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**.

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.

(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.

(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.

(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.

(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;

(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

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:

(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

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

,

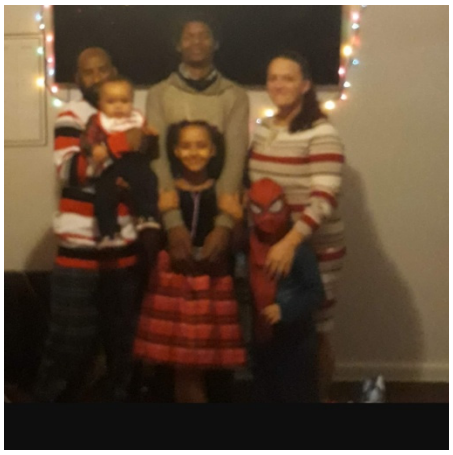
My name is S*******and I've been working at CPMI for six years now taking care of chronic pain patients.

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.

As evident from the court documents (Case 2020 CR B 001416) 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 (please see the picture obtained from the public presentation attached). 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....

Respectfully,

Ronald Johnson

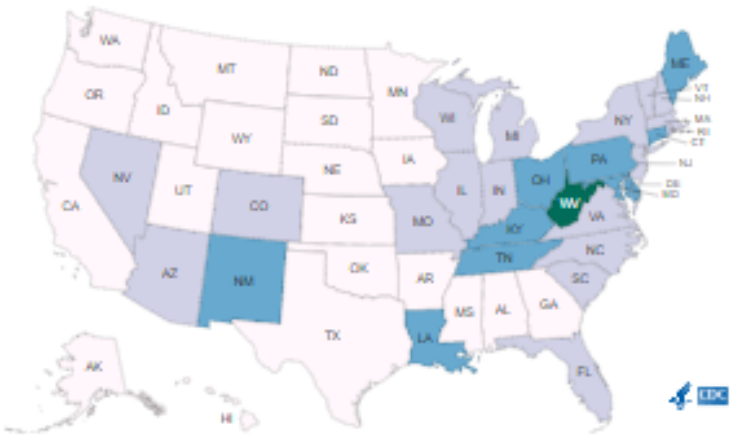
(the contact person for the patient group)

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.

DOI: 10.29011/2574-7568.001080

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

Leon Margolin[1*], David Streem[2], Daniel Margolin[1], Sandford Lefkowitz[1]

[1]Comprehensive Pain Management Institute, LLC (www.cpmiohio.com), Columbus, Ohio, USA

[2]Chief of Psychiatry and Medical Director of the Alcohol and Drug Recovery Center (Lutheran Hospital Division), Cleveland Clinic Foundation

Associate Professor of Medicine at the Cleveland Clinic Lerner College of Medicine of Case Western Reserve University

[*]**Corresponding author:** Leon Margolin, Comprehensive Pain Management Institute, LLC, Columbus, Ohio 43213, USA

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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.

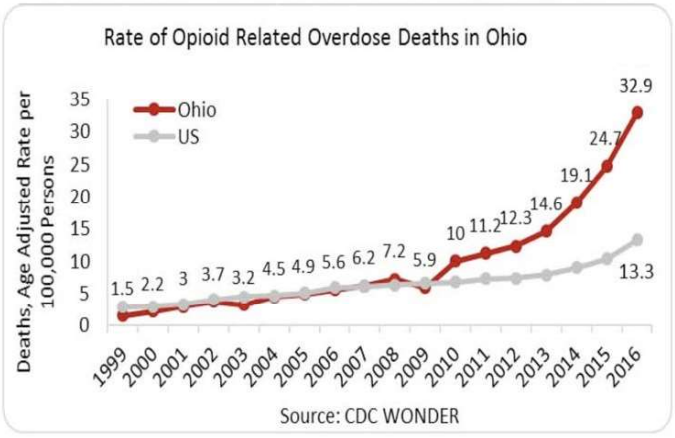


Figure 1: Based on 2017 government Opioid mortality data, Ohio is rated number two in the US with more than 2.6 times death rate per 100,000 population compared to US average rate (39.2 in OH vs. 14.6 average).

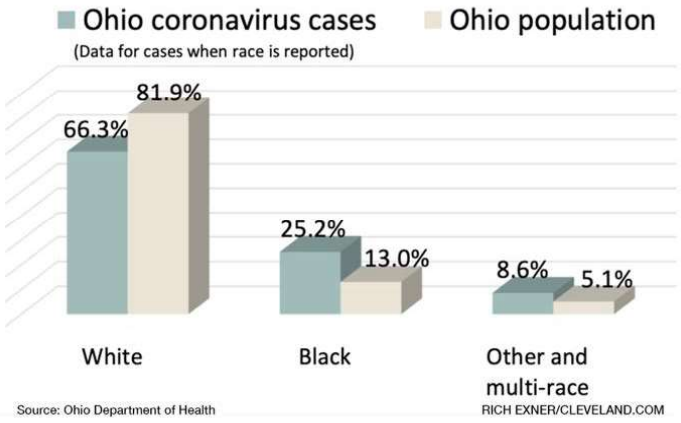


Figure 2: Based on the age, medical comorbidities, socio-economic challenges and possible immunosuppressive effect of Opioids, our patient is at increased risk for the COVID-19 pandemic.

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 December of 2019 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: DS. 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: LH, 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: LH

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: JM

Patient chart review shows that the patient was prescribed on October 20, 2016, 30 tablets of OxyCodone 5 /APAP 325 for 15 days as per state prescription monitoring system (OARRS). On 11/2/16 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 11/02/16 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

ST 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 MS

MS 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]. Mark 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.

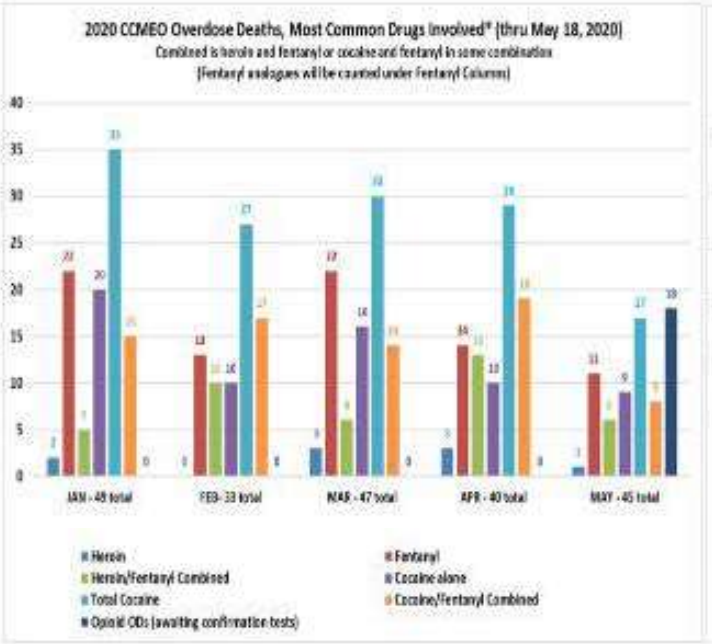
A functional improvement which is the main goal of pain management program (which is more important that pain reduction) has most strong statistically significant improvement with the use

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 2020 CR B 001416) 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

INDEX

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®

Table of Contents

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?

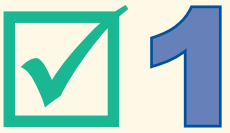
SBIRT is an evidence-based, early intervention approach for people with non-dependent substance use before they need more extensive or specialized treatment. This approach differs from specialized treatment for those with more severe substance misuse or a SUD.

SBIRT Benefits

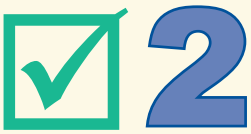
Using SBIRT services is easy in primary care settings. You can systematically screen people who may not seek substance use help and offer SBIRT treatment services access to:

- 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.

Billing Medicare SBIRT Services

HCPCS Code G2011	Alcohol and/or substance (other than tobacco) misuse structured assessment (e.g., audit, dast), and brief intervention 5–14 minutes	
HCPCS Code G0396	Alcohol and/or substance (other than tobacco) misuse structured assessment (e.g., audit, dast), and brief intervention 15 to 30 minutes	
HCPCS Code G0397	Alcohol and/or substance (other than tobacco) misuse structured assessment (e.g., audit, dast), and intervention, greater than 30 minutes	

Medicare Telehealth Includes SBIRT Services

You can provide SBIRT services via telehealth if you meet all requirements.

Substance Use Disorder Bundled Physician Fee Schedule Payments

HCPCS Code G2086	Office-based treatment for opioid use disorder, including development of the treatment plan, care coordination, individual therapy and group therapy and counseling; at least 70 minutes in the first calendar month	
HCPCS Code G2087	Office-based treatment for opioid use disorder, including care coordination, individual therapy and group therapy and counseling; at least 60 minutes in a subsequent calendar month	
HCPCS Code G2088	Office-based treatment for opioid use disorder, including care coordination, individual therapy and group therapy and counseling; each additional 30 minutes beyond the first 120 minutes (list separately in addition to code for primary procedure)	

Note: Don't bill HCPCS codes G2086–G2088 more than once per month per patient. These codes describe treatment for 1 or more SUDs.

Opioid Use Disorder: Part D Treatment Drugs

Medicare drug plan (Part D) sponsors **must** cover OUD Part D treatment drugs, when medically necessary, by including them on the formulary or by exception. Coverage isn't limited to single entity products (for example, Buprenorphine) but must include combination products when medically necessary (for example, Buprenorphine Naloxone and long-acting Naltrexone).

CMS sponsors must have a transition policy to prevent interruptions in Part D therapeutic treatment drugs when new patients transition into the benefit. This transition policy, along with CMS's non-formulary exceptions and appeals requirements, helps make sure all your patients have timely access to medically necessary OUD Part D drug therapies.

A pharmacy can dispense a Part D drug only upon prescription if the drug is helping treat a medically accepted indication. Medicare Prescription Drug Benefit Manual, Chapter 6 has more information.

Since January 1, 2021, you can prescribe a Medicare Part D Schedule II, III, IV, or V controlled substance electronically according to the electronic prescription drug program requirements.

Methadone isn't an OUD Part D drug because a retail pharmacy can't dispense it for treatment. 42 CFR 8.12(h)(2) has more FDA-authorized OUD investigational use medication information, and 42 CFR 8.1 has more OUD medication-assisted treatment information.

Note: Methadone is a Part D drug when indicated for pain. State Medicaid Programs may include the methadone costs in their bundled payment to qualified Opioid Treatment Programs (OTPs) or hospitals dispensing OUD methadone. Section 10.8 of Medicare Prescription Drug Benefit Manual, Chapter 6 has more information.

Opioid Treatment Programs

Since January 1, 2020, we pay certified OTPs Medicare Part B bundled OUD treatment services payments. Covered services include FDA-approved oral, injected, and implanted opioid agonist and antagonist medication-assisted treatment medications (including methadone, buprenorphine, and naltrexone) and their administration (if applicable), substance use counseling, individual and group therapy, toxicology testing, intake, and periodic assessments. Opioid Treatment Programs (OTPs) Medicare Billing & Payment booklet and Opioid Treatment Program Directory have more information.

There are 3 add-on codes to cover the cost of Naloxone:

HCPCS Code G2215	Take-home supply of Nasal Naloxone (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure. (This will include both a drug component and a non-drug component for overdose education).
HCPCS Code G2216	Take-home supply of Injectable Naloxone (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.
HCPCS Code G1028	**Beginning January 1, 2022, we cover HCPCS Code G1028:** Take-home supply of nasal Naloxone; 2-pack of 8mg per 0.1 mL nasal spray (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.

Note: Payment for HCPCS codes G1028, G2215, and G2216 is limited to once every 30 days unless an additional take home supply of the medication is medically reasonable and necessary.

After the conclusion of the COVID-19 Public Health Emergency (PHE), OTPs can furnish counseling and therapy services via audio-only interaction (for example, phone calls) in cases where audio and or video communication isn't available to the patient, including circumstances in which the patient isn't capable of or doesn't consent to using devices that permit a 2-way audio and or video interaction, provided all other applicable requirements are met.

There's no copayment for OTP services for people with Medicare.

Medicaid SBIRT

States may cover SBIRT as a Medicaid state plan service. Several Medicaid statutory authorities may cover SBIRT, including, but not limited to:

- 42 CFR 440.50: Physicians' services
- 42 CFR 440.60: Services of other licensed practitioners
- 42 CFR 440.130(c): Preventive services
- 42 CFR 440.130(d): Rehabilitative services

Section 1905(r) of the Social Security Act states the Early and Periodic, Screening, Diagnostic, and Treatment (EPSDT) benefit provides a comprehensive selection of eligible children's preventive, diagnostic, and treatment services if they're under age 21. Medicaid includes this mandatory benefit to make sure children get early detection and care to treat or avoid health problems.

States must arrange for children to get health screening services at regular intervals and diagnostic services when needed. They must also provide services or items within the Medicaid-covered benefits listed in section 1905(a) of the Social Security Act if that service or item is necessary and corrects or ameliorates defects and physical and mental illnesses or conditions.

A physician or other licensed practitioner of healing arts, within the scope of their practice under state law, must recommend preventive and rehabilitative services.

When state Medicaid plans cover SBIRT, the states establish which practitioners may provide services and their qualifications. Practitioner qualifications offering SUD treatment include, but aren't limited to those:

- Licensed or certified to perform SUD services by the state where they perform the services
- Qualified to perform specific SUD services
- Supervised by a licensed practitioner of healing arts (in some instances, when a qualified unlicensed professional provided the services)
- Working within their state scope-of-practice act

Documenting Medicaid SBIRT Services

You must comply with the state's Medicaid SBIRT documentation policy. You can often find the state's documentation policy in its Medicaid Provider Manual. Your state Medicaid agency has more documentation information.

Billing Medicaid SBIRT Services

If a state chooses to cover SBIRT under its Medicaid Program, the state may choose which codes to bill brief intervention services; for example, HCPCS codes:

HCPCS Code G0396	Alcohol and/or substance (other than tobacco) misuse structured assessment (e.g., audit, dast), and brief intervention 15 to 30 minutes	
HCPCS Code G0397	Alcohol and/or substance (other than tobacco) misuse structured assessment (e.g., audit, dast), and intervention, greater than 30 minutes	
HCPCS Code G0442	Annual alcohol misuse screening, 15 minutes	
HCPCS Code G0443	Brief face-to-face behavioral counseling for alcohol misuse, 15 minutes	
HCPCS Code G0444	Annual depression screening, 15 minutes	
HCPCS Code H0049	Alcohol and/or drug screening	
HCPCS Code H0050	Alcohol and/or drug services, brief intervention, per 15 minutes	

Check with your state Medicaid agency about which billing codes to use.

Medicaid National Correct Coding Initiative (NCCI) Policy Manual, Chapter 12, Section C(16), available in the Medicaid NCCI Reference Documents webpage, has billing codes G0396 and G0397 with evaluation and management codes and behavioral health codes information.

Medicaid Telemedicine Includes SBIRT

If the state allows it, you may provide SBIRT via telemedicine.

Dually Eligible Medicare-Medicaid Beneficiaries

For people enrolled in both Medicare and Medicaid Programs (dually eligible), Medicare-participating providers should bill Medicare and their Medicare Administrative Contractor (MAC) will transfer the claim to Medicaid after paying the Medicare-approved amount. Medicare providers must enroll in their state Medicaid Program(s) to get paid. States must accept the claim and decide if they'll pay the cost-sharing amounts.

States accept claims for all Medicare-covered services for certain dual eligible beneficiaries and pay cost-sharing amounts according to the state plan payment method.

Note: Nominal Medicaid cost sharing may apply for certain dually eligible beneficiaries. The state Medicaid Programs pay some cost sharing. However, you may not balance-bill dually eligible beneficiaries when Medicare and Medicaid payments fall below the approved Medicare rate.

Beneficiaries Dually Eligible for Medicare & Medicaid fact sheet has more information.

Find your MAC's website for more information.

Resources

- OTPs Medicare Enrollment
- Stopping the Misuse of Fentanyl and Other Synthetic Opioids

Exhibit K

Baldwin's Ohio Administrative Code Annotated
4731 Medical Board (Refs & Annos)
Chapter 4731-11. Controlled Substances (Refs & Annos)

OAC 4731-11-14

4731-11-14 Prescribing for subacute and chronic pain

Currentness

(A) Prior to treating, or continuing to treat subacute or chronic pain with an opioid analgesic, the physician shall first consider and document non-medication and non-opioid treatment options.

(1) If opioid analgesic medications are required as determined by a history and physical examination, the physician shall prescribe for the minimum quantity and potency needed to treat the expected duration of pain and improve the patient's ability to function.

(2) The physician shall comply with the requirements of rule 4731-11-02 of the Administrative Code.

(B) Before prescribing an opioid analgesic for subacute or chronic pain, the physician shall complete or update and document in the patient record assessment activities to assure the appropriateness and safety of the medication including:

(1) History and physical examination including review of previous treatment and response to treatment, patient's adherence to medication and non-medication treatment, and screening for substance misuse or substance use disorder;

(2) Laboratory or diagnostic testing or documented review of any available relevant laboratory or diagnostic test results. If evidence of substance misuse or substance use disorder exists, diagnostic testing shall include urine drug screening;

(3) Review the results of an OARRS check in compliance with rule 4731-11-11 of the Administrative Code;

(4) A functional pain assessment which includes the patient's ability to engage in work or other purposeful activities, the pain intensity and its interference with activities of daily living, quality of family life and social activities, and the physical activity of the patient;

(5) A treatment plan based upon the clinical information obtained, to include all of the following components:

(a) Diagnosis;

(b) Objective goals for treatment;

(c) Rationale for the medication choice and dosage; and

(d) Planned duration of treatment and steps for further assessment and follow-up.

(6) Discussion with the patient or guardian regarding:

(a) Benefits and risks of the medication, including potential for addiction and risk of overdose; and

(b) The patient's responsibility to safely store and appropriately dispose of the medication.

(7) The physician shall offer a prescription for naloxone to the patient receiving an opioid analgesic prescription under any of the following circumstances:

(a) The patient has a history of prior opioid overdose;

(b) The dosage prescribed exceeds a daily average of eighty MED or at lower doses if the patient is co-prescribed a benzodiazepine, sedative hypnotic drug, carisprodol, tramadol, or gabapentin; or

(c) The patient has a concurrent substance use disorder.

(C) Prior to increasing the opioid dosage to a daily average of fifty MED or greater the physician shall complete and document the following in the patient's medical record:

(1) The physician shall review and update the assessment completed in paragraph (B) of this rule, if needed. The physician may rely on an appropriate assessment completed within a reasonable time if the physician is satisfied that he or she may rely on that information for purposes of meeting the further requirements of this chapter of the Administrative Code;

(2) The physician shall update or formulate a new treatment plan, if needed;

(3) The physician shall obtain from the patient or the patient's guardian written informed consent which includes discussion of all of the following:

(a) Benefits and risks of the medication, including potential for addiction and risk of overdose.

(b) The patient's responsibility to safely store and appropriately dispose of the medication.

(4) Except when the patient was prescribed an average daily dosage that exceeded fifty MED before the effective date of this rule, the physician who is neither a specialist in the area of the body affected by the pain nor a pain management specialist shall document consideration of the following:

(a) Consultation with a specialist in the area of the body affected by the pain;

(b) Consultation with a pain management specialist;

(c) Obtaining a medication therapy management review by a pharmacist; and

(d) Consultation with a specialist in addiction medicine or addiction psychiatry, if aberrant behaviors indicating medication misuse or substance use disorder are noted.

(5) The physician shall consider offering a prescription for naloxone to mitigate risk of overdose.

(D) Prior to increasing the opioid dosage to a daily average of eighty MED or greater, the physician shall complete all of the following:

(1) Enter into a written pain treatment agreement with the patient that outlines the physician's and patient's responsibilities during treatment and requires the patient or patient guardian's agreement to all of the following provisions:

(a) Permission for drug screening and release to speak with other practitioners concerning the patient's condition or treatment;

(b) Cooperation with pill counts or other checks designed to assure compliance with the treatment plan and to minimize the risk of misuse or diversion;

(c) The understanding that the patient shall only receive opioid medications from the physician treating the chronic pain unless there is written agreement among all of the prescribers of opioids outlining the responsibilities and boundaries of prescribing for the patient; and

(d) The understanding that the dosage may be tapered if not effective or if the patient does not abide by the treatment agreement.

(2) Offer a prescription for naloxone to the patient as described in paragraph (B) of this rule.

(3) Except when the patient was prescribed an average daily dosage that exceeded eighty MED before the effective date of this rule, the physician who is neither a specialist in the area of the body affected by the pain nor a pain management specialist shall obtain at least one of the following based upon the patient's clinical presentation:

(a) Consultation with a specialist in the area of the body affected by the pain;

(b) Consultation with a pain management specialist;

(c) Obtain a medication therapy management review; or

(d) Consultation with a specialist in addiction medicine or addiction psychiatry if aberrant behavior indicating medication misuse or substance use disorder may be present.

(E) The physician shall not prescribe a dosage that exceeds an average of one hundred twenty MED per day. This prohibition shall not apply in the following circumstances:

(1) The physician holds board certification in pain medicine, board certification in hospice and palliative care, board certification in hematology, or board certification in oncology;

(2) The physician has received a written recommendation for a dosage exceeding an average of one hundred twenty MED per day from a board certified pain medicine physician or board certified hospice and palliative care physician who based the recommendation on a face-to-face visit and examination of the patient. The prescribing physician shall maintain the written recommendation in the patient's record; or

(3) The patient was receiving an average daily dose of one hundred twenty MED or more prior to the effective date of this rule. The physician shall follow the steps in paragraph (E)(2) of this rule prior to escalating the patient's dose.

(F) During the course of treatment with an opioid analgesic at doses below the average of fifty MED per day, the physician shall provide periodic follow-up assessment and documentation of the patient's functional status, the patient's progress toward treatment objectives, indicators of possible addiction, drug abuse or drug diversion and the notation of any adverse drug effects.

(G) During the course of treatment with an opioid analgesic at doses at or above the average of fifty MED per day, the physician shall complete and document in the patient record the following no less than every three months:

(1) Review of the course of treatment and the patient's response and adherence to treatment.

(2) The assessment shall include a review of any complications or exacerbation of the underlying condition causing the pain through appropriate interval history, physical examination, any appropriate diagnostic tests, and specific treatments to address the findings.

(3) The assessment of the patient's adherence to treatment including any prescribed non-pharmacological and non-opioid treatment modalities;

(4) Rationale for continuing opioid treatment and nature of continued benefit, if present.

(5) The results of an OARRS check in compliance with rule 4731-11-11 of the Administrative Code.

(6) Screening for medication misuse or substance use disorder. Urine drug screen should be obtained based on clinical assessment of the physician with frequency based upon presence or absence of aberrant behaviors or other indications of addiction or drug abuse.

(7) Evaluation of other forms of treatment and the tapering of opioid medication if continued benefit cannot be established.

(H) This rule does not apply to the physician who prescribes an opioid in any of the following situations:

(1) The medication is for a patient in hospice care.

(2) The patient has terminal cancer or another terminal condition, as that term is defined in rule 4731-11-01 of the Administrative Code.

(I) This rule does not apply to inpatient prescriptions as defined in rule 4729-17-01 of the Administrative Code.

Credits

HISTORY: 2020-21 OMR pam. # 4 (A), eff. 10-31-20; 2018-19 OMR pam. # 6 (E), eff. 12-23-18.

Periodic review date(s): 12-23-23

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

OAC 4731-11-14, OH ADC 4731-11-14

End of Document

Exhibit L

THE STATE MEDICAL BOARD OF OHIO
DISCIPLINARY GUIDELINES

(Revised July 2019)

Disciplinary Guidelines are primarily for the Board's reference and guidance. They are subject to revision at the Board's discretion without notice to the public. Disciplinary Guidelines are intended to promote consistency in Board-imposed sanctions, but are not binding on the Board. The Board recognizes that individual matters present unique sets of circumstances which merit individual consideration by the Board.

CATEGORY I: IMPROPER PRESCRIBING, DISPENSING, OR ADMINISTERING OF DRUGS

A. Prescribing, dispensing, or administering of any drug for excessive periods of time and/or in excessive amounts.

Maximum Penalty: Permanent revocation of certificate or permanent denial of application

Minimum Penalty: Definite suspension, min. 90 days; discretionary probation as appropriate, to include prescribing course

B. (Reserved)

C. (Reserved)

D. Failing to keep patient records of substances prescribed, dispensed or administered; and/or failing to perform appropriate prior examination and/or failure to document in the patient record performance of appropriate prior examination.

Maximum Penalty: Permanent revocation of certificate or permanent denial of application

Minimum Penalty: Reprimand; discretionary probation as appropriate, to include medical-recordkeeping course

E. (Reserved)

F. Inappropriate purchasing, controlling, dispensing, and/or administering of any drug.

Maximum Penalty: Permanent revocation of certificate or permanent denial of application

Minimum Penalty: Definite suspension, min. 60 days; discretionary probation, as appropriate

Exhibit M

OHIO AUTOMATED RX REPORTING SYSTEM

PMP Awarxe™

Ohio PDMP AWARXE

User Support Manual

STATE OF OHIO BOARD OF PHARMACY

11.6 Clinical Application

In work-flow use

Narx Scores are intended to be delivered into workflow automatically as discrete data and be easily viewable within a patient's record. Many systems choose to place the scores in the patient header, or alongside the patient's vital signs.

Narx Scores are best viewed at the beginning of a patient encounter, as such they should be obtained at or near the time a patient is registered.

General Considerations

- The primary purpose of providing Narx Scores is to raise provider awareness to the associated PDMP data available for review.
- Concerning Narx Scores are intended to trigger a *discussion,* **not a decision**. If a Narx Score raises concern the recommended course of action is to evaluate the PDMP data, review any additional pertinent data, and discuss any concerns with the patient.
- Just as there is no single blood pressure that can be considered *normal* for all people, there is no Narx Score that is *normal*. A Narx Score must be applied to the clinical scenario before evaluating appropriateness. For example, a blood pressure of 120/80 can simultaneously be:
    - Inappropriate for a 2-month-old infant
    - Appropriate for a 20-year-old woman
    - Inappropriate for an elderly patient with an average daily blood pressure of 200/100
- Narx Scores are distributed within the PDMP population as follows:
    - 75% of patients score below 200
    - 5% of patients score above 500
    - 1% of patients score above 650
    -

Example Use Cases

Narx Scores can be used to great effect in certain clinical scenarios. Again, the recommended course of action is to seek additional information and discuss concerns with the patient.

Case A – An 17y/o male basketball player with other significant history presents with a severe ankle sprain. His Narx Scores are:

Narcotic	Sedative	Stimulant
000	000	000

Important consideration: If considered for an opioid due to the severity of injury, this may be the patient's first exposure to the effects of an opioid. Recommend thorough review of the risks and benefits with the patient and consideration of an informed consent process.

Case B – an 81 y/o female presents with decreased level of consciousness following a fall where she suffered a closed head injury. Her Narx Scores are:

Narcotic	Sedative	Stimulant
341	501	000

Important Consideration: Many elderly patients are on chronic opioids and benzodiazepines. The use of opioids and benzodiazepines for this patient may have contributed to her fall. The patient may be taking enough medication to develop anxiety seizures due to benzodiazepine withdrawal, complicating the medical picture.

Case C – A 36 y/o male patient with mild chronic back pain frequently treated with opioids presents for a medication refill. On review of the PDMP record the patient has been to 17 different prescribers in the last year. His Narx Scores are:

Narcotic	Sedative	Stimulant
671	240	000

Important Consideration: Many patients obtain medications through multiple different providers. This can be due to the patient being seen in a clinic that is staffed by different providers, or can be due to *access to care* issues requiring visits to urgent care centers or emergency departments.

Score Based Guidance

Score/Range	**Notes**	**Recommendations***
000	This may be the first prescription of this type for the patient.	Discuss risks/benefits of using a controlled substance. Consider informed consent.
010-200	Approximately 75% of scores fall in this range.	Review use patterns for unsafe conditions.
	Occasionally, patients in this score range have a remote history of high usage (> 1 year ago).	Discuss any concerns with patient. See guidance below

		If previously high usage exists with recent abstinence, consider risk/benefits of new prescriptions
201-650	Approximately 24% of scores fall in this range.	Review use patterns for unsafe conditions. Discuss any concerns with patient. See guidance below.
> 650	Approximately 1% of scores fall in this range. Some patient records may have a score in this range and *still be within prescriber expectations.* Many patient records include some level of multiple provider episodes, overlapping prescriptions, or elevated milligram equivalency.	Review use patterns for unsafe conditions. If multiple providers involved in unsafe prescribing discuss concern with patient and consider contacting other providers directly. If multiple pharmacies involved in unsafe prescribing discuss concern with patient and consider pharmacy lock-in program. If overlapping medications of same or different type, discuss concern with patient and consider taper to lower dose and/or discontinuation of potentiating medications. If patient has evidence of a substance use disorder, consider inpatient admit or referral for outpatient evaluation and treatment.

Exhibit N

COMPREHENSIVE PAIN MANAGEMENT INSTITUTE, LLC

POLICY FOR THE RETENTION OF MEDICAL RECORDS

PURPOSE:

To provide standards for the retention of all documentation related to patient care within Comprehensive Pain Management Institute, LLC ("CPMI") and to ensure that medical records are current, detailed, and organized to allow effective patient care, maintain confidentiality, and facilitate quality review.

RESPONSIBILITY:

Physicians, Advanced Practice Providers ("APPs"), Nurses, Practice Administrators, Managers, and all other employees of CPMI.

POLICY:

All medical records shall be considered corporate assets of CPMI. CPMI will maintain an organized system of the retention of medical records. These records will be secure from loss, unauthorized access, unauthorized reproduction, corruption, damage or destruction. Medical records must be maintained and retained on an ongoing basis to ensure accuracy, detail, and organization. This policy shall provide for a process to ensure the ongoing creation, maintenance and storage of medical records as well as the archiving and/or purging of medical records and the data contained therein.

MEDICAL RECORDS:

Every physician and APP is aware of the need to maintain adequate medical records for each patients. Ohio, which also recognizes the need for adequate medical records, has passed statutes and rules regulating the content, retention and accessibility of medical records.

1. Patient medical records shall be made readily available for the provision of healthcare services and healthcare assessment.

2. CPMI shall ensure that medical records are stored and maintained to prevent the unauthorized access, use or disclosure and ensure confidentiality. CPMI shall store all medical records onsite in accordance with its HIPAA Plan and related policies. CPMI shall ensure that it has appropriate administrative, operational, and technical safeguards in place to prevent unauthorized use, disclosure, or access to medical records.

3. CPMI may store medical records offsite so long as the storage facility site is fully compliant with HIPAA and storage of medical record and other confidential information is within the facility's core business services.

4. The retention periods set forth in this policy are set to minimize storage expense and ensure compliance with state and federal law regarding record retention.

5. All medical records shall be destroyed in an appropriate manner consistent with this policy.

6. CPMI will keep all medical records for patients over the age for 21 years for a period of seven (7) years from the date of the last healthcare encounter.

7. CPMI will keep all medical records for unemancipated minors until 18 years of age plus seven (7) years after the last healthcare encounter.

8. Under no circumstances will any medical record be destroyed (1) before seven (7) years after the last healthcare encounter, or (2) in the event CPMI issues a hold on the destruction of patient medical records. In the event CPMI issues a hold on the destruction of patient medical records, CPMI shall not destroy patient medical records until the destruction hold has been lifted.

9. Records must be destroyed in a manner to ensure that they are no longer recognizable as records (e.g. shredding, pulverizing, etc.). CPMI will document the types and quantities of records destroyed as well as the date of destruction. Where feasible, CPMI will establish a record destruction schedule.

APPROVED _____ DATE _____

REVISIONS: _____
_____
_____
_____

Exhibit O

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Strategy to Combat Opioid Abuse, Misuse, and Overdose

A Framework Based on the Five Point Strategy

"The five-point HHS strategy to end the opioid crisis, unveiled under President Trump in 2017, uses the best science and evidence to directly address this public health emergency. Now, HHS is expanding the scope and improving the effectiveness of the strategy. The dedicated men and women of HHS will continue to support communities and families across America until, together, we have brought an end to this crisis."

SECRETARY OF HEALTH AND HUMAN SERVICES
ALEX M. AZAR II

"With this strategic framework, HHS is building upon the 5-point Strategy To Combat the Opioid Crisis using robust, scientific evidence as its foundation to set forth specific, concrete actions that can be taken by the Secretary and the agencies within HHS to end the worst public health crisis of our time."

ASSISTANT SECRETARY FOR HEALTH AND SENIOR ADVISOR FOR OPIOID POLICY
ADM BRETT P. GIROIR

BETTER ADDICTION PREVENTION, TREATMENT, AND RECOVERY SERVICES

Improve access to prevention, treatment, and recovery support services to prevent the health, social, and economic consequences associated with opioid misuse and addiction, and to enable individuals to achieve long-term recovery.

Prevention

- Implement science-based education campaigns to improve the public's understanding of substance use disorders as well as evidence-based treatments and prevention strategies, and to eliminate stigma associated with the disease.
- Increase the use of digital and social media technologies to amplify public health messages regarding prevention.
- Increase and support the use of school- and community-based prevention programs that are evidence-based to prevent misuse of opioids and other substances.
- Engage community and faith-based organizations to use evidence-based messages on prevention, treatment, and recovery.
- Identify individuals who are at risk of opioid use disorder and make available prevention and early intervention services and other supportive services to minimize the potential for the development of opioid use disorder (OUD).
- Educate the public and healthcare professionals regarding drug-drug interactions between opioids and other medications, including the interactions between opioids and benzodiazepines, alcohol, and gabapentin.
    - Working with the Department of Justice (DOJ), and the United States Postal Service (USPS), improve technologies and processes to detect illegal imports and human trafficking of illicit opioids.
    - Facilitate proper disposal of unused opioid prescription medications and other prescription drugs such as benzodiazepines and gabapentin.

Treatment

- Enable individuals, families, and caregivers to find, access, and navigate evidence-based, affordable treatments for opioid use disorder and home and community-based services and social supports.
- Identify and disseminate best practices related to medication-assisted treatment (MAT) and companion psychosocial treatment such as coordinated, holistic, culturally appropriate, person- and family-centered treatment of OUD, including the utilization of a broad range of providers, ancillary professionals, and team-based care.
- Test and implement new payment models that facilitate and incentivize coordinated care, and build in incentives for adoption of payment models across programs.

- Support broader adoption of Assisted Outpatient Treatment and Assertive Community Treatment models and provide technical assistance to states and tribes.
- Increase the number of behavioral health providers knowledgeable about substance use disorders, including psychiatrists, primary care providers with specialized addiction training, peer recovery specialists, social workers, and others.
- Support stakeholder efforts to make a full range of MAT available on demand to all individuals with OUD who meet the eligibility criteria for the specific MAT therapy.
    - Increase the number of providers, including nurse practitioners, physicians, and physicians assistants who are able and willing to provide MAT.
    - Advance telehealth direct care and consultation approaches to MAT.
    - Target workforce development, provider training, and recruitment incentives to underserved areas.
    - Advance innovative service delivery models that can address documented barriers to provider willingness to provide MAT.
    - Pursue a framework and work across different payers to reduce and remove coverage limitations on MAT.
- Track, screen, prevent, and refer to treatment patients with OUD and substance use disorder (SUD) who have infectious complications, including HIV, viral hepatitis, and endocarditis, particularly among persons who inject drugs. This can be done through Syringe Services Programs (SSPs) and other evidence-based strategies.
- Enable family-centered treatment that endeavors to keep families and caregivers together in their homes and communities, including utilizing out of home care only when in the best interest of the child.
- Provide support for pregnant and postpartum women to enter and adhere to family-centered OUD treatment, reduce the risk of relapse, and prevent, and reduce and manage medical complications in the newborn and other children, using approaches that minimize stigma and other barriers to care, and to support the long-term recovery of the women.
- In partnership with professional organizations, develop and implement a comprehensive educational plan for physicians, advanced practice nurses, pharmacists, and other healthcare professionals and providers in training, to improve the national professional expertise in the identification and treatment of addiction as well as safe pain management, treatment, and recovery.
- Enhance communication and formal feedback from state, tribal, and local providers, officials, and other stakeholders to continually improve federal funding, programs, and services.
- Work with states to address the complex challenges of those at risk of, or suffering from, SUD through Medicaid flexibilities as well as novel payment models for integrated care.

Recovery

- Provide culturally and linguistically appropriate education and support to individuals, families, and caregivers to understand the importance of recovery and to find and access a range of evidence-based services.

- Identify innovative ways to expand and fund recovery services as part of a continuum of services to support stable and long-term recovery.
- Support the development of recovery communities, recovery coaches, and recovery community organizations to expand the availability of and access to recovery support services.
- Enhance discharge coordination for people leaving inpatient treatment facilities who require linkages to home and community-based services and social supports, including case management, housing, employment, food assistance, transportation, medical and behavioral health services, faith-based organizations, and sober/transitional living facilities.
- Enhance the ability to provide MAT and transition of care for people exiting the criminal justice system, and in particular following incarceration.
- Expand peer workforce and programming as interventionists in various settings, including hospitals, emergency departments, law enforcement departments, jails, OUD treatment programs, and in the community.
- Strengthen the education process demonstrating the value of peer and recovery supports through Recovery Community Centers and other recovery oriented systems and services.
- Increase collaboration with law enforcement and first responders to enhance their capability of responding to and/or providing emergency treatment to those with OUD.
- Develop best practices, such as toolkits, guidelines and policy briefs, on the development of recovery housing that meets the needs of those with OUDs who may or may not be on MAT.

BETTER DATA

Strengthen public health data reporting and collection to improve the timeliness and specificity of data, and to inform a real-time public health response as the epidemic evolves.

- Collect and disseminate as close to “real-time” as possible, actionable data that can be used to target interventions, deployment of resources locally and regionally, and to assess impacts of federal, state, and local efforts.
- Enhance the speed of data collection and publication of results from HHS surveys on illicit drug use and abuse.
- Work with the Drug Enforcement Administration (DEA) and the U.S. Customs and Border Protection (CBP) to collect data about, and compile periodic and timely reports of, illicit drug seizures.
- Collect data that indicate durable outcomes, such as opioid deaths and non-fatal overdoses; as well as surrogate outcome markers, such as opioid prescriptions, new drug patterns, related harms, patients receiving MAT, and Neonatal Abstinence Syndrome (NAS) incidence, with minimal lag time in order to modify, expand, or change federal strategies to meet the ongoing needs.

- Collect, analyze, and disseminate data that provide insights into causes, risk and protective factors, comorbidities, and disparities of opioid misuse and other substance use, misuse, and addiction that can be used to devise long term solutions to the underlying causes and drivers.
- Collect state-, county-, and zip-code specific data when feasible.
- Improve linkages between disparate data systems, including among HHS operating divisions, to inform interventions as well as analytics and modeling.
- Effectively communicate the meaning of the data and its implications within HHS and externally.
- Conduct a comprehensive assessment of current data and key metrics, and implement strategies to address gaps and identify policy and research questions.
- Create incentives for states to develop, implement, and utilize Prescription Drug Monitoring Programs (PDMP) that are accessible by providers (prescribers and pharmacies) across state lines and integrated into the electronic health record.

BETTER PAIN MANAGEMENT

Advance the practice of pain management to enable access to high-quality, evidence-based pain care that reduces the burden of pain for individuals, families, and society while also reducing the inappropriate use of opioids and opioid-related harms.

- Provide prescribers with actionable information on the appropriate use of opioids and other pain treatment modalities, such as the Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain, which also ensure patients pain management needs are met.
- Develop evidence-based guidance on appropriate management of acute pain including non-opioid approaches and, when appropriate, short-term opioid management.
- Develop further evidence-based guidance on the management of chronic pain, including non-opioid approaches, pre/peri-operative treatment, and when appropriate, opioid management.
- Develop payment policies and other incentives to encourage best practices for the appropriate prescribing of opioids and the use of a full range of non-opioid pain treatments.
- Develop regulatory strategies, guidance, and policies to promote the appropriate use of opioids, including professional and patient labeling, and packaging at the time of marketing approval and in the post-marketing period.
- Assist states to monitor and support best practices by providers, including through the use of comprehensive prescription drug monitoring programs, other data integration mechanisms across states, and clinical decision support in electronic health records.
- Encourage the use of multidisciplinary team models for the management of pain.

- Promote best practices for safe and well-tolerated opioid tapering for people on potentially excessive and unsafe doses, based on established guidelines.
- Work with healthcare professional stakeholders to develop guidance on screening and treatment for co-occurring mental and substance use disorders and unresolved trauma in people living with chronic pain.
- Educate and empower patients, families, caregivers, and communities to understand the risks and benefits of opioid pain medication and non-opioid mechanisms to manage both acute and chronic pain.
- Work with healthcare professional stakeholders to develop guidance for prescribers of when to refer to or link to treatment for OUDs.
- Identify individuals who are at risk of developing chronic pain after an acute pain episode, and make available mental health, substance use, and other supportive services to minimize the potential for the development of chronic or persistent pain.

BETTER TARGETING OF OVERDOSE REVERSING DRUGS

Target the availability and distribution of overdose-reversing medications to ensure the broad provision of these drugs to people likely to experience or respond to an overdose, with a particular focus on targeting high-risk populations.

- Develop models to estimate the amount of naloxone required by communities to be able to reverse cases of opioid overdose.
- Explore development of over the counter naloxone, including an assessment of its impact on availability of naloxone in the community.
- Ensure widespread availability of naloxone, including through standing orders, co-prescription with other opioids, collaborative practice agreements, pharmacist prescriptive authority, targeting of high-risk populations such as people leaving incarceration, residential treatment, and recent opioid-related emergency department visits and hospitalizations.
- Expand availability and affordability of naloxone through grants, including grants to first responders, and the approval of generic products.
- Strengthen education and training on overdose prevention and naloxone administration to ensure that individuals likely to respond to an overdose can take the appropriate steps to reverse an overdose. Develop and assess intervention models across settings that leverage the overdose reversal as a bridge to treatment to reduce long-term dependence on naloxone as the only form of addressing harmful opioid use.

BETTER RESEARCH

Support cutting-edge research that advances our understanding of pain, overdose and addiction, leads to the development of new treatments, and identifies effective public health interventions to reduce opioid-related health harms.

- Support and evaluate novel integrated treatment delivery demonstration projects to bring together all HHS and other entities, including the criminal justice system, in regional projects with short-term and long-term objectives.
- Support the development of non-pharmacologic, non-opioid and/or non-addictive pain therapeutics.
- Support the development of novel opioid antagonists to combat highly potent synthetic opioids, including new antagonists with longer duration of action.
- Support development and evaluation of immunotherapies including vaccines against select opioids.
- Determine risk factors, including genomic, metabolomics, prenatal substance exposure, work history, social, behavioral, and psychological factors for SUD, OUD, and identify how these factors may affect responses to treatment. Explore the development of "personalized treatment" based on these factors to maximize efficacy.
- Develop technologies and systems to alert potential naloxone providers, such as family members, emergency medical services personnel, and others when a person is at imminent risk of overdose death.
- Assess current treatments and develop new treatments, including non-pharmacological treatments, for NAS, as well as appropriate care for all infants with sustained prenatal opioid exposure.
- Improve research and disseminate findings on safe and effective treatment for OUD during pregnancy, including the risks and benefits of pharmacotherapy to both the mother and infant.
- Develop longitudinal data systems to assess the ongoing potential developmental, social, educational, physical, and other disabilities of infants born to mothers with SUD, with a focus on infants with NAS.
- Expand service delivery and intervention implementation research and service delivery innovations in order to identify how best to quickly incorporate scientific advances into community and clinical practice.
- Utilize community based participatory research strategies when evaluating data in diverse communities including tribal communities.

Exhibit P

---------- Forwarded message ----------
From: **David Deppen** <ddeppen@practice-pro.net>
Date: 2013-03-11 11:39 GMT-04:00
Subject: RE: needle EMG coding
To: Leon Margolin <leon3087@gmail.com>

Here are the codes and the Utilization guidelines right from Medicare's policy for EMG and NCS:

95885: Needle electromyography, each extremity; done with nerve conduction study, limited
95886: Needle electromyography, each extremity; done with nerve conduction study, complete, 5 or more muscles studied, innervated by three or more nerves or four or more spinal levels

Utilization Guidelines
Services performed for excessive frequency are not medically necessary. Frequency is considered excessive when services are performed more frequently than generally accepted by peers and the reason for additional services is not justified by documentation.

The number of nerves tested should be the minimum necessary to address the clinical issue being evaluated. In almost all studies this will appropriately include evaluation of 1 or more nerves that have normal test results.

The following bullets summarize the reasonable maximum number of studies per diagnostic category necessary for a physician to arrive at a diagnosis in 90% of patients with that final diagnosis. In simple straightforward cases, fewer tests will be necessary, particularly when the most critical tests are normal. In the small number of cases that require testing in excess of these numbers, the physician must be able to justify the additional testing with supplementary documentation.

Carpal Tunnel (unilateral)
· Needle EMG - 1 test
· CPT codes 95907/95908Motor NCS with or w/o F-wave – 3 tests
· CPT code 95908 Sensory NCS – 4 tests

Carpal Tunnel (bilateral)
· Needle EMG - 2 tests
· CPT codes 95907/95908 Motor NCS with or w/o F-wave – 4 tests
· CPT code 95909 Sensory NCS – 6 tests

Radiculopathy
· Needle EMG - 2 tests
· CPT codes 95907/95908 Motor NCS with or w/o F-wave – 3 tests
· CPT code 95907 Sensory NCS – 2 tests
· CPT codes 95907 H-Reflex – 2 tests

Mononeuropathy
· Needle EMG - 1 test
· CPT codes 95907/95908 Motor NCS with or w/o F-wave – 3 tests
· CPT code 95908 Sensory NCS – 3 tests
· CPT codes 95934/95936 H-Reflex – 2 tests

Polyneuropathy/Mononeuropathy Multiplex
· Needle EMG - 3 tests
· CPT codes 95908 Motor NCS with or w/o F-wave – 4 tests
· CPT code 95908 Sensory NCS – 4 tests
· CPT codes 95934/95936 H-Reflex – 2 tests

Myopathy
· Needle EMG - 2 tests
· CPT codes 95907 Motor NCS with or w/o F-wave – 2 tests
· CPT code 95907 Sensory NCS – 2 tests

Motor Neuronopathy
· Needle EMG - 4 tests
· CPT codes 95908 Motor NCS with or w/o F-wave – 4 tests
· CPT code 95907 Sensory NCS – 2 tests

Plexopathy
· Needle EMG - 2 tests
· CPT codes 95908 Motor NCS with or w/o F-wave – 4 tests
· CPT code 95909 Sensory NCS – 6 tests
· CPT codes 95934/95936 H-Reflex – 2 tests

Neuromuscular Junction
· Needle EMG - 2 tests
· CPT codes 95907 Motor NCS with or w/o F-wave – 2 tests
· CPT code 95907 Sensory NCS – 2 tests

Tarsal Tunnel (unilateral)
· Needle EMG - 1 test
· CPT codes 95907/95908 Motor NCS with or w/o F-wave – 4 tests
· CPT code 95908 Sensory NCS – 4 tests

Tarsal Tunnel (bilateral)
· Needle EMG - 2 tests
· CPT codes 95908/95909 Motor NCS with or w/o F-wave – 5 tests
· CPT code 95909 Sensory NCS – 6 tests

Weakness, Fatigue, Cramps or Twitching (focal)
· Needle EMG - 2 tests
· CPT codes 95907/95908 Motor NCS with or w/o F-wave – 3 tests
· CPT code 95908 Sensory NCS – 4 tests

Weakness, Fatigue, Cramps or Twitching (general)
· Needle EMG - 4 tests
· CPT codes 95907/95908Motor NCS with or w/o F-wave – 4 tests
· CPT code 95908 Sensory NCS – 4 tests

Pain, Numbness or Tingling (unilateral)
· Needle EMG - 1 test
· CPT codes 95907/95908 Motor NCS with or w/o F-wave – 3 tests
· CPT code 95908 Sensory NCS – 4 tests
· CPT codes 95934/95936 H-Reflex – 2 tests

Exhibit Q

PRACTICEPRO

4494 Derr Rd
Springfield, OH 45503-1445

Caresource
Special Investigations Unit
PO Box 1940
Dayton, Ohio 45401

Ms. Katherine M Leff,

We are the billing company for Dr. Leon Margolin and his medical practice, Comprehensive Pain Management Institute, LLC. We are a pain management specific billing company that has over 30 years of experience billing every aspect of pain management services.

Dr. Margolin made us aware of the current investigation by Caresouce concerning the CPT code 95912. This code is defined in the 2017 CPT Manual as: Nerve Conduction Studies, 11-12 studies. Based on the testing that is done, this would be the correct code to bill for Dr. Margolin.

Caresource has a very complex automated claims review system in place to verify that billing that does not meet medical policy denies upon receipt. At no time during the almost 4 year period in question did Caresource ever deny this billing as not meeting medical policy. As a billing company we find that most often the Caresource system will deny claims in error for not meeting medical policy when in fact they do. We know that this is a system in place to prevent items from being paid that should not, but in this circumstance there was never a time that these claims were denied by Caresource.

The information sent to us states that 30 records were reviewed and due to a 100% error rate on your findings, there is a request for all reimbursement to be refunded for this code. Based on our review of the almost 2000 charts, we have found that there are hundreds of patients on the list that did have a needle EMG study done or were tested for diagnoses such as carpal tunnel or neck pain that includes carpal tunnel evaluation. The list of the patients does not seem to support the conclusions of the letter. Reviewing 2% of the charts would not give you enough data to request a refund from almost 2000 patients.

In conclusion, we see that Dr. Margolin billed the proper correct code for the testing he performs in office. Caresource's automated claims review system at no time denied these claims as being not medically necessary based on medical policy. Caresource reviewed a very small amount of the total charts billed for this investigation.

David Deppen
Billing Manager
Practice-Pro, LLC

Exhibit R

PRACTICESHIELDS

October 14, 2019

To whom it may concern:

I am a former police detective, former State of Ohio Medical Board Investigator, former Director of Compliance for Cincinnati Pain Physicians, CME trainer, healthcare regulatory expert witness, and healthcare regulatory consultant. (See attached CV) As a healthcare regulatory consultant, I only assist clients that demonstrate a lack of criminal intent.

On September 12, 2019, I conducted an extensive independent review and audit of Dr. Margolin's pain management practice located at 5245 E. Main St. in Columbus, OH. Dr. Margolin is one only a few pain physicians in Ohio that is double specialty boarded in pain. Dr. Margolin has dedicated his life and education to learning the newest and most advanced methods to treat his pain patients in a medically sound, regulatory compliant, and patient focused manner.

The practice review and audit included a review of medical records for regulatory compliance and standards of care, general practice and patient observations, staff observations with patient interactions, policy and procedure reviews, and State of Ohio Pain Management License practice compliance inspection.

I can testify to the high level of compliance demonstrated by Dr. Margolin's medical practice in regards to the State of Ohio Pain Clinic (PMC) license requirements, Ohio's Revised and Administrative Codes, and exceeding minimum standards of care (The standard in which all pain practices should be operated).

Dr. Margolin not only complies with all state requirements and standards of care, Dr. Margolin had already implemented several of the recommendations listed in HHS Pain Management Best Practices Inter-Agency Task Force Final Report. Examples of compliance- Page 17- Clinical Best Practices lays the ground work for quality and complaint patient care. Patients must be thoroughly evaluated including the medical and probable biopsychosocial factors contributing to a pain condition. Dr. Margolin utilizes EMG and NCV studies to determine the medical factors contributing to their pain condition. Clinical best practices goes on to emphasize the importance of screening for Substance Use Disorder and in the second paragraph states "Finally, quality care must be adequately reimbursed." Dr. Margolin screens all patients for substance use disorder because not only is it recommended and required by best practices and state law, it is the safer for the patient, their family, and the community. Page 30- 2.2.1 Overdose Prevention Education and Overdose Risk. Dr. Margolin educates his patients on the dangers of opioids

not only in person, but also in their opiate agreement, and other patient forms every patient visit as part of their assessment. Dr. Margolin offers Naloxone prescriptions to his patients as well. Pages 39-40 sections 2.5.1 and 2.5.2 go only to further list and justify SUD screening and psychological evaluation and treatment. Dr. Margolin has long practiced these recommendations even before the expert report was completed. These examples only highlight a few ways that Dr. Margolin's polices and procedures were above compliant from the start. The report actually models Dr. Margolin's current pain practice and compliments his compliance.

I would like to mentioned the State of Ohio Pain Clinic (PMC) license requirement to document organic pathology prior to prescribing opioid medications. Dr. Margolin fulfills this requirements by obtaining records, imaging reports and performing electro diagnostic studies (EMG and NCV) that provide immediate objective results that document organic pathology.

Dr. Margolin made compliance with the state and national guidelines a high priority. Dr. Margolin contacted AANEM and received a written response from Millie Suk, JD, MPP I AANEM Health Policy Director stating that "AANEM does not have any "best practices" established for pain management" and that AANEM endorses AAPMR policies. Dr. Margolin contacted AAPMR and its certifying body ABPMR and performed a voluntary practice improvement project under ABPMR guidance that showed a high level of compliance with the state and national guidelines, clear medical necessity and significant impact on patient care. This project received high reviews from the experts Dr. Wainepal and Dr. Kimura.

I would also like to mention Dr. Margolin's SBIRT protocol that is very thorough, efficient and compliant with the MLN (ICN 904084) (MLN requires physician to implement SBIRT as required by the state law (42CFR 410.20), the State of Ohio Pain Clinic (PMC) license requirements and HB 93 state law.

Dr. Margolin's practice treats high risk vulnerable patients that frequently require 30 min or more for procedures related to screening for substance use and alcohol. These procedures include face to face time spent by Dr. Margolin and his 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 review (of note Dr. Margolin's practice obtains OARRS for every patient visit which is the highest level of compliance with the SMBO policy and HB-93 law), and several educational materials. The initial evaluations include additional assessments such as SOAPP-R and ORT and additional educational materials.

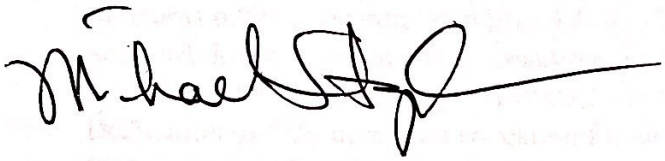
His SBIRT records document the time spent, rationale for ordering tests (i.e. urine screens), relevant history, assessment, plan of care for each encounter. Dr. Margolin identifies and manages the risk factors very efficiently (of note frequent consultation with a qualified pain psychologist, pharmacology doctors and other specialists).

Dr. Margolin's excellence in implementation of the SBIRT protocol as related to screening for substance use and alcohol is evident by the high number of referrals from major hospitals such as OSU, Riverside, Grant, Adena Health and University Hospitals in Cleveland and even other pain management practices. It's my understanding is that Dr. Margolin is going to present his experience in this field at the State and national meetings and educational events.

Finally, it should be noted that Dr. Margolin's office only sees an average of 15 patients per provider per day. This average patient number is extremely low compared to his peers that see upwards of 40-50 patients a day and does not indicate a physician that is interested more in profit than patient care.

If you have any questions or would like additional information, feel free to contact me on my cell at (513) 464-6721 or via email: Michael.Staples@practiceshields.com

Regards,



Michael Staples, CMBI

MICHAEL W. STAPLES, CMBI
(513) 464-6721 • Michael.Staples@practiceshields.com

Director of Compliance
Regulatory and Legal Heath Care Compliance

Over 20 years' experience in criminal investigations, regulatory license investigations, scope of medical practice investigations, health care regulatory and legal compliance, management, conflict resolution, drug diversion investigations, and drug diversion education.

Demonstrated success record in:

- Successful investigation and prosecution of licensed health care professionals.
- Successful investigation and administrative action of licensed health care professionals for standards of care and administrative violations.
- Successful investigation and prosecution of criminal drug diverters.
- Experienced with identifying, preventing, and deterring health care drug diversion.
- Dedication to drug diversion education for health care professionals.
- Proven record of regulatory compliance excellence.

CORE COMPETENCIES

• Criminal/Administrative Investigations • Regulatory Compliance • Public Speaking
• Drug Diversion Education • Drug Diversion Investigations • Safe Prescribing Practices

HIGHLIGHTED CAREER ACHIEVEMENTS

- 2+ years' experience as Director of Compliance for a large pain management office.
- 9+ years' experience as a Police Detective focusing on Criminal Drug Crimes.
- 9+ years' experience as a Medical Board Enforcement Investigator focusing on Controlled Substance Prescribing Investigations, prescriber education, scope of practice and minimum standards of care investigations.
- Earned National recognition as a Certified Medical Board Investigator "C.M.B.I." from the National Federation of Medical Boards.
- Staples, M & Practice Shields, LLC. "Comprehensive Controlled Substance Prescribing in the age of increased regulations, legal challenges, and diversion." Presented in conjunction with West Virginia Interventional Pain Physicians accredited with Commendation from the West Virginia State Medical Association for 17.25 Category 1 CME. February, 2019
- Staples, M & Practice Shields, LLC. "Comprehensive Controlled Substance Prescribing in the age of increased regulations, legal challenges, and diversion." Presented in conjunction with Tri Health Hospital for 15 Category 1 CME. February, 2019
- Staples, M. & Harding, K "APRNs and Schedule II Prescribing in Ohio." Presented in Conjunction with the Ohio Board of Nursing. Available for 6 Hours of Continuing Education Credit. Ohio Board of Nursing, Columbus, Ohio. March 31, 2014.
- Staples, M., Harding, K, & Galante, C. "APRNs and Schedule II Prescribing in Ohio." Presented in Conjunction with the Ohio Board of Nursing and Ohio State Board of Pharmacy.

Available for 6 Hours of Continuing Education Credit. Ohio Board of Nursing, Columbus, Ohio. November 25, 2013.

- Staples, M. "It Takes an Office: Protecting your Practice from Drug Diversion." Mercy Health Systems CME, June 15, 2015. https://youtu.be/tiFrhirb93M
- Former Director of Education and Training for Ohio Chapter of NADDI.
- Certified as a National Certified Investigator and Inspector Training (NCIT) both basic and specialized. Known as CLEAR Certification.
- Expert Report Admitted Cuyahoga County Common Pleas Court, State of Ohio, Case- CR-16-607224A-D State of Ohio vs. Rogaciano Trocio, MD, Maria Siwik, RN, Virginia Paulino, and Janet Paulino

PROFESSIONAL EXPERIENCE

Interventional Pain Specialists, Inc, 2019-Present
Crestview Hills, Kentucky
Compliance Officer

Regulatory and Legal Compliance Management
HIPPA Compliance Office
Medical Records Review
Staff Education
Policy and Procedure Implementation
Drug Diversion Reduction
Standards of Care Reviews

Cincinnati Pain Physicians, LLC, 2017 – 2019
Cincinnati, Ohio
Director of Compliance

- Regulatory and Legal Compliance Management
- Identification of Drug Diversion in patient population
- Policy and Procedure Implementation
- Medical Record's Review
- Staff education
  Prevention of Drug Diversion in practice
- Standards of Care Reviews

Practice Shields, LLC
Fairfield, Ohio 2017 – 2018
Founder and Owner

- Dedication to ensuring regulatory compliance for health care practices and prescribers
- Health Care Practice and Prescriber Education
- D.R.A.P. Accreditation Program (Drug Resistant Accredited Practice)
- Practice compliance audits
- Expert Testimony
- Standards of Care Reviews
- Practice Drug Diversion Defense Techniques

State Medical Board of Ohio, 2007 – 2017
Columbus, Ohio
Enforcement Investigator

- Investigations of Ohio Regulatory Rules and Laws
- Standards of Care Investigations
- Testimony at Federal, State, Local, and Administrative Hearings
- Prescriber Controlled Substance Education
- Drug Diversion Investigations
- CME Diversion program development and implementation
- Member of drug abuse and diversion task forces

City of Monroe Police Department, 1998 – 2007
Monroe, Ohio
Police Detective

- Criminal Drug Investigations
- Warren County Drug Task Force Participant
- Federal, State, and Local Court Testimony
- CVSA Lie Detection Operator
- Butler County Child Abuse Task Force Member
- Established a strict reporting system for allegations of stolen controlled medications

EDUCATION and CERTIFICATION

Certified Medical Board Investigator (CMBI)
Basic and Specialized CLEAR Certification
OSU-Newark, Criminal Justice
Central Ohio Technical College, Criminal Justice
UC-Clermont Pre-Law
1995 Butler Tech Police Academy, Police Certification 1998

Exhibit S

October 18, 2020

To Whom It May Concern,

I am a certified coder and medical auditor through the AAPC I have been a medical coder since 2012 with five years of auditing experience. Please see my review enclosed.

Compliance in the health care industry is the process of meeting regulations, recommendations, and expectations of Federal and State agencies that pay for health care services and regulate the industry. This summary of findings is given to assist in identifying any problem areas. I reviewed in depth all reports for the patient examples used in the SBIRT article Margolin, L. "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 Volume 5, Issue 01. I reviewed EMG reports for all patients (see enclosed item for patient list 2) I also reviewed in depth all patient records for NARX score analysis. (see enclosed item for patient list 3)

All findings and recommendations are based on standards for billing and coding, regulatory standards: CPT/American Medical Association - Professional Edition, ICD-9-CM/ICD-10-CM, Optum Professional, Office of Inspector General references (www.oig.gov), Guidelines for Ethical Behavior Relating to Clinical Practice Issues in Neuromuscular and Electrodiagnostic Medicine, www.cgsmedicare.com, MLN /Local coverage determination L36029 controlled substance monitoring and drugs of abuse testing. www.aafp.org, and American Academy of Professional Coders Medical Auditing (www.aapc.com). 1995 guidelines were used in this audit and the Marshfield audit tool was applied to level the visit.

Target codes for review included SBIRT (Screening and Brief Intervention) protocol for management of high-risk patients. Services for SBIRT include but are not limited to HCPCS and CPT medical codes, G0396, G0397/ 99408,99409 Alcohol and/or substance (other than tobacco) abuse structured assessment (e.g, AUDIT,DAST) and brief intervention based on time, OARRS, Urine drug testing 80305-80307/G0434. Nerve conduction studies 95907-95913, Autonomic studies 95923, 95924, 93922 and 93040 which are diagnostic test and minimally invasive procedures such as 76942, 64450, 64418, 64405, 64425. 20533 (injections and needle placement) which are services that help patients with chronic pain to improve functionality and reduce pain.

A focus on G0396 and G0397 for compliance and reimbursement was assessed. CSM introduced two G codes in 2008 for specific use for assessment and intervention services. CMS Pub 100-04 Medicare Claims Processing. Transmittal 1423 states,

"Instead, we have created two parallel G-codes to allow for appropriate Medicare reporting and payment for alcohol and substance abuse assessment and intervention services that are not provided as screening services, but that are performed in the context of the diagnosis or treatment of illness or injury. The codes are HCPCS code G0396 (Alcohol and/or substance (other than tobacco) abuse structured assessment (e.g., AUDIT, DAST) and brief intervention, 15 to 30 minutes) and HCPCS code G0397 (Alcohol and/or substance (other than tobacco) abuse structured assessment (e.g., AUDIT, DAST) and intervention greater than 30 minutes). Contractors shall consider payment for HCPCS codes G0396

and G0397 only when appropriate, reasonable and necessary (i.e., when the service is provided to evaluate patients with signs/symptoms of illness or injury) as per section 1862(a)(1)(A) of the Act."

The provider can utilize these codes in treating patients, when appropriate, reasonable and necessary and that patients should have signs and symptoms of illness. This is based on assessments, testing, reviewing risk factors, NARX scores and behavioral patterns,

Local coverage determination L36029 states, A physician who is writing prescriptions for medication to treat chronic pain can manage a patient better if the physician knows whether the patient is consuming another medication or substance, which could suggest the possibility of SUD or lead to drug-drug interactions. Additionally, UDT may help the physician monitor for medication adherence, diversion, efficacy, side effects, and patient safety in general." Dr. Margolin's practice established the SBIRT protocol standard of testing to correspond with NARX score (the analysis of the patient risk) that are also in line with the local coverage determination, that states, "Definitive testing may be ordered when accurate and reliable results are necessary to integrate treatment decisions and clinical assessment." Rational for testing patients are determined by the length of abstinence, from 1 test per week for patients with 0-30 consecutive days of abstinence, 1-3 tests per month for abstinence of 31-90 days and 1-3 test in three months for patients that are greater than 90 days of abstinence. I agree with Dr. Margolin's use of L36029 for SBIRT /G codes as described in this article as recommended by ICN MLN904084.

The determination also states that medical necessity is established on "patient-specific elements identified during clinical assessment." This happens through the patient's evaluation and management visit, the medical decision-making process that includes reviewing tests, consulting with other health providers, establishing a treatment plan, and medication management and the OARRS report. This is based on an individual's needs.

Nerve conduction studies 95910-95913, autonomic studies 95923, 95924, 93922 and ECG 93040 are diagnostic studies that help detect illnesses associated with nerve functionality. Many patients on chronic opioid therapy have chronic pain conditions such as chronic nerve pain (neuropathy) or sciatic nerve problems, musculoskeletal diseases, auto-immune diseases and other conditions. Patients that are in chronic pain turn to use of illicit pain medicines. These conditions can be a result of alcoholism and drug abuse. Autonomic studies are a collection of motor, sensory and autonomic data. Dr. Margolin uses this tool to help determine sources of pain, and to see if the autonomic nervous system is affected. This could affect internal functions such as blood pressure, heart rate, sweating, Guidelines for clinical practice of neuromuscular and electrodiagnostic studies is standardized by AANEM

Each patient in the article was examined in depth for compliant documentation standards, comprising of risk stratification, informed consent, diagnostic studies, additional records and treatment, as well as medical necessity which is the overarching criterion for treatment of a patient. Each chart was reviewed in detail for completeness of evaluation and management, including history, physical exam, labs, mental screenings, EMGs, pain assessment, NARX score, counseling and educational materials. Charts that included EMGs had informed consents and appear to be compliant and follow national standards and guidelines.

The cost to treat chronic pain patients is high. Dr. Margolin is combating the conflict between state and federal regulations that provide guidelines for treatment of these patients and payer denial of the

services (G codes) that put patients at higher risks. I would like to acknowledge the depth of assessment and documentation that Dr. Margolin submits establishing medical necessity for treatment of his patients. Quality patient care is the highest standard. The SBIRT protocol exemplifies this standard and is compliant, detailed, and methodical.

Finally, Dr. Margolin's utilization of the above codes appear to be applied correctly regarding billing and coding guidelines and abide by the standards of use as set in local coverage determinations through Medicare. I believe their use is innovative and cost effective for the payer and patient while still providing quality care. Good documentation is necessary for continuity of care. This is a top priority to Dr. Margolin and is evident in the high level of records that is kept for each patient. This along with his rationale and medical decision-making, support the use of the codes billed for reimbursement.

Please feel free to reach out to me with any questions or concerns. You may reach me at tleslie@mdbillingky.com.

Sincerely,

Tina Leslie

Tina Leslie CPC, CPMA, CEMC, CEDC, CHTS-TR,
tleslie@mdbillingky.com

Enclosures (2)

1. Copy of patient list 1 and list 2
2. Copy of patient list 3 NARX scores
3. Copy of the SBIRT article Margolin, L. "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 Volume 5, Issue 01

Exhibit T

William H. Vasilakis, Psy.D.

130 Tarkiln Road
Lancaster, OH 43130
1-740-503-5455

PROFESSIONAL EXPERIENCE

Hocking Valley Community Hospital
Logan Ohio
Work with geriatric population, counsel veterans and perform Gastric Bypass evaluation, pain management evaluations. Current

Apex Counseling
Ph: 614-751-1090
General counseling, psychological testing, forensic evaluations and custody evaluations, Pain management (Spinal Stimulator Evaluations), Work with LHI (Logistics Health Institution) evaluating candidates for military service. Current

Integrity Psychological Counseling, Inc 2005-2012
42 Hill Road South Pickerington, Oh 43137
Private Practice specializing in forensic evaluation, dual diagnosis, addictions, counseling, competency evaluations, psychological evaluations, Impaneled with Tricare for referrals with current service personal and veterans PTSD diagnosis and counseling with veterans of WWII, Vietnam, Desert Storm Legal work for Fairfield County Court System.
Bariatric & Gastric Bypass Evaluation, Spinal Stimulator Exams

Senior Life Consultants 2006-2011
6465 Reflections Drive, Suite 110
Dublin, OH 43017
Nursing Home evaluations, counseling geriatric population, consultation with physicians competency evaluations

Circleville Juvenile Correctional Facility 2006 - 2007
640 Island Road Circleville OH 43113
Clinical Experience: Psychology Supervisor.
Responsible for program development, scheduling, supervision of staff and caseloads, overall clinical management of institution, responsible for QI implementation and testing, and supervision of units.

River Valley Counseling 2001 - 2005
131 N. Ewing Street, Lancaster, OH 43130
Clinical Experience: Adult and adolescent individual and family psychotherapy, specialize in dual diagnoses; bariatric evaluations, spinal stimulator evaluations and evaluations for rehab, assessments for work injuries. BWC evaluations

Fairfield Medical Center 2001 -2012

401 North Ewing Street, Lancaster, OH 43130
Affiliate Staff Psychologist: Consultations, evaluations, therapy and triage of patients admitted to the Behavioral Health Unit.

Drug & Alcohol Recovery Center of Fairfield County 2000 -2001
1856 Cedar Hill Road, Lancaster, 01143130
Clinical Experience: Clinical Director: Responsible for program development, supervision of staff caseloads, crisis work, responsible for Q.I. implementation, and overall clinical management of agency.

Maryville Academy City of Youth 1996 - 1999
1150 North River Road, Des Plaines, Illinois 60016

Clinical Experience: Caseload involved assignment to two diagnostic group homes with youth and adolescents ages 7 years to 18 years. Tasks included psychological testing, individual therapy, develop group therapy for both group homes, court appearances on behalf of the youth, and staff training, and recommended alternate and additional placement and crisis intervention.
Doctoral Internship Jan. 1995 to Jan. 1996

Alexian Brothers Medical Center-Niehoff Mental Health Unit
995 Beisner Road, Elk Grove, Illinois 60007
Supervisor John Noto, PH.D.
Clinical Experience: Psychological testing, psychological reports, individual assessments, diagnosis, in-patient admissions, case management, supervision of practicum students, led groups for substance abuse and dual-diagnosis.

Samaritan House-Outpatient Adolescent Addictions 1994 - 1994
999A Leichester Road, Elk Grove, Illinois 60007
Supervisor: John Noto, Ph.D.
Clinical experience: Led adolescent addiction therapy groups, parent education groups, psychological testing, led multi-family educational groups, drug screens.

Alexian Brothers Medical Center-Addictions Treatment Center. 1993 - 1993
800 Beisterfield Road, Elk Grove, Illinois 60007
Supervisor Joan Stiech, RN CSADC
Clinical Experience: Coed psychotherapy groups, individual therapy, drug screens, intake und admissions, lecturer in addiction lectures series.

EDUCATIONAL BACKGROUND:

CHICAGO SCHOOL OF PROFESSIONAL PSYCHOLOGY 2009- 2009
Degree Conferred: Certificate of Forensic Psychology

ADLER SCHOOL OF PROFESSIONAL PSYCHOLOGY

65 East Wacker, Chicago, Illinois 60601
Degree Conferred: Doctor of Psychology, (Psy.D.) Clinical Psychology 1991 - 1996
Certification : Substance Abuse Counseling

NORTHEASTERN ILLINOIS UN1VERSITY
5500 North Louis, Chicago, Illinois 60625
Degree Conferred: M.A. Community & Family Counseling Sep. 1984 to Oct. 1986
Degree Conferred: M.A. History Jan. 1981 to Dec. 1983

NORTHEASTERN ILLINOIS UNIVERSITY
5500 North Louis, Chicago, Illinois 60625
Degree Conferred: B.A. Psychology. Sep. 1977 to Jun. 1980

HARPER COLLEGE
1200 W. Algonquin Rd., Palatine, Illinois, 60067
Degree Conferred: A.A. Liberal Arts Jan. 1975 to Aug. 1977

LICENSURE AND CERTIFICATIONS
State of Ohio #5481
Certificate: Forensic Psychology
Certificate Substance Abuse Counseling
(Alder School of Professional Psychology) Apr. 1994 to Dec. 1994

PRESENTATIONS
-Psychological Needs of the Substance Dependent Patient
-Pain Management Team, Fairfield Medical Center, Lancaster, OH
-Identifying Drug Abusers and Pain Management Technique in Patients
-With a History of Drug Abuse, Pain Management Physicians, Fairfield Medical Center, Lancaster, OH
-Peer Pressure and Anger Management; Thomas Ewing Junior High School, Lancaster, Ohio
-"Catch Me If You Can—Obsessive Compulsive Disorder", and
-"Stress and Anxiety Disorder in the Adult Population" 12th Annual
-Early Childhood Conference, Ohio University, Lancaster Campus, Sponsored By the Children's Committee,
a subcommittee of Fairfield County Family,
Adult and Children First Counsel
-"Competency Evaluation: presented to the Ohio State Bar Association, Lancaster, OH
-"Childhood Depression", interview for Medical Minute presented by WLOH Radio, Lancaster, OH
-"Signs and Symptoms of Childhood Depression: written for Lancaster Eagle Gazette through Fairfield Medical Center.
-Interview, Fairfield Focus, WLOH Radio, Lancaster, OH
-"Out of the Box" Workshop, presented with Dr. Miller and Dr. Wing

Ohio University Inn, Athens. OH
-"Emotional and Psychological Health: How to Support Employees", Women's Division, Lancaster Chamber of Commerce, Presented at Fairfield Medical Center, Lancaster, OH.

Book Written under Pseudonym T.L. Shull: Do They Have a Pill for That? Publisher I Universe Press, March 2019.

Exhibit U

APEX

· Counseling Services ·

10/13/2020

To whom it may concern:

I am a licensed psychologist, who has certification in Addiction Medicine and have taken training in pain management. I had been a clinical director of a recovery program in Lancaster, Ohio (please find my resume enclosed).

I have evaluated and followed up many of Dr. Leon Margolin's patients (including all the patients in the patient list enclosed), however, I am not an employee, colleague, or social friend of Dr. Margolin. I did not receive any payment for this review.

As described in my prior letters (dated October 10, 2019 and May 16, 2019), based on my experience of more than 20 years in the field of pain and addiction, I fully endorse the use of the SBIRT (G codes) and addressing psychological factors in EMG testing for the patients in the list enclosed. I think Dr. Margolin has created one of the best SBIRT programs in the state of Ohio which is medically necessary and fully compliant.

I fully endorse his publication in collaboration with the Cleveland Clinic Foundation published in a peer-reviewed journal:

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

There are several independent publications by American Medical Association, HHS, National Institute for Drug Abuse, Society for Addiction Medicine and other agencies that have recently endorsed similar findings. Dr. Margolin's SBIRT program is even more relevant and needed during the COVID-19 pandemic.

For example, Dr. Nora D. Volkow, Director, National Institute on Drug Abuse, National Institutes of Health (USA) recently (September, 2020) published the enclosed article calling for increase in screening of the pain and addiction patients, especially since this population is at increased risk for COVID-19.

American Medical Association (AMA) published the enclosed urgent brief on August 4th, 2020 marking Ohio as an area of a sharp increase in opioid mortality:

"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

5310 East Main Street
Columbus, OH 43213

PHONE (614) 751-1090
FAX (614) 751-1091

The opioid crisis has become an epidemic within the COVID-19 (see enclosed):

https://www.painmedicinenews.com/Multimedia/Article/08-20/Panel-COVID-19-Compounds-Opioid-Public-Health-Emergency/59293

It is absolutely clear to me that any denial of the SBIRT (G codes) or other services rendered by Dr. Margolin or marking them as "unallowed" and any recoupment of funds from Dr. Margolin's practice would not only contradict the acceptable national and state guidelines but in effect constitute a public health hazard that puts hundreds if not thousands of Ohioans at the risks of disability and death.

Such policies must be stopped to prevent danger to thousands of people in Ohio and nationwide as reflected by the HHS, AMA, National Institute for Drug Abuse (NIDA) policies and publications. Ohio is one of the most affected area devastated by the crisis, therefore urgent actions are required.

Sincerely,
William Vasilakis, Psy.D.
Dr. William Vasilakis, Psy.D

Clinical Psychologist #5481

5310 East Main Street
Columbus, OH 43213

PHONE (614) 751-1090
FAX (614) 751-1091

APEX

· Counseling Services ·

Addendum – October 10, 2019:

I would also like to clarify that each time the patient is defined as "low risk" or a "good candidate for narcotic medication" this assessment is based on the history and the data reported by the patient. There it is mandatory to continue SBRIT (G0397) protocol attached.

Literature shows that some patients will develop aberrant drug seeking behavior despite an initial recommendation to be a "good candidate for narcotic medication" or "low risk", that's why the guidelines mandate the SBRIT (G0397) monitoring that Dr. Margolin implemented in his practice.

Based on my clinical experience of 20+ years in this field of pain and addiction psychology, serving as the head of the Department of Addiction Medicine in the Lancaster Hospital, I think Dr. Margolin has created one of the best SBIRT programs in Ohio and maybe nationwide. Dr. Margolin's practice is located in the epicenter of the opioid epidemic and sub-specialized in the screening for drug and alcohol of high risk patients that require high frequency of such screening. Dr. Margolin receives referral for the screening for drug and alcohol of high risk patients from hospitals including OSU, Riverside, Mount Caramel, and University Hospital in Cleveland, OH and even from other pain management clinics in the area because of the outstanding quality of his SBRIT (G0397) protocol for screening high risk patients for drugs and alcohol.

My understanding is that he has presented his experience at the 2019 national meeting and is invited to present his SBIRT experience at the Case Western School of Medicine continuous medical education event.

Respectfully,

William H. Vasilakis, Psy.D.

William H. Vasilakis, Psy.D.

Clinical Psychologist

5310 East Main Street
Columbus, OH 43213

PHONE (614) 751-1090
FAX (614) 751-1091

Patient Name: **INS:** **DOB:** **Date:**

COMPREHENSIVE PAIN MANAGEMENT INSTITUTE, LLC (CPMI)
5245 E. Main Street, Columbus, OH; 43213
Ph. 614-557-6075, F. 614-453-8222

Screening And Brief Intervention Review Sheet

In compliance with the SMBO guidelines the CPMI provider reviewed:

- SOAPP R
- Review of PADT tool that includes 4As of chronic pain treatment (Analgesia, Activities of Daily Living, Aberrant Drug Related Behavior, Adverse Events) , patient progress towards objective for the duration of treatments.
- Review of Assessment Of Patient Receiving Protracted Prescription Medication For The Treatment Of Intractable Pain Form (Pursuant to State Medical Board of Ohio Administrative Rule 4731-21-02)
- Review Withdrawal Assessment form
- Review OARRS report
- ORT / COMM assessment tools on selected charts
- Results of the screening, history, physical examination, responses to and assessment of the particular items required for chronic prescription of controlled medications (including PADT tool enclosed), and alternatives to treatment reviewed and discussed with the patient

Total time spent - greater than 30 minutes

❑ at least 15-30 / other _____ minutes

Comments:

_____

_____

_____

_____

Leon Margolin MD, PhD / Jing Liu CNP

Exhibit V

CHAPTER 18 ELECTRODIAGNOSTIC EVALUATION OF ACUTE AND CHRONIC PAIN SYNDROMES

DOUGLAS G. CHANG AND ELAINE S. DATE

INTRODUCTION

Before a clinician can treat pain effectively, the utmost must be done to identify what condition is being treated, and identify what may be causing pain. For this purpose, electrodiagnostic studies are important in the evaluation of acute and chronic pain syndromes. They give valuable, quantitative information on the physiologic health and functioning of nerve and muscle. They help localize injuries, quantify the extent of injury, suggest age of injury, and give valuable prognostic information that can change treatment protocols. They can monitor interval progression. All of this complements the static, anatomic structural information provided by radiological imaging studies. In other words, radiological imaging can identify anatomy that may or may not be the cause of symptoms. Electrodiagnostic studies can quantify symptoms (e.g., show evidence of spinal nerve root compression) but cannot identify the anatomic cause (e.g., infection, tumor, or disk herniation). Together, electrodiagnostic and radiologic studies are extensions of the physical exam and serve to refine the differential diagnosis suggested by a clinical presentation.

Common reasons for ordering electrodiagnostic studies include symptomatic complaints (weakness, pain, numbness and/or tingling in an extremity) and physical examination findings (focal neurological deficits, abnormal reflexes, strength or sensory losses). Typical clinical scenarios involve radiculopathies, entrapment syndromes, trauma, and metabolic pathology seen in diabetes and alcoholism. Other important scenarios include rheumatologic disease, neuromuscular disease, and various infectious and neoplastic neuropathies. Further details about these conditions can be found in several electrodiagnostic textbooks.[1,2,3,4,5,6]

Practically, electrodiagnostic studies should be thought of when the diagnosis is in doubt, either during the initial patient presentation or as the result of nonresponse to treatment. The studies can evaluate the possibility of additional lesions (e.g., concomitant nerve entrapment syndromes, peripheral neuropathies, and so-called "double crush syndromes"), be used to follow the interval progression of both operative and nonoperative treatments, and provide pre-operative baselines. The objectives of this chapter are to introduce basic principles of electrodiagnosis. Hopefully, this will provide information on when to order electrodiagnostic tests, and help interpret and utilize the resulting electrodiagnostic reports.

TERMINOLOGY

Electrodiagnostic studies involve two components: nerve conduction studies (NCS) and needle electromyography (EMG). Al

Exhibit W

LCD for Nerve Conduction Studies and Electromyography (L35897)

Links in PDF documents are not guaranteed to work. To follow a web link, please use the MCD Archive site.

Please Note: This document version is not currently in effect. There may be more recent version(s) available in the Public Version(s) section below or on the CMS Medicare Coverage Database (MCD).

Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
CGS Administrators, LLC	MAC - Part A	15101 - MAC A	J - 15	Kentucky
CGS Administrators, LLC	MAC - Part B	15102 - MAC B	J - 15	Kentucky
CGS Administrators, LLC	MAC - Part A	15201 - MAC A	J - 15	Ohio
CGS Administrators, LLC	MAC - Part B	15202 - MAC B	J - 15	Ohio

LCD Information

LCD ID
L35897

LCD Title
Nerve Conduction Studies and Electromyography

Source Proposed LCD
DL35897 Nerve Conduction Studies and Electromyography

Applicable FARS/HHSARS apply.

Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

CMS National Coverage Policy

Code of Federal Regulations:
42 CFR Section 410.32 indicates that diagnostic tests may only be ordered by the treating physician (or other treating practitioner acting within the scope of his or her license and Medicare requirements) who uses the results in the management of the beneficiary's specific medical problem.

Federal Register:
Federal Register Vol. 62, 59047, Supervision of Diagnostic Tests, describes the degree of physician supervision required for diagnostic tests.

CMS Publications:
CMS Publication 100-03, Medicare National Coverage Determinations (NCD) Manual, Chapter 1, Part 2:
160.23 Sensory Nerve Conduction Threshold Tests (sNCTs)
Program Memorandum Carriers Transmittal B-01-28 Change Request 850, describes tests that may be performed by PTs with ABPTS certification
CMS IOM 100-2. Medicare Benefit Policy Manual Chapter 15 Section 80 Requirements for Diagnostic Tests p. 88-91. 2009.
Transmittal 2663 Change Request 8169 April Update to the CY 2013 Medicare Physician Fee Schedule Database (MPFSDB)

Date Information

Original Effective Date
For services performed on or after 10/01/2015

Revision Effective Date
For services performed on or after 09/26/2019

Revision Ending Date
10/23/2019

Retirement Date
N/A

Notice Period Start Date
01/19/2017

Notice Period End Date
03/05/2017

Coverage Guidance

Coverage Indications, Limitations and/or Medical Necessity

CGS Administrators expects healthcare professionals who perform electrodiagnostic (ED) testing will be appropriately trained and/or credentialed, either by a formal residency/fellowship program, certification by a nationally recognized organization, or by an accredited post-graduate training course covering anatomy, neurophysiology and forms of electrodiagnostics (including both NCS and EMG) acceptable to this contractor, in order to provide the proper testing and assessment of the patient's condition, and appropriate safety measures. It would be highly unlikely that this training and/or credentialing is possessed by providers other than Neurologists, or Physical Medicine & Rehabilitation physicians.

The electrodiagnostic evaluation is an extension of the neurologic portion of the physical examination. Both require a detailed knowledge of a patient and his/her disease. Training in the performance of electrodiagnostic procedures in isolation of knowledge about clinical diagnostic and management aspects of neuromuscular diseases, may not be adequate for proper performance of an electrodiagnostic evaluation and correct interpretation of electrodiagnostic

test results. Without awareness of the patterns of abnormality expected in different diseases and knowledge that the results of nerve conduction studies (NCS) and electromyography (EMG) may be similar in different diseases, diagnosis solely by EMG-NCS findings may be both inadequate and ultimately be detrimental to the patient.

Guidelines about proper qualifications for qualified health care professionals performing electrodiagnostic evaluations have been developed and published by AANEM (American Association of Neuromuscular and Electrodiagnostic Medicine) and other medical organizations, including the AMA, the American Academy of Neurology, the American Academy of Physical Medicine and Rehabilitation, American Neurological Association, the American Board of Physical Therapy Specialties (ABPTS) in Clinical Electrophysiology, and the Department of Veterans Affairs.

Both EMGs and NCSs are usually required for a clinical diagnosis of peripheral nervous system disorders. Performance of one type of testing does not eliminate the need for the other. The intensity and extent of testing with EMG and NCS are matters of clinical judgment developed after the initial pre-test evaluation, and later modified during the testing procedure.

Decisions to continue, modify or conclude a testing rely on knowledge of anatomy, physiology and neuromuscular diseases. Ongoing real-time assessment of data is required during the clinical diagnostic evaluation and especially during EMG examination.

Nerve conduction studies (NCS) are used to measure action potentials resulting from peripheral nerve stimulation which are recordable over the nerve or from an innervated muscle. With this technique, responses are measured between two sites of stimulation, or between a stimulus and a recording site.

Nerve conduction studies are of two general types: sensory and motor. Either surface or needle electrodes can be used to stimulate the nerve or record the response. Axonal damage or dysfunction generally results in loss of nerve or muscle potential response amplitude; whereas, demyelination leads to prolongation of conduction time and slowing of conduction velocity.

Obtaining and interpreting NCS results requires extensive interaction between the performing qualified health care professional and patient, and is most effective when both obtaining raw data and interpretation are performed concurrently on a real-time basis.

Results of the NCS reflect on the integrity and function of:

(I) the myelin sheath (Schwann cell derived insulation covering an axon), and
(II) the axon (an extension of neuronal cell body) of a nerve.

Interruption of axon and dysfunction of myelin will both affect NCS results.

It is often also valuable to test conduction status in proximal segments of peripheral nerves. This assessment can be accomplished by H-reflex, F-wave and blink reflex testing. These proximal segments include the first several centimeters of a compound nerve emerging from the spinal cord or brainstem. H-reflex, F-waves and Blink reflex testing accomplish this task better than distal NCS.

Electromyography (EMG) is the study and recording of intrinsic electrical properties of skeletal muscles. This is carried out with a needle electrode. Generally, the needles are of two types: monopolar or concentric. EMG is undertaken together with NCS. Unlike NCS, however, EMG testing relies on both auditory and visual feedback to the electromyographer. This testing is also invasive in that it requires needle electrode insertion and adjustment at multiple sites, and at times anatomically critical sites. As in NCS during EMG studies the electromyographer depends on ongoing real-time interpretation based knowledge of clinical diagnosis being evaluated to decide

whether to continue, modify, or conclude a test. This process requires knowledge of anatomy, physiology, and neuromuscular diseases.

EMG results reflect not only on the integrity of the functioning connection between a nerve and its innervated muscle but also on the integrity of a muscle itself. The axon innervating a muscle is primarily responsible for the muscle's volitional contraction, survival, and trophic functions. Thus, interruption of the axon will alter the EMG. A few prime examples of conditions in which EMG is potentially helpful are disc disease producing spinal nerve dysfunction, advanced nerve compression in peripheral lesions, Amyotrophic Lateral Sclerosis (ALS), polyneuropathy, etc. After an acute neurogenic lesion, EMG changes may not appear for several days to weeks in the innervated muscles. Primary muscle disease such as polymyositis will also alter a normal EMG pattern. Myotonic disorders may show a pattern of spontaneous repetitive discharges on needle exploration.

In summary, axonal and muscle involvement are most sensitively detected by EMGs, and myelin and axonal involvement are best detected by NCSs.

Physical Therapists Performing EMGs
Program Memorandum Transmittal B-01-28/Change Request 850 sets forth revised levels of physician supervision required for diagnostic tests payable under the Medicare Physician Fee Schedule. Effective July 1, 2001, certain codes in the range of CPT 95860-95937 were assigned new supervision levels (21, 22, 6a, 66, 77 or 77a). This implementation date would make it possible for physical therapists to acquire the certification required to perform these services without supervision. A physical therapist who is presently certified by the American Board of Physical Therapy Specialties can perform procedures assigned level of 21, 22, 66, 6a, 77, or 77a without supervision. These numeric levels assigned to the CPT codes are listed in the Medicare Physician Fee Schedule Database (MFSDB). Physical therapists who do not possess the ABPTS (American Board of Physical Therapy Specialties) certification by July 1, 2001, may continue to furnish those tests that require the certification if they have been furnishing such diagnostic tests prior to May 1, 2001.
Payment will be based on the Medicare Physician Fee Schedule level of supervision designation.

Nerve conduction code 95905 does not have one of the above designations and is therefore not allowed by Physical Therapists.

Nerve conduction codes 95907-95913 had their Physician Supervision of Diagnostic Procedures Indicators adjusted to 7A effective 01/01/2013 (CR 8169). Therefore if authorized by state law Physical Therapists are allowed the technical portion and professional component of the test according to the description of 7A which is included in the Billing and Coding Guideline attached.

The TC component of the Neuromuscular junction testing code 95937 had its Physician Supervision of Diagnostic Procedures Indicator changed to "7A" This change is effective January 1, 2013.

Needle electromyographic (EMG) codes 95860-95872 and 95885-95887 have the designation of 6A for the technical portion of the test.Therefore if authorized by state law Physical Therapists are allowed the technical portion of the test according to the description of 6A which is included in the Billing and Coding Guideline attached.

A. Nerve Conduction Studies
The dichotomy into axonal and demyelinating neuropathies provides a practical means of correlating electrical abnormalities with major pathophysiologic changes in the nerve. Electrical studies can be of help in localization of an abnormality, and in distinguishing one variety of neuropathy from another: for example, diffuse vs. multifocal; axonal vs. demyelinating. Such distinction has diagnostic value. Specific classification of nerve injuries into neuropraxia and axonotmesis can be made on the basis of conduction studies and electromyography. Such classification has a bearing on prognosis and treatment.

1. Focal neuropathies or compressive lesions such as carpal tunnel syndrome, ulnar neuropathies or root lesions, for localization.
2. Traumatic nerve lesions, for diagnosis and prognosis.
3. Diagnosis or confirmation of suspected generalized neuropathies, such as diabetic, uremic, metabolic or immune.
4. Repetitive nerve stimulation in diagnosis of neuromuscular junction disorders such as myasthenia gravis, myasthenic syndrome.
5. There may be other instances, not detailed here, where NCS may be of use. Not all possible or potential indications are addressed here.

The broad diagnostic scope of NCS is recognizable by the foregoing description. There may be instances where questions about an indication, or need for a study, will arise. The clinical history and examination, carried out before the study, must always describe and document clearly and comprehensibly the need for the planned test. A "rule-out" diagnosis is typically not acceptable. The Contractor is cognizant of the fact that patients are not always referred with a definite diagnosis in mind. Often, pain, paresthesia, or weakness in an extremity is the reason for an NCS or EMG. These common symptoms result not only from axonal and myelin dysfunction but also from systemic, non-neurological illnesses. EMG and NCV may help in making this distinction. Therefore, symptom-based diagnoses such as "pain in limb" weakness, disturbance in skin sensation or "paresthesia" are acceptable provided the clinical assessment unequivocally supports the need for a study. To cite but one example of many, an EMG or NCS is irrelevant as a first order diagnostic test for limb pain resulting from immediate antecedent trauma or acute bone injury.

Both EMGs and NCSs are required for a clinical diagnosis of peripheral nervous system disorders. EMG results reflect on the integrity of the functioning connection between a nerve and its innervated muscle and also on the integrity of a muscle itself. Performance of one does not eliminate the need for the other. The intensity and extent of testing with EMG and NCS are matters of clinical judgment developed after the initial pre-test evaluation, and later modified during the testing procedure.

Decisions to continue, modify or conclude a test also rely on a knowledge base of anatomy, physiology and neuromuscular diseases. There is a requirement for ongoing real-time clinical diagnostic evaluation, especially during EMG examination. Also, EMG examination is invasive. Needle placement in the exact muscle of interest is essential. It requires needle exploration near vital structures as the pleura, femoral neurovascular bundle, peritoneum, intraspinal spaces, carotid artery, orbit and brachial plexus. Risk of infection from AIDS, Hepatitis B-E, Creutzfeldt-Jakob encephalopathy, and hemorrhage from anticoagulation can be managed by proper techniques.

The electrodiagnostic evaluation is actually an extension of the neurologic portion of the physical examination. Both require a detailed knowledge of a patient and his/her disease. Training in the performance of electrodiagnostic procedures, in isolation without awareness and ability to diagnose and manage neuromuscular diseases, is not always adequate for electrodiagnostic consultation. Recognition and experience in the management of disparate diseases that produce common electrodiagnostic findings may be necessary. For example, EMG-NCS findings may overlap in the following pairs of disorders: inflammatory myopathies and ALS, ALS and multi-level radiculopathies, myotonia of channelopathies (periodic paralyses) and myotonic dystrophies, focal neuropathies as Carpal Tunnel Syndrome and proximal plexopathies. Other instances where knowledge of disease behavior is crucial are Chronic Inflammatory Demyelinating Neuropathy (CIDP) and Multifocal Motor Neuropathy. These entities display electrodiagnostic features that resemble generalized polyneuropathies. Neuromuscular transmission disorders require separation based on clinical presentation and electrical features. Treatment will depend on differentiating among them. Without awareness of the disease spectrum, diagnosis solely by EMG-NCS findings may be either wrong or detrimental to the patient.

The following definitions are from the American Association of Neuromuscular & Electrodiagnostic Medicine Recommended Policy for Electrodiagnostic Medicine (page 2)

http://www.aan.com/globals/axon/assets/4061.pdf

"The stimulation of nerves is similar across all NCSs; the characteristics of motor, sensory, and mixed NCSs are different and are discussed separately below. In each case, an appropriate nerve is stimulated and recording is made either from the appropriate nerves or from muscle supplied by the motor nerve.

a. Motor. Motor NCSs are performed by applying electrical stimulation at various points along **the course of a motor nerve** while recording the electrical response from an appropriate muscle. Response parameters include amplitude, latency, configuration, and motor conduction velocity.
b. Sensory. Sensory NCSs are performed by applying electrical stimulation near a nerve and recording the response from a distant site along the nerve. Response parameters include amplitude, latency, and configuration.
c. Mixed NCSs are performed by applying electrical stimulation near a nerve containing both motor and sensory fibers (a mixed nerve) and recording from a different location along that nerve that also contains both motor and sensory nerve fibers. Response parameters include amplitude, latency, configuration, and motor conduction velocity."
d. CPT code 95905 -Nerve conduction studies performed using automated devices (for example devices such as NC-stat® System) cannot support testing of other locations and other nerves as needed depending on the concurrent results of testing and they should not be billed to Medicare with the current CPT codes.

When the beneficiary has a high pre-test or a prior probability for having the diagnosis of Carpal Tunnel Syndrome, the NC-stat® System (alone) will be allowed, one service per arm, using CPT code 95905. The diagnosis codes G56.01, G56.02, or G56.03 should be used. All other diagnosis codes will be denied as not medically necessary.

Nerve conduction studies performed independent of needle electromyography (EMG) may only provide a portion of the information needed to diagnose muscle, nerve root, and most nerve disorders. When the nerve conduction study (NCS) is used on its own without integrating needle EMG findings or when an individual relies solely on a review of NCS data, the results can be misleading, and important diagnoses may be missed.

In most instances, both NCS and usually EMG are necessary to perform diagnostic testing. While a provider may choose to perform just a NCS, when performed alone it is usually considered not medically necessary. The only exception to this is a situation when a provider may consider it appropriate to perform a NCS without doing an EMG for the diagnosis of carpal tunnel syndrome with a high pre-test probability.

B. Electromyography
Neurogenic disorders can be distinguishable from myopathic disorders by a carefully performed EMG. For example, both polymyositis and ALS (Amyotrophic Lateral Sclerosis) produce manifest weakness. The former carries a very different prognosis and treatment than the latter. An EMG is very valuable in making this distinction. Similarly, classification of nerve trauma into axonal vs. demyelinating categories, with corresponding differences in prognoses, are possible with EMG. Below is a list of common disorders where an EMG, in tandem with properly conducted NCS, will be helpful in diagnosis:

1. Nerve compression syndromes, including carpal tunnel syndrome and other focal compressions.
2. Radiculopathy - cervical, lumbosacral.
3. Mono/polyneuropathy - metabolic, degenerative, hereditary.
4. Myopathy - including poly-and dermatomyositis, myotonic and congenital myopathies.
5. Plexopathy - idiopathic, trauma, infiltration.
6. Neuromuscular junction disorders - myasthenia gravis. Single fiber EMG is of special value here.
7. At times, immediately prior to botulinum toxin injection, for localization.
8. At times, immediately prior to injection of phenol or other substances for nerve blocking or chemodenervation.

There may be other instances, not detailed here, where EMG may be of use.

Use of EMG with Botulinum Toxin Injection
EMG may be used to optimize the anatomic location of botulinum toxin injection. It is expected there will be one study performed per anatomic location of injection, if needed.

Limitations:

Nerve Conduction Studies
Each descriptor (code) from codes 95907, 95908, 95909, 95910, 95911, 95912, and 95913, can be reimbursed only once per nerve, or named branch of a nerve, regardless of the number of sites tested or the number of methods used on that nerve. For instance, testing the ulnar nerve at wrist, forearm, below elbow, above elbow, axilla and supraclavicular regions will all be considered as a single nerve. Motor and sensory nerve testing are considered separate tests. CPT code 95905 is payable only once per limb studied and cannot be used in conjunction with any other nerve conduction codes.

Routine testing for polyneuropathy of diabetes or endstage renal disease (ESRD) is not considered medically necessary and is NOT covered. Testing for the sole purpose of monitoring disease intensity or treatment efficacy in these two conditions is also not covered.

Psychophysical measurements (current, vibration, thermal perceptions), even though they may involve delivery of a stimulus, are considered to be part of the physical exam and may not be billed as a separate service.

Current Perception Threshold/Sensory Nerve Conduction Threshold Test (sNCT) – is not covered by Medicare. This procedure is different and distinct from assessment of nerve conduction velocity, amplitude and latency. It is also different from short-latency somatosensory evoked potentials. Codes designated for eliciting nerve conduction velocity, latency or amplitude, and those designed for short latency evoked potentials are not to be used for sNCT. The sNCT has a unique code **G0255**: Effective October 1, 2002, CMS initially concluded that there was insufficient scientific or clinical evidence to consider the sNCT test and the device used in performing this test reasonable and necessary within the meaning of section 1862(a)(1)(A) of the law. Therefore, sNCT was noncovered. Based on a reconsideration [in March, 2004] of current Medicare policy for sNCT, CMS concludes that there continues to be insufficient scientific or clinical evidence to consider the sNCT test and the device used in performing this test as reasonable and necessary within the meaning of section 1862(a)(1)(A) of the law. CMS Publication 100-3, Medicare National Coverage Issues Manual, Chapter 1, Section 160.23

Examination using portable hand-held devices, or devices which are incapable of real-time wave-form display and analysis, and incapable of both NCS and EMG testing; will be included in the E/M service. They will not be paid separately. Examples include; The Axon II or delta fiber analysis testing and/or machines with other names.

Nerve conduction studies must provide a number of response parameters in a real-time fashion to facilitate provider interpretation. Those parameters include amplitude, latency, configuration and conduction velocity. Medicare does not accept diagnostic studies that do not provide this information or those that provide delayed interpretation as substitutes for Nerve conduction studies. Raw measurement data obtained and transmitted trans-telephonically or over the Internet, therefore, does not qualify for the payment of the electrodiagnostic service codes included in this LCD.

Medicare does not expect to receive claims for nerve conduction testing accomplished with discriminatory devices that use fixed anatomic templates and computer-generated reports used as an adjunct to physical examination routinely on all patients.

Electromyography
It is expected that providers will use CPT code 95870 for sampling muscles other than the paraspinals associated

with the extremities, which have been tested. Medicare would not expect to see this code billed when the paraspinal muscles corresponding to an extremity are tested and when the extremity EMG code 95860, 95861, 95863 or 95864 is also billed. The necessity and reasonableness of the following uses of EMG studies have not been established:

- exclusive testing of intrinsic foot muscles in the diagnosis of proximal lesions
- definitive diagnostic conclusions based on paraspinal EMG in regions bearing scar of past surgeries (e.g., previous laminectomies)
- pattern-setting limited limb muscle examinations, without paraspinal muscle testing for a diagnosis of radiculopathy
- EMG testing shortly after trauma, before EMG abnormalities would have reasonably had time to develop
- surface and macro EMG's
- multiple uses of EMG in the same patient at the same location of the same limb for the purpose of optimizing botulinum toxin injections.
  For outpatient settings other than Comprehensive Outpatient Rehabilitation Facility (CORF)s, references to "physicians" throughout this policy include non-physicians, such as nurse practitioners, clinical nurse specialists and physician assistants. Such non-physician practitioners, with certain exceptions, may certify, order and establish the plan of care as authorized by State law. (See Sections 1861[s][2] and 1862[a][14] of Title XVIII of the Social Security Act; 42 CFR, Sections 410.74, 410.75, 410.76 and 419.22; 58 FR 18543, April 7, 2000.) Each practitioner must provide only those services within the scope of practice for each state.

Summary of Evidence

N/A

Analysis of Evidence (Rationale for Determination)

N/A

General Information

Associated Information

Documentation Requirements

The patient's medical records must clearly document the medical necessity for the test. It is not necessary to include documentation with each claim submission. Data gathered during NCS, however, should be available which reflect the actual numbers (latency, amplitude, etc.), preferably in a tabular (not narrative) format. The reason for referral and a clear diagnostic impression are required for each study. In cases where a review becomes necessary, either a

hard copy of waveforms or a complete written report with an interpretation of the test must be submitted upon request.

Normal findings and abnormalities uncovered during the study should be documented with the muscles tested, the presence and type of spontaneous activity, as well as the characteristics of the voluntary unit potentials and interpretation.

Sources of Information

1.AANEM. Position Statement, Proper performance and interpretation of electrodiagnostic studies. Approved June 2014. Available at aanem.org
2. AANEM. Position Statement, Risks in electrodiagnostic medicine. Approved July 2014. Available at aanem.org
3. AANEM. Recommended Policy for Electrodiagnostic Medicine. Updated on 08/30/2014. Available at aanem.org
4. ABPTS, 2016 Clinical Electrophysiology Specialist Certification Candidate Guide. Available at: abpts.org.
5. Brown E. An Evidence Based Technology Assessment of the NC-stat® Device; March 19, 2007.
6. Morse, J. Office of the Medical Director, Department of Labor and Industries. Washington State Department of Labor and Industries. Technology Assessment: NC-stat System, NeuroMetrix, Inc. June 8, 2006. Available at: http://www.lni.wa.gov/claimsins/files/omd/tancstat0506.pdf

Bibliography

N/A

Revision History Information

Revision History Table

Revision History Number	Revision History Date	Revision History Explanation	Reason(s) for Change
14	09/26/2019	Revision#:R14 Revision Effective date: 09/26/2019 Revision Explanation: Converted policy into new template and moved all coding into related billing and coding article based on CR 10901. 09/20/2019 At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.	• Other (Code Migration)
13	10/01/2018	Revision#:R13 Revision Effective date: N/A Revision Explanation: Annual Review, no changes made. Added 21 Century Cures Act 04/15/2019 At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.	• Other (Added 21 Century Cures Act)
12	10/01/2018	Revision#:R12 Revision Effective: N/A Revision Explanation: Annual review no changes made.	• Other (Annual review, no changes made.)

Revision History Number	Revision History Date	Revision History Explanation	Reason(s) for Change
11	10/01/2018	Revision#:R11 Revision Effective: 10/01/2018 Revision Explanation:10/01/2018 ICD-10-CM code updates: deleted codes G51.3, G71.0, M79.1 from Group One and added codes G51.31, G51.32, G51.33, G71.01, G71.02, G71.09, M79.11, M79.12, and M79.18. Description change to M50.01, M50.11, M50.21, M50.31, and M50.81 in Group One. 08/27/2018-*At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.*	• Revisions Due To ICD-10-CM Code Changes
10	10/01/2017	Revision#:R11 Revision Effective: N/A Revision Explanation: Annual review no changes made.	• Other (Annual Review)
9	10/01/2017	Revision#:R10 Revision Effective: 10/01/2017 Revision Explanation: ICD-10 annual review update, added the following new codes E11.10, e11.11, G12.23, G12.24, G12.25, M33.03, M33.13, M33.93, M48.061, and M48.062.	• Revisions Due To ICD-10-CM Code Changes

Revision History Number	Revision History Date	Revision History Explanation	Reason(s) for Change
		08/23/2017-*At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.* Revision#:R9 Revision Effective: N/A Revision Explanation: Annual review no changes made.	
8	03/06/2017	Revision#:R8 Revision Effective: 03/06/2017 Revision Explanation: Releasing policy after taking back to CAC as a draft after reviewing policy and found some ICD-10 codes missing and others that were not appropriate for the LCD.	• Provider Education/Guidance

Revision History Number	Revision History Date	Revision History Explanation	Reason(s) for Change
7	10/01/2016	Revision#:R7 Revision Effective: 10/01/2016 Revision Explanation: ICD-10 Code updates added codes: G56.03, G56.13, G56.23, G56.33, G56.43, G56.83, G56.93, G57.03, G57.13, G57.23, G57.33, G57.43, G57.53, G57.63, G57.73, G57.83, G57.93, G61.82, M50.021, M50.022, M50.023, M50.121, M50.122, M50.123, M50.221, M50.222, M50.223, M50.321, M50.322, M50.323, M50.821, M50.822, M50.823. Deleted codes: M50.02, M50.12, M50.22, M50.32, M50.82. Revised description codes: S54.8X1A, S54.8X2A. Combined the CPT code groups and the ICD-10 code groups for clarification. Added that any code in list that has the 7th character of D or S also can be used in paragraph above the ICD-10 codes.	• Revisions Due To ICD-10-CM Code Changes
6	10/01/2015	Revision#:R6 Revision Effective: 10/01/2015 Revision Explanation: ICd-10 code M48.06 was left off in error and has been added.	• Typographical Error
5	10/01/2015	Revision#:R5 Revision Effective: N/A Revision Explanation: annual review no changes made.	• Other (Annual Review)
4	10/01/2015	Revision#:R4 Revision Effective: N/A Revision Explanation: Clarified in last paragraph above Nerve Conduction Studies section A that PTs can bill global for codes designated with 6A if certified and within scope of practice.	• Provider Education/Guidance
3	10/01/2015	Revision#:R3 Revision Effective: 10/01/2015 Revision Explanation: Added G62.9 to list of codes that support medical necessity.	• Reconsideration Request

Revision History Number	Revision History Date	Revision History Explanation	Reason(s) for Change
2	10/01/2015	Revision#:R2 Revision Effective: 10/01/2015 Revision Explanation: Corrected ICD-9 code left in error in the text to G56.01 and G56.02 concerning 95905	• Typographical Error
1	10/01/2015	Revision#:R1 Revision Effective: 10/01/2015 Revision Explanation: added notice period dates.	• Provider Education/Guidance

Associated Documents

Attachments

There are no attachments for this LCD.

Related Local Coverage Documents

Article(s)

A57307 - Billing and Coding: Nerve Conduction Studies and Electromyography

A55432 - Response to Comments: Nerve Conduction Studies and Electromyography

LCD(s)

DL35897 - Nerve Conduction Studies and Electromyography

Related National Coverage Documents

This LCD version has no Related National Coverage Documents.

All Versions

Updated on 04/30/2020 with effective dates 10/24/2019 - 04/28/2021

Updated on 10/15/2019 with effective dates 10/24/2019 - N/A

Updated on 09/20/2019 with effective dates 09/26/2019 - 10/23/2019

Updated on 04/15/2019 with effective dates 10/01/2018 - 09/25/2019

Updated on 04/10/2019 with effective dates 10/01/2018 - N/A

Updated on 08/27/2018 with effective dates 10/01/2018 - N/A

Updated on 04/30/2018 with effective dates 10/01/2017 - 09/30/2018

Updated on 08/23/2017 with effective dates 10/01/2017 - N/A

Updated on 01/13/2017 with effective dates 03/06/2017 - 09/30/2017

Updated on 09/12/2016 with effective dates 10/01/2016 - 03/05/2017

Updated on 06/21/2016 with effective dates 10/01/2015 - 09/30/2016

Updated on 04/19/2016 with effective dates 10/01/2015 - N/A

Updated on 02/25/2016 with effective dates 10/01/2015 - N/A

Updated on 12/30/2015 with effective dates 10/01/2015 - N/A

Updated on 04/14/2015 with effective dates 10/01/2015 - N/A

Updated on 04/02/2015 with effective dates 10/01/2015 - N/A

Updated on 04/02/2015 with effective dates 10/01/2015 - N/A

Additional Information

Keywords

N/A

Exhibit X

KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

Baldwin's Ohio Revised Code Annotated
Title XXIII. Courts--Common Pleas (Refs & Annos)
Chapter 2317. Evidence
Miscellaneous Provisions

R.C. § 2317.54

2317.54 Informed consent; health care facility liability precluded, when; form for written consent

Effective: September 30, 2021
Currentness

No hospital, home health agency, ambulatory surgical facility, or provider of a hospice care program or pediatric respite care program shall be held liable for a physician's failure to obtain an informed consent from the physician's patient prior to a surgical or medical procedure or course of procedures, unless the physician is an employee of the hospital, home health agency, ambulatory surgical facility, or provider of a hospice care program or pediatric respite care program.

Written consent to a surgical or medical procedure or course of procedures shall, to the extent that it fulfills all the requirements in divisions (A), (B), and (C) of this section, be presumed to be valid and effective, in the absence of proof by a preponderance of the evidence that the person who sought such consent was not acting in good faith, or that the execution of the consent was induced by fraudulent misrepresentation of material facts, or that the person executing the consent was not able to communicate effectively in spoken and written English or any other language in which the consent is written. Except as herein provided, no evidence shall be admissible to impeach, modify, or limit the authorization for performance of the procedure or procedures set forth in such written consent.

(A) The consent sets forth in general terms the nature and purpose of the procedure or procedures, and what the procedures are expected to accomplish, together with the reasonably known risks, and, except in emergency situations, sets forth the names of the physicians who shall perform the intended surgical procedures.

(B) The person making the consent acknowledges that such disclosure of information has been made and that all questions asked about the procedure or procedures have been answered in a satisfactory manner.

(C) The consent is signed by the patient for whom the procedure is to be performed, or, if the patient for any reason including, but not limited to, competence, minority, or the fact that, at the latest time that the consent is needed, the patient is under the influence of alcohol, hallucinogens, or drugs, lacks legal capacity to consent, by a person who has legal authority to consent on behalf of such patient in such circumstances, including either of the following:

(1) The parent, whether the parent is an adult or a minor, of the parent's minor child;

(2) An adult whom the parent of the minor child has given written authorization to consent to a surgical or medical procedure or course of procedures for the parent's minor child.

Any use of a consent form that fulfills the requirements stated in divisions (A), (B), and (C) of this section has no effect on the common law rights and liabilities, including the right of a physician to obtain the oral or implied consent of a patient to a medical procedure, that may exist as between physicians and patients on July 28, 1975.

As used in this section the term "hospital" has the same meaning as in section 2305.113 of the Revised Code; "ambulatory surgical facility" has the same meaning as in section 3702.30 of the Revised Code; "hospice care program" and "pediatric respite care program" have the same meanings as in section 3712.01 of the Revised Code, and "home health agency" has the same meaning as in section 3740.01 of the Revised Code. The provisions of this division apply to hospitals, doctors of medicine, doctors of osteopathic medicine, and doctors of podiatric medicine.

CREDIT(S)

(2021 H 110, eff. 9-30-21; 2019 H 166, eff. 10-17-19; 2017 H 49, § 130.31, eff. 9-29-18; 2012 H 303, eff. 3-20-13; 2008 H 125, eff. 6-25-08; 2002 S 281, eff. 4-11-03; 2002 S 124, eff. 9-17-02; 1986 S 22, eff. 3-1-87; 1977 H 213; 1976 H 1426; 1975 H 682)

Notes of Decisions (63)

R.C. § 2317.54, OH ST § 2317.54
Current through File 100 of the 134th General Assembly (2021-2022).

End of Document

Exhibit Y

912 F.3d 907
United States Court of Appeals, Sixth Circuit.

Shari GUERTIN, Individually and as Next Friend of Her Child, E.B., a Minor; Diogenes Muse-Cleveland, Plaintiffs-Appellees,
v.
STATE of Michigan, et al., Defendants,
City of Flint, Michigan, Howard Croft, Darnell Earley, and Gerald Ambrose (17-1699); Liane Shekter-Smith, Daniel Wyant, Stephen Busch, Michael Prysby, and Bradley Wurfel (17-1745); Nancy Peeler (17-1752); Robert Scott (17-1769); Eden Wells and Nick Lyon (17-1698), Defendants-Appellees.

Nos. 17-1698/1699/1745/1752/1769
|
Argued: June 6, 2018
|
Decided and Filed: January 4, 2019

Synopsis

Background: City residents brought § 1983 action against State of Michigan, City of Flint, and related government officials, alleging they sustained personal injuries and damages due to drinking and bathing in water supplied by defendants to customers without the addition of chemicals to counter river water's known corrosivity. The United States District Court for the Eastern District of Michigan, No. 5:16-cv-12412, Judith E. Levy, J., 2017 WL 2418007, dismissed claims in part. Residents appealed.

Holdings: The Court of Appeals, Griffin, Circuit Judge, held that:

[1] residents stated a bodily-integrity substantive due process claim against city's former emergency managers and former public works director;

[2] residents stated a bodily-integrity substantive due process claim against Michigan Department of Environmental Quality (MDEQ) officials;

[3] residents failed to state a bodily-integrity substantive due process claim against Michigan Department of Health and Human Services (MDHHS) employees;

[4] State, city, and related officials were not entitled to qualified immunity from residents' substantive due process claims; and

[5] city was not an arm of the State despite being under State's emergency management and, thus, was not entitled to Eleventh Amendment sovereign immunity from residents' substantive due process claims.

Affirmed in part and reversed in part.

McKeague, Circuit Judge, issued opinion concurring in part and dissenting in part.

Procedural Posture(s): On Appeal; Motion to Dismiss for Failure to State a Claim.

West Headnotes (53)

[1] Civil Rights Nature and elements of civil actions

Under § 1983, an individual may bring a private cause of action against anyone who, under color of state law, deprives a person of rights, privileges, or immunities secured by the Constitution or conferred by federal statute.

42 U.S.C.A. § 1983.

2 Cases that cite this headnote

[2] Public Employment Qualified immunity

Qualified immunity shields public officials from undue interference with their duties and from potentially disabling threats of liability.

7 Cases that cite this headnote

[3] Public Employment Qualified immunity

Qualified immunity is not a mere defense to liability; the doctrine provides immunity from suit.

permit of constitutional differentiation"). And more broadly, it is beyond debate that an individual's "interest in preserving her life is one of constitutional dimension." *Nishiyama v. Dickson Cty.*, 814 F.2d 277, 280 (6th Cir. 1987) (en banc), *abrogated on other grounds as recognized in* *Jones v. Reynolds*, 438 F.3d 685, 694–95 (6th Cir. 2006).

[20] Bodily integrity cases "usually arise in the context of government-imposed punishment or physical restraint," but that is far from a categorical rule. *Kallstrom*, 136 F.3d at 1062 (collecting cases). Instead, the central tenet of the Supreme Court's vast bodily integrity jurisprudence is balancing an individual's common law right to informed consent with tenable state interests, regardless of the manner in which the government intrudes upon an individual's body. *See, e.g.*, *Cruzan v. Dir., Missouri Dep't of Health*, 497 U.S. 261, 269–70, 110 S.Ct. 2841, 111 L.Ed.2d 224 (1990). Thus, to show that the government has violated one's right to bodily integrity, a plaintiff need not "establish any constitutional significance to the means by which the harm occurs[.]" *Boler v. Earley*, 865 F.3d 391, 408 n.4 (6th Cir. 2017). That is because "individuals possess a constitutional right to be free from forcible intrusions on their bodies against their will, absent a compelling state interest." *Planned Parenthood Sw. Ohio Region v. DeWine*, 696 F.3d 490, 506 (6th Cir. 2012).

A few examples illustrate the breadth of this tenet. Consider *Washington v. Harper*, which addressed the State of Washington's involuntary administration of antipsychotic medication to an inmate without a judicial hearing. 494 U.S. 210, 213–17, 110 S.Ct. 1028, 108 L.Ed.2d 178 (1990). There, the Supreme Court had "no doubt" that the inmate "possess[ed] a significant liberty interest in avoiding unwanted administration of antipsychotic drugs under the Due Process Clause of the Fourteenth Amendment." *Id.* at 221–22, 110 S.Ct. 1028. This "interest in avoiding the unwarranted administration of antipsychotic drugs is not insubstantial. The forcible injection of medication into a nonconsenting person's body represents a substantial interference with that person's liberty." *Id.* at 229, 110 S.Ct. 1028 (citing *Winston v. Lee*, 470 U.S. 753, 105 S.Ct. 1611, 84 L.Ed.2d 662 (1985), and *Schmerber*, 384 U.S. 757, 86 S.Ct. 1826, 16 L.Ed.2d 908). And this is especially so when the foreign substance "can have serious, even fatal, side effects" despite some therapeutic benefits. *Id.* But the extent of this interference, reasoned the Court, is circumscribed by the government's interest (there, administering ***920** medication in the custodial setting). *Id.* at 222–27, 110 S.Ct. 1028. Examining those interests, the Court permitted the physical intrusion upon a showing of certain circumstances—danger to self or others, and in the inmate's medical interest. *Id.* at 227, 110 S.Ct. 1028; *see also* *Riggins v. Nevada*, 504 U.S. 127, 135–38, 112 S.Ct. 1810, 118 L.Ed.2d 479 (1992) (applying *Harper* to the forced administration of drugs in trial and pretrial settings and focusing upon the state's "overriding justification and a determination of medical appropriateness" to justify the intrusion); *Sell v. United States*, 539 U.S. 166, 177–86, 123 S.Ct. 2174, 156 L.Ed.2d 197 (2003) (similar).

The Supreme Court's seminal "right to die" case, *Cruzan v. Director, Missouri Department of Health*, provides further explication. At issue in *Cruzan* was whether the parents of an individual in a persistent vegetative state could insist that a hospital withdraw life-sustaining care based on her right to bodily integrity. 497 U.S. at 265–69, 110 S.Ct. 2841. Writing for the Court, Chief Justice Rehnquist extensively detailed the line between the common law, informed consent, and the right to bodily integrity: "This notion of bodily integrity has been embodied in the requirement that informed consent is generally required for medical treatment," *id.* at 269, 110 S.Ct. 2841, "generally encompass[es] the right of a competent individual to refuse medical treatment," *id.* at 277, 110 S.Ct. 2841, and is a right that "may be inferred from [the Court's] prior decisions." *Id.* at 278–79, 110 S.Ct. 2841 (citing *Jacobson v. Massachusetts*, 197 U.S. 11, 25 S.Ct. 358, 49 L.Ed. 643 (1905); *Breithaupt v. Abram*, 352 U.S. 432, 77 S.Ct. 408, 1 L.Ed.2d 448 (1957); *Harper*, 494 U.S. 210, 110 S.Ct. 1028, 108 L.Ed.2d 178; *Vitek v. Jones*, 445 U.S. 480, 100 S.Ct. 1254, 63 L.Ed.2d 552 (1980); and *Parham v. J.R.*, 442 U.S. 584, 99 S.Ct. 2493, 61 L.Ed.2d 101 (1979)). And, although the Court assumed as much, "the logic of [these] cases ... embrace[s] ... a liberty interest" in "artificially delivered food and water essential to life." *Id.* at 279, 110 S.Ct. 2841. As with *Harper*, the Court's

Exhibit Z

NCD - Wrong Surgical or Other Invasive Procedure Performed on a Patient (140.6)

Links in PDF documents are not guaranteed to work. To follow a web link, please use the MCD Website.

Tracking Information

Publication Number

100-3

Manual Section Number

140.6

Manual Section Title

Wrong Surgical or Other Invasive Procedure Performed on a Patient

Version Number

1

Effective Date of this Version

01/15/2009

Implementation Date

07/06/2009

Description Information

Benefit Category

Diagnostic Tests (other)
Federally Qualified Health Center Services
Home Health Services
Inpatient Hospital Services
Outpatient Hospital Services Incident to a Physician's Service
Physicians' Services
Rural Health Clinic Services
Skilled Nursing Facility

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

Item/Service Description

A. General

In 2002, the National Quality Forum (NQF) published "Serious Reportable Events in Healthcare: A Consensus Report" [1], which listed 27 adverse events that were "serious, largely preventable and of concern to both the public and health care providers." These events and subsequent revisions to the list became known as "never events." This

concept and need for the proposed reporting led to NQF's "Consensus Standards Maintenance Committee on Serious Reportable Events," which maintains and updates the list which currently contains 28 items. Among surgical events on the list is "Wrong surgical procedure performed on a patient." Similar to any other patient population, Medicare beneficiaries experience serious injury and/or death if wrong surgeries are performed and may require additional healthcare in order to correct adverse outcomes resulting from such errors.

Indications and Limitations of Coverage

B. Nationally Covered Indications

N/A

C. Nationally Non-Covered Indications

The CMS does not cover a particular surgical or other invasive procedure to treat a particular medical condition when a practitioner erroneously performs a different procedure on a Medicare beneficiary because that particular surgical or other invasive procedure is not a reasonable and necessary treatment for the Medicare beneficiary's particular medical condition.

A surgical or other invasive procedure is considered to be the wrong procedure if it is not consistent with the correctly documented informed consent for that patient. Emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent are not considered erroneous under this decision. Also, the event is not intended to capture changes in the plan upon surgical entry into the patient due to the discovery of pathology in close proximity to the intended site when the risk of a second surgery outweighs the benefit of patient consultation; or the discovery of an unusual physical configuration (e.g., adhesions, spine level/extra vertebrae).

Surgical and other invasive procedures are defined as operative procedures in which skin or mucous membranes and connective tissue are incised or an instrument is introduced through a natural body orifice. Invasive procedures include a range of procedures from minimally invasive dermatological procedures (biopsy, excision, and deep cryotherapy for malignant lesions) to extensive multi-organ transplantation. They include all procedures described by the codes in the surgery section of the Current Procedural Terminology (CPT) and other invasive procedures such as percutaneous transluminal angioplasty and cardiac catheterization. They include minimally invasive procedures involving biopsies or placement of probes or catheters requiring the entry into a body cavity through a needle or trocar. They do not include use of instruments such as otoscopes for examinations or very minor procedures such as drawing blood.

D. Other

N/A

(NCD last reviewed January 2009.)

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[1]http://www.qualityforum.org/pdf/reports/sre.pdf

Claims Processing Instructions

TN 1755 (Medicare Claims Processing)
TN 1764 (Medicare Claims Processing)
TN 1778 (Medicare Claims Processing)

Transmittal Information

Transmittal Number

102

Coverage Transmittal Link

http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R102NCD.pdf

Revision History

06/2009 - Effective Date: 01/15/2009. Implementation Date: 07/06/2006. (TN 101) (CR6405)

07/2009 - Effective Date: 01/15/2009. Implementation Date: 07/06/2006 (TN 102) (CR6405). Transmittal 101, Change Request 6405, dated June 12, 2009 is being rescinded and replaced, to correct manual references to the Benefit Policy Manual. All other information remains the same.

National Coverage Analyses (NCAs)

This NCD has been or is currently being reviewed under the National Coverage Determination process.The following are existing associations with NCAs, from the National Coverage Analyses database.

- Original Consideration for Wrong Surgery Performed on a Patient (CAG-00401N)

Additional Information

Other Versions

Title	Version	Effective Between
Wrong Surgical or Other Invasive Procedure Performed on a Patient	1	01/15/2009 - N/A

Exhibit AA

AANEM PRACTICE TOPIC

GUIDELINES FOR ETHICAL BEHAVIOR RELATING TO CLINICAL PRACTICE ISSUES IN NEUROMUSCULAR AND ELECTRODIAGNOSTIC MEDICINE

NAOMI A. ABEL MD,[1] EDUARDO A. DE SOUSA MD, FAAN,[2] RAGHAV GOVINDARAJAN MD,[3] MATTHEW P. MAYER MD,[4] and DAVID A. SIMPSON DO, MS[5]

[1] Physical Medicine and Rehabilitation, Department of Neurosurgery & Brain Repair, University of South Florida, Tampa, Florida, USA
[2] Department of Neurology, University of Oklahoma Health Sciences Center, Oklahoma City, Oklahoma, USA
[3] Department of Neurology, University of Missouri, Columbia, Missouri, USA
[4] Department of Pediatric Rehabilitation Medicine, University of Missouri–Kansas City, Children's Mercy Kansas City, Kansas City, Missouri, USA
[5] MDA Clinic and ALS Center, Michigan Institute for Neurological Disorders, Farmington Hills, Michigan, USA

Received 10 June 2015; Revised 9 September 2015; Accepted 14 September 2015

ABSTRACT: The American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM) developed guidelines to formalize the ethical standards that neuromuscular and electrodiagnostic (EDx) physicians should observe in their clinical and scientific activities. Neuromuscular and EDx medicine is a subspecialty of medicine that focuses on evaluation, diagnosis, and comprehensive medical management, including rehabilitation of individuals with neuromuscular disorders. Physicians working in this subspecialty focus on disorders of the motor unit, including muscle, neuromuscular junction, axon, plexus, nerve root, anterior horn cell, and the peripheral nerves (motor and sensory). The neuromuscular and EDx physician's goal is to diagnose and treat these conditions to mitigate their impact and improve the patient's quality of life. The guidelines are consistent with the Principles of Medical Ethics adopted by the American Medical Association and represent a revision of previous AANEM guidelines.

Muscle Nerve **52**: 1122–1129, 2015

THE PATIENT–PHYSICIAN RELATIONSHIP IN NEUROMUSCULAR AND ELECTRODIAGNOSTIC MEDICINE

The Patient–Physician Relationship. The relationship between the patient and the physician is a key component to assure that excellent care is provided. The quality of this relationship can impact not only the success of the outcome of the interaction between patient and physician, but also the outcome of the patient's treatment. The physician has a fiduciary duty to first safeguard the interests of the patient. The physician must practice competently, respect patient autonomy and confidentiality, maintain patient safety, and protect the patient's best interests.

Beginning and Ending the Relationship. The physician is free to decide whether to perform an EDx or neuromuscular evaluation on a particular patient. The physician should not decline the evaluation on the basis of the patient's race, color, religion, national origin, gender, disability, age, or other personal characteristics. The physician also should not decline an evaluation on the basis of the patient's known or suspected medical diagnosis. The physician should decline performance of the EDx or neuromuscular evaluation if he or she believes it to be unnecessary or not beneficial to the patient.

If possible, it is best for the EDx physician and the referring physician to concur on who should inform the patient (or designated surrogate) of the results of the EDx or neuromuscular evaluation. The physician should discuss with the patient the reason for the evaluation and the methods to be employed. The physician should advise the patient as to who will be providing the patient with the results of the test. If the patient has a diagnosis that does not require EDx or neuromuscular testing, the physician should so inform the patient and cancel the study or give the patient the right to cancel the study (see subsection "Cooperation and Communication with Healthcare Professionals").

Once the evaluation has begun, the physician should complete the evaluation process unless the patient ends the relationship before the evaluation can be completed, or if medical contraindications to completing the evaluation become apparent during the evaluation. After completion, the physician should return the patient to the care of the referring physician. If the patient does not have a referring physician, the physician should take

Abbreviations: AANEM, American Association of Neuromuscular and Electrodiagnostic Medicine; EDx, electrodiagnostic; EMG, electromyography; FDA, Food and Drug Administration; HIV, human immunodeficiency virus; IRB, institutional review board; LAR, legally authorized representative; NCS, nerve conduction study; OSHA, Occupational Safety and Health Administration; TJC, The Joint Commission

Key words: electrodiagnostic medicine; ethics; genetic testing; informed consent; neuromuscular medicine

This document, by the AANEM Ethics and Peer Review Committee, was originally drafted by the 1994 Committee: Robert G. Miller, MD (chair); Neil A. Busis, MD; William W. Campbell, MD, MSHA; Andrew A. Eisen, MD; Donna L. Frankel, MD; Mark Hallett, MD; Janice M. Massey, MD; and Lois M. Nora, MD, JD. The association also acknowledges the contributions of J. Russell Burck, PhD; Yasoma B. Challenor, MD; Steven H. Horowitz, MD; Glenn A. Mackin, MD; Lawrence R. Robinson, MD; and Jay V. Subbarao, MD.Developed and reviewed by the AANEM Ethics and Peer Review Committee. Approved by the AANEM Board of Directors, May 2015. This manuscript did not undergo further peer review by *Muscle & Nerve*.

Correspondence to: AANEM, 2621 Superior Drive NW, Rochester, MN 55901; e-mail: aanem@aanem.org

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responsibility for urgent care of the patient until an appropriate referral can be made.

Informed Consent in Clinical Evaluation. The physician must obtain valid verbal or written consent from the patient. When the patient cannot give consent or lacks decisional capacity, a verbal or written consent must be obtained from the patient's appropriate legally authorized representative (LAR), who acts as a surrogate decision-maker. If the LAR is unavailable and the situation is urgent, the physician may proceed without consent. The physician must disclose information that the average person would need to know to make an appropriate medical decision. This information must include the benefits and risks of the proposed tests and should include the costs of the proposed tests if the patient desires this information. If the patient is referred for evaluation of a painful symptom, the physician should explain that the EDx studies are directed toward evaluation of certain measurable peripheral nerve abnormalities, not whether pain is present or absent. The patient must give consent voluntarily. If reasonable explanation fails to elicit a patient's consent to carry out the EDx examination, the physician should not undertake the evaluation. The patient may withdraw a prior consent; if this occurs at any point during testing, the physician should not continue with the examination. Physicians must comply with applicable state and federal laws governing informed consent requirements.

Federal Food and Drug Administration (FDA) and institutional review board (IRB) rules should be followed when conducting experimental or investigational studies of procedures, pharmaceuticals, or medical devices that involve human subjects (see section "Clinical Research").

Patient Communication, Comfort, and Preparation. The physician has a duty to communicate with the patient. The physician should convey relevant information in terms the patient can understand and allow adequate opportunity for the patient to raise questions and discuss matters related to a neuromuscular and/or EDx evaluation. Physicians should make every effort to ensure that patients are adequately prepared for planned neuromuscular evaluation and EDx procedures and that they are made as comfortable as possible during the examination. Physicians should be attentive to signs of patient discomfort and safety concerns and resolve them before proceeding. Physicians may decide whether to admit family members or significant others into the examination room during testing to provide support. Informing the patient of the findings of the examination should be coordinated with the referring physician (see previous subsection "Beginning and Ending the Relationship"). Moreover, suggestions for changes in clinical management should generally be made to the referring physician rather than the patient, unless the referring physician has requested that the physician participate in the direct clinical management of the patient.

Medical Risk to the Physician. Physicians have needs and concerns that are relevant for ethical decision-making in the context of evaluation. At the same time, a physician should provide appropriate, compassionate care to all patients, including patients with infectious and other communicable diseases [e.g., human immunodeficiency virus (HIV) or antibiotic-resistant infections]. A physician should not deny care to a patient solely because of real or perceived medical risk to the physician. Physicians must utilize appropriate universal precautions during the examination of any patient to minimize their own medical risk.

Ethical Considerations and the Management of Neuromuscular Disease. Some neuromuscular disorders are progressive or debilitating and may impact a patient's autonomy or competence. Many neuromuscular disorders have limited treatments, which may lead patients to seek unproven interventions. Others may have effective but costly treatments that their insurance may not cover or which patients may not be able to afford. Still others are known to shorten a patient's life expectancy with the prospect of a challenging final few months of life, leading the patient to seek alternatives for end-of-life care. In addition, genetically diagnosed diseases may include issues that affect relatives and future decision-making and have social implications.

Discussion of Disease Implications. First and foremost, physicians must provide patients with their best diagnostic and management skills. They also have a duty to discuss openly with their patients the implications of their EDx diagnosis and related illnesses. This discussion may require a great deal of sensitivity and compassion on the physician's part, particularly if the diagnosis is one that will severely impact the patient's quality or length of life. The physician's counsel should be honest yet allow the patient to preserve some level of realistic hope. The physician has a duty to help the patient understand, decide upon, and seek reasonable treatment, should this be available, and to help avoid ineffective treatments.

Progressive Disorders. For progressive disorders the physician should provide or refer the patient to services that will help maintain or prolong the patient's autonomy and independence. When the neuromuscular diagnosis is expected to limit life expectancy, the physician has a duty to provide this information to the patient as well as to provide

Exhibit BB

UNIVERSITY OF IOWA HOSPITALS & CLINICS

University of Iowa Health Care

George B Richerson, MD, PhD
Professor & Head
The Roy J Carver Chair in Neuroscience

Department of Neurology
University of Iowa Health Care
200 Hawkins Drive
Iowa City, IA 52242
319-356-4296 Tel
319-384-7199 Fax
www.uihealthcare.org

December 28, 2018

Leon Margolin MD, PhD
5245 E Main St
Columbus, OH 43213

Dear Dr. Margolin,

Thank you for asking me to review your project on chronic pain management, which is of considerable interest not only to physiatrists but also to other related specialties in general and neurology in particular. I am pleased to evaluate your proposal as a neurologist with special interest in clinical electrophysiology, which I practiced over 50 years.

The project you are undertaking relates to the role of nerve conduction studies (NCS) and needle electromyography (EMG) on clinical assessments of chronic pain patients. I find the study well designed using appropriate methodology to gain a positive impact on clinical practice. I am pleased to learn that the American Board of PM&R has approved this project that was highly evaluated by Dr. Wainapel, an expert in this field. As a neurologist, I too consider the project of considerable value and interest to other specialists and the third party payers.

From my personal experience, I consider NCS as one of the most important tests for evaluation of neuropathy and EMG as an essential tool for clinical study of radiculopathy, two very common conditions where chronic pain management plays an important role. As such these electrodiagnostic methods have demonstrated strong medical necessity on patient care dealing with chronic pain. I wish you continued success in this important endeavor.

Regards,

Jun Kimura, MD
Professor Emeritus
Department of Neurology
University of Iowa
Professor Emeritus
Kyoto University

Exhibit CC

Montefiore
THE UNIVERSITY HOSPITAL FOR
ALBERT EINSTEIN COLLEGE OF MEDICINE

November 14, 2018

Dear Dr Margolin,

I have reviewed your study on the role of neuromuscular electrodiagnostic testing (including nerve conduction studies and needle electromyography) in the context of your chronic pain practice, found its methodology to be well considered, and its positive impact on clinical outcome provocative and quite compelling. I commend you for making a significant contribution to the specialty area of chronic pain management. These findings would likely be of considerable interest to physiatrists, other specialists treating chronic pain patients, and to the third party payors responsible for authorizing payment for electrodiagnostic testing.

Yours truly,

Stanley F.Wainapel MD, MPH, Clinical Director, Department of Rehabilitation Medicine

Montefiore Medical Center

Professor of clinical Rehabilitation Medicine, Albert Einstein college of Medicine

Department of Rehabilitation Medicine
111 East 210 Street
Bronx, New York 10467
718-920-4133 Office
718-920-4083 Office
718-654-9831 Fax

Physiatric Consultation
Physical Therpy
Occupational Therapy
Speech Language Pathology

Exhibit DD

APEX

· Counseling Services ·

May 16, 2019

To Whom It May Concern:

I am a licensed psychologist, who has certification in addictions medicine and have taken training in pain management. I had been a clinical director of a recovery program in Lancaster, Ohio before transitioning to a hospital.

I have been working with the Comprehensive Pain Management Institute, LLC (CPMI) for several years now, but I am not employed by them and receive no compensation for services from them or Dr. Margolin for analysis.

I reviewed Dr. Margolin's voluntary practice improvement, submitted and approved to ABPMR.

After evaluating the patients I noticed that most of the patients in the sample (as well as many other high risk patients treated by CMPI) have psychological co-morbidities such as: anxiety, depression or concerns of aggressive/manipulative behavior (such as demanding a sharp increase in medications in response to an invasive test). The tests include EMG but because of higher risk patients, there is a chance of increasing psychopathology, like verbal aggression, therefore, a patient is required to give verbal consent.

These risks are clearly and objectively documents in the records as reflected in the initial follow-up evaluations. This includes urine drug screens, prescription monitoring program reports (OARRS), SOAPP-R, PADT, ORT and other assessment tools and referring provider records. All the patients on the list were treated in the framework of screening and brief intervention (SBIRT) approach which requires diagnostic testing. This includes nerve conduction studies within the framework of the Interventional Pain Management according to the state and federal guidelines.

Taking these factors into consideration, in my professional opinion Dr. Margolin made the correct clinical judgement within the framework of Interventional Pain Medicine by avoiding the needle EMG testing (for patients in sample two and in general of all CPMI patients) in case of lack of cooperation or clear understanding by the patient and/or concern of the aberrant behaviors described above.

5310 East Main Street
Columbus, OH 43213

PHONE (614) 751-1090
FAX (614) 751-1091

William H. Vasilakis, Psy.D.

130 Tarkiln Road
Lancaster, OH 43130
1-740-503-5455

PROFESSIONAL EXPERIENCE

Hocking Valley Community Hospital
Logan Ohio
Work with geriatric population, counsel veterans and perform Gastric Bypass evaluation, pain management evaluations. Current

Apex Counseling
Ph: 614-751-1090
General counseling, psychological testing, forensic evaluations and custody evaluations, Pain management (Spinal Stimulator Evaluations), Work with LHI (Logistics Health Institution) evaluating candidates for military service. Current

Integrity Psychological Counseling, Inc 2005-2012
42 Hill Road South Pickerington, Oh 43137
Private Practice specializing in forensic evaluation, dual diagnosis, addictions, counseling, competency evaluations, psychological evaluations, Impaneled with Tricare for referrals with current service personal and veterans PTSD diagnosis and counseling with veterans of WWII, Vietnam, Desert Storm Legal work for Fairfield County Court System.
Bariatric & Gastric Bypass Evaluation, Spinal Stimulator Exams

Senior Life Consultants 2006-2011
6465 Reflections Drive, Suite 110
Dublin, OH 43017
Nursing Home evaluations, counseling geriatric population, consultation with physicians competency evaluations

Circleville Juvenile Correctional Facility 2006 - 2007
640 Island Road Circleville OH 43113
Clinical Experience: Psychology Supervisor.
Responsible for program development, scheduling, supervision of staff and caseloads, overall clinical management of institution, responsible for QI implementation and testing, and supervision of units.

River Valley Counseling 2001 - 2005
131 N. Ewing Street, Lancaster, OH 43130
Clinical Experience: Adult and adolescent individual and family psychotherapy, specialize in dual diagnoses; bariatric evaluations, spinal stimulator evaluations and evaluations for rehab, assessments for work injuries. BWC evaluations

Fairfield Medical Center 2001 -2012

401 North Ewing Street, Lancaster, OH 43130
Affiliate Staff Psychologist: Consultations, evaluations, therapy and triage of patients admitted to the Behavioral Health Unit.

Drug & Alcohol Recovery Center of Fairfield County 2000 -2001
1856 Cedar Hill Road, Lancaster, 01143130
Clinical Experience: Clinical Director: Responsible for program development, supervision of staff caseloads, crisis work, responsible for Q.I. implementation, and overall clinical management of agency.

Maryville Academy City of Youth 1996 - 1999
1150 North River Road, Des Plaines, Illinois 60016

Clinical Experience: Caseload involved assignment to two diagnostic group homes with youth and adolescents ages 7 years to 18 years. Tasks included psychological testing, individual therapy, develop group therapy for both group homes, court appearances on behalf of the youth, and staff training, and recommended alternate and additional placement and crisis intervention.
Doctoral Internship Jan. 1995 to Jan. 1996

Alexian Brothers Medical Center-Niehoff Mental Health Unit
995 Beisner Road, Elk Grove, Illinois 60007
Supervisor John Noto, PH.D.
Clinical Experience: Psychological testing, psychological reports, individual assessments, diagnosis, in-patient admissions, case management, supervision of practicum students, led groups for substance abuse and dual-diagnosis.

Samaritan House-Outpatient Adolescent Addictions 1994 - 1994
999A Leichester Road, Elk Grove, Illinois 60007
Supervisor: John Noto, Ph.D.
Clinical experience: Led adolescent addiction therapy groups, parent education groups, psychological testing, led multi-family educational groups, drug screens.

Alexian Brothers Medical Center-Addictions Treatment Center. 1993 - 1993
800 Beisterfield Road, Elk Grove, Illinois 60007
Supervisor Joan Stiech, RN CSADC
Clinical Experience: Coed psychotherapy groups, individual therapy, drug screens, intake und admissions, lecturer in addiction lectures series.

EDUCATIONAL BACKGROUND:

CHICAGO SCHOOL OF PROFESSIONAL PSYCHOLOGY 2009- 2009
Degree Conferred: Certificate of Forensic Psychology

ADLER SCHOOL OF PROFESSIONAL PSYCHOLOGY

65 East Wacker, Chicago, Illinois 60601
Degree Conferred: Doctor of Psychology, (Psy.D.) Clinical Psychology 1991 - 1996
Certification : Substance Abuse Counseling

NORTHEASTERN ILLINOIS UN1VERSITY
5500 North Louis, Chicago, Illinois 60625
Degree Conferred: M.A. Community & Family Counseling Sep. 1984 to Oct. 1986
Degree Conferred: M.A. History Jan. 1981 to Dec. 1983

NORTHEASTERN ILLINOIS UNIVERSITY
5500 North Louis, Chicago, Illinois 60625
Degree Conferred: B.A. Psychology. Sep. 1977 to Jun. 1980

HARPER COLLEGE
1200 W. Algonquin Rd., Palatine, Illinois, 60067
Degree Conferred: A.A. Liberal Arts Jan. 1975 to Aug. 1977

LICENSURE AND CERTIFICATIONS
State of Ohio #5481
Certificate: Forensic Psychology
Certificate Substance Abuse Counseling
(Alder School of Professional Psychology) Apr. 1994 to Dec. 1994

PRESENTATIONS
-Psychological Needs of the Substance Dependent Patient
-Pain Management Team, Fairfield Medical Center, Lancaster, OH
-Identifying Drug Abusers and Pain Management Technique in Patients
-With a History of Drug Abuse, Pain Management Physicians, Fairfield Medical Center, Lancaster, OH
-Peer Pressure and Anger Management; Thomas Ewing Junior High School, Lancaster, Ohio
-"Catch Me If You Can—Obsessive Compulsive Disorder", and
-"Stress and Anxiety Disorder in the Adult Population" 12th Annual
-Early Childhood Conference, Ohio University, Lancaster Campus, Sponsored By the Children's Committee,
a subcommittee of Fairfield County Family,
Adult and Children First Counsel
-"Competency Evaluation: presented to the Ohio State Bar Association, Lancaster, OH
-"Childhood Depression", interview for Medical Minute presented by WLOH Radio, Lancaster, OH
-"Signs and Symptoms of Childhood Depression: written for Lancaster Eagle Gazette through Fairfield Medical Center.
-Interview, Fairfield Focus, WLOH Radio, Lancaster, OH
-"Out of the Box" Workshop, presented with Dr. Miller and Dr. Wing

Ohio University Inn, Athens. OH
-"Emotional and Psychological Health: How to Support Employees", Women's Division, Lancaster Chamber of Commerce, Presented at Fairfield Medical Center, Lancaster, OH.

Book Written under Pseudonym T.L. Shull: Do They Have a Pill for That? Publisher I Universe Press, March 2019.

Exhibit EE

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American Board of Physical Medicine and

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ABMS Insights Newsletter (quarterly)
ABMS Guide to Medical Specialties (annual)
ABMS Board Certification Report (annual)

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Physical Medicine and Rehabilitation

A specialist in Physical Medicine and Rehabilitation, also called a physiatrist, evaluates and treats patients with disorders or disabilities in the muscles, bones, and nervous system, including neck or back pain, sports and work injuries, stroke, brain injury, spinal cord injury, spasticity, and any other disability or disorder that affects function. A physiatrist may lead a team of medical professionals to help patients improve their physical, psychological, social, and vocational function, and are dedicated to the whole person, including treating pain, restoring function, and improving quality of life. Treatment modalities may include medications, injections, therapeutic exercise, electrodiagnosis, and any equipment required for daily activities.

Training required prior to initial board certification

Four years

Subspecialties

Certification in one of the following subspecialties requires additional training and assessment as specified by the board.

Brain Injury Medicine
A physiatrist who specializes in Brain Injury Medicine focuses on the prevention of brain injury as well as the evaluation, treatment and rehabilitation of individuals aged 15 or older with acquired brain injury. This specialist addresses a range of injury-related disorders that have psychosocial, educational, and vocational consequences, as well as related injuries of the central nervous system. He or she also works with an interdisciplinary team to facilitate recovery and improve patients' health and function.

Neuromuscular Medicine
A physiatrist who specializes in Neuromuscular Medicine focuses on the evaluation and treatment of disorders of nerve, muscle, or neuromuscular junction, including amyotrophic lateral sclerosis (ALS), peripheral neuropathies (e.g., diabetic), various muscular dystrophies, congenital and acquired myopathies, inflammatory myopathies (e.g., polymyositis), and neuromuscular transmission disorders (e.g., myasthenia gravis).

Pain Medicine
A physiatrist who specializes in Pain Medicine diagnoses and treats patients experiencing problems with

acute or chronic pain, or pain related to cancer, in both hospital and outpatient settings and coordinates patient care needs with other specialists.

Pediatric Rehabilitation Medicine

A physiatrist who specializes in Pediatric Rehabilitation Medicine diagnoses and manages congenital and childhood-onset impairments and disability such as cerebral palsy, spina bifida, acquired brain or spinal cord injury, amputation, sports injuries, and muscle and nerve diseases. This specialist works with an interdisciplinary team to improve a child's mobility and daily function at home, in the community, and at school by prescribing equipment and therapies and managing medical conditions such as spasticity, pain, bladder or bowel dysfunction, and nutrition.

Spinal Cord Injury Medicine

A physiatrist who specializes in Spinal Cord Injury Medicine evaluates and manages patients with spinal cord injuries caused by trauma or from medical conditions such as multiple sclerosis, Guillain Barré syndrome, arthritis, infection, transverse myelitis, cancer, and spina bifida. This specialist works with an interdisciplinary team and prescribes equipment and therapies to enhance mobility and self-care skills; manages medical conditions such as pressure ulcers, pain, spasticity, bladder and bowel dysfunction, respiratory health, and mood disorders; and works to help patients return to their communities and vocations.

Sports Medicine

A physiatrist who specializes in Sports Medicine focuses on the prevention, diagnosis, and treatment of injuries related to participating in sports and exercise. This specialist also treats illnesses and diseases that might have effects on health and physical performance.

Exhibit FF

PRACTICEPRO
4494 Derr Rd
Springfield, OH 45503-1445

To Whom It May Concern:

I find Dr. Margolin to be compliant with his billing standards. Based on my review of his billing and chart notes provided, Dr. Margolin is showing effort to be compliant with all known policies and guidelines. I have compared his billing to industry standards and find it very similar to other doctors of his specialty.

Sincerely,

David Deppen, ACS-PM
Billing Manager, Practice-Pro, LLC

Disclaimer: Practice-Pro LLC, and employees are not held responsible for any billing or collection issues that are the result of the providers services. The above statements are based on a review of a portion of the services provided, are not all inclusive, and cover only the known medical policies and guidelines. The provider retains full responsibility for proper billing and coding.

Exhibit GG

---------- Forwarded message ----------
From: **David Deppen** <ddeppen@practice-pro.net>
Date: 2013-03-11 11:39 GMT-04:00
Subject: RE: needle EMG coding
To: Leon Margolin <leon3087@gmail.com>

Here are the codes and the Utilization guidelines right from Medicare's policy for EMG and NCS:

95885: Needle electromyography, each extremity; done with nerve conduction study, limited
95886: Needle electromyography, each extremity; done with nerve conduction study, complete, 5 or more muscles studied, innervated by three or more nerves or four or more spinal levels

Utilization Guidelines
Services performed for excessive frequency are not medically necessary. Frequency is considered excessive when services are performed more frequently than generally accepted by peers and the reason for additional services is not justified by documentation.

The number of nerves tested should be the minimum necessary to address the clinical issue being evaluated. In almost all studies this will appropriately include evaluation of 1 or more nerves that have normal test results.

The following bullets summarize the reasonable maximum number of studies per diagnostic category necessary for a physician to arrive at a diagnosis in 90% of patients with that final diagnosis. In simple straightforward cases, fewer tests will be necessary, particularly when the most critical tests are normal. In the small number of cases that require testing in excess of these numbers, the physician must be able to justify the additional testing with supplementary documentation.

Carpal Tunnel (unilateral)
· Needle EMG - 1 test
· CPT codes 95907/95908Motor NCS with or w/o F-wave – 3 tests
· CPT code 95908 Sensory NCS – 4 tests

Carpal Tunnel (bilateral)
· Needle EMG - 2 tests
· CPT codes 95907/95908 Motor NCS with or w/o F-wave – 4 tests
· CPT code 95909 Sensory NCS – 6 tests

Radiculopathy
· Needle EMG - 2 tests
· CPT codes 95907/95908 Motor NCS with or w/o F-wave – 3 tests
· CPT code 95907 Sensory NCS – 2 tests
· CPT codes 95907 H-Reflex – 2 tests

Mononeuropathy
· Needle EMG - 1 test
· CPT codes 95907/95908 Motor NCS with or w/o F-wave – 3 tests
· CPT code 95908 Sensory NCS – 3 tests
· CPT codes 95934/95936 H-Reflex – 2 tests

Polyneuropathy/Mononeuropathy Multiplex
· Needle EMG - 3 tests
· CPT codes 95908 Motor NCS with or w/o F-wave – 4 tests
· CPT code 95908 Sensory NCS – 4 tests
· CPT codes 95934/95936 H-Reflex – 2 tests

Myopathy
· Needle EMG - 2 tests
· CPT codes 95907 Motor NCS with or w/o F-wave – 2 tests
· CPT code 95907 Sensory NCS – 2 tests

Motor Neuronopathy
· Needle EMG - 4 tests
· CPT codes 95908 Motor NCS with or w/o F-wave – 4 tests
· CPT code 95907 Sensory NCS – 2 tests

Plexopathy
· Needle EMG - 2 tests
· CPT codes 95908 Motor NCS with or w/o F-wave – 4 tests
· CPT code 95909 Sensory NCS – 6 tests
· CPT codes 95934/95936 H-Reflex – 2 tests

Neuromuscular Junction
· Needle EMG - 2 tests
· CPT codes 95907 Motor NCS with or w/o F-wave – 2 tests
· CPT code 95907 Sensory NCS – 2 tests

Tarsal Tunnel (unilateral)
· Needle EMG - 1 test
· CPT codes 95907/95908 Motor NCS with or w/o F-wave – 4 tests
· CPT code 95908 Sensory NCS – 4 tests

Tarsal Tunnel (bilateral)
· Needle EMG - 2 tests
· CPT codes 95908/95909 Motor NCS with or w/o F-wave – 5 tests
· CPT code 95909 Sensory NCS – 6 tests

Weakness, Fatigue, Cramps or Twitching (focal)
· Needle EMG - 2 tests
· CPT codes 95907/95908 Motor NCS with or w/o F-wave – 3 tests
· CPT code 95908 Sensory NCS – 4 tests

Weakness, Fatigue, Cramps or Twitching (general)
· Needle EMG - 4 tests
· CPT codes 95907/95908Motor NCS with or w/o F-wave – 4 tests
· CPT code 95908 Sensory NCS – 4 tests

Pain, Numbness or Tingling (unilateral)
· Needle EMG - 1 test
· CPT codes 95907/95908 Motor NCS with or w/o F-wave – 3 tests
· CPT code 95908 Sensory NCS – 4 tests
· CPT codes 95934/95936 H-Reflex – 2 tests

Pain, Numbness or Tingling (bilateral)
· Needle EMG - 2 tests
· CPT codes 95908 Motor NCS with or w/o F-wave – 4 tests
· CPT code 95909 Sensory NCS – 6 tests
· CPT codes 95934/95936 H-Reflex – 2 tests

Thanks,

David Deppen
Practice-Pro LLC
937-322-4911

From: Leon Margolin [mailto:leon3087@gmail.com]
Sent: Monday, March 11, 2013 11:33 AM
To: David Deppen
Subject: Re: needle EMG coding

OK - what are the codes and what are the regulations - please submit the EObs.

2013/3/11 David Deppen <ddeppen@practice-pro.net>
Dr. Margolin,

Please change the codes on your superbill to accurately reflect what you are doing and we will bill them out with whatever you mark. Please understand that there are some insurance policy that do limit the number of studies that are done and for what dx codes you use.

Thanks,
David Deppen
Practice-Pro LLC
937-322-4911

From: Leon Margolin [mailto:leon3087@gmail.com]
Sent: Saturday, March 09, 2013 10:46 PM

Exhibit HH

---------- Forwarded message ----------
From: **Leon Margolin** <leon3087@gmail.com>
Date: 2013-11-26 12:10 GMT-05:00
Subject: Re: EMG documentation
To: "hccmab@aol.com" <hccmab@aol.com>

Thanks, we r selective with EMGs, however most of our patients are referred for chronic neck or back pain code 724.4 or 723.1 and have a similar test protocol.

We do document clinical necessity for each pts, we don't have any standing orders. We document that EMG test was reviewed in the progress note.

Please review EMG paperwork I sent and let me know.

Sent from my iPhone

On Nov 26, 2013, at 10:45 AM, hccmab@aol.com wrote:

As long as your testing meets medical necessity, you are fine, sounds like the good doctor Leak had a protocol of tests he performed on everybody and that is always a red flag. If you were seen billing the same stuff on all your patients then you would be under the radar, I do not remember seeing any patterns like that when I reviewed your documentation. An assessment and plan of care are the key to success so that the patient's medical conditions and symptoms support the testing and treatments you are providing. I have had several doctors that I could not help because they had a standard protocol for every patient that walked in the door got a battery of testing and the patient's conditions did not support the extensive workup. I am certainly available if you want to speak at 614-327-6974, I am in FL on holiday but I still work too especially when the weather is off and today it is very cloudy but warm so its a great time to catch up on emails.

Regarding the credentialing for Lydia, I think David has it under control it just takes so long, first you have to get credentialed with regular Medicaid before you can get credentialed with any of the medicaid managed care plans and it is a consuming process, I only do for my retainer clients because it does take so much time and patience, from what he is telling me I believe he is working in the right direction.
MaryAnn Baughman

Also, David has sent me a lot of information I can review regarding you A/R and EOB's and I will keep you informed of what I find

-----Original Message-----
From: Leon Margolin <leon3087@gmail.com>

Exhibit II

---------- Forwarded message ---------
From: **Leon Margolin** <leon3087@gmail.com>
Date: вт, 22 мая 2018 г. в 22:09
Subject: specific evidence of habitual neglect, continued duties failure by Caresource/ examples of patient complaints
To: <Peggy.Beat@caresource.com>
Cc: Plinke, Eric <eric.plinke@dinsmore.com>, <Katherine.Leff@caresource.com>, <Pamela.Morris@caresource.com>, <Kurt.Lenhart@caresource.com>, <Ivy.Spitzer@caresource.com>, <Christina.Turner@caresource.com>

Dear Mrs Beats,

I acknowledge receipt of your letter dated 12/20/17 in which you reject the grounds of termination I had asserted in my termination letter of 12/1/17 but accepts termination effective 12/11/17.

I do not agree that CareSource's actions did not constitute "habitual neglect" and "continued failure" of its duties. The improper recoupment by CareSource on the following dates and amounts demonstrate my position:

11/8/17 - #0001179 - $17,090.56
11/15/17 - #0266746 - $13,494.05

11/22/17 - #0485925 - $20,374.71

11/29/17 - #0697837 - $6655.89

12/6/17 - #0987013 - $9265.51

12/20/17 - #1523478 - $8909.92

According to my records there was no advance notice and no billing disputes related to services provided to these patients identified in these EOBs. This recoupment was started with no advance information being given to CPMI and the sole information I received at all was by your 11/16/17 email in response to my billing company inquiry about the stoppage of payments. This occurrence, along with the prior 2016 recoupment and stoppage of payment, also without explanation or advance notice, were among the CareSource acts which interrupted and impacted "the quality of care being delivered to the Covered Person" leading to my letter of 12/1/17. Many patients sent me complaints regarding CareSource (please find examples attached – PHI is blotted) and I believe this recoupment action is retaliation for the business integrity issues I raised in good faith in response to the review of the NCS services in 2017. Please provide me with information regarding the above referenced recoupments. As you know I am represented by the counsel please direct all your future communication to my counsel as per accepted professional standard:

Exhibit JJ

COMPREHENSIVE PAIN MANAGEMENT INSTITUTE, LLC
5245 E. Main Street, Columbus, OH; 43213
Ph. 614-557-6075, F. 614-453-8222

---------- Forwarded message ---------
От: **Leon Margolin** <leon3087@gmail.com>
Date: вс, 17 июн. 2018 г. в 18:12
Subject: Caresource - please confirm the receipt of the attached appeal
To: <9375312398@myfax.com>

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Instructions for Appeal from CareSource manual:

CHAPTER 12: PROVIDER APPEALS PROCEDURES

Appeals of Claims Denials or Adverse Decisions

If you do not agree with the decision of a processed claim, you will have 365 days from the date of service or discharge to file an appeal. If the claims appeal is not submitted in the required time frame, the claim will not be considered and the appeal will be denied. If the appeal is denied, health partners will be notified in writing. If the appeal is approved, payment will show on the health partner's Explanation of Payment (EOP).

Please note: If you believe the claim was processed incorrectly due to incomplete, incorrect or unclear information on the claim, you should submit a corrected claim; you do not need to file an appeal. Health partners have 365 days from the date of service or discharge to submit a corrected claim.

How to Submit Appeals

Claims Appeals:

Health partners can submit claims through our secure Provider Portal, or in writing:

Provider Portal: https://providerportal.caresource.com/OH/

Under the Provider Portal, click on the "Claims Appeals" tab on the left.

Fax: 937-531-2398

Writing: CareSource
Attn: Health Partner Appeals
P.O. Box 2008
Dayton, OH 45401-2008

Use the Health Partner Claim Appeal Request Form located on our website. Please include:

- The member's name and CareSource member ID number
- The health partner's name and ID number
- The code(s) and reason why the determination should be reconsidered
- If you are submitting a timely filing appeal, you must send proof of original receipt of the appeal by fax or Electronic Data Information (EDI) for reconsideration
- If the appeal is regarding a clinical edit denial, the appeal must have all the supporting documentation as to the justification of reversing the determination

If you believe the claim was processed incorrectly due to incomplete, incorrect or unclear information on the claim, you should submit a corrected claim. You do not need to file an appeal.

Content of appeal:

As President of Comprehensive Pain Management Institute, LLC ("CPMI") and pursuant to Chapter 12 of the Provider Manual and Section 3.7 of the Provider Agreement, I am hereby appealing any and all overpayment determinations made by CareSource which have resulted in the off-setting of payments to CPMI for services previously rendered to CareSource beneficiaries. As background, when this off-set was first detected by my billing company, I enquired with Pamela Morris of CareSource on November 13, 2017. At that time, I had received no notice of any overpayment or other issue which would have led to the off-set and non-

payment to CPMI. In response to my inquiry, I received an email from CareSource Associate General Counsel, Peggy Beat, which indicated that she had research the matter and found that there was an overpayment by CareSource to CPMI. I have received no other notice or information as to this overpayment. I believe that this recoupment was initiated by Caresource in retaliation to the appropriate business integrity concerns I raised. It limited access to care for vulnerable Caresource population. Please consider this as an appeal of all claims and determinations involved in the overpayment referenced in Ms. Beat's November 16, 2017 email to me and any other overpayment determination made by CareSource involving CPMI for which I have likewise received no notice.

Sincerely,

Leon Margolin, M.D.

President, Comprehensive Pain Management Institute, LLC

Examples of the payments inappropriately withheld by Caresource:

11/8/17 - #0001179 - $17,090.56
11/15/17 - #0266746 - $13,494.05

11/22/17 - #0485925 - $20,374.71

11/29/17 - #0697837 - $6655.89

12/6/17 - #0987013 - $9265.51

12/20/17 - #1523478 - $8909.92

Exhibit KK

RE: the recent CareSource claims review and payments
Spitzer, Ivy K. Ivenore.Spitzer@caresource.com
Sent: 8/23/2016 5:34:41 PM
To: Leon Margolin <leon3087@gmail.com>

Dr. Margolin - I apologize for the late response, I have been out of the office. I am glad to hear that you have received the payments and it looks like all the recoveries that took place have been reimbursed. At this point of time if you feel that all money has been repaid there is no additional steps.

As and update, CareSource just updated our Interventional Pain Management Policy, which goes into effect 9/19/2016. I have attached it for your review.

Let me know if you have any questions. Have a good evening.

Ivy Spitzer
Resolution Manager, Health Partnership

230 North Main Street, Dayton, OH 45402
937.224.3300 | CareSource.com

p: 937.630.1029 | f: 937.396.0631
ivy.spitzer@caresource.com

From: Leon Margolin [mailto:leon3087@gmail.com]
Sent: Sunday, August 21, 2016 1:10 PM
To: Spitzer, Ivy K.
Subject: the recent CareSource claims review and payments

Dear Ivy:

It looks like the claims review process is complete. I appreciate the time and effort you and CareSource took in this claims review. The set offs were concerning in terms of the practice paying its bills and meeting payroll but the review was timely and appears to have been thorough. I understand that the set offs and prior claims were reviewed and corrected as part of this process and that is what was reflected in the recent payments. Is there anything else I need to do regarding this review?

Thank you again,

Dr. Margolin

Exhibit LL

CareSource™

eric.plinke@dinsmore.com

Received: Sep 19, 2017 11:10 AM
Expires: Nov 18, 2017 12:10 PM
From: nathan.duling@caresource.com
To: eric.plinke@dinsmore.com
Cc: matthew.nickley@caresource.com, katherine.leff@caresource.com, brian.depew@dinsmore.com, peggy.beat@caresource.com, janine.kumanchik@caresource.com
Subject: $ecure request for patient names
Attachments: image003.jpg

Hello Eric,

I am assisting with case #14-08384-OH on Comprehensive Pain Management Institute, LLC. I am contacting you today to request the names of patients described in your letter addressed to Katherine Leff, dated 7/28/17. On page two, section one of the letter you stated, "Twenty-one (21) of the thirty (30) patients included in the extrapolation sample had recognized clinical and medical exceptions to the AANEM policy. As set forth in the reports from Dr. Margolin, Mr. Deppen, and Mr. Cohen (Exhibits A, B, and C respectively), as well as in the enclosed medical records, eleven (11) of thirty (30) patients were being evaluated for carpal tunnel syndrome, while twelve (12) of the thirty (30) patients were on anticoagulation therapy or NSAIDs (two (2) out of the twelve (12) patients were both on anticoagulation and subject to carpal tunnel evaluations)."

We understand your statement to be broken down accordingly:

- 9 of the 30 were being evaluated for Carpal Tunnel
- 2 of the 30 were being evaluated for Carpal Tunnel & on anti-coagulation therapy or NSAIDs
- 10 of the 30 were on anti-coagulation therapy

21 of the 30 patients have medical exceptions

Patient names were not listed to show who meets the criteria of each bullet. Please supply the names of the patients in each category so that we may adequately respond.

Thank you,

NATHAN DULING

Fraud Examiner, Special Investigations Unit

230 North Main Street, Dayton, OH 45402

937.224.3300 | CareSource.com

p: 937.487.4084 f: 937.487.1643

Nathan.Duling@CareSource.com

Exhibit MM

Supplemental Statistical Report in Support of Leon Margolin, M.D. and Comprehensive Pain Management Institute, LLC

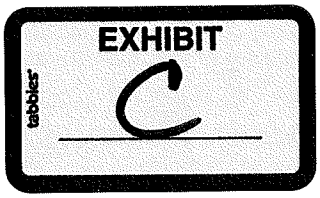
Challenge to the CareSource Extrapolation Analysis

Prepared by

Frank D. Cohen

July 11, 2017

1) My name is Frank Cohen and I am the Director of Analytics and Business Intelligence for DoctorsManagement, LLC, a Knoxville, TN based healthcare consulting firm. I have been actively and continuously employed in the healthcare field for 40 years. Since 1988, I have worked as a healthcare consultant with a particular focus on data analysis and healthcare related analytics.
2) My areas of expertise include applied statistics, predictive analytics, decision modeling and process improvement. I have authored several books on practice analytics, including *Mastering RBRVS, Lean Six Sigma for the Medical Practice* and most recently, *RVUs: Applications for Medical Practices.* In addition, I have participated in a significant number of studies related to healthcare analytics.
3) During the past seven years, I have been involved as an expert and/or consultant in several actions involving data mining and analysis of very large data sets. These include but are not limited to:
    a) *State of New York v. United Healthcare*
    b) *Darlery Franco, Et Al., v. Connecticut General Life Insurance Co., CIGNA corporation and Cigna Health Corporation*
    c) *IN RE: AETNA UCR Litigation*
    d) *Robert Sher, M.D. v. Oxford Health Plans, Inc.*



4) During the past four years, I have been involved as an expert and/or consultant in approximately 150 post-audit extrapolation mitigation and/or statistical analyses of medical practices and hospitals.

5) Additional information is available on my CV

My Assignment

6) I was retained by counsel for Dr. Leon Margolin to assist in reviewing the report a CareSource extrapolation audit conducted on claims submitted by Comprehensive Pain Management Institute Inc. (collectively referred to herein as "CPMI") 1/3/2013 through 10/7/2014 (Re: case #14-08384-OH).

7) My assignment included reviewing and analyzing the CareSource's claims concerning the steps that are defined under section E. PROCEDURE in their Corporate Policy/Procedure document revised 02/17. Within this policy and procedure document, CareSource states that in order to conduct an extrapolation, they need to define: (1) the universe of data to be reviewed; (2) the stratification selected; (3) the statistical validity of the sample; (4) the calculations for point estimates and error; and (5) the appropriateness of the extrapolation methodology.

Introduction

8) Section 8.4.2 of the CMS Program Integrity Manual[1] states the following:

   a) "If a particular probability sample design is properly executed, i.e., defining the universe, the frame, the sampling units, using proper randomization, accurately measuring the variables of interest, and using the correct formulas for estimation, then assertions that the sample and its resulting estimates are "not statistically valid" cannot legitimately be made."

[1] Pub 100-08 Medicare Program Integrity

9) While the above statement is specific to CMS and other government audits, it is also reflects generally accepted principles and practices amongst the statistical community. Accordingly, these criteria must be met in order for an extrapolation to take place.

10) Furthermore, in Section 4.1.5 of Chapter 8 of the Program Integrity Manual (PIM)[2], the guidelines state that *"The sampling methodology used to project overpayments must be reviewed by a statistician, or by a person with equivalent expertise in probability sampling and estimation methods."* In reviewing the entirety of the CareSource document provided to me by my client, I was unable to find any inclusion of information on the statistician required under this section, much less any mention that a statistician was even involved in creating the sampling methodology.

11) In order to arrive at my conclusions regarding these six criteria, I reviewed worksheets and documents provided to me by legal counsel for PHH. These included:

a) 14-08384-OH Comprehensive Pain Management Data for Encryption.xlsx

b) Attachment 2 - CPMI Random Probe Sample List .pdf

c) Attachment 3 - CPMI Medical Records Request.pdf

d) Attachment 4 - CPMI Sampling and Extrapolation Workbook.xlsx

e) Nerve Conduction Study Policy #1.pdf

f) Nerve Conduction Study Policy #2.pdf

g) Nerve Conduction Study Policy #3.pdf

12) Because the accuracy and applicability of an extrapolation is so heavily dependent upon the statistical validity of the sample, the first and perhaps the most important question to be answered is whether the sample is, in fact, statistically valid. In many cases, a sample is assumed valid if there

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[2] Medicare Program Integrity Manual, Chapter 8, section 4.1.5 – *Consultation with a Statistical Expert (Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)*

is a belief that the sample units were drawn randomly from the sampling frame or universe. The term 'random' is most often defined here as each audit unit of interest (beneficiary, claim, claim line, etc.) has an equal and non-zero chance of being selected. There is, however, an important difference between a sample being random and a sample being representative of the sampling frame from which it was drawn.

13) In simple terms, we want the sample to be representative of the sample frame from which it was drawn or, more colloquially, to "look like" the sample frame with regard to its characteristics. These characteristics might include what was paid for the procedure, coding characteristics, such as the differences between the vast array of procedure and service codes included in the HCPCS II coding universe. It may also have to do with specific characteristics found amongst the beneficiaries, which often more accurately define the types of diagnoses and treatments represented within the medical records.

14) Some characteristics, such as charge or paid amounts can be visualized by graphing data using histograms, for example. Non-valued characteristics, such as those subject to rules, regulations or guidelines, are more difficult to visualize in this way. For value-based characteristics, distribution and variance are two effective ways to look at representativeness of a sample to the universe (or sampling frame).

Executive Summary

15) While there are many problems with the expert's results of this audit, it is my opinion that the main problem is with the sample itself. Remember, Section E. of CareSource's Corporate Policy/Procedure document requires that certain procedures are followed to ensure that the sample is appropriate for extrapolation and as detailed throughout this report, it is my opinion that CareSource did not meet the minimum criteria as defined within their own policy guidelines.

16) It is simply not enough for a sample to be just random. As will be shown throughout this report and in general amongst the statistical community, the sample has to exhibit a high degree of precision, representativeness and homogeneity when compared to the sampling frame. In order for the sample to be considered as part of an extrapolation event, the sample *must* be representative of the universe to which the sample results will be inferred. This is not just statistically correct; it also concurs with good sense. It is simply illogical to attempt to take the results of a sample that does not statistically represent the universe and then try to extrapolate back to that universe for the purpose of estimating the impact of those erroneous results, particularly when attempting to extrapolate outside the bounds of the data set from which the sample was created.

17) In summary, CareSource:

a) Used the incorrect variable of interest when calculating the sample size, as cited by the OIG guidelines;

b) Failed to provide required information on the statistician, if any, that was involved in the design and analysis of the audit data;

c) Failed to provide the full universe, as required under both Section E. of their guidelines and Chapter 8 of the Program Integrity Manual;

d) Included, within the sample frame, data that should have been excluded due to policy guidelines;

e) Included data points within the sample that should have been excluded based on policy guidelines;

f) Included data points within both the sample frame and the sample that contained dates of service that were inappropriate based on specific clinical guidelines; and

g) Attempted to extrapolate the results of the audit to a sample frame that was not included when the sample was selected.

18) As supported throughout this report, it is my professional opinion that the sample, which was the basis for the extrapolation, did not meet the minimum requirements for either randomness or statistical significance and therefore was not a statistically valid sample. As such, the results of the audit cannot be used for the purposes of extrapolation.

Findings

19) Based on documentation provided by CareSource as well as data contained within "14-08384-OH Comprehensive Pain Management Data for Encryption.xlsx", the universe consisted of 981 claims with dates of service from 3/11/2013 through 10/7/2014. I was not, however, provided with the universe of claims data for this date range but rather the sample frame instead. The universe, by definition, would have contained *all* of the line-item data for the claims presented in this workbook. Instead, CareSource had already excluded all procedures codes except 95912 (Never Conduction Studies; 11-12 Studies), the focus of their audit.

20) The problem here is that, based on conversations with Dr. Margolin as well as information contained within the documentation provided by CareSource, claims that include procedure code 95886 along with 95912 validate payment and therefore should have been excluded from the sample frame used to select the sample. Since CareSource did not provide the universe, as required, I requested Dr. Margolin provide me with the full billing data for CPMI for the date range of the sample frame. I received the data from David Deppen, billing manager for Practice-Pro, LLC, CPMI's billing company.

21) During the analysis of the billing data, we discovered that there were dozens of examples where procedure code 95886 was an inclusive line within the claim that contained the targeted procedure code (95912) as well as claims with subsequent dates showing that the 95886 procedure was reported for that same patient. As such, these claims should not have been

included within the sample frame. In and of itself, this would completely negate the validity of the sample since there was some non-zero probability that an incorrect claim line could be included within the sample, creating a fatal error within the sampling methodology.

22) Contained within the CareSource documents was a statement that NCS is payable in the absend of a needle EMG when that particular patient is undergoing or has undergone an evaluation for carpal tunnel syndrome. In reviewing the universe of claims provided by Mr. Deppen, we found that some 6% of patients did, in fact, have a needle EMG performed and some 15% that reported carpal tunnel symptoms or neck pain did go through a carpal tunnel evaluation. As such, these claims should have been excluded from the sample frame, as well.

23) I believe that Mr. Deppen provided a detailed analysis of these exclusions in a separate document and I am repeating them here based on his data analysis. The information below reference tabs 1 and 2 from the workbook "14-08384-OH Comprehensive Pain Management Data for Encryption."

For the initial sample frame used to create the sample (tab 1):

01/03/2013-10/07/2014 – DOS range
982 Total Patients listed
164 Patient who had Neck Pain listed as ICD code (had carpal tunnel evaluation)
1 patient who had Carpal Tunnel listed as ICD code (had carpal tunnel evaluation)
1 patient had Neck Pain and Carpal Tunnel listed as ICD code (had carpal tunnel evaluation)
2 patient who had an EMG needle study performed

For the additional data set that was included in the extrapolation (tab 2):

10/8/14 – 9/3/16 – DOS range
1087 Total Patients listed
96 Patients who had Neck Pain listed as ICD code (had carpal tunnel evaluation)
11 Patients who had Carpal Tunnel listed as ICD code (had carpal tunnel evaluation)
123 patients who had an EMG needle Study performed

24) There is no other way to interpret these data, when considering the use of extrapolation, except as a fatally flawed methodology. It should quite clear, even to a non-statistician, that poisoning the sample frame with claims that should have been excluded, particular when applying a random

selection process to create the sample, will ultimately result in poisoned data being included in the sample. Fortunately, this is easy to test and Dr. Magolin was asked to examine the charts for each of the 30 claims selected for the sample and he reported that 21 of them (70%) contained exclusionary exemplars that require that these be removed from the sample. Specifically,

a) **12** should have been excluded because of anticoagulation therapy and NSAIDs medications (2 out of 12 were both on anticoagulation and subject to carpal tunnel evaluationss
b) 11 others were subject to carpal tunnel evaluations

25) Finally, notwithstanding the fatally flawed methods described so far, for some reason that defies statistical logic, CareSource chose to take the results of their audit using a flawed sample and extrapolate back not only to the original flawed sample frame, but then to include an additional 1,086 claims from a data set that not only was subject to the same flaws as stated above, but reported a data of service that was not inclusive of that of the sample. In essence, CareSource chose to extrapolate the results of the sample to a data set that was not considered when the sample was selected. There is nothing within the literature or among the statistical community that would render this as acceptable.

Conclusions

26) In conclusion, CareSource failed to meet their own criteria for extrapolation nor did their analysis represent standards that are commonly accepted within the statistical community. Specifically, CareSource did not define the universe or the sampling frame properly, did not define the sample properly, did not accurately measure the variable of interest and did not use the correct formula for estimation. In fact, their treatment of the sample and extrapolation in this case can easily be considered as egregious and by no stretch of the imagination would be considered as either a statistically valid or representative sample. Any one of the many errors committed by the CareSource would be reason enough to exclude the extrapolation from consideration - taken

together, they present an overwhelming case for excluding the extrapolation estimate. Therefore, it is my professional opinion that the extrapolation in this case is wholly inappropriate and should be disregarded in its entirety for the purpose of calculating overpayment amounts for this case.

July 21, 2017

Exhibit NN

8.4.1.2 - The Purpose of Statistical Sampling
(Rev. 906; Issued: 09-26-19; Effective: 01-02-19; Implementation: 01-02-19)

A statistical sample is used to estimate the amount of overpayment(s) made on claims. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), mandates that before using extrapolation (i.e., projection, extension, or expansion of known data) to determine overpayment amounts to be recovered by recoupment, offset, or otherwise, there must be a determination of sustained or high level of payment error, or documentation that educational intervention has failed to correct the payment error. By law, the determination that a sustained or high level of payment error exists is not subject to administrative or judicial review. In this chapter, details are provided on the use of statistical estimation (sometimes, especially in legal contexts, referred to as "extrapolation") to determine overpayment amounts.

8.4.1.3 - Steps for Conducting Statistical Sampling
(Rev. 906; Issued: 09-26-19; Effective: 01-02-19; Implementation: 01-02-19)

The major steps in conducting statistical sampling are --

(1) Identifying the provider/supplier;
(2) Identifying the period to be reviewed;
(3) Defining the universe (target population) and the sampling unit, and constructing the sampling frame;
(4) Assessing the distribution of the paid amounts in the sample frame to determine the sample design; it is very likely that the distribution of the overpayments will not be normal. However, there are many sampling methodologies (for example, use of the Central Limit Theorem) that may be used to accommodate non-normal distributions. The statistician should state the assumptions being made about the distribution and explain the sampling methodology selected as a result of that distribution.
(5) Performing the appropriate assessment(s) to determine whether the sample size is appropriate for the statistical analyses used, and identifying, relative to the sample size used, the corresponding confidence interval;
(6) Designing the sampling plan and selecting the sample from the sampling frame;
(7) Examining each of the sampling units and determining if there was an overpayment or an underpayment; and
(8) Estimating the overpayment. When an overpayment has been determined to exist, the contractor shall follow applicable instructions for notification and collection of the overpayment, unless otherwise directed by CMS.

For each step, the contractor shall provide complete and clear documentation sufficient to explain the action(s) taken in the step and to replicate, if needed, the statistical sampling.

8.4.1.4 - Determining When Statistical Sampling May Be Used
(Rev. 906; Issued: 09-26-19; Effective: 01-02-19; Implementation: 01-02-19)

The contractor shall use statistical sampling when it has been determined that a sustained or high level of payment error exists. The use of statistical sampling may be used after documented educational intervention has failed to correct the payment error. For purposes of extrapolation, a sustained or high level of payment error shall be determined to exist through a variety of means, including, but not limited to:

- high error rate determinations by the contractor or by other medical reviews (i.e., greater than or equal to 50 percent from a previous pre- or post-payment review);
- provider/supplier history (i.e., prior history of non-compliance for the same or similar billing issues, or historical pattern of non-compliant billing practices);
- CMS approval provided in connection to a payment suspension;
- information from law enforcement investigations;
- allegations of wrongdoing by current or former employees of a provider/supplier; and/or
- audits or evaluations conducted by the OIG.

When an overpayment is identified by data analysis alone, the contractor shall consult with its Contracting Officer's Representative (COR)/Business Function Lead (BFL) as defined in PIM Chapter 4, §4.7 – Investigations. In addition, if CMS approves the data driven overpayment, the contractor shall also consult with its COR/BFL on whether statistical sampling and extrapolation are necessary to identify the overpayment. Additionally, a UPIC shall consult with the appropriate MAC on whether an extrapolated overpayment is more efficient in processing a data-driven overpayment before requesting recoupment from the MAC.

If the contractor believes that statistical sampling and/or extrapolation should be used for purposes of estimation, and it does not meet any of the criteria listed above, it shall consult with its COR and BFL prior to creating a statistical sample and issuing a request for medical records from the provider/supplier. Examples of this may include, but are not limited to: billing for non-covered services, billing for services not rendered, etc. Extrapolation should not be used when the above criteria is not met unless prior approval is given by the COR and BFL.

Once a decision has been made that statistical sampling may be used, factors also to be considered for determining when to undertake statistical sampling for overpayment estimation instead of a claim-by-claim review, include, but are not limited to: the number of claims in the universe and the dollar values associated with those claims; available resources; and the cost effectiveness of the expected sampling results.

8.4.1.5 - Consultation With a Statistical Expert

(Rev. 906; Issued: 09-26-19; Effective: 01-02-19; Implementation: 01-02-19)

The sampling methodology used in estimations of overpayments must be reviewed and approved by a statistician or by a person with equivalent expertise in probability sampling and estimation methods. This is done to ensure that a statistically appropriate sample is drawn, and that appropriate methods for estimating the overpayments are

followed. The contractor shall obtain from the statistical expert a written approval of the methodology for the type of statistical sampling to be performed. Regardless of whether this sampling methodology is applied routinely and repeatedly, each time a sample size calculation or estimation is performed, a detailed methodology (See Section 8.4.7.1.) should be submitted by the statistical expert to the corresponding contractor.

Prior to releasing a findings letter or overpayment demand letter, the contractor shall have the statistical expert review the results of the sampling and any other subsequent overpayment estimation or extrapolation. The contractor shall verify that the statistical findings have been reviewed and agreed to by the contractor.

If questions or issues arise, the contractor shall also involve the statistical expert.

At a minimum, the statistical expert (either on-staff or consultant) shall meet one of the following criteria:

- Have significant coursework in probability and estimation methodologies, and at least 10 years of experience applying methods of statistical sampling and interpreting the results.
- Possesses a Bachelor's degree (e.g., B.A., B.S.) in statistics or in some related field (e.g., psychometrics, biostatistics, econometrics, mathematics) with significant coursework in probability and estimation methodologies, and at least 6 years of experience applying methods of statistical sampling and interpreting the results.
- Possesses a Master's degree (e.g., M.A., M.S.) in statistics or in some related field with significant coursework in probability and estimation methodologies, and at least 4 years of experience applying methods of statistical sampling and interpreting the results.
- Possess a Doctoral degree in statistics or in some related field with significant coursework in probability and estimation methodologies, and at least 1 year of experience applying methods of statistical sampling and interpreting the results.

If the contractor does not have staff with sufficient statistical experience as outlined here, it shall obtain such expert assistance prior to conducting statistical sampling.

8.4.1.6 - Use of Other Sampling Methodologies

(Rev. 906; Issued: 09-26-19; Effective: 01-02-19; Implementation: 01-02-19)

Once it is has been determined that statistical sampling may be used, nothing in these instructions precludes CMS or its contractor from relying on statistically sound sampling methodologies employed by other law enforcement agencies, including but not limited to the OIG, the DOJ, and/or the FBI. In these cases, a full explanation shall be provided explaining why the methodology was used and why it was statistically appropriate in the circumstances.

Exhibit OO

From: "Hayes, Lora" <lora.hayes@caresource.com>
Date: May 7, 2015 at 10:26:18 AM EDT
To: Leon Margolin <leon3087@gmail.com>
Subject: RE: It was nice meeting you in our office!

Dr. Margolin,

It was very nice meeting with you and your staff yesterday. I was very impressed with everything you do to care of patients. It was my pleasure getting to meet with you again. Please do not hesitate to contact me whenever I can be of assistance to you.

I have already recommend you this morning to a practice that needs to do referrals out for pain management and are being told they have to have MRI's done first. I told them I do not think you require that and that you do all of your own assessments etc.

LORA HAYES
HealthPartnership Representative

230 North Main Street, Dayton, OH 45402
937.224.3300 | CareSource.com

p: 937.531.3107 | f: 937.487.0304
Lora.Hayes@Caresource.com

From: Leon Margolin [mailto:leon3087@gmail.com]
Sent: Thursday, May 07, 2015 10:20 AM
To: Hayes, Lora
Subject: Fwd: It was nice meeting you in our office!

Dear Lora,

I was nice meeting you again in our office after meeting you in June 2013

I am glad we were able to discuss with you and provide you again with a sample of our policies, medical records and patient testimonials.

I attached a copy of the letter we sent to Caresource with the last chart request.

Please do not hesitate to call me 718-530-5953 should you have any questions.

Sincerely,

Leon Margolin MD, PhD

Exhibit PP

Closed Corporate Integrity Agreements

Below are the names of entities that have entered into Corporate Integrity Agreements (CIA) in the past 10 years and whose CIA is now closed. The list is updated monthly with newly closed CIAs as knowing which entities have previously been subjected to a CIA may be relevant to patients, family members, health care industry professionals, and other stakeholders. A link to a government press release describing the circumstances that led to the CIA is provided if it's available; not all settlements are accompanied by a press release. For more information, including any CIA enforcement actions taken by OIG, please visit CIA Enforcement.

#|A|B|C|D|E|F|G|H|I|J|K|L|M|N|O|P|Q|R|S|T|U|V|W|X|Y|Z

#

PROVIDER	CITY, STATE	EFFECTIVE	CLOSED	PRESS RELEASE
21ST CENTURY ONCOLOGY, LLC	FORT MYERS, FL	12-17-2015	04-12-2019	LINK

A

PROVIDER	CITY, STATE	EFFECTIVE	CLOSED	PRESS RELEASE
A & C HEALTH CARE SERVICES, INC.		1/4/2008	10/26/2011	
AA HEALTHCARE MANAGEMENT, SEE EXTENDICARE HEALTH SERVICES, INC.	SKOKIE, IL	10/03/14	11-25-2020	LINK
ABBOTT LABORATORIES	ABBOTT PARK, IL	10/11/2012	07/25/2018	LINK
ABICHANDANI, LACHMAN K., M.D.	CHESTERFIELD, MO; SAINT LOUIS, MO	11/9/2012	11/9/2017	
ABRAHAM, AKRAM R., M.D., P.C. AND ABRAHAM MEDICAL CLINIC	HOLLIS, OK	6/13/2012	8/18/2017	
ACELL, INC.	COLUMBIA, MD	05-13-2019	06/09/2021	
ADESOKAN, YINKA; FAMILY DERMATOLOGY, P.C., FAMILY DERMATOLOGY OF PENNSYLVANIA, P.C., AND FAMILY DERMATOLOGY OF DELAWARE, P.A.	LILBURN, GA	04-21-2015	04-21-2020	LINK

BELOIT OPERATIONS, LLC SEE EXTENDICARE HEALTH SERVICES, INC.	MILWAUKEE, WI	01/01/19	11-25-2020	LINK
BETHANY LUTHERAN HOME, INC.	COUNCIL BLUFFS, IA	5/31/2012	10/2/2017	LINK
BHC SIERRA VISTA HOSPITAL, INC.	SACRAMENTO, CA	4/23/2012	9/12/2017	
BIESEK, GENESIO W., M.D. AND MANCHESTER INTERNAL MEDICINE ASSOCIATES, P.C.	MANCHESTER, NH	1/21/2009	2/14/2014	
BIOVAIL CORPORATION N/K/A VALEANT PHARMACEUTICALS INTERNATIONAL	MISSISSAUGA, ONTARIO, XX	9/11/2009	3/12/2015	
BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.	RIDGEFIELD, CT	10/22/2012	5/24/2018	LINK
BORIO, JOSEPH, D.C. AND BORIO CHIROPRACTIC HEALTH CENTER	CICERO, NY	10/31/2014	1/2/2018	LINK
BOSTON SCIENTIFIC CORPORATION	WASHINGTOIN, DC	12/23/2009	4/23/2015	
BOTSCH, NOEL R., R.PH AND PHARMACY I.V. ASSOC. OF DEXTER, INC. DBA OPTION CARE PHARMACY DBA SPECIAL DESIGN HEALTH CARE	CAPE GIRARDEAU, MO	8/11/2009	1/8/2014	
BROOKS, NORMAN A., M.D., AND NORMAN A. BROOKS, INC. D/B/A THE SKIN CANCER MEDICAL CENTER	ENCINO, CA	03-30-2017	01-08-2021	LINK
BROOKHAVEN HOSPITAL	TULSA, OK	3/10/2008	3/17/2011	
BURTON, DANIEL J. AND HARMONY CARE HOSPICE, INC.	COLUMBIA, SC	11/15/2012	11/15/2017	LINK
BYRAM HEALTHCARE CENTERS, INC.	HUNTINGTON BEACH, CA	04-29-2016	02/10/2022	LINK

C TOP

PROVIDER	CITY, STATE	EFFECTIVE	CLOSED	PRESS RELEASE
CALLOWAY LABORATORIES, INC. (AMENDED AND RESTATED)	WOBURN, MA	05-15-2014	07-09-2019	LINK
CARDIAC MONITORING SERVICES	IRVINE, CA	2/24/2010	5/6/2015	
CARDIOVASCULAR SYSTEMS, INC.	ST. PAUL, MN	06-28-2016	09-27-2021	LINK
CAREALL, LLC; CAREALL MANAGEMENT, LLC, F/K/A DIVERSIFIED HEALTH MANAGEMENT, INC.; THE JAMES W. CARELL 2007 FAMILY TRUST; J.W. CARELL DYNASTY TRUST; AND J. W. CARELL ENTERPRISES LLC SEE CAREALL, INC.	COOKEVILLE, TN	10-29-2014	07-31-2018	LINK
CARELL, JAMES W. AND CAREALL MANAGEMENT, LLC	NASHVILLE, TN	8/10/2012	6/11/2015	LINK
CAREMED PHARMACEUTICAL SERVICES; SORKIN'S RX LTD.	LAKE SUCCESS, NY	12-01-2014	06-22-2020	LINK
CARESOURCE	DAYTON, OH	1/31/2011	7/7/2016	LINK
CARITAS CARNEY MEDICAL GROUP	DORCHESTER, MA	8/4/2008	10/18/2011	
CARLSON THERAPY NETWORK, P.C.	BROOKFIELD, CT; CHESHIRE, CT	9/10/2008	11/18/2013	
CATHEDRAL HEALTH SERVICES, INC.	NEWARK, NJ	1/23/2008	4/24/2013	
CATHEDRAL ROCK	FORT WORTH, TX	1/6/2010	11/16/2012	

Exhibit QQ

THE UNITED STATES DEPARTMENT of JUSTICE
STICE NEWS

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE Tuesday, February 1, 2011

Ohio-Based Managed Care Plan Contractor CareSource & Entities to Pay $26 Million to Resolve False Claims Allegations

WASHINGTON - CareSource, CareSource Management Group Co. and CareSource USA Holding Co. have agreed to pay the United States and the state of Ohio $26 million to resolve allegations that they caused Medicaid to make payments for assessments and case managements they failed to provide to children and adults, the Justice Department announced today.

CareSource, which is headquartered in Dayton, Ohio, provides managed care benefits to Medicaid beneficiaries in Ohio, Indiana and Michigan. The settlement resolves allegations that between January 2001 and December 2006, the CareSource entities knowingly failed to provide required screening, assessment and case management for adults, and children with special health care needs. As a result, it was alleged that CareSource received millions of dollars in Medicaid funds to which it was not entitled. The CareSource entities subsequently submitted false data to the state of Ohio so that it appeared they were providing these required services to improperly retain incentives received from Ohio Medicaid and to avoid penalties.

"Cash-strapped Medicaid programs, such as Ohio's, can ill afford conduct such as this, designed to improve this company's bottom line at the expense of a program benefitting the poor and disabled," said Tony West, Assistant Attorney General for the Civil Division.

"This settlement will help ensure the provision of crucial services to Medicaid patients, especially children with special health care needs," said Carter M. Stewart, U.S. Attorney for the Southern District of Ohio. "The cooperation between federal and state agencies, along with assistance from the former employees who brought this issue to the government's attention, demonstrates the determination necessary to protect the public's precious health care resources."

This settlement resolves a whistleblower action filed under the False Claims Act by two former employees at CareSource, Laura Rupert and Robin Herzog. The whistleblowers filed a suit in the Southern District of Ohio on behalf of the United States when they became aware of CareSource's practices and sought to rectify the harms caused to these Medicaid recipients. The False Claims Act's *qui tam,* or whistleblower, provisions allow private persons with knowledge of fraud to file suit on behalf of the United States and share in any recovery. As part of this settlement, Rupert and Herzog will receive a share of the federal portion of the settlement totaling approximately $3.1 million.

This settlement is part of the government's emphasis on combating health care fraud and another step for the Health Care Fraud Prevention and Enforcement Action Team (HEAT), which was announced in May 2009 by Attorney General Eric Holder and Kathleen Sebelius, Secretary of the Department of Health and Human Services (HHS). The partnership between the two departments has focused efforts to reduce and prevent Medicare and Medicaid fraud through enhanced cooperation. One of the most powerful tools in that effort is the False Claims Act, which the Justice Department has used to recover approximately $5.3 billion since January 2009 in cases involving fraud against federal health care programs. The Justice Department's total recoveries in False Claims Act cases since January 2009 have topped $6.8 billion.

This settlement was the result of a coordinated effort by the Commercial Litigation Branch of the Justice Department's Civil Division; the U.S. Attorney's Office for the Southern District of Ohio; the Health Care Fraud Section of the Ohio Attorney General's Office; and HHS Office of Inspector General in investigating and resolving the allegations.

Component(s):
Civil Division

Press Release Number:
11-138

Exhibit RR

---------- Forwarded message ---------
From: **Leon Margolin** <leon3087@gmail.com>
Date: пн, 13 нояб. 2017 г. в 14:41
Subject: the abrupt cessation of all payments by Caresource/patient safety
To: <Pamela.Morris@caresource.com>, <Peggy.Beat@caresource.com>
Cc: Brown, Harry M. <hbrown@beneschlaw.com>, DePew, Brian <BDePew@beneschlaw.com>, <Katherine.Leff@caresource.com>, <Kurt.Lenhart@caresource.com>, <Ivy.Spitzer@caresource.com>

By e mail and certified mail

Dear Ms. Morris,

My billing company has brought to my attention that Caresource has stopped any payments to my practice without any warning or explanation (EOB attached). They billing tried to reach Caresource but was not able to get an explanation to this situation.

Please explain the reason for this step and whether is was done as a retaliation to the recent business integrity concern and ethical committee review request dated October 19, 2017. Please clarify if this is the response Caresource mentioned in the communication from Ms. Beat dated October 30th.

We have expressed in the past the potential serious patient safety concern caused by such action. I will need to take appropriate steps to protect my patients including appropriate documentation on the patient charts as required by the guidelines, the SMBO regulations and the ethical policy of CMS and Medicaid.

Please respond in writing within the next 3 business days.

Sincerely,

Dr. Margolin

--

Exhibit SS

Addendum credentialing communications to Caresource:

fri, 19 nov. 2021 г. в 14:00, Tiffany Clauss <tiffany.clauss@unifiedrcm.com>:
Hello,

I am following up with this email. I have not heard back from anyone in contracting with Caresource. I sent in the contract over 90 days ago and have not heard back.

Warmest Regards,

Tiffany Clauss
Chief Revenue Officer

P. 888-505-7773
D. 614-412-7422
F. 614-443-0997

From: Brewer, Michelle L. <Michelle.Brewer@caresource.com>
Sent: Friday, October 29, 2021 7:12 PM
To: Tiffany Clauss <tiffany.clauss@unifiedrcm.com>
Subject: Leon Margolin, MD

Hi Tiffany,

I hope this email finds you well. I am trying to credential Dr. Margolin, however, his CAQH application has been expired since 10/20/2020. If you do not have access to the CAQH website to update and re-attest his CAQH application, please complete and return the attached application and have Dr. Margolin sign and date it. If you have any questions or need assistance, please let me know.

Thank you,

Michelle

Michelle Brewer
Provider Enrollment Coordinator II

220 E Monument Avenue
Dayton, OH 45402
937.224.3300 | CareSource.com

Exhibit TT

Ohio Medicaid announces CareSource wins bid to keep managing billions in state benefits

Caption

BUSINESS

By Kaitlin Schroeder

April 9, 2021

The state chose CareSource and five other insurance companies for a massive contract to manage benefits for the $20 billion Ohio Medicaid program.

These contracts announced Friday are the largest the state has ever issued, and the rules for how the money is spent is one of the most influential policy tools the state has. The contracts are the main

business line for Dayton-based CareSource, one of the largest area employers.

The new system is intended to overhaul clunky bureaucracy and make the health insurance program more user friendly for the 1 in 4 Ohioans covered.

“This is a bold, new vision for Ohio’s Medicaid program — one that focuses on people and not just the business of managed care,” Ohio Medicaid Director Maureen Corcoran said.

Ohio Medicaid aims to launch the new system in early 2022. Any company that wants to protest the decision will need to file a protest by April 23.

CareSource and the other insurance companies working with Ohio Medicaid were asked to refer requests for comment back to the state.

The contracts announced Friday are preliminary because they are not signed yet.

It's not clear yet how the new system will impact CareSource's core business — managing 1.3 million Ohioans' Medicaid benefits — compared to the old system or whether CareSource will lose market share.

Ohio Medicaid covers 3.2 million people with low incomes or certain disabilities, including more than 412,000 people in the local nine-county region. About 90% of Ohioans who are covered by Medicaid don't have their benefits managed directly by the state government. Instead, people get an insurance plan managed by insurance companies like CareSource.

Nearly half of Ohio children, half of Ohio births and the majority of nursing home care is covered by Medicaid. By rebidding the contracts and resetting the conditions for how the money gets spent, the DeWine administration is trying to engineer better outcomes for the different Ohioans with Medicaid.

Some examples of these changes include that providers will be able to work out one Medicaid contract, instead of having to broker deals with all the different Medicaid plans. Claims billing and prior authorizations will be processed through a single system instead of with each plan individually.

Loren Anthes, who researches Ohio Medicaid for Cleveland-based Center for Community Solutions, said providers can get bogged down in all the paperwork and redundancy that can come with Medicaid payments.

“By simplifying things, streamlining them administratively, means doctors and nurses and other folks who are serving the Medicaid population can focus more on delivering care, rather than appropriately managing the red tape,” Anthes said.

In addition, some of the changes include:

- A new separate program will help kids with lots of behavioral health needs and help their families navigate the different systems their child gets services from. Aetna will manage this new separate program.
- Insurance plans like CareSource must contribute 3% of annual profits to community reinvestment, and that number eventually increases to 5%.
- Ohio’s Medicaid plans will work with a single company that will transparently manage pharmacy benefits.
- There will also be provider advisory councils so that providers can be heard by the insurance companies.

Jim Tassie, Ohio Medicaid deputy director, said the department wants insurers in the new system to work together, “not competing against each other by offering certain bonuses or trinkets,” but instead working for a holistic, collective impact on the Medicaid population.

Along with working more with each other, Tassie said the insurance plans will work more with community organizations.

“One of the things that we learned from many of our members is they turn to their community organizations, whether it’s their community action agency or a federally qualified health center or even their primary care provider. Those are the folks to whom they look to get guidance on their health care,” Tassie said, adding that this is part of the reason why the insurers have to give some of their profits back to the community.

The new program will be carved up among six insurance companies with the possibility of a seventh.

Along with CareSource, others selected were UnitedHealthcare, Humana, Molina Healthcare, AmeriHealth Caritas, and Anthem Blue Cross and Blue Shield.

Centene's subsidiary Buckeye Community Health Plan could potentially be added to the program as a seventh but the department wrote that it is "deferring for additional consideration" on that decision. Centene is currently contesting a lawsuit filed by Ohio Attorney General Dave Yost.

When the state was deciding who to award these contracts to, they gave each of the bidding insurance companies a score and CareSource scored the lowest. UnitedHealthcare scored the highest.

Some people in the Dayton-area with Medicaid are covered by one of the insurance plans that lost their bid.

Members will continue to receive services with their current managed care plans until the transition in early 2022 and will not lose coverage. Members will have the opportunity to select a new plan during the 2021 open enrollment period later this summer. If members do not select a plan, one will be automatically assigned to them.

In Other News

1 Drone programs at Springfield airport expected to drive future job...

2 Air Force starting critical care training program at Beavercreek...

3 Pungent, blooming tree to be banned in Ohio next year

4 Gas prices dip, but expected to rise again with no long-term relief in...

5 P&G suspends operations in Ukraine, scales back in Russia

About the Author

Kaitlin Schroeder

Kaitlin Schroeder is a health care and business reporter with the Dayton Daily News. She covers the local hospitals, CareSource, public health, nursing homes, caregiving, and other related topics.

Exhibit UU

MedPro Group
a Berkshire Hathaway company

Account #	: 993-866-637RE
Invoice Date	: 01/10/2022
Policy Number	: C58062
Extension Contract Amount	: $2,608
Due Date	: 05/02/2022
Amount Enclosed:	

Your payment must be received on or before the above due date.
Please indicate your account # on your check.

Certified Mail / Return Receipt – Personal & Confidential
COMPREHENSIVE PAIN MANAGEMENT INSTITUTE
5245 EAST MAIN STREET
COLUMBUS, OH 43213

Remit to:
THE MEDICAL PROTECTIVE COMPANY
23289 NETWORK PLACE
CHICAGO IL 60673-1232

Please detach and return the top portion with your payment.

RE: Professional Liability Coverage
Policy Number : C58062
Expiration Date : 3/3/2022
Extension Contract Amount: $2,608
Notice of Non - Renewal

Dear Dr. Margolin :

We regret to inform you that Medical Protective will not be in a position to renew your current policy, which expires on 03/03/2022. As a result, you should make arrangements to replace your coverage with another carrier. Your billing for an Extension Contract from our Company at $1,000,000/$3,000,000 limits for the period of 03/03/2017 to 03/03/2022 is $2,608.

Pursuant to our underwriting guidelines, Insureds whose medical, dental, or DEA license or Medicare, Medicaid, or hospital privileges have been investigated, revoked or put on probation may not be offered renewal.

According to our records, it appears you have agreed to pay $650,000 to the US government to resolve False Claims Acts allegations. Because of the nature of this matter, we have decided not to renew your coverage..

Since your policy was issued on a Claims-Made basis, it provides no protection for claims filed after its expiration date – no matter when services were rendered.

You can protect yourself from future claims by selecting any one of the following:

1. Buy an Extension Contract from the Medical Protective Company. This extends the time for reporting claims based on services rendered between the retroactive date and the termination date of your Medical Protective policy.
2. Buy a claims-made policy through a separate professional liability carrier which maintains the same retroactive date as you had on your Medical Protective policy.

MedPro Group
a Berkshire Hathaway company

You MUST take one of these actions or you will have no coverage for future reported claims arising from the period of 03/03/2017 to 03/03/2022.

Lack of payment by the above specified Due Date will be deemed a rejection of such offer.

Policy: C58062
Account: 993-866-637RE

Additionally, you have 10 days to request of us a copy of your loss experience for at least the last three policy years, or the period of time during which you were coverage, whichever is less.

This is an offer for coverage and such coverage cannot be automatically paid for via any previously established automated bill payment options ("Auto Payments"). If you would like to purchase this Extension Contract please remit payment via check or our Customer Service Team at 800-4MEDPRO to discuss other payment methods.

Sincerely,
Drew Matz, Underwriter
MidEast Underwriting Team Underwriting Team
THE MEDICAL PROTECTIVE COMPANY

cc: file 113 GALLAGHER HEALTHCARE

20200417_nrcmreas

Exhibit VV

LEON MARGOLIN, MD PhD
Comprehensive Pain Management Institute

COMMUNICATION LOG

PATIENT NAME: [redacted]

DATE/TIME	NOTES
4/24/18	To CareSource:
	As of November 2017, I was not allowed to see my physicians without warning, You cut off access to care. I had to wait for another insurance (Med.caid Plan) to kickin. You caused me to Suffer. It was negligent of you, as a Company, Thank You for Dr. Leon Margolin for Continuing to see me.
	[redacted]

[redacted]

LEON MARGOLIN, MD PhD
Comprehensive Pain Management Institute

4.9th 2018

PATIENT NAME: [redacted]

COMMUNICATION LOG

DATE/TIME	NOTES
	TO: CARESOURCE
	Caresource disrupted my medical care w/ DR. MARGOLIN in my Nov. 4 2017 until 2018 I tried to contact them No Answer or return calls VERY UNPROFESSIONAL (Careless) My life was on hold Because my disabilities I'd like to Be heard + this doesn't happen to anyone else

[redacted]

LEON MARGOLIN, MD PhD
Comprehensive Pain Management Institute

PATIENT NAME: [redacted]

COMMUNICATION LOG

DATE/TIME	NOTES
4/3/18	Care Soure block my access to care to Dr. Margolin The Dis-Regarded my medicle Propes and try switch me back Care Soure dishonest Wed. I think Care Soure not honest and don't care about members Thank You [redacted]

LEON MARGOLIN, MD PhD
Comprehensive Pain Management Institute

COMMUNICATION LOG

PATIENT NAME: [redacted]

DATE/TIME	NOTES
2/16/18	Care Source has not helped me since Nov 2017 and I want to thank Dr Margolin Care Source has blocked my access to care and it was very difficult for me. It was not right what they did to me. And I would like to thank Dr Margolin for seeing me and caring for me.

[redacted]

LEON MARGOLIN, MD PhD
Comprehensive Pain Management Institute

[redacted] COMMUNICATION LOG

PATIENT NAME:

DATE/TIME	NOTES
2.152016	
	Caresource blocked my care with
	Dr Margolin which in turn I
	had to switch insurance plans.
	Because of Caresource doing this
	I had to change all of my
	insurance information both my
	pharmacy as well as my [illegible].
	this took many hours. It was
	an aggrevating thing and I
	appreciate Dr Margolin and his
	staff for working with me
	while I switched to Molina
	[redacted]

LEON MARGOLIN, MD PhD
Comprehensive Pain Management Institute

COMMUNICATION LOG

PATIENT NAME: [redacted]

DATE/TIME	[redacted]
2-9-18	CARE SOURCE Blocked MY ACCESS CARE TO DOC TO MARGOLIN I THINK THAT'S NOT RIGHT. I THINK CARE SOURCE DON'T CARE ABOUT THEIR PATIENTS THEY DIDN'T CARE ENOUGH TO LEAVE ME WITHOUT A DOCTOR LIKE DR MARGOLIN. I THINK MY DOC WAS STILL SEEING ME.
	[redacted]

[redacted]

LEON MARGOLIN, MD PhD
Comprehensive Pain Management Institute

[redacted]
PATIENT NAME:

COMMUNICATION LOG

DATE/TIME	NOTES
1-2-18 3:00pm	Concerning CARE Source, I am very displeased with the way CARE Source operates with regard to my access to care. They wouldn't pay there bills and it created a situation with my provider and my access to care. I had to switch providers out in the meantime I endured 2 weeks of pain and sleepless nights until I could get my appropriate paperwork with a new provider worked out. Very displeased w/ CARE Source and Anyone or affecting my care and needs as a patient. [redacted] Spoke with them on a few occasions (CARESOURCE) and it was just a run around over the phone and transferred to no one except a busy signal and/or continuous ringing.
insurance	
	[redacted] 1-2-18

LEON MARGOLIN, MD PhD
Comprehensive Pain Management Institute

[redacted] **COMMUNICATION LOG**

PATIENT NAME:

DATE/TIME	NOTES
7/21/20	Care Source has given me a hard time so I had to get a new insurance provider but Dr. Margolin helps me a lot making sure I make it. Care Source blocked my insurce to Dr. Margolin can this is Not Right [redacted] Thank you!

LEON MARCOLIN, MD PhD
Comprehensive Pain Management Institute

COMMUNICATION LOG

PATIENT NAME: [redacted] 1/30/18

DATE/TIME	[redacted]
	Im really upset with Caresounse because the blocked my actes to care. I its not right thank You [redacted]

LEON MARGOLIN, MD PhD
Comprehensive Pain Management Institute

COMMUNICATION LOG

PATIENT NAME: [redacted]

DATE/TIME	NOTES
1-30-18	Care Source blocked my access for care and I went thru severe pain and discomfort. I am very thankful to Dr. Margolin for his medical care.
	[redacted]

LEON MARGOLIN, MD PhD
Comprehensive Pain Management Institute

PATIENT NAME: [redacted] **COMMUNICATION LOG**

DATE/TIME	NOTES
1-29-18	Care Source is blocking my care to Dr Margolin to access my care I had to switch to different insurance it was difficult to me Thank you to Dr Margolin to keep helping me [redacted]

LEON MARGOLIN, MD PhD
Comprehensive Pain Management Institute

COMMUNICATION LOG

PATIENT NAME: [redacted] 1/26/18

DATE/TIME	NOTES
	I learned very abruptly that CareSource stopped paying my medical bills with Dr. Margolin. Thankfully Dr. Margolin continued to care for me while CareSource blocked me.
	[redacted]

LEON MARGOLIN, MD PhD
Comprehensive Pain Management Institute

COMMUNICATION LOG

PATIENT NAME: [redacted]

DATE/TIME	NOTES
1/23 - 12:30	Lou Ward very unhappy with Covesource was unable to get medication for pain for a whole month pain is at max level due to no coverage. CareSource has block my access of care and no longer am I able to see my Doctor Margolin. Am thankful to Dr. Margolin and his staff for seeing me the last two months. [redacted]

LEON MARGOLIN, MD PhD
Comprehensive Pain Management Institute

[redacted] COMMUNICATION LOG

PATIENT NAME:

DATE/TIME	NOTES
1-16-18	
	To whom it may concern
	Care Source blocked my access
	to care with DR Margolin very
	abruptly. It has caused me
	extreme hardship. I think it is
	unfair and inapropriate for them
	to do so. Thank goodness that
	DR Margolin still seen me until
	I was able to switch Insurance.
	because I do not know what I
	would have done.
	Thank ya
	[redacted]

LEON MARGOLIN, MD PhD
Comprehensive Pain Management Institute

COMMUNICATION LOG

PATIENT NAME: [redacted]

DATE/TIME	NOTES
1-16-18	Carescore blocked my access to my care with Dr. Margolin and I thought it was so wrong they should not have did things like that to Dr. Margolin. Dr. Margolin is a caring doctor and a wonderful person. I can deeply feel Dr. Margolin and his staff love [redacted]

LEON MARGOLIN, MD PhD
Comprehensive Pain Management Institute

COMMUNICATION LOG

PATIENT NAME: [redacted]

DATE/TIME	NOTES
1-16-18	I Lakita Staples was a patient At Care Source, Dr Margolin Office) I was Been on pain management doctor for Over a Year. I'm really dissatisfied But Care Source dropped all of their Clients for his office I don't understand Why this has happened. He isn't the only practice affected by The Change Please look into this and Change your policy back. Thank You

LEON MARGOLIN, MD PhD
Comprehensive Pain Management Institute

COMMUNICATION LOG

PATIENT NAME: [redacted] 1-16-18

DATE/TIME	NOTES
	A few Months ago Corrisonna blocked my Acess to Dr. Margolin office for Pain Management and I'm working 2 Jobs to support my family. Dr Margolin Cared me for 2 months to help me out. I believe without his help I would not have been able to make it. I really appreciate the kindness Dr Margolin + his staff showed me during that time. And it was NOT Fair to Cut Patients to him.
	[redacted]

LEON MARGOLIN, MD PhD
Comprehensive Pain Management Institute

COMMUNICATION LOG

PATIENT NAME: [redacted]

DATE/TIME	NOTES
01-11-18	As a patient of Dr. Margolin carrying Caresource insurance since in December 2017 I was refused necessary services to help with everyday activities of life. Within not receiving care for over 30 days I have been affected negatively due to having to wait long period of time for change of insurance. Now I am having hardships & having to pay for meds that I did not before all due to Caresource refusing payments to Dr. Margolin. This is an unacceptable way to practice. Blessings to Dr. Margolin for not dropping as a patient due to the inconvenience of non payment by Caresource. Please rectify the matter Thank you, [redacted]

PATIENT NAME: [redacted]

COMMUNICATION LOG

DATE/TIME	NOTES:
11-17-21	I'm Rather dismayed with Coresource I'm having Major interruptions in my Care, including my medications And in fact loss my injections. This has caused issues with effective pain control that is beyond the scope of control of you & my Medical Provider as Care Source has also denied service of my compounding pharmacy. I am very concerned about this. I filed a complaint about Care Source once already, the issue is with Care Source and them continuing to restrict access and deny continuous to pain control medicine and procedures, my doctor (Leon Marston) has sent above & beyond to try to help me however what Care Source has done I am very happy with my doctor I'm thankful that Yes [redacted] & his staff to help [redacted] when Care Source keeps denying appointments are out of date. What they do is totally unethical and illegal what happened to Montgomery at Care Source

[redacted]

LEON MARGOLIN, MD PhD
Comprehensive Pain Management Institute

COMMUNICATION LOG

[redacted] 01/09/18

DATE/TIME	NOTES
	I DAVID WALKER AM A PATIENT OF Dr margolin and i HAVE Severe Lung Disease And HAVE OUTHER Disabilities I am very upset THat care source quite PAying For my DOCTORS APPOINTMENTS And my DOCTOR was Nice enought To Allow me TO LET me Be A PATIENT For 2 MOUNTHS WITHOUT PAYMENT Because I HAD PROBLEMS CHanging From care source To medicare
	[redacted] 1-9-2018

LEON MARGOLIN, MD PhD
Comprehensive Pain Management Institute

[redacted]
PATIENT NAME: [redacted]

COMMUNICATION LOG

DATE/TIME	NOTES
1/9/18 3:46 pm	[redacted]

My care with Dr. Margolin is very important to my daily care. I've multiple health issues and it was an issue to switch to another health insurance. It was a hardship on my health to stop treatment in the middle of my treatment plan and have me switch to another. I really appreciate Dr. Margolin for the help I receive but I don't understand why Caresource would just tell him to drop his patients and make us switch in the middle. I had difficulty switch which left me uncovered a few days until the switch could be made. My care with Dr. Margolin was and is good until Caresource stopped paying for my treatments. That wasn't nice to stop payment on treatment for so many people.

LEON MARGOLIN, MD PhD
Comprehensive Pain Management Institute

COMMUNICATION LOG

PATIENT NAME: [redacted]

DATE/TIME	NOTES
1-16-18	With the change of the insurance it was troublesome and a hastle, not only for me but for my doctor as well. For me some medications were denied and some were not. Therefore out of pocket expenses had to have been paid from me as well as my doctor's. My physician carried me for 2 months out of pocket, while issues with insurance were (taken care of)

Kim Kelly [redacted]

LEON MARGOLIN, MD PhD
Comprehensive Pain Management Institute

[redacted] COMMUNICATION LOG

PATIENT NAME:

DATE/TIME	NOTES
01/17/18	I learned that Care Source switched me to My Care Ohio plan without my permission and blocked my access to care with Dr Margolin.
	I think this is not right.
	[redacted]

Exhibit WW

Ohio drug overdose deaths jumped 26% in a year

BY JUSTIN BOGGS OHIO
PUBLISHED 1:50 PM ET NOV. 17, 2021

OHIO — The state of Ohio saw a 26.6% increase in drug overdose deaths in the 12-month period ending April 2021 compared to the 12-month period ending April 2020, the National Center for Health Statistics reported.

What You Need To Know

- The U.S. had more than 100,000 drug overdose deaths for the first time in a 12-month period, federal officials said
- Nationally, there was an over 28% increase in drug overdose deaths in the one-year period ending April 2021 compared to April 2020
- Ohio had more than a 26% jump in overdose deaths
- Ohio's most populous county Franklin had a noticeable increase in drug overdose deaths, according to federal data

The updated statistics come as federal officials said Wednesday that the number of drug overdose deaths climbed above 100,000 for the first time in the U.S. in a 12-month period.

During the period of May 2020 to April 2021, Ohio had an estimated 5,585 overdose deaths. A year prior, there were 4,410 overdose deaths reported, according to the NCHS.

Drug overdose deaths previously peaked from July 2016 to June 2017 in Ohio. The NCHS estimated there were 5,293 overdose deaths in Ohio from July 2016 through June 2017. After a drop in drug overdose deaths late in 2017 and in 2018, figures began to rise again in 2020.

Nationally, there was a 28.5 rise in drug overdose deaths from May 2020 to April 2021 compared to the prior year, the NCHS reported.

While county-level data has not been released for April 2021, data from prior months show a rise in drug overdose deaths. Franklin County, the state's most populous county, had the most estimated overdose deaths with 852 during the period of April 2020 to March 2021, the National Center for Health Statistics reported.

While most counties in Ohio saw increases in drug overdose deaths, Hamilton County has not seen an increase. The county had a peak of 392 overdose deaths in the 12-month period ending April 2020. In the one-year period ending March 2021, there were an estimated 376 overdose deaths, the NCHS reported.

"Today, new data reveal that our nation has reached a tragic milestone: more than 100,000 lives were lost to the overdose epidemic from April of last year to April of this year," President Joe Biden said in a statement. "As we continue to make strides to defeat the COVID-19 pandemic, we cannot overlook this epidemic of loss, which has touched families and communities across the country."

Experts believe that the prevalence of fentanyl is driving the surge in overdose deaths, as well as the COVID-19 pandemic, which has left many Americans isolated and unable to find support. Synthetic

opioids such as fentanyl accounted for nearly two-thirds of those deaths.

According to the Ohio Department of Health, fentanyl was involved in 76% of overdose deaths in 2019, often in combination with other drugs.

Exhibit XX

Issue brief: Nation's drug-related overdose and death epidemic continues to worsen

***Updated May 12, 2022**

The nation's drug overdose epidemic continues to change and become worse. The epidemic affects every state and now is driven by illicit fentanyl, fentanyl analogs, methamphetamine, and cocaine, often in combination or in adulterated forms. More than 107,000 deaths were reported in the United States between December 2020 to December 2021. The AMA continues to urge policymakers' action to increase access to evidence-based care for substance use disorders, pain and harm reduction measures. The news articles and reports below cite data from multiple and varied sources, including national, state and local public health agencies, law enforcement, emergency medical services, hospitals, treatment centers, and journals. Recent AMA advocacy, resources and recommendations to end the epidemic:

- AMA-Manatt Health 2022 state policy toolkit provides more than 400 specific laws, regulations, policy guidance and other actions being implemented to help reduce mortality and improve outcomes. The toolkit builds on the 2020 AMA-Manatt Health national policy roadmap use of best practices to increase access to evidence-based care for mental illness, substance use disorders, comprehensive pain care and harm reduction initiatives.
- The U.S. Centers for Disease Control and Prevention on February 10, 2022, released a draft revision to its 2016 opioid prescribing guideline. In comments to the Federal Register on April 11, 2022, the AMA said that the CDC's new draft guideline—if followed by policymakers, health insurance companies and pharmacy chains—provides a path to remove arbitrary prescribing thresholds, restore balance and support comprehensive, compassionate care.
- AMA letter urging Congress to hold health plans accountable for nearly 15 years of failures in complying with the 2008 Mental Health Parity And Equity Addiction Act.
- AMA comments on Biden Administration's 2022 National Drug Control Strategy. Reduce barriers to medications to treat substance use disorders; broaden access to a wide range of harm reduction services, including naloxone, sterile needle and syringe exchange services, and drug checking supplies; require all health insurance programs to remove arbitrary restrictions for care for patients with pain; and take steps to develop and support a national, standardized reporting system for key metrics related to drug use. July 2021.
- Recommendations from the AMA Substance Use and Pain Care Task Force and AMA 2021 Overdose Epidemic national report Updated recommendations that highlight physicians' actions as well as additional steps that must be taken to have a meaningful impact on reducing drug-related mortality and improving patient outcomes. September 2021
- AMA issue brief on key considerations for employers during the drug overdose epidemic. This includes reviewing benefit plans for patients and families with substance use disorders, mental illness and/or pain; promoting harm reduction at work; and reducing stigma.

See below for national news and other reports from all 50 states and the District of Columbia.

For more information, please contact Daniel Blaney-Koen, JD, Senior Legislative Attorney, AMA Advocacy Resource Center, at daniel.blaney-koen@ama-assn.org

https://www.newsdakota.com/2020/03/10/drug-overdose-death-raises-concerns-in-the-area/ March 10, 2020

36. **Ohio**
    - **Ohio State campus warns of fake Adderall pills after two students die.** https://www.usatoday.com/story/news/nation/2022/05/06/drug-overdose-ohio-state-adderall/9672391002/ May 6, 2022
    - **An increase in potent "Frankenstein opioids" prompts warning from Ohio attorney general.** https://www.cbsnews.com/news/frankenstein-opioids-nitazene-ohio-attorney-general-dave-yost-warning/ April 20, 2022
    - **Methamphetamine the most prevalent illegal drug locally.** https://www.crescent-news.com/news/local_news/methamphetamine-the-most-prevalent-illegal-drug-locally/article_a445482e-8a7c-11ec-be85-8fe0becae98e.html February 11, 2022
    - **Fake prescription pills leading to overdose concerns in Portage County.** https://www.news5cleveland.com/news/local-news/oh-portage/fake-prescription-pills-leading-to-overdose-concerns-in-portage-county September 2, 2021
    - **'COVID has greatly exacerbated the crisis: Local, national overdose deaths increasing.** https://www.coshoctontribune.com/story/news/local/2021/07/20/drug-overdose-deaths-rise-coshocton-county-across-u-s/8001801002/ July 20, 2021
    - **New data: fatal overdoses leapt 22% in Ohio last year.** https://ohiocapitaljournal.com/2021/07/15/new-data-fatal-overdoses-leapt-22-in-ohio-last-year/ July 13, 2021
    - **New report shows overdose deaths are up in every state.** https://local12.com/news/addicted/new-report-shows-overdose-deaths-are-up-in-every-state-cincinnati June 3, 2021
    - **Ohio State Study Finds 'Opioid Treatment Deserts' Across Franklin County and Columbus.** https://www.thelantern.com/2021/05/ohio-state-study-finds-opioid-treatment-deserts-across-franklin-county-and-columbus/ May 26, 2021
    - **Fatal Drug Overdoses in Ohio in 2020 Spiked Weeks After National Emergency Declaration, Early Lockdowns.** https://www.psychiatryadvisor.com/home/topics/addiction/upticks-in-fatal-overdoses-in-ohio-after-initial-major-events-in-governmental-response-to-the-covid-19-pandemic/ May 6, 2021
    - **COVID-19: Ohio deaths up by 7.8% so far in 2020, coronavirus pandemic likely to blame.** https://www.dispatch.com/story/news/2020/11/15/ohio-deaths-up-nearly-8-so-far-2020-pandemic-likely-blame/6263306002/ November 15, 2020
    - **A legacy of distrust: The racial disparities that mean many can be reluctant to seek help.** https://www.cincinnati.com/story/news/2020/11/12/systemic-racism-addiction-treatment-outreach-ohio-and-kentucky/3731197001/ November 11, 2020
    - **Editorial: The addiction epidemic hasn't gone anywhere.** https://www.dispatch.com/story/opinion/editorials/2020/10/29/editorial-addiction-epidemic-hasnt-gone-anywhere/6053054002/ October 29, 2020
    - **Cuyahoga County sees 19 drug overdose deaths in a week, on pace for highest total in three years.** https://www.cleveland.com/metro/2020/10/cuyahoga-county-sees-19-drug-overdose-deaths-in-a-week-on-pace-for-highest-total-in-three-years.html October 13, 2020
    - **COVID-19 not slowing drug trafficking, overdose deaths.** https://www.dispatch.com/news/20200904/covid-19-not-slowing-drug-trafficking-overdose-deaths September 4, 2020
    - **Ohio drug overdose deaths back on rise.** https://www.newarkadvocate.com/story/news/local/2020/07/20/ohio-drug-overdose-deaths-back-on-rise/5473138002/ July 20, 2020

- **Overdose Incidents Rose Sharply Around Ohio Valley During Pandemic.** https://wfpl.org/overdose-incidents-rose-sharply-around-ohio-valley-during-pandemic/ July 5, 2020
- **Coronavirus can't stem central Ohio opioid abuse.** https://www.dispatch.com/news/20200603/coronavirus-cant-stem-central-ohio-opioid-abuse June 5, 2020
- **Don't forget the other epidemic; editorial.** https://www.toledoblade.com/opinion/editorials/2020/05/31/dont-forget-other-epidemic-opioids-naloxone-toledo-lucas-county/stories/20200526122 May 30, 2020
- **Narcan handed out to step opioid overdose rise amid COVID-19.** https://www.dispatch.com/news/20200523/narcan-handed-out-to-stem-opioid-overdose-rise-amid-covid-19 May 23, 2020
- **Ohio County Prosecutor: Pandemic Puts More Stress On Families Dealing With Addiction.** https://www.iowapublicradio.org/post/ohio-county-prosecutor-pandemic-puts-more-stress-families-dealing-addiction#stream/0 April 29, 2020
- **Coroner: 6 overdose deaths in Franklin County Friday.** https://www.nbc4i.com/news/local-news/coroner-6-overdose-deaths-in-franklin-county-friday/ April 25, 2020
- **Health officials fear COVID-19 could trigger rise in drug overdoses.** https://www.dispatch.com/news/20200420/health-officials-fear-covid-19-could-trigger-rise-in-drug-overdoses April 20, 2020
- **HEALTH ALERT: Canton latest to close its syringe program.** https://www.harmreductionohio.org/covid-19-updates-syringe-programs-ongoing/ March 29, 2020

37. **Oklahoma**

- **Wagoner Co. Officials raise awareness on the dangers of fentanyl.** https://www.kjrh.com/news/local-news/wagoner-co-officials-raise-awareness-on-the-dangers-of-fentanyl May 10, 2022
- **Addicted America: Law enforcement faces increase in fentanyl deaths.** https://ktul.com/news/addicted-america/addicted-america-law-enforcement-faces-increase-in-fentanyl-deaths January 27, 2022
- **Broken Arrow police see increase in fentanyl overdoses.** https://www.kjrh.com/news/local-news/broken-arrow-police-see-increase-in-fentanyl-overdoses January 20, 2022
- **Opioid crackdown had 'tremendous fallout,' with more suicides, drug overdoses among patients, lawmakers told.** https://tulsaworld.com/news/state-and-regional/govt-and-politics/opioid-crackdown-had-tremendous-fallout-with-more-suicides-drug-overdoses-among-patients-lawmakers-told/article_ae3ff49e-3b2d-11ec-b2e3-b74d9a33a2b9.html November 2, 2021
- **Manslaughter conviction of 21-year-old Oklahoma woman who suffered miscarriage sparks outcry.** https://www.cbsnews.com/news/brittany-poolaw-manslaughter-miscarriage-pregnancy/ October 20, 2021
- **Counterfeit pills laced with fentanyl are driving a spike in Oklahoma deaths.** https://www.readfrontier.org/stories/counterfeit-pills-laced-with-fentanyl-are-driving-a-spike-in-oklahoma-deaths/ September 6, 2021
- **Oklahoma Sees Increase In Overdose Deaths From 2019-2020.** https://www.newson6.com/story/60f4203b96d8d90c26db68ab/oklahoma-sees-nearly-30-increase-in-overdose-deaths-from-20192020 July 18, 2021

Exhibit YY

News Releases

Search News Releases: Search

Record Surges in Opioid Overdoses Prompts AG Yost to Urge Vigilance

1/11/2021

(COLUMBUS, Ohio) — More Ohioans died of an opioid overdose during a three-month period last year than at any time since the epidemic began, according to an analysis by a task force created by Ohio Attorney General Dave Yost.

The analysis by Yost's Scientific Committee on Opioid Prevention and Education (SCOPE) found the death rate in Ohio from opioid overdose at 11.01 per 100,000 population in the second quarter of 2020 – the highest rate in 10 years. The previous 10-year high was in the first quarter of 2017 at 10.87 opioid overdoses per 100,000 population.

"Opioid overdoses might have taken a backseat in our minds last year because of COVID-19, but make no mistake: Ohioans are dying at a devastating rate because of opioid overdoses," Yost said, urging vigilance about how prescription drugs are stored and encouraging people to seek medical care in the event of an overdose – despite concerns about COVID-19.

Surprisingly, the record-setting spike came after Ohio experienced a significant drop in its opioid-related death rate, which had fallen to between 6 and 8 overdose deaths per 100,000 people over the prior 24-month period.

"This is alarming data, and while COVID has rightly captured our attention, we cannot lose sight of the threat the opioid epidemic brings to all areas of Ohio," Yost said.

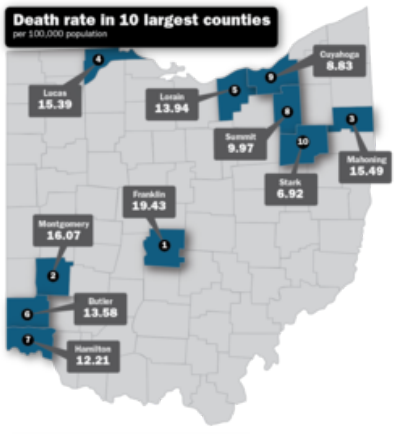
The hardest hit counties in the second quarter of 2020 were Scioto (35.22), Fayette (20.67) and Franklin (19.43).

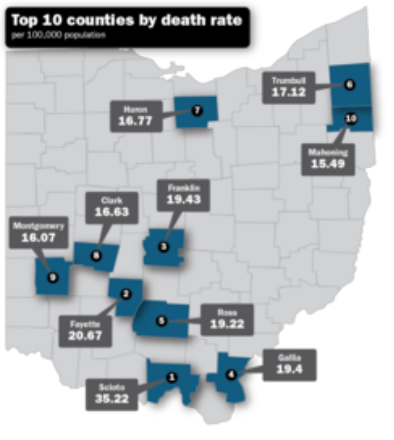
The analysis, which found an increase of deaths in 67 percent of Ohio's counties, can be found here.

The data is gathered by the Ohio Department of Health, which collects opioid overdose numbers. The data may lag by up to six months.

Addiction to opioids can start with a prescription being brought inside the home. Yost's office has released guidelines on how to safely store prescription drugs inside your residence.

Unsure about the signs of opioid abuse or addiction? More info can be found here.





MEDIA CONTACT:
Luke Sullican: 614-270-2662

-30-

Exhibit ZZ

United States Senate

WASHINGTON, DC 20510

March 1, 2018

Pamela B. Morris
President & Chief Executive Officer
CareSource
230 North Main Street
Dayton, Ohio 45402

Dear Ms. Morris:

We write to share our concern over the reported utilization of several industry practices that, when used in the context of pain management and substance use disorder treatment and recovery, may be counterproductive to efforts to address our nation's opioid epidemic. We urge you to reexamine CareSource's current policies and procedures to identify and, more importantly, rectify, any practices that could be contributing to or exacerbating our country's drug addiction crisis.

Our country continues to fight back against the worst drug overdose epidemic in its history. According to the Centers for Disease Control and Prevention (CDC), drug overdoses accounted for more than 63,600 deaths in 2016 – an average of 174 drug overdose deaths per day. These tragedies are not limited to one group of individuals; rather, deaths resulting from drug overdose continue to increase across all populations – men and women, young and old, urban and rural, and across all races. And the cost of this epidemic extends beyond the loss of human lives – according to a recent economic analysis conducted by the Council of Economic Advisors, the economic impact of this addiction crisis represents a loss of nearly $504 billion annually, a number roughly equivalent to three percent of the entire country's gross domestic product (GDP). Without additional investments and changes to the status quo, these numbers will only continue to increase at an exponential rate.

Despite these devastating statistics, the pain that drives many individuals to these addictive drugs in the first place remains a problem. A 2015 analysis by the National Institutes of Health (NIH) estimated that more than 25 million adults experience chronic pain and nearly 40 million adults experience severe levels of pain. These numbers will only continue to increase as our nation grows older. In order to make progress in our nation's fight against the addiction epidemic, we must do more to ensure all Americans – whether they are suffering from chronic or acute pain – have access to non-addictive pain management options.

Unfortunately, it is often much harder for an individual to seek non-addictive pain medications or non-pharmacologic treatment options at the outset of treatment than it is to get a prescription opioid. We understand that there are many reasons for this, including restrictions on benefit design, the high cost of alternative pain treatments, the limited availability and effectiveness of clinically proven alternatives, a lack of clinician awareness regarding alternatives, and ingrained prescribing practices. However, it is important to note that opioid prescribing decisions are not governed solely by clinicians. Health insurance coverage policies play a significant role when it comes to accessing non-addictive pain treatment options, which is why we are urging CareSource to look into its benefit design and internal practices and take a more active role as it relates to preventing and treating addiction. If a clinician chooses to prescribe a non-addictive therapy to treat chronic pain, which is simply overridden by an insurance algorithm that defaults to the cheapest opioid alternative, an opportunity to turn the tide against addiction may be missed.

Recent news reports have raised serious concerns over a lack of insurer accountability when it comes to this epidemic. Take Ms. Lauren Kafka, for example. Ms. Kafka recently wrote about her experience recovering from surgery to correct a torn rotator cuff.[1] Her surgeon and two separate physical therapists recommended renting a cool-therapy device to help manage her pain throughout her recovery. Coverage for this device was denied by her insurance plan, leaving Ms. Kafka with two options: (1) pay out-of-pocket for the device rental; or (2) resort to the opioid painkillers covered by her insurance. Ms. Kafka made the decision to try to take the minimum number of pills necessary to aid in her recovery, and while she was able to pay out-of-pocket for the device rental fees to help decrease her dependence on opioids throughout her recovery, others in her situation may opt to elect only the covered drugs and find themselves at a higher risk for dependence.

Ms. Alisa Erkes, a patient with chronic abdominal pain, was forced to switch from using Butrans, a pre-dosed buprenorphine painkiller patch, to morphine when her insurance provider stopped covering the patch.[2] Though both buprenorphine and morphine are opioids, morphine is categorized as having a higher risk of abuse, dependence, and overdose. Similarly, Ms. Amanda Jantzi, a patient with a painful bladder condition, weaned herself off opioids using the non-opioid painkiller drug Lyrica, only to find that it was not covered by her new insurance policy when she switched employers.[3] While we recognize that Lyrica remains an expensive option with its own set of risks, this example highlights how substituting a traditional opioid may not always be appropriate in circumstances where another option may exist – whether it be pharmacologic or non-pharmacologic. In each of these examples, despite the efforts by both patients and providers to seek out non-addictive pain management options, it was the default policies of the insurers that dictated the available therapy – pushing each individual toward the cheapest and easiest fix: a potentially addictive opioid. Whenever possible, non-addictive options and drugs with a lower risk of addiction and/or abuse should be utilized.

An insurance policy's benefit design may also hinder access to non-pharmacological, or nondrug, pain management alternatives, which can provide valuable support and relief for patients in lieu of narcotics. Mr. Douglas Scott is one such patient who experienced opioid dependence following back and spine injuries from two car accidents.[4] Luckily, Mr. Scott's insurance covered treatment at a local clinic specializing in alternative pain management techniques, and he was able to be successfully weaned off of opioids. Evidence has shown that patients participating in such comprehensive pain rehabilitation programs can experience significant and sustained improvement in pain severity and functioning.[5] Unlike Mr. Scott, however, not all patients have coverage for such programs, which can cost upwards of $20,000; and we encourage CareSource to explore such options and offer them to beneficiaries where clinically appropriate.

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[1] https://www.npr.org/sections/health-shots/2017/11/25/566032620/the-insurance-company-paid-for-opioids-but-not-cold-therapy
[2] https://www.nytimes.com/2017/09/17/health/opioid-painkillers-insurance-companies.html?_r=0
[3] https://www.nytimes.com/2017/09/17/health/opioid-painkillers-insurance-companies.html?_r=0
[4] https://www.nytimes.com/2016/06/23/business/new-ways-to-treat-pain-without-opioids-meet-resistance.html
[5] https://insights.ovid.com/pubmed?pmid=18804915

Lastly, we note reports that some insurance coverage plans appear to act as a barrier to accessing medication-assisted treatment (MAT) for individuals who are working to overcome addiction. Medical necessity requirements, high deductibles and copayments, prior authorization rules, and low reimbursement rates can delay and deter treatment, despite the wealth of evidence demonstrating the effectiveness of MAT. Furthermore, insurers that do cover MAT seldom cover all three Food and Drug Administration (FDA)-approved medications - methadone, buprenorphine and naltrexone – which are not interchangeable in their indications and uses. Similar hurdles exist for access to residential rehabilitation centers and detox facilities, for which insurers will often require "medical necessity" before covering care.

For example, Mr. Sean Mattos, a patient struggling with addiction, unsuccessfully went through two outpatient addiction programs before entering a residential facility, only to find that his insurer would not cover the full duration of treatment he required.[6] Despite agreement by his overseeing clinicians that he was not ready to leave the facility, Mr. Mattos was forced to call his insurer while in treatment to request coverage to remain under the facility's care, before ultimately paying $8000 of the $23,000 bill out of pocket. In response to such unfortunate situations and a desire to remedy them, we appreciate that multiple major insurers have recently lifted their prior authorization requirements for MAT – a step forward in reducing barriers to care. However, such efforts must be replicated and expanded across the industry in order for them to make a meaningful difference.

While we appreciate the work CareSource is already doing to help address this epidemic, and we are encouraged by recent industry led efforts to reevaluate some policies in light of the addiction epidemic, we remain concerned by the rules and authorization requirements that may be employed by insurance companies that could potentially limit beneficiary access to non-addictive and alternative pain management options as well as addiction treatment options. In order to effectively address this ongoing epidemic, we believe insurance companies must take additional steps to ensure they are playing a more active role in addiction prevention and treatment and providing beneficiaries full access to the range of clinically appropriate services available. Eliminating cost-sharing requirements for overdose reversal drugs is not enough. Insurer policies such as prior authorization, drug tiering, abrupt formulary changes, preferred pricing lists, restrictions or additional cost-sharing requirements for non-pharmaceutical interventions, lengthy and burdensome appeals process, and other clinician incentives can be insurance tools that, when used improperly, may harm efforts to combat addiction and should be reviewed to avoid furthering the current epidemic.

It is time for insurance industry leaders like CareSource to reexamine these policies in light of the substance/opioid use disorder and update your coverage policies in a way that maximizes the accessibility and affordability of a wide range of safe alternatives to narcotics. The insurance industry is on the front line of this epidemic, and we need your help identifying what policies are working and what barriers to less-addictive pain treatment options and substance use disorder treatments exist.

[6] http://www.modernhealthcare.com/special/opioid-addiction

Recognizing there is a difference in the way insurers are able to design their benefits across commercial, Medicare, and Medicaid books of business, we respectfully request that you respond to the following questions by March 30, 2018:

1. What internal policies and procedures does CareSource have in place that may create a barrier to accessing affordable non-addictive or less addictive pain treatments, including those that are non-pharmacological?

2. What flexibilities does CareSource offer to ensure that individuals struggling with acute or chronic pain receive the least addictive pain treatment option, in a timely manner?

3. What internal policies and procedures does CareSource have in place that may create a barrier to accessing affordable options for medication-assisted treatment and other behavioral therapy options for addicted individuals?

4. What flexibilities does CareSource offer to ensure that individuals struggling with substance use disorder receive the proper treatment, in a timely manner?

5. What non-pharmacological alternative pain therapies, such as acupuncture, does CareSource offer to beneficiaries? Do alternative pain therapy options vary by benefit design? If so, are there any barriers or restrictions preventing the use of alternative or innovative pain therapy options in federal programs, such as Medicare or Medicaid?

6. How often does CareSource review and update its list of approved pain management options and services, both pharmacological and non-pharmacological? As less addictive treatment options become available, how quickly are you able to cover them?

7. How often does CareSource review and update its list of approved addiction treatment options and services, both pharmacological and non-pharmacological? As additional substance use disorder treatments become available, how quickly are you able to cover them?

8. Does CareSource have a fail-first, stepped, or medical necessity standard for non-addictive, including non-pharmacological, or abuse-deterrent options for pain management?

9. Does CareSource have a fail-first or medical necessity standard for medication-assisted treatment or other behavioral therapy options for individuals who have a substance use disorder?

10. When reviewing coverage appeals from beneficiaries, members, or providers, at what level of appeal does CareSource implement a clinician review? How quickly are appeals escalated for individuals struggling with severe pain needs? How quickly are appeals escalated for individuals struggling with access to addiction services?

11. When it comes to opioids and other controlled substances, does CareSource implement a unique set of internal policies or controls?

12. What is the typical difference, if any, in cost-sharing for members/beneficiaries using non-addictive, including non-pharmacological pain management approaches vs. potentially addictive therapies?

13. What are the typical cost-sharing amounts for members/beneficiaries using medication-assisted treatment options or other behavioral therapy options offered by CareSource? Are any addiction treatment options offered to beneficiaries without cost-sharing requirements?

14. Does CareSource cover all three medication-assisted treatment drug options (methadone, buprenorphine and naltrexone) and if not, what is the rationale for exclusion?

15. How does CareSource identify individual members/beneficiaries who may already be struggling with substance use disorder? Are any policies or procedures waived for these individuals when it comes to accessing alternative options for pain management?

16. Is it your belief that all of CareSource's internal policies and procedures live up to both the letter and the spirit of the *Mental Health Parity Act*, as intended by Congress?

17. Recognizing there are always ways to improve these processes, are there other plan designs or benefit flexibilities you could implement to improve access to less addictive pain management options or the full range of treatment options?

18. Are there any additional factors that Congress should be aware of as it considers the nation's substance abuse/opioid crisis?

It is critical that we ensure access to clinically appropriate, non-addictive pain management options for all Americans across all payers as well as comprehensive coverage for the full range of addiction treatment services, from medication-assisted treatment options to inpatient and outpatient therapy.

Thank you for your attention to this matter. We look forward to working with you on policies that will make it as easy for an individual to access addiction treatment and non-addictive remedies for pain as it is for them to access opioids in the first place.

Sincerely,

Sherrod Brown
United States Senator

Edward J. Markey
United States Senator

Jeanne Shaheen
United States Senator

Tammy Baldwin
United States Senator

Margaret Wood Hassan
United States Senator

Sheldon Whitehouse
United States Senator

Chris Van Hollen
United States Senator

Richard Blumenthal
United States Senator

Cory A. Booker
United States Senator

Christopher Murphy
United States Senator

Tim Kaine
United States Senator

Patrick J. Leahy
United States Senator

Angus S. King, Jr.
United States Senator

Dianne Feinstein
United States Senator

Elizabeth Warren
United States Senator

Exhibit AAA

Civil Investigative Demand – Documentary Material

United States Department of Justice

Washington, D.C. 20530

TO: Leon Margolin, M.D.
5245 E. Main St.
Columbus, Ohio 43213

Civil Investigative
Demand No. 18-20

This Civil Investigative Demand is issued pursuant to the False Claims Act, 31 U.S.C. §§ 3729-3733, in the course of a False Claims Act investigation to determine whether there is or has been a violation of 31 U.S.C. § 3729. The False Claims Act investigation concerns whether Leon Margolin and Comprehensive Pain Management Institute violated the False Claims Act by knowingly submitting or causing to be submitted false claims to Medicare for nerve conduction studies and other procedures that were medically unnecessary.

This Demand requires Margolin (referred to throughout as "you") to provide documents to the Federal Government. This is the original of the Demand; no copies have been served on other parties. The information provided in response to this Demand may be shared, used, and disclosed as provided by 31 U.S.C. § 3733.

In accordance with the Definitions and Instructions set forth in Attachment A and the format specifications in Attachment C, you are required by this Demand to produce any and all of the following documents in your possession, custody or control requested in Attachment B. You must make this material available to Christopher Wilson, who has been designated as a False Claims Act custodian in this case. He may be reached at (614) 255-1630, if you have questions. These documents shall be produced no later than thirty (30) days from receipt of this Demand, at 5245 E. Main St., Columbus, Ohio 43213, or at another location to be mutually agreed upon by you and the False Claims Act custodians. The production of documentary material in response to this Demand must be made under a sworn certificate in the form printed in this Demand.

Issued at Washington, D.C., this 5th day of January, 2017.

Michael D. Granston /da
Michael D. Granston
Director
Commercial Litigation Branch

Exhibit BBB

Behavioral Health Care: Integrated

In this new era of health care CareSource is positioned to support you, our trusted partners, in delivering integrated health care to our members. CareSource believes that health care outcomes are improved if treatment is grounded in a strong relationship between patient and physician. And we know that good health means more than just taking care of physical needs.

Preventive and Comprehensive Care

At CareSource we are committed to a comprehensive, community-based health approach for our membership through strong collaboration and partnerships. Just as preventive screening for heart disease or diabetes is customary, diagnostic assessments for early detection of substance use disorder is critical to mitigate the more drastic effects on an individual's physical, behavioral, and psychosocial health. SBIRT, or Screening, Brief Intervention, and Referral to Treatment, treats behavioral health with the same importance as physical health.

Screening, Brief Intervention, and Referral to Treatment (SBIRT)

What is SBIRT?

Screening: Assessing a patient for risky substance use behaviors using standardized screening tools

Brief Intervention: Engaging a patient showing risky substance use behaviors in a short conversation, providing feedback and advice; and

Referral to Treatment: Providing a referral to brief therapy or additional treatment to patients who screen in need of additional services.

Recently Ohio has identified Medicaid payable codes* for you to bill and be reimbursed for SBIRT services.

HCPCS Code	Descriptor
G0396	Alcohol and/or substance (other than tobacco) abuse structured assessment (e.g. AUDIT, DAST), and brief intervention 15 to 30 minutes
G0397	Alcohol and/or substance (other than tobacco) abuse structured assessment (e.g. AUDIT, DAST), and intervention, greater than 30 minutes

*Advance Practice Nurses, Physicians, Physician Assistants and SBIRT provided in Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs) are eligible for reimbursement under Ohio Medicaid.

ADDITIONAL BEHAVIORAL HEALTH AND CARE MANAGEMENT SERVICES

Health Home – CareSource is a key member of the Health Home team in Ohio. Our goal is to strengthen the communication with you and enhance care coordination to ease service delivery and improve the lives of our membership.

Community Behavioral Health Care Coordinator (CBHCC) – This role was developed with you, our providers, in mind. The goal of the CBHCC is to reduce your workload and establish a single point of contact to collectively serve our shared member.

Care Transitions – CareSource prides itself in working to facilitate smooth transitions between various care systems and the home. This helps reduce the member's burden of navigating the complex health care system and enables them to focus on their well-being.

Behavioral Health 7-Day Post Discharge Follow-Up – Behavioral Health nurses reach out to members to coordinate post discharge care, medications, and access to Community Mental Health Centers (CMHC). Our aim is to decrease psychiatric readmissions and avoid unnecessary Emergency Room visits.

Behavioral Health Provider Inpatient – CareSource Behavioral Health representatives notify you of a shared member's hospital admission and assist with post discharge follow-up appointments. Our strong community partners and established ties with Community Mental Health Centers ensure the proper transitions and support network for our members.

CareSource24® Nurse Advice Line – This 24-hour nurse triage line provides an avenue for members to speak with a registered nurse at any time about health concerns and be directed to an appropriate level of care or supported with health education.

Medication Therapy Management (MTM) – Designed to help ensure members are taking the most effective medications, CareSource aims to increase understanding of safe medication use and engage members with their local pharmacist.

Care4U Case Management – This program manages care by focusing on the multifaceted, chronic and relapsing nature of substance use disorders. A community-based approach is used and addresses physical, behavioral, psychosocial and safety concerns.

Coordinated Services Program (CSP) – In the CSP, select Ohio Medicaid consumers are limited to the use of one pharmacy and receiving medical services through their primary care physician.

CareSource Transportation Assistance – CareSource provides help to members who have transportation needs to various medical appointments. This is one less barrier for your patient to overcome.

For more information:
1-855-708-4840
OhioBHInfo@CareSource.com

CareSource™
Health Care with Heart

CareSource.com

ACCREDITED
HEALTH PLAN (for Medicaid)
HEALTH CALL CENTER

January 2014

OH-P-814

Exhibit CCC

SETTLEMENT AGREEMENT

This Settlement Agreement ("Agreement") is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General (OIG-HHS) of the Department of Health and Human Services (HHS) (collectively, the "United States"), and Leon Margolin, M.D. and Comprehensive Pain Management Institute, LLC (CPMI) (together, Defendants) (hereafter collectively referred to as "the Parties"), through their authorized representatives.

RECITALS

A. Leon Margolin is an interventional pain physician in Columbus, Ohio. He owns and operates CPMI. Margolin performs a variety of pain management and diagnostic procedures, including nerve conduction studies (NCS) and alcohol/substance abuse structured assessments and brief interventions of 30 minutes of longer, under code G0397 (referred to below as, "SBIRT").

B. The United States contends that Margolin submitted or caused to be submitted claims for payment to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395lll ("Medicare").

C. The United States contends that it has certain civil claims against Defendants arising from their knowingly submitting, or causing to be submitted, false claims to Medicare during the period from January 1, 2013 through September 19, 2019 for: (1) NCS that were medically unnecessary because the patients did not need them and/or the studies were performed without electromyography, and (2) SBIRTs that were medically unnecessary and/or not provided as billed. That conduct is referred to below as the "Covered Conduct."

D. This Settlement Agreement is neither an admission of liability by Defendants nor a concession by the United States that its claims are not well founded.

To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, and in consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. Defendants shall pay to the United States $650,000 ("Settlement Amount") plus interest at a rate of 1.75 percent *per annum* from January 1, 2020, of which $325,849.00 is restitution. Defendants shall pay $450,000 of the total Settlement Amount no later than ten days after the Effective Date of this Agreement and shall pay the remaining $200,000 plus interest within four months of the Effective Date of this Agreement. Defendants shall make these payments by check pursuant to written instructions to be provided by the Civil Division of the United States Department of Justice.

2. Subject to the exceptions in Paragraph 3 (concerning excluded claims) below, and conditioned upon Defendants' full payment of the Settlement Amount, the United States releases Defendants, together with CPMI's current and former parent corporations; direct and indirect subsidiaries; brother or sister corporations; divisions; current or former corporate owners; and the corporate successors and assigns of any of them, from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; or the common law theories of payment by mistake, unjust enrichment, and fraud.

3. Notwithstanding the release given in Paragraph 2 of this Agreement, or any other term of this Agreement, the following claims of the United States are specifically reserved and are not released:

a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);

b. Any criminal liability;

c. Except as explicitly stated in this Agreement, any administrative liability, including mandatory or permissive exclusion from Federal health care programs;

d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;

e. Any liability based upon obligations created by this Agreement;

f. Except as explicitly stated in this Agreement, any liability of individuals; and

g. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.

4. Defendants waive and shall not assert any defenses Defendants may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action.

5. Defendants fully and finally release the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that Defendants have asserted, could have asserted, or may assert in the future against the United States, and its agencies, officers, agents, employees, and servants related to the Covered Conduct and the United States' investigation and prosecution thereof.

6. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare contractor (e.g., Medicare Administrative Contractor, fiscal intermediary, carrier) or any state payer, related to the Covered Conduct; and Defendants agree not to resubmit to any Medicare contractor or any state payer any previously denied claims related to the Covered Conduct, agree not to appeal any such denials of claims, and agree to withdraw any such pending appeals.

7. Defendants agree to the following:

a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395lll and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Defendants, including CPMI's present or former officers, directors, employees, shareholders, and agents in connection with:

(1) the matters covered by this Agreement;

(2) the United States' audit(s) and civil investigation(s) of the matters covered by this Agreement;

(3) Defendants' investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil investigation(s) in connection with the matters covered by this Agreement (including attorney's fees);

(4) the negotiation and performance of this Agreement; and

(5) the payments Defendants make to the United States pursuant to this Agreement

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program (FEHBP) (hereinafter referred to as Unallowable Costs).

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by Defendants, and Defendants shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by Defendants or any of CPMI's subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Defendants further agree that within 90 days of the Effective Date of this Agreement they shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and FEHBP fiscal agents, any Unallowable Costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Defendants or any of CPMI's subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the unallowable costs. Defendants agree that the United States, at a minimum, shall be entitled to recoup from Defendants any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The

United States reserves its rights to disagree with any calculations submitted by Defendants or any of CPMI's subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on Defendants' or any of CPMI's subsidiaries or affiliates' cost reports, cost statements, or information reports.

d. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine Defendants' books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

8. Defendants agree to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, Defendants shall encourage, and agree not to impair, the cooperation of CPMI's directors, officers, and employees, and shall use its best efforts to make available, and encourage, the cooperation of former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. Defendants further agree to furnish to the United States, upon request, complete and unredacted copies of all non-privileged documents, reports, memoranda of interviews, and records in its possession, custody, or control concerning any investigation of the Covered Conduct that they have undertaken, or that has been performed by another on their behalf.

9. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraph 10 (waiver for beneficiaries paragraph), below.

10. Defendants agree that it waives and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.

11. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

12. Each Party and signatory to this Agreement represents that it freely and voluntarily enters in to this Agreement without any degree of duress or compulsion.

13. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the Southern District of Ohio. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

14. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

15. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

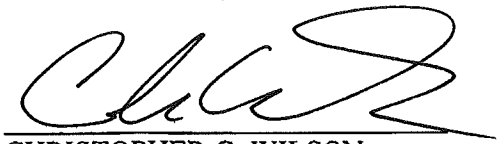
16. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

17. This Agreement is binding on Defendants' successors, transferees, heirs, and assigns.

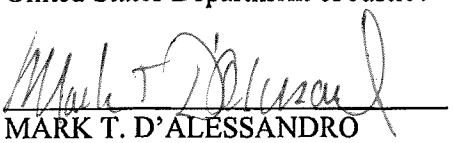
18. All Parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

19. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Facsimiles and electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

THE UNITED STATES OF AMERICA

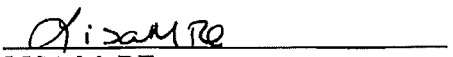
DATED: 1/22/2020 BY: 

CHRISTOPHER G. WILSON
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: 1/22/2020 BY: 

MARK T. D'ALESSANDRO
Civil Chief

ANDREW M. MALEK
Assistant United States Attorney
United States Attorney's Office
for the Southern District of Ohio

DATED: 01/21/20 BY: 

LISA M. RE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

MARGOLIN AND CMPI - DEFENDANTS

DATED: 01/15/2020 BY: _____
LEON MARGOLIN, M.D.

Individually and on behalf of Comprehensive Pain Management Institute, LLC

DATED: 1.15.20 BY: _____
NICK OBERHEIDEN

Counsel for Margolin and Comprehensive Pain Management Institute, LLC

AMENDMENT TO THE SETTLEMENT AGREEMENT BETWEEN THE UNITED STATES OF AMERICA, LEON MARGOLIN, AND COMPREHENSIVE PAIN MANAGEMENT INSTITUTE, LLC

Pursuant to Paragraph 14 of the Settlement Agreement between the United States of America (the "United States"), and Leon Margolin, M.D., and Comprehensive Pain Management Institute, LLC (together, Defendants), executed on January 22, 2020, the parties hereby in writing amend the Settlement Agreement as follows:

A. Paragraph 1 of the Settlement Agreement shall be amended to read as follows (emphasis added only to show change):

1. Defendants shall pay to the United States $650,000 ("Settlement Amount") plus interest at a rate of 1.75 percent per annum from January 1, 2020, of which $325,839.00 is restitution. Defendants shall pay $450,000 of the total Settlement Amount no later than ten days after the Effective Date of this Agreement and shall pay the remaining $200,000 plus interest on or before October 1, 2020. Defendants shall make these payments by check pursuant to written instructions to be provided by the Civil Division of the United States Department of Justice.

B. The sole purpose of this amendment is to extend the time for making the second, final payment of $200,000, plus interest. This amendment does not modify any other term of the Settlement Agreement.

IN WITNESS WHEREOF, the parties have executed this Amendment to the Settlement Agreement, intending to be bound.

THE UNITED STATES OF AMERICA

DATED: _____ BY: _____

CHRISTOPHER G. WILSON
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: _____ BY: _____

MARK T. D'ALESSANDRO
Civil Chief

ANDREW M. MALEK
Assistant United States Attorney
United States Attorney's Office
for the Southern District of Ohio

DATED: 05/14/2025 BY: Lisa M. Re

LISA M. RE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

THE UNITED STATES OF AMERICA

DATED: 5/18/2020 BY: 

CHRISTOPHER G. WILSON
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: _____ BY: _____

MARK T. D'ALESSANDRO
Civil Chief

ANDREW M. MALEK
Assistant United States Attorney
United States Attorney's Office
for the Southern District of Ohio

DATED: _____ BY: _____

LISA M. RE
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DATED: _____ BY: _____

CHRISTOPHER G. WILSON
Trial Attorney
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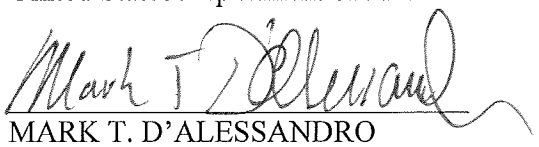
DATED: 5/13/2020 BY: 

MARK T. D'ALESSANDRO
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Assistant United States Attorney
United States Attorney's Office
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Office of Inspector General
United States Department of Health and Human Services

MARGOLIN AND CMPI - DEFENDANTS

DATED: 05/13/20 BY: _____
LEON MARGOLIN, M.D.

Individually and on behalf of Comprehensive Pain Management Institute, LLC

DATED: 5/13/20 BY: _____
KATE HICKNER
SEAN MALONE

Counsel for Margolin and Comprehensive Pain Management Institute, LLC

Exhibit DDD

Federal Rules of Evidence Rule 702, 28 U.S.C.A.

Rule 702. Testimony by Expert Witnesses [Rule Text & Notes of Decisions subdivisions I, II]

Currentness

<Notes of Decisions for 28 USCA Federal Rules of Evidence Rule 702 are displayed in multiple documents.>

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

(a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;

(b) the testimony is based on sufficient facts or data;

(c) the testimony is the product of reliable principles and methods; and

(d) the expert has reliably applied the principles and methods to the facts of the case.

CREDIT(S)
(Pub.L. 93-595, § 1, Jan. 2, 1975, 88 Stat. 1937; Apr. 17, 2000, eff. Dec. 1, 2000; Apr. 26, 2011, eff. Dec. 1, 2011.)

ADVISORY COMMITTEE NOTES
1972 Proposed Rules

An intelligent evaluation of facts is often difficult or impossible without the application of some scientific, technical, or other specialized knowledge. The most common source of this knowledge is the expert witness, although there are other techniques for supplying it.

Most of the literature assumes that experts testify only in the form of opinions. The assumption is logically unfounded. The rule accordingly recognizes that an expert on the stand may give a dissertation or exposition of scientific or other principles relevant to the case, leaving the trier of fact to apply them to the facts. Since much of the criticism of expert testimony has centered upon the hypothetical question, it seems wise to recognize that opinions are not indispensable and to encourage the use of expert testimony in non-opinion form when counsel believes the trier can itself draw the requisite inference. The use of opinions is not abolished by the rule, however. It will continue to be permissible for the experts to take the further step of suggesting the inference which should be drawn from applying the specialized knowledge to the facts. See Rules 703 to 705.

Whether the situation is a proper one for the use of expert testimony is to be determined on the basis of assisting the trier. "There is no more certain test for determining when experts may be used than the common sense inquiry whether the untrained layman would be qualified to determine intelligently and to the best possible degree the particular issue without enlightenment from those having a specialized understanding of the subject involved in the dispute." Ladd, Expert Testimony, 5 Vand.L.Rev. 414, 418 (1952). When opinions are excluded, it is because they are unhelpful and therefore superfluous and a waste of time. 7 Wigmore § 1918.

The rule is broadly phrased. The fields of knowledge which may be drawn upon are not limited merely to the "scientific" and "technical" but extend to all "specialized" knowledge. Similarly, the expert is viewed, not in a narrow sense, but as a person qualified by "knowledge, skill, experience, training or education." Thus, within the scope of the rule are not only experts in the strictest sense of the word, e.g., physicians, physicists, and architects, but also the large group sometimes called "skilled" witnesses, such as bankers or landowners testifying to land values.

2000 Amendments

Rule 702 has been amended in response to *Daubert v. Merrell Dow Pharmaceuticals, Inc*., 509 U.S. 579 (1993), and to the many cases applying *Daubert*, including *Kumho Tire Co. v. Carmichael*, 119 S.Ct. 1167 (1999). In *Daubert* the Court charged trial judges with the responsibility of acting as gatekeepers to exclude unreliable expert testimony, and the Court in *Kumho* clarified that this gatekeeper function applies to all expert testimony, not just testimony based in science. *See also Kumho*, 119 S.Ct. at 1178 (citing the Committee Note to the proposed amendment to Rule 702, which had been released for public comment before the date of the *Kumho* decision). The amendment affirms the trial court's role as gatekeeper and provides some general standards that the trial court must use to assess the reliability and helpfulness of proffered expert testimony. Consistently with *Kumho*, the Rule as amended provides that all types of expert testimony present questions of admissibility for the trial court in deciding whether the evidence is reliable and helpful. Consequently, the admissibility of all expert testimony is governed by the principles of Rule 104(a). Under that Rule, the proponent has the burden of establishing that the pertinent admissibility requirements are met by a preponderance of the evidence. *See Bourjaily v. United States*, 483 U.S. 171 (1987).

Daubert set forth a non-exclusive checklist for trial courts to use in assessing the reliability of scientific expert testimony. The specific factors explicated by the *Daubert* Court are (1) whether the expert's technique or theory can be or has been tested---that is, whether the expert's theory can be challenged in some objective sense, or whether it is instead simply a subjective, conclusory approach that cannot reasonably be assessed for reliability; (2) whether the technique or theory has been subject to peer review and publication; (3) the known or potential rate of error of the technique or theory when applied; (4) the existence and maintenance of standards and controls; and (5) whether the technique or theory has been generally accepted in the scientific community. The Court in *Kumho* held that these factors might also be applicable in assessing the reliability of non-scientific expert testimony, depending upon "the particular circumstances of the particular case at issue." 119 S.Ct. at 1175.

No attempt has been made to "codify" these specific factors. *Daubert* itself emphasized that the factors were neither exclusive nor dispositive. Other cases have recognized that not all of the specific *Daubert* factors can apply to every type of expert testimony. In addition to *Kumho*, 119 S.Ct. at 1175, *see Tyus v. Urban Search Management*, 102 F.3d 256 (7th Cir. 1996) (noting that the factors mentioned by the Court in *Daubert* do not neatly apply to expert testimony from a sociologist). *See also Kannankeril v. Terminix Int'l, Inc*., 128 F.3d 802, 809 (3d Cir. 1997) (holding that lack of peer review or publication was not dispositive where the expert's opinion was supported by "widely accepted scientific knowledge"). The standards set forth in the amendment are broad enough to require consideration of any or all of the specific *Daubert* factors where appropriate.

Courts both before and after *Daubert* have found other factors relevant in determining whether expert testimony is sufficiently reliable to be considered by the trier of fact. These factors include:

(1) Whether experts are "proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying." *Daubert v. Merrell Dow Pharmaceuticals, Inc*., 43 F.3d 1311, 1317 (9th Cir. 1995).

(2) Whether the expert has unjustifiably extrapolated from an accepted premise to an unfounded conclusion. *See General Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) (noting that in some cases a trial court "may conclude that there is simply too great an analytical gap between the data and the opinion proffered").

(3) Whether the expert has adequately accounted for obvious alternative explanations. *See Claar v. Burlington N.R.R.*, 29 F.3d 499 (9th Cir. 1994) (testimony excluded where the expert failed to consider other obvious causes for the plaintiff's condition). *Compare Ambrosini v. Labarraque*, 101 F.3d 129 (D.C. Cir. 1996) (the possibility of some uneliminated causes presents a question of weight, so long as the most obvious causes have been considered and reasonably ruled out by the expert).

(4) Whether the expert "is being as careful as he would be in his regular professional work outside his paid litigation consulting." *Sheehan v. Daily Racing Form, Inc.*, 104 F.3d 940, 942 (7th Cir. 1997). *See Kumho Tire Co. v. Carmichael*, 119 S.Ct. 1167, 1176 (1999) (*Daubert* requires the trial court to assure itself that the expert "employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field").

(5) Whether the field of expertise claimed by the expert is known to reach reliable results for the type of opinion the expert would give. *See Kumho Tire Co. v. Carmichael*, 119 S.Ct.1167, 1175 (1999) (*Daubert's* general acceptance factor does not "help show that an expert's testimony is reliable where the discipline itself lacks reliability, as for example, do theories grounded in any so-called generally accepted principles of astrology or necromancy."), *Moore v. Ashland Chemical, Inc.*, 151 F.3d 269 (5th Cir. 1998) (en banc) (clinical doctor was properly precluded from testifying to the toxicological cause of the plaintiff's respiratory problem, where the opinion was not sufficiently grounded in scientific methodology); *Sterling v. Velsicol Chem. Corp.*, 855 F.2d 1188 (6th Cir. 1988) (rejecting testimony based on "clinical ecology" as unfounded and unreliable).

All of these factors remain relevant to the determination of the reliability of expert testimony under the Rule as amended. Other factors may also be relevant. *See Kumho*, 119 S.Ct. 1167, 1176 ("[W]e conclude that the trial judge must have considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable."). Yet no single factor is necessarily dispositive of the reliability of a particular expert's testimony. *See, e.g., Heller v. Shaw Industries, Inc.*, 167 F.3d 146, 155 (3d Cir. 1999) ("not only must each stage of the expert's testimony be reliable, but each stage must be evaluated practically and flexibly without bright-line exclusionary (or inclusionary) rules."); *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1317, n.5 (9th Cir. 1995) (noting that some expert disciplines "have the courtroom as a principal theatre of operations" and as to these disciplines "the fact that the expert has developed an expertise principally for purposes of litigation will obviously not be a substantial consideration.").

A review of the caselaw after *Daubert* shows that the rejection of expert testimony is the exception rather than the rule. *Daubert* did not work a "seachange over federal evidence law," and "the trial court's role as gatekeeper is not intended to serve as a replacement for the adversary system." *United States v. 14.38 Acres of Land Situated in Leflore County, Mississippi*, 80 F.3d 1074, 1078 (5th Cir. 1996). As the Court in *Daubert* stated: "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." 509 U.S. at 595. Likewise, this amendment is not intended to provide an excuse for an automatic challenge to the testimony of every expert. *See Kumho Tire Co. v. Carmichael*, 119 S.Ct.1167, 1176 (1999) (noting that the trial judge has the discretion "both to avoid unnecessary 'reliability' proceedings in ordinary cases where the reliability of an expert's methods is properly taken for granted, and to require appropriate proceedings in the less usual or more complex cases where cause for questioning the expert's reliability arises.").

When a trial court, applying this amendment, rules that an expert's testimony is reliable, this does not necessarily mean that contradictory expert testimony is unreliable. The amendment is broad enough to permit testimony that is the product of competing principles or methods in the same field of expertise. *See, e.g., Heller v. Shaw Industries, Inc.*, 167 F.3d 146, 160 (3d Cir. 1999) (expert testimony cannot be excluded simply because the expert uses one test rather than another, when both

tests are accepted in the field and both reach reliable results). As the court stated in *In re Paoli R.R. Yard PCB Litigation*, 35 F.3d 717, 744 (3d Cir. 1994), proponents "do not have to demonstrate to the judge by a preponderance of the evidence that the assessments of their experts are correct, they only have to demonstrate by a preponderance of evidence that their opinions are reliable.... The evidentiary requirement of reliability is lower than the merits standard of correctness." *See also Daubert v. Merrell Dow Pharmaceuticals, Inc*., 43 F.3d 1311, 1318 (9th Cir. 1995) (scientific experts might be permitted to testify if they could show that the methods they used were also employed by "a recognized minority of scientists in their field."); *Ruiz-Troche v. Pepsi Cola*, 161 F.3d 77, 85 (1st Cir. 1998) ("*Daubert* neither requires nor empowers trial courts to determine which of several competing scientific theories has the best provenance.").

The Court in *Daubert* declared that the "focus, of course, must be solely on principles and methodology, not on the conclusions they generate." 509 U.S. at 595. Yet as the Court later recognized, "conclusions and methodology are not entirely distinct from one another." *General Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). Under the amendment, as under *Daubert*, when an expert purports to apply principles and methods in accordance with professional standards, and yet reaches a conclusion that other experts in the field would not reach, the trial court may fairly suspect that the principles and methods have not been faithfully applied. *See Lust v. Merrell Dow Pharmaceuticals, Inc*., 89 F.3d 594, 598 (9th Cir. 1996). The amendment specifically provides that the trial court must scrutinize not only the principles and methods used by the expert, but also whether those principles and methods have been properly applied to the facts of the case. As the court noted in *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 745 (3d Cir. 1994), "*any* step that renders the analysis unreliable ... renders the expert's testimony inadmissible. *This is true whether the step completely changes a reliable methodology or merely misapplies that methodology*."

If the expert purports to apply principles and methods to the facts of the case, it is important that this application be conducted reliably. Yet it might also be important in some cases for an expert to educate the factfinder about general principles, without ever attempting to apply these principles to the specific facts of the case. For example, experts might instruct the factfinder on the principles of thermodynamics, or blood clotting, or on how financial markets respond to corporate reports, without ever knowing about or trying to tie their testimony into the facts of the case. The amendment does not alter the venerable practice of using expert testimony to educate the factfinder on general principles. For this kind of generalized testimony, Rule 702 simply requires that: (1) the expert be qualified; (2) the testimony address a subject matter on which the factfinder can be assisted by an expert; (3) the testimony be reliable; and (4) the testimony "fit" the facts of the case.

As stated earlier, the amendment does not distinguish between scientific and other forms of expert testimony. The trial court's gatekeeping function applies to testimony by any expert. *See Kumho Tire Co. v. Carmichael*, 119 S.Ct. 1167, 1171 (1999) ("We conclude that *Daubert's* general holding--setting forth the trial judge's general 'gatekeeping' obligation--applies not only to testimony based on 'scientific' knowledge, but also to testimony based on 'technical' and 'other specialized' knowledge."). While the relevant factors for determining reliability will vary from expertise to expertise, the amendment rejects the premise that an expert's testimony should be treated more permissively simply because it is outside the realm of science. An opinion from an expert who is not a scientist should receive the same degree of scrutiny for reliability as an opinion from an expert who purports to be a scientist. *See Watkins v. Telsmith, Inc*., 121 F.3d 984, 991 (5th Cir. 1997) ("[I]t seems exactly backwards that experts who purport to rely on general engineering principles and practical experience might escape screening by the district court simply by stating that their conclusions were not reached by any particular method or technique."). Some types of expert testimony will be more objectively verifiable, and subject to the expectations of falsifiability, peer review, and publication, than others. Some types of expert testimony will not rely on anything like a scientific method, and so will have to be evaluated by reference to other standard principles attendant to the particular area of expertise. The trial judge in all cases of proffered expert testimony must find that it is properly grounded, well-reasoned, and not speculative before it can be admitted. The expert's testimony must be grounded in an accepted body of learning or experience in the expert's field, and the expert must explain how the conclusion is so grounded. *See, e.g*., American College of Trial Lawyers, Standards and Procedures for Determining the Admissibility of Expert Testimony after *Daubert*, 157 F.R.D. 571, 579 (1994) ("[W]hether the testimony concerns economic principles, accounting standards, property valuation or other non-scientific subjects, it should be evaluated by reference to the 'knowledge and experience' of that particular field.").

The amendment requires that the testimony must be the product of reliable principles and methods that are reliably applied to the facts of the case. While the terms "principles" and "methods" may convey a certain impression when applied to scientific knowledge, they remain relevant when applied to testimony based on technical or other specialized knowledge. For example, when a law enforcement agent testifies regarding the use of code words in a drug transaction, the principle used by the agent is that participants in such transactions regularly use code words to conceal the nature of their activities. The method used by the agent is the application of extensive experience to analyze the meaning of the conversations. So long as the principles and methods are reliable and applied reliably to the facts of the case, this type of testimony should be admitted.

Nothing in this amendment is intended to suggest that experience alone--or experience in conjunction with other knowledge, skill, training or education--may not provide a sufficient foundation for expert testimony. To the contrary, the text of Rule 702 expressly contemplates that an expert may be qualified on the basis of experience. In certain fields, experience is the predominant, if not sole, basis for a great deal of reliable expert testimony. *See, e.g., United States v. Jones*, 107 F.3d 1147 (6th Cir. 1997) (no abuse of discretion in admitting the testimony of a handwriting examiner who had years of practical experience and extensive training, and who explained his methodology in detail); *Tassin v. Sears Roebuck*, 946 F.Supp. 1241, 1248 (M.D.La. 1996) (design engineer's testimony can be admissible when the expert's opinions "are based on facts, a reasonable investigation, and traditional technical/mechanical expertise, and he provides a reasonable link between the information and procedures he uses and the conclusions he reaches"). *See also Kumho Tire Co. v. Carmichael*, 119 S.Ct. 1167, 1178 (1999) (stating that "no one denies that an expert might draw a conclusion from a set of observations based on extensive and specialized experience.").

If the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts. The trial court's gatekeeping function requires more than simply "taking the expert's word for it." *See Daubert v. Merrell Dow Pharmaceuticals, Inc*., 43 F.3d 1311, 1319 (9th Cir. 1995) ("We've been presented with only the experts' qualifications, their conclusions and their assurances of reliability. Under *Daubert*, that's not enough."). The more subjective and controversial the expert's inquiry, the more likely the testimony should be excluded as unreliable. *See O'Conner v. Commonwealth Edison Co*., 13 F.3d 1090 (7th Cir. 1994) (expert testimony based on a completely subjective methodology held properly excluded). *See also Kumho Tire Co. v. Carmichael*, 119 S.Ct. 1167, 1176 (1999) ("[I]t will at times be useful to ask even of a witness whose expertise is based purely on experience, say, a perfume tester able to distinguish among 140 odors at a sniff, whether his preparation is of a kind that others in the field would recognize as acceptable.").

Subpart (1) of Rule 702 calls for a quantitative rather than qualitative analysis. The amendment requires that expert testimony be based on sufficient underlying "facts or data." The term "data" is intended to encompass the reliable opinions of other experts. See the original Advisory Committee Note to Rule 703. The language "facts or data" is broad enough to allow an expert to rely on hypothetical facts that are supported by the evidence. *Id*.

When facts are in dispute, experts sometimes reach different conclusions based on competing versions of the facts. The emphasis in the amendment on " sufficient facts or data" is not intended to authorize a trial court to exclude an expert's testimony on the ground that the court believes one version of the facts and not the other.

There has been some confusion over the relationship between Rules 702 and 703. The amendment makes clear that the sufficiency of the basis of an expert' s testimony is to be decided under Rule 702. Rule 702 sets forth the overarching requirement of reliability, and an analysis of the sufficiency of the expert's basis cannot be divorced from the ultimate reliability of the expert's opinion. In contrast, the "reasonable reliance" requirement of Rule 703 is a relatively narrow inquiry. When an expert relies on inadmissible information, Rule 703 requires the trial court to determine whether that information is of a type reasonably relied on by other experts in the field. If so, the expert can rely on the information in reaching an opinion. However, the question whether the expert is relying on a *sufficient* basis of information--whether admissible information or not--is governed by the requirements of Rule 702.

The amendment makes no attempt to set forth procedural requirements for exercising the trial court's gatekeeping function over expert testimony. *See* Daniel J. Capra, *The Daubert Puzzle*, 38 Ga.L.Rev. 699, 766 (1998) [*sic*, should be "32 Ga.L.Rev. 699, 766 (1998)"] ("Trial courts should be allowed substantial discretion in dealing with *Daubert* questions; any attempt to codify procedures will likely give rise to unnecessary changes in practice and create difficult questions for appellate review."). Courts have shown considerable ingenuity and flexibility in considering challenges to expert testimony under *Daubert*, and it is contemplated that this will continue under the amended Rule. *See, e.g., Cortes-Irizarry v. Corporacion Insular*, 111 F.3d 184 (1st Cir. 1997) (discussing the application of *Daubert* in ruling on a motion for summary judgment); *In re Paoli R.R. Yard PCB Litig*., 35 F.3d 717, 736, 739 (3d Cir. 1994) (discussing the use of *in limine* hearings); *Claar v. Burlington N.R.R*., 29 F.3d 499, 502-05 (9th Cir. 1994) (discussing the trial court's technique of ordering experts to submit serial affidavits explaining the reasoning and methods underlying their conclusions).

The amendment continues the practice of the original Rule in referring to a qualified witness as an "expert." This was done to provide continuity and to minimize change. The use of the term "expert" in the Rule does not, however, mean that a jury should actually be informed that a qualified witness is testifying as an "expert." Indeed, there is much to be said for a practice that prohibits the use of the term "expert" by both the parties and the court at trial. Such a practice "ensures that trial courts do not inadvertently put their stamp of authority" on a witness's opinion, and protects against the jury's being "overwhelmed by the so-called 'experts'." Hon. Charles Richey, *Proposals to Eliminate the Prejudicial Effect of the Use of the Word "Expert" Under the Federal Rules of Evidence in Criminal and Civil Jury Trials*, 154 F.R.D. 537, 559 (1994) (setting forth limiting instructions and a standing order employed to prohibit the use of the term " expert" injury trials).

GAP Report--Proposed Amendment to Rule 702

The Committee made the following changes to the published draft of the proposed amendment to Evidence Rule 702:

1. The word "reliable" was deleted from Subpart (1) of the proposed amendment, in order to avoid an overlap with Evidence Rule 703, and to clarify that an expert opinion need not be excluded simply because it is based on hypothetical facts. The Committee Note was amended to accord with this textual change.

2. The Committee Note was amended throughout to include pertinent references to the Supreme Court's decision in *Kumho Tire Co. v. Carmichael*, which was rendered after the proposed amendment was released for public comment. Other citations were updated as well.

3. The Committee Note was revised to emphasize that the amendment is not intended to limit the right to jury trial, nor to permit a challenge to the testimony of every expert, nor to preclude the testimony of experience-based experts, nor to prohibit testimony based on competing methodologies within a field of expertise.

4. Language was added to the Committee Note to clarify that no single factor is necessarily dispositive of the reliability inquiry mandated by Evidence Rule 702.

2011 Amendments

The language of Rule 702 has been amended as part of the restyling of the Evidence Rules to make them more easily understood and to make style and terminology consistent throughout the rules. These changes are intended to be stylistic only. There is no intent to change any result in any ruling on evidence admissibility.

Notes of Decisions (1437)

Fed. Rules Evid. Rule 702, 28 U.S.C.A., FRE Rule 702

Including Amendments Received Through 5-1-22

End of Document

Exhibit EEE

Baldwin's Ohio Revised Code Annotated
Ohio Rules of Evidence (Refs & Annos)
Article VI Witnesses

Evid. R. Rule 601

Evid R 601 General rule of competency

Effective: July 1, 2021
Currentness

(A) General Rule. Every person is competent to be a witness except as otherwise provided in these rules.

(B) Disqualification of Witness in General. A person is disqualified to testify as a witness when the court determines that the person is:

(1) Incapable of expressing himself or herself concerning the matter as to be understood, either directly or through interpretation by one who can understand him or her; or

(2) Incapable of understanding the duty of a witness to tell the truth.

(3) A spouse testifying against the other spouse charged with a crime except when either of the following applies:

(a) a crime against the testifying spouse or a child of either spouse is charged;

(b) the testifying spouse elects to testify.

(4) An officer, while on duty for the exclusive or main purpose of enforcing traffic laws, arresting or assisting in the arrest of a person charged with a traffic violation punishable as a misdemeanor where the officer at the time of the arrest was not using a properly marked motor vehicle as defined by statute or was not wearing a legally distinctive uniform as defined by statute.

(5) A person giving expert testimony on the issue of liability in any medical claim, as defined in R.C. 2305.113, asserted in any civil action against a physician, podiatrist, or hospital arising out of the diagnosis, care, or treatment of any person by a physician or podiatrist, unless:

(a) The person testifying is licensed to practice medicine and surgery, osteopathic medicine and surgery, or podiatric medicine and surgery by the state medical board or by the licensing authority of any state;

(b) The person devotes at least one-half of his or her professional time to the active clinical practice in his or her field of licensure, or to its instruction in an accredited school and

(c) The person practices in the same or a substantially similar specialty as the defendant. The court shall not permit an expert in one medical specialty to testify against a health care provider in another medical specialty unless the expert shows both that the standards of care and practice in the two specialties are similar and that the expert has substantial familiarity between the specialties.

If the person is certified in a specialty, the person must be certified by a board recognized by the American board of medical specialties or the American board of osteopathic specialties in a specialty having acknowledged expertise and training directly related to the particular health care matter at issue.

Nothing in this division shall be construed to limit the power of the trial court to adjudge the testimony of any expert witness incompetent on any other ground, or to limit the power of the trial court to allow the testimony of any other witness, on a matter unrelated to the liability issues in the medical claim, when that testimony is relevant to the medical claim involved.

This division shall not prohibit other medical professionals who otherwise are competent to testify under these rules from giving expert testimony on the appropriate standard of care in their own profession in any claim asserted in any civil action against a physician, podiatrist, medical professional, or hospital arising out of the diagnosis, care, or treatment of any person.

(6) As otherwise provided in these rules.

CREDIT(S)
(Adopted eff. 7-1-80; amended eff. 7-1-91, 7-1-16, 7-1-20, 7-1-21)

STAFF NOTES
2016:

Nonsubstantive revisions are made to Evid.R. 601(D) to make clear that the rule applies only to expert testimony as to liability in any medical claim, as defined by R.C. 2305.113, asserted against a physician, podiatrist, or hospital arising out of the diagnosis, care, or treatment of any person by a physician or podiatrist. The rule does not apply to expert testimony for any other medical claims, or for any dental, optometric, or chiropractic claims, as defined by R.C. 2305.113.

The structure and provisions of Evid.R. 601(D) are also revised to more-closely resemble the structure of R.C. 2743.43 and to incorporate the provisions of that statute that are not inconsistent with the provisions of the current rule. Pursuant to authority of Article IV, Section 5(B) of the Ohio Constitution, the provisions of R.C. 2743.43 are superseded in their entirety by the amended rule.

1991:

Rule 601(A) Children and Mental Incompetents

Evid. R. 601(A) was amended by deleting “and;” from the end of the rule. This is a technical change only.

Rule 601(B) Spouse Testifying

As adopted in 1980, Evid. R. 601(B) provided that a witness was incompetent to testify against his or her spouse in a criminal case unless the charged offense involved a crime against the testifying spouse or the children of either spouse. The rule was based

on the policy of protecting the marital relationship from "dissension" and the "natural repugnance" for convicting a defendant upon the testimony of his or her "intimate life partner." 8 J. Wigmore, Evidence 216-17 (McNaughton rev. 1961).

The important issue is who can waive the rule--the defendant or the witness. Under the old rule, the defendant could prevent his or her spouse from testifying. In some situations the policy underlying the rule simply does not apply, but the rule does. For example, if a husband kills his mother-in-law and his wife is a witness, she could be prevented from testifying. This would be true even if they were separated and she desired to testify. Cf. *Locke v. State* (1929), 33 Ohio App. 445, 169 N.E. 833. The amendment changes this result, by permitting the wife to elect to testify.

This approach is supported by a number of commentators. As McCormick has pointed out: "The privilege has sometimes been defended on the ground that it protects family harmony. But family harmony is nearly always past saving when the spouse is willing to aid the prosecution. The privilege is an archaic survival of a mystical religious dogma and of a way of thinking about the marital relation that is today outmoded." C. McCormick, Evidence 162 (3d ed. 1984). *See also* 8 J. Wigmore, Evidence 221 (McNaughton rev. 1961) ("This marital privilege is the merest anachronism in legal theory and an indefensible obstruction to truth in practice."); Huhn, "Sacred Seal of Secrecy": The Rules of Spousal Incompetency and Marital Privilege in Criminal Cases (1987), 20 Akron L. Rev. 433.

The 1991 amendment does not abolish the spousal incompetency rule. The spouse could not be compelled to testify if he or she did not want to testify. In January 1981, the Supreme Court proposed an amendment that would have deleted Evid. R. 601(B). 54 Ohio Bar 175 (1981). This amendment subsequently was withdrawn. 54 Ohio Bar 972 (1981). The current amendment differs from the 1981 proposal. The 1981 proposal would have abolished the spousal incompetency rule in its entirety, thereby permitting the prosecution to force the spouse to testify even when he or she did not wish to testify. The 1991 amendment does not permit the prosecutor to force testimony from an unwilling spouse.

Moreover, the amendment still leaves the defendant with the protection of the confidential communication privilege, which is recognized in R.C. 2317.02(C). and R.C. 2945.42 and governed by Evid. R. 501. This privilege is not affected by Evid. R. 601(B).

Rule 601(D) Medical Experts

Evid. R. 601(D) was amended to prevent the application of the rule in cases in which a physician, podiatrist, hospital, or medical professional is sued as a result of alleged negligence on the part of a nurse or other medical professional. Some cases have held that a nurse is not competent under Evid. R. 601(D) to testify about the standard of nursing care in such a case. *See Harter v. Wadsworth-Rittman* (August 30, 1989), Medina App. No. 1790, unreported, motion to certify record overruled (December 20, 1989), 47 Ohio St.3d 715, 549 N.E.2d 170.

The amendment limits the rule to claims involving care by a physician or podiatrist, and does not prohibit other medical professionals, including nurses, from testifying as to the appropriate standard of professional care in their field.

Also, the requirement that an expert medical witness devote three-fourths of his or her time to active clinical practice or instruction was reduced to at least one-half. The phrase "accredited university" was changed to "accredited school" because some accredited medical schools are not associated with a university.

1980:

Rule 601, of necessity, varies significantly from Federal Evidence Rule 601 which declares all witnesses competent in federal matters, except as otherwise provided in the Federal Rules of Evidence, and also declares that in state matters, the competency of witnesses is to be determined by state law. Rule 601 states the general rule of witness competency for Ohio. In so doing, the rule embodies certain prior Ohio practices and discards others.

One of the purposes of Federal Evidence Rule 601 was to preserve statutes such as the dead man's statute in state matters in those states where such a statute existed. Ohio has chosen to eliminate the exclusion. Rule 601 supersedes R.C. 2317.03, the dead man's statute. By declaring all witnesses to be competent and not providing an exception for the exclusionary provisions of the dead man's statute, a conflict between the rule and the statute is created and the statute is superseded under constitutional provision. Concomitantly, Rule 804(B)(5) provides that the statements formerly excluded by the dead man's statute are exceptions to the hearsay rule. (Editor's Note: This last sentence is incorrect. Rule 601 supersedes the "dead man" statute, thereby permitting the surviving party to testify at trial. Rule 804(B)(5) recognizes a hearsay exception for the *decedent's* statements; these statements were excluded because of the hearsay rule, not the dead man statute.)

R.C. 4733.24 is also superseded by Rule 601. That section conditioned a surveyor's testimony upon his oath, if required, that the chain used conformed to the established standard.

Rule 601(A) Children and Insane Persons

Rule 601(A), in excepting persons of unsound mind and persons under ten years of age who appear incapable of receiving or relating facts properly, restates, *verbatim,* R.C. 2317.01. Ostensibly, a provision relating to civil cases, it also applies in criminal cases. R.C. 2945.41 provides that the rules of evidence in civil causes, where applicable, govern in all criminal causes.

Rule 601(B) Spouse Testifying

R.C. 2945.42 governed the competency of a spouse to testify in a criminal prosecution involving the other spouse and continues to govern the privilege accorded to a spouse. The concepts are to be distinguished. Rule 601 is directed to competency. Rule 501 is directed to privilege and is a general rule serving to maintain R.C. 2945.42 as to privilege. Rule 601(B) modifies R.C. 2945.42 as to competency.

R.C. 2945.42 provided that a spouse could testify in behalf of the other spouse in all criminal prosecutions. That concept is preserved by declaring all persons to be competent witnesses. R.C. 2945.42 provided that a spouse could not testify against the other spouse in a criminal prosecution, but could testify against the other in actions and proceedings, for personal injury of either by the other, bigamy, failure to provide for, neglect of, or cruelty to children under eighteen, twenty-one if mentally or physically handicapped. Additionally, the statute provided that a wife could testify against her husband in a prosecution for felonious assault, aggravated assault, assault, non-support of dependent, or endangering children based upon cruelty to, neglect of, or abandonment of the wife. Rule 601(B) is less restrictive than the statute was under the former practice. The rule establishes the absence of competence in a spouse to testify against the other spouse in a criminal prosecution with the broad exception of any crime against the testifying spouse or any crime against the children of either spouse. No age limit is set for such child, and the language is broad enough to encompass all adult children as well as minors.

Rule 601(B) supersedes R.C. 2945.42 as to spousal competency, but not as to spousal privilege.

Rule 601(C) Traffic Officer

Rule 601(C) restates R.C. 4549.14 and R.C. 4549.16 and preserves the provisions of those statutes.

Rule 601(D) Expert Testimony in Malpractice Cases

Subdivision (D) incorporates into the rule on competency of witnesses the provisions of R.C. 2743.43 with respect to expert testimony on medical liability issues. The application of this subdivision is in accordance with the definition of a "medical claim" as provided in R.C. 2305.11(D)(3).

The rule as adopted supersedes R.C. 2743.43 but does not supersede 2305.11(D)(3) which continues to have a function independent of considerations of competency of witnesses.

Rule 601(E) As Otherwise Provided in These Rules

Rule 605 provides that a judge is not competent to testify in a trial at which he presides. Rule 606(A) provides that a juror is not competent to testify in a trial in which he is serving as a juror. The rule does not exclude an attorney from testifying in a case in which he serves as counsel. Such practice is proscribed by DR5-101(B) and DR5-102 of the Code of Professional Responsibility.

Notes of Decisions (394)

Rules of Evid., Rule 601, OH ST REV Rule 601
Current with amendments received through March 1, 2022. Some rules may be more current, see credits for details.

End of Document

Exhibit FFF

42 U.S.C.A. § 1395

§ 1395. Prohibition against any Federal interference

Currentness

Nothing in this subchapter shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided, or over the selection, tenure, or compensation of any officer or employee of any institution, agency, or person providing health services; or to exercise any supervision or control over the administration or operation of any such institution, agency, or person.

CREDIT(S)

(Aug. 14, 1935, c. 531, Title XVIII, § 1801, as added Pub.L. 89-97, Title I, § 102(a), July 30, 1965, 79 Stat. 291.)

Notes of Decisions (60)

42 U.S.C.A. § 1395, 42 USCA § 1395
Current through P.L. 117-120. Some statute sections may be more current, see credits for details.

End of Document

Exhibit GGG

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

QUESTIONABLE BILLING FOR MEDICARE ELECTRODIAGNOSTIC TESTS

Daniel R. Levinson
Inspector General

April 2014
OEI-04-12-00420

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS partially concurred with our first two recommendations and concurred with the third one. With regard to the first recommendation, CMS partially concurred and stated that it will evaluate the cost-effectiveness of implementing new thresholds for questionable billing and conducting medical record reviews of physicians who exceed them. CMS also provided information about its efforts to monitor Medicare billing for electrodiagnostic tests. Specifically, CMS will share this report with its Recovery Auditors for possible review and overpayment recovery. CMS will also consider including a model that monitors for unusually high billing for electrodiagnostic tests in its Fraud Prevention System. Finally, CMS will develop CBRs on electrodiagnostic testing that include neurologists and physiatrists.

With regard to the second recommendation, CMS partially concurred and stated that it established revised values for new codes that bundle needle EMG and NCT codes, which has resulted in simplified coding and savings to the Medicare program for these services. CMS noted that it is prohibited from providing guidance on the practice of medicine to physicians and, therefore, it may be a violation to emphasize the importance of providing NCTs in conjunction with needle EMGs. In response to CMS's comments, we clarified this recommendation to state that CMS should educate physicians on industry guidance regarding performing and billing for these services together. We are not recommending that CMS provide guidance on the practice of medicine to physicians.

With regard to the third recommendation, CMS concurred and will instruct the Supplemental Medical Review Contractor to review some or all of the physicians identified in this report. CMS will also ask these contractors to determine which of the seven questionable billing measures were the best predictors of improper payments. Finally, any suspicions of potential fraud will be referred to the appropriate Zone Program Integrity Contractor.

We support CMS's efforts to address these issues and encourage it to continue making progress. For the full text of CMS's comments, see Appendix G.

Exhibit HHH

Bernard M. Abrams, MD
10701 Nall Ste 120
Overland Park, KS 66211
816-322-4834
Fax: 816-322-2005
Email: babrams@kc.rr.com

February 17, 2018

To whom it may concern:

Re: review of Electrodiagnostic procedures concerning Leon Margolin, M.D., PhD.

Task: I was asked to review Dr. Margolin's policy and procedures including informed consent, training of personnel in an entity doing business as CPMI.

Qualifications: I am Clinical Professor Emeritus, University of Missouri-Kansas City School of Medicine, Past President of the AANEM (then the AAEE), a six year member of the Board of Directors of the AANEM, Board Certified in EMG by the AANEM, author of numerous textbook chapters on Electrodiagnosis in major pain textbooks and have lectured dozens of times on Clinical Neurophysiology and its use in Pain Medicine.

Disclaimer: I have not requested nor have I been paid for rendering my opinion. I am not a colleague or social friend of Dr. Margolin.

Materials reviewed: Updated CPMI NCV EMG policy, NCV 2012 policy informed consent, Pain Medicine CME, CPMI informed consent and EMG paperwork, Staff education in service sessions, NCV technician certificates, AANEM informed consent policy, 5 outside billing and coding reviews, Ohio LCD Medicare policy and EMG CME and the CMPI NCV/EMG medical indications form.

Conclusions:
1. CPMI's informed consent is appropriate and based on the AANEM informed consent policy.
2. CPMI NCV EMG policy appropriately addresses documenting medical necessity.
3. The CMPI NCV/EMG medical indications form appropriately addresses documenting medical necessity.
4. The policy description of our scope of practice according to Ohio LCD is appropriate.
5. In pain medicine practice it is reasonable to use NCV/EMG to document organic pathology as required for proper narcotic medication/ pain program management.
6. The attached CMEs, outside reviews and staff education are appropriate.

Very truly yours,

Bernard M. Abrams, M.D.

Exhibit III

United States Code Annotated
Title 42. The Public Health and Welfare
Chapter 7. Social Security (Refs & Annos)
Subchapter XVIII. Health Insurance for Aged and Disabled (Refs & Annos)
Part E. Miscellaneous Provisions (Refs & Annos)

42 U.S.C.A. § 1395ddd

§ 1395ddd. Medicare Integrity Program

Effective: July 22, 2016
Currentness

(a) Establishment of Program

There is hereby established the Medicare Integrity Program (in this section referred to as the "Program") under which the Secretary shall promote the integrity of the medicare program by entering into contracts in accordance with this section with eligible entities, or otherwise, to carry out the activities described in subsection (b).

(b) Activities described

The activities described in this subsection are as follows:

(1) Review of activities of providers of services or other individuals and entities furnishing items and services for which payment may be made under this subchapter (including skilled nursing facilities and home health agencies), including medical and utilization review and fraud review (employing similar standards, processes, and technologies used by private health plans, including equipment and software technologies which surpass the capability of the equipment and technologies used in the review of claims under this subchapter as of August 21, 1996).

(2) Audit of cost reports.

(3) Determinations as to whether payment should not be, or should not have been, made under this subchapter by reason of section 1395y(b) of this title, and recovery of payments that should not have been made.

(4) Education of providers of services, beneficiaries, and other persons with respect to payment integrity and benefit quality assurance issues.

(A) In general

In the case of a provider of services or supplier that is determined to have received an overpayment under this subchapter and that seeks a reconsideration by a qualified independent contractor on such determination under section 1395ff(b)(1) of this title, the Secretary may not take any action (or authorize any other person, including any medicare contractor, as defined in subparagraph (C)) to recoup the overpayment until the date the decision on the reconsideration has been rendered. If the provisions of section 1395ff(b)(1) of this title (providing for such a reconsideration by a qualified independent contractor) are not in effect, in applying the previous sentence any reference to such a reconsideration shall be treated as a reference to a redetermination by the fiscal intermediary or carrier involved.

(B) Collection with interest

Insofar as the determination on such appeal is against the provider of services or supplier, interest on the overpayment shall accrue on and after the date of the original notice of overpayment. Insofar as such determination against the provider of services or supplier is later reversed, the Secretary shall provide for repayment of the amount recouped plus interest at the same rate as would apply under the previous sentence for the period in which the amount was recouped.

(C) Medicare contractor defined

For purposes of this subsection, the term "medicare contractor" has the meaning given such term in section 1395zz(g) of this title.

(3) Limitation on use of extrapolation

A medicare contractor may not use extrapolation to determine overpayment amounts to be recovered by recoupment, offset, or otherwise unless the Secretary determines that--

(A) there is a sustained or high level of payment error; or

(B) documented educational intervention has failed to correct the payment error.

There shall be no administrative or judicial review under section 1395ff of this title, section 1395*oo* of this title, or otherwise, of determinations by the Secretary of sustained or high levels of payment errors under this paragraph.

(4) Provision of supporting documentation

In the case of a provider of services or supplier with respect to which amounts were previously overpaid, a medicare contractor may request the periodic production of records or supporting documentation for a limited sample of submitted claims to ensure that the previous practice is not continuing.

(5) Consent settlement reforms

(A) In general

Exhibit JJJ

386 F.Supp.3d 644
United States District Court, E.D. Virginia, Alexandria Division.

LIVINRITE, INC., Plaintiff,
v.
Alex M. AZAR, II, Secretary of the United States Department of Health and Human Services, Defendant.

Civil Action No. 1:18-cv-00603
|
Signed 06/17/2019

Synopsis

Background: Medicare-certified home health services provider sought review of decision by Medicare Appeals Council (MAC) that provider had been overpaid approximately $1 million for certain Medicare claims. Parties cross-moved for summary judgment.

Holdings: The District Court, T. S. Ellis, J., held that:

[1] MAC's decision that sampling methodology could be accurately replicated was rational and based on substantial evidence;

[2] MAC adequately explained its determination that there was no Medicare coverage for occupational therapy visit;

[3] MAC adequately explained its determination that there was no Medicare coverage for nursing services;

[4] substantial evidence supported MAC's determination that there was no Medicare coverage for physical therapy services;

[5] MAC adequately explained its determination that there was no Medicare coverage for initial period of skilled nursing services;

[6] MAC's determination that provider was not entitled to limitation of its liability to reimburse overpayments was supported by substantial evidence and not contrary to law; and

[7] MAC's determination that provider was not entitled to waiver of recoupment for overpayments was supported by substantial evidence and not contrary to law.

Plaintiff's motion denied; defendant's motion granted.

Procedural Posture(s): Review of Administrative Decision; Motion for Summary Judgment.

West Headnotes (26)

[1] **Administrative Law and Procedure** Judicial role or function in general

When a party seeks judicial review of agency action under the Administrative Procedure Act (APA), the district judge sits as an appellate tribunal. 5 U.S.C.A. § 706.

[2] **Administrative Law and Procedure** Standards and grounds for summary judgment or disposition; evidence

Given a district court's limited role in reviewing an administrative record under the Administrative Procedure Act (APA), the ordinary summary judgment standard does not apply; the key difference in an APA case is that the presence or absence of a genuine dispute of material fact is not in issue, as the facts are all set forth in the administrative record. 5 U.S.C.A. § 706.

1 Cases that cite this headnote

[3] **Administrative Law and Procedure** Questions of law or fact in general

In a review of agency action under the Administrative Procedure Act (APA), the entire case on review is a question of law. 5 U.S.C.A. § 706.

[4] **Health** Evidence

"Substantial evidence," as required to support factual findings by the Medicare Appeals Council (MAC), does not mean a large or

that is, (i) the method must be capable of selecting a set of enumerable, distinct samples from the sampling frame and (ii) each sampling unit must have a known probability of being selected that is greater than zero.[4] Fifth, the contractors must review each unit in the selected sample and determine if an overpayment has been made. *Id.* §§ 8.4.1.3, 8.4.6.3. Sixth, the contractor must estimate the total overpayment to the provider during the review period by extrapolating the results from the selected sample to the entire sampling frame. *Id.* §§ 8.4.1.3, 8.4.5.

A provider may challenge a Medicare contractor's calculation of overpayment through the administrative appeals process.[5] The use of statistical sampling by the contractor "creates a presumption of validity as to the amount of an overpayment." CMS Ruling 86-1 at 11. It is the provider's burden to overcome this presumption by demonstrating either (i) that the sample is not statistically valid or (ii) that the contractor's determinations of overpayment with respect to specific units in the selected sample are incorrect. *Id.*

First, the provider may challenge the statistical validity of the sample selected by the contractor. A challenge to the validity of the sample "must be predicated on ***654** the actual statistical validity of the sample as drawn and conducted." MPIM § 8.4.1.1. Accordingly, "[i]f a particular probability sample design is properly executed" in accordance with the six steps set forth above, "then assertions that the sample and its resulting estimates are 'not statistically valid' cannot legitimately be made." *Id.* § 8.4.2. Put simply, "a probability sample and its results are always 'valid.' " *Id.*

Second, the provider may challenge the contractor's determination that certain sampling units in the selected sample are not covered by the Medicare Act and thus resulted in an overpayment to the provider. In this respect, home health services qualify for Medicare coverage if such services are "reasonable and necessary" and are provided to a beneficiary who is (i) confined to the home, (ii) under the care of a physician who establishes a plan of care in accordance with 42 C.F.R. § 409.43, and (iii) in need of "skilled services" as certified by a physician. 42 U.S.C. §§ 1395f(a)(2)(C), 1395y(a)(1)(A); 42 C.F.R. § 409.42. A skilled service is one that is "so inherently complex that it can be safely and effectively performed only by, or under the supervision of, professional or technical personnel." 42 C.F.R. § 409.32

IV.

[7] Plaintiff first argues that the MAC's decision should be set aside because the MAC's decision that AdvanceMed's sampling methodology could be accurately replicated is arbitrary and capricious, incorrectly applies the relevant legal standards, and is not supported by substantial evidence in the record. Notably, plaintiff does not challenge the MAC's determination that the sampling methodology applied by AdvanceMed was statistically valid.[6] Rather, plaintiffs argument, distilled to its essence, is that AdvanceMed's extrapolated overpayment determination must be invalidated because it is impossible to replicate the sample based on the materials in the record.

In addition to providing contractors with instructions on the proper execution of statistical sampling for overpayment calculation, the MPIM also requires Medicare contractors to document the sampling methodology, the sampling universe and frame, and the random number selection process that were used to estimate overpayment. MPIM §§ 8.4.4.2, 8.4.4.4, 8.4.4.4.1, 8.4.4.4.3. The purpose of these documentation requirements is to ensure that the sampling frame and the sample can be replicated in the event that the methodology is challenged. *Id.* §§ 8.4.4.2, 8.4.4.4.1. As previous MAC decisions have concluded, failure to supply the provider with sufficient documentation to recreate the sampling frame and sample effectively deprives the provider of its right to challenge the statistical validity of the sample and thus may constitute a ground for invalidating the overpayment extrapolation. *See William Vecchioni, D.C.*, M-13-3700 (H.H.S. Nov. 20, 2013); *Global Home Care, Inc.*, M-11-116 (H.H.S. Jan. 11, 2011); *Podiatric Medical Associates*, M-10-230 (H.H.S. June 22, 2010).

But here, as the MAC concluded, plaintiff was provided with ample documentation to enable plaintiff to replicate the sampling frame and the sample. The record confirms that the statistical sampling information CMS provided to plaintiff included, ***655** *inter alia*, an electronic spreadsheet of the frame used in the overpayment review; a memorandum explaining the universe, sampling frame, sampling unit, sample size, and sample design; the sample that was selected from the frame; and the exact random numbers that were generated and used to select the sample from the frame. And it is undisputed that applying the random numbers provided by CMS to the sampling frame provided by CMS would generate the same sample as the one selected and

