IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

UNITED STATES, *ex rel*. DUSTIN POOLE & THOMAS STILLINGS, Plaintiff, v. MASTER EQUITY TEXAS LIMITED PARTNERSHIP D/B/A EMERGING SOLUTIONS, AND MICHAEL BINGHAM, INDIVIDUALLY, Defendants.	Civil Action No. 3:20-CV-02824-E JURY TRIAL DEMANDED

UNITED STATES OF AMERICA'S
COMPLAINT-IN-INTERVENTION

The United States of America (the "Government") brings this action to recover treble damages and civil penalties under the False Claims Act, as amended, 31 U.S.C. §§ 3729–33 (FCA), as well as common law and equitable theories of fraud, unjust enrichment, and payment by mistake. The United States' claims arise out of Defendants' illegal schemes to knowingly cause to be submitted claims to Medicare for non-covered medical devices and related services that were false and fraudulent.

I. PRELIMINARY STATEMENT

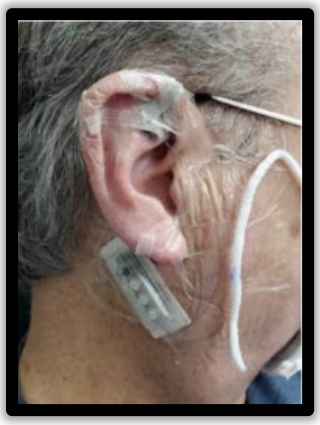
1. From 2019 through at least 2024 (the Relevant Period), Master Equity Solutions d/b/a Emerging Solutions in Pain ("Emerging Solutions"), at the direction of Michael Bingham, Emerging Solutions' CEO and beneficial owner, engaged in a brazen multi-million-dollar scheme to fraudulently market and distribute "Drug Relief," a line of

peripheral auricular (ear) nerve stimulation devices, as reimbursable by Medicare using Health Care Common Procedure Coding System (HCPCS) L8679, which is a Medicare billing code for an *implantable* neurostimulator or pulse generator that, when used, would improperly generate significant Medicare payments for the providers.

2. "Drug Relief" is the trade name for a line of class II medical devices manufactured by DyAnsys, an India-based company. The Drug Relief products are small battery-powered medical devices that consist of a hearing aid style generator and electrodes connected via wires. A picture of one version of the Drug Relief devices follows:

3. Each electrode contains a short penetrating needle which is used to provide periodic electrical impulses to points on the ear. Through this mechanism, Drug Relief purports to provide patients with temporary relief from opioid withdrawal symptoms during periods of detoxification. The procedure to affix "Drug Relief" to patients is straightforward and could be completed in just 10-15 minutes. No surgery was required (not even an incision) and could be performed in-office without the use of general or local anesthesia. The body of the device is placed behind the ear and kept in place with tape. The stimulating electrodes are connected via wires and placed at points on the ear.

Each electrode contains tiny needles that are inserted subcutaneously (no more than 3 millimeters) and kept in place using tape. A picture showing one Drug Relief device applied to a patient follows:



Once applied, patients were instructed not to get the device wet and to return to the office after 10-12 days for removal. Once removed, Drug Relief was discarded and could not be used for additional treatments.

4. Defendant Emerging Solutions is a health care marketing and distribution company based in North Texas. During the relevant period, Emerging Solutions marketed and distributed Drug Relief to sub-distributors, medical clinics, and providers throughout the United States.

5. Drug Relief was not cheap. Emerging Solutions sold Drug Relief in boxes of 10 at a cost of $17,500 to $24,000 ($1,750 to $2,400 per device). Given the high cost of the device and the narrow indications for use (as discussed below), Drug Relief was difficult to sell.

6. To drive sales of the device, Defendants understood that they needed to convince providers that Drug Relief was an effective treatment, covered by insurers, including Medicare, and would generate reimbursements sufficient to cover the high cost and still turn a profit. To do so, Defendants implemented an aggressive marketing and billing scheme.

7. The Drug Relief line of devices were *not* cleared by the FDA as implantable devices for the treatment of chronic pain.[1] DyAnsys obtained FDA clearance for the Drug Relief devices through 510(k) premarket submissions as percutaneous nerve field stimulator systems ("PNFS")[2] to treat symptoms associated with opioid withdrawal (K173861).

8. The Drug Relief line of devices, herein referred to collectively as "Drug Relief," does *not* qualify as an implantable neurostimulator and cannot be billed using HCPCS L8679 because the Drug Relief device is not implanted. The procedure to implant implantable neurostimulators requires surgery, anesthesia, and usually involves the use of an operating room or ambulatory surgical centers.

9. Defendants understood that Drug Relief was not an implantable neurostimulator and was not reimbursable by Medicare under HCPCS L8679. Drug Relief is a PNFS device. It is not a qualified electrical nerve stimulator which required an invasive surgical center. The procedure to implant a qualified electrical nerve stimulator

[1] DyAnsys obtained FDA clearance for three "Drug Relief" devices under three separate 510(k) clearances.
[2] PNFS refers to the use of a lead placed to stimulate the subcutaneous distal distribution of an area of pain (indirectly stimulating the peripheral nerve).

is invasive and requires the implantation of the neurostimulation device and a generator (battery) *underneath* the skin. Additionally, attached lead wires and electrodes are surgically implanted at locations in the spine, brain, or at the peripheral nerve source of pain. Drug Relief used an external generator and no surgery was required.

10. Defendants understood that Drug Relief was not a qualified implantable neurostimulator and could not be billed to Medicare as such under HCPCS L8679. Drug Relief is a PNFS device that stimulates peripheral nerves rather than central nerves and could be affixed to patients without surgery, anesthesia, or the use of an operating room or an ambulatory surgical center. The procedure was not invasive, and no portion of the device was implanted within the body of the patient. Physicians could affix the Drug Relief device to the patient with tape in a procedure that could be performed in 10-15 minutes in an office setting. The Drug Relief device is not surgically implanted inside the body of the patient.

11. Defendants were notified, repeatedly, from multiple sources that Drug Relief was not an implantable neurostimulator and should not be billed to Medicare using HCPCS code L8679. This included Medicare guidance, as well as numerous warnings from third parties including investors, providers, and consultants.

12. Nonetheless, Defendants falsely informed providers that the device was covered by Medicare and reimbursable under HCPCS code L8679 as a *trial* implantable neurostimulator. Defendants purportedly based this claim on National Coverage Determinations (NCD) §160.7 and § 160.7.1 which addresses CMS payment for electrical

nerve stimulators and related diagnostic services, respectively. Neither NCD § 160.7 nor § 160.7.1 establish coverage for the Drug Relief device under HCPCS L8679.

13. CMS issued NCD § 160.7 to address coverage for two classifications of electrical stimulators employed to treat chronic intractable pain: peripheral nerve stimulators and central nervous system stimulators. In recognition of the invasive surgery required to implant these devices, CMS noted that providers should first assess a patient to determine whether their chronic pain could be controlled through electrical stimulation. As such, CMS issued NCD § 160.7.1 providing that program payment *may* be made for ***PENS*** and Transcutaneous Electrical Nerve Stimulation ("TENS") devices "when used to determine the potential therapeutic benefit [pain relief] of an electrical nerve stimulator."

14. While NCD § 160.7.1 provided limited coverage for diagnostic services associated with the use of a PENS or TENS device under specific circumstances—it did not provide DME coverage for the device itself. As CMS made clear in NCD § 160.7, "such use of the stimulator is covered as part of the *total diagnostic service* furnished to the beneficiary *rather than as a prosthesis*." (emphasis added).

15. To qualify for coverage under NCD §160.7.1, a provider needed to use a PENS or a TENS device indicated for the treatment of chronic pain (as well as other requirements). Drug Relief did not meet these (and other) requirements. The FDA cleared Drug Relief as PNFS—not a PENS—devices for treating symptoms of opioid withdrawal—not chronic pain.

16. To support their claim of coverage under NCD § 160.7 and § 160.7.1, Defendants falsely claimed that Drug Relief was FDA cleared as a PENS device for the

treatment of pain. Defendants made these material misrepresentations about Drug Relief to providers directly. To support this claim (and the attendant claim for coverage), Bingham fraudulently altered the FDA 510(k) decision letter[3] for the first Drug Relief device (K173861) to create the false appearance that the device was a PENS and indicated for the treatment of pain.

17. Bingham made the following changes to the "Indications for Use" ("IFU") attached to the May 2018, 510(k) decision letter for Drug Relief (K173861) (italicized and strike through indicates edits by Bingham):

> The Drug Relief / *Primary Relief V1* is a percutaneous nerve field stimulatory (PNFS) ~~system~~ *for drug relief and percutaneous electrical nerve stimulator for pain (PENS) System*, that can be used as an aid to reduce the symptoms of opioid withdrawal *and pain*, through the application to branches of Cranial Nerves V, VII, IX, and X, and the occipital nerves by transillumination.

18. Then Bingham and the rest of the Emerging Solutions team provided the forged FDA 510(k) letter to sub-distributors, medical clinics, and providers, to support their false claim that Drug Relief was eligible for coverage under NCD § 160.7 and § 160.7.1 as a trial implantable neurostimulator.

19. Defendants' ability to sell Drug Relief depended on this deception. In a September 26, 2020, email to DyAnsys owner Srini Nageshwar, Bingham explained that "my doctors think the device is a PENS. If I go back and say, no it is not a PENS [then]

[3] When a decision is made whether a device is cleared to market, FDA will issue a decision letter to the 510(k) applicant/sponsor that states whether it determined the device is substantially equivalent and therefore cleared. The Indications for Use and the applicant/sponsor's 510(k) Summary are included as attachments to the decision letter. Collectively, the documents are known as the SE Package. Here, we refer to the forged IFU attachment as the "FDA letter."

all sales stop . . . . The 160.7.1 is for PENS and not a PNSF. PNSF does not qualify to use the L8679 . . . . CMS considers the PNSF to be acupunctural device. CMS will accept a PENS to not be an acupunctural device." Laying bare the fraudulent scheme, Bingham wrote further: "***I have not wanted to put this in writing because I did not want to have a record that we all knew the device was not a PENS***." (emphasis added).

20. Defendants' efforts extended beyond the fraudulent marketing. They maintained close control of the billing process at every stage to facilitate prompt Medicare payment. In connection with the sale of the device, Defendants (with limited exceptions), provided billing and management services through agreements with providers in exchange for a fee (typically consisting of 10% of collected claims for the device). Under these agreements, Defendants issued providers billing packets that included form letters of medical necessity, "copy and paste" templates for procedure and patient notes, and other records, all of which was carefully designed to meet Medicare requirements to bill HCPCS L8679.

21. Through these billing packets and other instructions, Defendants caused providers to create medical and billing records that obfuscated the true nature of the Drug Relief, its indications, and the associated procedure. For example, providers were instructed to describe the device in supporting medical records as either an implantable neurostimulator or a PENS device cleared for the treatment of chronic pain. Defendants directed providers to describe the procedure to affix Drug Relief (tape and tiny needles) as a surgical percutaneous implantation of electrodes targeting peripheral nerves. Defendants warned providers not to use certain words that might tip off the scheme, such

as "auricular," "vagus," or "acupuncture." Providers closely followed Emerging Solutions' instructions and used the tailored templates to generate false or otherwise misleading records to facilitate reimbursement of claims for the non-covered device. When claims were denied or additional medical records requested (which happened routinely), Defendants handled responses, writing letters filled with falsehoods and mischaracterizations, and attaching provider records that had been reviewed and scrubbed of anything that would reveal the fraud.

22. Defendants' plan worked. Numerous claims for Drug Relief were paid and providers made significant profits (and so did Defendants). As of August 24, 2021, Defendants had successfully submitted or caused the submission of 304 claims to Medicare for Drug Relief that resulted in reimbursements of $2,668,140 (averaging $8,235 per claim).

23. As the sales of Drug Relief grew larger, Defendants' ambitions—fueled by unrelenting greed for additional profits—kept pace. Up until that point, Defendants largely focused their marketing efforts on independent providers and small medical clinics. Now, Defendants began eyeing bigger deals with larger hospitals and healthcare systems (including the Cleveland Clinic), Native American reservations, and even the Department of Defense.

24. While Defendants understood that duping providers and small clinics was one thing, scamming larger and more sophisticated customers was another. To gain access to these purchasers (and the thousands of federal beneficiaries under their care), Defendants recognized that they could no longer stand on a forged FDA letter to support

their false claims about Drug Relief, its indications, and coverage as a trial implantable neurostimulator.

25. Defendants knew that no specific Medicare billing code applied to their device and that larger purchasers would conduct due diligence before entering into a sales agreement. To close these deals, Defendants needed to establish that Drug Relief was *actually* covered by Medicare (and not just claim it was based on a forged FDA letter). In 2020, Defendants prepared an application to CMS to request the assignment of a HCPCS Level II code to the Drug Relief device. In doing so, of course, Defendants recognized that no specific billing code applied to Drug Relief – including HCPCS L8679 (an HCPCS Level II Code).

26. Defendants paid a third-party consultant (Connect 4 Strategies, LLC) to develop a coverage, coding, and payment strategy to support the planned request to CMS for the assignment of an HCPS Level II code for Drug Relief. The billing consultant identified significant issues with Defendants' marketing and billing of Drug Relief. Among other problems, the billing consultant noted that Drug Relief was not FDA cleared as a PENS device indicated for pain, and that NCD § 160.7.1 (Defendants' purported basis for Drug Relief coverage) did not cover treatment for symptoms of opioid withdrawal (Drug Relief's only cleared indication).

27. The billing consultant warned Defendants that MAC issued guidance (LCDs), "if followed, could raise program integrity concerns and result in clinicians having to return Medicare payments or even face false claims investigations." Based on

applicable MAC LCDs, the consultant made clear to Defendants that providers should *not* be billing Medicare for Drug Relief using HCPCS L8679.

28. In 2020, Defendants, through DyAnsys, submitted a request to CMS to establish a new Level II HCPCS code to identify the S.T. Genesis (an alternate DyAnsys trade name for Drug Relief) (request # 20.163). Unlike the claims Defendants submitted or caused to be submitted to Medicare for Drug Relief, the request did not characterize the device as a PENS or indicated for the treatment of pain. Instead, the request described Drug Relief as a non-implantable PNFS system for treating opioid withdrawal for which no HCPCS Level II code applied. CMS did not assign S.T. Genesis (Drug Relief) a HCPCS Level II code in response to DyAnsys's request.

29. On July 7, 2021, CMS reconsidered the application (noting that it was a resubmission of the same 2020 request) to assign a HCPCS Level II code to S.T. Genesis (Drug Relief) (request #21.035). CMS, again, did not approve the request to assign a HCPCS Level II code to the device. The agency explained that "CMS continues to believe this product is not suitable for a HCPCS Level II code." CMS found, instead, that the single use device and related service is "most consistent with HCPCS Level I (CPT) coding."

30. Incredibly, despite CMS's position that Drug Relief was not suitable for a HCPCS Level II code, Defendants continued to direct providers to submit claims for Drug Relief to Medicare using HCPCS L8679—*an HCPCS Level II code*.

31. From March 2021 to the end of 2024, Defendants submitted or caused the submission of more than 1,000 claims to Medicare for Drug Relief under HCPCS L8679

which resulted in reimbursements of more than $4,000,000. Over the relevant period, Defendants submitted or caused the submission of more than 1,400 Medicare claims under HCPCS L8679 that resulted in reimbursements of more than $7,000,000. Each of these claims was false.

II. JURISDICTION AND VENUE

32. This Court has subject matter jurisdiction over False Claims Act claims under 31 U.S.C. § 3730(a) and 28 U.S.C. §§ 1331 & 1345, and supplemental jurisdiction over the common law and equitable causes of action under 28 U.S.C. § 1367(a).

33. This Court may exercise personal jurisdiction over each of the Defendants pursuant to 31 U.S.C. §§ 3732(a) & (b). Jurisdiction is proper over each of the Defendants because the acts committed in violation of the False Claims Act occurred in the Northern District of Texas, and because one or more of the Defendants can be found in, resides in and/or transact business in the Northern District of Texas.

34. Venue is proper in this district under 31 U.S.C. § 3732, 28 U.S.C. §§ 1391(b)–(c), and 28 U.S.C. § 1395, because Defendants reside in and/or transact business in the Northern District of Texas.

III. PARTIES

35. Plaintiff United States brings this action on behalf of the United States Department of Health and Human Services ("HHS"), specifically the Centers for Medicare & Medicaid Services ("CMS"), which is the operating division of HHS charged with administering the Medicare Program, 42 U.S.C. §§ 1395 *et seq*. ("Medicare").

36. Defendant Master Equity Solutions d/b/a Emerging Solutions is a Healthcare Marketing company headquartered at 3901 Accent Drive, #1116, Dallas, TX 75287. Emerging Solutions is owned by Master Equity Texas Limited Partnership d/b/a Emerging Solutions which is composed of two partners, Bingham 1999, LP, and the Michael Bingham Living Trust.

37. Michael Bingham is an individual with a primary residence at 372 Bingham Lane, Laurel Springs, NC 28644. At all times relevant, Bingham served as the CEO and majority beneficial owner of Emerging Solutions. Bingham, through the Michael Bingham Living Trust, is the majority beneficial owner of Emerging Solutions.

IV. LEGAL BACKGROUND

A. The False Claims Act

38. The False Claims Act imposes civil liability, treble damages, and civil penalties on "any person who" (among other things) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval to the United States government. 31 U.S.C. § 3729(a)(1)(A).

39. The False Claims Act imposes civil liability, treble damages, and penalties on any person who knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim. 31 U.S.C. § 3729(a)(1)(B). The False Claims Act also imposes civil liability, treble damages, and penalties on any person who "conspires to commit a violation" of the False Claims Act. *Id.* at § 3729(a)(1)(C).

40. For purposes of the False Claims Act, the term "knowingly" means that a person, with respect to information, (i) has actual knowledge of the information, (ii) acts

in deliberate ignorance of the truth or falsity of the information, or (iii) acts in reckless disregard of the truth or falsity of the information. *Id*. at § 3729(b). No proof of specific intent to defraud the federal government is required to show that a person acted knowingly under the False Claims Act. *Id.*

41. The False Claims Act defines "material" to mean "having a natural tendency to influence or be capable of influencing, the payment or receipt of money or property." *Id.* at § 3729(b)(4).

42. Violations of the False Claims subject the defendant to civil liability, including mandatory civil penalties per false violation, plus three times (treble) the amount of damages that the Government sustains as a result of the defendant's actions. *Id.* at § 3729(a).

B. <u>The Medicare Program</u>

43. In 1965, Congress enacted The Health Insurance Program for the Aged and Disabled through Title XVIII of the Social Security Act, 42 U.S.C. § 1395, *et seq*., known as the Medicare program. Medicare is a federal health care program providing benefits to persons who are over the age of 65 and some under that age who are blind or disabled. 42. U.S.C. §§ 426, 426-1, 426a.

44. The regulations implementing Medicare are found at 42 C.F.R. § 405, *et seq*. Part B of Title XVIII of the Act (42 U.S.C. §§ 1395j–1395w-6), commonly referred to as the "Medicare Part B Program" (Part B), is administered by the United States through HHS and its component agency, CMS. Part B is a federally funded national health insurance program providing medical insurance protection for covered services to

any person 65 years of age or older or to certain disabled patients. Benefits are paid on the basis of reasonable and necessary charges for covered services furnished by physicians and other suppliers of medical services. Individuals who receive benefits under Medicare are referred to as Medicare "beneficiaries."

45. Medicare reimburses only reasonable and necessary items and services furnished to Medicare beneficiaries and excludes from payment services that are not reasonable and necessary. 42 U.S.C. § 1395y(a). Providers must provide items and services to Medicare beneficiaries "economically and only when, and to the extent, medically necessary." 42 U.S.C. § 1320c-5(a)(1). Medicare does not pay for items and services that were not provided, since those services are not reasonable and necessary. *Id.*

46. Medicare utilizes "Medicare Administrative Contractors" or "MACs" to administer Medicare Part B in accordance with rules developed by CMS. These contractors are charged with and are responsible for receiving Medicare Part B claims, determining coverage, and making payments from the Medicare Trust Fund. 42 U.S.C. § 1395u.

47. MACs generally act on behalf of CMS within a specified jurisdiction to process and pay Medicare claims submitted by health care providers. At all relevant times, Novitas Solutions, Inc. was the MAC that administered Medicare Part B claims in Texas, Delaware, Arkansas, Pennsylvania, and Louisiana. At all relevant times, Noridian Healthcare Solutions administered Part B claims in Utah and Washington.

48. To submit claims to Medicare Part B, and to be paid from the Medicare trust fund, providers must file a provider agreement with the Secretary of HHS. 42 U.S.C. § 1395cc. The agreement, the Medicare Federal Healthcare Provider/Supplier Enrollment Application, CMS form 855B and/or 855I, contain certification statements in which the applicant agrees, *inter alia*, that he or she (a) will abide by Medicare laws, regulations and program instructions, (b) understands that payment of a claim is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions, and (c) will comply with all applicable conditions of participation in the Medicare program.

49. To enroll for electronic billing with a MAC, a provider must submit a Medicare Part B Electronic Data Interchange (EDI) Enrollment application. By signing the application, the provider agrees, *inter alia*, to submit "claims that are accurate, complete, and truthful." *See* EDI Enrollment for Novitas Solutions. Further, the provider acknowledges that submitting claims using the provider's NPI "constitutes assurances that the services were performed as billed." *Id*.

50. If a provider has entered into a Medicare participation agreement, the provider may bill Medicare Part B directly for each procedure he or she performed on a Medicare beneficiary. *See* Forms 855B and 855I. To bill Medicare Part B, a provider must submit a hard copy CMS-1500 Health Insurance Claim Form (CMS 1500) and/or its electronic equivalent, known as the 837p format. *See* 42 C.F.R. § 424.32. When the provider submits the claim, he or she certifies that the provider knows Medicare's requirements and that the claim complies with applicable laws and regulations.

51. A provider has a duty to familiarize itself with the statutes, regulations, and guidelines regarding coverage for the Medicare services it provides. *Heckler v. Cmty. Health Servs. of Crawford Cty., Inc*., 467 U.S. 51, 64 (1984).

52. For a claim to be eligible for payment by Medicare Part B, the claim must identify each service, supply, or equipment rendered or provided to the patient. Medicare requires the provider to use standardized numerical procedure codes known as CPT (Current Procedure Terminology) and Healthcare Common Procedure Coding System ("HCPCS") codes, that identify the diagnosis, services rendered and for which reimbursement is sought, and the unique billing identification number of the "rendering provider" and the "referring provider or other source. 45 C.F.R. § 162.1002(a)–(b); Medicare Claims Processing Manual, Ch. 23 § 20.7, *et seq.*

53. CPT codes are widely used in the United States as the way medical providers seek reimbursement for professional services from health care payors, including Medicare, other federal health care programs, and many private insurers.

54. HCPCS Level II codes are widely used in the United States as the way medical providers seek reimbursement for medical products, supplies, and equipment from health care payors, including Medicare, other federal health care programs, and many private insurers.

55. The American Medical Association ("AMA") defines the CPT and HCPCS codes in manuals published annually. CMS also issued HCPCS codes, specifically Level II Codes. *See* www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system.

56. At all relevant times, the AMA coding manual has stated these instructions for selecting appropriate codes: "Select the name of the procedure or service that accurately identifies the service performed. Do not select a CPT code that merely approximates the service provided."

57. Not Otherwise Classified ("NOC") codes are used when a specific code for the service, procedure, drug or biological being provided does not exist. Claims using NOC codes are subject to additional documentation requirements detailing the item on the claim given that the code description for the item is generic. When a specific HCPCS code does not exist, providers must list the appropriate NOC code.

58. These codes are used by Medicare and its contractors to determine whether a service qualifies for Medicare coverage at all, and, if so, how much should be paid to the provider. CMS assigns different reimbursement amounts to CPT and HCPCS codes to reflect the services provided.

59. Generally, payment of claims under Part B is largely automated, such that once a Part B provider submits a CMS 1500 form or the electronic equivalent to the Medicare program, the claim is paid directly to the provider, in reliance on the foregoing certifications.

60. Pursuant to the plain language of the claim forms themselves, by submitting the claim to Medicare, the provider is certifying that the information on the form is "true, accurate, and complete" and that the services were actually furnished. *See* CMS 1500 Form; *see also* 42 C.F.R. § 424.24 (addressing certification requirements for medical and other health services furnished by providers under Medicare Part B).

61. At the highest level, CMS promulgates National Coverage Determinations ("NCDs"), which are determinations of national application by CMS "granting, limiting or excluding Medicare coverage for a specific medical [item] or service." 68 Fed. Reg. 55634 at 55635; *see also* 42 C.F.R. § 405.1060 (stating the promulgation of an NCD "is a determination by the secretary of whether a particular item or service is covered nationally under Medicare").

62. An NCD is binding on all private Medicare contractors. 42 C.F.R. § 405.1060(a)(4), (b)(1). The private contractors are also bound by the terms of the Medicare statute in making reimbursement decisions. Among other things, the statute provides that "no payment may be made…for any expenses incurred for items…[which] are not reasonable and necessary for the diagnosis of illness or injury…" 42 U.S.C. § 1395y(a)(1)(A). The private Medicare contractors determine which items are reasonable and necessary for purposes of the statute.

63. If there is no NCD in place, Medicare contractors such as Novitas, each of which have jurisdiction over particular regions, may issue guidance documents, called "Local Coverage Determinations" ("LCDs") or "Local Coverage Articles" ("LCAs"), to address whether it is medically proper to bill under certain codes. LCDs are binding only in the local areas for which the particular contractor has authority. 42 U.S.C. § 1395ff(f)(2)(B).

64. All Medicare providers must have, in each of their patients' files, the medical documentation to establish that the Medicare items or services for which they

have sought Medicare reimbursement are reasonable and medically necessary. 42 U.S.C. § 1395y(a)(1)(A).

65. Providers that participate in any federal health care program, including Medicare, may not make false statements or misrepresentations, or cause others to make false statements or misrepresentations, of materials facts concerning payment requests. *See* 31 U.S.C. § 3729, *et seq*.

NCD § 160.7

66. In NCD §160.7, CMS established coverage and payment for two classifications of electrical nerve stimulators: (A) Implanted Peripheral Nerve Stimulators; and (B) Central Nervous System Stimulators (Dorsal Column and Depth Brain Stimulators). *See* NCD § 160.7 (NCD for Electrical Nerve Stimulators) (effective August 7, 1995). For "Implanted Peripheral Nerve Stimulators", CMS provided as follows:

> Payment may be made under the prosthetic device benefit for implanted peripheral nerve stimulators. Use of this stimulator involves implantation of electrodes around a selected peripheral nerve. The stimulating electrode is connected by an insulated lead to a receiver unit which is implanted under the skin at a depth not greater than ½ inch.
>
> Stimulation is induced by a generator connected to an antenna unit which is attached to the skin surface over the receiver unit. Implantation of electrodes requires surgery and usually necessitates an operating room.
>
> **NOTE**: Peripheral nerve stimulators may also be employed to assess a patient's suitability for continued treatment with an electric nerve stimulator. As explained in § 160.7.1, such use

> of the stimulator is covered as part of the total *diagnostic service* furnished to the beneficiary rather than as a prosthesis.

Id. (emphasis added).

67. In 2006, CMS issued NCD § 160.7.1 to provide further guidance with respect to the use of transcutaneous electrical nerve stimulation ("TENS") and percutaneous electrical nerve stimulation ("PENS") when assessing a patient's candidacy for implantation of a qualified electrical nerve therapy device. *See* NCD § 160.7.1 (NCD for Assessing Patient's Suitability for Electrical Nerve Stimulation Therapy) (effective June 19, 2006). In NCD § 160.7.1, CMS provides that "[e]lectrical nerve stimulation is an accepted *modality* [service] for assessing a patient's suitability for ongoing treatment with a transcutaneous or an implanted nerve stimulator." *Id*. (emphasis added). The suitability assessment or diagnostic can be made using a TENS unit or a PENS and is covered when *performed* by a physician or incident to a physician's service. *Id*. (emphasis added).

68. In NCD § 160.7.1, CMS identifies the use of PENS as an appropriate diagnostic procedure when properly used for the purpose of assessing a patient's suitability for implantation of a qualified electrical nerve stimulator device. *Id*. CMS explains that:

> This diagnostic procedure which involves stimulation of peripheral nerves by a needle electrode inserted through the skin is performed only in a physician's office, clinic, or hospital outpatient department. Therefore, it is covered only when performed by a physician or incident to physician's service. If pain is effectively controlled by percutaneous stimulation, implantation of electrodes is warranted.

Id. CMS stated that PENS are intended to be used on a trial basis, typically for one month, to determine whether an actual implanted nerve stimulator would provide therapeutic benefits. *Id*. CMS notes that if successful, "it is expected that a stimulator will be implanted". *Id*.

69. Through NCD § 160.7.1, CMS did *not* establish that a TENS or PENS unit is a type of implanted nerve stimulator that is covered under NCD § 160.7. Rather, it is described as a "modality" or a "diagnostic service" that is "performed" by a physician or incident to a physician's service. *Id*. As CMS explains in NCD § 160.7, "the use of the [peripheral nerve] stimulator is covered as part of the total diagnostic service furnished to the beneficiary rather than as a prosthesis." NCD § 160.7. Neither NCD § 160.7 nor § 160.7.1 identify PENS or TENS devices used for this purpose as a "trial implantable neurostimulator device" or establish coverage as if a PENS or TENS was a qualified implantable neurostimulator.

C. FDA 510(k) Premarket Approval and Clearance

70. All medical devices marketed in interstate commerce in the United States fall into one of three regulatory classes under the FDCA. The classification assigned to each device is based on the degree of risk they present. Class I devices are deemed to be low risk and are therefore subject to the least regulatory controls. Class II devices are higher risk devices and require greater regulatory controls to provide reasonable assurance of the device's safety and effectiveness. Class III devices are generally the highest risk devices and are therefore subject to the highest level of regulatory control.

71. A sponsor or manufacturer that intends to market a medical device must first file a premarket submission with FDA, unless the device is exempt from these requirements. Most Class III medical devices require a Premarket Application to be filed and approved by the FDA before marketing.

72. Class II medical devices require a Premarket Notification, known as a 510(k), to be filed and cleared by FDA before marketing. *See* 21 U.S.C. § 360(k)).

73. The 510(k) notification must demonstrate that the medical device is "substantially equivalent to another device" that is already on the market, *i.e.*, a "predicate device." 21 U.S.C. § 360c(f)(1)(A)(ii); 21 U.S.C. § 360c(f)(2)(B)(i); 21 C.F.R. 807.92(a)(3).

74. The meaning of "substantially equivalent" is defined as follows:

> [T]he term "substantially equivalent" or "substantial equivalence" means, with respect to a device being compared to a predicate device, that the device and that the Secretary by order has found that the device— (i) has the same technological characteristics as the predicate device; or (ii) (I) has different technological characteristics and the information submitted that the device is substantially equivalent to the predicate device contains information, including appropriate clinical or scientific data. . . that demonstrates that the device is as safe and effective as a legally marketed device, and (II) does not raise different questions of safety and effectiveness than the predicate device.

21 U.S.C. § 360c(i)(1)(A).

75. Thus, FDA will make a determination that a device is substantially equivalent only if a 510(k) demonstrates that the device has "the same technological characteristics as the predicate device," 21 C.F.R. § 807.100(b)(2)(i) or "is safe and as

effective as a legally marketed device [and d]oes not raise different questions of safety and effectiveness." 21 C.F.R. § 807.100(b)(2)(ii).

76. If FDA makes a finding of substantial equivalence, the device is then cleared for marketing and can be marketed only for the intended use stated on the label as cleared by the FDA.

77. Once FDA makes a determination whether a device is substantially equivalent, FDA will issue a letter to the 510(k) sponsor/manufacturer applicant stating its decision and whether the device is cleared. The Indications for Use (IFU) and the applicant's 510(k) Summary are included as attachments to the decision letter. Collectively, the documents are known as the SE Package.

78. If there is no legally marketed predicate device, a manufacturer or sponsor may make a "De Novo" request to FDA under Section 513(f)(2). A De Novo request provides a marketing pathway to classify novel medical devices for which general controls alone, or general and special controls, do not provide reasonable assurance of safety and effectiveness for the intended use. De Novo classification is a process where FDA analyzes whether the probable benefits of the device outweigh the probable risks. If the probable benefits outweigh the probable risks, the FDA may grant the request, and the new device is thereby authorized to be marketed. Devices that are classified into Class I or Class II through a De Novo classification request may be marketed and used as predicates for future premarket notification (510(k)) submissions, when applicable.

79. A determination by FDA that the device intended for introduction into commercial distribution is substantially equivalent to a predicate device does not in any

way denote official approval of the device. 21 C.F.R. § 807.97. "Any representation that creates an impression of official approval of a device because of complying with premarket notification regulations is misleading and constitutes misbranding." *Id.*

80. FDA has an important role in Medicare reimbursement decisions, but its approval and/or clearance does not automatically secure payments for a medical device. While FDA approval and/or clearance has been adopted as a prerequisite to Medicare coverage, "FDA approval/clearance alone does not generally entitle that device to coverage." 68 Fed. Reg. 55,635; *see also* 42 C.F.R. § 405.201(a)(1).

81. While Medicare may adopt FDA determinations regarding safety and effectiveness, CMS and its contractors determine when a device is reasonable and necessary, and thus eligible for coverage, under the Medicare statute. *See* 68 Fed, Reg. 55,634 (Sept. 26, 2003). FDA conducts premarket review of products under different statutory standards than CMS does to determine reimbursability. *Id.* A device may be approved or cleared by FDA and still not be eligible for Medicare coverage. *Id.*

V. FACTUAL BACKGROUND

82. Defendant Emerging Solutions is a medical device marketing and distribution company based in North Texas. Emerging Solutions was founded, operated, and majority owned, directly or indirectly, by Defendant Michael Bingham through the Michael Bingham Living Trust.

83. Beginning in 2019 and continuing through at least 2024, Emerging Solutions marketed and distributed a line of medical devices, along with an accompanying programmable technical unit ("PTU"), all of which were manufactured by DyAnsys, an

India-based company. Defendants marketed and distributed the line of medical devices under various trade names, including "Drug Relief," "Primary Relief V1," "First Relief," and "OpiRelief."[4]

84. Beginning in 2019, Emerging Solutions operated as a sub-distributor of Eclipse Health Solutions, LLC, an Austin, Texas-based distributor that held the exclusive rights to market and distribute Drug Relief in North America. In or about July 2020, Emerging Solutions amended its distribution agreement with Eclipse and obtained the exclusive rights to market and distribute Drug Relief in North America.

85. At all relevant times, Bingham served as the majority beneficial owner and CEO of Emerging Solutions. Bingham was integral to Emerging Solutions' day-to-day operations as well as developing and implementing the company's marketing and billing strategy for Drug Relief. As CEO, Bingham oversaw Emerging Solutions' provision of management and billing services provided to customers, which included the submission of claims to health care payers, including Medicare.

86. AS CEO, Bingham was assisted by Mark Keck, who served as President, Lynn Fossum, who served as COO, as well as other individuals. As President, Keck supervised three regional managers, Jennifer Stewart, Kit Williams, and Katherine Matangos, and was responsible for growing Emerging Solutions through increased sales

[4] FDA cleared three Drug Relief devices. "Drug Relief" was cleared on June 6, 2022, under the 510(k) submission, K173861. A second device, "Drug Relief v1" was cleared on December 5, 2021, under K211971. A third device, "Drug Relief v1" was cleared on June 6, 2022, under K221231. Because Emerging Solutions marketed these various devices collectively as "Drug Relief," the "Drug Relief," "Primary Relief V1," "First Relief," and "OpiRelief" devices are referred to collectively as "Drug Relief" in this complaint.

across regions. As COO, Lynn Fossum oversaw operations, which included billing and revenue management services provided by Emerging Solutions to its health care provider customers.

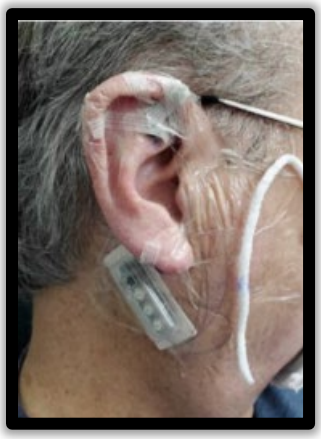
87. During the relevant period, Emerging Solutions also worked with two physician partners: Dr. Kenneth Alo and Dr. Richard Nichols. Drs. Alo and Nichols provided various services on behalf of Emerging Solutions, including marketing Drug Relief as an effective solution for chronic pain and a revenue driver for clinics. As a provider, Dr. Nichols treated patients with Drug Relief, including Medicare beneficiaries, for which he sought and obtained reimbursements of federal funds. Emerging Solutions used Dr. Nichols' successful submissions of claims for Drug Relief to Medicare and other payers to market Drug Relief to potential customers. In exchange for these services, Emerging Solutions provided Drs. Alo and Nichols with a contingent ownership interest in the company worth up to $2 million, as well as other forms of remuneration.

A. The Drug Relief Device

88. Drug Relief is a small, battery-operated device that consists of a hearing aid style generator (battery) and electrodes connected via wires. A picture of one version of the Drug Relief device from Emerging Solution's marketing and training materials is below:

Each electrode contains a short penetrating needle which is used to deliver periodic electrical impulses to auricular points on the external ear. Through this mechanism, Drug Relief purports to provide patients with temporary relief from symptoms associated with opioid withdrawal during periods of detoxification.

89. The procedure to attach Drug Relief was typically performed in an office setting by a medical professional (whether a qualified physician was required depended on state requirements) and took approximately 10–15 minutes to complete. Application of the device did not require surgery of any kind or the use of anesthesia. The device could be applied to a patient without any incision or implantation. A picture showing a Drug Relief device attached to a patient follows:



90. To attach the device, providers used a PTU (which could be used multiple times) to identify cranial nerve points on the external ear based on electrodermal activity (e.g., skin conductance). After locating the cranial nerve points, electrodes with short penetrating needle were inserted (not implanted) just beneath the skin's surface (not deeper than 3 millimeters) in the outer edge of the patient's ear (similar to acupuncture) and held in place with tape. The procedure to attach Drug Relief was so efficient, that providers often attached 10 or more devices in a single afternoon.

91. Once attached, the Drug Relief device delivered gentle electrical pulses over approximately 10-12 days before running out of batteries. Patients wearing the device were instructed to avoid contact with water and to refrain from washing their hair during the treatment period. At the end of the treatment period, the patient returned to the provider to remove the device which was then discarded.

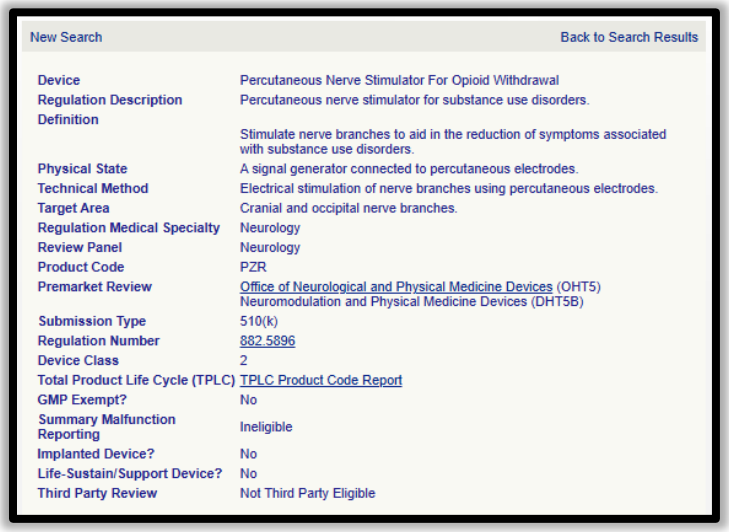
B. FDA cleared Drug Relief as a PNFS device to treat symptoms of opioid withdrawal

92. Drug Relief is classified by the FDA as a Percutaneous Nerve Field Stimulator ("PNFS") for Opioid Withdrawal under 21 C.F.R. § 882.5896. The FDA 510(k) premarket notification for Drug Relief (K173861) identifies the following Indications for Use:

> The Drug Relief is a percutaneous nerve field stimulatory (PNFS) system, that can be used as an aid to reduce the symptoms of opioid withdrawal, through the application to branches of Cranial nerves V, VII, IX, and X, and the occipital nerves identified by transillumination.

Drug Relief's *only* indicated use identified in the 510(k) (K173861) is to aid in the reduction of opioid withdrawal symptoms—not the treatment of pain.[5]

93. The publicly available FDA database for 510(k) Premarket Notifications provides additional information regarding Drug Relief, which was classified under product code PZR. An image of the FDA website for Product Classifications reflecting the PZR product classification of one of the Drug Relief devices follows:



New Search | Back to Search Results

Device	Percutaneous Nerve Stimulator For Opioid Withdrawal
Regulation Description	Percutaneous nerve stimulator for substance use disorders.
Definition	Stimulate nerve branches to aid in the reduction of symptoms associated with substance use disorders.
Physical State	A signal generator connected to percutaneous electrodes.
Technical Method	Electrical stimulation of nerve branches using percutaneous electrodes.
Target Area	Cranial and occipital nerve branches.
Regulation Medical Specialty	Neurology
Review Panel	Neurology
Product Code	PZR
Premarket Review	Office of Neurological and Physical Medicine Devices (OHT5) Neuromodulation and Physical Medicine Devices (DHT5B)
Submission Type	510(k)
Regulation Number	882.5896
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
Summary Malfunction Reporting	Ineligible
Implanted Device?	No
Life-Sustain/Support Device?	No
Third Party Review	Not Third Party Eligible

A PZR device is described as a "Percutaneous Nerve Stimulator for Opioid Withdrawal" that is used to "Stimulate nerve branches to aid in the reduction of symptoms associated with substance use disorders." The FDA product classification indicates that Drug Relief is not an implanted device.

[5] The Drug Relief line of devices are all cleared for the same Indications for Use.

94. Drug Relief was not classified by FDA as a PENS device. FDA classifies PENS devices using a separate product code "NHI." An image of the FDA webpage for Product Classifications of a NHI (PENS) product classification follows:

New Search | Back to Search Results

Device	Stimulator, Nerve, Electrical, Percutaneous (Pens), For Pain Relief
Regulation Description	Transcutaneous electrical nerve stimulator for pain relief.
Definition	Percutaneous electrical nerve stimulator (pens) is a device used for the treatment of pain. Unlike the classified transcutaneous electrical nerve stimulator that apply an electrical current to electrodes on a patient's skin to deliver stimulation, a pens uses electrodes that are placed percutaneously to deliver stimulation.
Regulation Medical Specialty	Neurology
Review Panel	Neurology
Product Code	NHI
Premarket Review	Office of Neurological and Physical Medicine Devices (OHT5) Neuromodulation and Physical Medicine Devices (DHT5B)
Submission Type	510(k)
Regulation Number	882.5890
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
Summary Malfunction Reporting	Eligible
Implanted Device?	No
Life-Sustain/Support Device?	No
Third Party Review	• Eligible for 510(k) Third Party Review Program

95. FDA described PENS devices as "Stimulator, Nerve, Electrical, Percutaneous (Pens), For Pain Relief." Drug Relief was not cleared as a PENS for "Pain Relief."[6] Like PNFS, PENS devices are also not implanted.

[6] The manufacturer of Drug Relief, DyAnsys, later obtained expanded clearances for the other nerve stimulation devices under separate trade names. This includes, "First Relief v1," cleared as a non-implanted percutaneous electrical nerve field stimulator for use in treating patients with functional abdominal pain associated with irritable bowel syndrome on December 29, 2020, under (K202940. Dec. 29, 2020), "First Relief," was cleared as a PENS device for use in treating chronic pain associated with diabetic peripheral neuropathy on September 8, 2021, under (K221859. Sept. 8, 2021), and "Primary Relief," was cleared as a PENS device for symptomatic relief of post-operative pain following cesarean section delivery on January 31, 2022, under (K213188). A second Primary Relief device was cleared on September 13, 2022, under K221425. Jan. 31, 2022). First Relief v1, First Relief, and Primary Relief used the same mechanism as Drug Relief and did not require surgery or involve implantation of any kind.

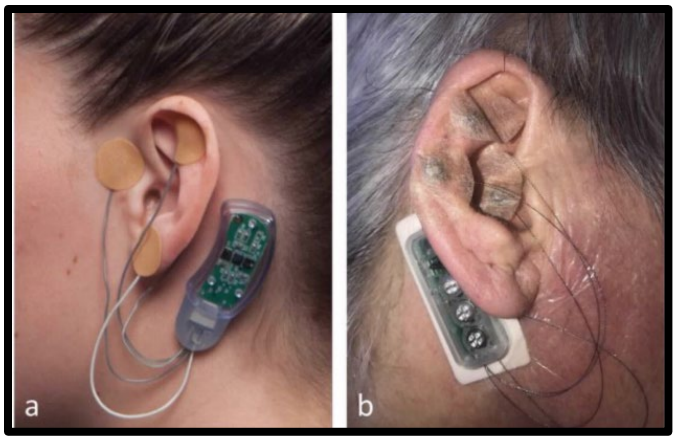
C. Drug Relief's FDA clearance is based on its substantial similarity to NSS-2 Bridge and ANSiStim-PP

96. FDA cleared DyAnsys's premarket notification of their intent to market the Drug Relief device (K173861) pursuant to Section 510(k) of the Food, Drug and Cosmetic Act, which allows manufacturers to market and sell a device that is "substantially equivalent" to a product already cleared for sale in the United States.

97. In May 2018, when FDA cleared the first Drug Relief device for marketing and sale (K173861), it determined that Drug Relief was substantially equivalent (for the submitted indications for use) to the legally marketed predicate device NSS-2 Bridge (DEN170018). The predicate device, the NSS-2 Bridge, was reviewed by the FDA via the De Novo premarket review, a regulatory pathway for some low-to moderate-risk devices that are novel and for which there is no legally marketed predicate device to which the device can claim substantial equivalence.

98. The NSS-2 Bridge device is marketed as an "aid to reduce the symptoms of opioid withdrawal, through application to branches of Cranial Nerves V, VII, IX, and X, and the occipital nerves identified by transillumination" and is a Class II device. The Drug Relief device cleared under K173861 has the same Indications For Use as the NSS-2 Bridge device.

99. A picture comparing the (a) NSS-2 Bridge device and (b) a Drug Relief device follows:



As shown above, the NSS-2 Bridge and Drug Relief devices both consist of a small battery-operated generator that is placed behind a patient's ear and connected to wires that are attached to specific points on the outer ear.

100. With respect to the hardware components of the Drug Relief device, DyAnsys explained in its May 2018 510(k) summary to FDA for premarket notification (K173861) that "[a]ll the hardware components" are "similar to the 510(K) cleared device ANSiStim-PP (K170391)." The ANSiStim-PP device (also manufactured by DyAnsys) is an electro-acupuncture device and is classified as a non-implantable device that FDA determined to be substantially equivalent to DyAnsys's own legally marketed predicate device, the ANSiStim (K141168), which is also a non-implantable electro-acupuncture device.

101. The ANSiStim-PP 510(k) (K170391) summary describes the device as "a wearable, battery-operated device that is designed to administer continuous low-level electrical pulses to the ear over four days / 96 hours from the time of activation of the device. The electrical pulse from the device will be delivered to the stimulation point on the ear through a set of wire assembly and Stimulation needles. . . . There are three

stimulation needles and one ground electrode – which consist of a needle and lead/wire with the snap-fit ring. The stimulation needles are inserted at three specific points, which have the ability to stimulate the auricular cranial nerves."

102. Like ANSiStim-PP, Drug Relief is described in the 510(k) summary (K173861) as a "wearable, battery-operated device that is designed to administer periodical low-level electrical pulses to the ear over five days / 120 hours . . . from the time of activation of the device. The electrical pulse from the device will be delivered to the branches of Cranial Nerves on the ear through a set of wire assembly and stimulation needles. There are three stimulation electrodes and one ground electrode—which consist of a needle and lead/wire with the snap-fit ring. The stimulation needles are inserted at three specific points, which have the ability to stimulate the auricular cranial nerves."

103. The descriptions of the ANSiStim-PP device and the Drug Relief device are nearly identical. The difference is that the ANSiStim-PP device is described as an electro-acupuncture stimulator whereas the Drug Relief is described as a percutaneous nerve field stimulator that can be used as an aid to reduce the symptoms of opioid withdrawal. Functionally, the ANSiStim-PP and Drug Relief are the same device.

D. Novitas Article A55240 identifies NSS-2 Bridge as non-covered

104. As described above, DyAnsys's 510(k) clearance for the first Drug Relief device is based on its substantial similarity to the NSS-2 Bridge. These devices, and others, were identified or otherwise described as non-covered in Novitas' revised A55240 re "Billing and Coding: Auricular Peripheral Nerve Stimulation (Electro-Acupuncture Device)" (Effective June 14, 2018).

105. In A55240, Novitas specifically identified ANSiStim (the predicate device to ANSiStim-PP, cleared under K141168) as a non-covered device. Novitas described ANSiStim as an "electro-acupuncture device[ ] used for stimulation of auricular points and as such [is] non-covered. Acupuncture for stimulation of auricular points is not a covered Medicare benefit."

106. In A55240, Novitas made clear that devices falling under separate classifications, including the NSS-2 Bridge, were also non-covered when used for auricular peripheral nerve stimulation. Novitas described NSS-2 Bridge as an "FDA classified as a percutaneous nerve stimulator for substance use disorders; Class II device." Novitas explained that NSS-2 Bridge is an "electrical nerve stimulator (percutaneous nerve field stimulator [PNFS] that is placed behind the patient's ear (auricular)). The NSS-2 is described as nearly identical to the Electronic Auricular Device ("EAD") for a different intended use (to aid in the reduction of opioid withdrawal symptoms). This device is non-covered by Medicare when used for acupuncture (stimulation of auricular acupuncture points) for any indication."

107. For any such devices (whether classified as electro-acupuncture devices, PNFS devices, or otherwise) used for auricular peripheral nerve stimulation, Novitas directed providers to report the associated services using the NOC CPT code 64999 – unlisted procedure, nervous system. Novitas stated that the trade name for the device used for this procedure (e.g., NeuroStim/NSS, P-Stim, ANSiStim, E-Pulse, Elector-Acupuncture, NSS-2 Bridge) should be reported in the Remarks area of the claim for Part

A and the Narrative areas of the claim for Part B. Novitas made clear that services for auricular peripheral nerve stimulation will be denied as non-covered.

108. Novitas' revised A55240 also provided that "[w]hile the information given in this article is directed to Neurostim system/NSS, P-Stim, ANSiStim, E-Pulse, and NSS-2 Bridge, other current or future devices when used for the procedure auricular peripheral nerve stimulation or electro-acupuncture, would also be considered a non-covered service."

109. Novitas A55240 made clear that Drug Relief, like the NSS-2 Bridge, is not covered when used for auricular peripheral nerve stimulation. Although not specifically identified by Novitas in A55240, Drug Relief is substantially similar to the NSS-2 Bridge, and also received FDA clearance as a Class II medical device percutaneous nerve stimulator for substance use disorders. Like the NSS-2 Bridge, Drug Relief is a PNFS system that is placed behind the patient's ear to deliver auricular peripheral nerve stimulation.

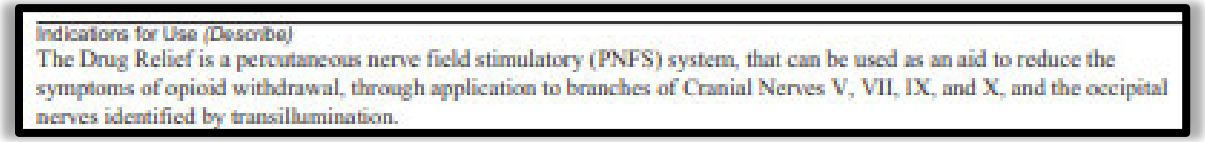
110. At all relevant times, Defendants understood that the NSS-2 Bridge was a substantially equivalent device and a direct competitor to Drug Relief.

E. Defendants marketed Drug Relief as cleared by the FDA as a PENS device to treat pain

111. Emerging Solutions falsely marketed Drug Relief as an FDA-cleared PENS device to treat pain. The following is an excerpt from an Emerging Solutions' marketing brochure (2020) for the Drug Relief device:

112. Bingham represented to providers in communications that Drug Relief was cleared by the FDA as a PENS device. For example, on November 26, 2019, Bingham emailed a provider group representative regarding Drug Relief. In the email, Bingham explained that "[t]here is only one product, the DyAnsys Drug Relief, DBA Primary Relief V1 that has a FDA cleared [sic] as a Neurostimulation device. The device is listed both as a PNSF (Percutaneous Nerve Field Stimulatory) and a PENS (Percutaneous Electrical nerve Stimulation)."

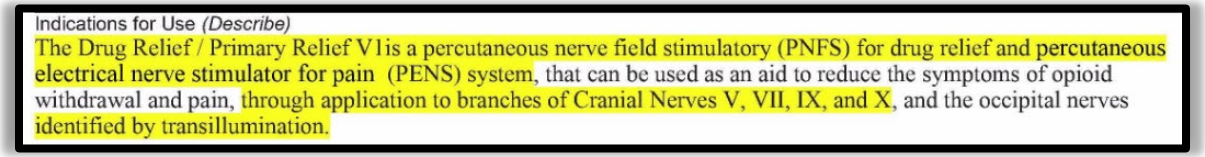
113. These claims were false. Drug Relief was not cleared by the FDA as a PENS device or to treat chronic pain. The actual "Indications for Use" from the May 2018 cleared FDA 510(k) submission for Drug Relief[7] is below:


Indications for Use (Describe)
The Drug Relief is a percutaneous nerve field stimulatory (PNFS) system, that can be used as an aid to reduce the symptoms of opioid withdrawal, through application to branches of Cranial Nerves V, VII, IX, and X, and the occipital nerves identified by transillumination.

114. Thus, the FDA 510(k)-cleared Indications for Use do not match Emerging Solutions' marketing claims that Drug Relief was cleared as a PENS device for the treatment of pain. Instead of changing its marketing to match the 510(k) clearance,

[7] The referenced 510(k) decision letter is for the initial "Drug Relief" device, cleared under K173861. The Indications for Use for the "Drug Relief v1" devices, cleared under two separate 510(k) submissions, are the same as "Drug Relief."

Emerging Solutions simply changed the FDA 510(k)-cleared Indications for Use, which was attached to the FDA decision letter, to match their marketing. Stated differently, Bingham, on behalf of Emerging Solutions, fraudulently altered the FDA 510(k) clearance decision letter to create the appearance that the Drug Relief was cleared as a PENS device for the treatment of pain. A copy of the Emerging Solutions altered FDA 510(k) clearance letter's Indications for Use (highlighted by Emerging Solution) is below:


Indications for Use *(Describe)*
The Drug Relief / Primary Relief V1is a percutaneous nerve field stimulatory (PNFS) for drug relief and percutaneous electrical nerve stimulator for pain (PENS) system, that can be used as an aid to reduce the symptoms of opioid withdrawal and pain, through application to branches of Cranial Nerves V, VII, IX, and X, and the occipital nerves identified by transillumination.

Then, Defendants included the forged FDA 510(k) document in materials provided to prospective investors, sub-distributors, medical clinics, and providers to back up its false claims about the device, its indications, and coverage. These communications did not disclose the fact that *Bingham*—not the FDA—had altered Drug Relief's cleared indications.

115. For example, on June 15, 2020, an Emerging Solutions representative (Tod Zhang) emailed a provider (Dr. S. Justin Badiyan) responding to billing concerns that the device was not covered by Medicare. In the email, Zhang writes that "the device we will be using is NOT a P-Stim or any 'electro-acupuncture' device; it is a *Percutaneous Electrical Nerve Stimulator* (PENS System), **Primary Relief V1** . . ., which is a FDA-cleared programmable PENS system for the treatment of chronic pain, opioid withdrawal, etc." (emphasis in original). In support of these claims, Zhang "attached a few pieces of relevant documents for [the provider] to review regarding FDA clearance," including

"'Primary Relief V1' filed and approved by FDA as PENS system (not acupuncture)." Zhang attached the FDA 510(k) letter that had been fraudulently altered by Bingham to falsely indicate that Drug Relief (marketed as Primary Relief V1) was cleared as a PENS device for the treatment of pain.

116. On October 16, 2020, Bingham sent an email to Kit Williams, another Emerging Solutions representative, providing information and records to respond to a separate provider's concern about the Drug Relief device. In the email to Williams, Bingham explains that "[o]ur device FDA cleared as a Class 2 device making it a medical device," and "CMS said they will pay for PENS medical devices." Bingham refers Williams to an attached FDA 510(k) decision letter for Drug Relief (K173861), writing: "See page 3 highlighted in yellow FDA cleared as PENS." The referenced attachment is the FDA 510(k) letter fraudulently altered by Bingham to create the appearance that Drug Relief was cleared as a PENS for the treatment of pain.

117. Providers relied on Defendants' false representations regarding the scope of FDA's clearance of the device. For example, on March 27, 2020, an Emerging Solutions representative emailed a medical clinic (Anadel Center for Foot & Ankle Reconstruction) explaining that the device "is a FDA-cleared programmable PEN system for the treatment of chronic pain, neuropathic pain, opioid withdrawal, etc." The Emerging Solutions representative attached the fraudulently altered FDA 510(k) letter for K173861, the initial 510(k) for Drug Relief, to the email.

118. The medical clinic, Anadel Center for Foot & Ankle Reconstruction, later submitted a claim to Medicare for the Drug Relief device on behalf of Medicare

beneficiary J.A. for a date of service on October 27, 2020. In the supporting medical records, the provider, Tritsenere Onosode, described the device as a "PENS (percutaneous electrical nerve/field stimulator) … It is a CLASS 2 (LOW TO MODERATE RISK) device specifically for opioid withdrawal and pain relief via Cranial nerves 5, 7, 9, 10 and the occipital nerves (cranial nerves C1-2-) identified by transillumination."[8] Multiple other providers' narratives contained identical descriptions of the device as a PENS indicated for *both* opioid withdrawal and pain relief.

119. Not everyone was fooled by Defendants' false and misleading claims. Certain outside investors and providers expressed serious concerns that Defendants' claims about Drug Relief were inaccurate or otherwise fraudulent. For example, on December 10, 2019, an outside attorney representing a potential investor wrote that the "FDA approved 'Drug Relief' to be used for opioid withdrawal symptoms. Thus, the use of the device [under a separate trade name "Primary Relief"] (for pain management) may be 'off label.'"

120. On June 18, 2020, a provider, Joo-Hyung Lee, demanded that Emerging Solutions "email/state that this is an FDA APPROVED DEVICE FOR USE FOR PAIN TREATMENT." After the provider spoke with the manufacturer of NSS-2 Bridge (Innovative Health Solutions), he called Emerging Solutions out on their false claims, writing: "Why are you trying to con my office?? I will plan on reporting you and your company to the FDA and Medicare to let them know of fraud."

[8] 135503

121. Bingham, of course, understood that the Drug Relief was not FDA cleared as a PENS device for the treatment of chronic pain (which is why he forged the fraudulent FDA letter in the first place). Bingham knew that the FDA clearance was a big problem and posed a significant risk to Drug Relief's marketability and billing strategy. In a June 30, 2020, email to Eclipse (a separate contracted distributor of Drug Relief), Bingham explained that they needed to apply to the FDA for a new trade name and to expand the device's clearance to match their marketing claims. Bingham wrote: "[a]t this time the device [Drug Relief] is only cleared as a PNSF and for opioid withdraw. As you know our two companies Eclipse and [Emerging Solutions], have been marketing the product as a medical solution for chronic pain for a product not cleared for chronic pain. **To use the L8679 and 64555 all payors are relying on the device we represent to be a PENS, *which it is not*, and had a FDA clearance for chronic pain, *which again is not*.**" (emphasis added).

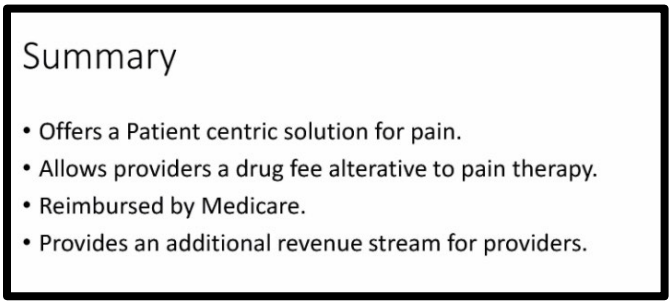
122. In an email to DyAnsys owner Srini Nageshwar on September 26, 2020, Bingham explained that "my doctors think the device is a PENS. If I go back and say, no it is not a PENS [then] all sales stop until we get the FDA PENS clearance. The 160.7.1 is for PENS and not a PNSF. PNSF does not qualify to use the L8679 or 64555 code. . . . CMS considers the PNSF to be acupunctural device. CMS will accept a PENS to not be an acupunctural device." Bingham wrote further that "The NSS-2 Bridge is not a PENS. Once you get the clearance your device will be the only one that qualifies meeting the CMS requirements. . . . ***I have not wanted to put this in writing because I did not want to have a record that we all knew the device was not a PENS*** but I feel with calls you have

not taken me serious or the importance of having a PENS FDA clearance." (emphasis added)

F. Defendants falsely claim Drug Relief is covered by Medicare

123. While FDA clearance makes a device *eligible* for Medicare coverage, FDA approval *alone* is not a basis for coverage. Each payor, including Medicare, can develop their own medical policy regarding coverage. As described further above, multiple MACs and CMS issued guidance making clear that peripheral auricular nerve stimulators, like Drug Relief, are not implantable neurostimulators and should not be billed to Medicare as such.

124. Ignoring MACs' and CMS's guidance, and the warnings of other third parties, Defendants implemented an aggressive marketing scheme to promote the device as covered by Medicare. The following is a slide from an Emerging Solutions marketing presentation (May 2020) shared with potential sub-distributor and provider customers.



In the marketing slide, Emerging Solutions markets Drug Relief as offering a "patient centric solution for pain," that is "Reimbursed by Medicare," and "Provides an additional revenue stream for providers."

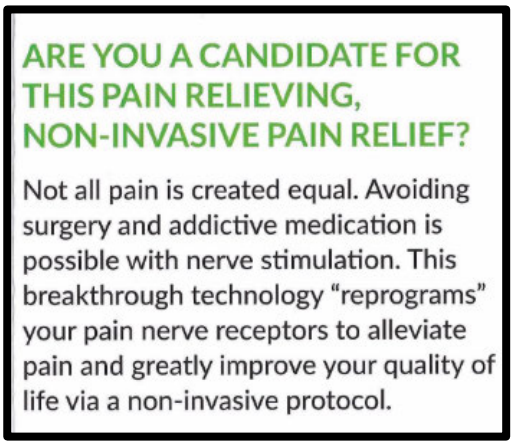
125. The revenue component of Defendants' pitch for Drug Relief was key to the marketing scheme. The devices were expensive, and Defendants understood

providers would balk at the cost absent assurances of reimbursement. Defendants provided such assurances, claiming that Drug Relief was covered by Medicare (and other payers) and providers could expect $7,000 to more than $10,000 *per claim*—more than enough to cover costs and still deliver a significant profit.

126. To obtain these reimbursements, Defendants directed providers to bill Drug Relief using HCPCS L8679—an expensive code reserved for "implantable neurostimulators, pulse generator any type." HCPCS L8679 is a device billing code that describes an electrical nerve stimulator (sometimes referred to as a neurostimulator or a pulse generator). These Medicare covered devices—which include Spinal Cord Stimulators ("SCS")—require surgical implantation into the central nervous system or targeted peripheral nerve. Qualified devices are implanted via procedures that require local or general anesthesia and are performed in an operating room or ambulatory surgical clinic. As part of the surgical procedure, electrical wires (leads) are implanted on or near the relevant nerve *and* the neurostimulator is implanted beneath the patient's skin.

127. Drug Relief is not an implantable neurostimulator and should not be billed to Medicare under HCPCS L8679. As described further above, Drug Relief is a battery-operated device that is affixed *externally* to patients with tape through a procedure that can be performed in-office in as little as 10 minutes. No surgery is involved—not even an incision—and there is no implantation of any device or electrical leads under the skin at the source of nerve pain.

128. Defendants' own marketing brochures for Drug Relief described the procedure as a non-invasive treatment for pain that did not involve surgery:



In the above excerpt, Emerging Solutions explains that "*[a]voiding surgery* and addictive medication is possible with nerve stimulation . . . .via a *non-invasive* protocol."

129. The following chart highlights the key differences between Drug Relief and qualified implantable neurostimulators:

Device	Surgery	Anesthesia	Incision	Leads Implanted at Pain Source	Generator Implanted Under the Skin	Covered by Medicare
Drug Relief	No	No	No	No	No	No
Implantable Neurostimulator	Yes	Yes	Yes	Yes	Yes	Yes

G. Defendants claim Drug Relief can be billed under HCPCS L8679 as a "Trial Implantable Neurostimulator"

130. Despite the clear differences between Drug Relief and qualified implantable neurostimulators, Defendants claimed that the non-implanted device could still be billed to Medicare under HCPCS L8679 as a *trial* implantable neurostimulator.

131. In support of this claim, Defendants cited to CMS's NCD § 160.7. In NCD §160.7, CMS established coverage and payment for electrical nerve stimulators as follows:

> Payment may be made under the prosthetic device benefit for *implanted* peripheral nerve stimulators. Use of this stimulator involves implantation of electrodes around a selected peripheral nerve. The stimulating electrode is connected by an insulated lead to a receiver unit which is implanted under the skin at a depth not greater than ½ inch.
>
> Stimulation is induced by a generator connected to an antenna unit which is attached to the skin surface over the receiver unit. Implantation of electrodes requires surgery and usually necessitates an operating room.

NCD § 160.7 (NCD for Electrical Nerve Stimulators) (effective August 7, 1995) (emphasis added).

132. NCD § 160.7 included a note addressing the use of peripheral nerve stimulators as diagnostic tool for determining whether a patient was an appropriate candidate for an implanted electrical nerve stimulator:

> **NOTE**: Peripheral nerve stimulators may also be employed to assess a patient's suitability for continued treatment with an electric nerve stimulator. As explained in § 160.7, such use of the stimulator is covered as part of the total diagnostic service furnished to the beneficiary rather than as a prosthesis.

Id. (emphasis in original).

133. A subsequent NCD (NCD § 160.7.1), issued in 2006, provided further guidance with respect to the use of PENS devices to assess a patient's suitability for electrical nerve stimulation therapy. NCD § 160.7.1 provides that "[e]lectrical nerve

stimulation is an accepted *modality* [service] for assessing a patient's suitability for ongoing treatment with a transcutaneous or an implanted nerve stimulator." CMS explained that the diagnostic procedure for PENS devices involves a "needle electrode inserted through the skin" and "is covered only when *performed* by a physician or incident to physician's service." *Id.* (emphasis added). CMS stated that PENS are intended to be used on a trial basis, typically for one month, to determine whether an actual implanted nerve stimulator would provide therapeutic benefits. Where the trial is successful, "it is expected that a stimulator will be implanted . . . ." *Id*.

134. Defendants claimed that NCD § 160.7, along with § 160.7.1, establish that the Drug Relief device could be billed as a *trial* implantable neurostimulator under HCPCS L8679. That claim is false. Drug Relief is not cleared as PENS device for the treatment of pain. Even if it was, NCD § 160.7 and § 160.7.1 do not establish that a provider can bill the PENS device under an expensive code reserved for qualified implantable neurostimulators (which Drug Relief is not). NCD § 160.7.1 provides only that CMS may provide payment for the use of a PENS device as part of the "total *diagnostic service* provided to the beneficiary" to assess whether actual implantation of a qualified device is appropriate.

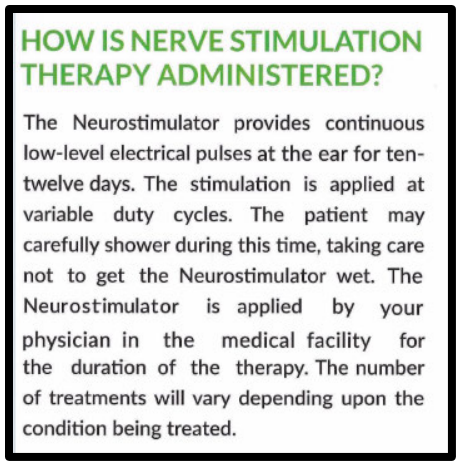
135. To support their false claims of coverage under NCD § 160.7.1, Defendants fraudulently claimed that that Drug Relief was a PENS device cleared for the treatment of pain – which was not true.[9] As Bingham explained in his own words, "**to use the L8679**

[9] Defendants' fraudulent scheme to market the Drug Relief as a PENS device indicated for pain is addressed further *supra*.

and 64555 all payors are relying on the device we represent to be a PENS, *which it is not*, and had a FDA clearance for chronic pain, *which again is not*." (emphasis added).

136. Even if these claims were true and Drug Relief was cleared by the FDA as a PENS device for the treatment of pain, NCD § 160.7.1 still would not establish coverage under a diagnostic service code (let alone the expensive HCPCS L8679 code). In NCD § 160.7.1, CMS made clear that it expected successful PENS diagnostic assessments will lead to the implantation of a covered implantable neurostimulator device. Providers did not use Drug Relief for that purpose. Even though Defendants claimed that "[o]ver 80% of treatments have achieved desirable outcomes," there is no indication that any Medicare beneficiaries treated with Drug Relief treatment underwent a subsequent procedure to implant a qualified electrical nerve stimulator.

137. It was a scam—providers had no intention of implanting a covered electrical nerve stimulator following the Drug Relief "trial." Instead, patients were routinely provided with another *trial* Drug Relief device and Medicare was billed under HCPCS L8679 for multiple additional treatments. Indeed, Drug Relief's marketing materials expressly noted that patients may receive more than one treatment:



HOW IS NERVE STIMULATION THERAPY ADMINISTERED?

The Neurostimulator provides continuous low-level electrical pulses at the ear for ten-twelve days. The stimulation is applied at variable duty cycles. The patient may carefully shower during this time, taking care not to get the Neurostimulator wet. The Neurostimulator is applied by your physician in the medical facility for the duration of the therapy. The number of treatments will vary depending upon the condition being treated.

The above excerpt from an Emerging Solutions' marketing brochure notes that "[t]he number of treatments will vary depending upon the condition being treated."

138. Defendants also issued procedure and billing instructions directing that providers should consider patients for multiple Drug Relief treatments. For example, in a document given to providers titled "Clinic Neurostimulator Pre-Install Instructions," Emerging Solutions explained that after the patient returns for removal of the Drug Relief, "[i]t will be decided at that time with the Provider and the patient, whether the patient will return after 7 days (minimum timeframe between therapies) for a second therapy procedure." Notably absent from these or other instructions is any direction that providers should refer patients with successful Drug Relief treatments for a permanent implantation of a qualified electrical nerve stimulator device.

139. For example, on March 18, 2020, an Emerging Solutions representative explained to a provider that the purpose of the Drug Relief was not as a trial but rather to provide pain relief treatment *without* the need for an implanted device. The representative explained that "Auricular stimulation may not be a 'one and done' scenario

in terms of permanent pain relief, and thus why Medicare is approving for up to 2 placements per year for 2 consecutive years." The representative stated further that "[c]urrent and predominant usage is to see if intermittent stimulation offers a pain relief benefit for select patients without placement of a permanent device."

H. Defendants marketed the significant reimbursements associated with Drug Relief claims

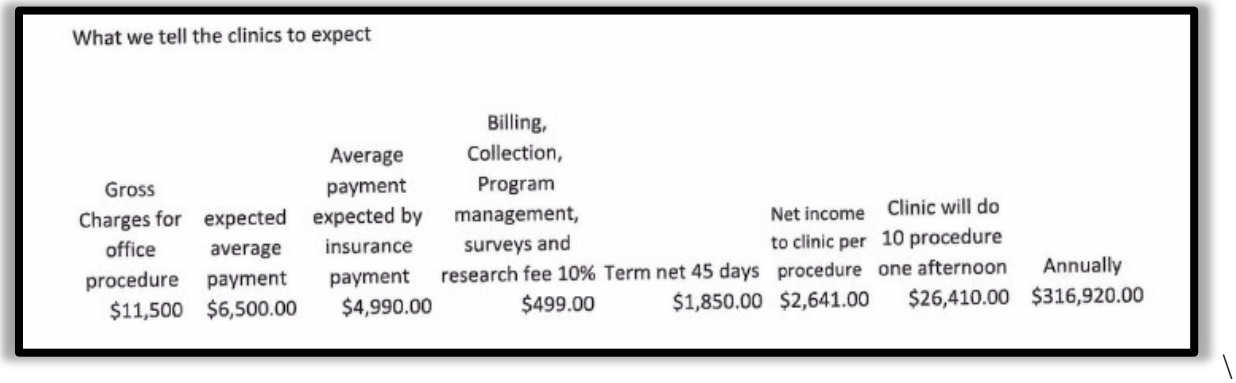
140. To get in the door, Defendants needed to convince providers that Drug Relief was covered by Medicare. To close the deal, Defendants pushed Drug Relief as a revenue driver for clinics, capable of generating thousands of dollars in profits from a procedure that could be performed in as little as 10-15 minutes.

141. Defendants' ability to market Drug Relief as a revenue driver was based on their false claim that the device was covered under HCPCS L8679. Payers, including Medicare, reimbursed HCPCS L8679 between $6,000 to more than $8,000 per device (not including additional reimbursements from accompanying surgical procedure codes).

142. Defendants routinely highlighted these significant reimbursement amounts in marketing communications and materials provided to sub-distributors (working on commission) as well as directly to provider customers. For example, in a May 6, 2020, email to Kevin Donahower (sub-distributor), Bingham provided records demonstrating that one provider placed 58 Drug Relief devices on patients over a 58-day period. After providing Drug Relief to his patients, Bingham claimed the provider "netted $168,083.99 in profits all in 58 days." Bingham noted that "if this clinic continued doing 58 patients every 60 days, this clinic would net over $1,000,000 just providing our product."

143. In a June 23, 2020, email to a provider, Bingham explained Drug Relief is "Covered by Medicare, Tricare, Worker's Comp, and commercial insurances." Bingham wrote that after "[a]fter cost of goods ($2,450/device, including all revenue cycle mgmt. fees), each 15–20 mins procedure produces a *net profit of $3,000 to $5,000* (depending on specific types of insurance)" (emphasis in original). Bingham attached a representative "Medicare EOB (as of 4/15/2020)" showing a reimbursement of $6,601.9 for HCPCS L8679 and $1,282 for CPT 64555 (an accompanying surgical code) to back up his claim.

144. In addition to providing potential customers with EOBs, Emerging Solutions provided financial models of anticipated clinic income ranges for Drug Relief. For example, Emerging Solutions used a document called "One Clinics Income" (excerpted below) to promote the revenue clinics could expect to generate from Drug Relief:

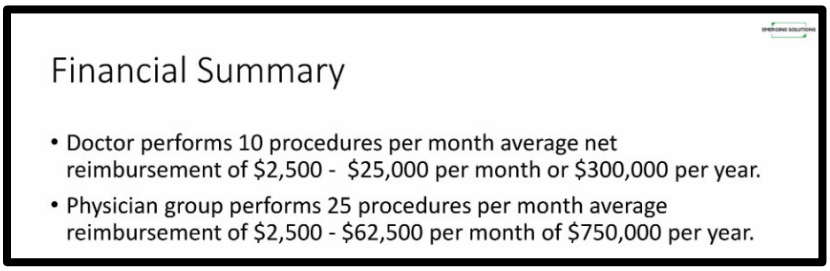


What we tell the clinics to expect

Gross Charges for office procedure	expected average payment	Average payment expected by insurance	Billing, Collection, Program management, surveys and research fee 10%	Term net 45 days	Net income to clinic per procedure	Clinic will do 10 procedure one afternoon	Annually
$11,500	$6,500.00	$4,990.00	$499.00	$1,850.00	$2,641.00	$26,410.00	$316,920.00

In the above model, Emerging Solutions represented that clinics could expect to generate $26,410 (after deducting cost of devices and Emerging Solutions' fee) ***in a single afternoon***. These revenue projections were also shared in marketing presentations,

including the following financial summary estimating $300,000 to $700,000 in net reimbursements (depending on single doctor or physician group):



145. Defendants made clear that providers could multiply their profits by stacking patients and performing multiple procedures in a single day. They did so by emphasizing that the procedure could be completed quickly and in-office. For example, the following Emerging Solutions' marketing materials claim that "[t]he placement of the device takes about ten minutes."

146. The fact that Drug Relief could be placed quickly on numerous patients in a single afternoon was a force multiplier for Defendants' marketing pitch. Obtaining $2,641 for a single procedure was one thing—but the potential to obtain $26,410 in a single afternoon was something else altogether. Defendants highlighted both the efficiency and profitability of Drug Relief to drive sales of the devices.

I. Defendants controlled Drug Relief billing to facilitate payment

147. Under the arrangement with Emerging Solutions, providers were typically not required to pay for the device or the accompanying PTU upfront.[10] Rather, Emerging Solutions offered to recoup the cost of the devices through payer reimbursements. In doing so, Emerging Solution accepted the risk that the claims would not be reimbursed, or reimbursement would be delayed due to medical reviews and appeals. To mitigate these risks, Emerging Solutions exerted close control over the billing process to facilitate the payment of Drug Relief claims.

148. Emerging Solutions typically required that each customer enter into a "Neuro-Stimulation Billing and Management Agreement."[11] Under these agreements, Emerging Solutions served as a third-party biller on behalf of the contracted provider for all device-related claims, including claims submitted to Medicare.[12] In exchange for providing billing and management services, which included pre-authorization and appeals of denied claims, Emerging Solutions received 10% of reimbursements for the device-related claims.

149. Defendants understood that payers, including Medicare, would deny claims that fully and accurately described the Drug Relief device and the related procedures (which were not covered). To facilitate approvals, Defendants assigned each facility a

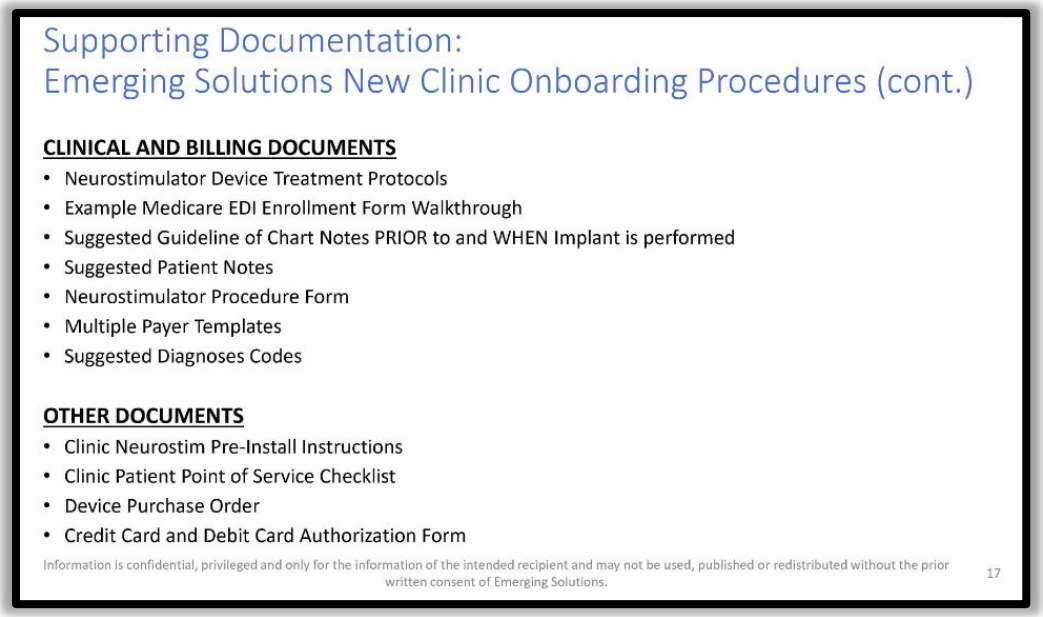
[10] Emerging Solutions charged providers about $1,800 for the PTU which could be used multiple times for all Drug Relief procedures.

[11] The agreements were also described as Sales and Service Agreements for Revenue Cycle Management ("RCM") Services.

[12] During certain periods, Emerging Solutions contracted with a third party—Catalyst RCM, LLC—to provide billing services on behalf of Emerging Solutions' customers.

billing manager and provided customers with packets that included "copy and paste" examples for chart notes, patient notes, procedure forms, and suggested diagnoses codes (e.g., G89.4 (chronic pain) should be the "first diagnosis code listed") to support the false claims for reimbursement under HCPCS L8679 (and in some instances, CPT 64555).

150. A representative slide from Emerging Solutions "Neurostimulator Onboarding Process" presentation (dated January 15, 2020) describes the documentation provided to new Drug Relief customers:



Supporting Documentation:
Emerging Solutions New Clinic Onboarding Procedures (cont.)

CLINICAL AND BILLING DOCUMENTS

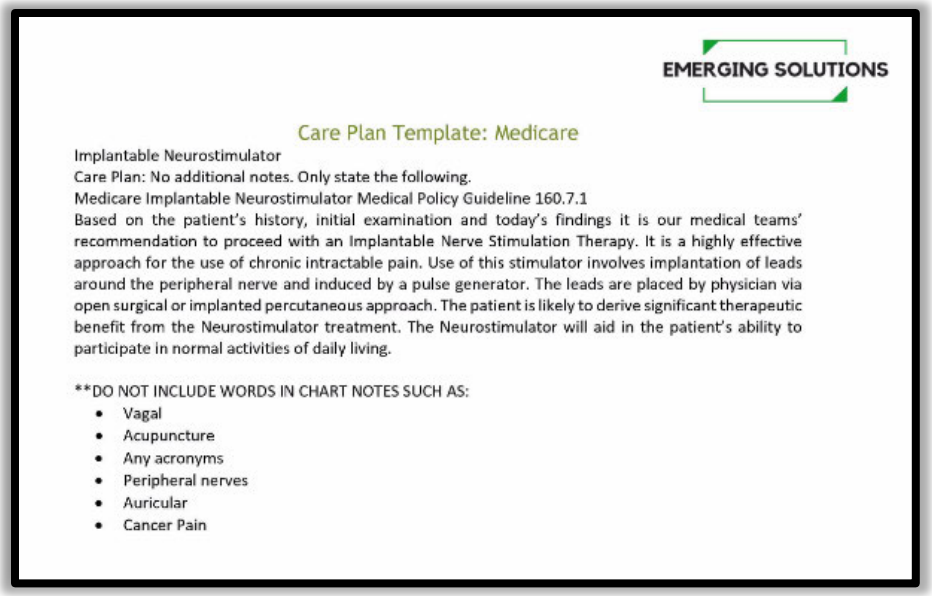
- Neurostimulator Device Treatment Protocols
- Example Medicare EDI Enrollment Form Walkthrough
- Suggested Guideline of Chart Notes PRIOR to and WHEN Implant is performed
- Suggested Patient Notes
- Neurostimulator Procedure Form
- Multiple Payer Templates
- Suggested Diagnoses Codes

OTHER DOCUMENTS

- Clinic Neurostim Pre-Install Instructions
- Clinic Patient Point of Service Checklist
- Device Purchase Order
- Credit Card and Debit Card Authorization Form

Information is confidential, privileged and only for the information of the intended recipient and may not be used, published or redistributed without the prior written consent of Emerging Solutions. 17

151. As noted in the slide above, Emerging Solutions provided customers with care plan templates tailored to specific to payors. An example of a care plan template for Medicare that Emerging Solutions provided to customers follows:



EMERGING SOLUTIONS

Care Plan Template: Medicare

Implantable Neurostimulator
Care Plan: No additional notes. Only state the following.
Medicare Implantable Neurostimulator Medical Policy Guideline 160.7.1
Based on the patient's history, initial examination and today's findings it is our medical teams' recommendation to proceed with an Implantable Nerve Stimulation Therapy. It is a highly effective approach for the use of chronic intractable pain. Use of this stimulator involves implantation of leads around the peripheral nerve and induced by a pulse generator. The leads are placed by physician via open surgical or implanted percutaneous approach. The patient is likely to derive significant therapeutic benefit from the Neurostimulator treatment. The Neurostimulator will aid in the patient's ability to participate in normal activities of daily living.

**DO NOT INCLUDE WORDS IN CHART NOTES SUCH AS:

- Vagal
- Acupuncture
- Any acronyms
- Peripheral nerves
- Auricular
- Cancer Pain

The above "Care Plan Template: Medicare" instructs providers to "[not] include additional notes" and "[o]nly state the following." It also warns providers to "NOT INCLUDE WORDS IN CHART NOTES SUCH AS: "Vagal, Acupuncture. . . Peripheral nerves, Auricular . . . ." The template does not identify the device as "Drug Relief" or describe it as a percutaneous nerve field stimulatory (PNFS) system. Doing so, of course, would have made clear that the device was not covered.[13] Instead, the template provides a generic description of the device ("Neurostimulator") and the procedure ("leads placed via open surgical or implanted percutaneous approach") to align with the requirements under HCPCS L8679 and required surgical billing codes.

152. The canned notes provided by Defendants were routinely adopted (copied and pasted) by provider customers and used to generate medical records in support of the Drug Relief claims submitted to Medicare and other payors. These notes provided

[13] Novitas, in A55240, expressly directed providers to identify the name of the device in claims for this very purpose.

inaccurate or otherwise misleading descriptions of the device, its indications, and the nature of the associated procedures.

153. Emerging Solutions reviewed provider notes and supporting records prior to claim submission to ensure that necessary information was included and that appropriate codes were utilized. As Bingham explained in a February 22, 2020, email to a provider, "we read all medical records and if the doctors are describing the wrong patient or ***not using the words that payors will accept*** we send back to educate or say wrong patient for this device or correct as follows." (emphasis added). Bingham boasted that through this control, "[w]e have been collecting 96% using our methods."

J. Defendants directed providers to bill CPT 64555 to circumvent additional CMS controls designed to identify improper billing of HCPCS L8679

154. In 2020, Medicare contractors began cracking down on the provider submission of claims for auricular peripheral nerve stimulation devices that were being incorrectly billed under HCPCS L8679 as implantable neurostimulators. To circumvent additional controls put in place by MACs to flag these false claims, Defendants directed providers to report HCPCS L8679 along with CPT 64555—a surgical code—to create the false appearance that Drug Relief was an eligible device for which surgery was required.

155. CMS signaled its increased scrutiny of claims for auricular peripheral nerve stimulation devices in a January 29, 2020, CMS article (MLN Matters Number: SE20001) re "Incorrect Billing of HCPCS L8679—Implantable Neurostimulator, Pulse Generator, Any Type." CMS published the article based on its awareness "that some providers are submitting claims incorrectly to Medicare using HCPCS code L8679."

156. In the article, CMS noted that providers are "inappropriately coding electro-acupuncture devices as implantable neurostimulators" under HCPCS L8679 "which are Medicare-covered devices that require surgical implantation into the central nervous system or targeted peripheral nerve, and are usually implanted via procedures performed in operating rooms." (citing NCD 160.7). CMS explained that electro-acupuncture devices "are non-invasive (that is do not require surgical implantation and/or an incision), and have an external battery source." To ensure that only Medicare-covered implantable neurostimulators are billed under HCPCS L8679, CMS directed that an accompanying surgical procedural code should also be billed (indicating that a surgery had, in fact, been performed).

157. CMS announced that beginning March 1, 2020, "MACs will reject claims for HCPCS code L8679 submitted without an appropriate HCPCS/CPT surgical procedure code," and will suspend for medical review claims for HCPCS code L8679 billed without an appropriate surgical procedure code.

158. Following the article's publication, Defendants implemented a new billing strategy designed to circumvent the CMS controls.[14] Defendants directed providers to bill Drug Relief using both HCPCS L8679 and CPT 64555—a code used to describe the surgical implantation of peripheral nerve neurostimulator electrodes, accessed through the skin. Medicare provided reimbursements of more than $1,000 for CPT 64555 claims.

[14] Defendants' new strategy was limited to the submission of claims to Medicare only. Defendants continued to bill Drug Relief to other payers using just HCPCS L8679.

When combined with HCPCS L8679, these claims often exceeded $10,000 in total reimbursements for Drug Relief.

159. Drug Relief was not covered under CPT 64555. In 2018, MAC Novitas issued guidance through article A55240 (discussed further above) to address the improper billing of auricular peripheral nerve stimulation using CPT 64555. In the A55240, Novitas made clear that auricular peripheral nerve stimulation devices were not covered by Medicare and should not be billed using CPT 64555. In the A55240, Novitas identified NSS-2 Bridge (the substantially similar device upon which Drug Relief's FDA 510(k) clearance was based) as a non-covered device that could not be billed under 64555 when used for auricular peripheral nerve stimulation.

160. Defendants' new strategy to circumvent these controls proved successful. As Bingham explained in an April 19, 2020, email, "[w]e have received Medicare payments for services performed after 3-1-20 so doctors are excited about that." As before, Defendants continued to exert close control over the billing of all claims for Drug Relief to facilitate payment under these expensive billing codes.

161. In a December 18, 2020, memo to DyAnsys, Bingham emphasized the importance of Emerging Solutions' close management of claims submission, explaining that it "is required for the product to be sold because of the large number of clawback[s] the past and current markets experience." Bingham further noted that "everyone using the L8679 code is being challenged and we are the only one providing a package that turns the denials to payments. . . . We have a team that has found how to get these device[s] approved and paid for."

K. Defendants, through DyAnsys, sought but did not obtain assignment of an HCPCS Level II Code for Drug Relief

162. As the sales of Drug Relief grew larger, Defendants' ambitions—fueled by unrelenting greed for additional profits—kept pace. Initially, Defendants targeted independent providers and small medical clinics for the sale of Drug Relief. As the company experienced success, Defendants eyed bigger deals with larger hospitals and health care systems, Native American reservations, and even the Department of Defense.

163. Defendants highlighted its ambitions to scale up in a "Business Overview" designed to drive outside investment in the company. In the overview, Emerging Solutions highlighted two potential opportunities. First, Emerging Solutions identified a "renowned and highly respected hospital group, with nearly 250 hospital locations." Emerging Solutions noted that it anticipated potential sales of "more than 300 devices (30 boxes of devices) per month." Second, Emerging Solutions explained that "an Indian Nation tribe plans to use ES's neurostimulator to treat chronic pain," and forecasted "sales to Indian Nation tribes will reach more than 250 devices" per month."

164. Defendants understood that duping small providers was one thing but scamming larger and more sophisticated customers was another. To gain access to sophisticated purchasers, like hospital systems and Indian Nation tribes (and the thousands of federal beneficiaries under their care), Defendants realized they could no longer stand on a forged FDA letter to support their false claims about Drug Relief, its indications, and coverage as an implantable neurostimulator (or *trial* implantable neurostimulator).

165. At the same time, Defendants also recognized that their current billing practices created a significant risk of liability. In a July 24, 2020, email to distributor Eclipse, Bingham explained the need to take action to justify their continued submission of claims to Medicare. "If we do not move quickly we believe CMS could start an investigation of those billing the Primary Relive V1 [Drug Relief] using the L8679 when the product was not a PENS. . . . Even this week we have reason to believe the product shipped to our client could be considered by FDA as any acupunctural device not being a product that is programable."

166. In the hopes of establishing Drug Relief as an approved device covered by Medicare, Defendants prepared an application to CMS requesting the assignment of a HCPCS Level II billing code. Defendants paid a third-party consultant (Connect 4 Strategies, LLC) to develop a coverage, coding, and payment strategy to support the planned CMS application for Drug Relief.

167. Connect 4 Strategies quickly identified significant issues with Emerging Solutions' characterization of the device and historical billing strategy. Among other problems, the billing consultant noted that Drug Relief was not FDA cleared as a PENS device indicated for pain, and that NCD § 160.7.1 (Defendants' purported basis for Drug Relief coverage) did not cover treatment for symptoms of opioid withdrawal (the device's only cleared indication). The consultant noted that there was no specific CPT or HCPCS codes for PENS or Percutaneous Neuromodulation Therapy (PNT) services. She advised that providers should use the unlisted code CPT 64999 (unlisted procedure, nervous system) to bill for related services.

168. Connect 4 Strategies warned Defendants that guidance issued by MACs, "if followed, could raise program integrity concerns and result in clinicians having to return Medicare payments or even face false claims investigations." Pursuant to such guidance, the consultant made clear that providers should not be billing Medicare for the Drug Relief using CPT 64555 or HCPCS L8679.

169. In 2020, Defendants, through DyAnsys, submitted a request to CMS to establish a new level II HCPCS code to identify the S.T. Genesis (an alternate trade name for Drug Relief) (request # 20.163). Unlike claims submitted to Medicare for Drug Relief, the request did not characterize the device as a PENS or indicated for the treatment of pain. The request described the device as a non-implantable PNFS system for treating opioid withdrawal for which no HCPCS level II code applied. CMS did not assign S.T. Genesis (Drug Relief) a HCPCS level II code in response to DyAnsys's request.

170. On July 7, 2021, CMS reconsidered the application (noting that it was a resubmission of the same 2020 request) to assign a HCPCS Level II code to S.T. Genesis (Drug Relief) (request #21.035). CMS, again, did not approve the request to assign a HCPCS Level II code to the device. The agency explained that "CMS continues to believe this product is not suitable for a HCPCS Level II code." CMS found, instead, that the single use device and related service is "most consistent with HCPCS Level I (CPT) coding."

171. Despite CMS' decision and its position that Drug Relief was "not suitable for a HCPCS Level II code," Defendants continued to direct providers to submit claims for the device using HCPCS L8679—a *HCPS Level II code*.

L. Defendants ignored warnings that Drug Relief was not covered

172. Throughout the relevant period, Defendants were warned, repeatedly, by third parties that their billing practices were improper, and that Drug Relief cannot be billed to Medicare using HCPCS L8679 or an accompanying surgical code.

173. For example, in a December 10, 2019, email, an attorney representing a potential third party investor expressed "potential legal concerns about the Primary Relief [Drug Relief]" highlighting questions as to whether the device was reimbursable and flagging the risk of "being drawn into a government investigation." Noting that CMS/MACs had issued guidance that peripheral stimulation devices are non-covered, the investor explained that Drug Relief "does the same thing and is administered in an identical way as P-Stim devices," and "it truly seems to be the case that they are the same devices." The investor explained that "Medicare does not reimburse auricular electrostimulation devices, and has released multiple statements to this effect."

174. On April 1, 2020, another provider, Gregory Crisp, shared his concerns that the Drug Relief device was not covered by Medicare under HCPCS L8679. The provider emphasized that the device was placed on the ear and "NOT IMPLANTED IN SPINE". In response to these concerns, President Keck recommended that "we end this billing relationship," to which COO Fossum replied: "Yes I agree."

175. On June 5, 2020, another provider, flagged concerns with the billing directions provided by Defendants. The provider wrote: "After closer inspection, the billing codes L8679 you sent me were for permanent implanted neurostimulator device which my pain management guys use in their outpatient surgical centers. Isn't this more like a P-Stim that we used to use many years ago, but Medicare no longer covers this." In a subsequent exchange, the provider wrote that "CMS says that we need to bill a surgical code with the procedure code you have supplied for us. I cannot bill that code since it's not done at a surgical center."

176. Two weeks later, on June 19, 2020, the same provider shared his concerns (and anger) with Defendants over their claims of Drug Relief coverage. "Just got off the phone with Innovate Health Solutions for their cutaneous neuromodulator systems, and they also have said that these units are cleared by the FDA, but NOT APPROVED FOR USE BY MEDICARE. They state we cannot bill Medicare!! Why are you trying to con my office?? I will plan on reporting you and your company to the FDA and Medicare to let them know of fraud." In an internal email to Bingham and Lynn Fossum (COO), President Mark Keck wrote that "[t]his guys [sic] feel like trouble to me. I spoke to Jen [Stewart] and said I think we should back away but I told her I was going to speak to you Mike [Bingham]."

177. The providers and investor's concerns about Drug Relief were warranted. Beginning in late 2019, United States Attorney's Offices began announcing a series of settlements and civil actions related to the improper billing of auricular electrostimulation devices that were nearly identical to the Drug Relief device. In a September 17, 2019

press release issued by the United States Attorney's Office for the Eastern District of Pennsylvania, the government explained that Medicare does not reimburse for "P-Stim [brand name of a separate device] as a neurostimulator or as implantation of neurostimulator electrodes."[15] The press release highlighted that other devices besides the P-Stim—including the "NSS-2 Bridge" (the substantially similar device that served as the basis of Drug Relief's FDA 510(k) clearance)—were also not covered.

178. In March 2021, a third party (Marcy Rogers) working with Emerging Solutions, shared a press release from a law firm identifying the government's increased efforts to investigate and take action against the improper submission of HCPCS L8679 claims for ineligible devices. In an email to COO Lynn Fossum, Rogers wrote: "This is real and its something we must pay attention to immediately. I told Mike [Bingham] at the onset there was a narrow window before Medicare pushed back and launched RAC audits because of utilization, coding and the funds being reimbursed to physicians. It appears they have begun that process to recover those funds."

M. Defendants caused the submission of false claims that resulted in Medicare reimbursements

179. During the relevant period, Defendants caused the submission of numerous false claims for the Drug Relief to Medicare that resulted in the payment of federal funds.

[15] *See* DOJ Press Release: "Doctor and Physician Practice to Pay $178,000 top Resolve False Claims Act Liability Arising from billing 'P-Stim' Devices," (Sept. 17, 2019), *available at* https://www.justice.gov/usao-edpa/pr/doctor-and-physician-practice-pay-178000-resolve-false-claims-act-liability-arising (last accessed August 22, 2025) (Declaring that federal agencies and United States Attorneys' Offices would be working together "to hold accountable any other providers who inappropriately billed for this device and any distributors or marketers who carried out such billing scheme.").

For example, on March 29, 2021, Bingham circulated a summary ("Summary of paid claims as of 03/24/202) highlighting Emerging Solutions' success in facilitating the payment of claims for the Drug Relief, including claims reimbursed by Medicare. In the summary, Emerging Solutions identifies 304 paid claims from Medicare with an average reimbursement amount of $8,235.[16] Bingham's summary breaks down the claims paid by Medicare as follows:

Insurance	Average Reimbursement	Total No. Paid Claims	Total Payment[17]
DE Medicare	$8,040.52	17 claims	$136,688.84
FL Medicare	$8,479.17	3 claims	$25,437.51
LA Medicare	$8,588.44	39 claims	$334,949.16
PA Medicare	$7,900.04	10 claims	$79,000.40
TX Medicare	$8,171.52	235 claims	$1,920,307.20
UT Medicare	$7,241.61	6 claims	$43,449.66
Total Medicare Payments (as of March 24, 2021)			**$2,539,832.77**

180. Defendants' submission of claims to Medicare increased in the periods that followed. From March 2021 to the end of 2024, Defendants obtained more than

[16] The overwhelming majority of paid claims in the summary are from Medicare. For example, the total number of paid commercial claims is listed as 68 with a lower average reimbursement of $6,639.

[17] Based on average reimbursement multiplied by total number of paid claims.

$4,000,000 in reimbursements through the submission of more than 1,000 claims to Medicare for Drug Relief.

181. In total, Defendants caused the submission of more than 1,400 *paid* Medicare claims resulting in reimbursements of more than $7,000,000.

N. Representative Example 1: Alta Pain Solutions

182. On January 16, 2020, Emerging Solutions Regional Director Jennifer Stewart emailed Terri Clawson, a physician assistant at Alta Pain Physicians (NPI 1063721850), a medical clinic located at 11333 S. 1000 E., Sandy, Utah. In the email, Stewart touted the "[s]uccess we are seeing with the device. . . and the success our billing company is having with claims and reimbursement!" She highlighted the success of providers working with Emerging Solutions, noting that the company manages "claims from beginning to end." Stewart expressed enthusiasm about working with Alta Pain Physicians and her hope that they could "come to an agreement to move forward."

183. On January 16, 2020, Clawson responded that she had discussed the device and proposal with Dr. Chen (the primary provider at Alta Pain Physicians). Noting the significant cost of the device, Clawson explained that she wanted to line up patients that were preapproved before moving forward with any purchase order of the devices.

184. Stewart responded to Clawson's email in an attempt to address her concerns about cost. Stewart explained that there would be no balance due until 45 days after the devices were ordered. She stated that this would provide "ample time for reimbursements to pay for the cost." She added that "[w]ith the reimbursement we are seeing, we are expecting a net return for you, the provider[,] being approximately $2500

per device." Stewart added that "[w]e may be able to get this going for you sooner than later, offering better pain relief option for your patients and an incredible reimbursement for your clinic."

185. On January 14, 2020, Stewart sent another email to Clawson to address her "concern of device costs if not reimbursed." Stewart explained that she was "attaching one clinics device income and the success they are having." Stewart attached to the email a document titled "One Clinics income 1-14-20." The attachment included a Novitas Solutions, Inc. (MAC) explanation of benefits for Drug Relief claims (submitted by Dr. Richard Nichols) showing payment of $6,542.50 under HCPCS L8679 (per device). The attachment also included a revenue projection for Medicare cases of $5,539.90 per device or $55,399 for each box of ten devices. Assuming a provider performed ten procedures each month, Emerging Solutions projected that a clinic/provider would generate annual revenue of $664,788 from Drug Relief.

186. On January 31, 2020, Clawson sent an email to Stewart expressing concerns with Emerging Solutions' representation that Drug Relief was a covered implantable neurostimulator. In the email, Clawson explained that "[t]he CPT code you're using to bill is for an 'implantable device.' There are many audits going on as a result of using this code. Since your electrodes are not implanted, how are you legally using this code? This code would account for your high level of reimbursement currently, but is not consistent with the device itself. What are your attorneys saying?"

187. On January 31, 2020, Stewart responded to Clawson's email, explaining that the Drug Relief device was a PENS device and distinct from the acupuncture devices

that had been the subject of recent audits. Stewart explained that Emerging Solutions has been "able to bill successfully and are having great success in treating patient[']s pain, billing and reimbursements."

188. In support, Stewart attached certain documents, including a document titled "FDA Premarket Notification Number K173861 highlighted." The attached document was the FDA 510(k) letter that had been fraudulently altered by Bingham to create the false appearance that Drug Relief was approved as a PENS device for the treatment of pain. Stewart also attached a document titled "Neurostimulator Overview" which identifies NCD 160.7.1 as the basis of coverage for the Drug Relief device as a PENS. In the overview, Emerging Solutions attempted to distinguish Drug Relief from electro-acupuncture devices which were the subject of audits and lawsuits. Emerging Solutions claimed that "[c]omparing a PSTIM to a PENS is akin to comparing an apple to an orange."

189. In response, Clawson wrote: "[b]ut you can see where I'm nervous, right?" Clawson noted that the "pictures of the stimulator you have in the neurostimulation overview you sent me is, indeed, just electrodes attached with tape. While it is not applied by acupuncturists and may have needle insertion, it still seems like someone could come after us for repayment of insurance premiums. And heaven forbid we be accused of fraud. . . . With this much reimbursement in play, it makes one pause." Clawson and Stewart arranged a phone call to discuss Clawson's billing concerns.

190. Four days later, on February 4, 2020, Michael Chen, DO, on behalf of Alta Pain Physicians, entered into Neuro-Stimulation Services Agreement with Emerging

Solutions. Shortly thereafter, Alta Pain Physicians ordered its first box of Drug Relief devices from Emerging Solutions. Emerging Solutions issued an invoice (dated February 26, 2020) to Alta Pain for one box of Drug Relief devices (pack of 10) for $18,500, and a PTU for $1,799.

191. On February 10, 2020, Stewart sent Clawson instructions for enrolling in "our clearing house for Medicare billing." As part of this process, Clawson completed an EDI enrollment application with Noridian Healthcare Solutions (MAC responsible for processing Part B claims in Utah) to submit claims electronically as an authorized provider using her NPI (1992992952). By completing the application, Clawson certified, among other things, to submit claims that are accurate, complete, and truthful. Additionally, by submitting claims under her NPI, Clawson certified that the services were performed as billed.

192. In or about February and March 2020, Stewart provided Clawson with billing templates, including: (i) "Letter of Medical Necessity for Implantation of Neurostimulator" in support of billing the Drug Relief under HCPCS L8679 for the treatment of patients suffering from "chronic intractable pain"; (ii) a pre-filled Neurostimulator Procedure Form that described the device as a "TRIAL implantable neurostimulator pulse generator, any type"; (iii) a "Neurostimulator Device Treatment Protocols," that identified Drug Relief's indications, which included various types of chronic pain (e.g., back pain and body aches, headaches and neck pain, pain in upper and lower extremities, etc.); and (iv) a form titled "Neurostimulator Requisition / Patient

Consent" indicating that multiple Drug Relief treatments may be needed before a patient sees results.

193. Beginning March 2020 through June 2020, Emerging Solutions submitted six (6) claims to Medicare seeking reimbursement under HCPCS L8679 and CPT 64555 for Drug Relief treatment provided by Clawson to Medicare beneficiaries. Medicare provided reimbursement for these claims totaling $42,086.13:

Patient Name	Insurance	DOS	POS	Reimbursement
J.B.	Medicare	3/5/2020	11	$6,723.90
B.R.	Medicare	3/5/2020	11	$7,917.75[18]
K.B.	Medicare	6/8/2020	11	$6,861.12
D.B.	Medicare	6/8/2020	11	$6,861.12
M.W.	Medicare	6/15/2020	11	$6,861.12
F.O.	Medicare	6/15/2020	11	$6,861.12

194. On April 20, 2020, Emerging Solution COO, Lynn Fossum, sent an invoice to Alta Pain Physicians, for medical claims processing services in the amount of $1,464.20.

Quantity	Description	Unit Price	Line Total
0	Neurostim Device 10-pack	$ 18,500.00	$ -
0	Neurostim Programming Technical Unit (PTU)	$ 1,799.00	$ -
1	Medical Claims processing, preauth, research & management fee. Carrier payments received totaling $14,642 10% activity fee thru 04/17/2020	$ 1,464.20	$ 1,464.20

The invoice reflects that the amount is based on 10% of payments received totaling $14,642 through April 17, 2020. In support of the invoice, Emerging Solutions provided a record reflecting the underlying Medicare payments received to date for Drug Relief.

[18] Medicare provided reimbursement for both HCPCS L8679 ($6,732.90) and CPT 64555 ($1,193.85). All other paid claims were for HCPCS L8679 only.

Patient Name	Insurance	Provider	Facility	DOS	Billing Date	Remit Date	Posting Date	Paid
[redacted]	Medicare	Terri Clawson	Alta Pain Physicians	3/5/2020	3/12/2020	4/14/2020	4/17/2020	$6,724
	Medicare	Terri Clawson	Alta Pain Physicians	3/5/2020	3/12/2020	4/14/2020	4/17/2020	$7,918
	Total Claims	2						$14,642

195. In or about May 2020, Alta Pain Physicians ordered another box of Drug Relief devices from Emerging Solutions. Emerging Solutions issued an invoice (dated May 7, 2020) to Alta Pain Physicians for one box of Drug Relief devices (pack of 10) for $18,500.

196. In or about June 2020, Alta Pain Physicians ordered another box of Drug Relief Devices from Emerging Solutions. Emerging Solutions issued an invoice (dated June 2, 2020) to Alta Pain for one box of Drug Relief devices (pack of 10) for $17,500.

197. In or about August through October 2020, Emerging Solutions submitted nine (9) claims to Medicare seeking reimbursement under HCPCS L8679 and CPT 64555 for Drug Relief treatment provided by Clawson to Medicare beneficiaries. Noridian issued additional document requests (ADR) for each of the (9) claims submitted.

Patient Name	Insurance	DOS	POS	Reimbursement
C.L.	Medicare	8/3/2020	11	$0.00
T.F.	Medicare	8/10/2020	11	$0.00
C.B.	Medicare	8/10/2020	11	$0.00
J.G.	Medicare	8/24/2020	11	$0.00
L.T.	Medicare	10/12/2020	11	$0.00
E.S.	Medicare	10/13/2020	11	$0.00
S.F.	Medicare	10/26/2020	11	$0.00
D.H.	Medicare	10/27/2020	11	$0.00
K.H.	Medicare	10/27/2020	11	$0.00

198. In response to Noridian's ADR for the submitted claims, Emerging Solutions provided medical records in support of the billed codes. For example,

Emerging Solutions submitted records in support of the HCPCS L8679 and CPT 64555 claim for beneficiary C.L. The medical records in support of the claims utilized Emerging Solutions' templates designed to facilitate payment under HCPCS L8679 and CPT 64555. Each of these claims was subsequently denied by Noridian.

199. Internally, Emerging Solutions recognized that Noridian was no longer paying claims for Drug Relief under HCPCS L8679 and CPT 64555. Emerging Solutions' notes from a December 16, 2020, meeting provide that claims are "[A]t risk in Utah with Medicare. Jayce thinks something has happened. Noridian." Notes from an internal December 18, 2020, meeting reflect Emerging Solutions' view of how different MAC jurisdictions were treating claims for Drug Relief. While certain states, such as Texas, are described as "green" (meaning claims are being paid), others were described as yellow (meaning mixed results) or red (no payments). Emerging Solutions explained that "Utah has put breaks on. red." Despite the pushback, Emerging Solutions was determined to challenge these denials. The notes reflect the company's view that "we have good documentation and will push all the way." Emerging Solutions suggested a "peer to peer" method of challenging denials, noting that it could "be done by Clawson."

200. In March 2021, Clawson sent an email to Emerging Solutions regarding their proposal to continue to appeal the denied Medicare claims. Clawson explained that "we are choosing not to move forward with appeals for the Emerging Solutions device. Research has been done by our billers and it has become clear that billing under the code L8679 was inappropriate, hence the numerous denials and request for further notes."

O. **Representative Example 2: Bratton Healthcare Enterprises**

201. Sheletha Bratton is a Family Nurse Practitioner (NPI 1649642497) and the owner and operator of Bratton Healthcare Enterprises, PLLC (NPI 1467917435), a medical clinic located at 7912 Joshua Tree Ct., Arlington, TX 76002.

202. On or about January 2, 2020, Bratton entered into a Neuro-Stim Services Agreement with Emerging Solutions for the sale of Drug Relief devices and the provision of billing and management services. Bratton ordered her first box of Drug Relief devices from Emerging Solutions on or about February 27, 2020, for $18,550.

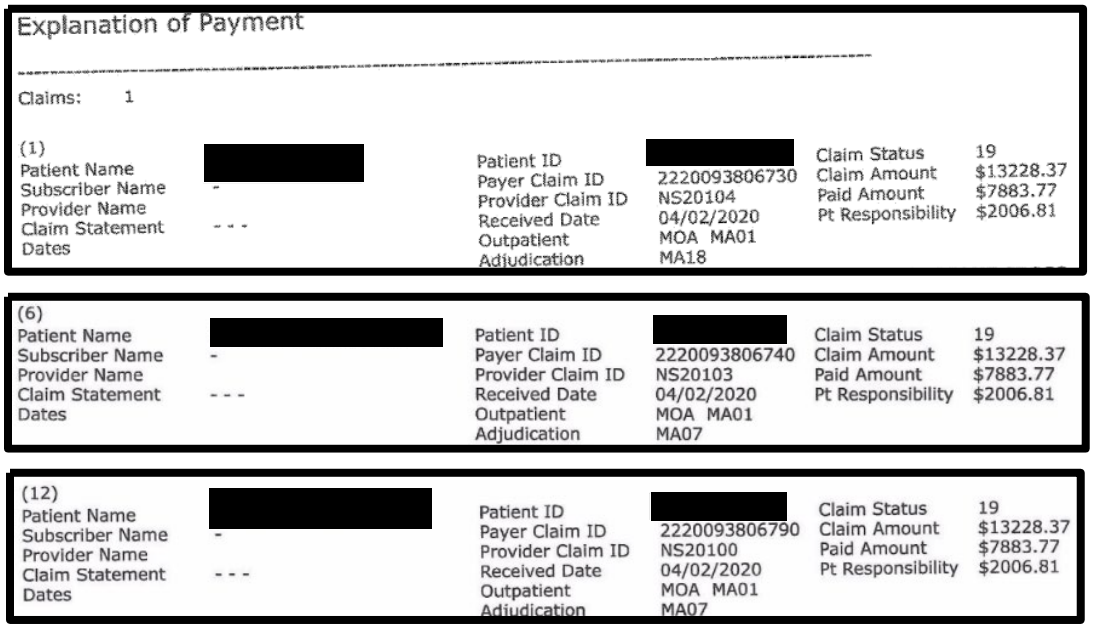
203. In or about March 2020, Bratton completed an enrollment application with Novitas Solutions (MAC responsible for processing Part B claims in Texas) to submit claims electronically as an authorized provider using her NPI (1649642497). By completing the application, Bratton certified, among other things, to submit claims that are accurate, complete, and truthful. Additionally, that by submitting claims under her NPI, Bratton certified that the services were performed as billed.

204. In or about March 2020, Emerging Solutions provided Bratton with billing templates, including "Letter of Medical Necessity for Implantation of Neurostimulator" in support of billing the Drug Relief under HCPCS L8679 for the treatment of patients suffering from "chronic intractable pain," as well as other guidance.

205. In or about March 2020, Emerging Solutions submitted four (4) claims to Medicare seeking reimbursement under HCPCS L8679 and CPT 64555 for Drug Relief treatment provided by Bratton to Medicare beneficiaries.

Patient Name	Insurance	DOS	POS	Reimbursement
S.B.	Medicare	3/10/2020	11	$7,883.77
L.C.	Medicare	3/10/2020	11	$7,883.77
J.S.	Medicare	3/10/2020	11	$7,883.77
J.A.[19]	Medicare	3/11/2020	11	$7,883.77

EOBs provided to Bratton by TX Medicare Part B evidencing reimbursement for Drug Relief for beneficiaries S.B., J.S., J.A. follows:



Explanation of Payment

Claims: 1

(1)
Patient Name [redacted]
Subscriber Name -
Provider Name
Claim Statement Dates - - -
Patient ID [redacted]
Payer Claim ID 2220093806730
Provider Claim ID NS20104
Received Date 04/02/2020
Outpatient MOA MA01
Adjudication MA18
Claim Status 19
Claim Amount $13228.37
Paid Amount $7883.77
Pt Responsibility $2006.81

(6)
Patient Name [redacted]
Subscriber Name -
Provider Name
Claim Statement Dates - - -
Patient ID [redacted]
Payer Claim ID 2220093806740
Provider Claim ID NS20103
Received Date 04/02/2020
Outpatient MOA MA01
Adjudication MA07
Claim Status 19
Claim Amount $13228.37
Paid Amount $7883.77
Pt Responsibility $2006.81

(12)
Patient Name [redacted]
Subscriber Name -
Provider Name
Claim Statement Dates - - -
Patient ID [redacted]
Payer Claim ID 2220093806790
Provider Claim ID NS20100
Received Date 04/02/2020
Outpatient MOA MA01
Adjudication MA07
Claim Status 19
Claim Amount $13228.37
Paid Amount $7883.77
Pt Responsibility $2006.81

In total, Medicare reimbursed Bratton $31,535.08 for the claims.

206. On or about April 18, 2020, Emerging Solutions issued Bratton an invoice for "Medical Claims processing, preauth, research & management fee. Carrier payments received totaling $62,935.00 10% activity fee thru 04/17/2020":

[19] Bratton subsequently billed Medicare for Drug Relief on behalf of the same beneficiary six (6) more times (a total of seven (7) claims) on the following dates: (i) 10/21/2021; (ii) 5/11/2022; (iii) 11/1/2022; (iv) 7/3/2023; (v) 1/13/2024; and (vi) 8/28/2024. In total, Bratton obtained reimbursements from Medicare for HCPCS L8679 and CPT 64555 totaling $60,473.92 for a single beneficiary.

Quantity	Description	Unit Price	Line Total
0	Neurostim Device 10-pack	$ 18,500.00	$ -
0	Neurostim Programming Technical Unit (PTU)	$ 1,799.00	$ -
1	Medical Claims processing, preauth, research & management fee. Carrier payments received totaling $62,935.00 10% activity fee thru 04/17/2020	$ 6,293.50	$ 6,293.50

Under the terms of the billing agreement, Emerging Solutions was entitled to a percentage of collected reimbursements (including Medicare reimbursements) in exchange for providing billing and management services.

207. On or about June 9, 2020, Bratton terminated the billing and management services agreement with Emerging Solutions but continued to purchase and utilize Drug Relief in her medical practice. Although Bratton submitted the claims for Drug Relief to Medicare, she continued to utilize the templates and billing guidance provided by Emerging Solutions.

208. In response to Novitas additional document requests in support of Drug Relief claims, Emerging Solutions provided Bratton with templates to justify the billing of HCPCS L8679 and CPT 64555. This included, for example, Letters of Medical necessity describing the device as an "implanted neurostimulator pulse generator," and a "*Class 2* (LOW TO MODERATE RISK) device specifically for opioid withdrawal and pain relief".

209. After Bratton submitted documents in response to these requests, she recounted her interactions with a "Medicare Rep" in a July 29, 2020, email to Katharine Matangos (Emerging Solutions). Matangos forwarded the email to Emerging Solutions

management and expressed her enthusiasm that Bratton had referred to the device "as a percutaneous neurostimulator" in her notes and was "using the template we provided with the paragraph we suggested providers use."

210. In the periods that followed, Bratton became one of Emerging Solutions' largest customers by volume and consistently ordered boxes of Drug Relief on a recurring basis—as often as one box each week. For example, from June 23 through July 31, 2020, Bratton ordered six (6) boxes of Drug Relief (60 devices total) at a cost of $111,729:

Customer	Invoice Amount	Invoice Date
Bratton Healthcare, PLLC	$18,550.00	6/23/2020
Bratton Healthcare, PLLC	$18,550.00	7/2/2020
Bratton Healthcare, PLLC	$18,550.00	7/8/2020
Bratton Healthcare, PLLC	$18,693.00	7/14/2020
Bratton Healthcare, PLLC	$18,693.00	7/22/2020
Bratton Healthcare, PLLC	$18,693.00	7/31/2020
	Total $111,729	

211. During the same period, Bratton submitted a total of 51 claims to Medicare seeking reimbursement under HCPCS L8679 and CPT 64555 for Drug Relief treatment provided to Medicare beneficiaries.[20]

Patient Name	Insurance	DOS	POS	Reimbursement
D.B.	Medicare	6/25/2020	12	$8,044.66
J.C.	Medicare	6/25/2020	11	$8,044.66

[20] These claims included POS reflecting that the services were rendered in the patient's home (POS 12) as well as in a standard office setting (POS 11).

Patient Name	Insurance	DOS	POS	Reimbursement
B.G.	Medicare	6/25/2020	11	$8,044.66
T.S.	Medicare	6/25/2020	11	$8,079.63
W.G.[21]	Medicare	6/25/2020	11	$8,044.66
L.J.	Medicare	6/25/2020	11/12[22]	$8,044.66
R.S.	Medicare	6/25/2020	11/12[23]	$7,992.91
H.V.	Medicare	6/25/2020	11	$8,044.66
R.B.	Medicare	6/28/2020	11	$7,992.91
D.S.	Medicare	6/28/2020	11	$8,044.66
C.J.	Medicare	7/3/2020	11	$8,044.66
B.B.	Medicare	7/3/2020	11	$8,044.66
V.H.	Medicare	7/3/2020	12	$8,044.66
E.N.[24]	Medicare	7/3/2020	11	$8,044.66
I.O.	Medicare	7/3/2020	11	$8,044.66
J.R.	Medicare	7/3/2020	11	$8,044.66
T.W.	Medicare	7/3/2020	12	$8,044.66
J.R.	Medicare	7/5/2020	11	$8,044.66
C.W.	Medicare	7/5/2020	11	$8,044.66
J.D.	Medicare	7/9/2020	11	$8,044.66
A.D.	Medicare	7/9/2020	11	$8,044.66
M.J.	Medicare	7/9/2020	11	$8,044.66
B.J.	Medicare	7/9/2020	11	$8,044.66
T.L.	Medicare	7/9/2020	11	$8,044.66
M.M.	Medicare	7/9/2020	11	$8,044.66
F.S.	Medicare	7/9/2020	11	$8,044.66
D.K.	Medicare	7/10/2020	11	$8,044.66
J.J.	Medicare	7/10/2020	11	$8,044.66
K.P.[25]	Medicare	7/16/2020	11	$8,044.66

[21] Bratton subsequently billed Medicare for Drug Relief on behalf of the same beneficiary six (6) more times (a total of seven (7) claims) on the following dates: (i) 2/24/2021; (ii) 6/28/2021; (iii) 4/07/2022; (iv) 8/2/2023; (v) 8/23/2023; and (vi) 12/12/2024. In total, Bratton obtained reimbursements from Medicare for HCPCS L8679 and CPT 64555 totaling $57,608.31 for a single beneficiary.

[22] Bratton listed POS 12 for CPT 64555 and POS 11 for HCPCS L8679 for the same DOS.

[23] Bratton listed POS 12 for CPT 64555 and POS 11 for HCPCS L8679 for the same DOS.

[24] Bratton subsequently billed Medicare for Drug Relief on behalf of the same beneficiary seven (7) more times (a total of eight (8) claims) on the following dates: (i) 6/9/2021; (ii) 9/17/2021; (iii) 7/15/2022; (iv) 10/6/2022; (v) 8/2/2023; (vi) 12/3/2023; and (vii) 10/23/2024. In total, Bratton obtained reimbursements from Medicare for HCPCS L8679 and CPT 64555 totaling $69,010.12 for a single beneficiary.

[25] Bratton subsequently billed Medicare for Drug Relief on behalf of the same beneficiary six (6) more times (a total of eight (7) claims) on the following dates: (i) 7/8/2021; (ii) 5/3/2022; (iii) 9/27/2022; (iv)

Patient Name	Insurance	DOS	POS	Reimbursement
L.M.[26]	Medicare	7/16/2020	11	$8,044.66
J.C.	Medicare	7/16/2020	11	$8,044.66
B.R.	Medicare	7/16/2020	11	$8,044.66
J.C.	Medicare	7/16/2020	11	$8,044.66
F.C.	Medicare	7/16/2020	11	$8,044.66
A.M.	Medicare	7/16/2020	11	$8,079.63
A.M.	Medicare	7/16/2020	11	$8,044.66
C.P.	Medicare	7/16/2020	11	$8,044.66
G.R.	Medicare	7/16/2020	11	$8,044.66
T.M.	Medicare	7/28/2020	11	$8,044.66
B.R.	Medicare	7/28/2020	11	$8,044.66
K.B.	Medicare	7/28/2020	11	$8,079.63
P.H.[27]	Medicare	7/28/2020	11	$8,044.66
A.H.	Medicare	7/28/2020	11	$8,079.63
W.M.	Medicare	7/28/2020	11	$8,044.66
D.B.[28]	Medicare	8/6/2020	11	$8,044.66
P.C.	Medicare	8/6/2020	11	$8,044.66
S.F.	Medicare	8/6/2020	11	$8,044.66
J.M.	Medicare	8/6/2020	11	$8,079.63
N.R.	Medicare	8/6/2020	11	$8,044.66
D.S.	Medicare	8/6/2020	11	$8,044.66
F.W.[29]	Medicare	8/6/2020	11	$8,044.66

6/23/2023; (v) 10/17/2023; and (vi) 6/24/2024. In total, Bratton obtained reimbursements from Medicare for HCPCS L8679 and CPT 64555 totaling $60,577.93 for a single beneficiary.

[26] Bratton subsequently billed Medicare for Drug Relief on behalf of the same beneficiary seven (7) more times (a total of eight (8) claims) on the following dates: (i) 7/8/2021; (ii) 5/3/2022; (iii) 9/27/2022; (iv) 6/3/2023; (v) 10/17/2023; (vi) 6/5/2024; and (vii) 12/12/2024. In total, Bratton obtained reimbursements from Medicare for HCPCS L8679 and CPT 64555 totaling $69,675.12 for a single beneficiary.

[27] Bratton subsequently billed Medicare for Drug Relief on behalf of the same beneficiary seven (7) more times (a total of eight (8) claims) on the following dates: (i) 3/31/2021; (ii) 2/30/2021; (iii) 4/1/2022; (iv) 9/16/2022; (v) 5/17/2023; (vi) 10/11/2023; and (vii) 5/20/2024. In total, Bratton obtained reimbursements from Medicare for HCPCS L8679 and CPT 64555 totaling $68,775.51 for a single beneficiary.

[28] Bratton subsequently billed Medicare for Drug Relief on behalf of the same beneficiary seven (7) more times (a total of eight (8) claims) on the following dates: (i) 3/24/2021; (ii) 2/11/2022; (iii) 6/16/2022; (iv) 2/17/2023; (v) 7/24/2023; (vi) 3/25/2024; and (vii) 9/25/2024. In total, Bratton obtained reimbursements from Medicare for HCPCS L8679 and CPT 64555 totaling $69,566.33 for a single beneficiary.

[29] Bratton subsequently billed Medicare for Drug Relief on behalf of the same beneficiary five (5) more times (a total of six (6) claims) on the following dates: (i) 4/7/2021; (ii) 10/21/2021; (iii) 7/6/2022; (iv) 2/17/2023; and (v) 7/10/2023. In total, Bratton obtained reimbursements from Medicare for HCPCS L8679 and CPT 64555 totaling $60,298.31 for a single beneficiary.

Medicare reimbursed Bratton a total of $410,349.01 for these 51 claims under HCPCS L8679 and CPT 64555.

212. From 2020 through 2024, Emerging Solutions submitted or caused to be submitted a total of 499 claims to Medicare seeking reimbursement under HCPCS L8679 and CPT 64555 for Drug Relief treatment provided by Bratton to Medicare beneficiaries. Medicare reimbursed Bratton a total of $4,252,246.10 for these claims.

P. Representative Example 3: Summit Specialists of Pain, PLLC

213. Dr. Whisenant (NPI 1740349836) is an anesthesiologist specializing in pain management and is the sole owner of Summit Specialist of Pain, LLC (NPI 1982806204), a medical clinic located at 8301 Lakeview Pkwy, Rockwall, TX.

214. On or about January 28, 2020, Dr. Stanley Whisenant, on behalf of Summit Specialists of Pain, PLLC, entered into a Neuro-Stimulation Services Agreement with Emerging Solutions for the sale of Drug Relief devices and associated billing and management services.

215. In or about January 2020, Emerging Solutions provided Dr. Whisenant with billing templates, including a "Letter of Medical Necessity for Percutaneous Implantation of Neurostimulator" in support of billing Drug Relief under HCPCS L8679. The prefilled form provided support for the provider's prescription of "L8679 implantable neurostimulator, pulse generator, any type," which would be used to treat the patient's "chronic intractable pain." Additional forms included a "Neurostimulator Requisition / Patient Consent" indicating that multiple Drug Relief treatments may be needed before a patient sees results.

216. On or about February 1, 2020, Dr. Whisenant executed an Electronic Data Interchange (EDI) enrollment application as an authorized provider with MAC Novitas Solutions (MAC responsible for processing Part B claims in Texas) under NPI 1740349836. By signing the EDI application, Dr. Whisenant certified that he would "submit claims that are accurate, complete, and truthful." Additionally, by submitting claims under his NPI, Dr. Whisenant certified that the "services were performed as billed."

217. On or about February 12, 2020, Whisenant ordered a box of 10 Drug Relief devices for $18,550. On or about February 17, 2020, Whisenant ordered a second box of 10 Drug Relief devices for $18,550.

218. In or about February through March 2020, Dr. Whisenant submitted the following claims to Medicare seeking reimbursement for Drug Relief under HCPCS L8679 for which he received payment totaling $79,216.68:

Patient Name	Insurance	DOS	POS	Reimbursement
J.H.	Medicare	2/14/2020	11	$6,601.39
C.R.	Medicare	2/14/2020	11	$6,601.39
D.D.	Medicare	2/14/2020	11	$6,601.39
D.S.	Medicare	2/14/2020	11	$6,601.39
R.G.	Medicare	2/14/2020	11	$6,601.39
J.H.	Medicare	2/21/2020	11	$6,601.39
B.M.	Medicare	2/21/2020	11	$6,601.39
F.C.	Medicare	2/21/2020	11	$6,601.39
J.W.	Medicare	2/21/2020	11	$6,601.39
D.L.	Medicare	2/21/2020	11	$6,601.39
S.B.	Medicare	2/21/2020	11	$6,601.39
R.G.	Medicare	2/28/2020	11	$6,601.39

219. In or about March 2020, Dr. Whisenant submitted the following claims to Medicare seeking reimbursement for Drug Relief under HCPCS L8679 and CPT 64555 for which he received payment totaling $31,750.48:

Patient Name	Insurance	DOS	POS	Reimbursement
E.M	Medicare	3/6/2020	11	$7,937.62
V.M.	Medicare	3/6/2020	11	$7,937.62
E.M.	Medicare	3/13/2020	11	$7,937.62
W.S.	Medicare	3/20/2020	11	$7,937.62

220. On or about April 10, 2020, Emerging Solutions issued Dr. Whisenant an invoice for two boxes of Drug Relief devices ($37,000) and a management and billing services fee of 10% of collected claims ($11,268.40) (which included collected Medicare and private payor claims):

Quantity	Description	Unit Price	Line Total
1	Neurostim Device 10-pack purchased 02/12/2020	$ 18,500.00	$ 18,500.00
1	Neurostim Device 10-pack purchased 02/17/2020	$ 18,500.00	$ 18,500.00
1	Medical Claims processing, preauth, research & management fee. Carrier payments received totaling $112,684.00, 10% activity fee.	$ 11,268.40	$ 11,268.40

221. In connection with the April 10, 2020, invoice, Bingham emailed Dr. Whisenant explaining that Emerging Solutions had provided "your patients with [a] new method to lower or remove chronic [pain]. Your practice benefitted by the additional income of over $112,000, and we expect by this date of over $128,000." Bingham further explained that Emerging Solutions had billed Medicare using HCPCS L8679 for all procedures performed prior to March 1, 2020. Bingham noted that for procedures

performed after March 1, 2020, Emerging Solutions had billed HCPCS L8679 with an additional billing code to follow updated CMS requirements.

222. In total, Medicare provided $110,967.16 in reimbursements to Dr. Whisenant for 16 claims related to Drug Relief under HCPCS L8679 and CPT 64555 submitted by Emerging Solutions.

FIRST CAUSE OF ACTION
False Claims Act, 31 U.S.C. § 3729(a)(1)(A)
Causing and Presenting False Claims

223. The United States realleges and incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

224. As detailed above, Defendants knowingly caused to be presented, materially false and fraudulent claims for payment or approval to the United States, including claims for reimbursement by the Medicare Program. Specifically, Defendants caused the submission of claims to Medicare under HCPCS code L8679 (implantable neurostimulator, pulse generator, any type) and CPT 64555 (percutaneous implantation of a neurostimulator electrode array for a peripheral nerve) resulting in reimbursement to providers despite the fact that the services rendered to patients: (a) did not qualify for HCPCS L8679 because there was no implantation of any device; (b) did not involve surgery or the implantation of a device or a neurostimulator electrode array); and (c) were otherwise not reimbursable at all.

225. These false claims were material to the United States' payment decision. Had the United States known the services provided by Defendants did not qualify for reimbursement, the United States would not have paid the claims.

226. Defendants presented or caused to be presented such claims with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

227. Because of Defendants' acts, the United States sustained damages in an amount to be determined at trial, and, as a result, the United States is entitled to treble damages under the FCA, plus all civil penalties authorized by law. Defendants are jointly and severally liable to the United States for these damages and penalties.

SECOND CAUSE OF ACTION

Violation of False Claims Act, 31 U.S.C. § 3729(a)(1)(B)
Using False Records and Statements Material to False Claims:

228. The United States realleges and incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

229. As detailed above, Defendants Bingham and Emerging Solutions knowingly made, used, or caused to be made or used, false records or statements material to false or fraudulent claims.

230. These false records and statements include, but are not limited to, false certifications and representations on forms CMS 1500 and/or its electronic equivalent, known as the 837P form, to obtain approval for and payment by the United States for false or fraudulent claims.

231. Defendants' false representations were made for the purpose of causing the Medicare Program to pay false or fraudulent claims, which was a reasonable and foreseeable consequence of Defendants' statements and actions.

232. The false certifications and representations caused to be made by Defendants were material to the payment of the false claims by the United States. Had the United States known that the service provided by Defendants' provider customers did not qualify for reimbursement, the United States would not have paid the claims.

233. The false certifications and representations were made with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

234. Because of Defendants' acts, the United States sustained damages in an amount to be determined at trial, and, as a result, the United States is entitled to treble damages under the FCA, plus all civil penalties authorized by law. Defendants are jointly and severally liable to the United States for these damages and penalties.

THIRD CAUSE OF ACTION

Common Law Fraud:

235. The United States realleges and incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

236. During the relevant time period, Defendants presented or caused to be presented, materially false and fraudulent claims for payment or approval to the United States. Specifically, Defendants submitted or caused the submission of claims to Medicare under HCPCS code L8679 (implantable neurostimulator, pulse generator, any type) and CPT 64555 (percutaneous implantation of a neurostimulator electrode array for a peripheral nerve) resulting in reimbursement to providers despite the fact that the services rendered to patients: (a) did not qualify for HCPCS L8679 because there was no

implantation of any device; (b) did not involve surgery or the implantation of a device or a neurostimulator electrode array); and (c) were otherwise not reimbursable at all.

237. Defendants presented these claims with the intent to deceive and induce the United States into paying these claims.

238. The United States relied on the materially false representations made by Defendants and took action in reliance upon the same, including payment of claims to provider customers of Emerging Solutions to which they were not entitled.

239. Because of Defendants' acts, the United States sustained damages in an amount to be determined at trial, and, as a result, the United States is entitled to compensatory damages consisting of the total amount paid as a result of the fraudulent claims, plus interest and other compensatory or punitive damages to be determined at trial.

FOURTH CAUSE OF ACTION

Unjust Enrichment:

240. The United States realleges and incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

241. The United States claims the recovery of all Medicare monies by which Defendants have been directly or indirectly enriched.

242. By retaining monies for the sale of Drug Relief devices and related billing and management services obtained directly or indirectly though Part B services that were not reimbursable, Defendants retained money that was the property of Medicare and to which they were not entitled.

243. As a consequence of the acts set forth above, Defendants were unjustly enriched at the expense of the United States in an amount to be determined at trial and which, under the circumstances, in equity and good conscience, should be returned to the United States.

FIFTH CAUSE OF ACTION

Payment by Mistake of Fact:

244. The United States realleges and incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

245. As a result of the conduct described above, the United States paid Emerging Solutions' provider customers federal funds under the Medicare programs to which they were not entitled. The United States paid providers who followed Defendants' billing directions, either directly or indirectly, for services that did not satisfy the requirements of the Medicare program, without knowledge of material facts, and under the mistaken belief that providers who followed Defendants' billing directions were entitled to receive payment for such claims.

246. The mistaken belief of the United States was material to their decision to pay providers who followed Defendants' billing directions for such claims.

247. The United States reasonably relied on the submission of claims made by providers who followed Defendants' billing directions that the United States believed were accurate, complete, and truthful, in accordance with the express requirements of the Medicare Program.

248. The United States has been damaged as a result of this mistaken payment, and Defendants are thus liable to account and pay to the United States such amounts, which are to be determined at trial.

PRAYER FOR RELIEF AND JURY DEMAND

Accordingly, the United States respectfully request judgment in its favor as follows:

I. As to the First and Second Causes of Action (False Claims Act) against Defendants for statutory damages in an amount to be established at trial, trebled as required by law, and such penalties as required by law;

II. As to the Third Cause of Action (Common Law Fraud) against Defendants for the amounts the United States paid as a result of the fraudulent claims, plus interest and other compensatory or punitive damages to be determined at trial;

III. As to the Fourth and Fifth Causes of Action (Unjust Enrichment and Payment by Mistake) against Defendants for the amounts the United States paid by mistake, plus interest, costs, and expenses, and for all such further relief as may be just and proper;

IV. All costs associated with prosecuting this civil action, as provided by law;

V. Interest on all amounts owed to the United States; and

VI. All other relief the Court deems just and proper, to be determined at trial by jury.

The United States demands a jury trial on all claims alleged herein.

Respectfully submitted this 26th day of December, 2025:

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