---------- Forwarded message ---------
From: **Leon Margolin** <leon3087@gmail.com>
Date: Thu, Apr 10, 2025 at 7:01 PM
Subject: Re: Your Submission JRS-240032R1
To: The International Journal of Risk and Safety in Medicine <lezign@gmail.com>

Thank you so much! We will definitely get back to you with the comments, minor revisions response to the comments.

On Thu, Apr 10, 2025 at 6:42 PM The International Journal of Risk and Safety in Medicine <em@editorialmanager.com> wrote:
CC: axana.scherbeijn@sagepub.co.uk

Ref.: Ms. No. JRS-240032R1
MISGUIDED MEDICAL INSURANCE AND GOVERNMENT POLICIES IN THE OPIOID EPIDEMIC: A CHART REVIEW AND NARX SCORE ANALYSIS.
The International Journal of Risk & Safety in Medicine

Dear Dr Margolin,

Reviewers have now commented on your paper and we are pleased to inform you that your manuscript will be accepted for publication in The International Journal of Risk & Safety in Medicine pending minor revisions. For your guidance, reviewers' comments are appended below.

If you decide to revise the work, please submit a list of changes or a rebuttal against each point which is being raised when you submit the revised manuscript.

Your revision is due by May 10, 2025.

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Yours sincerely,
on behalf of the Journal Editors,

Liliya Eugenevna Ziganshina, MD, PhD, DSci
Editor-in-Chief
The International Journal of Risk & Safety in Medicine

The International Journal of Risk & Safety in Medicine

MISGUIDED MEDICAL INSURANCE AND GOVERNMENT POLICIES IN THE OPIOID EPIDEMIC: A CHART REVIEW AND NARX SCORE ANALYSIS.

--Manuscript Draft--

Manuscript Number:	
Full Title:	MISGUIDED MEDICAL INSURANCE AND GOVERNMENT POLICIES IN THE OPIOID EPIDEMIC: A CHART REVIEW AND NARX SCORE ANALYSIS.
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Abstract:	OBJECTIVES: Despite the investment of significant effort and resources, our country remains exposed to an alarming risk of opioid overdoses due to opioid addiction. This study demonstrates the impact of misguided medical insurance and government policies on the opioid epidemic. METHODS: This is a retrospective chart review study of 142 patients who were denied access to care by insurance companies (CareSource, Molina, Aetna, government regulators, and contractors). The study provides a systematic analysis of the risk stratification of these patients based on the NARX score, prescribed medications, and OARRS report analysis. FINDINGS: Patient who were denied access to care by the major insurance carriers in Ohio, CareSource, Aetna, and Molina had an average high NARX score of 309.8-310.5 range. The review of the prescribing provider lists on Ohio Automated RX Reporting System reports showed that, in most occasions, patients had significant difficulty in finding a qualified pain provider for three months or more. CONCLUSIONS: Review of denied-care patient NARX scores shows, conclusively, that very high-risk patients were affected the most. These misguided medical insurance and government policies have exposed the most vulnerable and high risk patients to significant risk of mortality and morbidity. KEYWORDS: opioids, SBIRT, Nerve Conductive Studies, drug screening, prescription drugs, health care law and regulation, pharmaceutical industry, insurance, medically necessary
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Sanford Lefkowitz has an M.Sc. in mathematics from Michigan State University. He has 40 year experience applying data analytics to problems in private industry and not for profit organizations.

Richard Ancowitz is Counsel to the Chair of the New York State Assembly Ways and Means Committee, and has written widely on medicolegal matters, including constitutional law. He also serves as a Master Arbitrator for the New York State Department of Financial Services, and since 1999 has adjudicated over 2,000 disputes between health care providers and vehicular insurers. False Claims Act Attorney | Whistleblower Advocate | Ancowitz Law

Sanford Rosenblum is the senior healthcare and personal injury attorney at Rosenblum Law. Sandy has successfully won over $200 million in recoveries for clients. Sandy, who has nearly 60 years of experience in personal injury law, actively litigated civil and criminal cases for many years.
Sandy has long been active in many local and national charities. He is a member of the Association of Trial Lawyers of America (ATLA) and was recently honored as an ATLA "Stalwart." He is also a member of the New York State Trial Lawyers Association and the New York State Bar Association: Sanford Rosenblum Esq. - Personal Injury Lawyer - %%sitename%% (rosenblumlaw.com)

	Clinical and research experience, ASAM activism

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Question	Response
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BACKGROUND

The explosion of overdose risk in the opioid epidemic since 1999;and the concomitant Opiate Use Disorder (OUD) have cost in excess of $600 billion, killing tens of thousands nationally, devastating families, and harming communities and the country. Another opioid epidemic cost estimate from 2011 by the Institute of Medicine put the cost in the vicinity of 560-635 billion dollars annually (74). Since 1999, more than 600,000 people in the USA and Canada have died from an opioid overdose;. Indeed, the rate of mortality in each country exceeds that of the worst of the HIV/AIDS epidemic (75). In 2007-2014 opioid dependence rose 3,203% (per cent), and, between 2011-2015, privately insured opioid abuse charges rose from 72$ million to 722$ million. A sizable portion of the public has opioids in their blood, with opioid-impaired driving implicated in multiple accidents, from 2011 to 2014 pregnancy drug dependence diagnoses rising 511%, and neonatal abstinence syndrome diagnosis rising more than fourfold (76).

According to the Centers for Disease Control and Prevention (CDC), between 2015-2020, Ohio had consistently been one of the top-5 states for drug overdose mortality rates. (CDC 2022). In 2015, Ohio tied with Kentucky for the third highest drug overdose mortality rate in the United States, with 29.9 deaths per 100,000 people (3,310 total deaths). (CDC 2022). In 2016, Ohio had the second highest drug overdose mortality rate with 39.1 deaths per 100,000 people (4,329 total deaths). (CDC 2022). In 2017, Ohio had the second highest drug overdose mortality rate in the nation with 46.3 deaths per 100,000 people (5,111 total deaths). (CDC 2022). Additional research conducted in 2017, focusing on opioid mortality, found Ohio to have the second-highest opioid mortality rate in the US, representing more than 2.6 times the death rate compared to the US average (39.2 per 100,000 people in OH vs. 14.6 per 100,000 people in US, see **Figure 1a** below).

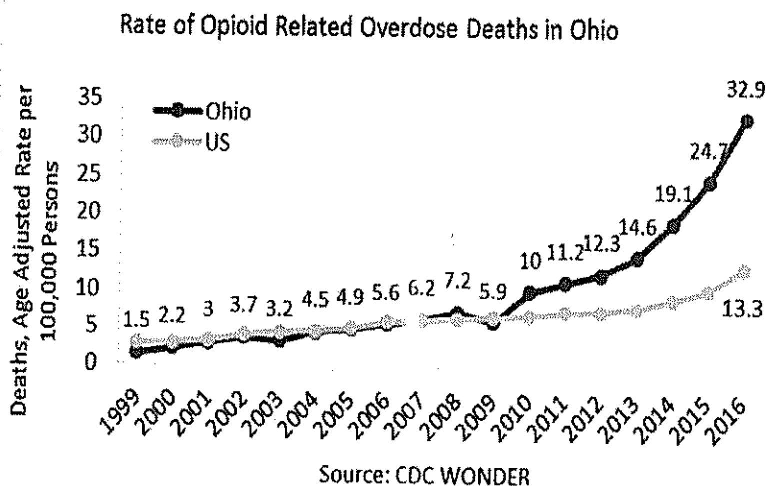


Figure 1.a

Note: Based on 2017 CDC data, Ohio has the second highest opioid mortality rate in the U.S. with more than 2.6 times the U.S. national average mortality rate (OH = 39.2 deaths per 100,000 people; National Average = 14.6 deaths per 100,000).

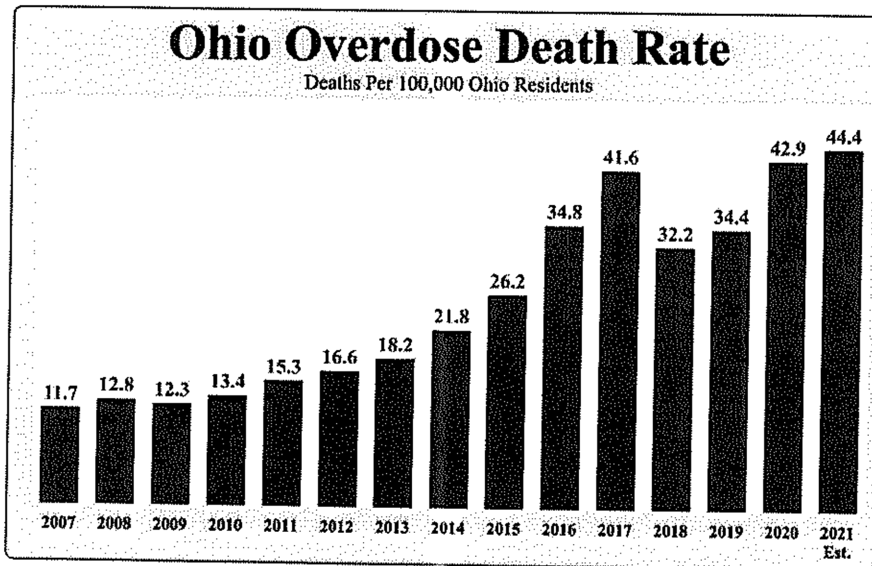


Figure 1.b

Note: Unintentional overdose death rate (based on harm Reduction Ohio).

Source:

The above data clearly demonstrates the devastating effect the opioid epidemic has had on the state of Ohio. DEA data shows that, on average, at least 12-15 people die in Ohio. Franklin county alone reported than 11,300 overdoses since 2018. (DEA 2020). According to the CDC, in 2020, Ohio saw 47.2 unintentional drug overdose deaths per 100,000 residents.(CDC 2022) This was the fourth highest drug overdose rate death in the United States and resulted in 5,204 total deaths.(CDC 2022) That same year, 86% of overdose deaths involved opioids, with 81% included fentanyl or fentanyl analogs, according to the Ohio Department of Health, which appropriately noted that "every community has been impacted by the disease of addiction." (Ohio Attorney General 2021). As evidenced above, opioid-related deaths have increased annually since 2010 (except for one-year interval between 2017-18), and fatalities exceeded 5,200 in 2020, with a 26 percent increase following the previous year. (CDC 2022).

In Ohio, a serial cross-sectional analysis for all fatal opioid poisonings between January 1, 2010 and December 31, 2016 (N = 12,782). Calculated the burden of fatal opioid overdoses in Years of Life Lost (YLL). YLL were mapped with respect to geographic and cultural regions. Opioid overdoses resulted in 508,451 total YLL. In the year 2016 alone, there were 136,679 YLL attributable to fatal opioid poisonings. Fentanyl-related YLL rose from 7.5% of all YLL related to opioid overdose in 2010 to 69.0% in 2016, while overall opioid overdose mortality continued to rise annually. (O.T. Hall, *et al.* 2020).

Notably, both addiction professionals (O.T. Hall, *et al.* 2020) and the Substance Abuse and Mental Health Services Administration (SAMHSA 2017) have identified Screening, Brief Intervention, and Referral to Treatment (SBIRT) services as being effective in preventing opioid mortality, improving function, and decreasing pain. SBIRT services are evidence-based, early interventions that physicians 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 short conversations 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. (CMS 2022).

Notably, a large study of SBIRT outcomes found that SBIRT, at the six-month follow-up point, lowered illicit drug use by 68% and lowered heavy alcohol use by 39%. (Agerwala, SM, *et al.* 2012). Moreover, SBIRT protocols are often mandatory for the compliant operation of a pain management clinic, especially clinics providing medical management to populations with a significant portion of high-risk patients in high-risk areas, like Ohio. By way of example, Ohio law sets stringent requirements for pain management clinics and physicians that prescribe controlled substances as part of their pain management services. (OAC § 4731-29-01).

Despite the clear benefit (and potential necessity for compliance purposes), SBIRT services are frequently denied coverage by insurance carriers. Defining them as "unallowable costs," cCoverage denials for these services by third-party payers have placed both patients and pain medicine staff at considerable risk. This article aims discusses how specific policies and methods implemented by certain insurers have impacted Ohio families, communities, and the state.

Pain Medicine Practice Protocols Based on the American Society of Addiction Medicine Guidance.

The American Society of Addiction Medicine (ASAM) recommends pain medicine practitioners provide SBIRT screening and other services to monitor and assess pain patients and/or patients with substance use disorders (SUDs). Over the past several decades, there has been an increased call for "universal precautions" in the evaluation and management of patients with SUDs and serious pain issues, particularly chronic pain. Similar to the management of patients with infectious diseases (wherein clinicians generally assume that all patients are potential carriers of serious transmissible agents (*e.g.*, HIV, hepatitis B/C, etc.) and must take appropriate precautions), clinicians specializing in pain management must consider each patient presenting with pain issues to potentially suffer from (or be at risk for) substance use disorders, including the potential for aberrant behaviors and adverse outcomes.(ASAM 2017; Douglas Gourlay, *et al.* 2006; Laxmaiah Machikanti, *et al.* 2010; Ohio Dept. MHAS 2023).

Somatic pain comes from damage to musculoskeletal structures and certain soft tissues (*e.g.*, bones, muscles, skin, and mucus membranes). Somatic pain is the type of pain you experience from cuts to your skin or overused muscles. (Cleveland Clinic 2024). Analgesics such as opioids block the experience of somatic pain. For this reason, they sometimes are referred to as anti-nociceptive agents because they block the perception of noxious (painful) information. In the case of inflammatory pain (in contrast to visceral pain or musculoskeletal pain), where inflammation is the cause of the pain, an analgesic such as a non-steroidal, anti-inflammatory drug (NSAID) actually blocks the generation of the pain. However, neuropathic pain does not signal injury to a bone, muscle, or organ in the body, but rather an injury to a nerve cell. This distinction is important in clinical practice because traditional anti-nociceptive agents are typically ineffective at relieving neuropathic pain. (R. Dworkin, *et al.* 2010). Therefore, distinguishing between somatic (nociceptive) and neuropathic pain is an important component of clinical care. (ASAM 2017; M. Bennett 2001). The general lack of efficacy of anti-nociceptive agents to treat neuropathic pain provides the basis for the medical necessity of alternative treatments, such as electro diagnostic and autonomic studies in chronic pain management. Moreover, the availability of an opioid-alternative treatment for chronic pain patients should be viewed as a positive considering the current state of the opioid epidemic.

InsurersOften Deny SBIRT and Opioid-Alternative Treatments

Many insurance companies operate as for-profit corporations that are invested in the stock market, with a strong financial incentive to maximize their bottom line. Even federal healthcare programs are under significant pressure to cut healthcare costs with strong financial incentive programs. Unfortunately, this focus appears to provide insurers a strong financial incentive to adopt policies that inappropriately deny life-saving services, such as SBIRT and other pain management services and procedures.

Notably, fifteen U.S. Senators recognized this problem and sent a letter to the largest Ohio Medicaid insurer, CareSource, in 2018 to voice their concerns over the insurer's pain management and substance use disorder policies. In brief, the U.S. senators expressed their concerns to CareSource that it had adopted certain policies which were exacerbating the nation's opioid epidemic. (Sherrod Brown 2018). The Senators urged CareSource to reexamine its policies and to adopt new policies to promote non-addictive pain management options. In addition to CareSource, Molina has adopted similar policies restricting non-addictive pain management options, which could also exacerbate the nation's opioid epidemic. We are concerned based on the documents enclosed that Molina demonstrated similar concerns to the issues described in the letter (please find Molina patient complaints enclosed).

Inappropriate denials of beneficial SBIRT services can result in insufficient testing, monitoring, screening and lack of alternatives to opioid medications which could very likely lead to: (i) providers prescribing opioids in inappropriate situations to patients with heightened risks of substance abuse or diversion to other people; or (ii) providers not prescribing appropriate pain medications to patients who may look for alternatives "on the street." Both situations pose significant risks of morbidity and mortality. Moreover, the inappropriate denials could lead to increased costs for patients. The cost of SBIRT is minimal: about 50-60 dollars per 30 minutes of physician time of level 3 or 4 office visit charge. The cost of hospitalization, including ER, inpatient care, ICU, detoxification, and maintenance programs is astronomic. These risks and costs can be reduced by appropriate patient screening and treatment in outpatient programs like our practice (Comprehensive Pain Management Institute).

Until insurers adopt policies insurers that promote (and cover the costs of) services focused on better monitoring (*e.g.*, SBIRT services) and provide_opioid-alternative treatment options (*e.g.*, EMGs) to high-risk patients, opioid-related mortality and crime rates will continue to rise. Families, communities, the state, and the country will face growing negative implications from the opioid epidemic. For instance, in 2022, every branch of the U.S. military announced record low recruitment due, in part, to the opioid epidemic.(NBC News 2022).

METHOD

Inclusion criteria for the records included:

This is a retrospective review of the overdose risk as reflected by the NARX score of the individuals who were referred SBIRT and urine drug screens, evaluation, and treatment by our program but were denied coverage by insurance. We have obtained a Prescription Monitoring Data (PMD) report for each **of the 142 patients.** The charts were selected randomly from the database of the denied referrals available.

Exclusion criteria for the records included:

The patients who got the insurance denial overturn and were able to obtain access to the services.

Ethical considerations:

All data was collected and processed in compliance with the Comprehensive Pain Management Institute (CPMI) HIPAA and CFR 42 part2 policy, state, and federal regulations.

Statistical analysis:

To determine if there is a significant difference in NARX score based on MME, a t two sample t-test was used. For each insurer, the t-test compared the average NARX score for low MME patients (<=15) and high MME (>15) patients.

To measure the efficacy of participation in the treatment program, patients were measured in terms of Functional Improvement and Pain reduction. Patients were compared based on their length of participation in the program (less than 2 years, versus 2 years or more) versus their degree of improvement. A chi square test was used to measure efficacy versus treatment length.

The actual p-values are shown (not just whether the value exceeds a threshold value, such as .05).

Medical Legal Literature Review:

The authors utilized state news and press release archives, state, and federal government websites (including those pertaining to opioid statistics and the opioid epidemic), medical journals, medical insurer websites, professional organization websites, state and federal regulations, and medical records to investigate the impact of medical insurance and governmental regulators policies on public safety and the opioid epidemic (see "Discussion") .

Point-of-care (POC) urine drug screen studies (UDS) testing was performed in compliance with 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.

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

RESULTS

Table 1:

Insurer	AVERAGE NARX SCORE	Number Patients
Aetna	310.5	43
Caresource	309.8	59

Molina	310.0	34

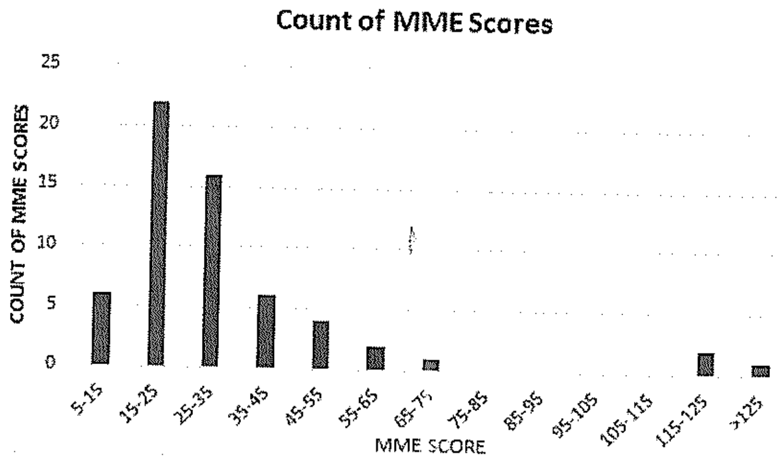
Review of the prescribing provider lists on Ohio Automated RX Reporting System (OARRS) reports show that, on most occasions, the patients had significant difficulties in finding a qualified pain provider for three months or more.

Analysis of NARX/MME Data by Insurer (DATA SUMMARY).

There are one-hundred forty-two (142) data points. Of these, eighty-two (82) had a morphine milligram equivalent (MME) value of zero (0) and the medication was "None." These points were excluded from the analysis. One (1) patient had a medication of "None" but had a non-zero MME score. This patient was included in the analysis. Three (3) patients had MME values that were outliers (illustrated below). Since the MME values were more than six (6) standard deviations above the mean, it was assumed these values were incorrect and were excluded from the analysis. After these adjustments, we had fifty-six (56) data points remaining for analysis.

Based on the review of NARX score of patients denied care, it is abundantly evident that the very high-risk patients (*i.e.*, NARX score above 300, which indicates they are more than 25 times above average risk of overdose) were affected the most (see Fig. 2 below). The systematic denial of SBIRT services resulted in a higher risk for overdose and death which was about 10 times higher than average.[1]

The patients' high MME values reflect the fact that the vast majority of patients in the study who were denied access to care were already on significant doses of opioids, initiated by their primary care or other providers.This fact greatly increases the risks of denial of access to care.



[1] Please refer to the NARX score review material enclosed.

Figure 2: MME scores analysis

SUMMARY OF RESULTS

For Aetna, the average NARX score was significantly higher for high MME patients than for low MME patients.

For CareSource, the average NARX score was NOT significantly higher for high MME patients than for low MME patients.

For Molina, the average NARX score was higher for high MME patients than for low MME, but the result was not strong enough to be considered statistically significant.

DETAILS

AETNA

	NARX AVERAGE	NUMBER PATIENTS
MME<=15	232.9	7
MME>15	366.7	18
Difference	133.8	

Difference in means is tested with a t-test

t= -2.93 p=.008

The probability of seeing a difference this large by chance is .008 (i.e., negligible). This large difference is statistically significant and corroborates our hypothesis that denial of these tests has a clear detrimental effect for high MME patients.

CARESOURCE

	NARX AVERAGE	NUMBER PATIENTS
MME<=15	310.0	5
MME>15	322.7	11

Difference	12.7	

Difference in means is tested with a t-test

t= -.18   p=.85

The probability of seeing a difference this large by chance is .85. As such, we conclude that this difference is not statistically significant.

MOLINA

	NARX AVERAGE	NUMBER PATIENTS
MME<=15	233.2	3
MME>15	260.9	12
Difference	127.6	

Difference in means is tested with a t-test.

t= -1.27   p=.23

The probability of seeing a difference this large by chance is .23. Again, we conclude that this difference is not statistically significant..

AETNA DATA

Patient	NARX	MME	Medication
R *	260	15	Percocet 5/325mg
D*	50	15	Percocet 5/325mg
S *	180	15	Norco 5/325mg
L *	260	15	Norco 5/325mg
P *	200	15	Norco 5/325mg
S *	450	10	Norco 5/325mg

M*	230	15	Percocet 5/325mg
L *	160	30	Norco 7.5/325mg
L *	520	37.5	Oxycodone 5mg
A *	500	22.5	Percocet 5/325mg
B *	300	60	Oxycodone 10mg
A *	270	22.5	Percocet 5/325mg
B *	470	30	Oxycodone Sol 5mg/5ml
J *	280	30	Percocet 5/325mg
F *	320	30	Norco 7.5/325mg
J *	320	30	Percocet 10/325mg
M *	480	45	Oxycodone 10mg
C *	380	40	Norco 10/325mg
E *	380	33.75	Percocet 7.5/325mg
B *	300	45	Percocet 7.5/325mg
P *	450	40	Norco 10/325mg
M *	300	20	Norco 5/325mg
W *	450	40	Tramadol ER 100mg
K *	360	18.75	Percocet 5/325mg
M *	360	67.5	Oxycodone 15mg

CARESOURCE DATA

Patient	**NARX**	**MME**	**Medication**
S *	190	15	Same (Norco 5/325mg)
T *	340	15	Same (Norco 5/325mg)
L *	340	10	Same (Norco 5/325mg)

P*	250	15	Same (Percocet 5/325mg)
C *	430	10	Same (Tramadol 50mg)
D *	470	22.5	Same (Oxycodone 5mg)
L *	160	30	Same (Percocet 5/325mg)
B *	440	37.5	Same (Oxycodone 5mg)
R *	540	45	Same(Percocet7.5/325mg)
C *	310	20	Same (Tramadol 50mg)
J *	320	40	Same (Tramadol 50mg)
H *	320	33.75	Same(Percocet7.5/325mg)
B *	340	22.5	Same (Percocet 5/325mg)
K *	420	30	Same (Norco 10/325mg)
T *	120	60	Same(OxycontinER 20mg)
L *	110	30	None
D *	270	15	Same Norco 5/325mg
C *	220	7.5	Same Butrans Patch 20mcg
V *	390	30	Same Oxycodone 5mg
G *	50	11.63	Same Percocet 7.5/325mg

MOLINA DATA

Patient	**NARX**	**MME**	**Medication**
D *	270	15	Same Norco 5/325mg
C *	220	7.5	Same Butrans Patch 20mcg
V *	390	30	Same Oxycodone 5mg
G *	50	11.63	Same Percocet 7.5/325mg

T *	430	10	Same Norco 5/325mg
B *	270	30	Same Tramadol 50mg
T *	430	22.5	Percocet 5/325mg
R *	150	30	Same Norco 7.5/325mg
T *	630	45	Same Oxycodone 10mg
J *	280	30	Same Tramadol 50mg
C *	540	22.5	Same Percocet 5/325mg
S *	160	30	Same Norco 7.5/325mg
L *	370	20	Different Tramadol 50mg
E *	340	30	Same Tamadol 50mg
J *	410	22.5	Same Oxycodone 5mg

As demonstrated in a previous publication, the SBIRT services, which were unjustly denied by the insurers, often results in a very significant functional improvement and pain reduction over 1-2 years of treatment. (L. Margolin, D. Streem, *et al.* 2020). Moreover, SBIRT services can help prevent aberrant drug-seeking behavior and opioid use disorder.(L. Margolin, D. Streem, *et al.* 2020).

Functional Improvement Analysis

Based on the previously data (31,32), 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:

	Moderate	Significant	Very

Less than 2 years	55.2%	24.1%	20.7%
2 years	19.2%	3.8%	76.9%

Note: % of Row Totals for the table above.

For example, of the 26 patients with two years of treatments (for whom we also had data on Functional Improvement), 20 of them (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

Based on the previously data (31,32), 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's functional improvement – which is the main outcome measure of the pain management program.

Pain Reduction analysis

Table 4:

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

Table 5:

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

Note: % of Row Totals for the table above.

Most patients had only moderate pain reduction (72.2%). Of the patients in the program for two years, 15% (4 out of 26) had Very Significant pain reduction while 65% of the two-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 statistically significant difference in "months of Treatment" ($p=.02$).

Pain Reduction analysis results

Based on the previously data (31,32), we could demonstrate a very significant pain (p=.02) reduction over time in our program. As time and participation in the program increases (more than 2 years), the pain reduction becomes more significant.

DISCUSSION

CPMI is a specialty pain management practice with offices in Columbus and Cleveland, Ohio. CPMI provides comprehensive care for hundreds of Medicaid patients and many others. CPMI primarily receives patients through referrals from hospitals and other physician practices (including primary care physicians). CPMI also takes patient referrals from other pain medicine practices for patients that have proven to be very difficult and/or very high risk. Generally, CPMI's patient population are complex, medium-to-high risk chronic pain patients with multiple medical and/or psychological co-morbidities. CPMI is licensed as a terminal distributor of dangerous drugs with a "pain management" classification through the Ohio Board of Pharmacy as required by Ohio law. (ORC § 4729.552).

CPMI employs one pain-medicine physician, Dr. Leon Margolin, M.D., as well as several certified nurse practitioners. Dr. Margolin is responsible for coordinating narcotic prescriptions for CPMI patients following appropriate screening and providing interventional pain management. Due to CPMI's unique patient population and the increased risk for drug abuse or overdose, CPMI relies on SBIRT services to screen and track patient compliance with their opioid treatment regimen. Moreover, CPMI seeks to identify and provide non-opioid treatment alternatives and **provide free evidence based patient education (see www.cpmiohio.com)** to further minimize the risk of opioid abuse and overdose.

I. CONCERNS WITH INSURER POLICES THAT DO NOT COMPLY WITH EXPERT ADVICE AND REGULATORY REQUIREMENTS

It appears that insurers with policies that frequently deny SBIRT services and Nerve Conductive Study ("NCS") treatments, autonomic studies and other services to treat chronic pain patients are bereft of any consideration for accepted medical practices in pain medicine, legal requirements, or social demands (*i.e.*, to shift away from opioid-dependent treatments).

Academic and Expert Evidence Support SBIRT and NCS for Treatment of Chronic Pain Patients

By implementing policies that denied coverage for opioid-alternative treatments (*e.g.*, NCS without EMG, autonomic studies and other testing) and SBIRT services, insurers fail to acknowledge the plethora of evidence from academic and pain medicine expert sources that supports the use of SBIRT and NCS, autonomic studies and other services to treat chronic pain patients. The American Board of Physical Medicine and Rehabilitation (ABPMR) and numerous pain medicine experts have published academically reviewed articles and research in support of the medical necessity of such services for the treatment of chronic pain patients.

By way of example, CPMI and the Chief of Psychiatry and Medical Director of the Alcohol and Drug Recovery Center at Cleveland Clinic Foundation published a peer-reviewed article demonstrating the benefits of SBIRT and NCS with or without EMG, autonomic studies and other services in treating chronic pain patients. (L. Margolin, D. Streem, *et al.* 2020). The publication reviewed fifty (50) high-risk CPMI chronic pain patients, seventy-four (74%) percent of whom had high-to-extremely high NARX scores ranging from 100-350. Patients with these ranges of high-risk NARX scores are 10-12 times more likely to overdose on opioids than the average patient. Accordingly, SBIRT services and NCS without

EMG autonomic studies and other services to treat chronic pain patients.were deemed essential to combat the heightened risks of over-prescription, overdose, and/or diversion. (L. Margolin 2020).

Additionally, CPMI has engaged with the American Board of Physical Medicine and Rehabilitation (ABPMR) and several pain medicine experts, to assess CPMI's protocols and patient outcomes pertaining to NCS, autonomic studies and other services to treat chronic pain patients. Upon review of CPMI's NCS protocols and outcomes, the pain medicine experts confirmed the medical necessity of such services in the interventional pain medicine setting. (Jim Kimura 2018; Stanley Wainapel 2018; William Vasilakis 2019).

II. INSURER POLICIES DO NOT COMPLY WITH STATE AND FEDERAL REGULATION AND CMS REQUIREMENTS

Insurer policies that frequently deny coverage for SBIRT and NCS, autonomic studies and other services also fail to appropriately consider state laws, which may require such services. By way of example, Ohio law requires pain specialists prescribing controlled substances to continuously monitor their high-risk patients. (OAC § 47311-11-14). In fact, pain specialists are prohibited from allowing more than three (3) months to pass between assessments. (OAC § 47311-11-14). 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.

Ohio Law Supports SBIRT and NCS for Treatment of Chronic Pain Patients

In May 2011, Ohio passed H.B. 93, which established new rules and requirements for dispensing controlled substances and new requirements for pain management clinics (*e.g.*, CPMI) and pain medicine physicians (*e.g.*, Dr. Margolin). (Ohio 129th General Assembly 2011). Notably, the new law required for the first time:

- For pain management clinics seeking to possess, sell, deliver, or distribute dangerous drugs and/or controlled substances to obtain a license as a terminal distributor of dangerous drugs (86) with a pain management clinic classification from the Ohio State Board of Pharmacy (ORC §§ 4729.51, 4729.54, and 4729.552);
- The Ohio State Medical Board to adopt rules establishing standards for physician operation of pain management clinics and physicians who treat patients with chronic pain (ORC § 4729.54); and
- The Ohio State Medical Board to adopt rules and standards for physicians who provide care at pain management clinics. (ORC §§ 4729.54 and 4729.552)

In accordance with Ohio H.B. 93, the Ohio State Medical Board issued certain rules setting forth minimal standards, with which pain management clinics must comply. By way of example, those standards include:

- 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. (OAC 4731-11-14(A));
- When prescribing or personally furnishing a reported drug (including Schedule II-V controlled substances), a physician shall take into account all the following: (i) potential for abuse; (ii) the possibility that use of the drug may lead to dependence; (iii) the possibility the

patient will obtain the drug for a nontherapeutic use or distributed it to others; and (iv)the potential existence of an illicit market for the reported drug. (OAC 4731-11-11(B)(1));

- Physicians seeking to prescribe or personally furnish a reported drug shall obtain and review a report from The Ohio Automated Rx Reporting System ("OARRS") (*i.e.*, Ohio Board of Pharmacy's database, accessible by physicians, and certain others, used to track controlled substance prescriptions) prior to prescribing or personally furnishing any opiate analgesic or benzodiazepine to a patient, unless an exception applies. (OAC §§ 4731-11-11(B)(2) and 4731-11-11(C);

- Physicians shall obtain and review an OARRS report when a patient's course of treatment with a reported drug (other than an opioid analgesic or benzodiazepine) lasts more than 90 days. OAC § 4731-11-11(C);

- Physicians ***shall obtain and review an OARRS report when certain delineated "red flags" pertain to the patient, including inconsistent drug screenings***, a history of chemical abuse and/or dependency, and increasing dosages beyond the prescribed amount. (OAC 4731-11-11(C)(3);

- Physicians must perform a history and physical examination of the patient, including a review of prior treatments, patient's adherence to the medication or non-medication treatment, and ***screening for substance misuse or substance use disorder***. (OAC § 4731-11-14(B)(1));

- ***Physicians must perform 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***. (OAC § 4731-11-14(B)(2));

- Physicians must perform a functional pain assessment, which includes the patient's ability to engage in work and 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. (OAC § 4731-11-14(B)(4));

- Physicians must develop a treatment plan based on clinical information obtained, which must include a diagnosis, objective goals for treatment, rationale for the medication, planned duration of treatment, and steps for follow up. (OAC § 4731-11-14(B)(5));

- Physicians must have a discussion with the patient regarding the risks and benefits of the medication, including risks for addiction and overdose. (OAC § 4731-11-14 (B)(6));

- For patients being treated with opioid analgesics at doses below fifty (50) morphine equivalent dosage (MED) per day, ***physicians must provide periodic follow-up assessment and documentation of the patient's functional status***, the patient's progress towards treatment objectives, ***indicators of possible addiction, drug abuse or drug diversion***, and the notation of any adverse drug effects. (OAC § 4731-11-14(F));

- For patients being treated with opioid analgesics at doses at or above fifty (50) MED per day, the physician must complete and document certain information no less than every 3 months, which includes: (i) a review of any complications or exacerbation of the underlying condition causing pain through appropriate interval history, patient examination, appropriate diagnostic tests, and specific treatments to address the findings; (ii) assessment of patient's adherence to treatment including any prescribed non-pharmacological and non-opioid treatment modalities; (iii) *screening for medication misuse or substance use disorder via urine drug screenings based on the clinical assessment of the physician with frequency based upon*

presence or absence of aberrant behaviors or other indications of addiction or drug abuse; and (iv) *evaluation of other forms of treatment and tapering of opioid medication if continued benefit cannot be established.* (OAC § 4731-11-14(G)); and

- Pain clinics must establish and ensure compliance with 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*. (*See* O.A.C. § 4731-29-01(E)(3)).

As clearly evidenced above, Ohio law requires frequent contact and interventions between a pain specialist and patient. Urine drug screenings and frequent assessments are required to not only track a patient's progress with their treatment regiment, but also to monitor the patient for potential addiction and overdose risks. In short, Ohio law effectively requires pain specialists and physicians treating patients with opioids to perform SBIRT services (*i.e.*, screenings, interventions, and referrals for additional treatments). Further, as demonstrated above, Ohio law requires physicians to consider and implement (if necessary) non-opioid alternative treatments for patients. Accordingly, insurer policies should neither seek to limit the provision of SBIRT services nor promote opioid-based treatments over non-opioid-based treatments, as such policies would directly conflict with Ohio law.

HB 93 law sets requirements for proper pain clinic licensing and mandatory audits of pain clinics. Our program has passed several licensing inspections (86) that required most of our services as part of the licensing requirement. Ironically, the same services are being denied by the insurance providers and government regulators discussed below.

As demonstrated above, 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. (L. Margolin, D. Streem, *et al.* 2020). Deference should be given to experts in the medical field (*e.g.*, ABPMR and other licensed medical providers specializing in pain medicine) in determining the medical necessity of services (*e.g.*, NCS and SBIRT services autonomic studies and other CPMI services) for treating chronic pain patients. This multitude of failures by the insurers to promote SBIRT services (and other services aimed at reducing opioid dependence and associated risks) appear far from accidental to the point they could be deemed motivated purely by unjustified financial objectives, which put vulnerable members at risk.

Federal Guidelines and Guidance Supports SBIRT and NCS for Treatment of Chronic Pain Patients

Utilization of SBIRT services and NCS, autonomic studies and other services. for treatment of chronic pain patients is also supported by federal and state guidance, which insurer policies often fail to appropriately consider. CMS issued guidance regarding both SBIRT (CMS 2022) and NCS services (CMS 2019). Further, the Ohio Automated Rx Reporting System (OARRS) Manual, which sets forth certain requirements for Ohio-based prescribers, requires consultations and assessments with patients that are being treated with opioids based on their NARX scores. (State Medical Board of Ohio 2019). The higher the NARX score, the more frequent the need for consultations and assessments. Accordingly, pain clinics and pain specialists treating vulnerable, high-risk chronic pain patients would need to perform frequent consultations and assessments to meet this requirement.

In addition to the above requirements, national and state guidelines require documentation of the organic pathology as part of a comprehensive evaluation in a pain management clinic. By way of example, Mayo Clinic Proceedings 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 "[t]he predominant reason for inappropriate care was a failure of the prescribing physician to adequately verify patient's prior medical history."

(Chantal Berna 2015).Autonomic (SSR, RSW, NCV/EMG) testing is a 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 impact on the proper choice of medications, proper procedures for chronic pain patients, and strongly associated with functional improvement and pain reduction.(DEA 2020).Using Pain Assessment and Documentation Tool (*see* **Figure 3** – PADT) and other validated assessment tools, these services demonstrate a statistically significant impact 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 – Comprehensive Pain Management Institute, LLC (CPMI) – has been able to identify patients in need and refer more than 2,000 high-risk patients to addiction medicine evaluation and treatment who would otherwise be at significant risk of opioid mortality, morbidity, diversion, and incarceration.

Evidence-based literature supports the use of autonomic studies (SSR/ PSW) for Treatment of Chronic Pain Patients

Scientific studies have consistently shown that autonomic nervous system function is disturbed in chronic pain patients (Bruehl and Chung, 2004). Acute pain also impacts the autonomic nervous system in predictable and measureable ways (Koenig, 2014). In chronic pain, the balance between the two branches of the autonomic nervous system is disturbed, such that the sympathetic branch excessively dominates over the parasympathetic, resulting in all the negative long-term effects of low HRV (Tracy, LM, Ioannou L, et al., 2016). The relationship between the autonomic nervous system and both chronic and acute pain has important implications for the complete medical treatment of chronic pain.

As Koenig outlined in his 2013 review paper on the topic, "The systems controlling cardiovascular function are closely coupled to systems modulating the perception of pain (Randich and Maixner, 1984) and extensive interactions between the neural structures involved in pain sensation and autonomic control can be observed (Benarroch, 2001; Benarroch, 2006)." Koenig further stated in his 2016 review that, "The functional interaction of these systems is an important component involved in the endogenous modulation of pain, and there is strong evidence that the functionality of these networks is altered in patients with chronic pain" (Koenig J et al, 2016). Indeed, a recent study using simultaneous HRV and fMRI showed that bodily pain does in fact induce pain- processing brainstem nuclei to function in concert with autonomic nuclei in the production of the observed cardio-vagal pain response (Sclocco R, 2016).

Koenig's 2016 systematic review and meta-analysis, the most extensive review of the current evidence, concluded that chronic pain patients had significantly lower heart rate variability than healthy controls (Koenig J et al, 2016) and a separate experimental study the same year again confirmed this conclusion (Koenig J, Loerbroks A, 2016). Another study of 6,783 individuals published in 2018 likewise found that "beyond effects of age, sex and body mass index, the CP [chronic pain] group displayed significantly lower HRV" than the control group (Bruehl S, Olsen RB, et al., 2018).

Numerous studies have shown the relationship between HRV, as a measure the balance between the parasympathetic and sympathetic branches of the ANS, and the body's experience of, and response to, pain. Both the sympathetic and parasympathetic nervous systems are intimately involved in the body's pain regulation system. The balance between the two branches is disturbed in chronic pain such that the sympathetic branch excessively dominates over the parasympathetic, resulting in negative long term effects (Tracy, LM, et al., 2015).

Chronic pain, via its correlation to sympathetic dominance, is therefore associated with reduced heart rate variability. Study results suggest that patients with chronic pain also have decreased parasympathetic activity when compared to controls and that these alterations in the ANS's effects on the CV system "influence the central processing and subjective experience of pain" (Tracy, LM, et al., 2015). Notably,

regions of the brain that control the autonomic nervous system and those that control pain regulation lie in close physical proximity (Bruehl and Chung, 2004).

Reduced HRV has also been reported in numerous studies on chronic pain itself, as well as in studies looking at ANS responses to acute pain. Following up on this correlation, an investigational study found that reducing pain improves heart rate variability, indicating improved ANS balance with improved pain control (Koenig, et al., 2015).

The applications of HRV measurement in pain management are many. HRV is a sensitive quantitative measure of the body's experience of pain. When used as a monitoring tool, i.e. before and after changes in medications or other treatments, HRV can act as a quantitative indicator of pain level change with treatment. HRV also has tremendous potential to help evaluate pain in patients who cannot communicate well, such as very young children and those who have suffered stroke, trauma or degenerative CNS disease.

Federal and Ohio State Guidelines and Guidance Support Regular Office Visits (E/M codes and modifier 25) and Pain Management Procedures Use for Treatment of Chronic Pain Patients

1. Ohio law sets stringent requirements for pain management clinics and physicians who prescribe controlled substances as part of their pain management services. CPMI has met each of these requirements, including the rigorous licensure process to obtain a Category III Terminal Distributor of Dangerous Drugs ("TDDD") license, which is required for any practice seeking to possess and/or distribute Schedule I-V controlled substances or other dangerous drugs.[2]
2. Significantly, 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. 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).[3] 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 has a high to extremely high-risk NARX score, meaning they are at extreme risk and must be closely monitored during treatment.[4]
3. Ohio law also mandates that physicians continuously monitor their patients utilizing high levels of opioids due to the heightened risk of addiction, substance abuse, and overdose with opioids.[5] A physician who 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.[6] Appropriate and required monitoring includes assessments and discussions with the patient regarding the benefits and risks of their medication

[2] *See* Ohio Rev. Code § 4729.552.

[3] *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).

[4] *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).

[5] *See* OAC § 4731-11-14.

[6] *See* OAC § 4731-11-14(B).

treatment plan.[7] The physician is also required to discuss the patient's responsibility to appropriately store and dispose of the prescribed opioids.[8]

Reassessments are also required whenever a patient is on a continuous course of treatment with opioids at or above 50 morphine equivalent daily dose ("MED").[9] In such circumstances, the physician must continuously review the patient's response/adherence to the treatment and screen the patient for opioid misuse.[10] Such screenings must occur noless than once every three months.[11]

4. For all of the evaluation and management ("E&M") services reviewed, that provider has billed a medically necessary E&M visit was performed and appropriately documented. In cases where a procedure (e.g., injection for pain management) was performed, the E&M visit note documents work performed above and beyond the usual pre- and post-procedure evaluations. The patients required and received an evaluation of their multi-body systems, screening for non-compliance, required risk/benefit assessment for opioid prescriptions, and Ohio Automated RX Reporting System ("OARRS") review.
5. Pain management procedures (including the ultrasound guided and X ray guided procedures) are required as opioid alternative treatments. Implementation of such alternatives is one of the requirements of the Ohio pain management clinic license and HB 93 law (39, 65, 83).

Potential Risks from Insurer Policies that Deny SBIRT and/or NCS, Autonomic Studies, office visits, pain management procedures and other Chronic Pain Patients Services

Denying coverage for SBIRT or defining the services as "Unallowable costs" can pose serious compliance issues for pain practices pertaining to governmental requirements and the professional guidelines described above. Ultimately, insurer denials of SBIRT services make the ethical operation of pain practices impossible and places both patients and staff at considerable risk. These procedures include: (i) face-to-face time spent by physicians and nurse practitioners for more than 30 min of telecommunication video to conduct a structured review of several assessments (including patient's history and physical examination); (ii) PADT; (iii) COMM; (iv)completion of withdrawal assessment forms; (v) point of care and conformation urine and saliva drug screen reviews; (vi) OARRS reviews; and (vii) provision of certain educational materials pertaining to opioid treatment. Moreover, initial evaluations of a chronic pain patient often require additional assessments (*e.g.*, SOAPP-R and ORT) and provision of additional educational materials pertaining to opioid-based treatments.

Denying appropriate testing and screening procedures for drugs and alcohol (which are required by the state and national guidelines) not only significantly impacts a pain program's ability to function as a business, but also puts an extremely vulnerable patient population at risk. Insufficient testing, monitoring, SBIRT screening and lack of alternatives to opioid medications can potentially result in either: (i) prescribing opioid medications to inappropriate candidates, which can increase risk of overdose or

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[7]*See* OAC § 4731-11-14(B)(6)(a)).

[8]*See* OAC § 4731-11-14(B)(6)(b)).

[9]*See*OAC § 4731-11-14(G)).

[10]*See* OAC § 47311-11-14(G)(6)).

[11]*See* OAC § 47311-11-14(G)).

diversion; or (ii) failing to prescribe appropriate dosages/quantities of pain medications to patients, which could lead the patients to searching for alternative "street" drugs with morbidity/mortality significant risks. Moreover, the cost of hospitalization (including ER, inpatient care, ICU, detoxification, and maintenance programs) is astronomic, but can be reduced by patient screenings and non-opioid treatments (such as provided by CPMI) in outpatient programs like CPMI. Importantly, this approach of frequent screenings and preference of non-opioid treatments complies with the 5-Point Opioid Strategy to reduce opioid-related deaths launched by the U.S. Dept. of Health and Human Services in 2017. (HHS 2017).

III. EXAMPLES OF OTHER INAPPROPRIATE INSURER POLICIES

Failure to credential qualified providers and blocking beneficial services/treatments.

In addition to the issues with CareSource (the largest Ohio Medicaid HMO) described above, CPMI has faced credentialing issues with Molina (the second largest Medicaid HMO in Ohio). Since 2019, Molina has continuously denied credentialing for CPMI providers, which provide pain management services to high-risk patients in one of the epicenters of the Ohio opioid epidemic. Franklin County, which CPMI serves, has one of the highest opioid overdose death rates in the state with a rate of 19.43 per 100,000 people. (ONDCP 2015).

Insurer failure to credential qualified pain providers in an epicenter of the opioid epidemic places an unjustified risk to patients' safety, health, and lives. Such failure could cause increases in preventable opioid-related deaths, crime, family violence, drug-related human trafficking, increased medical expenses related to hospital stays/ICU/ER/detox programs, and drug-related motor vehicle accidents. Additionally, there is additional cost to treat other medical problems related to opioid use (*e.g.*, Hepatitis C cases are spiking with more than 15,000 people dying annually).

As discussed throughout this article, SBIRT services and non-opioid treatments (*e.g.*, NCS) are vital to combating the opioid epidemic. However, Molina's policies have blocked access to SBIRT services and NCS treatment, which place high-risk (predominantly minority) patients at increased risk of opioid overdose. Ultimately, the current, unjustified focus on meeting financial objectives as means to save limited Medicare and Medicaid resources has led to exacerbating results for the opioid epidemic, including potential increased risk to overdose, opioid misuse, and conversion which would ultimately result in greater losses of resources to the Medicare and Medicaid programs.

Focus on unjustified financial objectives over policies that combat the opioid epidemic.

Insurer policies that typically deny payment for NCS and SBIRT services fail to properly take into consideration the potential cost-savings (and life-savings) effect such services could have on patients. By way of example, CPMI's SBIRT and NCS policy and outcomes demonstrate that such services can result in overwhelming cost savings to both the patient and the overall treatment costs billed to insurers.

CPMI's patient population is unique as compared to many of our peers. Most CPMI patients are referred to our practice for the evaluation of chronic pain in two or more extremities or have been diagnosed with peripheral neuropathy, lumbar, or cervical radiculopathy by the referring provider. Our patients are extremely complex and we take pride in creating individualized treatment plans, which require a significant amount of testing and screening for substance and alcohol use. However, this allows our patients to achieve an extraordinary level of function relative to managing their pain with opioids alone, without any SBIRT services and/or non-opioid treatment options. After 2011, 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 and challenging patient populations (86). Many of these chronic pain patients seen by CPMI suffer from anxiety, depression, substance use disorders, and/or drug-seeking behavior.

The numbers of NCV/EMG, autonomic and other tests performed at our practice are based on the OH local coverage determination. (CMS 2019).All patients undergo a comprehensive evaluation including initial, follow up evaluation forms, PADT forms enclosed, and extensive review of OARRS reports. The patients are also offered, and each signed, a written consent based on the AANEM guidelines with a detailed explanation of the risk and benefits of the tests. (AANEM 2022; AANEM 2023). NCV is reviewed and incorporated into the treatment plan.

In addition to lowering costs to our patients by cutting down on hospitalization costs, our practice performs the Autonomic (SSR, PSW, 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. This is another cost-reducing benefit of having these services available through outpatient facilities, such as CPMI. 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. As noted above, the drug overdose death rate in Ohio is one of the highest in the nation (rising more than 800% since 2013). The cost of the opioid epidemic is estimated as more than 500 billion nationwide. (Jeri D. Ropero-Miller 2019). CPMI runs a low-cost program that saves hundreds of thousands of dollars to Medicare by identifying and referring patients for addiction treatments using our SBIRT protocol, which ultimately cuts down on inevitable hospitalization costs and other opioid-related costs. All the insurance providers and government regulators discussed below ignored expert opinions, national academy review and independent billing and coding review available to them (83) because of the unjustified financial objectives.

Major providers in Ohio (Aetna, CareSource, Molina) inappropriately denied services because of unjustified financial objectives and bias:

Molina

Molina Medicaid HMO is the second largest Medicaid HMO insurer in the state of Ohio, and one of the biggest Medicare advantage plans in the Franklin County.

Molina HealthCare put unjustified financial objectives above vulnerable member's safety bydenying coverage for SBIRT and other life-saving services (Figure 2 – Molina denial letter). This has led to a severe limitation of patient access to certain lifesaving addiction screening and pain management care throughout Ohio (our findings show a NARX score of about 310 and a lack of access to care based on the OARSS report, including traditionally underserved mostly minority communities, like the one served by CPMI, and an increase in opioid-related mortality and death rates) please review the original patient complaints below, (68). These complaints were ignored by Molina who justified their denial of coverage as a "pure business decision". Molina leadership enjoyed exuberant salary compensation and stock bonuses with their CEO's annual salary reaching 22.1 million in 2022 (67).

In February 2022 Molina abruptly, and without warning, recouped close to 34 thousand dollars from the CPMI program. Molina's recoupment was corrected after a formal complaint and concern for legal intervention. In fact, on June 2nd, 22, Paul N St. Germain RN, the quality-of-care supervisor for Ohio, wrote the following email to Comprehensive Pain Management Institute, LLC (see attached):"Thank You Dr. Margolin, many Thanks for the GREAT (capitalized by Mr. Garmin) care that you take care of our Molina members and all of your patients!!" (68)

Four days later, Molina again abruptly and without any warning or explanation terminated coverage for this life-saving program, blocking access to SBIRT care and putting hundreds of vulnerable, mostly minority members at risk of opioid overdose death (Figure 2).

In addition, Molina refused to process the program credentialing application (Figure 3- application denial).

CareSource

In May 2015, our practice, CPMI, has voluntary invited a CareSource investigator to review CPMI's practice, policies, and patient interactions, as part of CPMI self audit policy. Notably, the CareSource investigator stated that she was impressed with CPMI's practice and everything that Dr. Margolin did to care for his patients. (65, Exhibit OO). In fact, the CareSource investigator was so impressed with Dr. Margolin/CPMI quality of care, that she directed referrals for pain management services from other CareSource-enrolled providers to CPMI (Id.)

Despite this positive review, driven by unjustified financial objectives, CareSource kept denying services and inappropriately withholding payments.

CPMI, has submitted several business integrity complaints (71) to CareSource between 2016 and 2022 related to abrupt denial of services and unannounced recoupment attempts (70) of tens of thousands of dollars in 2016 and 2017.

We did not receive a formal response from CareSource. Rather, CareSource inappropriately denied credentialing for the CPMI program that provides life-saving services to high-risk CareSource patients in the epicenter of the opioid epidemic over more than six years (85), while hundreds of the CareSource members died in the opioid epidemic due to lack of access to these services. Many CareSource patients submitted complaints that were ignored by CareSource (69).

Aetna

Unfortunately, our experience with Aetna (as detailed below) indicates that the insurer has focused its efforts on pursuing unjustified financial objectives over implementing policies that are focused on effectively combating the opioid epidemic and prioritizing member safety.

Unpaid Aetna services:

Summarized Data			
Insurance Name	CPT Code	Line Items	Sum of Charge Amount
AETNA	76942	226	33,507.36
AETNA	64450	184	65,548.08
AETNA	99213	213	26,221.46
AETNA	93922	16	8,388.78
AETNA	95923	19	8,684.3
AETNA	95925	19	6,129.36
AETNA	64418	17	5,670.36
AETNA	33301	171	5,142.59
AETNA	99204	9	2,925
AETNA	80305	109	2,665.55
AETNA	80307	33	2,310
AETNA	20553	10	1,375
AETNA	99214	10	1,045.3
AETNA	93040	24	639.55
AETNA	27096	3	547.54
AETNA	99215	1	400
AETNA	99490	5	315.98
AETNA	80320	1	20
AETNA BETTER HEALTH OF OHIO	76942	114	23,064.52
AETNA BETTER HEALTH OF OHIO	99213	52	5,197.69
AETNA BETTER HEALTH OF OHIO	64450	27	2,458.51
AETNA BETTER HEALTH OF OHIO	93922	3	1,800
AETNA BETTER HEALTH OF OHIO	99214	7	935.98
AETNA BETTER HEALTH OF OHIO	95923	2	240
AETNA BETTER HEALTH OF OHIO	95924	2	700
AETNA BETTER HEALTH OF OHIO	99204	2	561.93
AETNA BETTER HEALTH OF OHIO	64405	1	460
AETNA BETTER HEALTH OF OHIO	80305	20	430.31
AETNA BETTER HEALTH OF OHIO	64418	1	400
AETNA BETTER HEALTH OF OHIO	80307	7	351.41
AETNA BETTER HEALTH OF OHIO	20553	3	375
AETNA BETTER HEALTH OF OHIO	33301	25	280.18
AETNA BETTER HEALTH OF OHIO	27096	1	250
AETNA BETTER HEALTH OF OHIO	93040	1	133.5
AETNA BETTER HEALTH OF OHIO	99490	2	107.94
AETNA BETTER HEALTH OF OHIO	80320	2	40
Grand Total		1346	258,891.28

Total Charges $ Claims	
No Of Claims	Charge Am
478	258,891.2

On December 25, 2022, CPMI submitted a formal complaint to Aetna. It had been brought to CPMI's attention that Aetna had been denying pain management procedures (even after giving authorization confirmation), requesting unreasonable amounts of records, holding reviews of standard services for 90 days or more, and inappropriately labeling standard procedures (*e.g.*, SIJ injection - first approved more than 30 years ago) as "experimental." These insurer policies focused on cost-savings inappropriately denied coverage of services, blocked patients from receiving legitimate life-saving services, and resulted in heightened risk to patient health (which were often vulnerable, high-risk chronic pain patients). The services (*i.e.*, UDT, office visits, pain procedures, and other tests) appear to have been denied across the board without a proper review or justification, as required per the Medicare Medicaid manual and applicable state and federal regulations. Aetna failed to respond to the complaint.

Even when Aetna approved services for coverage, CPMI often underwent timely record reviews (*i.e.*, often 90+ days) before payment would be remitted. These denials and delays have resulted in a severe limitation on patient access to certain addiction screenings and pain management care throughout Ohio. Such delays/denials can have a tremendously negative impact on opioid-related drug abuse and overdose in traditionally underserved, minority communities, such as Franklin County, Ohio (served by CPMI). Such communities are often impacted the hardest by the opioid epidemic. By way of example, the Franklin County Forensic Science Center issued a report in August 2022 demonstrating that the 2021 drug overdose fatality rate in Franklin County (825 deaths) had increased by 48% since 2019 (556 deaths). (FCFSC 2022).

Government regulatory agencies

In 2020, the government regulatory agencies labeled SBIRT and other chronic pain patient services as not "allowed" and issued a public press release (73). To our knowledge, no medical experts were involved in this decision. In fact, the data indicates that the government regulatory agencies were avoiding expert opinions (for example the government regulatory agencies refused to wait for the results of the review of

our program by the national academy, ABPMR), independent experts, which was published a month after the press release by the government regulatory agencies (see the white paper and exhibits) (65).

The government regulatory agencies failed to acknowledge the plethora of evidence that the national and government agencies (CDC, SAMSHA, NIDA), independent experts, and our office provided in support of the medical necessity of the lifesaving services they denied (65). The government regulatory agencies ignored a written warning about these issues sent to them in October 2020.
In a sense, the government inadvertently (and inappropriately) engaged in the practice of medicine without a license when it failed to consider all of the evidence from expert and governmental sources and disallowed SBIRT and other similar opioid alternative services.

The government regulatory agencies/insurers position has had devastating effects on pain specialists in Ohio, essentially handcuffing them from appropriately practicing pain management. Ohio law explicitly requires frequent monitoring of opioid patients (*See e.g.*, OAC 4731-11-14(F)-(G)), which creates a catch-22 with the government regulatory agencies/insurers position. We have evidence of over 100 complaints submitted by Ohio patients to Medicaid insurers regarding the lack of access to vital pain management services. *(67, 69)*

The government regulatory agencies/insurers policy has far-reaching implications, including a negative impact on opioid-related death and crime rates. While these are nationwide issues, Ohio is a key focal point of the opioid epidemic, with one of the highest death rates in the U.S. due to drug overdose for years (65). The year the government regulatory agencies /insurers published the above-cited press release regarding its settlement with CPMI, Ohio experienced a 22% increase in drug-related overdoses (77).

Ohio-based pain medicine practices have also experienced increased criminal activity from drug-seeking patients, including property destruction, attempted break-ins, and assaults on staff (80, 81). Many drug-seeking patients are lashing out due to a lack of access to appropriate pain management services.

So long as the government regulatory agencies/insurers continue to target pain specialists by limiting their ability to provide medically necessary services to pain patients, the opioid-related death and crime rate will continue to rise, and our society will continue to face negative implications from the opioid epidemic.

Covent Bridge

Covent Bridge is a contractor for Medicare, which is supposed to educate providers and enforce compliance. They have a clear financial incentive to deny services or label them as "not allowable" or "not necessary" since this increases the Covent Bridge reimbursement and bonus structure.

In 2021 Covent Bridge sent us an "educational letter" labeling most of the program services including urine drug screens, office visits, and screening for drug and alcohol (which are required by the state and federal guidelines) as "not medically necessary" or "not covered". When we contacted Coven Bridge it turned out that the review was performed by a former insurance agent with no medical background and subsequently by a RN with no background in pain management or addiction services. No appropriately educated/trained/experienced medical expert was involved. The reviewers had no basic understanding of the life-saving services they denied and the "catch 22" the denial created in regard to state and federal regulations/guidelines. (77)

We submitted a detailed complaint to the Covent Bridge legal advisor but to no avail. In 2024 Covent Bridge expanded their "not medically necessary" or "not covered" services to 92% of the services provided in our practice (78).

IV. CONCERNING INSURER POLICIES HAVE THE POTENTIAL TO SINGLE OUT MINORITIES

There are multiple concerns raised about racial disparity and social injustice in context of the opioid crisis. (PBS 2023). Specifically, there are significant concerns related to minority populations being subject to policies and practices which unjustly deny SBIRT and other essential services. On many occasions, these denials may be made in disregard to the proper review process specified in the Medicare integrity manual. Denials may be made without adequate expert review by a medical specialist (or with no expert review at all). Consequently, the opioid mortality rate for minorities is growing significantly larger than the national average (*i.e.*, 2.6 times higher in Ohio. *see* Figure 1).

Notably, Case Western Reserve University, Board of Health of Cuyahoga County scheduled a conference on the Racial Disparity, Social Justice and the Opioid Crisis Conference at Case Western Reserve University in April 2020. (Case Western Reserve University 2020). The conference focused on addressing the issue of structural racism, which prevents communities of color from receiving the necessary treatment, recovery, and wrap around social services to combat opioid use disorders. Similar concerns pertaining to racial disparity were acknowledged and reviewed in our presentations at Case Western Reserve University (Leon Margolin 2019) and the Ohio Opioid Task Force. (Leon Margolin 2020).

Further, as discussed during the Case Western Reserve University meeting, audits and supervision are necessary to combat the opioid crisis. Case Western Reserve University 2020. However, simultaneously, there are excessive regulations that interfere with the efficient function of the pain clinics (*i.e.*, the "first responders" in the opioid crisis).

V. CONCERNING INSURER POLICIES REPRIORITIZE RESOURCES AWAY FROM PRACTICE OPERATIONS, POTENTIALLY RESULTING IN PROVIDER SAFETY RISKS

A recent survey by the American Academy of Pain Medicine found high rates of violent threats toward pain practitioners. (AAPM 2020). Per the survey, more than two-thirds of responding pain providers reported that a patient had threatened them physically at least once a year, and roughly half reported that they had been threatened regarding their management of opioids. Moreover, the survey found that 8.9% or responding pain providers reported that they had actually been physically attacked.

By way of example, our practice has suffered from property damage, threats to the staff, and most recently an unprovoked assault of a physician and two female medical assistants by a violent patient with aberrant drug seeking behavior. Unfortunately, many pain practices lack the funding to appropriately address these rising security concerns. In fact, during the investigation related to assault of our staff members, 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." These rising security risks to pain providers and their staff is yet another example of why a different approach to combating the opioid epidemic is necessary.

Each insurance plan creates several-hundred-page regulations that are ambiguous, convoluted, and different from the regulation of another insurance plan. Moreover, the insurer rules and regulations are not fully applicable to the reality facing pain management clinics. This is doomed to increase denial of services that can potentially save the lives of vulnerable patients without involving an expert, medical director or applying clinical judgment. Our practice is credentialed with 11 different plans which makes

adhering to the ongoing changes of requirements for each plan a stagnant daunting task and causes denial of essential services by the insurance plans.

Management of high-risk patients is frequently performed in a private practice setting. In contrast to more typical compensation arrangements for hospitals, private practices get neither government assistance nor grants, and receive much lower reimbursements for the same services (CPT codes). For example, CPT 62311, an interlaminar or caudal epidural steroid injection, when performed in a hospital surgical care center, can be reimbursed by government insurance at between $1,200-1,400 . The same injection given at a private practice setting is reimbursed at $80 only. Remarkably, despite receiving much lower reimbursements, private practices must still compete with hospitals in hiring, offering competitive salary and benefit packages, and retaining quality staff.

In 2017, the U.S. Dept. of Health and Human Services announced its "Strategy to Combat Opioid Abuse, Misuse, and Overdose: A Framework Based on the Five Point Strategy." (25) One of its five focal points is the development and enhancement of pain management programs. One wonders how such commendable goal can be accomplished by retaining patently flawed insurance company policies and government regulations that achieve the opposite result.

Some insurance plans use sophisticated software based on the frequency of services and sometimes compares codes to a specialty average and other criteria. Pain Management and opioid medication programs are highly specialized tertiary facilities that cannot be compared to other practices in the same specialty that do not prescribe opioids or do not manage high-risk patients (testing and assessment frequency are defined by the patient risk for opioid misuse, such NARX score, ORT, SOAPP-R, COMM, and clinical judgment). It is unreasonable to use these programs without proper clinical judgment by an independent expert.

Further, manipulation of the regulatory framework by insurers and government regulators, results in a significant negative impacts on of the opioid crisis. (*See* Figure 1.) The current regulatory and legal system creates legal loopholes and practically exempts the insurance policy makers and government regulatory agents from any personal or financial liability towards the physicians or victims of opioids.

We have documented evidence of abusive behavior by the insurance managers toward the staff and patients, such as ignoring and dismissing valid patient complaints (67,69) abrupt unannounced fund recoupment and defunding life-saving services (70), or denial of one week extension to pull the paper charts from storage while maintaining COVID precautions for a high-risk manager which resulted in the manager's hospitalization.(84)

Small to mid-size private practices (like CPMI) that carry limited legal resources and budgets are frequently "soft targets" for denials, flawed overpayment demands, false labeling of life-saving services as unnecessary, and other abusive actions motivated by bias and unjustified financial objectives.

CONCLUSION

Insurer policies have had far-reaching implications in the ongoing opioid crisis. Ohio is a key focal point of the opioid epidemic, having one of the highest annual death rates in the United States over the past decade due to drug overdose. Unfortunately, current insurer and government regulatory agencies policies in Ohio appear to be contributing to opioid-related death toll and crime rates. While there are viable screening and treatment options (e.g. SBIRT, urine drug screening, and other screening and treatment options at the CPMI program) that could greatly benefit high-risk chronic pain patients, insurers often

deny such services and treatment options as not medically necessary. This article focuses on potential policy updates (*i.e.*, covering SBIRT and services and testing for screening and treatment of chronic pain patients on opioid medications) that could not only decrease treatment costs to patients and healthcare programs, but significantly mitigate the impact of the ongoing opioid epidemic. Academic/expert evidence and CPMI's own experience indicates that SBIRT and NCS services could potentially lower opioid dependence and abuse, which could potentially result in decreased opioid reliance, overdose, crime rates, motor vehicle accidents, domestic violence, divorce, child abuse, and human trafficking.

Until action is taken, current insurer policies in Ohio (and out of state) that deny SBIRT and viable opioid-screening and treatment options will continue to subject the most vulnerable, high-risk chronic pain patients (*i.e.*, patients with NARX scores equal or greater than300) to increased risks of opioid abuse, overdose, and conversion. Failure to adequately address these issues will impact high-risk minority groups at a much higher rate than the national average, leaving impoverished areas battling increased rates of opioid-related mortality and crime. It is patently clear that insurers must shift their focus from unjustified financial goals to solutions that are supported by academic findings, pain specialist clinical judgments, and the plethora of governmental (state and federal) guidance that promote screening (*i.e.*, SBIRT, UDS, SOAPP-R, COMM, etc.), testing (NCS, imaging), and opioid alternative treatment options. The importance of this shift is only further supported by the significant increase of the illicit Fentanyl use in the United States. The number of individual pills containing fentanyl seized by law enforcement was 2,300 times greater in 2023 compared to 2017, with 115,562,603 pills seized in 2023 vs. 49,657 in 2017. (79).

In 2022 alone, over 107,000 people died of a drug overdose (82), with 75% of those deaths involving an opioid.

We call for urgent legislative or executive action that will prescribe reasonable "checks and balances", legal and regulatory accountability, and require the establishment of an independent pain medicine or addiction medicine expert review before denial of these services. Such action will save tens of thousands of lives and billions of healthcare dollars annually.

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75. Humphreys K, Shover CL, Andrews CM, et al. Responding to the opioid crisis in North America and beyond: recommendations of the Stanford-Lancet Commission. *Lancet.* 2022;399(10324):555-604. doi:10.1016/S0140-6736(21)02252-2
76. The Consortium Pain Task Force White Paper: https://dpbh.nv.gov/uploadedFiles/dpbhnvgov/content/Resources/opioids/Evidence_Based_Non pharmacologic_Strategies_for_Comprehensive_Pain_Care_White_Paper.pdf

77. CPMI letter to CoventBridge 2021: https://cpmiohio.com/wp-content/uploads/2024/05/Letter-to-CoventBridge-2021.x68908.pdf
78. CPMI letter to CoventBridge 2024: https://cpmiohio.com/wp-content/uploads/2024/05/Letter-to-CoventBridge-Feb-24.x68908.pdf

79. NIH press release May 13, 2024: https://www.nih.gov/news-events/news-releases/over-115-million-pills-containing-illicit-fentanyl-seized-law-enforcement-2023

80. Evidence of high risk patients aggressive behavior: https://cpmiohio.com/wp-content/uploads/2024/06/High-risk-patients.x92936.pdf

81. Survey Finds High Rate of Violent Threats Toward Pain Practitioners:

https://www.painmedicinenews.com/Multimedia/Article/05-20/Survey-Finds-High-Rate-of-Violent-Threats-Toward-Pain-Practitioners/58619?utm_source=Social&utm_medium=facebook&utm_campaign=0615violentvid

82. 2022 Opioid mortality (CDC press release): https://www.cdc.gov/nchs/products/databriefs/db491.htm

83. CPMI Independent Billing and Coding review (mdbillingky.com): https://cpmiohio.com/wp-content/uploads/2020/12/Billing-and-coding-review.x92936.pdf
84. CPMI Manager Amanda Rutherford letter to CovenBridge: CPMI-manager-Amanda-letter-to-CoventBridge.x88572.pdf (cpmiohio.com)
85. Evidence of CareSource application denial: Margolin-Letter-to-CareSource-re-Credentialing-Status-4874-4318-7492v1.x79175.pdf (cpmiohio.com)
86. CPMI Pain Management Clinic category 3 license based on Ohio law: https://cpmiohio.com/wp-content/uploads/2024/06/CamScanner-06-14-2024-12.51.x28381.pdf

June 7, 2022

Comprehensive Pain Management Institute, LLC
5340 E. Main Street, Ste. 100
Columbus, OH 43213

Re: *Termination of Provider Services Agreement Without Cause*

Dear Comprehensive Pain Management Institute, LLC:

Pursuant to Section 4.2, Termination Without Cause, of your Provider Services Agreement between Molina Healthcare of Ohio, Inc. and Comprehensive Pain Management Institute, LLC ("Agreement"), Molina Healthcare of Ohio, Inc. is terminating your Agreement without cause.

The Agreement will be terminated ninety (90) days after receipt of this letter, and shall be effective September 6, 2022.

If you have any other questions, please contact Brad Bryant at brad.bryant@molinahealthcare.com.

Sincerely,

Brad Bryant
Director, Provider Contracting

December 1, 2023

Leon Margolin, MD
Comprehensive Pain Management Institute LLC
1120 Polaris Parkway, Ste 202
Columbus, OH 43240

Dear Leon Margolin:

Molina Healthcare of Ohio has received your application for participation in our provider network. We regret to inform you that we will not be processing your application at this time.

Should you have any questions or concerns, please contact me at 614-540-3223 or by email at Toni.Hopewell@molinahealthcare.com

Sincerely,

Toni Hopewell
Molina Healthcare of Ohio, Inc