THE HEALTH LAW PARTNERS

WHITEPAPER: OVERVIEW OF CPMI'S PROVISION OF PAIN MANAGEMENT SERVICES TO CHRONIC PAIN PATIENTS AND THE DOJ'S WRONGFUL INVESTIGATION AND SETTLEMENT

This Whitepaper addresses the events and circumstances surrounding the Dept. of Justice's ("**DOJ**") investigation into Dr. Margolin's and Comprehensive Pain Management Institute, LLC's ("**CPMI**")[1] provision of medically necessary pain management services to chronic pain patients. While Dr. Margolin/CPMI ultimately agreed to a settlement with the DOJ, the decision was made under duress and Dr. Margolin has adamantly maintained his position that the pain management services provided by CPMI complied with all applicable laws/regulations.

I. BACKGROUND

A. CPMI'S COMPLIANT PAIN PRACTICE

CPMI is a pain management clinic owned by Dr. Margolin with over two decades of experience providing vital pain management services to patients in central Ohio. CPMI has taken proactive steps to ensure that it meets and continues to meet all applicable requirements for the operation of a pain management clinic under federal and Ohio law. Ohio law sets stringent requirements for pain management clinics and physicians that prescribe controlled substances as part of their pain management services.[2] CPMI has met each of these requirements, including the rigorous licensure process to obtain a Category III Terminal Distributor of Dangerous Drugs ("**TDDD**") license,[3] which is required for any practice seeking to possess and/or distribute Schedule I-V controlled substances or other dangerous drugs. Dr. Margolin is a highly specialized physician maintaining double board certification in Physical Medicine and Rehabilitation and Pain Medicine. Dr. Margolin has received numerous awards recognizing his unique and high quality services, compassion, and dedication to his patients and the community, including multiple American Medical Association Physician's Recognition Awards, multiple Certificates of Merit from the American College of Physicians, and multiple Patient's Choice Awards.[4,5] Dr. Margolin has continued to dedicate himself to the treatment of high-risk patients through the opioid epidemic and the COVID-19 pandemic, despite the DOJ's wrongful investigation and settlement increasing the inherent risks of pain management. For example, Dr. Margolin and two of his

[1] Dr. Margolin and CPMI are referred to interchangeably throughout this Whitepaper.

[2] *See* OAC 4731-29-01, attached as **Exhibit A**.

[3] *See* Ohio Rev. Code § 4729.552, attached as **Exhibit B**.

[4] Dr. Margolin has also received several Most Compassionate Physician Awards, a "Top Ten Physicians" Award in Pain Medicine, and multiple America's Most Honored Professionals Awards; *See* Dr. Margolin's CV attached hereto as **Exhibit C**.

[5] *See* Letter from Ohio Top Doctors Magazine acknowledging Dr. Margolin's award as a Top Pain Management Specialist in Columbus, OH, attached as **Exhibit D**; *see also* Google "My Business" Statistics showcasing Dr. Margolin's 4.3/5 star rating on Google, attached as **Exhibit E**.

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female staff were assaulted by a drug-seeking patient that Dr. Margolin was unable to appropriately treat due to the DOJ's investigation and settlement. This continued dedication has resulted in tremendous support from Dr. Margolin's patients and staff, who have submitted letters to the DOJ in support of Dr. Margolin's practice.[6]

Dr. Margolin practices in the highly regulated subfield of pain medicine. Many of CPMI's patients are on long-term opiate therapy due to injury or illness. These patients present a significant risk of addiction, overdose, and death. Moreover, Ohio had one of the highest death rates in the U.S. due to drug overdose in 2017 – 5,111 deaths (46.3% death rate).[7] A patient's risk level is determined by their NARX score (*i.e.*, an analytic score based on the patient's prescriptions, MED, and other data). The higher the NARX score, the higher the patient's risk of substance abuse. The majority of CPMI's patients have a high to extremely high-risk NARX score, meaning they are at extreme risk and must be closely monitored during treatment.[8]

To ensure CPMI operated in accordance with applicable laws, regulations, and payor guidance, Dr. Margolin implemented a comprehensive compliance program in 2011 (the "**Compliance Program**").[9] The Compliance Program required periodic audits of randomly selected patient records to verify: (i) bills were accurately coded; (ii) documentation supported the coding; (iii) documentation was completed appropriately; (iv) the services provided to each patient were reasonable and necessary; and (v) no incentives existed for unnecessary services.[10]

B. SBIRT SERVICES

Screening, Brief Intervention, and Referral to Treatment ("**SBIRT**") services are evidence-based, early interventions that physicians, including Dr. Margolin, use to address the risk of substance abuse, overdose, and death with patients receiving treatment with opioids or other dangerous drugs. SBIRT consists of three primary components:

(1) screenings to assess a patient's risk for substance abuse and to determine the appropriate level of treatment;
(2) brief interventions by engaging the patient in a short conversation to increase their awareness of risky substance use behaviors and to provide feedback, motivation, and advice; and
(3) referral for additional treatment or services when necessary.[11, 12]

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[6] *See* CPMI staff letters and a CPMI patient letter (representing approximately 100 patients) in support of Dr. Margolin and CPMI, attached as **Exhibit F**.

[7] *See* CDC, *Drug Overdose Mortality by State*, National Center for Health Statistics (available at https://www.cdc.gov/nchs/pressroom/sosmap/drug_poisoning_mortality/drug_poisoning.htm), attached as **Exhibit G**.

[8] *See* Margolin L., *et al.*, *Impact of Screening and Brief Intervention (SBIRT), Urinary Drug Testing, Minimally Invasive Procedures, and Electromyography on Pain Reduction, Functional Improvement, and Continuity of Care in Chronic Pain Patients*, Journal of Diabetes and Treatment, Vol. 5, Issue 1, p. 2 (July 14, 2020), attached as **Exhibit H.**

[9] *See* CPMI, Compliance Program Manual, attached as **Exhibit I.**

[10] *Id* at 7-8.

[11] *See* CMS, *SBIRT Services*, Medicare Learning Network MLN 904084 (Jan. 2022) (available at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/SBIRT_Factsheet_ICN904084.pdf), attached as **Exhibit J**.

[12] SBIRT services are commonly billed for with HCPCS G Codes G2011, G0396, G0397, G2086, G 2087, and G2088, depending on the duration and type of service provided. *See* **Exhibit H**, p. 9.

The benefits of SBIRT services include reduced health care costs, decreased drug and alcohol use severity, reduced physical trauma risk, and reduced need for specialized treatment. By utilizing SBIRT services, pain management specialists are able to avoid the inappropriate prescription of opioids, which often lead to overdose, diversion, and/or drug-seeking habits.[13]

SBIRT services are mandatory in Ohio for a pain management clinic screening a patient population with high-risk of substance abuse or overdose.[14] There are certain requirements applicable to SBIRT services under state law, Centers for Medicare & Medicaid Services' ("**CMS**") policies, and other guidance.

Below is an overview of the various requirements applicable to the provision of SBIRT and CPMI's compliance efforts associated with providing SBIRT services to chronic pain patients.

1. Ohio Law Requires Frequent SBIRT Services

Ohio law imposes rigorous care-related requirements on pain specialists (like Dr. Margolin) that prescribe controlled substances, including the requirement to continuously monitor their patients utilizing high levels of opioids due to the heightened risk of addiction, substance abuse, and overdose with opioids.[15] A physician that prescribes an opioid analgesic for subacute or chronic pain is required to complete and document an assessment with the patient to determine the appropriateness and safety of the medication prior to its prescription.[16] ***Appropriate and required monitoring includes assessments and discussions with the patient regarding the benefits and risks of their medication treatment plan***.[17] The physician is also required to discuss the patient's responsibility to appropriately store and dispose of the prescribed opioids.[18] This creates a requirement for an SBIRT screening and intervention with the patient to ensure they understand the risk of opioid treatment and adhere to an appropriate treatment plan.

SBIRT assessments are also required whenever a patient is on a continuous course of treatment with opioids at or above 50 morphine equivalent daily dose ("**MED**").[19] In such circumstance, the physician must continuously review the patient's response/adherence to the treatment and screen the patient for opioid misuse.[20] ***Such screenings must occur no less than once every three months***.[21] Ohio law does not set a minimum period of time between patient screenings. Frequency of screenings is a clinical decision of the treating physician.

Importantly, Ohio law acknowledges the value placed on a pain specialist's clinical judgment. The law requires physicians who are not board-certified in pain medicine to consult a pain management specialist (or other appropriately trained addiction medicine specialist) prior to

[13] *See* **Exhibit I**, p. 3.

[14] *See* **Exhibit I**, p. 1.

[15] *See* OAC 4731-11-14, attached as **Exhibit K**.

[16] *See* **Exhibit K** (OAC 4731-11-14(B)).

[17] *See* **Exhibit K** (OAC 4731-11-14(B)(6)(a)).

[18] *See* **Exhibit K** (OAC 4731-11-14(B)(6)(b)).

[19] *See* **Exhibit K** (OAC 4731-11-14(G)).

[20] *See* **Exhibit K** (OAC § 47311-11-14(G)(6)).

[21] *See* **Exhibit K** (OAC § 47311-11-14(G)).

prescribing a patient an average opioid dose of 80 MED or greater.[22] Moreover, only certified pain specialists (or specialists in hospice and palliative care, hematology, or oncology) are permitted to prescribe opioid dosages in excess of an average opioid dose of 120 MED.[23]

Given CPMI's patient population, to comply with these, and other requirements, CPMI developed a policy and practice for its high-risk chronic pain patients to receive SBIRT services. Had Dr. Margolin failed to conduct appropriate SBIRT services for his high-risk chronic pain patients, among other sanctions, his license could have been subject to reprimand, probation, suspension, or even permanent revocation. [24]

II. PAIN MEDICINE EXPERTS AND STATE GUIDANCE SUPPORT FREQUENT SBIRT SERVICES

The medical necessity of SBIRT services for the treatment of chronic pain patients is well established by expert research and studies. Dr. Margolin, several CPMI physicians, and the Chief of Psychiatry/Medical Director of the Alcohol and Drug Recovery Center at the Cleveland Clinic Foundation published a peer-reviewed article demonstrating the medical necessity of frequent SBIRT services to treat chronic pain patients.[25] The article reviewed fifty (50) high-risk CPMI chronic pain patients, seventy-four (74%) percent of which had high-extremely high NARX scores ranging from 100-350+.[26] Patients within these ranges of high-risk NARX scores are 10-12 times more likely to overdose on opioids than the average patient.[27] As noted in the article, ***high-risk patients need more frequent SBIRT services due to the heightened risk of over-prescription, overdose, and/or diversion***.[28]

The medical necessity of frequent SBIRT services for the treatment of chronic pain patients is further supported by the Ohio Automated RX Reporting System User Support Manual (the "**OARRS Manual**"). The OARRS Manual states that ***NARX scores should be utilized in daily workflow to trigger a discussion with the patient regarding any concerns about their prescription drug use***.[29] Dr. Margolin's utilization of SBIRT services complied with the OARRS Manual. The OARRS Manual includes specific treatment recommendations for certain ranges of NARX scores.[30] In fact, the OARRS Manual specifies that physicians should conduct regular consultations and assessments (*i.e.*, SBIRT services) for patients with NARX scores as low as 10.[31] High-risk NARX patients would certainly require more frequent SBIRT services.

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[22] *See* **Exhibit K** OAC § 47311-11-14(D)(3)).

[23] *See* **Exhibit K** (OAC § 4731-11-14(E)).

[24] *See* State Medical Board of Ohio, *Disciplinary Guidelines*, Cat. 1: Improper Prescribing, Dispensing, or Administering of Drugs, p. 3 (July 2019) (available at: https://www.med.ohio.gov/Portals/0/Regulation/Disciplinary%20Guidelines%20rev.%2007-2019.Final.pdf?ver=0A5Y-4G4x8uUJliB7lRoyA%3d%3d), attached as **Exhibit L**.

[25] *See* **Exhibit H**.

[26] *Id* at 4 (Sixteen (16%) percent of the patients had high NARX scores (*i.e.*, NARX 100-189), thirty-four (34%) percent of the patients had very high NARX scores (*i.e.*, NARX above 200), and twenty-four (24%) percent of the patients had extremely high NARX scores (*i.e.*, NARX above 350)).

[27] *Id*.

[28] *Id* at 3-4.

[29] *See* Ohio Bd of Pharmacy, *Ohio Automated RX Reporting System PDMP Aware User Support Manual*, p. 60 (available at https://www.ohiopmp.gov/Documents/OARRS%20User%20Manual.pdf), attached as **Exhibit M**.

[30] *Id* at 61-62.

[31] *Id*.

CPMI's SBIRT policy, practice, and procedures comply with these requirements by ensuring patients receive the appropriate level of services based on their NARX risk level. High-risk patients receive more SBIRT services than low-risk patients, in order to address the increased risk of opioid misuse, diversion, and overdose.

III. HHS/CMS Guidance Acknowledges the Medical Necessity of Frequent SBIRT Services

CMS issued guidance acknowledging that physicians treating high-risk patients requiring specialized treatment may require frequent SBIRT services.[32] The guidance provides a generalized approach for the provision of SBIRT services to low-risk patients. CMS acknowledges that the generalized approach is not sufficient for high-risk patients.[33]

CMS' guidance specifies that certain SBIRT services (*i.e.*, counseling services, substance use disorder screenings, and a review of the beneficiary's opioid prescriptions) should be billed using HCPCS Codes G0396 or G0397.[34] During the period of the DOJ's investigation, Dr. Margolin billed for SBIRT services using HCPCS G0396 or G0397, consistent with CMS' guidance. Further, ***CMS' guidance does not specify any limitations as to how often HCPCS Codes G0396 or G0397 may be used to bill for SBIRT services***.[35] This is distinguishable from several other SBIRT codes (*e.g.*, HCPCS G2086-2088) which are limited to being used once per month per patient.[36]

The guidance also specifies personnel[37] and documentation[38] requirements for SBIRT services. CPMI provided SBIRT services through physicians and nurse practitioners, as permitted under CMS guidance. Further, Dr. Margolin/CPMI complied with the documentation requirements by maintaining detailed documentation of each SBIRT service provided to a CPMI patient, including the rationale for such service.[39]

Further, the Dept. of Health and Human Services ("**HHS**") issued guidance in 2017 regarding its strategy to combat the opioid epidemic.[40] HHS' guidance set forth a five-point strategy to address opioid abuse, misuse, and overdose. One of HHS' five key points was improved pain management, which requires evidence-based pain care management that relies on data and non-opioid treatments.[41] HHS' goal is to taper patients' dependence on opioids and to

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[32] *See* **Exhibit H**.

[33] *See* **Exhibit H**.

[34] *Id*.

[35] *See* **Exhibit H**, at p. 8.

[36] *Id* at 9.

[37] CMS' guidance specifies that physicians (*i.e.*, MDs and DOs), physician assistants, nurse practitioners, clinical nurse specialists, clinical psychologists, clinical social workers, certified nurse-midwives, and independently practicing psychologists with appropriate qualifications are eligible to provide SBIRT services. *See* **Exhibit J**, at p.6-7.

[38] Documentation requirements include: (i) complete and legible records; (ii) recording of start/stop times or total face-to-face time with a patient; (iii) documentation of patient's progress, response to treatment changes, and diagnosis revisions; (iv) documentation of the rationale for any diagnostic or other ancillary services; (v) documentation of the assessment/clinical impression/diagnosis, date, provider identity, physical exam findings, plan of care, and encounter reason with relevant history; (vi) identification of appropriate health risk factors; (vii) documentation of past and present diagnoses made accessible to treating and consulting physicians; and (viii) signatures for all services provided/ordered. *See* **Exhibit J**, at p. 7.

[39] *See* CPMI, Policy for the Retention of Medical Records, attached as **Exhibit N.**

[40] *See*, HHS, *Strategy to Combat Opioid Abuse, Misuse, and Overdose: A Framework Based on the Five Point Strategy* (2017), attached as **Exhibit O.**

[41] *Id* at 6-7.

ensure patients and their families/caregivers are appropriately educated on appropriate pain management.[42] CPMI's SBIRT policy falls within the spirit of HHS' guidance.

As CPMI's patients are high-risk patients requiring specialized pain management treatment consisting of high doses of opioids, SBIRT services are necessary to ensure compliance with proper opioid medication use, which is consistent with HHS guidance, Medicare guidance, and appropriate care.

IV. CPMI AUDITS OF SBIRT SERVICES

To ensure good faith compliance with applicable laws, regulations, and guidelines, CPMI engaged a number of experts (*e.g.*, regulatory attorneys, billing/coding experts, healthcare policy experts, and medical experts.)[43] These experts conducted audits, reviewed patient records, and reviewed CPMI's SBIRT policy and operations. The experts determined that CPMI was in full compliance with applicable laws, regulations, and guidelines:

- March 2014 – PracticePro[44] was engaged to provide guidance on whether physicians and nurse practitioners could perform/bill for SBIRT services using HCPCS G0396/G0397.
  - ✓ PracticePro confirmed that nurse practitioners and physicians could perform/bill for SBIRT services using HCPCS G 0396 and G0397.[45]
- Early 2015 – PracticePro was engaged to review CPMI's SBIRT policy and approximately 2,000 CPMI claims for compliance with applicable laws, regulations, and guidance.
  - ✓ PracticePro determined CPMI's SBIRT policy complied with applicable laws/regulations/guidance[46] and that the SBIRT services were appropriately billed.[47]
- October 2019 – Michael Staples (former Ohio Medical Board Investigator and Director of Compliance for Cincinnati Pain Physicians) was engaged to review/audit CPMI's SBIRT policy and CPMI patient records for compliance with applicable laws, regulations, and guidance.[48]
  - ✓ Mr. Staples determined CPMI's SBIRT policy was "very thorough, efficient, and compliant" with applicable laws/regulations/guidance[49] and that the SBIRT services were appropriately provided and billed.[50]
- October 2020 – Tina Leslie, Certified Professional Medical Auditor ("**CPMA**")[51] was engaged to review/audit CPMI's SBIRT policy and patient records (including patient records subject to the DOJ's investigation) for compliance with applicable laws, regulations, and guidance.

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[42] *Id.*

[43] *See* **Exhibit I.**

[44] Medical billing/coding and compliance experts.

[45] *See* E-Mail from PracticePro Billing Manager David Deppen, attached as **Exhibit P**.

[46] *See* PracticePro Letter to CareSource re CareSource's Audit of CPMI patient records, attached as **Exhibit Q**.

[47] *Id.*

[48] *See* Michael Staples, Audit and Compliance Report re Dr. Margolin and CPMI, p. 1 (Oct. 14, 2019), attached as **Exhibit R**.

[49] *Id* at 2.

[50] *Id* at 2-3.

[51] Certified by the American Academy of Professional Coders.

- ✓ The CPMA determined CPMI's SBIRT policy complied with applicable laws/regulations/guidance,[52] that each patient record supported the medical necessity of the SBIRT services, and such services were appropriately billed.[53]

- October 2020 – William Vasilakis, Psy.D (Clinical psychologist specializing in addiction and pain management at Hocking Valley Community Hospital and former Clinical Director of the Drug & Alcohol Recovery Center of Fairfield County)[54] was engaged to review CPMI's SBIRT policy and approximately fifty (50) patient charts for compliance with applicable laws, regulations, and guidance.
  - ✓ Dr. Vasilakis determined CPMI's SBIRT policy complied with applicable laws/regulations/guidance[55] and the patient charts supported the medical necessity of the SBIRT services.
  - ✓ Upon reviewing the patient charts (including many of the patients included in the DOJ investigation) Dr. Vasilakis determined SBIRT services were medically necessary and endorsed CPMI's SBIRT program as "one of the best" in Ohio.
  - ✓ Dr. Vasilakis cautioned against the use of EMG for CPMI's patient population (most of which have comorbidities, such as: aggressive/manipulative behavior, anxiety, and depression). CPMI's use of written consent for the needle part of the EMG (which CPMI sought for each patient per AANEM and CMS guidelines) is crucial for CPMI's patient population and consistent with expert guidance.

CPMI engaged multiple medical and billing/coding experts to review/audit CPMI's SBIRT policy, practice, and procedures. Each expert's review/audit determinations supported Dr. Margolin's/CPMI's use and billing of SBIRT services in the treatment of chronic pain patients.

c. NCS Services

As part of CPMI's/Dr. Margolin's practice, CPMI also performs medically necessary Nerve Conductive Studies ("**NCS**") to help assess and document the patient's organic pathology (*i.e.*, neuropathy) to support clinical complaints of neuropathic pain for proper prescribing of opioid medications and other treatment. NCS are a type of electrodiagnostic study ("**EDS**"), which provides valuable, quantitative information on the physiologic health and functioning of nerves and muscles.[56] EDS (including NCS) assist pain specialists to localize injuries, quantify the extent of the injury, determine injury age.[57] Moreover, NCS provides valuable prognostic information to update chronic pain patients' treatment protocols.[58] NCS are essential to identifying and treating pain conditions.[59] NCS utilize electrical impulses through a patient's nerves to determine nerve damage and causes of pain. As pain conditions change over time, CPMI must re-test its chronic pain patients to update their treatment plans. NCS may utilize either

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[52] *See* Tina Leslie, CPMC, Audit Report of CPMI, p. 2, attached as **Exhibit S**.

[53] *Id* at 3.

[54] *See* Dr. Vasilakis' CV, attached as **Exhibit T.**

[55] *See* Letter from Dr. Vasilakis re his review of CPMI patients and SBIRT program, attached as **Exhibit U**.

[56] *See* Douglas Chang and Elaine Date, *Bonica's Management of Pain*, Chapter 18: Electrodiagnostic Evaluation of Acute and Chronic Pain Syndromes, 5th Edition (Nov. 2018), attached as **Exhibit V.**

[57] *Id*.

[58] *Id*.

[59] *Id*.

surface or needle electrodes to stimulate the patient's nerves. While it is not required in the subspecialty of pain medicine, NCS may be utilized in conjunction with needle electromyography ("**EMG**"). EMG is an invasive test that requires up to twelve (12) needle electrodes to be inserted into the patient to capture auditory and visual feedback.[60] A physician interprets the feedback in real-time to determine the integrity of nerves and muscles.[61] Informed consent is required per state[62] and federal law,[63] American Academy of Neuromuscular & Electrodiagnostic Medicine ("**AANEM**") guidelines, and CMS guidelines.[64] AANEM issued guidelines specifically for the ethical use of electrodiagnostic medicine (*e.g.*, NCS), which requires physicians to obtain verbal or written consent prior to performing any electrodiagnostic clinical evaluations (*e.g.*, NCS or EMG).[65]

Below is an overview of the various requirements applicable to the provision of NCS and CPMI's compliance efforts associated with providing NCS to chronic pain patients.

1. *Pain Medicine Experts Support the Medical Necessity of NCS without EMG*

The use of NCS without EMG to assess a chronic pain patient's level and cause of pain is the standard of care for pain medicine. In fact, Dr. Margolin performed a detailed study through the American Board of Physical Medicine and Rehabilitation ("**ABPMR**") confirming the medical necessity of NCS without EMG in the interventional pain medicine setting. The ABPMR study was reviewed and verified by two separate pain medicine experts.[66] ***Each expert determined the study was well developed and supported Dr. Margolin's study and determinations regarding NCS***.[67]

NCS without EMG is considered medically necessary in the subfield of pain medicine to assist pain specialists in determining the appropriate choice of medications and treatment for chronic pain patients. Dr. Margolin's patients generally exhibit a poor tolerance to the needle portions of NCS/EMG testing – Dr. Margolin performed the EMG on patients who consented to the test as per AANEM, CMS, and federal/state requirements.[68] However, many patients refuse the EMG portion of the test because of the invasive needle aspect of EMG.[69] Consequently,

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[60] See CMS, Local Coverage Determination: Nerve Conduction Studies and Electromyography, L35897 (available at https://localcoverage.cms.gov/mcd_archive/view/lcd.aspx?lcdInfo=35897:24), attached as **Exhibit W**.

[61] *Id.*

[62] *See* ORC § 2317.54, attached as **Exhibit X.**

[63] *See Guertin v. State*, 912 F.3d 907, 920 (6th Cir. 2019) ("informed consent is generally required for medical treatment…a competent individual [has the right] to refuse medical treatment"), attached as **Exhibit Y.**

[64] *See* CMS, National Coverage Determination: Wrong Surgical or Other Invasive Procedure Performed on a Patient (Jan. 15, 2009)(Medicare requires appropriately documented informed consent for surgical and invasive procedures (*e.g.*, NCS or EMG)), attached as **Exhibit Z.**

[65] *See* AANEM, *Guidelines for Ethical Behavior Relating to Clinical Practice Issues in Neuromuscular and Electrodiagnostic Medicine*, p. 2, attached as **Exhibit AA**.

[66] *See* Letter from Jim Kimura, MD validating Dr. Margolin's ABPMR study (Sept. 28, 2018), attached as **Exhibit BB**; *see also* Letter from Stanley F. Wainapel, MD, MPH validating Dr. Margolin's ABPMR study (Sept. 14, 2018), attached as **Exhibit CC**; *see also* Letter from William Vasilakis, Psy.D. validating Dr. Margolin's ABPMR study (May 16, 2019) and Addendum to Letter (Oct. 10, 2019), attached as **Exhibit DD**.

[67] *Id.*

[68] *See* **Exhibit H**, p. 3.

[69] *Id.*

during the period of the DOJ's investigation, Dr. Margolin typically performed the non-invasive NCS surface electrode method to assess chronic pain patients.

Dr. Margolin published a peer-reviewed journal article demonstrating the medical necessity and appropriateness of pain specialists utilizing NCS with or without EMG.[70] As noted in the article, ***both national and state guidelines require pain specialists to document the organic pathology as part of a comprehensive evaluation in a pain management clinic***.[71] ***At a minimum, such an assessment requires NCS without EMG to assist the pain specialist in determining the root cause of the patient's pain***.[72] In short, NCS without EMG is essential to developing an appropriate pain management treatment plan. NCS without EMG can also be essential to ensure patients adhere to their treatment plan, as it can decrease the likelihood of street drug use.[73]

Further, the credentialing boards for interventional pain medicine (*i.e.*, the ABPMR, the American Society of Interventional Pain Physicians, or the American Board of Interventional Pain Physicians) support the use of NCS services without EMG. It is well understood amongst pain medicine experts that NCS without EMG is medically necessary and well within the standard of care for the subfield.[74]

CPMI utilized NCS without EMG to develop an appropriate treatment plan and to monitor the patient's pain levels in compliance with the applicable standard of care.

II. CMS GUIDANCE ACKNOWLEDGES THE MEDICAL NECESSITY OF NCS WITHOUT EMG

CMS issued a local coverage determination for Nerve Conduction Studies and Electromyography (the "**LCD**").[75] The LCD states that NCS and EMG are ***usually*** required for a clinical diagnosis of peripheral nervous system disorders.[76] CMS does not state that EMG and NCS must ***always*** be performed in conjunction. Further, the LCD specifies that "***[t]he intensity and extent of testing with EMG and NCS is a matter of clinical judgment***" **for the** ***treating physician***.[77] The LCD language clearly gives deference to the physician's clinical judgment to determine whether, and to what extent, NCS and/or EMG are necessary to be performed on a patient-by-patient basis.

While assessing a chronic pain patient's injury/ailment, NCS is not required to be performed in conjunction with EMG. Pain medicine is a subspecialty of medicine that focuses on the diagnosis and treatment of a patient's chronic pain syndrome, including acute or chronic pain or pain related to cancer,[78] and not lesion localization or surgical assessment like other subfields of medicine (*e.g.*, neurology or neurosurgery).

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[70] *See* **Exhibit H**.

[71] *Id* at 3.

[72] *Id*.

[73] *See* **Exhibit AA**, p. 2.

[74] *See* **Exhibits H**, **BB**, **CC**, and **DD**.

[75] *See* **Exhibit W**.

[76] *Id at 4*.

[77] *Id*.

[78] *See* American Board of Medical Specialties' list of subspecialties for Physical Medicine and Rehabilitation (available at https://www.abms.org/board/american-board-of-physical-medicine-rehabilitation/#abpmr-pm), attached as **Exhibit EE**.

Notably, the LCD also provides an exception for when NCS may be performed without EMG. The LCD provides that NCS may be performed without EMG when the patient is being assessed for carpal tunnel syndrome.[79] As part of its practice, CPMI often utilizes NCS to assess patients for carpal tunnel syndrome. For such services, the use of NCS without EMG clearly complies with the LCD.

Dr. Margolin ordered NCS after conducting a full patient assessment, which was documented in the patient record. Dr. Margolin assessed the patient to determine if NCS with or without EMG was medically necessary to develop a treatment plan. ***Dr. Margolin would order and perform NCS without EMG after making the clinical determination that such service was medically necessary.***

III. CPMI's Proactive Audits to Ensure Compliance with Applicable NCS Requirements

Similar to his proactive compliance approach with SBIRT services, Dr. Margolin engaged numerous experts to review CPMI's NCS policy, practice, and operations. The experts determined that CPMI's NCS policy, practice, and operations were in full compliance with applicable laws, regulations, and guidelines:

- October 2012 – PracticePro was engaged to audit CPMI's NCS policy and patient charts for compliance with applicable laws, regulations, and guidance.[80]
  - ✓ PracticePro determined NCS policy complied with applicable laws/regulations/guidance[81] and that the patient charts complied with applicable medical necessity and billing/coding standards.[82]
- November 2013 – PracticePro was engaged to provide guidance regarding the frequency of which NCS could be appropriately billed.[83]
  - ✓ PracticePro provided guidance specifying the frequency limitations for certain NCS tests (*e.g.*, carpal tunnel, radiculopathy, mononeuropathy, etc.)[84] and that any tests performed beyond the referenced frequency limitations must be justified by sufficient documentation.[85]
- November 2013 – MaryAnn Baughman, Certified Professional Coder ("**CPC**") was engaged to review CPMI's NCS policy and patient charts for compliance with applicable laws, regulations, and guidance.[86]
  - ✓ The CPC determined CPMI's NCS policy complied with applicable laws/regulations/guidance and the patient charts complied with applicable medical necessity and billing/coding standards.[87]

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[79] *See* **Exhibit W**, p. 7.

[80] *See* PracticePro Compliance and Chart Review re NCS Policy (Oct. 2012), attached as **Exhibit FF.**

[81] *Id.*

[82] *Id.*

[83] *See* PracticePro e-mail re NCS frequency limitations, attached as **Exhibit GG**.

[84] *Id.*

[85] *Id.*

[86] *See* Mary Ann Baughman E-Mail re Review of CPMI, attached as **Exhibit HH**.

[87] *Id.*

- March 2015 – PracticePro to review CPMI's NCS policy and approximately 2,000 claims for compliance with applicable laws, regulations, and guidance.
  - ✓ PracticePro determined CPMI's NCS policy complied with applicable laws/regulations/guidance[88] and the patient claims complied with applicable billing/coding standards.[89]
- October 2019 – Michael Staples was engaged to review/audit CPMI's NCS policy and patient records for compliance with applicable laws, regulations, and guidance.[90]
  - ✓ Mr. Staples determined CPMI's NCS policy complied with applicable laws/regulations/guidance [91] and the patient records supported the medical necessity of the NCS services provided to each patient.[92]
- October 2020 – Tina Leslie, CPMA was engaged to review/audit CPMI's NCS policy and patient records (including patient records subject to the DOJ's investigation) for compliance with applicable laws, regulations, and guidance.
  - ✓ The CPMA determined CPMI's NCS policy complied with applicable laws/regulations/guidance,[93] the patient records supported the medical necessity of NCS services, and the NCS services were appropriately billed.[94]

CPMI engaged multiple medical and billing/coding experts to review/audit CPMI's NCS policy, practice, and procedures. Each expert's review/audit determinations supported Dr. Margolin's/CPMI's use and billing of NCS in the treatment of chronic pain patients.

II. DOJ'S WRONGFUL INVESTIGATION AND SETTLEMENT

A. *CareSource Audit*

In 2016, CareSource (an Ohio-based Medicaid/Medicare Advantage organization) initiated an audit of CPMI's use of NCS without EMG. CareSource's audit was based on a statistical sample of thirty (30) CPMI patients. CareSource took the position that NCS provided without EMG were not medically necessary. CareSource took this position without appropriately considering that pain medicine is a specialized subfield, in which NCS without EMG is considered medically necessary. Upon completing its audit, CareSource extrapolated its findings to apply to CPMI's entire patient population. In November 2017, without any prior notice, CareSource began recouping for NCS services billed by CPMI.[95] To date, CareSource has recouped more than $75k from CPMI for NCS-related billings.[96] In March 2018, Dr. Margolin notified CareSource that CPMI would be filing an appeal to the 2017 audit and recoupment regarding NCS.[97] CPMI submitted its appeal in compliance with CareSource's requirements,[98] yet CareSource failed to respond to the appeal for over four (4) years. Notably, in June 2016,

[88] *See* **Exhibit Q**.

[89] *Id*.

[90] *See* **Exhibit R**, p. 1.

[91] *Id* at 2.

[92] *Id*.

[93] *See* **Exhibit S**, p.3.

[94] *Id* at 2.

[95] E-Mail from Dr. Margolin to CareSource re recoupments without any prior notice, attached as **Exhibit II.**

[96] *See* **Exhibit II**.

[97] *Id*.

[98] *See* Dr. Margolin Appeal E-Mail to CareSource, attached as **Exhibit JJ**.

CareSource initiated a similar recoupment without notice.[99] CareSource recouped approximately $40k in 2016 for services and supplies CPMI provided to its patients. However, CareSource's 2016 recoupment was later determined to be inappropriate and CareSource was required to refund the money it recouped.[100]

The CareSource audit failed to consider that ***eleven (11) of the thirty (30) patients reviewed (i.e., more than 1/3 of the audit sample) were being evaluated by Dr. Margolin for carpal tunnel syndrome. Notably, the LCD explicitly provides that NCS without EMG is appropriate for the diagnosis of carpal tunnel syndrome***.[101] CareSource acknowledged the carpal tunnel exception to EMG, as well as an exception for patients on anti-coagulation therapy.[102] Twelve (12) of the patients included in CareSource's audit sample were on anticoagulation therapy. However, CareSource failed to appropriately apply the exceptions in its investigation. As such, CareSource's determination that NCS without EMG was medically unnecessary for those patients on anticoagulation therapy or being evaluated for carpal tunnel syndrome was wholly unsupported.

As part of its audit, CareSource wrongly used a statistical sample that did not comply with Medicare/Medicaid requirements. CPMI engaged a third-party expert statistician to review the CareSource audit's statistical sample.[103] ***The statistician determined the statistical sample failed to meet generally accepted principles and practices for audits, as set forth in the Medicare Provider Integrity Manual*** ("**MPIM**").[104] The MPIM requirements for statistical samples reflect the general requirements for statistical samples amongst the statistical community.[105] ***Only statistical samples meeting the MPIM requirements may be extrapolated to a larger patient population***.[106] ***The statistician determined the statistical sample did not comply with MPIM standards for randomness and statistical significance, rendering any audit determinations erroneous***.[107] As previously noted, PracticePro was also engaged to review approximately 2,000 claims in response to the CareSource audit. PracticePro confirmed that CPMI appropriately provided and billed its NCS services. Moreover, Practicepro found that the CareSource audit determinations were not supported by the patient records. [108]

CareSource's audit determinations conflicts with its prior reviews of CPMI. In May 2015, CareSource sent an investigator to review CPMI's practice, policies, and patient interactions. Notably, the CareSource investigator stated that she was impressed with CPMI's practice and everything that Dr. Margolin did to care for his patients. [109] ***In fact, the CareSource investigator***

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[99] *Id.*

[100] *See* CareSource E-Mail re Repayment of Improper 2016 Recoupments (Aug. 23, 2016), attached as **Exhibit KK.**

[101] *See* **Exhibit W**, p. 7.

[102] *See* CareSource E-Mail re Exceptions to EMG (Sep. 19, 2017), attached as **Exhibit LL.**

[103] *See* Frank D. Cohen, *Supplemental Statistical Report in Support of Leon Margolin, M.D. and Comprehensive Pain Management Institute, LLC: Challenge to the CareSource Extrapolation Analysis*, DoctorsManagement, LLC (July 11, 2017), attached as **Exhibit MM**.

[104] *Id* at 2; *See also* MPIM §§ 8.4.1.3 and 8.4.1.5, attached as **Exhibit NN.**

[105] *See* **Exhibit MM** at 3.

[106] *Id.*

[107] The statistician determined that CareSource: (i) used incorrect data to determine the audit sample size; (ii) failed to engage a statistician to review/approve the audit design and analysis; (iii) included data that should have been excluded from the audit; and (iv) inappropriately extrapolated audit data to apply to all of CPMI's patients. *Id* at 5-6.

[108] *See* **Exhibit Q**.

[109] *See* E-Mail from Lora Hayes to Dr. Margolin (dated May 7, 2015), attached as **Exhibit OO**.

was so impressed with Dr. Margolin/CPMI that she directed referrals for pain management services from other CareSource-enrolled providers to CPMI.[110]

Notably, prior to this audit, CPMI filed a number of business integrity complaints against CareSource,[111] including complaints regarding its quality of care, habitual neglect, and continuous failure to perform its obligated duties. CPMI believed CareSource's policies endangered thousands of its members by placing them at increased risks of morbidity and mortality. At the time CPMI issued these complaints, CareSource was subject to a five (5) year Corporate Integrity Agreement ("**CIA**") with the OIG due to a settlement agreement for false claims allegations.[112] CareSource allegedly submitted false data to the state of Ohio to receive certain incentives from Ohio Medicaid.[113] The DOJ determinations mirror many of the complaints filed by Dr. Margolin/CPMI (CareSource (*e.g.*, complaints regarding neglect and failure to perform obligated duties). Dr. Margolin and CPMI filed these complaints out of concern for their patients. Dr. Margolin believes the business integrity complaints filed against CareSource (which was still subject to the CIA at the time) led to CareSource's actions against him.[114]

Currently, CareSource is inappropriately stalling Dr. Margolin's credentialing process. Dr. Margolin submitted all the necessary documentation for the credentialing process to CareSource in July 2021.[115] Dr. Margolin has reached out to CareSource for updates on his credentialing status yet has received no response. In fact, as of the date of this Whitepaper, Dr. Margolin is still awaiting a response from CareSource. As CareSource beneficiaries comprise nearly one-third Dr. Margolin's patients (and nearly 40% of entire Ohio Medicaid Market[116]), CareSource's stalling tactics are inhibiting Dr. Margolin's ability to provide care to his community.[117] More than twenty (20) CPMI patients have issued complaints to CareSource regarding disruption to their care.[118] This is extremely problematic as the unintentional drug overdose rate in Ohio continues to rise. In 2021, the rate increased by over twenty-six (26%) percent.[119] Moreover, the Ohio Attorney General has listed Franklin County (a county in which

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[110] *Id.*

[111] *See* **Exhibit II**.

[112] *See* OIG, *Closed Corporate Integrity Agreements*, CareSource (available at https://oig.hhs.gov/compliance/corporate-integrity-agreements/closed-cias.asp#c), attached as **Exhibit PP**.

[113] *See* DOJ Press Release re CareSource, attached as **Exhibit QQ**.

[114] *See* E-Mail from Dr. Margolin to CareSource re his concern as to the reasoning behind the audit, attached as **Exhibit RR**.

[115] *See* E-Mail from Tiffany Clauss re Dr. Margolin's credentialing status, attached as **Exhibit SS**.

[116] CareSource manages Medicaid benefits for 1.3 million Ohio residents out of a total of 3.1 million Medicaid beneficiaries. *See* Kaitlin Schroeder, *Ohio Medicaid Announces CareSource Wins Bid to Keep Managing Billions in State Benefits*, Springfield News-Sun (Apr. 9, 2021) (available at https://www.springfieldnewssun.com/local/ohio-medicaid-announces-caresource-wins-bid-keep-managing-billions-in-state-benefits/FWVAFBQNAFBE5KRACHYYUISRJY/), attached as **Exhibit TT**.

[117] CPMI has suffered negative PR and lost approximately 40% of its business due to its inability to provide care to CareSource beneficiaries. Moreover, CPMI was recently unable to renew its Professional Liability Coverage and had to change carriers. *See* Letter from MedProGroup (dated Jan. 10, 2022), attached as **Exhibit UU**.

[118] *See* Patient Complaints to CareSource re Disruption to Care, attached as **Exhibit VV**.

[119] Justin Boggs, *Ohio Drug Overdose Deaths Jumped 26% in a Year*, Spectrum News (Nov. 17, 2021) (available at https://spectrumnews1.com/oh/columbus/news/2021/11/17/ohio-drug-overdose-deaths-jumped-26--in-a-year), attached as **Exhibit WW**; *see also* American Medical Association, *Issue Brief: Nation's Drug-Related Overdose and Death Epidemic Continues to Worsen*, Advocacy Resource Center (Feb. 15, 2022) (available at https://www.ama-assn.org/system/files/issue-brief-increases-in-opioid-related-overdose.pdf), attached as **Exhibit XX**.

CPMI has an office) as one of the three worst counties for opioid overdose deaths with a rate of 19.43 per 100,000 people.[120]

Since CareSource's audit, fifteen (15) U.S. Senators issued a letter to CareSource to urge CareSource to update its pain management policies, which they believed were exacerbating the nation's opioid epidemic.[121] The overriding purpose of the letter was to get CareSource to revise its policies to cover non-opioid treatments that steer patients from opioid use. Notably, CPMI's use of SBIRT and NCS without EMG were both non-opioid treatments, which were designed, in part, to limit the over-prescription of opioids.

Given the flawed audit, lack of response to CPMI's audit for over four years, lack of prior notice before initiating overpayment, and stalled credentialing process, CareSource appears to have acted in bad faith and in retaliation against CPMI due to its filing of business integrity complaints. Based upon available information (*e.g.*, the CareSource audit is mentioned in the DOJ's Civil Investigative Demand ("**CID**") and referenced by DOJ representatives as a source for the DOJ's conclusions), it appears CareSource coordinated with the DOJ, providing it with erroneous information regarding CPMI's use of NCS.

B. DOJ'S WRONGFUL INVESTIGATION

As part of a coordinated effort, the DOJ issued a CID[122] requesting patient records for fifty (50) patients and documentation regarding CPMI's NCS policies and procedures. The DOJ alleged that NCS services provided without EMG were medically unnecessary. Dr. Margolin readily and fully complied with the CID. After issuing the CID, the DOJ expanded its investigation to include a review of CPMI's SBIRT services. The DOJ alleged that CPMI was providing medically unnecessary SBIRT services, due to its frequent provision of SBIRT services. Then the DOJ wrongly extrapolated its 50-patient review to apply to all of the NCS and SBIRT services CPMI performed on its patients between January 1, 2013 – September 19, 2019.

During this process, the DOJ refused to appropriately consider evidence presented by Dr. Margolin in support of the medical necessity and appropriateness of the NCS and SBIRT services. Dr. Margolin and his attorneys met with the DOJ on two occasions and provided numerous pieces of evidence and documentation in support of the medical necessity of CPMI's SBIRT and NCS services, including: (i) Ohio pain management clinic and controlled substance laws; (ii) patient records detailing Dr. Margolin's clinical decision-making regarding the medical necessity of the services; (iii) CMS guidance; (iv) medical expert opinions; (v) billing/coding expert opinions; and (vi) peer-reviewed studies confirming the medical necessity of the services.

The DOJ also claimed CPMI's billing of HCPCS G Codes G0396 and G0397 exponentially rose from zero claims to a large number of patient claims, which the DOJ argued was evidence of inappropriate SBIRT billings. However, the DOJ failed to appropriately consider that G0396 and G0397 were first approved for billing Ohio Medicaid in 2014.[123] The increase in

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[120] *See* Ohio Attorney General, *Record Surges in Opioid Overdoses Prompts AG Yost to Urge Vigilance*, News Release (Jan. 11, 2021) (available at https://www.ohioattorneygeneral.gov/Media/News-Releases/January-2021/Record-Surges-in-Opioid-Overdoses-Prompts-AG-Yost), attached as **Exhibit YY**.

[121] *See* Letter from 15 U.S. Senators to CareSource (Mar. 1, 2018), attached as **Exhibit ZZ.**

[122] *See* DOJ, Civil Investigative Demand No. 18-20 (Jan. 5, 2017), attached as **Exhibit AAA.**

[123] *See*, CareSource Notice, *Behavioral Health Care: Integrated*, p. 1 (Jan. 2014), attached as **Exhibit BBB**.

CPMI's billings of G0396 and G0397 coincided with Ohio Medicaid's approval of the codes. This is not evidence of improper billing by CPMI.

In October 2019, in the midst of the investigation, CPMI's attorneys abruptly resigned. Based on publicly available information, it appears that Dr. Margolin's/CPMI's attorneys had close ties with the DOJ and OIG. In fact, one of CPMI's initial attorneys was a former U.S. Attorney for the Southern District of Ohio. Dr. Margolin believes his initial counsel failed to zealously advocate on his behalf.

While under duress, CPMI/Dr. Margolin agreed to settle with the DOJ to avoid the cost and expense of lengthy litigation,[124] but more importantly to ensure that Dr. Margolin could continue to provide much needed pain management services to high-risk patients in a large minority community during the opioid crisis. Dr. Margolin agreed to pay $650,000 plus interest to settle the DOJ's allegations of inappropriate claims between January 1, 2013 and September 19, 2019.[125] The settlement amount was to be paid two (2) installments. Significantly, the settlement agreement acknowledges that it is not an admission of liability by Dr. Margolin.[126] Moreover, Dr. Margolin was not excluded from Medicare, Medicaid, or any other federal healthcare program. Dr. Margolin fully complied with all requirements under the settlement agreement with the DOJ.[127] Dr. Margolin made the final payment required under the settlement agreement in October 2020.

Despite agreeing to a settlement, Dr. Margolin has adamantly maintained his position that he provided medically necessary SBIRT and NCS services in compliance with all applicable laws, regulations, and guidelines.

In fact, Dr. Margolin sent a letter to the DOJ emphasizing the negative impact that a DOJ decision, which relies on false data and ignores expert opinions, would have on providers' attempts to combat the opioid epidemic in Ohio. Significantly, since the DOJ publicly announced its investigation and settlement with Dr. Margolin/CPMI in the media and online, drug overdose rates in Ohio have skyrocketed by over twenty-six (26%) percent.[128] The DOJ's position that screening patients for drugs and alcohol is unnecessary and the imposition of such a large financial penalty on a small practice may have swayed other providers from screening patients for drugs and alcohol. Such a policy/position by the DOJ could have aided the increase in opioid morbidity and mortality in Ohio.

III. THE ERRORS AND WRONGFUL ACTIONS OF THE DOJ

Below is a summary of the errors and wrongful actions the DOJ took during its investigation and settlement.

A. DOJ FAILED TO ENGAGE A MEDICAL EXPERT

The DOJ failed to engage a medical expert to determine whether the SBIRT or NCS services CPMI provided its patients were medically necessary. Instead, the DOJ independently

[124] *See* Settlement Agreement between DOJ and Dr. Margolin, p. 2 attached as **Exhibit CCC.**

[125] *Id* at 1.

[126] *Id.*

[127] *Id* at 10.

[128] *See* **Exhibit WW**.

determined the medical necessity of SBIRT and NCS services for treating chronic pain patients, which constitutes the unlicensed practice of medicine. State and federal rules of evidence require medical experts providing an expert opinion to meet certain knowledge, training, and education requirements.[129] Ohio also requires medical experts to spend at least 50% of their time in active clinical practice.[130] The DOJ met none of these requirements. Further, Federal law prohibits federal officers and employees from interfering with the practice of medicine.[131] In fact, CMS has stated it is prohibited from providing guidance on the practice of medicine,[132] which is precisely what the DOJ did in this case.

While the DOJ alleged that CPMI filed claims for medically unnecessary NCS and SBIRT services, it failed to provide evidence in support of such allegations. Further, the DOJ failed to provide evidence in support of its allegations that Dr. Margolin billed for SBIRT services which he did not actually perform.

B. DOJ Failed to Appropriately Consider the Evidence Submitted by Dr. Margolin

The DOJ also failed to acknowledge the plethora of evidence that Dr. Margolin provided in support of the medical necessity of NCS without EMG and frequent SBIRT services for the treatment of chronic pain patients. Dr. Margolin provided medical expert evidence supporting the medical necessity of NCS without EMG and frequent SBIRT services for treating chronic pain patients. Such evidence consisted of a peer-reviewed article published by Dr. Margolin and several pain medicine experts[133] and a medical study conducted with the ABPMR, which was reviewed and verified by two pain medicine experts.[134] In fact, the ABPMR study confirmed the medical necessity of NCS and SBIRT services provided to each patient reviewed by the DOJ. The experts that reviewed and verified the ABPMR study found the study to be well supported and compelling.[135] Instead, the DOJ maintained its position regarding SBIRT frequency and applied a standard of care from a separate subfield of medicine – neuromuscular medicine – for the provision of NCS in pain medicine.

The DOJ also failed to appropriately consider Ohio law that specifically requires pain specialists prescribing controlled substances to continuously monitor their high-risk patients.[136] In fact, pain specialists are prohibited from allowing more than three (3) months to pass between assessments.[137] The purpose of the law is to ensure opioid-using patients are properly monitored for signs of misuse, diversion, and risk of overdose. Aside from the 3-month rule, the frequency of SBIRT services is a clinical determination made by the treating physician, with high-risk patients requiring more frequent SBIRT services.

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[129] *See* FRE 702, attached as **Exhibit DDD**; *see also* Ohio Rules of Evidence, Rule 601, attached as **Exhibit EEE**.

[130] *See* **Exhibit DDD** (Rule 601(B)(5)(b)).

[131] *See* 42 U.S.C.A. § 1395, attached as **Exhibit FFF**.

[132] *See* OIG, *Questionable Billing for Medicare Electrodiagnostic Tests*, p. 21 (Apr. 2014), attached as **Exhibit GGG**.

[133] *See* **Exhibit H**.

[134] *See* **Exhibits BB**, **CC**, and **DD**.

[135] *Id.*

[136] *See* **Exhibit K.**

[137] *See* **Exhibit K** (OAC § 47311-11-14(G)).

CPMI's utilization of NCS and SBIRT services also complied with federal and state guidance, which the DOJ failed to appropriately consider. CMS issued guidance regarding both SBIRT (*i.e.*, CMS' SBIRT guidance)[138] and NCS services (*i.e.*, the LCD).[139] Dr. Margolin/CPMI complied with the requirements in both the NCS LCD and the SBIRT guidance. CPMI's use of SBIRT services also complied with state guidance, such as the OARRS Manual. The OARRS Manual requires consultations and assessments with patients that are being treated with opioids based on their NARX scores.[140] The higher the NARX score the more frequent the need for consultations and assessments.

The DOJ also failed to appropriately consider that CPMI complied with AANEM guidelines for informed consent. AANEM guidelines prohibit the use of EMG of NCS without obtaining patient informed consent prior to the service. In compliance with AANEM guidelines, Dr. Margolin maintained patient records, including documentation of informed consent or refusal of NCS and/or EMG services. In fact, former president and six-year board member of AANEM, Bernard M. Abrams, M.D., reviewed and determined CPMI's NCS/EMG policy, practice, and procedures complied with AANEM and medical necessity.[141] While the DOJ acknowledged that Dr. Margolin obtained valid consent for the NCS services he performed, it did not appropriately consider Dr. Margolin's documentation and the importance of patient autonomy. If a patient refuses to consent to a procedure, Dr. Margolin is prohibited (by law and state/federal guidelines) from performing the service. Yet, the DOJ maintained its position that Dr. Margolin should have performed EMG for each of his patients that received NCS, including those that refused EMG.

Further, the DOJ failed to appropriately consider the various expert determinations made by the multiple medical and billing/coding experts engaged by CPMI.[142] In fact, based on e-mails between the DOJ and CPMI's substituted counsel, the DOJ showed no interest in objective medical and billing/coding expert opinions. These experts conducted in-depth audits of CPMI's NCS and SBIRT policies, practice, and procedures and found that CPMI complied with applicable laws, regulations, and guidance. Moreover, these experts reviewed numerous CPMI patient charts, including charts for the patients being reviewed by the DOJ. The experts found that Dr. Margolin complied with the appropriate standard of care and that the records fully supported the medical necessity of the NCS and SBIRT services provided.

Moreover, deference should have been given to Dr. Margolin's clinical decisions determining the medical necessity of NCS and SBIRT services for his patients. Numerous federal courts have determined that a treating physician's determination of "medical necessity" should be given deference over a paper reviewer's determination.[143] The DOJ should have provided significant deference to Dr. Margolin's clinical determinations per the Treating Physician Rule.

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[138] *See* **Exhibit J**.

[139] *See* **Exhibit W**.

[140] *See* **Exhibit L**, p. 60.

[141] *See* Letter from Dr. Bernard M. Abrams re CPMI NCS/EMG policy, attached as **Exhibit HHH.**

[142] *See* Section I(B)(iv) for a full overview of the expert determinations regarding SBIRT services.

[143] *See e.g.*, *U.S. v. Prabhu*, 442 F.Supp.2d 1008, 1032 (D. Nev. 2006); *Klementowski v. Secretary of HHS*, 801 F.Supp. 1022 (1992); *Wickline v. California*, 228 Cal. Rptr. 661 (Cal. App. 2d Dist. 1986); *Gartmann v. Secretary*, 633 F.Supp. 671, 680–82 (E.D.N.Y.1986); *Breeding v. Weinberger*, 377 F.Supp. 734 (1974); *Collins v. Richardson*, Medicare/Medicaid Manual, ¶ 26,500 (Iowa 1972); *Pillsums v. Harris*, CCH, Medicare/Medicaid Manual, ¶ 309,080 (Cal. 1981); *Henderson v. Harris*, No: 80 8066, Slip Opinion at 622 (2nd Cir., Dec. 17, 1980); and *Stearns v. Sullivan*, NO: 88-2756-Z, CCH Medicare/Medicaid Manual, ¶ 38,273 (D.C. Mass 1989).

c. The DOJ Inappropriately Extrapolated an Invalid Patient Sample

The DOJ's investigation wrongfully relied on inappropriate statistical sampling. The DOJ's investigation consisted, in part, on a review of 50 CPMI patients' records. The DOJ never provided evidence that this 50-patient sample met applicable statistical sampling requirements. Federal law prohibits extrapolation of overpayments from a statistical sample unless it is statistically valid.[144] As specified in the MPIM (which sets standard requirements for statistical samples), a statistical sample must be reviewed and verified by a statistician to ensure it meets the minimum requirements for a statistical sample.[145] The DOJ never indicated such a review occurred. ***As the DOJ provided no evidence that its 50-patient sample was reviewed and verified to meet applicable standards by a statistician, the DOJ's 50-patient sample was invalid***.[146] While the DOJ also appears to rely on the CareSource audit, the CareSource audit sample was also determined to be erroneous by an expert statistician. ***Consequently, the DOJ was prohibited from extrapolating any determinations based upon either statistical sample, the CareSource audit sample or its own 50-patient sample, to CPMI's entire patient population***.

IV. Conclusion

Dr. Margolin is a highly specialized pain specialist providing essential pain management services to patients in a community that has suffered greatly during the opioid pandemic. Dr. Margolin has taken considerable steps to ensure that all the services provided to his patients are in full compliance with applicable laws, regulations, and guidance. Dr. Margolin/CPMI were targeted and subject to a wrongful DOJ investigation, resulting in a settlement made under duress. Despite this settlement, and subsequent attacks on Dr. Margolin, his practice, and staff, Dr. Margolin/CPMI continue to provide high quality pain management services to the community. While CPMI has lost funding and been publicly denounced by the government, Dr. Margolin and CPMI, through great personal expense, have maintained one of the top-rated pain management programs in Ohio. Moreover, Dr. Margolin continues to conduct and publish peer-reviewed studies and present his lauded research at international conferences.

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[144] *See* 42 U.S.C.A. § 1395ddd(f)(3), attached as **Exhibit III**.

[145] *See LivinRite, Inc. v. Azar*, 386 F.Supp.3d 644, 653-654 (E.D. Va. 2019) (audit samples developed by a Medicare contractor may be challenged as illegitimate for failure to comply with MPIM requirements for statistical samples), attached as **Exhibit JJJ**.

[146] *Id.*

Exhibit A

Baldwin's Ohio Administrative Code Annotated
4731 Medical Board (Refs & Annos)
Chapter 4731-29. Pain Management Clinic (Refs & Annos)

OAC 4731-29-01

4731-29-01 Standards and procedures for the operation of a pain management clinic

Currentness

(A) For the purposes of this rule:

(1) “Board” means state medical board of Ohio.

(2) “Chronic pain” means pain that has persisted after reasonable medical efforts have been made to relieve the pain or cure its cause and that has continued, either continuously, or episodically, for longer than three continuous months. “Chronic pain” does not include pain associated with a terminal condition or with a progressive disease that, in the normal course of progression, may reasonably be expected to result in a terminal condition.

(3) “Hospital” means a hospital registered with the department of health under section 3701.07 of the Revised Code.

(4) “Informed consent” means a process of communication between a patient and physician that results in the patient's signed authorization or agreement to undergo a specific medical intervention after all of the following subjects are discussed:

(a) The patient's diagnosis;

(b) The nature and purpose of the proposed treatment or procedure;

(c) The risks and benefits of a proposed treatment or procedure;

(d) Alternatives regardless of their costs or the extent to which the treatment options are covered by health insurance;

(e) The risks and benefits of the alternative treatment or procedure; and

(f) The risks and benefits of not receiving or undergoing a treatment or procedure.

(5) “Owner” means each person included on the list maintained under division (B)(5) of section 4729.552 of the Revised Code.

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(6) "Pain management clinic" means a facility in which the majority of patients of the prescribers at the facility are provided treatment for chronic pain that includes the use of controlled substances. In determining whether the facility meets the requirements of this paragraph:

(a) Calculation of the majority of patients will be based upon the number of patients treated in a calendar month;

(b) Patients receiving controlled substances for treatment of an injury or illness that lasts or is expected to last thirty days or less shall not be considered in the calculation of the majority.

(7) "Pain management clinic" does not include the following:

(a) A hospital;

(b) A facility operated by a hospital for the treatment of pain or chronic pain;

(c) A physician practice owned or controlled, in whole or in part, by a hospital or by an entity that owns or controls, in whole or in part, one or more hospitals;

(d) A school, college, university, or other educational institution or program to the extent that it provides instruction to individuals preparing to practice as physicians, podiatrists, dentists, nurses, physician assistants, optometrists, or veterinarians or any affiliated facility to the extent that it participates in the provision of that instruction;

(e) A hospice program licensed under Chapter 3712. of the Revised Code;

(f) An ambulatory surgical facility licensed under section 3702.30 of the Revised Code;

(g) An interdisciplinary pain rehabilitation program with three-year accreditation from the commission on accreditation of rehabilitation facilities;

(h) A nursing home licensed under section 3721.02 of the Revised Code or by a political subdivision certified under section 3721.09 of the Revised Code; or

(i) A facility conducting only clinical research that may use controlled substances in studies approved by a hospital-based institutional review board or an institutional review board accredited by the association for the accreditation of human research protection programs.

(8) "Physician" means an individual authorized under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery.

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(9) “Prescriber” has the same meaning as in section 4729.01 of the Revised Code.

(B) In the operation of a pain management clinic, the following requirements shall be met:

(1) The pain management clinic shall be owned and operated by one or more physicians. Each physician owner of a pain management clinic shall complete at least twenty hours of category I continuing medical education in pain medicine every two years, to include one or more courses addressing the potential for addiction. The courses completed in compliance with this rule shall be accepted toward meeting the category I requirement for certificate of registration renewal for the physician.

(2) Each physician owner of a pain management clinic must meet one of the following requirements:

(a) Hold current subspecialty certification in pain medicine by the American board of medical specialties, or hold a current certificate of added qualification in pain medicine by the American osteopathic association bureau of osteopathic specialists; or

(b) Hold current subspecialty certification in hospice and palliative medicine by the American board of medical specialties, or hold a current certificate of added qualification in hospice and palliative medicine by the American osteopathic association bureau of osteopathic specialists; or

(c) Hold current board certification by the American board of pain medicine; or

(d) Hold current board certification by the American board of interventional pain physicians; or

(e) Meet both of the following:

(i) Hold current board certification in anesthesiology, psychiatry, neurology, physical medicine and rehabilitation, occupational medicine, or rheumatology by the American board of medical specialties or hold current primary certification in anesthesiology, psychiatry, neurology, physical medicine and rehabilitation, occupational medicine, or rheumatology by the American osteopathic association bureau of osteopathic specialists.

(ii) Demonstrate conformance with the minimal standards of care.

(3) To demonstrate conformance with the minimal standards of care pursuant to paragraph (B)(2)(e)(ii) of this rule, the board shall conduct an inspection of the facility pursuant to division (E) of section 4731.054 of the Revised Code.

(4) The pain management clinic shall be licensed as a category III terminal distributor of dangerous drugs with a pain management clinic classification under section 4729.552 of the Revised Code.

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(5) The pain management clinic shall be operated in compliance with the drug prevention and control act, 21 U.S.C. 801 to 971, in effect as of May 1, 2016, and Chapters 3719., 4729., 4730., and 4731. of the Revised Code.

(6) The pain management clinic shall have proper equipment, materials, and personnel on premises to provide appropriate medical treatment, as required by the minimal standards of care.

(C) Each physician who provides care at a pain management clinic shall complete at least twenty hours of category I continuing medical education in pain medicine every two years, to include one or more courses addressing the potential for addiction. The courses completed in compliance with this rule shall be accepted toward meeting the category I requirement for certificate of registration renewal for the physician.

(D) No physician owner of a pain management clinic, employee of the clinic, or person with whom the clinic contracts for services shall:

(1) Have ever been denied a license to prescribe, dispense, administer, supply, or sell a controlled substance by the drug enforcement administration or appropriate issuing body of any state or jurisdiction, based, in whole or in part, on the prescriber's inappropriate prescribing, dispensing, administering, supplying or selling a controlled substance or other dangerous drug.

(2) Have held a license issued by the drug enforcement administration or a state licensing agency in any jurisdiction, under which the person may prescribe, dispense, administer, supply or sell a controlled substance, that has ever been restricted, based, in whole or in part, on the prescriber's inappropriate prescribing, dispensing, administering, supplying, or selling a controlled substance or other dangerous drug.

(3) Have been subject to disciplinary action by any licensing entity that was based, in whole or in part, on the prescribers inappropriate prescribing, dispensing, diverting, administering, supplying or selling a controlled substance or other dangerous drug.

(E) In providing supervision, direction, and control of individuals at a pain management clinic the physician owner shall establish and ensure compliance with the following:

(1) A requirement that a log of patients be maintained for each day the clinic is in operation.

(a) Each log sheet shall contain the month, day, and year;

(b) Each log entry shall include the legible first and last name of each patient;

(c) Each patient shall be required to sign the log at each visit; and

(d) Patient logs shall be maintained for seven years.

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(2) A requirement that providers obtain informed consent for each patient prior to the commencement of treatment.

(3) An on-going quality assurance program that objectively and systematically monitors and evaluates the quality and appropriateness of patient care, evaluates methods to improve patient care, identifies and corrects deficiencies within the clinic, and provides the opportunities to improve the clinic's performance and quality of care.

(4) A requirement that the background, training, certification, and licensure of all clinical staff be documented. Verification of certification and licensure shall be made on an annual basis.

(5) A requirement that adequate billing records are maintained for all patients and made available to the board, immediately upon request.

(a) Billing records shall include the amount paid, method of payment, description of services, sufficient information to identify the patient, and the amounts charged to the patient for each date of service,

(b) Billing records shall be maintained for seven years from the last date of treatment of the patient.

(6) A requirement that adequate patient records are maintained for all patients and made available to the board, immediately upon request.

(a) Patient records shall contain sufficient information to identify the patient, support the diagnosis, justify the treatment and document the course and results of treatment accurately, by including, at a minimum:

(i) Patient history and physical examination, including history of drug abuse or dependence;

(ii) Diagnostic, therapeutic, and laboratory results, including drug testing results;

(iii) Reports of evaluations, consultations, and hospitalizations;

(iv) Treatment objectives, including discussion of risks and benefits;

(v) Records of drugs prescribed, dispensed or administered, including the date, type, and dosage;

(vi) Treatments;

(vii) Receipt and assessment of drug database or prescription monitoring program reports;

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(viii) Copies of records or reports or other documentation obtained from other health care practitioners at the request of the physician and relied upon by the physician in determining the appropriate treatment of the patient. Records provided by the patient shall be designated as such.

(b) Patient records shall be maintained for seven years from the last date of treatment of the patient.

(c) In the treatment of chronic pain the patient records shall contain the information required in rule 4731-21-02 of the Administrative Code in lieu of the requirements of paragraphs (E)(6)(a)(i) to (E)(6)(a)(vi) of this rule.

Credits

HISTORY: 2016-17 OMR pam. # 12 (A), eff. 6-30-17; 2011-12 OMR pam. # 2 (E), eff. 8-31-11; 2010-11 OMR pam. # 12 (E*), eff. 6-20-11.

Periodic review date(s): 6-30-22; 3-28-17; 8-31-16

Rules and appendices are current through April 15, 2022. Emergency rules are more current.

OAC 4731-29-01, OH ADC 4731-29-01

End of Document

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Exhibit B

KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

Baldwin's Ohio Revised Code Annotated
Title XLVII. Occupations--Professions (Refs & Annos)
Chapter 4729. Pharmacists; Dangerous Drugs (Refs & Annos)
Dangerous Drugs

R.C. § 4729.552

4729.552 Eligibility requirements for category III terminal distributor of dangerous drugs license with a pain management clinic classification

Effective: September 29, 2017
Currentness

(A) To be eligible to receive a license as a category III terminal distributor of dangerous drugs with a pain management clinic classification, an applicant shall submit evidence satisfactory to the state board of pharmacy that the applicant's pain management clinic will be operated in accordance with the requirements specified in division (B) of this section and that the applicant meets any other applicable requirements of this chapter.

If the board determines that an applicant meets all of the requirements, the board shall issue to the applicant a license as a category III terminal distributor of dangerous drugs and specify on the license that the terminal distributor is classified as a pain management clinic.

(B) The holder of a terminal distributor license with a pain management clinic classification shall do all of the following:

(1) Be in control of a facility that is owned and operated solely by one or more physicians authorized under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery;

(2) Comply with the requirements for the operation of a pain management clinic, as established by the state medical board in rules adopted under section 4731.054 of the Revised Code;

(3) Ensure that any person employed by the facility complies with the requirements for the operation of a pain management clinic established by the state medical board in rules adopted under section 4731.054 of the Revised Code;

(4) Require any person with ownership of the facility to submit to a criminal records check in accordance with section 4776.02 of the Revised Code and send the results of the criminal records check directly to the state board of pharmacy for review and decision under section 4729.071 of the Revised Code;

(5) Require all employees of the facility to submit to a criminal records check in accordance with section 4776.02 of the Revised Code and ensure that no person is employed who has previously been convicted of, or pleaded guilty to, either of the following:

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(a) A theft offense, described in division (K)(3) of section 2913.01 of the Revised Code, that would constitute a felony under the laws of this state, any other state, or the United States;

(b) A felony drug abuse offense, as defined in section 2925.01 of the Revised Code.

(6) Maintain a list of each person with ownership of the facility and notify the state board of pharmacy of any change to that list.

(C) No person shall operate a facility that under this chapter is subject to licensure as a category III terminal distributor of dangerous drugs with a pain management clinic classification without obtaining and maintaining the license with the classification.

No person who holds a category III license with a pain management clinic classification shall fail to remain in compliance with the requirements of division (B) of this section and any other applicable requirements of this chapter.

(D) The state board of pharmacy may impose a fine of not more than five thousand dollars on a person who violates division (C) of this section. A separate fine may be imposed for each day the violation continues. In imposing the fine, the board's actions shall be taken in accordance with Chapter 119. of the Revised Code.

(E) The state board of pharmacy shall adopt rules as it considers necessary to implement and administer this section. The rules shall be adopted in accordance with Chapter 119. of the Revised Code.

CREDIT(S)

(2017 H 49, eff. 9-29-17; 2012 S 301, eff. 3-13-13; 2011 H 153, eff. 9-29-11; 2011 H 93, eff. 5-20-11 (Provisions subject to different effective dates))

R.C. § 4729.552, OH ST § 4729.552
Current through File 100 of the 134th General Assembly (2021-2022).

End of Document

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Exhibit C



Dr. Leon Margolin MD, PhD, FAPMR, FAPM

Comprehensive Pain Management Institute Contact

- Phone: 614-557-6817
- Email: info@cpmiohio.com
- Website: https://cpmiohio.com/

Accomplishments

- More than 30 publications (including a research manuscript), recent original study performed at the practice accepted for presentation at the national meeting, request for 2nd manuscript being processed
- Physician's Recognition Award from the American Medical Association (2008, 2014), Resident/ Fellow Award from the American Society of Regional Anesthesia and Pain Medicine
- Two Certificates of Merit of the American College of Physicians, the Medical Society of Pennsylvania Award, the Pfizer Scholars in Pain Management Award, Patient's Choice Award (several years including 2019).
- Most Compassionate Physician Award (several years) and "Top Ten Physicians" Award in Pain Medicine (2014).
- America's Most Honored Professionals Award (2017, 2018, 2019) 1% percent ranking.

Unique professional credentials

- Double Board Certification by Board Certified by the American Board of Physical Medicine and Rehabilitation and Fellowship training and Board-Certified in Pain Medicine.
- Additional training by The American Academy of Addiction Medicine.
- Training/courses in Neurology by AANEM and Radiology (MRI and X rays reading)

- Lab Director training and certification by CLIA/COLA.

Awards

- TMedPM 2022 Certificate
- CAM Therapies 2021 E-poster Participation
- CAM Therapies 2021
- Ohio top doctors award
- Top 3 Pain Management Doctors in Columbus, Ohio.
- Physician's Recognition Award, 2020-2021
- Best Pain Management Doctors in Columbus.
- Patients Choice Award 2020
- Best of 2020 Columbus
- On-Time Doctor Award 2019
- Patient Choice Award 2019
- Patient Choice Award 2019
- Top Pain Medicine Specialist 2019
- America's Most Honored Prof. 2018
- Compassionate Dr. Award 2018
- Top 10 Doctor 2014

Exhibit D

Google My Business

Dr. Leon Margolin

3,601 PEOPLE FOUND YOU ON GOOGLE

Here are the top search queries used to find you:

71

asked for directions

9.2% FROM SEPTEMBER 2019

137

visited your website

4.6% FROM SEPTEMBER 2019

207

called you

NO CHANGE FROM SEPTEMBER 2019

WHAT CUSTOMERS ARE SAYING ABOUT YOU

Congrats, **Dr. Leon Margolin** has a **4.3** star rating on Google

Exhibit E

Ohio
MAGAZINE
TOP DOCTORS
PAIN MANAGEMENT SPECIALIST

September 20, 2019

T25 P1 919PL-OL-D

Dr. Leon Margolin MD
5245 E Main St
Columbus, OH 43213-2503

Top Pain Management Specialist 2019/2020



Dear Dr. Margolin,

We are pleased to include you among the influential few to be featured as a **Top Pain Management Specialist** representing Columbus, OH. We will be featuring you in our 2019/2020 Top Doctor list which will appear both online and in our nationally syndicated publications.

Your expertise in interventional pain treatments and dedication to improving patient mobility, function, and quality of life, is something to be recognized. This full-color wall plaque is a beautiful addition to your wall of achievements.

Tiffany Byrne
Selection Committee

Tiffany Byrne

Visit Your Personalized Website to Receive Your Plaque Now

www.LeonMargolin.TopDoctor.com

Exhibit F



To whom it may concern, my name is K********* and I work for Comprehensive Pain Management LLC., for about 4 years now. Our office deals with all kinds of chronic pain, we've worked the front line for people that are constantly in pain. Since the corona virus pandemic it has caused cost of supplies sent up, and is finically cutting into our office budget. I have 3 children that depend on me, with minimal to no outside help...

Thanks K



,

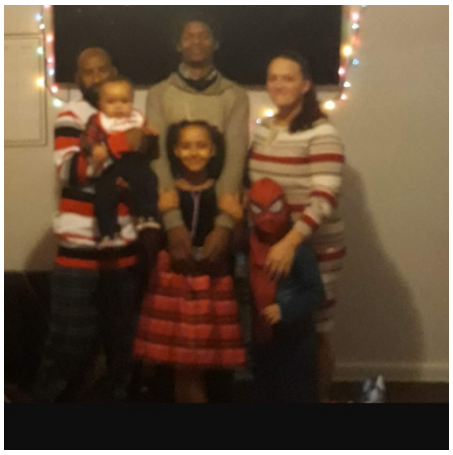
My name is S*******and I've been working at CPMI for six years now taking care of chronic pain patients.

Since the recent pandemic Coronavirus ,and the raising cost of supplies, we've had to have some financial cuts at work causing great stress, since this is how I take care of myself and my four children.

By writing this letter I hope that we will be able to receive some financial assistance from the government, to help us in this difficult time.

Thank you for your time

S



To whom it may concern:

My Name is N****** and I have been working for Dr. Margolin at Comprehensive Pain Management for about two years. We handle patients suffering from all types of chronic pain. We also have been on the front line of fighting against Opioid abuse in Columbus, Ohio. With this new pandemic, COVID-19, our office needs better safety equipment. Our office can't just shut down and expect our patients to wait until we reopen again to get pain relief. If we were to shut down, our patients would go through withdrawals, and that could lead to more serious and dangerous outcomes, and we really don't want that. Medical Supplies alone have gone up a lot since the COVID-19 pandemic began. Our patients need us now more then ever at a time like this. Our office contains about 10-15 employees, and we all have family's to take care of. Some of our spouses have already been laid off due to this virus, meaning that we are now the main source of income in our homes at this time. With our staff taking both hourly cuts and pay cuts, it has been difficult for all of us here as well at the practice. Myself alone having to take a pay cut and an hourly cut with four children in the home; I can barely make rent and am now having to skip out on paying some of my bills just to be able to make sure that my children have food every day. These decisions have been very hard om my and my family, as well as those of my co-workers. Please consider helping our practice during this difficult time of crisis.

Thank you for your consideration.







My name is T**********. I have been working for Dr Margolin and Comprehensive Pain Management for almost 7 years. Our office deals with all differnt kinds of chronic pain. We have been on the front lines of fighting the opioid epidemic for years. With this new pandemic Coven19 we are falling behind. Our office needs better safety equipment.

We can't close up shop like other Drs offices. Closing our bussiness would put all are patients at risk of going threw withdrawals which can be life threatening and would increase their risk of contracting Coven19. The cost of medical supplies and price gauging has put our practice at jeopardy. Our patients need us more then ever now but the cost of living has tripled since this crisis reached our shores so much so we have had to take pay cuts and houly cuts. I have 2 small children at home I'm raseing without help from their father or the government.

I dont receive snap benefits and since the schools are closed in Ohio Im forced to find alternative means of childcare to work. Im paying double what I did while my children were in school.I use to depend on the schools to provide breakfeast and lunch. My food buget was 350 $ that would pay for meals for my children threw out the month. After the shut downs and quarantines it has gone up to 450$. Im having to skip out on bills to pay for the extra food alone. I'm afraid im am going to lose everything I have worked so hard to obtain. Please consider our practice. We have been fighting with you against the opiod epidemic for years please help us recover from this so we can continue to fight Coven19 and the Opiod crisis.

T





My name is T*********I have worked for Dr. Leon Margolin Comprehensive Pain Management for 3 years. We see roughly 400 to 500 patients a month. We treat chronic pain patients. If we would have to close due to expenses, our patients would face withdrawl and this would weaken their immune systems, making them more of a target for the corona virus. Since the covia19 outbreak are practice and employees have suffered. We are faced with cut hours and pay cuts as well. This is our job and we rely on this to be able to pay our bills. I have 3 children at home that rely on me to provide for them. We dont receive snap benefits or public assistance to meet our monthly housing cost or for food. Since schools and daycares are closed I have to spend more on food for the week and this is taking a toll on us as employees and on our practice. So please if you could help our parctice get thru this covia 19 epidemic.



This is J********, who have been working with Comprehensive Pain Management and Dr Margolin over 4 years. The clinic had been supported and taken care of over 500 patients with different chronic pain issues on the monthly basis, supporting about 15 employees and their families. It provided high quality patient care by passionate staffing members who worked together closely.

Due to recent COVID-19 pandemic situation, our clinic is facing financial difficulty due to staffing resign, sickness, increasing cost of supply, ect,. As the health provider, me and my coworker need to compensating care for sickness staffing, management pay cut, providing extra step of care to thoroughly care of patient to provide safely and high quality care; and our staffing are working extra step to carefully screening pt, keep some patients in safe area to maintain safe environment, managing limited supplies, vigorously sanitizing patient care area, extensively reassuring patient' about our continuous care and managing their decreased payment too. As of our society fighting the COVID-19, the increased number of infected patient has been overwhelmed our health system, our patients are more than ever to rely on us to provide continuously high quality of care to avoiding adding more burden to the current health system. As we are facing these uncertainties, difficulties, stress in our clinic and our beloved families, I really hope the government could offer any help including approving any grant to help our clinic to go through this crisis for our patients, our staffing and their families.

Sincerely yours

J**********



My name is T********** I have worked with Dr. Margolin for over two years now and it's very important to our patients that we do not lose our practice covid19. That would not be very good for their health being that they are on opioids. We do carry our practice very well we abide by the guidelines we have been inspected several times and have passed with flying colors but this covid 19 virus is beginning to affect us we've had to cut hours take pay cuts and that is affecting the patient's so if you could please work with us and see if you could give us help because our patients need us very dearly, once again T**********, concerned for our patient's thank you.

Evidence of racist OH DOJ policies towards minority patients and providers (see attached)

Dear Mr. DeVillers,

We are a group of about 100 patients who would like to draw your attention to the issue of racial bias and disparities that result in denial of essential services to vulnerable (mostly minority) patients.

I would like to bring to your attention the attached peer reviewed journal publication by Dr. Leon Margolin and Dr. David Streem (Chief of Psychiatry and Medical Director of the Alcohol and Drug Recovery Center (Lutheran Hospital Division), Cleveland Clinic Foundation):

https://www.gavinpublishers.com/assets/articles_pdf/1595045423article_pdf1130015263.pdf

The publication reviews Dr. Margolin's treatment and screening protocols including the nerve conduction testing and screening and brief interventions including the same charts and patient examples allegedly reviewed by your department (a total of 155 charts over 2 year period) with the clear conclusion of the full compliance and significant effectiveness of these treatments. Denial of such services exposes a vulnerable patient population to a significant risk which has become significantly worse during the COVID-19 pandemic (as per the AMA July 8, 2020 brief quoted in the article).

This article raises a justified concern about retaliation by the Medicaid HMOs (especially Caresource) to exposure of such denials. These concerns regarding Caresouce were raised by several US senators (Figure 7 in the attached article). This study was presented at the CWRU, Ohio Opioid task force (presentations available online) and endorsed by a wide array of the top state and national experts in the field including:

Professor Stanley Wainepal MD, Professor and Clinical Director, Department of Rehabilitation Medicine, Montefiore Medical Center, Albert Einstein College of Medicine, NY.

Professor Jun Kimura MD, Professor of Neurology, University of Iowa; Kyoto University; Distinguished Researcher Award by the American Association of Neuromuscular & Electro diagnostic Medicine; Author of a major textbook recommended by the AANEM and ABPMR; Lecturer in the AANEM NCV and EMG courses; Author of more than 500 publications in the field / 25 professional honorary society membership all around the world.

Expert panel of the American Board of Physical Medicine and Rehabilitation (ABPMR).

Roneet Lev MD, Chief Medical Office, White House Office of National Drug Control PolicyExecutive Office of The President.

Sabaitu I. Mansarai a Senior Executive Service (SES) with the Office of National Drug Control Policy where she is the Assistant Director for Public Health, Education and Treatment Task Force in support of combating the opioid crisis.

Ohio Opioid Task Force, Cuyahoga County Board of Health.

Case Western Reserve University continuous education program expert panel.

This data was also reviewed and approved by the **American Board of Physical Medicine and Rehabilitation.**

Please kindly share with us any expert opinions that lead your department to label these services as improper and unallowed services (see attached) or comment on whether Medicare integrity manual was upheld by your department.

Please comment on the legal basis by non physicians making such a dangerous clinical decision and forcing physician and other clinical staff to comply and practice Medicine based on this decision (that all SBIRT codes are unallowed service for all the current and future patients).

To our amazement we learned from public sources that DOJ and Ohio Attorney General under your guidance has authorized denial of such screening and brief intervention services and prohibited them in the future exposing several hundred vulnerable (mostly minority) patients, to a significant risk(see documents attached):

https://www.justice.gov/opa/pr/columbus-pain-clinic-and-owner-agree-pay-650000-resolve-allegations-unnecessary-procedures

It is our concern that no expert review or any other steps required by the Medicare Integrity Manual were performed, the officials involved in this decision were aware that they are acting on the false and retaliatory data provided by the Caresource HMO. The individuals directly involved in this decision are: CHRISTOPHER G. WILSON, MARK T. D'ALESSANDRO, ANDREW M. MALEK, LISA M RE (see attached).

These individuals were provided with the expert opinions, statistical data about all the charts and the detailed review and analysis by the national academy and a written patient safety warning attached.

Therefore we cannot help but to conclude that this exorbitant sum of money was leveraged based on the racist bias and unjustified financial objectives putting patients and staff at a significant risk.

Please comment on why no proper steps were taken to assess this credible warning and whether this was related to the minority status of the medical staff and us (the patients) at risk. We want to know on whether your staff made threats of bad faith charges, or Medicare privileges suspension in retaliation to the submitted good faith patient safety concerns. Please see this letter as formal grievance against all the lawyers involved.

[redacted] shortly after this warning, one of the high risk patients that you have denied screening, assaulted and injured Dr. Margolin and 2 other female members of his team because of the lack of screening and proper funds for the office security [redacted] In

addition, at least 9 patients and one staff member contracted COVID-19. The office sustained significant property damage (office furniture and staff cars damaged, office building transformer destroyed etc.) The court documents show that the damaged could have been avoided if not for the unjustified recoupment by your department that left the office without proper funds for staff and patient security and protective equipment.

In addition, several hundred vulnerable patients are exposed to a very significant risk. On a large scale these inappropriate policies expose thousands of Ohions to a very significant risk and require immediate attention. Please review the May 2020 warning of the Medical Examiner in the attached article and other documents.

We are aware that during the current crisis you were notified in writing that:

"Maintaining adequate staffing has been another ongoing concern for CPMI [Dr. Margolin's practice]. Its employees are risking their health and safety to treat vulnerable patients and scrambling to locate and pay for safety equipment. Until recently, CPMI had no access to testing and was forced to operate at reduced capacity. **Multiple staff members, including Dr. Margolin, were quarantined after potential exposure to COVID-19 or from COVID-19-like symptoms.** CPMI received reports about several patients with clinical symptoms of COVID 19. Last week, CPMI patients were confirmed to have the virus. CPMI cut physician and nurse practitioner salaries to avoid layoffs. **Many CPMI employees are struggling to pay for food and child care with schools operating remotely.** ***[see staff letters attached]***

As of April 22, 2020, he[Dr. Margolin] and his wife had received only six weeks of pay for the entire year, out of sixteen weeks total. He has a mortgage on his only residence in Beachwood, Ohio, and he supports his wife and four children, as well as his wife's parents, who have been forced to shelter with his family during the pandemic and are at high-risk of COVID-19 infection due to pre-existing medical conditions.

CPMI recently applied for and is receiving loan from the SBA's Paycheck Protection Program to cover payroll expenses for the next eight weeks, and received ….the Cares Act for COVID-19-related expenses, due to its treatment of vulnerable populations. Forcing CPMI to make the final payment under the Settlement Agreement this month will completely negate the benefits of the SBA loan and Cares Act assistance, likely forcing CPMI to lay off staff and/or shut down operations entirely, putting employees out of work and hundreds of patients at further risk."

Despite this credible warning supported by financial documents, your department is still enforcing this racist recoupment in an inhumane cruel manner putting patients and staff at a very significant risk… On August 4th, 2020 American Medical Association requested immediate action to support the treatments like provided by Dr. Margolin and his team in fighting the recent increase in upload deaths (Ohio is marked as an area with a sharp increase in opioid deaths):

"Policymakers need to act to remove barriers to evidence-based care for patients with pain and those with a substance use disorder or the epidemic will continue to worsen." (AMA report below page 4):

https://www.ama-assn.org/system/files/2020-07/opioid-task-force-progress-report.pdf

The SBIRT and other services marked as "unallowed" by your department are recommended by the WHO, HHS, SAMSHA, Society for the Study of Addiction (for example):

https://onlinelibrary.wiley.com/doi/epdf/10.1111/add.13676

We request immediate cessation of such denials and recoupment, independent review and investigation of this issue by independent experts from state or national agencies (such as CCF, CRWU, SAMSHA, ONDC). We are deeply concerned about possible past retaliation practices by your department described in this letter and would appreciate your written commitment to non retaliation for this good faith concern to all parties involved as required by law.

We are familiar with Dr. Margolin's practice for years. Besides being minorities, Dr. Margolin's team's only "crime" was saving over the last 10 years close to 2000 mostly minority patients and referring them to addiction treatment using the scientifically validated screening and brief intervention methods and testing validated by the best experts in the field. The attached publication and the expert opinions prove beyond a reasonable doubt the medical necessity and the cost effectiveness of his approach that over the years saved thousands of dollars to Medicare and other payers. His practice has been consistently ranked as "the Best in Columbus", "Top Ten Pain medicine", "Patient Choice" and "Most Compassionate Doctor" awards.

https://threebestrated.com/pain-management-doctors-in-columbus-oh

The current crisis showed how Dr. Margolin's team selflessly risked their health and the health of their families to save vulnerable patients while your department seems to be motivated by inappropriate financial objectives and shameful racial bias.

We humbly require your immediate attention to this issue (please respond within 10 business days). We are considering appropriate legal steps such as civil right investigation, media involvement and peaceful protests.

It's about the health and safety of our communities and racial justice. It would be a grave mistake to think it can be ignored with a shallow "thank you for your concern letter" or shoveled under the rug....

[redacted]

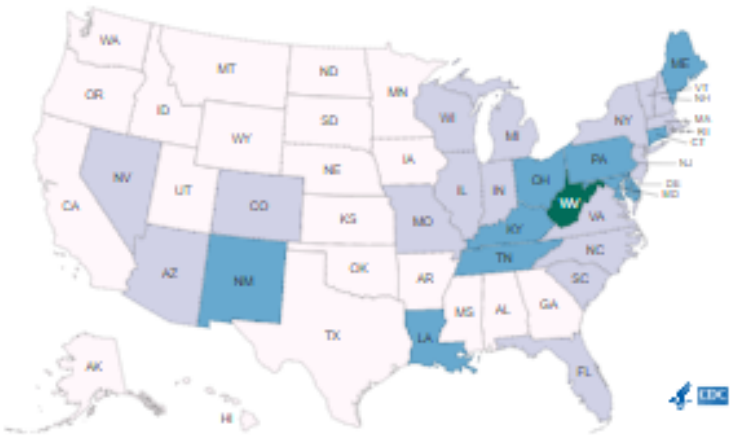
(the conta[redacted]n for the patient group)

Exhibit G

NCHS Pressroom
Weekly COVID-19 Mortality Overview
2022 Release Schedule
Upcoming
Publications Archives
QuickStats Archives
State of the States
Drug Overdose Mortality by State
Most Recent Data on Health Topics
Statcasts
Videos
Press Release Archives
Join NCHS Media List

Related Sites
Health Statistics Blog
CDC Online Newsroom
FastStats
NCHS Publications and Products

Drug Overdose Mortality by State



Age-Adjusted Death Rates[1]

- 10.3 - < 21.52
- 21.52 - < 33.74
- 33.74 - < 52.96
- 52.96 - < 67.10
- 67.10 - 81.4

Filters

Year: 2020

Data Table

Location	Death Rate (Click for...	Deaths
Alabama	22.3	1,029
Alaska	22	160
Arizona	35.8	2,550
Arkansas	19.1	546
California	21.8	8,908
Colorado	24.9	1,482
Connecticut	39.1	1,371
Delaware	47.3	464
Florida	35	7,231
Georgia	18	1,916
Hawaii	18.3	274
Idaho	15.9	287
Illinois	28.1	3,549
Indiana	36.7	2,331
Iowa	14.3	432
Kansas	17.4	490
Kentucky	49.2	2,083
Louisiana	42.7	1,890
Maine	38.7	490
Maryland	44.6	2,771
Massachusetts	33.9	2,302
Michigan	28.6	2,759
Minnesota	19	1,050
Mississippi	21.1	590
Missouri	32.1	1,875
Montana	15.6	162
Nebraska	11.3	214
Nevada	26	832
New Hampshire	30.3	393
New Jersey	32.1	2,840
New Mexico	39	784
New York	25.4	4,965
North Carolina	30.9	3,146
North Dakota	15.6	114
Ohio	47.2	5,504
Oklahoma	19.4	762
Oregon	18.7	803
Pennsylvania	42.4	5,168
Rhode Island	36.2	397
South Carolina	34.9	1,739
South Dakota	10.3	83
Tennessee	45.6	3,034
Texas	14.1	4,172
Utah	20.5	622
Vermont	32.9	190
Virginia	26.6	2,240
Washington	22	1,733
West Virginia	81.4	1,330
Wisconsin	27.7	1,531
Wyoming	17.4	99

Nevada	26	832
New Hampshire	30.3	393
New Jersey	32.1	2,840
New Mexico	39	784
New York	25.4	4,965
North Carolina	30.9	3,146
North Dakota	15.6	114
Ohio	47.2	5,204
Oklahoma	19.4	762
Oregon	18.7	803
Pennsylvania	42.4	5,168
Rhode Island	38.2	397

Exhibit H

GAVIN PUBLISHERS

OPEN ACCESS

Journal of Diabetes and Treatment

Margolin L, et al. J Diabetes Treat 5: 1080.

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Review Article

Impact of Screening and Brief Intervention (SBIRT), Urinary Drug Testing, Minimally Invasive Procedures, and Electromyography on Pain Reduction, Functional Improvement, and Continuity of Care in Chronic Pain Patients

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Abstract

With the alarming explosion of overdose risk in the opioid epidemic since 1999, Opiate Use Disorder (OUD) has cost in excess of $600 billion, harming the economy and killing tens of thousands nationally. According to research conducted in 2017 on opioid mortality, data showed Ohio to be the second-highest opioid mortality state in the US, representing more than 2.6 times the death rate per 100,000 population compared to the US average (39.2 in OH vs. 14.6 in US, see Figure 1 below).

Although socioeconomic factors play a role, authors suggest that lack of availability or the consistent denial of these services by insurance carriers play a role in this situation. A recent Ohio Department of Health report showed that the population of patients susceptible to the opioid epidemic was in fact at least twice the non-minority risk level for COVID 19 pandemic (Figure 2). The recent AMA brief [26] alarms about great concern over increased opioid mortality during COVID 19 pandemic.

This retrospective chart review study provides a systematic analysis of the Screening and Brief Intervention (SBIRT), urinary drug testing, minimally invasive procedures and electromyography on the pain reduction and functional improvement of moderate to high risk chronic pain patients, with risk level determined by NARX scores.

Key Points

SBIRT protocol is mandatory for the compliant operation of a pain management clinic providing medical management to the population with a significant percent of high-risk patients in the high-risk area like Ohio.

Nerve Conduction Studies (NCS)/ Nerve Conduction Velocity (NCV) with or without needle EMG tests as part of the effort to document organic pathology (both initial tests and follow up tests) are medically necessary tests and cost-effective tests that have a strong statistically significant contribution to the proper choice of medications and procedure for chronic pain patients and strongly associated with functional improvement and pain reduction [18].

Using Pain Assessment and Documentation Tool (Figure 3 – PADT) and other validated assessment tools, we demonstrated a statistically significant impact of these services on pain reduction and functional improvement of moderate to high risk (as defined by NARX score and other factors) chronic pain patients over a 2 year period. Using these services and testing since 2011, our practice has been able to identify patients in need and refers to Addiction medicine evaluation and treatment for more than 2000 high-risk patients (who would otherwise be at significant risk of opioid mortality, morbidity, diversion, and incarceration).

Denial coverage for these services by third-party payers or defining them as "Unallowable costs" puts the practice in noncompliance with the guidelines described above, making the ethical operation of the practice impossible and putting patients and staff at considerable risk.

Objective data (Figure 1) shows that a new approach described in this review by the medico-legal system and third

party payors required to address the opioid crisis and protect the population at the high risk for COVID 19 epidemic (Figure 2).

Background

Opioid epidemic crisis affects the lives of thousands of Americans on a daily basis. Since 1999 hundreds of thousands of Americans have died from overdoses. On an average day in the US close to 5,800 people misuse opioids for the first time, and over 1,000 Americans on an average day are treated in the emergency departments for issues related to opioid misuse. The societal and healthcare cost of the opioid epidemic is at least 600 billion dollars and it continues to rise. Proper screening of pain management program patients (including SBIRT protocol G codes, POC UDS, and NCV/EMG) for narcotic medications is extremely important in the prevention of street drug use. The 2018 National Drug Threat Assessment conducted by the Drug Enforcement Administration, showed that prescription drugs such as "Opioids were responsible for the most overdose deaths of any illicit drugs since 2001" and "heroin-related deaths nearly doubled from 2013 to 2016". Ohio is one of the states most affected by the opioid crisis. Ohio has one of the highest death rates related to the Opioid crisis. Efficient and Ethical pain management program that uses appropriate testing to document organic pathology and screen appropriate candidates for pain medications and refer other patients to Addiction medicine evaluation is extremely important in this challenging environment of the opioid epidemic crisis.

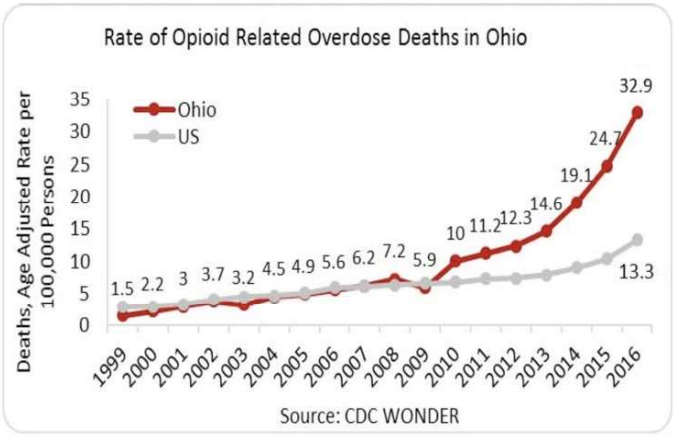


Figure 1: Based on 2017 government Opioid mortality data, Ohio is rated number two in the US with more than 2.6 times death rate per 100,000 population compared to US average rate (39.2 in OH vs. 14.6 average).

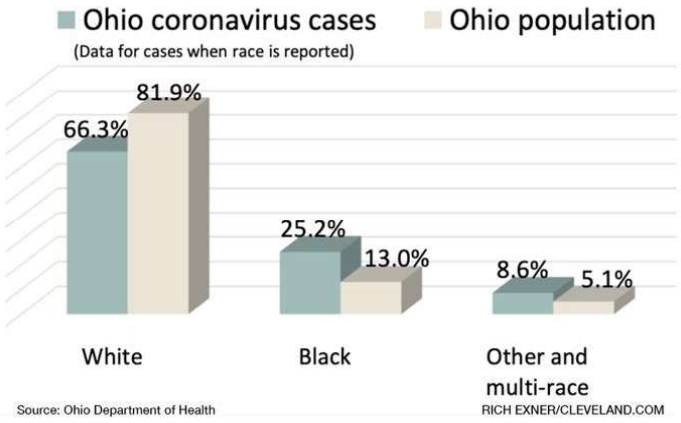


Figure 2: Based on the age, medical comorbidities, socio-economic challenges and possible immunosuppressive effect of Opioids, our patient is at increased risk for the COVID-19 pandemic.

The national and state guidelines require risk stratification and close monitoring of patients on chronic Opioid medication [1]. This study tests the impact of the frequency of the SBIRT protocol (G codes such as G0397), of the POC UDS (80307, 80304) and minimally invasive procedures on the pain reduction (76942, 64450, 64418, 20533 and other similar codes) functional improvement and continuity of care of chronic pain patients. This is frequency of the SBIRT protocol (G codes such as G0397), POC UDS (80307, 80304) and minimally invasive procedures (76942, 64450, 64418, 20533 and other similar codes are based on the "Pain Management Best Practices Inter-Agency Task Force Report", Medicare MLN and LCD OH L36029, Medicare guidelines for the presumptive and definitive testing [1,10,15].

Our practice is a tertiary referral practice that gets referrals for high-risk patients. This is the reason for conducting this study that tests the impact of the frequency of the SBIRT protocol (G codes such as G0397), of the POC UDS (80307, 80304) and minimally invasive procedures on the pain reduction (76942, 64450, 64418, 20533 and other similar codes) functional improvement and continuity of care of chronic pain patients for the quality of care documentation and information for the third-party payers.

Consequences of denial labeling as unallowed service for SBIRT and other services.

Unfortunately, on many occasions' providers face denial of the SBIRT and other services by the private and the government insurance plans. When the insurance carriers challenge the

necessity of SBIRT protocol (G codes), it denies coverage for procedures that are required by the Ohio state law (please review Michael Staples attached) and creates a "catch 22 scenario" that puts the patients and the staff at risk. These procedures include face to face time spent by physician and the nurse practitioners, more than 30 min of telecommunication video material, structured review of several assessments including patient's history and physical examination, PADT [2], COMM [3], Flowchart form based on SMBO Administrative Rule 4731-21-02 [4], withdrawal assessment form, point of care and conformation urine and saliva drug screen reviews, OARRS reviews, and several educational materials. The initial evaluations include additional assessments such as SOAPP-R and ORT and additional educational materials.

Denial payments for the appropriate testing and screening procedures for drugs and alcohol required by the state and national guidelines not only significantly impact pain program ability to function as a business, but also puts an extremely vulnerable patient population at risk. Our patient population is unique as compared to many of our peers. Our patients are extremely complex; we take pride in creating individualized treatment plans which do require a significant amount of testing and time for screening for substance and alcohol use. However, this allows our patients to achieve an extraordinary level of function relative to managing their pain and prevent morbidity and mortality.

At the time of the COVID-19 pandemic additional requirements for SBIRT, withdrawal screening and mental screening suggested by the American Academy of Pain Medicine [17]. Denial of these services exposes staff and patients for additional risks during the pandemic and depletes necessary practice funds required for the personal protection equipment suggested by the American Academy of Pain Medicine [17] during the COVID-19 pandemic.

National and state guidelines require documentation of the organic pathology as part of a comprehensive evaluation in a pain management clinic. NCV, EMG, and Autonomic testing is part of such evaluation.

For example, Mayo Clinic Proceedings [5] that were adopted by the state of Ohio and referenced on each printed copy of the OARRS report, reported that in the area of pain management "The predominant reason for inappropriate care was a failure of the prescribing physician to adequately verify patient's prior medical history". Appropriate testing including NCV and EMG is a step in such verification.

Most of the patients referred to Comprehensive Pain Management Institute, LLC (CPMI) for the evaluation of chronic pain in two or more extremities, or have the diagnosis of peripheral neuropathy, lumbar, or cervical radiculopathy suggested by the referring provider.

The numbers of NCV/EMG tests are based on the OH local coverage determination [6]. All patients had a comprehensive evaluation including initial, follow up evaluation forms, PADT forms enclosed, and extensive review of OARRS reports offered a written consent based on the AANEM guidelines [7] with a detailed explanation of the risk and benefits of the tests. NCV is reviewed and incorporated into the treatment plan.

The most commonly tested nerves in the upper extremities were sensory ulnar, median and radial studies, motor median, ulnar, radial, and in selected cased Axillary studies with Median and Ulnar F waves. For the low extremities the studies included sensory Sural, Superior Peroneal, Motor studies included Common Peroneal, Tibial nerves, and Common Peroneal, and Tibial nerve; F waves and H reflex studies selected based on the comprehensive assessment results. The needle examination typically included (UE) Cervical Paraspinals, Deltoid, Biceps, Extensor Carpi Radialis, Triceps, Flexor Carpi Radialis, APB muscle, (LE) Lumbar Paraspinals, Vastus medialis, Extensor Hallucis Longus, Biceps Femoris, Peroneus Longus, Medial Gastrocnemius, the studies selected based on the comprehensive assessment result.

Between 2011-2015 as a result of regulatory changes in the state of Ohio (including HB 93 law), CPMI received a high number of referral/evaluation requests for high risk challenging patient populations.

Many of these chronic pain patients seen by the CPMI suffer from anxiety and depression, and/or substance use disorders, drug-seeking behavior and had a poor tolerance of the NCV/EMG testing and poor cooperation with the test, especially with the needle part of the test (EMG), (this part performed with inserting EMG needle in 6-12 sites) and frequently refused by the challenging patient population. All the patients signed a written consent based on the AANEM guidelines [6,7].

Cost Efficiency

The cost of the opioid epidemic is more than 600 billion dollars and keeps rising annually. Pain Management programs like our practice that carefully screen and test patients to properly document organic pathology and utilize alternative treatments, careful monitoring, and SBIRT approach not only prevent significant morbidity and mortality but save very significant costs to the healthcare system.

Insufficient testing, monitoring, SBIRT screening and lack of alternatives to opioid medications can potentially result in either prescribing opioid medications to not appropriate candidates that can potentially overdose or divert medications to other people, or not prescribing 5/9 appropriate pain medications to patients who may look for alternatives "On the street" with significant risks or morbidity and mortality.

The host of hospitalization including ER, inpatient care, ICU, detoxification, and maintenance programs is astronomic and can be reduced by patient screening treatment in outpatient programs like our practice (Comprehensive Pain Management Institute). This approach is also supported by the 2017 five-point strategy by the HHS.

When the insurance carriers challenge the necessity of SBIRT protocol (G codes), it denies coverage for procedures that are required by the Ohio state law and creates a "catch 22 scenario" that puts the patients and the staff at risk. These procedures include face to face time spent by physician and the nurse practitioners, more than 30 min of telecommunication video material, structured review of several assessments including patient's history and physical examination, PADT, COMM, Flowchart form based on SMBO Administrative Rule 4731-21-02, withdrawal assessment form, point of care and conformation urine and saliva drug screen reviews, OARRS reviews, and several educational materials. The initial evaluations include additional assessments such as SOAPP-R and ORT and additional educational materials.

Insufficient testing, monitoring, SBIRT screening, can potentially result in either prescribing opioid medications to not appropriate candidates that can potentially overdose or divert medications to other people, or not prescribing appropriate pain medications to patients who may look for alternatives "on the street" with significant risks or morbidity and mortality. The host of hospitalization including ER, inpatient care, ICU, detoxification, and maintenance programs are astronomic and can be reduced by patient screening and testing including NCV/EMG testing and other testing.

Our practice performs the NCV/EMG testing and another testing for a fraction of the cost charged by main hospitals in the area including the Ohio State University clinic.

It is difficult for many patients to find alternative providers. If left untreated, patients may turn to illicit means of obtaining substitute medications which drastically increases the risk of overdose and death (overdose death rate in Ohio is the highest in the nation and is up more than 800% since 2013). The cost of the opioid epidemic is estimated as more than 600 billion nationwide, we run a low-cost program that saves hundreds of thousands of dollars to Medicare by identifying and referring for addiction treatments for hundreds of patients using our SBIRT protocol. We billed much lower rates than comparable hospital-based programs and chose lower-cost codes (i.e. G codes vs. office visit and time codes).

In summary, denial payments for the appropriate testing and screening procedures for drugs and alcohol put in danger about several hundred high-risk patients (just in [redacted] we had a case of assault by a discharged drug-seeking patient and an attempted assault by another patient at our office).

Denial payments for the appropriate testing and screening procedures for drugs and alcohol required by the state and national guidelines would not only significantly impact pain program (such as CPMI) ability to function as a business, but would also put an extremely vulnerable patient population at risk. Our patient population is unique as compared to many of our peers. Our patients are extremely complex; we take pride in creating individualized treatment plans which do require a significant amount of testing and time for screening for substance and alcohol use. However, this allows our patients to achieve an extraordinary level of function relative to managing their pain and prevent morbidity and mortality.

Methodology

Risk Stratification for the patient in sample 1 (please see NARX table below):

NARX Score analysis of the patients in the sample.

Our treatment protocol, including the SBIRT protocol (G codes such as G0397), of the POC UDS (80307, 80304) and minimally invasive procedures on the pain reduction (76942, 64450, 64418, 20533 and other similar codes) is based on patient risk stratification, NARX risk stratification (validated by the CMS) LCD OH L36029 [27] and state and national guidelines.

NARX score is a nationally validated risk score accepted in the state of Ohio and many other states [9]. There are no frequency guidelines for the G code, however, the NARX score (that shows the risk of overdose and death) seems to be the golden standard accepted by the CMS and Medicare. The clinical recommendations by the CMS and SMBO attached (attachment NARX Manual, NARX clinical application).

Only 6% of the sample 1 patients (3/50 pts) are low risk (NARX below 100)

Only 16% are high risk (NARX 100-189) Odd ratio for overdose increased 10 times (chapter 12 Overdose Risk Score page 63 attached).

The rest are at a very high risk of 34% (NARX above 200) and an extremely high risk of 24% (NARX above 350). The odds ratio for death from overdose is 10-12 times average (see the clinical application of the NARX score attached page 67). The odd ratio for overdose increased 10-12 times or more (chapter 12 Overdose Risk Score page 63 attached).

Undoubtedly the patient with this type of risk would require frequent G code screening and another testing such as EMG.

The vast majority of the "sample 1" patients were on increased risk dose of the opioids (more than 20 MME- increased risk of death as per CDC 2016 guidelines increased adjusted Hazard Ratio (HR) for an overdose and death) [10], many patients obtained opioids

from more than one prescriber, used multiple pharmacies and multiple classes of opioid medications, some also used sedatives or stimulates that greatly increased the risk according to the CDC guidelines and NARX score database (please find original NRAX score reports for each patient attached).

These types of risky patients require a high frequency of SBIRT (G code use) based on the criteria discussed above.

Risk stratification of sample 2 (sent by a separate email) demonstrated similar results.

Use of SBIRT G code vs. use of the E/M office visit codes.

Many of the CPMI patients have multiple medical comorbidities and dependent on transportation (can schedule only a limited number of visits). Therefore on many occasions, we have to schedule the minimally invasive procedure and the office visit for medical management on the same date.

This study shows the advantages of using SBIRT/G codes rather instead of E/M level 3 or 4 codes in these encounters. This approach provides cost-saving to third party insurance payers and emphasizes the screening and brief intervention approach which is crucial in managing high-risk patients on opioid medications.

Cost-saving secondary to use of G code use vs more expensive office visit (E/M) codes:

According to the national standards for Pain Medicine [11] office visit codes, 99213 and 99214 combined constitute almost 100% of the total visit billings (48.8% for 99213 + 44.9% 99214). These codes are more expensive than G codes and can also be combined with time codes.

Our billing data analysis below shows that in our practice these more expensive office visit codes (99213 and 99214) constitute only 16-30 percent of the total annual visits.

Our practice started the appropriate use of G codes since its inception in 2014 (which explains the 91% percent increase in comparison to 2013).

The use of these codes was based on the certified biller and coder review below and saved Medicare tens of thousands of dollars (as proven by the billing and coding data below).

Between 16-30 % of our follow up visits were billed as the more expensive E/M codes 99213, 99214, the rest were billed as G codes instead of more expensive office visit codes.

In other words, analysis of G code and office visit codes E/M codes billed shows significant cost savings in using G codes vs. the use of more expensive E/M codes for the office visits. That is clearly demonstrated in the patient example 1: the 79 times the G code was billed - it was billed for 79 follow up visits instead of more expensive office visit code.

Coding and billing statistics for our office

	Office Visits	G Codes	Total Visits
2014	2330	5104	8239
2015	2056	5622	8157
2016	1146	6621	7885
2017	1373	7294	8491
2018	1160	7907	8111
2019	2317	8838	9494

Implementation of the LCD OH L36029 [27]

Our study also provides a clear proof that frequency of the SBIRT/G code monitoring should depend on the compliance with the prescribed opioid medications and NARX score risk stratification, rather than reliance on the self-reported risk factors like alcohol or drug use in the initial evaluation by the staff or by a pain psychologist.

LCD OH L36029 [27] sets the frequency of monitoring that depends on prescribed opioid medications and other elements and not only on the initial psychological evaluation that used. These are the factors that set the frequency of testing and screening (including the SBIRT/ G codes use).

- Patient history, physical examination, and previous laboratory findings
- Current treatment plan
- Prescribed medication(s)
- Risk assessment plan

The rationale for such screening LCD OH L36029 defines as:

- Identifies the absence of prescribed medication and potential for abuse, misuse, and diversion;
- Identifies undisclosed substances, such as alcohol, unsanctioned prescription medication, or illicit substances;
- Identifies substances that contribute to adverse events or drug-drug interactions;
- Provides objectivity to the treatment plan; e. Reinforces therapeutic compliance with the patient;
- Provides additional documentation demonstrating compliance with patient evaluation and monitoring; g. Provide diagnostic information to help assess individual patient response to medications (e.g., metabolism, side effects, drug-drug interaction, etc.) over time for ongoing management of prescribed medications.

All these elements and factors are documented in our records and evaluated in our study. We would like to illustrate the importance of this approach using the examples below:

Patient examples that show an efficient SBIRT implementation that enables successful patient participation in the program and timely detection of aberrant drug-seeking behavior.

(Patient examples reviewed by the ABPMR without protective health care information disclosure and provide examples of the common cases mistakenly denied overlooked by providers and denied by third party payers).

Example #1: [redacted] This patient-reported the last drink 26 years ago, however, this patients meet criteria for a high-risk patient with a chronic pain syndrome failed back syndrome after (s/p) 4 back surgeries). This is an example of SBIRT screening directed towards compliance with the prescribed opioid substances and confirmation of the lack of the non prescribed narcotic substances as per SMBO, Ohio Board of Pharmacy and NARX [25], CDC, and LCD OH L36029 We will analyze the necessity and the frequency of the SBIRT and G code screening (SBIRT /G code) code at least 79 SBIRT (G code) performed since 2015) and the impact on patient compliance and participation in the program.

Case Review: This is a patient s/p 4 back surgeries that require chronic pain management.

NARX score analysis/ example 1

Narcotic Score 470 Sedative Score 170 Overdose Risk Score 190 (Odds ratio for overdose and death is about 10 times higher than average please refer to the NARX score review material enclosed (25 In addition, he is currently on 60 MME daily (Three times the dangerous dose threshold per CDC guidelines), he has received more than 150 prescriptions from 5 different prescribers using 2 different pharmacies including high-risk substances like Oxycodone, Morphine Sulphate and Fentanyl (that is responsible for a large number of overdoses and death).

Since this is a high-risk patient on chronic opioid medications, he requires frequent follow-ups and compliance monitoring. Our practice monitored the patient compliance with at least 79 screenings and brief interventions performed over the span of the last 3-4 years. This number is conservative for this type of patient and required by the SMBO, Ohio Board of Pharmacy and NARX, CDC, and LCD OH L36029.

The screenings are related to continuous exposure to different narcotic substances and not to his prior drinking history as described above. Of note, this chart was reviewed by the Board of Pharmacy in 2015 and found fully compliant.

Use of different codes for this patients would have resulted in increased cost for the third party payers.

This example shows how efficient and cost-effective use of the SBIRT screening (G0397 code) use saves significant costs funds for the third party payers and enforces compliance for the high-risk patients.

Also, this patient has been coming to our practice for close to 5 years (despite multiple competing providers just a few miles away) and even volunteered a video testimonial (together with close to 70 other patients).

Example #2: [redacted]on the initial interview with the pain psychologist – the patient did not report any history of alcohol or drug abuse. The Board of Pharmacy NARX score defines this patient as a very high-risk patient:.

NARX score analysis/example 2

Narcotic Score 451 Sedative Score 290 Overdose Risk Score 370 Stimulant Score 20 (Odds ratio for overdose and death is about at least 12 times higher than average or more please refer to the NARX score review material enclosed [25] Additional risk factor more than 100MME with an average 40 MME daily (please find the original NARX report enclosed). Recently patients are getting 60 MME daily. These are very dangerous doses according to the NARX and CDC guidelines attached that require frequent SBIRT (G code screenings).

The patient received more than 82 prescriptions for several types of medications including Percocet, Oxycodone, Morphine, Hydrocodone, Phentermine, Lyrica, and Gabapentin from 7 prescribers and 5 pharmacies.

44 screenings and brief interventions (SABIRT/G code) performed over the span of the last 3-4 years for such risk patients is a reasonable required number as per SMBO, Ohio Board of Pharmacy, and NARX, CDC, and LCD OH L36029. The screenings are related to continuous exposure to different narcotic substances.

Use of different codes for this patients would have resulted in increased cost for the third party payers.

This example shows how efficient and cost-effective use of the SBIRT screening (G0397 code) saves enforcement for the very high-risk patients on multiple controlled substances and saves funds for third-party payers.

Example #3: [redacted]

Case Review: This is a chronic pain patient with a symptomatic spinal stenosis who requires chronic pain management. Besides, the patient reported being a victim of physical domestic abuse (additional risk factor) and required chronic benzodiazepine therapy (alprazolam).

The patient had multiple prescriptions of alprazolam (potent benzodiazepine) combined with opioids [12] which is an additional high-risk factor for overmedication and death that requires SBIRT interventions each time the combination is prescribed according to the CDC guidelines. Please find the list of the prescriptions enclosed.

The patient had an abnormal urine drug screen which positive for non prescribed benzodiazepine (which a very high-risk factor combination of medications as per accepted guidelines) and the follow up pain psychology report that conditioned patient clearance for opioids with closed monitoring (SBIRT protocol/G codes). 26 screenings and brief interventions (SBIRT/ G codes) performed over for such a very high-risk patient is a reasonably required r as per SMBO, Ohio Board of Pharmacy and NARX, CDC, and LCD OH L36029.

The screenings are related to continuous exposure to a combination of benzodiazepines narcotic substances and not to the patient's prior drinking history. Use of different codes for this patients would have resulted in increased cost for the third party payers. This example shows how efficient and cost-effective use of the SBIRT screening (G0397 code) saves enforcement for the high-risk patients on opioids and benzodiazepines and saves funds for the third-party payers.

Cases 1-3 show that despite the initial denial of prior risk factors (i.e drinking history) on the initial psychological interview, NARX score and structured assessment analysis can help to implement proper SBIRT/ G code screening for safety and compliance.

Example #4: [redacted]

Patient chart review shows that the patient was prescribed on [redacted] 2016, 30 tablets of OxyCodone 5 /APAP 325 for 15 days as per state prescription monitoring system (OARRS). On [redacted] our practice performed a random urine screen that was NEGATIVE for prescribed OxyCodone. The urine screen was reviewed by a Doctor of Pharmacology consultant and discussed with a pain psychologist, both of them requested tight monitoring because of concern for medication diversion (which is considered a felony by the state of Ohio and federal law).

Also, the follow-up note dated [redacted] states that the patient did not bring medication bottles for a pill count. The patient claimed she "has a lot of Percocet at home" raising additional concerns about hoarding and medication misuse. Unfortunately, the patient was not compliant with the reasonable monitoring and self-discharged herself.

NARX score analysis/example 4

This patient has a high NARX score (Narcotic score 371, Sedative score 150, Overdose risk score 170), she received opioid medications from 7 prescribers, using 4 pharmacies based on the Board of Pharmacy database.

In summary, our management of the case was appropriate and mandated by the federal and state law, SMBO, Ohio Board of Pharmacy, DEA, and CDC regulations. Patient examples of proper use of informed consent and respect for patient autonomy based on the AANEM policies and guidelines [6,7].

In the previous part of the study dedicated to the EMG/ NCV protocol, we introduced the use of informed consent in our practice. The following examples analyze the use of the informed consent by the patients.

Example # 5

[redacted] This is a high-risk patient (NARX score analysis defines her as a high-risk patient: Narcotic Score 441 Sedative Score 200 Overdose Risk Score 340 (Odds ratio for overdose and death is about 10 times higher than average as per Ohio PMDS (OARRS) manual [25]. The Board of pharmacy summary also mentioned more than 5 opioids or sedative providers from 4 pharmacies. Proper testing such as NCV/EMG testing is necessary for such a patient for documentation of organic pathology.

This patient "First refused the needle EMG, then left the box unchecked and then agreed to the needle EMG test". The patient refused the needle EMG in 2014, later when the patient required prolonged care in 2016, and in 2017 she agreed to the needle testing. In 2016 she gave verbal consent (not marking the checkbox is irrelevant based on the AANEM ethical guidelines enclosed) and 2017 she gave both verbal and written consent which is also consistent with the guidelines. Patient informed consent for and against the testing was respected each time as per AANEM and Medicare consent policy. The 2014 and 2016 tests were both carpal tunnel evaluation exempt by the AANEM policy and provided credible information even without the needle testing.

Example # 6 [redacted]

[redacted] is a high-risk patient. (NARX score analysis defines her as a high-risk patient: Narcotic Score 381 Sedative Score 160 Overdose Risk Score 210 (Odds ratio for overdose and death is about 10 times higher than average please refer to the NARX score review material enclosed [25]. [redacted] recently had a urine screen positive for use of illicit marijuana (as per consultation with the Doctor of Pharmacology consultant). The Board of pharmacy also mentioned more than 4 opioids or sedative providers from 2 pharmacies (total more than 50 prescriptions). Proper monitoring testing such as NCV/EMG testing and alternative procedures are necessary for this patient.

This patient also has been seen at our practice for several years (despite multiple competing providers just a few miles away) that testifies for the quality of care she has received. Close follow up that included an interview by pain psychologist and psychological assessments helped to address patient anxiety. This patient initially refused the needle EMG testing. Even though the test is called "Needle" EMG, the test is performed using a recording probe (and not a needle) in a conventional sense (nothing is injected through the EMG "needle"). Therefore it's quite natural for a patient to refuse the needle EMG testing that does not directly relieve the pain (and also involves 6-12 probe sticks).

At the same time, the patient agreed to the nerve block injection that involved one small needle stick that provides immediate pain relief through medications injected through the needle. Patient informed consent for and against the testing was respected each time as per AANEM and Medicare consent policy. The 2014 and 2016 tests were both carpal tunnel evaluation exempt by the AANEM policy and provided credible information even without the needle testing.

POC UDS testing

Use of the POC UDS testing performed in compliance with the state and federal guidelines as part of the patient monitoring program using the risk stratification scale discussed above. Data shows a significant impact of the testing on the patient treatment plan and compliance [13-15].

Ultrasound-guided procedures

Ultrasound-guided procedures (peripheral nerve blocks, trigger point injections, and others). The minimally invasive procedures are cost-effective alternatives to the opioid medications required by the guidelines. All the patients received the informed consent and the medical necessity forms. Statistical analysis shows a strong impact of these procedures on the patient treatment plan and compliance.

Analysis of sample 2 – discharged patients

We have reviewed the charts of patients positively screened for non-compliance with the patient contract (illicit substance abuse, failed pill counts, doctor shopping, urine screens negative for prescribed medications, and other issues) using the SBIRT protocol (G codes) that we discussed.

Methods

- A retrospective review of charts of regular and incomplete studies to assess the impact of the test on the treatment decision making (such as choosing non-opioid adjuvant medications and opioid medications, pain reduction and functional improvement as documented by PADT forms and performance of proper clinical assessment that justify study repletion in the selected group of patients.
- The retrospective review studies the impact of the frequency of the SBIRT protocol (G codes such as G0397), of the POC UDS (80307, 80304) and minimally invasive procedures on the pain reduction (76942, 64450, 64418, 20533 and other similar codes) on the treatment decision making (such as choosing non-opioid adjuvant medications and opioid medications), pain reduction and functional improvement as documented by PADT forms and performance of proper clinical assessment as all the compliance and participation in the program (lengths of participation in months).

When pain reduction was 30%-50% we defined it as a "Moderate", above 50% a "Significant" and more than 70% a very significant pain reduction. When functional improvement as documented by PADT included 2 parameters or more, we called it significant, if only one parameter we called it a "moderate" functional improvement. If three or more functional parameters improved we called a very significant improvement. The effect is illustrated with several patient example analyses.

Results

SBIRT and UDS and procedure impact analysis

Sample 1

NARX Score (risk stratification) and SBIRT protocol screening effectiveness analysis.

The table below how the average NARX scores change with Months in Program:

Table 1:

Months	Average	Max	Number Patients
Short (1 month)	308	450	6
Medium (>1 month, < 2 years)	271	390	13
Long (2 years)	309	770	23

NARX Score (risk stratification) and SBIRT protocol screening effectiveness analysis results

Enforcing and monitoring patient compliance is a major challenge for pain management programs. The average and the maximum NARX scores reflect the high risk and the very high-risk profile of our patient population. Our SBIRT protocol and other tests and treatment described in the study is effective in monitoring and enforcing the high-risk patient compliance for prolonged periods (more than 23 months).

Functional Improvement Analysis

The table below compares Months in Program vs Functional Improvement (based on the PADT and other tools). Given the low number of patients in the 'less than a 2-year group, these 3 groups are combined.

Table 2:

	Moderate	Significant	Very	Total
Less than 2 years	16	7	6	29
2 years	5	1	20	26
	21	8	26	55

Table 3:

% of Row Totals for the table above.

	Moderate	Significant	Very
Less than 2 years	55.2%	24.1%	20.7%
2 years	19.2%	3.8%	76.9%

For example, of the 26 patients with 2 years of treatments (for whom we also had data on Functional Improvement), 20 of them or 76.9% showed Very Significant Improvement.

Performing a chi-square test in Table 3 (combining the first 2 columns to enhance the test) shows there is a significant difference in 'months of Treatment ($p<.01$).

Functional Improvement Analysis Results

There is a significant relation (at .05 level) between Months in Program and Functional Improvement. The SBIRT protocol and other treatments in our program showed a strong statistically significant impact on the patient functional improvement – which is the main outcome measure of the pain management program.

Pain Reduction analysis

Table 5:

	Moderate	Significant	Very	Total
Less than 2 years	22	4	2	28
2 years	17	5	4	26
Total	39	9	6	54

Table 6:

% of Row Totals for Table above

	Moderate	Significant	Very
Less than 2 years	78.6%	14.3%	7.1%
2 years	65.4%	19.2%	15.4%

Most patients had only moderate pain reduction (72.2%). Of the patients in the program for 2 years, 15% (4 out of 26) had Very Significant pain reduction while 65% of the 2-year patients had Moderate Pain Reduction.

Performing a chi-square test on Table 5 (combining the last 2 columns to enhance the test) shows there is a significant difference in 'months of Treatment ($p=.02$).

Pain Reduction analysis results

We demonstrated a very significant pain ($p=.02$) reduction over time in our program. As time participation in the program increases (more than 2 years), the pain reduction becomes more significant.

Statistical analysis

Sample 2

NARX Score (risk stratification) and SBIRT protocol screening effectiveness analysis

The table below how the average NARX scores change with Months in Program

Table 7:

NARX Score vs Months in Program

	Average	Max	Number Patients
< 2 years	317	480	9

NARX Score (risk stratification) and SBIRT protocol screening effectiveness analysis results (sample 2):

Enforcing and monitoring patient compliance is a major challenge for pain management programs. As we have observed in sample 1, in sample 2 the average and the maximum NARX scores reflect the high risk and the very high-risk profile of our patient population. Our SBIRT protocol and other tests and treatment described in the study is effective in monitoring and enforcing the high-risk patient compliance for prolonged periods (more than 23 months).

Functional Improvement Analysis

The table below compares Months in Program vs Functional Improvement (based on the PADT and other tools). Given the low number of patients in the 'less than a 2-year group, these 3 groups are combined.

Table 8:

Months in Program vs Functional Improvement

	Significant	Very	Total
< 2 years	5	6	11
2 years	8	25	33

Table 9:

% of Row Totals for the table above

	Significant	Very
< 2 years	45.5%	54.5%
2 years	24.2%	75.8%

The table below compares Months in Program vs Functional Improvement (based on the PADT and other tools). Given the low number of patients in the 'less than a 2-year group, these 3 groups are combined.

Functional Improvement Analysis Results

All the patients in the sample stayed in the program for 6 months or longer, most of the patients for 2 years or longer. All the patients achieved functional improvement at 6 months and continue with significant or very significant improvement after that.

Pain Reduction analysis

Table 10:

Months in Program vs Pain Reduction

	Moderate	Significant	Very	Total
< 2 years	4	5	0	9
2 years	0	21	11	32

The difference between the "< 2 years" group and the "2 years" group is statistically significant (binomial test, P<.01)

Table 11:

% of Row Totals for Above Table

	Moderate	Significant	Very
<2 years	44.4%	55.6%	0.0%
2 years	0.0%	65.6%	34.4%

Pain Reduction analysis results

We demonstrated a very significant pain (p=.01) reduction over time in our program. As time participation in the program increases (more than 2 years), the pain reduction becomes more significant.

Sample 3 (discharged patients)

Discharge Reason	Number Patients	% Total Patients	3 months	6 Months	12 Months	2 years	Average NARX Score	Number with NARX Score
COC	14	35.9%	7	2	4	1	367	14
THC	2	5.1%	2	0	0	0	160	1
METH	2	5.1%	2	0	0	0	80	1
ETOH	12	30.8%	2	2	5	3	442	11
FENT	1	2.6%	1	0	0	0	50	1
ADLTERATION OF URINE	3	7.7%	3	0	0	0	236	3
BUP	5	12.8%	4	0	0	1	486	5

Two-thirds of all Discharge reasons were for COC or FPC.

Dividing the patients into 3 groups, COC, FPC, ALL Others, there is no significant difference in Average NARX Score amongst the 3 groups (t-test at .05 level).

Discharged patient analysis results

Data shows the high complexity and the high-risk status of our patients. The most discharged patient tested positive for cocaine (COC) and ETOH (35.9 and 30.8 percent), the highest NARX score was associated with buprenorphine (486).

NCV/EMG study analysis results

All initial and repeated tests were performed after a comprehensive evaluation and proper documentation of medical necessity as required by the AANEM guidelines and Ohio LCD.

All NCV tests with or without EMG testing had a documented impact on the narcotic and non-narcotic medication prescriptions, pain reduction, and functional improvement.

There was a significant association between pain reduction and functional improvement.

	Pain Reduction	Functional Improvement
Moderate	58.3%	20.8%
Significant	16.7%	25.0%
Very Significant	25.0%	54.2%

Applying a chi-square statistic to patient outcomes of functional improvement, we observe: that NCV and NCV+EMG are statistically significant at the .05 level.

Association between the repetition of the test and functional improvement (number of studies and percent of patients):

	Moderate	Significant
No Repeat	5	5
Repeat	0	14

	Moderate	Significant
No Repeat	20.8%	20.8%
Repeat	0.0%	58.3%

Conclusion

SBIRT analysis

The use of the SBIRT protocol (G codes such as G0397), of the POC UDS (80307, 80304) and minimally invasive procedures on the pain reduction (76942, 64450, 64418, 20533 and other similar codes) show a significant documented positive effect on increasing overall patient safety, encouragement of safe controlled substance prescribing for practitioners, maintaining compliance with State and Federal laws and regulations, reduction of patient overdose deaths, early detection and intervention of substance use disorder, and improving overall standards of care.

The vast majority of patients in the sample fit the high-risk profile which requires frequent SBIRT monitoring. CPMI SBIRT protocol is associated with effective long-term monitoring of compliance of the chronic pain patients on opioid medications and effective diagnostics of aberrant drug-seeking behavior and referral to Addiction Medicine evaluation. Our protocol is based on the "Pain Management Best Practices Inter-Agency Task Force Report", Medicare MLN and LCD OH L36029, Medicare guidelines for the presumptive and definitive testing, Medicare CPT code definitions.

This study has important conclusions for third-party payers and clinicians. SBIRT protocol (G codes such as G0397) is mandatory for a compliant pain management practice. Without proper implementation of the SBIRT protocol (G codes such as G0397), a safe and compliant pain management program is hardly possible, and patients and staff are exposed to significant risks.

Alcohol/substance abuse structured assessments and brief interventions of 30 minutes or longer, under code G0397 (SBIRT protocol) performed at Comprehensive Pain Management Institute, LLC are based on the accepted guidelines and "HHS Pain management best practices inter-agency task report" and required for the state and federal guidelines compliance. The SBIRT protocol is documented on all the charts in the study and compliant with the Medicare MLN # and LCD OH L36029.

This study shows a significant positive impact of the SBIRT protocol on pain reduction and function improvement is well documented in this study. SBIRT protocol is mandatory for the compliant operation of a pain management clinic providing medical management to the population with a significant percent of high-risk patients in the high-risk area like Ohio. Denial coverage for these services by third-party payers or defining them as "unallowable costs" puts the practice in noncompliance with the guidelines described above making the ethical operation of the practice impossible and putting patients and staff at considerable risk.

Denial payments for the appropriate testing and screening procedures for drugs and alcohol (such as of the SBIRT protocol (G codes such as G0397) required by the state and national guidelines) would not only significantly impact of a pain program ability to function as a business, but would also put an extremely vulnerable patient population at risk. The chronic pain patient population is unique as compared to many other specialties. Our patients are extremely complex; we take pride in creating individualized treatment plans which do require a significant amount of testing and time for screening for substance and alcohol use and other tests and procedures described in this study. However, this allows our patients to avoid the risk of morbidity and mortality (Ohio has one of the highest rates of opioid mortality per 1000 population in the country) and achieve significant pain relief and improvement in the level of function relative to managing their pain.

NCV/EMG analysis

Using a chi-square test, we can and conclude (with $P<.01$) that repeating the test has a positive association with functional improvement.

The association can be explained by the fact that an additional comprehensive evaluation was performed prior to the test and additional NCV and EMG test results were incorporated in the treatment plan that helped to achieve additional functional improvement.

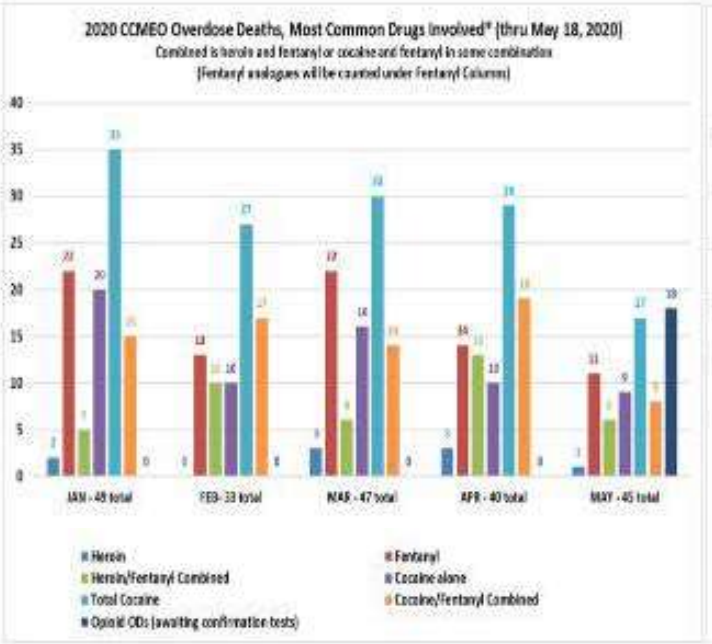
A functional improvement which is the main goal of pain management program (which is more important that pain reduction) has most strong statistically significant improvement with the use

of the NCV and EMG testing (with or without the needle testing). These findings underscore the medical necessity and cost-effectiveness of the NCV and EMG tests based on the sample examined.

NCV with or without needle EMG tests as part of the effort to document organic pathology (both initial tests and follow up tests) are medically necessary tests and cost-effective tests that have a strong statistically significant contribution to the proper choice of medications and procedure for chronic pain patients and strongly associated with functional improvement and pain reduction.

Despite a possible improvement in 2018-2019 data, objective data (Figure 1) shows that a new approach described in this review by the medico-legal system and third party payers required to address the opioid crisis and protect the population at the high risk for COVID 19 epidemic (Figure 2). These trends are confirmed by the Cuyahoga County Medical Examiner's Office (Figure 4 and 5) for 2019 and the beginning of the 2020. Of note, Cuyahoga County is one the most affected counties by COVID-19 as well.

Figure 4,5 and 6 (Cuyahoga County Medical Examiner's Office)



As a small independent office, without a special research budget me have done our best to provide SBIRT care with is compliant with the best standards in the specialty based on the American Board of Physical medicine and Rehabilitation and HHS guidelines discussed above.

We advocate for large prospective studies and provider and third party payor education on these subjects.

Additional risks of SBIRT denials during the COVID-19 pandemic American Academy of Pain Medicine (AAPM)

American Academy of Pain Medicine (AAPM) recently made recommendations for COVID-19 pandemic 20) additional requirements for SBIRT including additional withdrawal screening and mental screening suggested. Denial of the SBIRT and other services exposes staff and patients for additional risks during the pandemic. In addition the AAPM guidelines required using expensive personal protective equipment (such as N-95 masks). Denials of the SBIRT and other services deplete necessary practice funds required for the personal protection equipment and creates additional risks for staff and patients. The recent AMA brief [26] alarms about great concern over increased opioid mortality during COVID 19 pandemic.

Concerns for singling out minority patient populations and practices

There are multiple concerns raised about racial disparity, social injustice in context of the opioid crisis. Specifically concerns related to the fact that minority populations and practices targeted with unjust denials of the SBIRT and other essential services. On many

occasions, these denials are done without a proper review process specified in the Medicare integrity manual, without adequate expert review and with no expert review at al. That is one the reasons for the increased gap between opioid mortality in Ohio and average nation levels (2,6 time higher in Ohio, see Figure 1).

Huge Medicare Medic Aid HMOs silence criticism of these policies and denials by ignoring business integrity and patients safety retaliatory recoupment and forcing providers to resign from the plan. Several concerns were raised about Caresource the billion dollar HMO that controls more then 50% of the Ohio market by more than ten senators (Figure 7) in 2018. In April 2020 Case Western Reserve University, Board of Health of Cuyahoga County organized a conference on the Racial Disparity, Social Justice and the Opioid Crisis Conference at Case Western Reserve University [21] (the conference had to be postponed because of the pandemic). In June 2020, both Columbus and Cleveland proclaimed racism a public health emergency [22,23]. It is important to see these declaration and concerns translated into practical changes to avoid additional risk to the medical personnel and patients.

Concerns of the overregulated environment

As discussed during the Case Western Reserve University meeting [16], regulations, audits and supervision are necessary in middle of the opioid crisis. At the same time excessive regulations that interfere with efficient function of the pain clinics (the first responders in the opioid crisis), manipulation of the regulatory agencies by the retaliatory complaints from patients discharged for non compliance result in a significant worsening of the opioid crisis. (Figure 1).

SBIRT and other services denials and security risks to the staff and patients

The recent survey by the American Academy of Pain Medicine found high rate of finds high rate of violent threats toward pain practitioners [24]. Our practice has suffered from property damage, threats to the staff and recently from an unprovoked assault of the physician and two female medical assistants by a violent patient with aberrant drug seeking behavior.

The Columbus city prosecutor (Case [redacted] mentioned that "Because of the lack of funding secondary to insurance denials of essential services (such as screening and brief intervention for drug and alcohol) (pain practices like ours) do not have appropriate funding for additional security measures".

This is a real public safe and health crisis that requires urgent attention.

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Expert panel of the American Board of Physical Medicine and Rehabilitation (ABPMR)

Roneet Lev MD, Chief Medical Office, White House Office of National Drug Control Policy Executive Office of The President.

Sabaitu I. Mansarai a Senior Executive Service (SES) with the Office of National Drug Control Policy where she is the Assistant Director for Public Health, Education and Treatment Task Force in support of combating the opioid crisis.

Ohio Opioid Task Force, Cuyahoga County Board of Health

Case Western Reserve University continuous education program expert panel

This data was reviewed and approved by the American Board of Physical Medicine and Rehabilitation [19].

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Exhibit I

Comprehensive Pain Management Institute, LLC

Compliance Program Manual

Adopted: 3|1|2011

Revisions/Updates:

10|2019

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INTRODUCTION

This Compliance Program Manual, including the Compliance Plan and Code of Conduct, is adopted as part of Comprehensive Pain Management Institute, LLC's (the "Practice") commitment to voluntarily comply with all applicable laws and regulations, and as a part of our overall mission and purpose. This documented Compliance Plan also helps the operational efficiencies of the Practice by speeding up and optimizing proper payment of claims, minimizing billing mistakes, and avoiding conflicts with the self-referral and anti-kickback statutes.

We are committed to those ideals reflected in our Statement of Purpose and in the Code of Conduct. We are equally committed to assuring that our actions consistently reflect our words. In this spirit, we expect all of our colleagues' actions to reflect the high standards set forth in our Code of Conduct.

Areas of particular focus are those identified by the OIG as specific compliance risk areas for physicians, including: (1) proper coding and billing; (2) ensuring that services are reasonable and necessary; (3) proper documentation; and (4) avoiding improper inducements, kickbacks, and self-referrals. These risk areas reflect areas in which the OIG has focused its investigations and audits related to physician practices. The Practice will focus on identifying risk areas including documentation and billing problems and on correcting any problems appropriately.

This Compliance Plan will address some or all of the following:

1. conducting internal monitoring and auditing through the performance of periodic audits;

2. implementing compliance and practice standards through the development of written standards and procedures;

3. designating a Compliance Officer and/or contact(s) to monitor compliance efforts and enforce practice standards;

4. conducting appropriate training and education on practice standards and procedures;

5. responding appropriately to detected violations through the investigation of allegations and the disclosure of incidents to appropriate government entities;

6. developing open lines of communication regarding erroneous or fraudulent conduct issues; and

7. enforcing disciplinary standards through well-publicized guidelines.

STATEMENT OF PURPOSE

Comprehensive Pain Management Institute, LLC (the "Practice") has adopted this Compliance Program to enhance the care of our patients. Through this Program, the Practice is committed to achieving the following goals:

1. **To provide the highest quality care;**
2. **To properly document the nature of professional care provided to our patients;**
3. **To submit claims for reimbursement to federal health care programs and other third-party payors as promptly and accurately as possible;**
4. **To continually educate and keep all employees of the Practice informed as to changes and updates in billing procedures and programs;**
5. **To strive to achieve zero mistake billing; and**
6. **To promptly correct any billing errors that may be discovered.**

The Practice realizes that financial resources to provide quality care are generated through timely and accurate billing for services performed by our physicians. This Compliance Program will provide guidance to avoid improper referrals or other circumstances that may create an appearance of unauthorized conduct so that the Practice will remain in compliance with all government rules and regulations and contract terms with third-party payors.

If any employee of the Practice has any questions or concerns, they should immediately bring those items to the attention of the Practice's Compliance Officer. The Compliance Officer is: _____ or his/her designee.

COMPLIANCE PLAN

Section I – Compliance Officer

The Practice shall designate a Compliance Officer to supervise and aid in The Practice's compliance with the terms of this program. _____ (or his/her designee) is designated the Chief Compliance Officer with overall responsibility for compliance issues.

The following identifies the basic responsibilities for the Compliance Officer. In addition to these items, the Compliance Officer shall perform such other duties as may be appropriate to meet the objectives of this Compliance Program. The Compliance Officer will:

1. Oversee and monitor the implementation of the Compliance Program;

2. Establish methods to improve the Practice's efficiency and quality of services delivery;

3. Develop methods of evaluating the Practice's efficiency in billing including, where appropriate, conducting periodic audits;

4. Be responsible to review all government or private-payor health plan bulletins, reports, and updates and make appropriate changes in the Practice's procedures;

5. In the event an outside billing service is used by the Practice, will review the compliance programs of the billing service and to obtain written commitments from those services to use compliance programs;

6. If computerized billing software is used by the Practice, will coordinate with the designated representative of the software vendor to assure updates are promptly included in software and to obtain reasonable verification of the updates;

7. Develop and coordinate training programs for all appropriate personnel and employees of the Practice, upon hire or other engagement as part of their orientation within sixty (60) days of being hired and annually thereafter, in regards to the compliance programs and to maintain appropriate records of participation in those training programs;

8. Review the HHS-OIG's List of Excluded Individuals and Entities, the General Services Administration's List of Parties Excluded from Federal Procurement & Non-Procurement Programs, and the Medicaid Exclusion List ("Exclusion Lists") prior to employment of any individual or entering into contractual relationships with independent contractors and third parties, and every 6 months thereafter for the same individuals, independent contractors, and third parties;

9. Communicate the Practice's commitment to compliance to independent contractors and other agents working with or on behalf of the Practice;

10. Investigate any report or allegation concerning possible unethical or improper business for billing practices and report to the Practice's administration the results of such inquiries if there is a verification of improper conduct;

11. Assure that all employees are provided access to this Compliance Program and that they have been made aware of the terms of the Program;

12. Take steps to monitor corrections to prior errors or incorrect business practices;

13. Take such other steps that may be reasonably prudent or necessary to remain in compliance with government rules and regulations;

14. Maintain the Compliance Program binders, which will include this program plan, current updates and releases from government sources including, but not limited to, CGS Medicare, other Medicare and Medicaid carriers, the OIG Special Fraud Alerts, and OIG and CMS Advisory Opinions; and

15. Maintain separate records of any communications from Medicare regarding billing inquiries or documents related to disallowance of claims, and to report to the Practice's administration any patterns of claim rejection or disallowance and make recommendations for corrective steps for the future.

Section II – Auditing and Monitoring

A. Monitoring and Internal Audits.

On a periodic basis and at least once a year, the Compliance Officer will review the Practice's standards and procedures to determine if the Practice is utilizing the complete and most current standards and procedures contained in the government regulations. The Compliance Officer will at least quarterly verify that there have not been changes in the Current Procedural Terminology (CPT) and ICD-10 Codes. In the event of a change in codes or procedures, the Compliance Officer shall maintain an archival copy of the former codes under the Practice's Records Retention Plan as provided in Section IV hereafter.

B. Review of Submitted Claims.

The Compliance Officer will conduct a baseline audit of an appropriate sampling of claims and documentation. This baseline audit may include the use of external auditors. If the baseline audit results in any negative findings, the Practice will work with legal counsel to take corrective action in the areas indicated and will modify the Compliance Plan as appropriate.

C. Periodic Audits.

On a periodic basis and at least once a year, the Compliance Officer will conduct an audit of a randomly selected number of medical records to verify that coding was performed accurately and that appropriate documentation was prepared for the services rendered. The Compliance Officer, after consultation with the Practice's administration, may use external auditors to assist in annual audits.

In addition to periodic audits of bills that have been prepared for submission but not yet submitted, the Compliance Officer will periodically review rejected claims to evaluate whether a billing error was the result of an occasional human error or if there was a system or procedure error for which immediate corrective action will be undertaken.

The internal audits will be conducted to determine:

1. Whether bills are accurately coded and reflect the services provided;

2. That the documentation in the medical record supports the coding;

3. That the documentation is completed correctly;

4. That the documentation explains why the services or items provided were reasonable and necessary for the patient; and

5. Verification that no incentives existed for unnecessary services.

D. Procedures for Corrective Action.

In the event of a baseline audit, a periodic audit, or a review of claim rejections indicates that an overpayment has been received, the Compliance Officer will immediately report his/her findings to the Practice's administration. When appropriate, the Compliance Officer will contact the carrier to arrange repayment or other financial adjustments in accordance with applicable regulations on the reporting and returning of overpayments, as appropriate. For overpayments identified from government payors, the Practice will report and return such overpayments within 60 days or as otherwise required by applicable law. In the event that the matter is of greater significance, the Compliance Officer will contact legal counsel for The Practice. If the Compliance Officer has any questions, they may also contact the appropriate carrier. Any call should be documented in the Communication Section of this Compliance Plan as to date, topic, the name of the person at the carrier, the response, and future action.

Section III – The Practice Standards and Procedures

It is the policy of the Practice that its physicians and all employees will strive to provide the highest quality of care for its patients. To achieve this goal, the Practice is committed to providing complete and thorough information to its patients and to appropriately document and bill for the services performed.

The Compliance Officer will update this manual based upon periodic releases and changes from government offices, and where appropriate to update clinical forms periodically to assure that the forms accurately reflect current processes and billing procedures. In the event of any changes, the Compliance Officer will also retain the copy of the prior form for historical purposes.

As noted above, the Compliance Officer will maintain a binder that will contain relevant directives, carrier bulletins, and appropriate OIG documents including Special Fraud Alerts and Advisory Opinions. The binder will be retained in an accessible area to all appropriate personnel.

A. Coding and Billing.

The Practice recognizes that it is important to accurately record and bill for services that are reasonably necessary for the benefit of our patients and to bill for only those services that are covered for third-party payment. The Practice acknowledges that there are some services that are necessary for the best interest of the patient but may not be covered for payment from a third party.

It is the policy of the Practice, in connection with coding and billing, that the Practice will:

1. accurately bill for items or services that were rendered by the Practice;

2. only submit claims for equipment, medical supplies, and services that are reasonable and are necessary for the patient;

3. avoid any double billing for services or items;

4. not bill for non-covered services (except to obtain a denial in order to submit to secondary payors);

5. only use appropriate provider identification numbers;

6. use coding modifiers when appropriate (see the CMS Medicare Provider Manual and National Correct Coding Initiative);

7. not unbundle services unless appropriate;

8. not cluster bill;

9. only use the code for the service actually performed;

10. follow the official coding guidelines as promulgated; and

11. prepare medical record documentation to support billing.

B. Hold Bills Until Questions are Answered.

In the event of any questions concerning coding, a bill should not be submitted until the question has been resolved by the Compliance Officer.

C. Review of Rejected Claims.

The Compliance Officer will review periodically all claims that were rejected based upon the diagnosis and procedures codes and will initiate such corrective or improvement steps as may be appropriate.

D. Reasonable and Necessary Services.

The physicians providing services on behalf of the Practice, whether as employees or independent contractors, shall be free to make independent professional judgments concerning the care and treatment for our patients based upon their independent professional judgment and National and Local Coverage Determinations ("NCDs" and "LCDs"). The physicians should, where appropriate, order such tests that their judgment indicates is appropriate for patients whether or not third parties will pay for such services. Occasionally, there are services that may be appropriate for the patient but which are not covered for reimbursement through Medicare. If the patient has a secondary payor, a physician may bill Medicare for the service in order to obtain a denial of coverage so that the group may seek reimbursement from the secondary payor.

E. Advance Beneficiary Notices.

If a physician believes that a service or treatment is warranted for a patient, but the physician believes

that the service or treatment is not covered by Medicare, a physician will be required to provide an Advance Beneficiary Notice of Non-coverage ("ABN"), Form CMS-R-131, to such patient, which requires the patient's acknowledgement. The ABN will provide that in the event Medicare does not pay, the patient is responsible for payment and which requires the patient's acknowledgement:

1. Lack of medical necessity;
2. Prohibited, unsolicited telephone contacts;
3. Supplier number requirements not met; or
4. Denial of an Advanced Determination of Medicare Coverage (ADMC) request; or

Each ABN must: (1) be in writing on the CMS -approved form; (2) identify the service address, and telephone number; (3) identify the beneficiary; (4) identify the prescription or item that may be denied (by procedure name and code if possible); (~~3) identify the~~ 5) state that you believe Medicare is likely (or certain) to deny payment for the particular prescription or item; (6) identify the reason why the physician believes that service coverage may be denied; (47) state the estimated cost of the service; and (5) state that the ABN must be executed and signed by the patient.. Blank ABN forms should never be presented to a patient for signature.

F. Documentation.

The Practice physicians and other licensed professionals are responsible for appropriately documenting all patient information, including diagnosis and instructions to patients. All medical records should be documented according to the CMS Documentation Guidelines for Evaluation and Management Services, as well as such appropriate other requirements. Documentation should meet the following standards:

1. Be legible, complete, and timely;
2. State the primary reason for the visit, test or procedure (chief complaint or diagnosis);
3. If appropriate, specify relevant patient history, physical examination findings and any prior diagnostic test results, the assessment, clinical impression, or diagnosis, the instructions to the patient or the plan of care, the date of the visit/test or procedure, and the legible identity of the physician conducting the

evaluation;

4. While in some circumstances, the rationale for ordering diagnostic services may be inferred by an independent reviewer, it is better practice to specifically note why a diagnostic test or ancillary service was requested;

5. A bill under specific CPT or ICD-10 Codes should be supported by the documentation in the medical records;

6. Where appropriate, health risk factors should be identified; and

7. On subsequent visits, if any, the patient's progress, their response to treatment, and any changes in the diagnosis or treatment plan should be documented.

G. Claim Submission.

The following practices will assist in insuring the proper completion of claim submission forms, whether electronic or on Form CMS-1500, as allowed under the Administrative Simplification Compliance Act:

1. Link the diagnosis code with the reason for the visit or service;

2. Use modifiers when appropriate; and

3. Provide Medicare with all information about secondary payors when such information is known.

The Compliance Officer will periodically review denials related to documentation and will recommend appropriate corrective steps for future compliance and assistance to the Practice. If available, the Compliance Officer will likewise review denial rates for similar specialties when that information is made available from the carrier.

H. Improper Inducements, Kickbacks, and Referrals.

It is the policy of the Practice to fully comply with all federal laws and regulations that prohibit the taking of any remuneration to induce business or making referrals to entities or providers that may contradict federal law. Specifically, the Practice will not offer, pay, solicit, or receive bribes or kickbacks or other remuneration in order to induce business reimbursable by federal health care programs. The Practice further

will not make any referrals to an entity with which a physician within the Practice or any member of their immediate family has a financial relationship, if the referral is for the furnishing of designated health services, unless the relationship fits within one of the regulatory exceptions. Additionally, Practice physicians, employees, and marketing and sales representatives will not offer physicians, patients, or other potential referral sources remuneration or incentives, in cash or in kind, in exchange for their business.

It is the policy of the Practice that its physicians shall make informed professional judgments in the best interests of the patient, without regard to any potential benefit, direct or indirect, to the physician by any referral to or from particular sources for additional care or treatment.

If the Practice has any contractual relations with third parties regarding referrals or the like, all such contracts or arrangements must be reviewed by legal counsel for the Practice to verify that the arrangements are in compliance with the current law. In the event that that the Practice has any business arrangements where physicians may refer business to or order services or items from an outside entity, all such financial arrangements must be on a fair market value basis for those goods or services.

I. Professional Courtesy and Deductible Waivers.

Because of the complexity of the issues where there may be an appearance of an inducement or potential inducement, it shall be the policy of the Practice not to provide free services or waive co-insurance or deductible payments for anyone except in those circumstances where the patient is in financial need and cannot make reasonable alternative arrangements without creating a hardship to the patient or their family.

J. Gifts and Business Courtesies.

Other than nominal gifts having a value of $25 or less per occurrence, and $392 per year (for 2016, to be adjusted annually as allowed under the federal Stark Law), it is the Practice's policy not to give gifts to physicians or other parties who might be or become referrals sources to the Practice. Furthermore, the Practice and its employees will not accept gifts, other than those with nominal value as defined above, from other physicians or entities who may desire referrals from the Practice. At no time will the Practice or any of its

employees accept, offer, solicit, or receive cash or cash equivalents as gifts to or from referral or potential referral sources or a party to whom the Practice does or may refer. Finally, the Practice and its employees will not offer gifts to beneficiaries in exchange for conducting business with the Pharmacy.

K. Certification of Medical Equipment, Supplies and Home Health Services.

It is the policy of the Practice that Certificates of Medical Necessity ("CMN") and DME Information Forms ("DIF") will only be signed by the Practice physicians if:

a. The physician is the patient's treating physician and the physician will verify the NPI and address is correct;

b. That the CMN/DIF was completed as required by the supplier in advance of the physician's signature; and

c. That the portions of the CMF/DIF for which the physician is responsible are accurate and the physician believes in good faith that the item or service is reasonable and necessary based upon all of the conditions and circumstances involved with the patient.

L. Billing for Non-Covered Services.

Occasionally a service will be provided that is not covered by Medicare but that is covered under a secondary payor program. Claims may be submitted to Medicare in order to obtain a denial from Medicare, thereby making the claim eligible for the secondary payor. All claims submitted for this purpose should conspicuously note on the claim submission that the claim is being submitted for purposes of receiving a denial. In the event, however, that the carrier pays the claim even though it is not covered, the billing department should immediately make arrangements to return the incorrect payment.

M. Third Party Billing Services.

If the Practice elects to use a third party billing service, the billing service must have a written compliance program that substantially meets the obligations described in the Practice's Compliance Program. In addition, the arrangement with the billing service will provide that any billing must be done under the

Practice's name and tax identification number and that all receipts from such billings must be deposited into an account controlled by the Practice.

N. Rental of Space or Equipment.

Any rental agreement between the Practice and any party that may make referrals to the Practice or may accept referrals from the Practice shall be in writing with a term of one year. The rental fees must be consistent with fair market value in the area and may not be related to the volume or value of referrals or business otherwise generated by referrals between the parties.

Section IV – Record Retention and Security

The Practice recognizes that it is important to preserve the confidentiality of all patient records and to restrict access to such records to central personnel. Further, the Practice acknowledges that certain records must be retained to verify compliance standards and to otherwise conduct its business on an ongoing basis.

A. Security of Records.

Medical records of patients shall be maintained in separately identified patient electronic records. Only designated persons shall have access to patient records. When not needed for patient examination or chart review, all patient records will be maintained securely in accordance with the Practice's HIPAA Compliance Program.

The office manager shall be responsible to assure that at the end of each business day all electronic medical record equipment and the office are locked and secured.

Patient files shall be maintained in accordance with the Practice's record retention schedule. There are federal and state regulations that may affect record retention schedules. The Practice will ensure that its record retention schedule complies with applicable laws and regulations.

B. Medical Records and Electronic Media

Only designated personnel within the Practice shall have access to electronic medical records and shall require a security password to obtain access to computers and other equipment containing patient medical information. Electronic records will be stored and backed up to prevent an inadvertent loss of information.

C. Electronic Transmission.

In the event the transmission of medical records is required electronically, the Compliance Officer will verify that the receiving party has taken adequate security precautions to accept medical record information and that they are prepared to retain the information in a secure and safe environment.

D. Business Information.

All documents and information regarding the business of the Practice, including billing and collections,

shall be retained in accordance with the Practice's record retention schedule, which shall comply with state and federal laws and regulations.

E. Archival Records.

The Compliance Officer will assure that in the event a change occurs in any carrier manual, CPT code listing, or the like should occur, that the Practice will retain archival copies of the former version of such volumes.

Correspondence with carriers, CMS, or other government agencies will be retained for a period of 10 years; except in the event that any inquiry had been initiated concerning any matter involving the Practice, the records related to time periods of the inquiry shall be maintained indefinitely.

Section V – Training and Education

The Practice believes that it is important for all employees to participate in ongoing training programs including training related to compliance. The Practice will offer the following training:

A. Initial Compliance Training.

In conjunction with the Compliance Officer, all employees will be trained concerning the commitment of the Practice to compliance, including the importance of compliance, the role of each employee in compliance, and consequences for violating standards and procedures. All employees hired subsequent to the initial training program will go through an individualized training program with the focus on the importance of compliance within the first 60 days of employment. The Compliance Officer will conduct annual compliance training for all employees, as well as other trainings as may be necessary or appropriate. Training courses shall include the current materials that CMS requires providers to complete and may be conducted in house or may be offered by outside sponsors or through on-line training programs such as those offered by CMS or the carrier.

B. Specialized Training for Coding and Billing.

All employees who are directly involved with billing, coding, or other aspects of federal health care programs shall receive additional training in connection with their individual responsibilities. That training will generally include coding requirements, claim submission processes, documentation, billing standards, and procedures. In addition to the process of billing, additional topics will include sanctions and consequences for inappropriate billing and steps to improve billing procedures in the event of rejections.

~~C~~C. Specialized Training for Sales and Marketing.

All employees or independent contractors who are directly involved with sales and marketing for the Pharmacy shall receive additional training in connection with their individual responsibilities. That training will generally include such topics as prohibitions on paying or receiving remuneration to induce referrals, disguising referral fees as salaries, high pressure marketing of noncovered or unnecessary services, improper patient

solicitation, and duty to report misconduct.

D. Training Format.

In general, training will be conducted on-site as part of general staff training. From time to time, the Compliance Officer will inform appropriate employees of seminars and other training sessions that are available, including on-line training programs. In addition, in the event of important changes in billing procedures or applicable law, the Compliance Officer may post those changes in appropriate locations, circulate memorandums to key employees, or conduct updates as part of regular staff meetings. The Compliance Officer will maintain a log of training experiences for all employees.

~~D~~E. Employee Certification.

Employees should provide a written certification that they received a copy of the Compliance Program and have read the policies and understand the rules and regulations of the Compliance Program. This certification should be retained in the Practice's records.

~~E~~F. Corrective Action.

Although the goal of this Compliance Program is to have zero errors, an occasional human mistake may occur. In the event there is suspected non-compliance discovered by any employee, the employee should immediately report the discovery to the Compliance Officer or his designee. As soon as possible, the Compliance Officer will investigate the error and take the following actions:

1. Verify whether an error has occurred on behalf of the Practice or another party;

2. Log the error in a log book identifying the date, description, and the person noting the entry;

3. Correct and note the error in the log book identifying what corrective action was taken;

4. In the event an overpayment has occurred, report and return the overpayment to the carrier, patient, or insurer in accordance with applicable laws; and

5. Follow-up to make any adjustments in co-insurance payments.

After identification of the cause of the error, appropriate correction steps will be taken if the error is a

system error or educational steps will occur if it is a human error. If a human error is determined, then the Compliance Officer will investigate if it is an isolated problem or if it is a part of a pattern of errors. In the event of a pattern, the matter should be discussed with legal counsel, including whether disciplinary action or termination is required. The Practice is aware of the opportunity to use the OIG Provider's Self-Disclosure Protocol. The Compliance Officer will review all denied claims (other than those submitted solely for purposes of obtaining denial) and evaluate the reasons for the denial and where appropriate take the necessary corrective or educational steps.

Section VI – Communication and Compliance Reporting

A. Reporting Guidelines.

The Practice encourages all employees to be aware of the goal of the Practice to be error free and to make suggestions to improve the billing and documentation procedures of the Practice. All employees are responsible for monitoring and reporting any compliance concern that may arise. In the event that any employee should become aware of an error in billing, documentation, or another violation of law, the employee must immediately report those concerns to his or her supervisor. If the employee is uncomfortable reporting a concern to the supervisor, or if the supervisor is unresponsive towards the concern, then the employee may report the concern to the Compliance Officer or the Practice's administration. If the employee desires, reports can also be submitted anonymously or to the Practice's legal counsel, as indicated below. Occasionally, a perceived error or violation may, in fact, not be an error or violation, and it is more important when in doubt to discuss the proper approach to compliance than to assume incorrectly and perhaps suffer consequences in the future. Thus, it is important to try to address perceived errors and violations internally before reporting them to outside parties.

If the Practice uses an independent billing company, then the billing company shall designate a senior person to be the primary contact to coordinate billing and compliance activities of the Practice with the billing company. Any issues concerning compliance or errors will be brought to the immediate attention to the contact person.

We understand that given the size of the Practice, it may not be totally possible to assure confidentiality or anonymity within the Practice. Thus, an employee may anonymously report concerns to legal counsel for the Practice. Employees may contact:

Amanda L. Waesch, Esq.
Brennan, Manna & Diamond, LLC
75 East Market Street
Akron, Ohio 44308
(330) 253-5060

Once again, in the event of any question as to compliance, it is better to report and discuss an issue rather than submit a bill that may not be correct.

B. Whistleblower Protection.

All employees are responsible for promptly reporting actual or potential infringements of law, regulation, policy, or procedure related to federal or state law, including but not limited to potential billing errors, false claims concerns, and other fraud and abuse concerns. Because of the importance of compliance, any reported errors or violations that are reported in good faith with a sincerely held belief that the conduct is erroneous or potentially fraudulent will result in no retribution or adverse employment action to the employee making the report. **Under no circumstances will the good faith reporting of any concerns or possible impropriety serve as a basis for any retaliatory action(s) against any employee reporting such concerns.**

Section VII – Employment and Employee Discipline

A. Hiring and Background Checks.

The Practice will verify that its employees are not excluded from participation in government reimbursement programs and will take the following steps prior to hiring any individual:

1. The applicant must complete an application that includes signatures, dates, and references if desired by the Practice's administration;

2. The applicant must produce a valid form of government-issued identification;

3. The Compliance Officer will verify that the person is not included on the Exclusion Lists;

4. The Practice will verify the applicant's references;

5. The Practice will provide an overview of the Compliance Program Manual and indicate that compliance with this procedure is an ongoing condition of employment; and

6. The Compliance Officer will also conduct a review every six months of the Exclusion Lists for every Practice employee.

B. Ongoing Training.

As noted above, all employees will be required to participate in training and continued education concerning compliance issues.

C. Discipline.

The Practice is committed to full and complete compliance with the law, including the terms of this Compliance Plan. Any illegal or unethical conduct by any employee will result in immediate and appropriate disciplinary action, including the potential for termination of employment. Beyond employment termination, however, the Practice may, in appropriate circumstances, refer former employees to appropriate authorities for criminal prosecution and seek restitution of damages if applicable. All employees remain at-will employees.

Section VIII – Inspection

In the event any employee of the Practice is contacted by any government agency or carrier concerning an audit or billing, the employee must immediately notify the Compliance Officer or his or her designee.

The Compliance Officer will adhere to the following procedure in the event of such government inquiry:

1. If the inquiry is in writing, the Compliance Officer will immediately advise the Practice's administration of the inquiry, will review any requested information and will confer with legal counsel prior to any response; and

2. If the visit is in person, the Compliance Officer will take the following steps:

    a. Verify the identity of the government agency;

    b. Determine the exact nature of the inquiry of the agent;

    c. Require that any requested documents be reviewed by the Compliance Officer and legal counsel prior to releasing to the agent.

To avoid any confusion or misunderstanding, it is important to coordinate all communications with government agents through the Compliance Officer or his or her designee, and no other employee should have any discussions or release information without the prior consent of the Compliance Officer or legal counsel.

Section IX – Conclusion

The Practice is committed to those ideals reflected in our mission and purpose and Code of Conduct. We intend to fully complying with government rules and regulations and assisting its employees to achieve their goal of 100% compliance.

If any employees have suggestions to improve this Compliance Program or note any situation that may possibly be a violation of the Program, we urge their cooperation and assistance in discussing and seeking solutions to those situations.

The Compliance Officer, in addition to the officers, managers, or members listed below have acknowledged, reviewed, and approved the foregoing guidelines for the said Compliance Program.

Name	Signature	Date
Leon Margolin	Leon Margolin	10-3-2019

CODE OF CONDUCT

A. General Principles

The Practice is committed to implementing strict rules to guard against fraud or dishonesty and guidelines for conducting day-to-day operations, as set forth in this Code of Conduct ("Code"). Any employee, officer, manager, or member ("Representative") that detects or suspects any improper activities on the part of any other Representative or other agent of the Practice, or any person with whom the Practice deals, must report this information immediately so that the appropriate investigation is initiated. Withholding knowledge of improper activities is a violation of the Code. If evidence of a violation of this Code is established, then any Representative involved in the violation may be subject to disciplinary action up to and including dismissal. Reports of misconduct will be reviewed and investigated by the Compliance Officer.

B. Business Relationship Standards

1. Workplace Relations

The Practice is committed to providing a work environment that is free from harassment in all areas. Harassment based upon an individual's sex, race, ethnicity, national origin, age, religion, or any other legally protected characteristics will not be tolerated. All Representatives are expected and required to abide by this policy. No person shall be adversely affected in employment as a result of bringing complaints of unlawful harassment.

2. Honesty and Financial Reporting

The Practice is dedicated to honest, accurate and timely reporting of all information, including financial data. Any Representative contributing data to an external or internal report must provide data that is thorough, complete, and accurate in order to assure that others who use or review the information are not misled. The Practice shall maintain a system of internal controls to provide reasonable assurance that it meets financial and other data reporting obligations. The Practice's financial statements shall be prepared in conformity with generally accepted accounting principles and other applicable standards. Outside payments must be made only with a draft or check or through other properly documented sources. No payment on behalf of the Practice should be approved or made without adequate supporting documentation or with the intention or understanding that any part is to be used in any way other than as described in the supporting documents.

3. Hiring and Retention

The appointment of and retention of independent contractors, and Representatives of the Practice is contingent upon acceptance of and compliance with the Compliance Plan and this Code. It is expected that outside colleagues, e.g., vendors, consultants, and others whose actions could be attributed to the Practice, will adhere to similar standards in their dealings with the Practice and with others on our behalf. In addition, evaluation of managers and supervisors will include elements of compliance.

4. Confidentiality

Representatives shall not disclose to others any confidential information obtained while representing the Practice. Confidential information includes the Practice's methods, processes, techniques, computer software, equipment, service marks, copyrights, research data, clinical data, marketing and sales information, personnel

data, financial data, plans, and all other propriety information that is in the possession of the Practice and that has not been published or disclosed to the public. Representatives are responsible and accountable for the integrity and protection of business information. Particular attention must be paid to the security of data stored on the computer system. Any Representative that observes misuse of confidential information or unrecognized individuals using the Practice's computer terminals should immediately report this to the Compliance Officer. In addition, Representatives may not disclose confidential information (including software, data, and reports) received from any third parties for the benefit of the Practice unless allowed by terms of use expressly agreed to by the Practice and the other party. Where information is disclosed, no more information should be disclosed than is necessary to accomplish the task for which it is being disclosed.

5. Conflicts of Interest

A conflict of interest arises when an individual has competing personal and professional interests. Representatives must promptly disclose any existing or new relationships that may give the appearance of a conflict of interest to the Compliance Officer. In order to avoid improper conflicts of interest, Representatives should adhere to the following guidelines:

- Substantial ownership in a competitor health care provider may create a conflict of interest. Any doubts or questions about an investment should be addressed with the Compliance Officer.
- Immediate family members should not supervise or report to each other.
- Outside employment is prohibited to the extent it interferes with an employee's performance.
- Equipment, materials, or proprietary information owned by the Practice may only be used to further the purpose of the Practice and not to serve the personal interest of an individual or any other purpose.

C. Fraud, Waste, and Abuse

1. False Claims Act

The federal False Claims Act prohibits the submission of false or fraudulent claims to the government. In addition, the Act allows individuals to bring lawsuits on behalf of the government ("whistleblower" suits) against individuals or entities that are defrauding the government. The Practice will not retaliate against any individual for reporting a suspected false claim in good faith.

2. Stark Law

Under the physician self-referral law (42 U.S.C. §1395nn), also known as the "Stark Law," a physician is prohibited from making a referral for designated health services payable by government payors (e.g., Medicare and Medicaid) to any entity in which the physician (or an immediate family member) has an investment or ownership interest or compensation arrangement unless the arrangement satisfies an exception. Designated health services include, but are not limited to: clinical laboratory services; physical therapy services; occupational therapy services; radiology services, including magnetic resonance imaging, axial tomography scans, and ultrasound services; nuclear medicine services; radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment and supplies; prosthetics, orthotics, prosthetic devices and supplies; home health services; outpatient prescription drugs; and inpatient and outpatient hospital services. The Practice is committed to structuring all arrangements within and outside of the Practice to comply with applicable exceptions to the Stark Law. The Practice shall consult with legal counsel to determine if the Stark Law is implicated in any arrangements.

3. Anti-Kickback Statute

The Anti-Kickback Statute makes it a crime to knowingly and willfully solicit, receive, offer, or pay remuneration of *any* kind (e.g., money, goods, services) for the referral of an individual to another for the purpose of supplying items or services that are covered by a federal health care program or for purchasing, leasing, ordering, or arranging for any good, facility, service, or item that is covered by a federal health care program. The Practice must scrupulously avoid either offering or receiving any improper inducement. Relationships should be structured so as not to create a situation where the Practice's contractors or Representatives appear to be offering an improper inducement to those who may be in a position to refer or influence the referral of patients. The Practice shall consult with legal counsel if it believes that the Anti-Kickback Statute is implicated in any arrangements and will structure such arrangements to meet applicable safe harbors.

D. Other Applicable Laws, Regulations, and Legal Issues

1. SEC Regulations

In the event the Practice sells any of its membership interests, the Practice shall comply with the Securities Act of 1933, the Financial Industry Regulatory Authority ("FINRA"), and all regulations and guidance published by the Securities and Exchange Commission ("SEC").

2. Unfair Trade Practices

The Practice will comply with all restraint of trade and unfair competition laws. Generally, these laws forbid any kind of understanding or agreement, whether written or verbal, between competitors to fix or control fees for services or to engage in any other conduct that results in restraint of competition.

3. Labor and Employment Laws

It is the Practice's policy to comply fully with all applicable labor laws and other statutes regulating the employer-employee relationship and the workplace environment. The Practice will not discriminate in employment, recruitment, advertisements for employment, compensation, termination, upgrading, promotions, and other conditions of employment against any employee or job applicant based on race, sex, religion, national origin, physical disability, age, or any other legally protected class or status. No Representative may interfere or retaliate against any other Representative who seeks to invoke his or her rights under this policy or applicable laws.

4. Immigration

Consistent with federal law, the Practice only hires persons who are legally authorized to work in the United States. The appropriate documentation of citizenship status must be presented to the Practice at the time of hire.

E. Cooperation with Government Investigations

It is the Practice's policy to cooperate fully with any investigations or requests for information or assistance from local, state, and federal agencies. All Representatives are also expected to cooperate with these investigations but should only do so with guidance and assistance from the Practice. Any individual receiving

any of the following as a Representative of the Practice should consult with the Compliance Officer prior to responding: summons, subpoena, inquiry, or other communication from a court, law enforcement official, government agency, or lawyer. The Compliance Officer will consult legal counsel as necessary.

COMPREHENSIVE PAIN MANAGEMENT INSTITUTE, LLC COMPLIANCE PLAN AND CODE OF CONDUCT

ACKNOWLEDGEMENT AND CERTIFICATION OF COMPLIANCE

I, Leon Margolin, hereby acknowledge and affirm that I have received a copy of the Comprehensive Pain Management Institute, LLC Compliance Program Manual, including the Code of Conduct and Compliance Plan (the "Manual"), and I understand the information set forth in the Manual. If I have any questions relating to the Manual, I will contact the Compliance Officer directly. I hereby agree to comply with all of the guidelines set forth in the Manual and any of its amendments. I understand that failure to do so could lead to disciplinary action, which could include termination where appropriate.

Signature

10/3/2019
Date

Exhibit J

mln
BOOKLET
KNOWLEDGE • RESOURCES • TRAINING

SBIRT Services



CMS CENTERS FOR MEDICARE & MEDICAID SERVICES
Medicare Learning Network®

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What's Changed?

- Beginning January 1, 2022, we cover Naloxone HCPCS Code G1028 (page 11)

You'll find substantive content updates in dark red font.

This Screening, Brief Intervention, & Referral to Treatment (SBIRT) booklet provides Medicare and Medicaid SBIRT services coverage information:

- Eligible providers
- Covered SBIRT services
- Documenting SBIRT services
- Billing SBIRT services
- Dually eligible Medicare-Medicaid beneficiaries

Together we can advance health equity and help eliminate health disparities for all minority and underserved groups. Find resources and more from the CMS Office of Minority Health:

- Health Equity Technical Assistance Program
- Disparities Impact Statement

Note: We cover Alcohol Misuse Screening and Counseling (preventive screening once per year for adults who use alcohol but don't meet dependency criteria; if you detect misuse, we cover up to 4 brief face-to-face counseling sessions per year if the patient is alert and competent during them). We also cover Medicare Wellness Visits. These visits include a review of your medical and social history related to your health and education and counseling about preventive services, including Substance Use Disorder (SUD) screenings, current opioid prescriptions review, and referrals to treatment as appropriate.

Throughout this booklet, **we** refers to **Medicare**.

Different requirements apply to Medicare and Medicaid. Medicare & Medicaid Basics fact sheet explores the differences.

We also cover several mental health services. Medicare Mental Health booklet has more information on qualifications, coverage, and payment guidelines.

What's SBIRT?

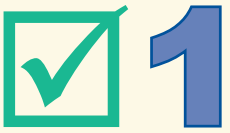
SBIRT is an evidence-based, early intervention approach for people with non-dependent substance use before they need more extensive or specialized treatment. This approach differs from specialized treatment for those with more severe substance misuse or a SUD.

SBIRT Benefits

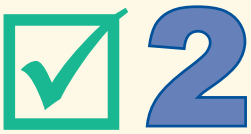
Using SBIRT services is easy in primary care settings. You can systematically screen people who may not seek substance use help and offer SBIRT treatment services access to:

- Reduce health care costs
- Decrease drug and alcohol use severity
- Reduce physical trauma risk
- Reduce patient-percentage who go without specialized treatment

SBIRT has 3 major components:



Screening:
Screen or assess a patient for risky substance use behaviors with standardized assessment tools to identify the appropriate level of care (known as Medicare Structured Assessment). Screening quickly assesses the substance use severity and identifies the appropriate treatment level.



Brief Intervention:
Brief intervention increases substance use insight and awareness and motivates behavioral change. Engage the patient in a short conversation to increase their awareness of risky substance use behaviors and provide feedback, motivation, and advice. We cover 1 preventive screening per year and up up to 4 brief face-to-face counseling sessions per year at no cost to the patient.



Referral to Treatment:
Refer patients whose assessment or screening shows a need for additional services to brief therapy or specialty care treatment.

SBIRT Assessment & Screening Tools

The first SBIRT element is assessment or screening. You may use tools including the World Health Organization's Alcohol Use Disorders Identification Test (AUDIT) Manual and the Drug Abuse Screening Test (DAST). Substance Abuse and Mental Health Services Administration (SAMHSA) Resources for SBIRT has more SBIRT assessment and screening tools information.

Substance Use Disorders: The Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) no longer uses the terms substance abuse and substance dependence. Instead, it refers to "Substance Use Disorders" (SUDs), classified as mild, moderate, or severe. The number of diagnostic criteria an individual meets determines their severity level. SAMHSA's Mental Health and SUDs webpage has common SUD facts. SAMHSA's Behavioral Health Treatment Locator can help you find mental health treatment facilities and programs around the country.

Medicare SBIRT

Medicare-Eligible Providers

We pay medically reasonable and necessary SBIRT services in physicians' offices and outpatient hospital settings. In these settings, you assess and identify people with, or at risk for, substance use-related issues and provide limited interventions or treatment. We have specific, authorized SBIRT supplier qualifications.

Eligible SBIRT Services Health Care Suppliers

Provider Type & Reference	Qualifications
Physicians (Medical Doctors [MDs] and Doctors of Osteopathy [DOs]), particularly psychiatrists 42 CFR 410.20 Section 30 of Medicare Benefit Policy Manual, Chapter 15	• Legally authorized to practice medicine in the state where you provide services • Perform services within the scope of your licenses, as defined by state law

Physician Assistant (PA)
42 CFR 410.74
Section 190 of Medicare Benefit Policy Manual, Chapter 15
	• Licensed by the state where you practice and 1 of these criteria:
	  ○ Graduated from a PA educational program accredited by the Accreditation Review Commission on Education for the Physician Assistant (or its predecessor agencies, the Commission on Accreditation of Allied Health Education Programs, and Committee on Allied Health Education and Accreditation)
	  ○ Passed the National Commission on Certification of Physician Assistants exam

Nurse Practitioner (NP)
42 CFR 410.75
Section 200 of Medicare Benefit Policy Manual, Chapter 15
	• Registered Nurse (RN) licensed and authorized by the state where you provide NP services according to state law
	• Got Medicare NP billing privileges for the first time since January 1, 2003, and:
	  ○ NP certified by a recognized national certifying body with established NP standards
	  ○ Master's degree in nursing or a Doctor of Nursing Practice degree
	• Got Medicare NP billing privileges for first time before January 1, 2003, and meets certification requirements
	• Got Medicare NP billing privileges for first time before January 1, 2001

Eligible SBIRT Services Health Care Suppliers (cont.)

Provider Type & Reference	Qualifications
Clinical Nurse Specialist (CNS) 42 CFR 410.76 Section 210 of Medicare Benefit Policy Manual, Chapter 15	• RN currently licensed in the state where you practice and authorized to provide CNS services according to state law • Doctor of Nursing Practice or master's degree in a defined clinical nursing area from an accredited educational institution • Certified as a CNS by a recognized national certifying body with established CNS standards
Clinical Psychologist (CP) 42 CFR 410.71 Section 160 of Medicare Benefit Policy Manual, Chapter 15	• Psychology doctoral degree • Licensed or certified in the state where you practice at the independent level and directly provide diagnostic, assessment, preventive, and therapeutic patient services
Clinical Social Worker (CSW) 42 CFR 410.73 Section 170 of Medicare Benefit Policy Manual, Chapter 15	• Social Work master's or doctoral degree • At least 2 years supervised clinical social work • Licensed or certified CSW by the state where you provide services • If you practice in a state that doesn't have licensure or certification, and complete at least 2 years or 3,000 supervised social work practice clinical hours, post-master's degree in an appropriate setting (for example hospital, Skilled Nursing Facility [SNF], or clinic)
Certified Nurse-Midwife (CNM) 42 CFR 410.77 Section 180 of Medicare Benefit Policy Manual, Chapter 15	• RN legally authorized to practice as a nurse-midwife in the state where you provide services • Successfully completed a nurse-midwives program of study and clinical experience accredited by an accrediting body the U.S. Department of Education approved • Certified as a nurse-midwife by the American College of Nurse-Midwives or the American College of Nurse-Midwives Certification Council

Independently Practicing Psychologist (IPP)
Section 80.2 of Medicare Benefit Policy Manual, Chapter 15
	• Psychologist who isn't a CP
	• Meets 1 of these criteria:
	  ○ Practices independent of an institution, agency, or physician's office and licensed or certified to practice psychology in the state or jurisdiction where you provide services
	  ○ Practicing psychologist who provides services in a jurisdiction that doesn't issue licenses

Medicare-Covered SBIRT Services

According to section 1862(a)(1)(A) of the Social Security Act, we cover reasonable and necessary SBIRT services that meet the required diagnosis or illness treatment or injury (you provide the service to evaluate or treat patients with signs or symptoms of illness or injury).

We pay these services under the Medicare Physician Fee Schedule (PFS) and the hospital Outpatient Prospective Payment System (OPPS). Section 200.6 of Medicare Claims Processing Manual, Chapter 4 has more Medicare SBIRT OPPS payment services information.

We currently pay for screening and brief intervention as a preventive service in the primary care setting.

Documenting Medicare SBIRT Services

The patient's medical record must support all Medicare claims. The SBIRT-covered services medical record must:

- Be complete and legible
- Record start and stop times or total face-to-face time with the patient (some SBIRT HCPCS codes are time based)
- Document patient's progress, response to treatment changes, and diagnosis revision
- Document rationale for ordering diagnostic and other ancillary services or ensure it's easily inferred
- For each patient encounter, document:
  - Assessment, clinical impression, and diagnosis
  - Date and legible provider identity
  - Physical exam findings and prior diagnostic test results
  - Plan of care
  - Encounter reason and relevant history
- Identify appropriate health risk factors
- Make past and present diagnoses accessible for treating and consulting physicians
- Have signatures for all services provided or ordered

Note: Incomplete records place you at risk of partial or full Medicare payment denial.

Physicians, Certified Registered Nurse Anesthetists (CRNAs), PAs, CNMs, CNSs, and NPs may review and verify (sign and date), rather than re-document, notes in a patient's medical record made by physicians; residents; nurses; medical, PA, and APRN students; or other medical team members, including, as applicable, notes documenting the physician's, CRNA's, PA's, CNM's, CNS's, and NP's presence and service participation.