound was not clinically helpful and served no medical purpose.

86. Another long-time employee confirmed that BHATTI's standard practice was to only use the ultrasound machine to take a picture of the injection location after the injection was complete, and that BHATTI did not use ultrasound to guide the injection.

87. Patient 1 explained to investigators that BHATTI never used any kind of radiological guidance during her injections; but that BHATTI performed the injection so quickly as to foreclose the procedures and time necessary for the use of radiological guidance.

88. Patient 2 similarly explained to investigators that BHATTI never used any kind of radiological guidance during her injections. In fact, Patient 2 further stated she had never seen any radiological imaging equipment at BHATTI's practice.

89. Patient 3 stated that they had observed BHATTI use an ultrasound wand during injections, but that BHATTI did so only after the injection was completed, and that BHATTI did not use the ultrasound to guide the insertion of the needle into Patient 3.

90. BHATTI also claimed, in nearly every patient record, that he used ultrasonic guidance because the patients receiving these injections possessed abnormally high Body Mass Indexes (BMI), a body fat measurement. A patient's high BMI is a risk factor that can justify the use of radiological guidance. BHATTI's descriptions of his patients' high BMIs, however, is likewise contradicted by the reality of those patients' physical condition; investigators identified numerous purportedly obese patients who were, in fact, at normal or below-average BMIs.

91. On or about the dates noted below, in the Eastern District of Virginia, for the purpose of executing the above-described scheme and artifice to defraud, JAWAD BHATTI, aided and abetted by others, knowingly submitted, and caused to be submitted, the following false claims

to Medicaid or Medicare, each of which falsely and fraudulently represented that services had actually been rendered consistent with Medicaid or Medicare requirements, when in truth and fact, as BHATTI well knew, the services had not been rendered in compliance with Medicaid or Medicare requirements, each such instance constituting a separate count of the Indictment:

Count	Date (On or About)	Code Billed	Description of Execution
15	March 4, 2020	76942	BHATTI billed Medicare for using radiological guidance to insert a needle into Patient 1 when in fact BHATTI did not use radiological guidance during the insertion of the needle, as required.
16	September 17, 2020	76942	BHATTI billed Medicare for using radiological guidance to insert a needle into Patient 1 when in fact BHATTI did not use radiological guidance during the insertion of the needle, as required.
17	January 20, 2020	76942	BHATTI billed Medicare for using radiological guidance to insert a needle into Patient 2 when in fact BHATTI did not use radiological guidance during the insertion of the needle, as required.
18	September 21, 2020	76942	BHATTI billed Medicare for using radiological guidance to insert a needle into Patient 2 when in fact BHATTI did not use radiological guidance during the insertion of the needle, as required.
19	January 15, 2020	76942	BHATTI billed Medicaid for using radiological guidance to insert a needle into Patient 3 when in fact BHATTI did not use radiological guidance during the insertion of the needle, as required.
20	April 29, 2020	76942	BHATTI billed Medicaid for using radiological guidance to insert a needle into Patient 3 when in fact BHATTI did not use radiological guidance during the insertion of the needle, as required.

92. In total, BHATTI through his practice submitted $3,261,170.64 in fraudulent billing to Medicare and Medicaid related to his purported but non-existent radiological insertion of a needle, and these government healthcare programs paid BHATTI a total of $741,338.38 to

which he was not entitled.

(In violation of Title 18, United States Code, Sections 1347 and 2).

COUNTS 21 - 26
(False Statements Related to Health Care Matters)

93. The allegations in paragraphs 1 through 10 and 75 through 92 of this Indictment are re-alleged and incorporated as though set forth in full here.

94. On or about the dates noted below, in the Eastern District of Virginia, the defendant, JAWAD BHATTI, knowingly and willfully made materially false, fictitious, and fraudulent statements and representations, as set forth below, with each instance constituting a separate count of the Indictment, in connection with the delivery of and payment for health care benefits, items, and services involving Medicaid and Medicare, health care benefit programs as defined in 18 U.S.C. § 24(b), in violation of Title 18, United States Code, Section 1035.

Count	Date (On or About)	Description of Execution
21	March 4, 2020	BHATTI falsely stated in his patient's medical record that he used radiological guidance to insert a needle into Patient 1 when in fact no such guidance was used to insert a needle into Patient 1.
22	September 17, 2020	BHATTI falsely stated in his patient's medical record that he used radiological guidance to insert a needle into Patient 1 when in fact no such guidance was used to insert a needle into Patient 1.
23	January 20, 2020	BHATTI falsely stated in his patient's medical record that he used radiological guidance to insert a needle into Patient 2 when in fact no such guidance was used to insert a needle into Patient 2.
24	September 21, 2020	BHATTI falsely stated in his patient's medical record that he used radiological guidance to insert a needle into Patient 2 when in fact no such guidance was used to insert a needle into Patient 2.
25	January 15, 2020	BHATTI falsely stated in his patient's medical record that he used radiological guidance to insert a needle into Patient 3 when in fact no such guidance was used to insert a needle into Patient 3.

26	April 29, 2020	BHATTI falsely stated in his patient's medical record that he used radiological guidance to insert a needle into Patient 3 when in fact no such guidance was used to insert a needle into Patient 3.

(In violation of Title 18, United States Code, Section 1035(a)(2)).

FORFEITURE ALLEGATION

Pursuant to Rule 32.2(a) Fed. R. Crim. P., the defendant is hereby notified that upon the conviction of any of the offenses listed in Counts One through Twenty-Six of this Indictment, the defendant shall forfeit to the United States any property, real or personal, that constitutes or is derived, directly or indirectly, from gross proceeds traceable to the commission of the offense.

Property subject to forfeiture includes, but is not limited to:

The sum of at least $1,206,690.92, representing the gross proceeds of the offenses charged in Counts One through Twenty-Six, which sum shall be reduced to a monetary judgment against the defendant in favor of the United States. This is a sum for which the defendant will be solely liable.

If property subject to forfeiture cannot be located, the United States will seek an order forfeiting substitute assets.

(In accordance with Title 18 United States Code § 982(a)(7) and Title 21, United States Code, Section 853(p)).

A TRUE BILL:

FOREPERSON

ERIK S. SIEBERT
UNITED STATES ATTORNEY

By: _____
Shea Matthew Gibbons
Assistant United States Attorney

Pursuant to the E-Government Act, the original of this page has been filed under seal in the Clerk's Office