Balancing Safe and Effective Opioid Management to Treat Pain in 2023

Michigan Osteopathic Association

David R. Neff, DO
Associate Clinical Professor, MSUCOM
Former Chief Medical Director, Michigan Medicaid (Retired)
Former Medical Strategy Leader, Merck Global Medical Affairs (Retired)

Founding Member, MOA Safe Opioid Task Force
Founding Member, Michigan Health Society Safe Opioid Collaborative
Educational Requirements – MI LARA Pain Management & US DEA MATE Act

• This program meets 1.0 of 3.0 hours required by MI LARA for pain & symptom management

• It also meets 1.0 of 8 hours required by the US DEA to meet requirements of the Medication Access and Training Expansion (MATE) Act noted in Section 1263 of the ‘Consolidated Appropriations Act of 2023’
  • DEA license registrants are required to have completed a total of at least 8 hours of training on opioid or other substance use disorders, as well as the safe pharmacological management of pain

• This program complements the 1.0 hour program titled “Harm Reduction Services Update” by Pam Lynch, LMSW, CAADC which also qualifies for both MI LARA and MATE requirements noted above for a total of 2.0 hours.
Primary Goal: Help the Provider to Balance Effective Pain Management When Using Opioids While Mitigating Overdose Risk, Diversion, Misuse and Abuse
Objectives

This 90-minute presentation is intended to help the health care provider put principles of opioid management into daily practice by:

1. Better understanding America's Opioid Ecosystem in 2023 in how opioids are used, misused, abused or diverted
2. How to effectively manage opioids for acute and chronic pain without abandoning the pain refugee
3. How to minimize risk for diversion, misuse and abuse
4. How to effectively identify and manage opioid and polysubstance use disorder with medications to treat opioid use disorder (MOUD)

Desired result

1. Increase provider confidence in managing pain with opioids as needed while mitigating risk for overdose, diversion, misuse or abuse but not abandoning the "pain refugee" who cannot get access to care
2. Increase willingness and ability to identify opioid use disorder (OUD) and ensure a pathway to effective therapy
3. Increase provider willingness to help reverse the ongoing opioid mortality crisis over the last 2 1/2 decades

Housekeeping Chores

1. Most slides are hyperlinked to their source documentation and can be selected from the slide directly to the URL for further information
Topics – Examining 11 Interrelated Key Themes

1. The Challenges That Impact Ability to Appropriately Manage Opioids in 2023
   Go Back At Least Six Millenia
2. The Overdose Landscape in 2023
3. What’s Happening with Current Prescription Trends and Rates of Patient Misuse
4. What’s Being Done to Combat Trafficking of Illicit Synthetic Opioids (ie, Fentanyl)
5. What’s Being Done in 2023 to Curb Addiction, Overdose and Other Harms
6. The Negative Impact to “Legacy” Pain Patients Already Taking Chronic Opioids
7. The Impact of Sedatives, Alcohol and Stimulants With and Without Opioids
8. Weighing Benefit and Risk When Prescribing Opioids
9. Introducing the 2022 CDC Pain Guidelines
10. Approaches to Treat Acute and Chronic Pain in 2022
11. Approaches to Enhance Medical Documentation, Communication and Coordination of Care
1. The Challenges That Impact The Ability to Appropriately Manage Opioids in 2023 Go Back At Least Six Millenia
The Controversy About Opioid Use is Over 6000 Years Old

~5700 BC
- Archeological Evidence of Poppy Seeds and Opium Were in Use in Italy & Iberia (which is now Spain, Portugal, South-western France)
- Eased pain
- Created Euphoria
- Decrease anxiety
- Induced Sleep
- Eased Diarrheal Diseases

1880's
- Early discoveries - Morphine (1804) & Codeine (1832) isolated from opium
- Opium Wars (1839 & 1856) – China leases Hong Kong to the UK to stop opium trading
- Laudinum (a mixture of opium, wine and spices) used to treat pain during the Civil War
- Later discoveries - Heroin (diamorphine) (1874)

1900's
- More potent semi-synthetics and synthetics emerged
- These include ultrapotent fentanyl (1959), buprenorphine (1972), most potent carfentanil (1974)
- The Controlled Substances Act (CSA) of 1970 relaxed the harshness of the Harrison Act (1970)
- NEJM publishes an editorial stating that narcotics do not cause addiction in pain patients (Jan 1980)
- Oxycodone Approved by the FDA (1995)
- The Food & Drug Modernization Act (FDAMA) (1997) was passed to better cope with advancing technical, trade and public health issues

2020-2023
- Opioid deaths reach an all-time high largely driven by illicit fentanyl from China through Mexico
- Opioid Rx's drop to 2000 prescribing levels
- Over ½ of chronic pain patients cannot get access to care
- The updated 2022 CDC Guideline (to be released Fall 2022) focuses on patient centered care & restates the original purpose of how it should and should not be used
- X-waiver program retired to allow more prescribers to provide MAT (MOUD) – The MATE Act of 2022

460 BC – 1700's AD
- Multiple Purpose Use in the Mediterranean & Middle East – Medicinal, Recreational, Religious & Economic
- The British East India Tea Company traded opium in China to balance deficits (1683)

2000 - 2020
- Pain Declared as the 5th Vital Sign Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), no "upper limit" (2000)
- Overdosed Deaths Started Being Identified with Increase Prescription Rates (2001-2011)
- Opioid Prescriptions Peaked as Opioid Deaths Increased (2011)
- Heroin Deaths Increased and Illicit Fentanyl Arises as Prescription Rates Fall (2013)
- Fentanyl-related Deaths Begin to Outpace Heroin and Prescription Opioid Deaths (2015)
- CDC Chronic Pain Guidelines Emerge and Inadvertently Became the Yardstick For Regulators (2016)
- Chronic Pain Patients Begin to Lose Access to Care

2000
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Early 1900's
- Heroin addictions began to soar leading to the Harrison Narcotics Tax Act, the first opioid control legislation in the U.S.
- The industrial age and world war accelerated demand for newer agents
- ~150 synthetic opioids developed to improve pain relief without causing dependence, none found
- Discoveries included oxymorphone (1913), oxycodone (1916), hydrocodone (1920), hydromorphone (1924), meperidine (1932), and methadone (1937)

Mid to Late 1900's
- More potent semi-synthetics and synthetics emerged
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- The Food & Drug Modernization Act (FDAMA) (1997) was passed to better cope with advancing technical, trade and public health issues
The Ongoing Conundrum in 2023

- Illicit Fentanyl-Related Deaths Reach an All-time High
- The Number of “Pain Refugees” Who Truly Need Relief Has Grown Due to Restrictive Access to Care
The Ability to Provide Adequate Pain Relief When Using Opioids is Confounded by the Unchecked Number Deaths Related to Illicitly Manufactured Fentanyl and Stimulants
2. The Overdose Landscape in 2023
The Overdose Landscape for 2023: U.S.
Based on data available for analysis on: April 2, 2023

12 Month-ending Provisional Counts of Drug Overdose Deaths: United States

12 month ending period: January 2015
Reported number of deaths: 47,523
Predicted number of deaths: 48,126

12 month ending period: November 2022
Reported number of deaths: 103,550
Predicted number of deaths: 108,712

- 215% Higher Than in January 2015
- -4 % Higher Than the Previous 12 months

12 Month-ending Provisional Number of Drug Overdose Deaths by Drug or Drug Class: United States

12 months-ending April 2023 (Predicted)
All opioids 82,224
Fentanyl-Related 74,507
Amphetamines 34,135
Cocaine 27,529
Prescription Opioids 11,945
Heroin 6,143
Methadone 3,346

The Overdose Landscape for 2023: Michigan
Based on data available for analysis on: April 2, 2023

12 Month-ending Provisional Counts of Drug Overdose Deaths: Michigan

12 month ending period: January 2015
Reported number of deaths: 1,796
Predicted number of deaths: 1,798

12 month ending period: November 2022
Reported number of deaths: 2,721
Predicted number of deaths: 2,913

161% - Higher Than 1/1/2015
-6% - Over Last 1 Year

12 Month-ending Provisional Number of Drug Overdose Deaths by Drug or Drug Class: Michigan

12 months-ending April 2023
(Predicted)

- All opioids 2,358
- Fentanyl Related 2,358
- Cocaine 1021
- Amphetamines 480
- Prescription Opioids 312
- Heroin 163
- Methadone 86
The Overdose Landscape for 2023: Comparison Across States

Based on data available for analysis on: April 2, 2023

Percent Change in Predicted 12 Month-ending Count of Drug Overdose Deaths, by Jurisdiction:
November 2021 to November 2022

Legend for Percent Change in Drug Overdose Deaths Between 12-Month Ending Periods

-19.2 23.7

Select predicted or reported number of deaths

- Predicted
- Reported

Michigan
Predicted Cases, November 2022: 2,913
Predicted Cases, November 2021: 3,090
Percent Change: -5.73%
*Underreported due to incomplete data.

Percent Change for United States

0.6

3. What’s Happening with Current Prescription Trends and Rates of Patient Misuse
Per capita prescription opioid use continues to decline to levels seen in 2000, however overdose deaths continue to rise

Exhibit 18: Prescription opioid use overall and opioid-involved overdose deaths

Source: IQVIA Xponent, IQVIA National Prescription Audit, Sep 2022; IQVIA Institute, Mar 2023; National Institute on Drug Abuse, Feb 2023.
Most Chronic Pain Patients Don’t Misuse Opioids

Of chronic pain patients prescribed opioids

- 65% have never misused medication
- 10% have an OUD
- 25% have misused medications

4. What’s Being Done in 2023 to Combat Trafficking of Illicit Synthetic Opioids (ie, Fentanyl)
Commission on Combating Synthetic Opioid Trafficking

Final Report

The United States Senate
The United States House of Representatives
The Office of National Drug Control Policy
The Drug Enforcement Administration
The Department of Homeland Security
The Department of Defense
The Department of the Treasury
The Department of State
The Office of the Director of National Intelligence

Published February 2022 - Posted on RAND.org on February 08, 2022

URL: http://www.rand.org/hsrd/hsoac/commission-combating-synthetic-opioid-trafficking
Current Challenges In 2023

These challenges include --

1. Serious geopolitical issues significantly impede actions to disrupt supply
   • Fentanyl trafficked from Mexico with raw materials coming from China

2. Synthetic opioids are highly potent and easy to make, and small amounts can be transported for large profits

3. Social media and encryption platforms, as well as established logistics systems, make distribution difficult to disrupt

4. The pull of demand continues to drive the supply of synthetic opioids
   • The advent of synthetic opioids in pill form leverages Americans’ familiarity with taking pills and does away with the social stigma of injection, snorting, and smoking.
   • It is being laced into heroin or manufactured as counterfeit tablets, including such brand names as OxyContin, Percocet, Vicodin, Adderall, and Xanax, driving overdose deaths.

5. External factors, including the coronavirus disease 2019 (COVID-19) pandemic, have driven increases in substance use

6. Overall, synthetic opioids offer economic and tactical advantages that allow criminals to vastly outpace enforcement efforts

URL: http://www.rand.org/hsrd/hsoac/commission-combating-synthetic-opioid-trafficking
New Challenges Call For a New Response

The United States must --

1. Develop a more unified, central body to coordinate planning, implementation, and evaluation of all U.S. drug policies
2. Disrupt drug supply through targeted oversight and enforcement
3. Make public health demand-reduction approaches central in the fight against opioid trafficking to reduce the number of potential buyers
4. Collaborate with other countries involved in the production and distribution of synthetic opioids and precursors
5. Improve surveillance and data analysis to allow for more timely and effective interventions

URL: http://www.rand.org/hsrdr/hsoac/commission-combating-synthetic-opioid-trafficking
5. What’s Being Done in 2023 to Curb Addiction, Overdose and Other Harms
America's Opioid Ecosystem
How Leveraging System Interactions Can Help Curb Addiction, Overdose, and Other Harms

Key Findings

• U.S. issues surrounding opioids are most appropriately viewed in the context of an ecosystem
  • Like a biological ecosystem, the opioid ecosystem is dynamic, and its components often interact.
  • Ecosystem components often focus on individuals, but families are also at the heart of the system. Each ecosystem component has its own mission, priorities, and funding; policies furthering those priorities may hamper the efforts of other system components.
• Current responses to U.S. opioid problems are insufficient—innovation is needed
  • Increasing access to and use of high-quality treatment for substance use disorder remains the top priority, but it will not be enough to stem the tide of overdose deaths and addiction.
  • The federal government should make it easier for states or localities to pilot and evaluate interventions intended to reduce harms associated with opioids and other drugs.
• It is not always clear who is responsible for coordinating among ecosystem components or managing the transition from one component to another
  • By making clear who is responsible at these junctures and providing the resources necessary to meet the commitment, some of the disconnects that hamper the provision of treatment and support could be decreased.
• The United States is often flying blind, which makes it difficult to evaluate existing interventions, develop new ones, or improve understanding of ecosystem interactions
  • Unlike many prior public health challenges, the onset of the overdose crisis has not motivated substantial new surveillance efforts.
  • The data infrastructure for understanding people who use drugs, drug consumption, and markets urgently needs improving.

The Opioid Ecosystem

- Person who uses opioids
  - Medical care
  - Criminal legal system
  - Illegal supply and supply control
- Employment
- Education
- Income support and homeless services
- Child welfare
- First responders
- Harm reduction
- Substance use disorder treatment

Federal and state policy over the last decade has sought to overcome the long-term effects of substance misuse impacting individuals, families, communities, and those charged with resource allocation.

To expand access to care, a major effort is underway to integrate therapy into primary care.

The traditional x-waiver program has been retired.

Most recently, Section 1263 of the ‘Consolidated Appropriations Act of 2023’ otherwise known as the Medication Access and Training Expansion (MATE) Act, requires new or renewing Drug Enforcement Administration (DEA) registrants, as of June 27, 2023, to have completed a total of at least 8 hours of training on opioid or other substance use disorders, as well as the safe pharmacological management of dental pain.

Practitioners can meet this requirement in one of three ways:

- A total of 8-hours of training from a range of training entities on opioid or other substance use disorders; or
- Board certification in addiction medicine or addiction psychiatry from the American Board of Medical Specialties, American Board of Addiction Medicine, or the American Osteopathic Association; or
- Graduation within 5 years and in good standing from a medical, advanced practice nursing, or physician assistant school in the United States that included successful completion of an opioid or other substance use disorder curriculum of at least 8 hours. This curriculum must have included teaching on the treatment and management of patients with opioid and other substance use disorders, including the appropriate clinical use of all drugs approved by the Food and Drug Administration for the treatment of a substance use disorder.

The 8 required hours of training can occur through classroom situations, seminars at professional society meetings, virtual platforms, or via other accredited continuing education sources. Practitioners who previously took training to meet the requirements of the DATA-2000 waiver to prescribe buprenorphine can count this training towards the 8-hour training requirement. Additionally, the 8 hours do not have to be completed in one session and can be satisfied through cumulative CME hours, as long as the training is provided by or approved by participating organizations.

Recommendations for Curricular Elements in Substance Use Disorders Training | SAMHSA
Accessed 5/2/2022
Improving Access to Opioid Use Disorder Treatment

Medications for Opioid Use Disorder (MOUD) involves a combination of medications that targets the brain, and psychosocial interventions (e.g., counseling, skills development) aimed at improving treatment outcomes. Research shows that medications and therapy together may be more successful than either treatment method alone.

Historically, pharmacological treatment for opioid use disorder was referred to as "Medications for Addiction Treatment (MAT)," but more recently it has been determined that the more appropriate term is "Medications for Opioid Use Disorder (MOUD)." PCSS trainings, resources and website will use MOUD going forward.

URL - Medications for Opioid Use Disorder (MOUD) - PCSS (pcssnow.org) Accessed 5/6/23
Improving Access to Opioid Use Disorder Treatment

**Buprenorphine**

Buprenorphine works similarly to methadone, but only partially activates opioid receptors, often reducing drug use and protecting patients from overdose. Because buprenorphine is considered safer than methadone, less monitoring is needed, and it can be prescribed by primary care providers who complete a special training course.

**Methadone**

Methadone works by activating opioid receptors in the brain, and blocking the effects of heroin and painkillers. Patients taking methadone often have less craving for heroin/opioids and less withdrawal symptoms. As a result, they tend to use less heroin, have fewer medical complications, and often have improved social and work functioning. Methadone is one of the most effective medications we have, however it is a potent medication and can cause sedation, even death. Therefore, dispensing methadone is highly regulated and it can only be used in Opioid Treatment Programs.

**Naltrexone**

Naltrexone works differently from methadone or buprenorphine. It completely blocks opioid receptors, and is used after detoxification to prevent relapse. It has no abuse potential, no overdose risk, and there is no withdrawal when the medication is stopped. Naltrexone can be administered in a primary care physician's office with single doses effective for up to 30 days.

URL - [Medications for Opioid Use Disorder (MOUD) - PCSS (pcssnow.org)](https://pcssnow.org)  Accessed 5/6/23
6. The Negative Impact to “Legacy” Chronic Pain Patients Already Taking Opioids
“Legacy” Chronic Pain Patients Cannot Find Appropriate Access to Primary Care

• 41% of clinics won't accept new pain patients on opioids
• Providers are reluctant to “inherit” the “legacy” patient due to regulatory constraints
• These patients may require long-term opioid use
• They are typically tolerant and dependent on opioids and would go into withdrawal if they were abruptly discontinued
• Most due not misuse opioids and exhibit addictive behaviors
• These patients typically have “cancer quality pain” without dying of cancer and are being treated palliatively.
• By some definitions – they have a “dual diagnosis” of “chronic pain disorder” and “opioid use disorder”
• There is potential for subsequent harm is high if abandoned.
Many Pain Clinics Also Have Restrictive Acceptance Policies

- Roughly half (48%) of pain clinics did not accept Medicaid.
- Over half (51%) required a referral before accepting new patients.
- An additional 23% required a referral based on insurance type.

Lagisetty et al. JGIM. 2020.
With Loss of Access, “Legacy” Pain Patients Have Become “Pain Refugees” and Are Now Facing Harm

Patients whose medications were inappropriately tapered or stopped were:

- 1.75 x more likely to use illicitly obtained Rx’s (including counterfeits which may be laced with fentanyl)
- 1.57 x more likely to use heroin (with or without fentanyl)
- 2.3 x more likely to experience a mental health crisis
- 1.69 x more likely to have an overdose event
- At increasingly greater risk for overdose or suicide the longer they have been on long term opioid therapy
Primary Barriers to Pain Care

1. Policy
2. Payment
3. Care Coordination
4. Stigma
5. Racial Disparities
Policy Changes Being Made in 2022-23 About Being Compensated for Intensive Pain and OUD Services

UPDATE: 9/1/2022

• The U.S. Centers for Medicare and Medicaid Services (CMS) Announced a Large Step Forward for Chronic Pain Management (CPM) and Opioid Use Disorder (OUD) Services Utilizing Chronic Care Management (CCM)

• The codes can be billed monthly for each beneficiary.

7. The Impact of Sedatives, Alcohol and Stimulants With and Without Opioids – Polysubstance Use Disorders
In 2020, 16 percent of overdose deaths involving opioids also involved benzodiazepines.
Benzodiazepine Deaths With Opioid Co-involvement (2019 - June 2020)


Abbreviations: co- = co-involved; IMFs = illicitly manufactured fentanyl; Rx = prescription.
Age-adjusted Rates of Drug Overdose Deaths Involving Cocaine and Psychostimulants Abuse Potential (Methamphetamine and Other Amphetamines) - United States, 2003–2017
The Role of Alcohol Use Disorder (AUD) With or Without Coexisting Illicit Drug Addiction

Alcohol Use Disorder Diagnoses Among Age Groups

- Ages 26+: 22,393 - 16% diagnosed with AUD in 2020, 4,189 diagnosed with AUD and an illicit drug addiction
- Ages 18-25: 5,215 - 31% diagnosed with AUD in 2020, 1,921 diagnosed with AUD and an illicit drug addiction
- Ages 12-17: 712 - 32% diagnosed with AUD in 2020, 340 diagnosed with AUD and an illicit drug addiction

Causes of Alcohol-Related Deaths

- Liver Disease 31.08%
- Neurological Disease 5.37%
- Other Acute Causes 5.72%
- Car Crashes 7.45%
- Homicide 7.86%
- Other Chronic Causes 8.05%
- Heart Disease 9.18%
- Alcohol Poisoning 14.85%
- Suicide 10.44%

95.2K Total Deaths

COVID Effect on Alcohol Consumption

- Drinking Decreased 12.82%
- No Change 27.04%
- Drinking Increased 60.14%

Alcohol Abuse Statistics [2022]: National + State Data - NCDAS (drugabusestatistics.org) Accessed 9/5/2022
8. Weighing Benefit and Risk When Prescribing Opioids
When The Need for Effective Pain Management Using an Opioid May Outweigh Risk In 4 Pain Types

1. Acute Pain
2. Chronic Pain
3. High Impact Chronic Pain
4. Intractable Pain That Is Otherwise Untreatable
Acute pain is defined as self-limited discomfort that typically lasts from a few moments to several weeks but less than 3 to 6 months. It can relate to soft tissue or skeletal damage, and may be categorized as spontaneous or post-traumatic, with the trauma planned (surgical) or unplanned (accidental). As the injured tissues heal, acute pain gradually resolves.

Pain can vary in severity from mild to severe. Some therapies, such as opioids, are reserved for more severe pain. However, even if pain is severe, it is important to recognize that not all acute pain requires opioid therapy.
Chronic and High Impact Pain

1. Chronic pain is based on responses of “most days” or “every day” to the survey question.
2. High-impact chronic pain is based on responses of “frequently limits life or work activities.”

FIGURE. Prevalence of chronic pain* and high-impact chronic pain† among adults — United States, 2019-2021§."
Chronic and High Impact Pain

1. Chronic pain is based on responses of “most days” or “every day” to the survey question.
2. High-impact chronic pain is based on responses of “frequently limits life or work activities”

### Overall and By Gender

Figure 1. Percentage of adults aged 18 and over with chronic pain and high-impact chronic pain in the past 3 months, overall and by sex: United States, 2019

<table>
<thead>
<tr>
<th></th>
<th>Overall</th>
<th>Men</th>
<th>Women</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic pain</td>
<td>20.4%</td>
<td>19.0%</td>
<td>21.7%</td>
</tr>
<tr>
<td>High-impact chronic pain</td>
<td>7.4%</td>
<td>6.3%</td>
<td>8.5%</td>
</tr>
</tbody>
</table>

### Age

Figure 2. Percentage of adults aged 18 and over with chronic pain and high-impact chronic pain in the past 3 months, by age group: United States, 2019

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Chronic Pain</th>
<th>High-Impact Chronic Pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>18-29</td>
<td>6.5%</td>
<td>14.6%</td>
</tr>
<tr>
<td>30-44</td>
<td>30.8%</td>
<td>25.8%</td>
</tr>
<tr>
<td>45-64</td>
<td>4.4%</td>
<td>4.4%</td>
</tr>
<tr>
<td>65 and over</td>
<td>11.8%</td>
<td>10.3%</td>
</tr>
</tbody>
</table>

### Ethnicity

Figure 3. Percentage of adults aged 18 and over with chronic pain and high-impact chronic pain in the past 3 months, by race and Hispanic origin: United States, 2019

<table>
<thead>
<tr>
<th>Race and Hispanic Origin</th>
<th>Chronic Pain</th>
<th>High-Impact Chronic Pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-Hispanic white</td>
<td>23.6%</td>
<td>12.3%</td>
</tr>
<tr>
<td>Non-Hispanic black</td>
<td>12.3%</td>
<td>13.0%</td>
</tr>
<tr>
<td>Hispanic</td>
<td>11.5%</td>
<td>3.7%</td>
</tr>
<tr>
<td>Non-Hispanic Asian</td>
<td>12.2%</td>
<td>8.8%</td>
</tr>
</tbody>
</table>

### Locale

Figure 4. Percentage of adults aged 18 and over with chronic pain and high-impact chronic pain in the past 3 months, by urbanization level: United States, 2019

<table>
<thead>
<tr>
<th>Urbanization Level</th>
<th>Chronic Pain</th>
<th>High-Impact Chronic Pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Large central metro</td>
<td>16.1%</td>
<td>16.3%</td>
</tr>
<tr>
<td>Large fringe metro</td>
<td>22.8%</td>
<td>28.1%</td>
</tr>
<tr>
<td>Medium and small metro</td>
<td>6.1%</td>
<td>0.4%</td>
</tr>
<tr>
<td>Rural</td>
<td>6.0%</td>
<td>10.0%</td>
</tr>
</tbody>
</table>
Intractable Pain (IP)

• IP is defined as “pain that is excruciating, constant, incurable, and of such severity that it dominates virtually every conscious moment, produces mental and physical debilitation and may produce a desire to commit suicide for the sole purpose of stopping the pain”

Common Characteristics of Intractable Pain

<table>
<thead>
<tr>
<th>Pain reduces sleep and food intake</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bed-, chair-, or house-bound in the absence of opioid treatment</td>
</tr>
<tr>
<td>Depression, attention deficit, confusion, and suicide tendencies</td>
</tr>
<tr>
<td>Underlying cause is incurable, non-removable, and fails to respond to customary pain therapies</td>
</tr>
<tr>
<td>Elevated blood pressure and pulse rate</td>
</tr>
<tr>
<td>Serum adrenal hormone and immune abnormalities</td>
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Common Causes of Intractable Pain

<table>
<thead>
<tr>
<th>Admitted to Treatment</th>
<th>% Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Degenerative spinal disease post-surgery</td>
<td>32%</td>
</tr>
<tr>
<td>Degenerative spinal disease non-operable</td>
<td>22%</td>
</tr>
<tr>
<td>Fibromyalgia</td>
<td>15%</td>
</tr>
<tr>
<td>Migraine-vascular headache</td>
<td>8%</td>
</tr>
<tr>
<td>Neuropathies</td>
<td>6%</td>
</tr>
<tr>
<td>Congenital skeletal disease</td>
<td>5%</td>
</tr>
<tr>
<td>Headache-post trauma</td>
<td>3%</td>
</tr>
<tr>
<td>Reflex sympathetic dystrophy</td>
<td>3%</td>
</tr>
<tr>
<td>Osteoporosis</td>
<td>2%</td>
</tr>
<tr>
<td>Systemic lupus erythematosus</td>
<td>2%</td>
</tr>
<tr>
<td>Abdominal adhesions</td>
<td>1%</td>
</tr>
<tr>
<td>Interstitial cystitis</td>
<td>1%</td>
</tr>
<tr>
<td>Total</td>
<td>100%</td>
</tr>
</tbody>
</table>

Palliative Care is Commonly Required

• It is often characterized as one having “cancer quality” pain but “not dying of cancer”
• IP patients often systematically fail the usual treatments for acute and chronic pain including anti-inflammatory, mild opioid and non-opioid analgesics, antidepressants, muscle relaxants, and anti-seizure medications.
• They also don’t respond well to corticosteroid injections in and around the spinal column or peripheral nerves.
• Physical therapy, exercise, and psychological interventions have usually been of little or no avail because the pain is so profoundly uncontrolled that participation in these therapies is not possible.
• Chronic Opioid Therapy (COT) may be required
• This treatment should be regarded as end-stage or last resort due to its expense and inherent complications.

What is Intractable Pain and How Does it Differ From Chronic Pain (practicalpainmanagement.com) – Accessed 4/30/22
The Magnitude of Chronic Pain in Michigan Adult Residents Aged ≥18
(Best Estimate of NCHS 2020 Data Brief Extrapolated to the 2020 US Census Estimates for MI Residents)

- About 20% of all Michigan adults have chronic pain
- Chronic pain can occur with severe acquired illness
  - Cancer
  - Infection
  - Chronic Autoimmune and inflammatory disorders
- Long-term permanent injury
  - Auto
  - Work
  - Military Service
  - Sports Injuries
  - Slips and Falls
- Certain genetic disorders

Data on File

- Up to 60,000 (~4%) of the adult MI population has Intractable Pain (IP) which is a moderate to severe, constant pain that is typically relentless and debilitating, not curable by any known means, causes suffering, and leads to a house-bound or bed-bound state and possibly to premature death
- Intractable Pain patients cannot get access to care
- Abandoning the intractable pain patient challenges medical ethics, professional duty, the public health code and perhaps more
When Risk Begins to Outweigh Benefit

Effective Pain Management

Risk of OUD and Overdose
The Downside to Using Opioids Beyond 7-10 Days For Acute Pain: The Risk for Continued Opioid Use Goes Up with Days Supply and Number of Prescriptions in the First Episode of Care
The Percentage of Adults With Any Pain

3 in 5 Have Adults Have Experienced Pain Within 3 Months of Being Asked

~1 in 5 Patients with Chronic Pain Have Used an Opioid Within 3 Months of Being Asked

NCHS Data Brief ■ No. 415 ■ July 2021
Long-Term Opioid Exposure Can Lead to Neurodegenerative and Neurocognitive Disorders

Loss of Neural Dendrites (Prolonged Drug Exposure)

Normal Dendrites

Loss of Brain Function Including the Frontal Lobe

Biological and Social Consequences of Ongoing Tolerance, Dependence and Addictive Behavior

- Prolonged exposure leading to downregulated epigenetic control of nerve cell structure and function (decreased neurotransmitters, receptors and structural proteins)
- The brain can no longer synthesize these molecules and requires exogenous source of these molecules until cells can resume synthesizing them
- Loss of self control and executive function, ie, judgement
- Inability to calculate risk versus benefit
- Possible severe, uncontrollable drug seeking to satisfy craving and avert withdrawal symptoms when opioids are rapidly discontinued
- Potential Loss of Family, Job and Shelter Leading to Possible Petty Theft, Larger Crimes, Arrest and Incarceration
- Possible Accidental overdose, cardiorespiratory arrest, anoxic-hypoxic brain injury and death

NOTE: A person's health is determined by their genes and the environment they live in. Epigenetics is the study of functional, and sometimes inherited, changes in the regulation of gene activity and expression that are not dependent on gene sequence.
Substance Misuse Can Promulgate From Generation to Generation with the Cyclical Nature of Post-traumatic Stress Triggers and Adverse Childhood Events (ACE’s) That Lead to Aberrant Behaviors

Landmark study of 17,000 participants from 1995-1997 by the Centers for Disease Control in partnership with Kaiser Permanente

**Aberrant Adult Behaviors Increase Risk for ACE’s**
- Physical abuse
- Sexual abuse
- Emotional abuse
- Physical neglect
- Emotional neglect
- Intimate partner violence
- Mother treated violently
- Substance misuse within household
- Household mental illness
- Parental separation or divorce
- Incarcerated household member

Findings: A person’s ACEs score has a strong relationship to numerous health, social and behavioral problems across a lifespan, including substance use disorders

**ACE’s Increase Risk for Aberrant Adult Behaviors**
- Alcoholism and alcohol abuse
- Chronic obstructive pulmonary disease (COPD)
- Depression
- Fetal death
- Health-related quality of life
- Illicit drug use
- Ischemic heart disease (IHD)
- Liver disease
- Risk for intimate partner violence
- Multiple sexual partners
- Sexually transmitted diseases (STDs)
- Smoking
- Suicide attempts
- Unintended pregnancies
- Early initiation of smoking
- Early initiation of sexual activity
- Adolescent pregnancy
- Diabetes
- Lung cancer

9. Introducing the New 2022 CDC Guideline
Introducing the New 2022 CDC Guideline

Process Timeline
Updating the CDC Guideline for Prescribing Opioids

- **2018**
  - Federal partner engagement occurs throughout the update process

- **DEC 2019**
  - BSC/NCIPC, a federal advisory committee, establishes the OWG and nomination process begins

- **JUL 2020**
  - Community Engagement: Individual Conversations FRN on Management of Acute and Chronic Pain begins

- **JUN 2021**
  - OWG meetings conclude

- **EARLY 2022**
  - Public Comment FRN: Anticipated posting of the draft updated Guideline in the Federal Register for a 60-day public comment period
  - Independent peer review of the draft updated Guideline

- **LATE 2022**
  - Anticipated release of updated Guideline

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**ABBREVIATIONS**

AHRQ – Agency for Healthcare Research & Quality
BSC/NCIPC – Board of Scientific Counselors of the National Center for Injury Prevention and Control
CDC – Centers for Disease Control and Prevention
FRN – Federal Register Notice
HHS – U.S. Department of Health and Human Services
OWG – Opioid Workgroup

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Process for Updating the Opioid Prescribing Guideline | CDC’s Response to the Opioid Overdose Epidemic | CDC – Accessed 4/30/2022
Summary

This clinical practice guideline is

- A clinical tool to improve communication between clinicians and patients and empower them to make informed, person-centered decisions related to pain care together
- Intended for primary care clinicians and other clinicians providing pain care for outpatients aged ≥18 years old with:
  - acute pain (duration <1 month);
  - subacute pain (duration of 1-3 months); or
  - chronic pain (duration of >3 months)
- Intended to be flexible to enable person-centered decision-making, taking into account an individual’s expected health outcomes and well-being.

This clinical practice guideline is not

- A replacement for clinical judgment or individualized, person-centered care
- Intended to be applied as inflexible standards of care across patients, and/or patient populations by healthcare professionals, health systems, pharmacies, third-party payers, or governmental jurisdictions or to lead to the rapid tapering or discontinuation of opioids for patients
- A law, regulation, and/or policy that dictates clinical practice or a substitute for FDA-approved labeling
- Applicable to the following types of pain treatment:
  - sickle cell disease-related pain
  - cancer pain
  - palliative care
  - end-of-life care

URL - CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022 (Accessed 5/20/22)
URL - Prescribing Opioids for Pain — The New CDC Clinical Practice Guideline | NEJM (Accessed 5/20/22)
CDC Clinic Practice Guideline for Prescribing Opioids – United States, 2022

Summary

1. For all patients with acute, subacute, or chronic pain
   • Initiate the lowest opioid dose to achieve expected effects
   • For opioid naïve patients, start with immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids
   • Use extreme caution when prescribing opioids, benzodiazepines and other sedating substances concurrently
     • consider whether benefits outweigh risks
     • Taper cautiously to a less risky dose or discontinue
   • Check the state prescription drug monitoring program (PDMP) also known as the Michigan Automated Prescription Service (MAPS), to determine whether the patient is receiving opioid dosages or combinations that put the patient at high risk for overdose
     • When initiating therapy
     • Periodically when continuing
   • Consider toxicology testing to assess for prescribed medications as well as other prescribed and non-prescribed controlled substances
   • Offer naloxone and other overdose mitigation strategies when risk factors for opioid overdose are present

2. For acute pain, consider initiating opioid therapy only if benefits are anticipated to outweigh risks to the patient
   • Nonopioid therapies are effective for many common types of acute pain
   • Prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids
3. For subacute and chronic pain, consider initiating opioid therapy only if expected benefits for pain and function are anticipated to outweigh risks to the patient
   • Work with patients to establish treatment goals for pain and function
   • Nonopioid therapies are preferred
   • Discuss the known risks and realistic benefits of opioid therapy
   • Consider how opioid therapy will be discontinued when benefits do not outweigh risks
   • If opioids are continued
     • use caution when prescribing opioids at any dosage
     • avoid increasing dosage above levels likely to yield diminishing returns in benefits relative to risks to patients
     • re-evaluate benefits and risks after starting opioid therapy or when escalating dose
     • Initially at 1 to 4 weeks
     • Then every 3 months (or more frequently as indicated)

4. Carefully weigh benefits and risks for patients already receiving higher opioid dosages
   • Do not abruptly discontinue opioid therapy unless there are indications of a life-threatening issue, such as warning signs of impending overdose (e.g., confusion, sedation, or slurred speech)
   • Exercise care when reducing or continuing opioid dosage
   • Work closely with patients to optimize other therapies
   • Gradually taper to lower dosages if risks outweigh benefits of continued opioid therapy
   • Taper and discontinue opioids if warranted based on the individual clinical circumstances of the patient
   • Consider transitioning to buprenorphine if opioids cannot be sufficiently tapered or discontinued

5. **Offer Medications for Opioid Use Disorder (MOUD) to patients without pain and exhibiting opioid used disorder (OUD)**
10. Approaches to Treat Acute and Chronic Pain in 2023
THE CHRONIC PAIN JOURNEY

Opportunities for Action

Be the Guide On the Patient’s Journey to Adequate Care

This journey map visually describes the experiences of persons living with chronic, non-cancer pain and identifies key stages of the journey that have critical touchpoints with the health system. Each stage of the journey illustrates the patients’ roles and responsibilities, challenges that deviate from the path to good pain management, and opportunities for action to support those with chronic pain. This map is available in an interactive version, which provides more insight into the chronic pain journey and links to tools and resources.

Chronic Pain Journey Map - National Academy of Medicine (nam.edu) – Accessed 5/9/22
Coordinate Care With a Multimodality Treatment Plan

Coordinated Care

- Pain Specialist
- Behavioral Support
- Alternative Therapies

PCP — Patient

Medications
+ Behavioral Health Approaches
+ Restorative Therapies
+ Complementary and Integrative Health
+ Interventional Approaches

Effective Multimodal Treatment

Utilize a Systematic Approach to Reducing Unnecessary Opioid Prescription Use, Misuse and Diversion

**Recommendations**

1. Assess Severity and Anticipated Duration of Pain
2. Assess Overdose Risk
3. Limit Initial Dose & Ongoing Duration
4. Securely Store Medications
5. Promote Disposal of Unused Doses
Don’t Ignore or Abandon Inherited “Legacy” Pain Patients Already on Opioids

Inherited Patients Taking Opioids for Chronic Pain — Considerations for Primary Care

Phillip O. Coffin, M.D., and Antje M. Barreved, M.D.

Steps in Caring for Patients with Chronic Pain Who Have Received Long-Term Opioid Therapy from a Previous Clinician.

1. Review the case with the former clinician if possible. Try to develop a treatment plan that slowly adjusts to your style of management while avoiding a radical divergence from the previous plan of care.

2. Consider providing a therapeutic bridge for the patient until a plan of care is determined, given the risks associated with stopping opioid therapy. Abruptly tapering or stopping opioid therapy can be dangerous for multiple reasons. Opioids may be crucial for the patient’s condition (e.g., sickle-cell disease), and the patient may be at risk for other harms when opioids are tapered or discontinued (see figure).

3. Develop a patient-centered care plan. If a taper is needed, empower the patient to make decisions, including which medications to taper first and how fast. Successful tapers may take years.

4. Assess the patient for opioid use disorder and start discussing medication options right away. Patients may find it challenging to accept an opioid use disorder diagnosis; give them time.

5. Document opioid stewardship and the rationale for the treatment plan. Investigations into opioid prescribing are often based on insufficient documentation.
When Using Opioids Long-term – Consider a Taper or Switch to Buprenorphine If and When Possible, Then Go Slow

Opioid Tapering Flowchart

Assess benefits and risks of continuing opioids at current dose

- Risks outweigh benefits
  - Discuss, educate, offer taper, start slow taper when ready
  - Able to taper down until benefits outweigh risks
  - Re-evaluate benefits and risks quarterly

- Benefits outweigh risks
  - Document risk-benefit assessment
  - Re-evaluate benefits and risks quarterly

Not able to taper down until benefits outweigh risks

- Meets criteria for opioid use disorder (OUD)
  - Transition to medication for OUD

- Does not meet criteria for OUD
  - Slow taper or transition to buprenorphine for pain
  - Re-evaluate benefits and risks quarterly

Orient Patients to Dispose of Expired or Unused Medications to Avoid Pilfering and Accidental Overdose

Safe Opioid Disposal - Remove the Risk Outreach Toolkit | FDA  (Accessed 9/5/22)
Check for Anticipated and Unanticipated Medications and Other Substances

• If you don’t check, you will have no idea.

• Qualitative - in Office
  • Test either positive or negative
  • Immunoassay

• Quantitative (in Lab)
  • Test measures concentration of drug
  • GC/MS or LC/MS
  • Can check for all psychoactive substances prescribed and unprescribed
  • Matrix - Urine, Saliva, Blood, Hair, Exhaled Air (breathalyzer), etc.
11. Approaches to Enhance Medical Documentation, Communication and Coordination of Care
Identify and Treat the Pain Source  
(Starting with a Good History)

Patient Instructions: Please fill out both sides of this questionnaire as completely as possible.

1. HISTORY OF THE PAIN
   ▶ Do you believe the pain is due to:
     □ a car accident  
     □ a work-related injury  
     □ physical trauma (examples: a fall, a fight, sports injury, etc.)  
   □ other: ________  
   □ unknown cause  
   □ date: _______ a.m. / p.m.
   □ time: _______ a.m. / p.m.
   □ Did the pain appear:  
     □ suddenly  
     □ gradually  
   □ Right now, is the pain:  
     □ better  
     □ worse  
     □ unchanged

   □ How long have you had this pain?  
   □ days — how many?  
   □ weeks — how many?  
   □ months — how many?  

2. LOCATION AND INTENSITY OF PAIN
   ▶ The most intense pain is located:  
   ▶ On the diagrams to the right:
     • mark an X or a series of Xs where you feel pain.
     • shade the area where you have numbness.
     • use arrows to point to where the pain radiates or travels to.
   ▶ Has the pain changed in its location?

   ▶ On the scale below, mark an X where it best describes the intensity of your pain:

3. DESCRIPTION OF THE PAIN
   ▶ Is the pain:
     □ continuous (no relief)
     □ intermittent (periods of relief)
   □ amount of time pain usually lasts:
     □ amount of time relief usually lasts:
     □ other: ________

   ▶ Would you describe the pain as:
     □ sharp, stabbing
     □ dull, aching
     □ throbbing
     □ burning like a hot poker
     □ steady, persistent
     □ waxing and waning
     □ feeling like a tight band
     □ easy to pinpoint
     □ difficult to pinpoint
     □ other: ________

   ▶ Does pain occur:
     □ upon awakening
     □ in the morning
     □ in the afternoon
     □ in the evening
     □ 2-3 hours after falling asleep
     □ any time of day or night
     □ only on weekends
     □ only at work
     □ only at home
     □ other: ________

4. DO YOU ALSO HAVE:

   □ runny bloodshot eyes
   □ blurred or double vision
   □ nasal congestion/turkey nose
   □ high blood pressure
   □ muscle weakness
   □ numbness in arms or hands
   □ numbness in legs or feet
   □ felt a “sudden snap”
   □ felt a “twisting” sensation
   □ muscle aches and pains
   □ joint pain
   □ morning joint stiffness
   □ fever
   □ abdominal pain

5. PREVIOUS MEDICAL WORKUP INCLUDES:

   □ seeing other doctors
   □ neck x-rays
   □ lumbar and pelvis x-rays
   □ EEG/brain wave study
   □ CT scan
   □ skull x-rays
   □ MRI
   □ Evoked potentials
   □ EMG
   □ blood work
   □ other:

6. DOES ANY BLOOD RELATIVE HAVE A HISTORY OF:

   □ arthritis
   □ diabetes
   □ osteoarthritis
   □ cerebral aneurysm
   □ migraines
   □ high blood pressure
   □ stroke
   □ brain tumor
   □ spinal cord tumor
   □ poor leg circulation
   □ disk problems
   □ spinal stenosis
   □ multiple sclerosis (MS)
   □ muscular dystrophy
   □ arteriovenous malformation
   □ Lou Gehrig’s disease
   □ other neurological disease:

7. IS THE PAIN MADE WORSE OR BETTER BY:

   □ inactivity or sleep
   □ solid activity
   □ exercising or stretching
   □ heavy work
   □ climbing stairs
   □ walking
   □ standing
   □ sitting
   □ car riding
   □ standing at stool
   □ reclining or lying down
   □ lying on a firm bed or on the floor
   □ lying on one side
   □ getting up from bed
   □ bending forward
   □ lifting ______ lbs.
   □ carrying ______ lbs.
   □ stooping
   □ twisting
   □ reaching overhead
   □ coughing/sneezing
   □ sudden movement
   □ other movement:
   □ touching a certain point:
   □ sexual intercourse
   □ drinking alcohol
   □ emotional tension
   □ fatigue
   □ changes in weather
   □ menstrual periods
   □ massage
   □ heat
   □ trying to forget about it
   □ spinal manipulation
   □ spine injections (blocks)
   □ physical therapy
   □ surgery
   □ other:

   Medications:

   □ ______________________
   □ ______________________
   □ ______________________
   □ ______________________
   □ ______________________
   □ ______________________
   □ ______________________
   □ ______________________
   □ ______________________
   □ ______________________
Confirm Medical Necessity and Appropriateness of Care (DIRE Score)

Name: ___________________________  DOB __/__/____

**DIRE Score: Patient Selection for Chronic Opioid Analgesia**
For each factor, rate the patient's score from 1-3 based on the explanations in the right-hand column.

<table>
<thead>
<tr>
<th>SCORE</th>
<th>FACTOR</th>
<th>EXPLANATION</th>
</tr>
</thead>
</table>
| DIAGNOSIS | 1 = Benign chronic condition with minimal objective findings or no definite medical diagnosis. Examples: fibromyalgia, migraine headaches, non-specific back pain.  
2 = Slowly progressive condition concordant with moderate pain, or fixed condition with moderate objective findings. Examples: failed back surgery syndrome, back pain with moderate degenerative changes, neuropathic pain.  
3 = Advanced condition concordant with severe pain with objective findings. Examples: severe ischemic vascular disease, advanced neuropathy, severe spinal stenosis. | |
| INTRACTABILITY | 1 = Few therapies have been tried and the patient takes a passive role in his/her pain management process.  
2 = Most customary treatments have been tried but the patient is not fully engaged in the pain management process, or barriers prevent (insurance, transportation, medical illness).  
3 = Patient fully engaged in a spectrum of appropriate treatments but with inadequate response. | |
| RISK | (R = Total of P+C+R+S below) | |
| Psychological | 1 = Serious personality dysfunction or mental illness interfering with care. Example: personality disorder, severe affective disorder, significant personality issues  
2 = Personality or mental health interferes moderately. Example: depression or anxiety disorder.  
3 = Good communication with clinic. No significant personality dysfunction or mental illness. | |
| Chemical Health | 1 = Active or very recent use of illicit drugs, excessive alcohol, or prescription drug abuse.  
2 = Chemical coper (uses medications to cope with stress) or history of chemical dependence (CD) in remission.  
3 = No CD history. Not drug-focused or chemically reliant. | |
| Reliability | 1 = History of numerous problems: medication misuse, missed appointments, rarely follows through.  
2 = Occasional difficulties with compliance, but generally reliable.  
3 = Highly reliable patient with meds, appointments & treatment. | |
| Social Support | 1 = Life in chaos. Little family support and few close relationships. Loss of most normal life roles.  
2 = Reduction in some relationships and life roles.  
3 = Supportive family/close relationships. Involved in work or school and no social isolation. | |
| EFFICACY SCORE | 1 = Poor function or minimal pain relief despite moderate to high doses.  
2 = Moderate benefit with function improved in several ways (or insufficient info - hasn't tried opioid yet or very low doses or too short of a trial).  
3 = Good improvement in pain and function and quality of life with stable doses over time. | |

Total score = D + I + R + E

Score 7-13: Not a suitable candidate for long-term opioid analgesia
Score 14-21: May be a good candidate for long-term opioid analgesia

NOTES
A DIRE Score of 5-13 indicates that the patient may not be suitable for long-term opioid pain management. Used with permission by Miles J. Bragonie, MD
Assess for Opioid Use Disorder  
(DSM-5 Criteria)

A problematic pattern of opioid use leading to clinically significant impairment or distress, as manifested by at least 2 of the following, occurring within a 12-month period:

1. Opioids are often taken in larger amounts or over a longer period than was intended.
2. There is a persistent desire or unsuccessful efforts to cut down or control opioid use.
3. A great deal of time is spent in activities necessary to obtain, use, or recover from the effects of opioids.
4. Craving, or a strong desire or urge to use opioids.
5. Recurrent opioid use resulting in a failure to fulfill major role obligations at work, school, or home.
6. Continued opioid use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of opioids.
7. Important social, occupational, or recreational activities are given up or reduced because of opioid use.
8. Recurrent opioid use in situations in which it is physically hazardous.
9. Continued opioid use is continued despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance.
10. Tolerance, as defined by either of the following:
   a. A need for markedly increased amounts of opioids to achieve intoxication or desired effect, or
   b. Markedly diminished effect with continued use of the same amount of an opioid.
      *Note: This criterion is not considered to be met for those taking opioids solely under appropriate medical supervision.*
11. Withdrawal, as manifested by either of the following:
   a. The characteristic opioid withdrawal syndrome, or
   b. Opioids (or a closely related) substance is taken to relieve or avoid withdrawal symptoms.
      *Note: This criterion is not considered to be met for those taking opioids solely under appropriate medical supervision.*

Mild: Presence of 2-3 symptoms
Moderate: Presence of 4-5 symptoms
Severe: Presence of 6 or more symptoms

Assess for Signs of Withdrawal (Using COWS)

<table>
<thead>
<tr>
<th>PATIENT NAME:</th>
<th>DATE OF ASSESSMENT:</th>
</tr>
</thead>
<tbody>
<tr>
<td>PATIENT DATE OF BIRTH:</td>
<td>MEDICAL RECORD NUMBER:</td>
</tr>
</tbody>
</table>

**Clinical Opioid Withdrawal Score (COWS)**

For each item, write in the number that best describes the patient’s signs or symptom. Rate only the apparent relationship to opiate withdrawal. For example: If heart rate is increased because the patient was jogging just prior to assessment, the increased pulse rate would not add to the score.

<table>
<thead>
<tr>
<th>Enter scores at time zero, 30 minutes after first dose, 2 hours after first dose, etc.</th>
<th>Time:</th>
<th>Time:</th>
<th>Time:</th>
<th>Time:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Resting Pulse Rate:</strong> Record beats per minute after patient is sitting or lying down for one minute</td>
<td>0 - pulse rate 80 or below</td>
<td>2 - pulse rate 101-120</td>
<td>4 - pulse rate greater than 120</td>
<td></td>
</tr>
<tr>
<td><strong>Sweating:</strong> Over past ½ hour not accounted for by room temperature or activity</td>
<td>0 - no chills or flushing</td>
<td>3 - beads of sweat on brow or face</td>
<td>4 - sweat streaming off face</td>
<td></td>
</tr>
<tr>
<td>1 - subjective chills or flushing</td>
<td>2 - flushed or observable moistness on face</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Restlessness:</strong> Observation during assessment</td>
<td>0 - able to sit still</td>
<td>3 - frequent shifting or extraneous movement of legs/arms</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 - reports difficulty sitting still, but is able to do so</td>
<td>4 - unable to sit still for more than a few seconds</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Pupil size:</strong></td>
<td>0 - pupils pinned or normal size for light</td>
<td>2 - pupils moderately dilated</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 - pupils possibly larger than normal for light</td>
<td>5 - pupils dilated that only rim of the iris is visible</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Bone or joint aches:</strong> If patient was having pain previously, only the additional component attributed to opiate withdrawal is scored</td>
<td>0 - not present</td>
<td>4 - patient is rubbing joints or muscles and is unable to sit still because of discomfort</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 - mild/diffuse discomfort</td>
<td>2 - patient reports severe diffuse aching of joints/muscles</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 - patient reports severe diffuse aching of joints/muscles</td>
<td>5 - patient is rubbing joints or muscles and is unable to sit still because of discomfort</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Runny nose or tearing:</strong> Not accounted for by cold symptoms or allergy</td>
<td>0 - none present</td>
<td>2 - nose running or tearing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 - nasal stuffiness or unusually moist eyes</td>
<td>4 - nose constantly running or tears streaming down cheeks</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>GI upset:</strong> Over last ½ hour</td>
<td>0 - no GI symptoms</td>
<td>2 - nausea or loose stool</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 - stomach cramps</td>
<td>3 - vomiting or diarrhea</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 - bloating or distention</td>
<td>5 - multiple episodes of diarrhea or vomiting</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Tremor:</strong> Observation of outstretched hands</td>
<td>0 - no tremor</td>
<td>2 - slight tremor observable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 - tremor can be felt, but not observed</td>
<td>4 - gross tremor or muscle twitching</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Yawning:</strong> Observation during assessment</td>
<td>0 - no yawning</td>
<td>2 - yawning three or more times during assessment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 - yawning once or twice during assessment</td>
<td>4 - yawning several times/minute</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Anxiety or irritability:</strong></td>
<td>0 - none</td>
<td>2 - patient obviously irritable or anxious</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 - patient reports increasing irritability or anxiousness</td>
<td>4 - patient so irritable or anxious that participation in the assessment is difficult</td>
<td></td>
<td></td>
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</tr>
<tr>
<td><strong>Gooseflesh skin:</strong></td>
<td>0 - skin is smooth</td>
<td>3 - piloerection of skin can be felt or hairs standing up on arms</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 - skin is rough</td>
<td>5 - prominent piloerection</td>
<td></td>
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</tbody>
</table>

5—12 = mild; 13—24 = moderate; 25—36 = moderately severe; > 36 = severe withdrawal

**TOTAL**

**OBSERVER INITIALS**
Assess Risk for Overdose (Using RIOSORD)

### Risk Index for Overdose or Serious Opioid-Induced Respiratory Depression (RIOSORD)

<table>
<thead>
<tr>
<th>Question</th>
<th>Points for Positive Response</th>
<th>Actual Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>In the past 6 mo, has the patient had a health care visit (outpatient,</td>
<td></td>
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<tr>
<td>inpatient, or emergency department) involving any of the following health</td>
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<tr>
<td>conditions</td>
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<tr>
<td>Substance use disorder (abuse or dependence), including alcohol,</td>
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<tr>
<td>amphetamines, antidepressants, cannabis, cocaine, hallucinogens,</td>
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<tr>
<td>opioids, and sedatives</td>
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<tr>
<td>Bipolar disorder or schizophrenia</td>
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<td></td>
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<tr>
<td>Stroke or other cerebrovascular disease</td>
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<td></td>
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<tr>
<td>Kidney disease with clinically significant renal impairment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heart failure</td>
<td></td>
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</tr>
<tr>
<td>Nonmalignant pancreatic disease (e.g., acute or chronic pancreatitis)</td>
<td></td>
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<tr>
<td>Chronic pulmonary disease (e.g., emphysema, chronic bronchitis, asthma,</td>
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<tr>
<td>pneumoconiosis, asbestosis)</td>
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<td></td>
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<tr>
<td>Recurrent headache (e.g., migraine)</td>
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<tr>
<td>Does the patient use any of the following substances?</td>
<td></td>
<td></td>
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<tr>
<td>Fentanyl</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Morphine</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Methadone</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hydromorphone</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the patient use an extended-release or long-acting formulation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>of any prescription opioid?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prescription benzodiazepine (e.g., diazepam, alprazolam)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prescription antidepressant (e.g., fluoxetine, citalopram, venlafaxine,</td>
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<td></td>
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<tr>
<td>amitriptyline)</td>
<td></td>
<td></td>
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<tr>
<td>Is the patient’s current maximum prescribed daily morphine- equivalent</td>
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<tr>
<td>dose ≥100 mg for all opioids used on a regular basis</td>
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<tr>
<td>Total possible score</td>
<td>146</td>
<td></td>
</tr>
</tbody>
</table>

### Risk Classes and Predicted Probability of Serious Opioid-Induced Respiratory Depression during the Next 6 Months.

<table>
<thead>
<tr>
<th>Risk Class</th>
<th>RIOSORD Score</th>
<th>Average Predicted Probability (Percent)</th>
<th>Actual Observed Incidence (Percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>&lt;5</td>
<td>1.9</td>
<td>2.1</td>
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<tr>
<td>2</td>
<td>5–7</td>
<td>4.8</td>
<td>5.4</td>
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<tr>
<td>3</td>
<td>8–9</td>
<td>6.8</td>
<td>6.3</td>
</tr>
<tr>
<td>4</td>
<td>10–17</td>
<td>15.1</td>
<td>14.2</td>
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<tr>
<td>5</td>
<td>18–25</td>
<td>29.8</td>
<td>32.2</td>
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<tr>
<td>6</td>
<td>26–41</td>
<td>55.1</td>
<td>58.8</td>
</tr>
<tr>
<td>7</td>
<td>≥42</td>
<td>83.4</td>
<td>82.4</td>
</tr>
</tbody>
</table>
Check the Michigan Automated Prescription Service (MAPS) to Assess for Potential Misuse, Abuse, Diversion, or Overdose Risk

![Map of Michigan's Automated Prescription Service](https://michigan.pmpaware.net)

<table>
<thead>
<tr>
<th>Narx Report</th>
<th>Resources</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date: 06/15/2017</td>
<td></td>
</tr>
<tr>
<td>Justin Cooper</td>
<td></td>
</tr>
<tr>
<td>Risk Indicators</td>
<td></td>
</tr>
</tbody>
</table>

**NARX SCORES**

<table>
<thead>
<tr>
<th>Narcotic</th>
<th>Sedative</th>
<th>Stimulant</th>
</tr>
</thead>
<tbody>
<tr>
<td>672</td>
<td>512</td>
<td>190</td>
</tr>
</tbody>
</table>

**OVERDOSE RISK SCORE**

650 (Range 0-999)

**ADDITIONAL RISK INDICATORS (2)**

- Active MME > Threshold
- Patient has Benzodiazepine/Narcotic overlap

**Graphs**

- RX GRAPH
  - Narcotic
  - Sedative
  - Stimulant

**Prescribers**

10. King, James
9. Hawkins, Norma
8. Jenkins, Gerald
7. Ramos, Jesse
6. Jackson, Janice
5. Medina, Martha

[Visit Michigan's Automated Prescription Service](https://michigan.pmpaware.net)
# Create a Multi-Modal Chronic Pain Management Plan

<table>
<thead>
<tr>
<th>Name</th>
<th>DOB</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Visit</th>
<th>Visit 1</th>
<th>Visit 2</th>
<th>Visit 3</th>
<th>Visit 4</th>
<th>Visit 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date</td>
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</tbody>
</table>

## Disease/Conditions Causing Pain

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
</tr>
</thead>
</table>

## Pain Levels

**Worst Pain Level:**

**Current Pain Level:**

**Achievable Pain Level:**

## Pain Management Goals

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
</tr>
</thead>
</table>

## Specialty Consultation

1. General Surgery
2. Orthopedic Surgery
3. Interventional Pain Medicine
4. Physical Medicine & Rehabilitation
5. Manual Medicine (OMM/PT/Chiropractic)
6. Neurology
7. Sleep Medicine
8. Acupuncture
9. Hypnosis/Biofeedback
10. Other: ____________________

## Self Care

1. Ice/Heat Therapy
2. Exercise
3. Substance Management
   - Caffeine
   - Nicotine/Tobacco
   - Marijuana
   - Vaping
   - Kratom
   - Other: ____________________
3. Nutrition
4. Weight Management
5. Sleep Hygiene
Obtain Meaningful Informed Consent (Sample)

Controlled Medication Management Agreement and Informed Consent

Patient Name: ____________________________
DOB: __/__/____
Provider: ____________________________
Facility: ____________________________
Date: __/__/____

<table>
<thead>
<tr>
<th>#</th>
<th>Controlled Medication</th>
<th>Dose</th>
<th>Quantity</th>
<th>Directions</th>
<th>New Start</th>
<th>Refill</th>
<th>Switch</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
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</tbody>
</table>

The terms "I," "my" and "you" in this document refer to the patient. Where the patient is under age 18, or an adult for whom a guardian is signing the Agreement, the terms "I," "my" and "you" refer to the patient and to his or her parent or guardian.

This document lists commitments I will make before beginning one or more of these medications or continue them, if already being taken. I have received and have read the following patient education:
- Opioids (Opioid Medication for Chronic Pain fact sheet)
- Stimulants (Stimulant Medication for ADHD fact sheet)
- Benzodiazepines, Sedatives, Hypnotics and Sleeping Pills (Sedatives and Sleeping Pills: Understanding the Risks fact sheets)
- Gabapentin (Gabapentin fact sheet)
- Others (Describe) __________________________________________________________________________

1. I will work with my provider(s) in a collaborative manner to develop a balanced treatment plan that considers both benefits and risks to any given treatment.

2. I have discussed the medication(s) and had the chance to ask questions about the medications being prescribed with my provider(s).
   a. all my questions have been answered in a way I understand.
   b. I will engage in all activities to continue my ongoing therapy
   c. I acknowledge that I might develop tolerance, dependence, addiction or other serious and potentially life-threatening conditions when taken improperly, either individually or in combination with other controlled medications or addictive substances.
   d. I will refrain from taking actions that could endanger myself or the public.

3. I understand that insurers and regulatory authorities have the right to review my records when taking controlled substances
   a. I understand that my medical and insurance claims records may be reviewed by an independent review team to evaluate my ongoing opioid and controlled substance usage.
   b. the Michigan Department of Licensing and Regulatory Affairs (LARA) maintains and makes available a database of my controlled drug prescriptions to all medical providers providing my care.

7. I acknowledge that unwillingness or inability to work collaboratively with my provider(s) and adhere to this agreement may result in discharge from the provider's care
   a. Any action on my part that may be threatening to safety of your provider(s) and their staff may be subject to subsequent action

8. I acknowledge that my provider and I have reviewed this document.

9. I acknowledge the potential benefits and risks of controlled substances prescribed by my provider along with the responsibility of properly managing my medication as stated above.

10. For OPIOID USE ONLY, I understand that there are inherent risks for using opioids that are associated with increasing doses and when used in combination with other drugs. Naloxone, also known as Narcan, is an antidote that can reverse overdose of opioids by blocking their sedating effects that may slow down breathing and lead to cardiopulmonary arrest. Naloxone can be helpful to reverse over sedation and may be lifesaving when too much opioid is taken by myself or others. I acknowledge that Naloxone has been offered by prescription from my provider and is also available by request at participating pharmacies under standing orders of the Chief Medical Executive for the State of Michigan. Additional information regarding Naloxone and its proper use can be found at https://www.michigan.gov/opioids/0,9938,7-377-440935~0,00.html

My signature confirms that I have had an opportunity to ask questions about this agreement, and that I understand and agree to all the statements above. I have been given a copy of this Agreement and agree to keep the copy for my future reference.

Patient or Legal Guardian: __________________________________________________________________________

Date: __/__/____

(Patients aged 12 to 17 may sign in addition to the parent or guardian)

Patient (aged 12-17)

X

Date: __/__/____

Provider: __________________________________________________________________________

Date: __/__/____
Confirm the Need for Chronic Pain Management and Palliative Care

Chronic Pain Management & Palliative Care Certification Form

Patient Information

<table>
<thead>
<tr>
<th>Patient Name:</th>
<th>Telephone #:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of Birth:</td>
<td>Fax #:</td>
</tr>
<tr>
<td>Address:</td>
<td>Cellphone #:</td>
</tr>
<tr>
<td>City, STATE, Zip:</td>
<td>Email</td>
</tr>
</tbody>
</table>

Primary Diagnoses (relating to persistent intractable pain)

Certification Criteria

<table>
<thead>
<tr>
<th>Palliative Care Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ YES ☐ NO</td>
</tr>
<tr>
<td>☐ YES ☐ NO</td>
</tr>
<tr>
<td>☐ YES ☐ NO</td>
</tr>
<tr>
<td>☐ YES ☐ NO</td>
</tr>
<tr>
<td>☐ YES ☐ NO</td>
</tr>
</tbody>
</table>

Certification

I have performed a comprehensive and detailed examination for __________________________ and have developed a collaborative palliative care plan.

I have determined that this person has intractable pain and satisfied the criteria for Palliative Care Status. Support documentation is included in the patient’s medical record with this certification.

I, hereby, certify this pain management and palliative care plan is medically necessary. This plan will be recertified annually or sooner if there is substantive change beforehand.

PROVIDER
Signature of Provider: __________________________ Date: __/__/__

Provider Name Printed: __________________________

PATIENT
By signing below, and I hereby agree to all terms and conditions set forth under this certification document and accompanying treatment agreement.

Signature of Patient: __________________________ Date: __/__/__

Patient Name Printed: __________________________
Implement a Taper Plan Whenever Practicable

Name: ___________________________ DOB __/__/__

Opioid and/or Benzodiazepine Tapering Plan Agreement

The purpose of this document is to develop a specific tapering plan with a timeline for discontinuation or reaching a taper “target dose”.

We will work with you to develop a plan that is safe, effective and will minimize any symptoms that may be associated with tapering. Enclosed is a sample of a tapering schedule that can be used to help keep everyone apprised.

Taper Schedule

<table>
<thead>
<tr>
<th>Visit</th>
<th>Date</th>
<th>Medication</th>
<th>Taper Frequency (# weeks)</th>
<th>Single Dose</th>
<th>Dose Frequency</th>
<th>Total Daily Dose</th>
<th>Total Dose/Day</th>
<th>Quantities Needed</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
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</tbody>
</table>

We will allow for gradual dose reductions and will reassess regularly and adjust accordingly.

Sign and Date below:

Patient or Patient’s Representative (required):

_________________________ __________________________

Date: ______________________

Mature Minor Patient:

_________________________ __________________________

Date: ______________________

Physician Signature or Provider:

_________________________ __________________________

Date: ______________________
1. We must continue to effectively treat pain but still mitigate overdose risk
2. We cannot abandon the “pain refugee” because many will go to the street
3. We must improve access to care for both Pain Management Services and Substance Use Disorders
4. We must help diminish supply and demand for illicit opioids, benzodiazapines and stimulants through community-based initiatives
5. The updated 2022 CDC Guideline for prescribing opioids focuses on patient centered decision-making, multi-modality pain management and clarifies key outstanding misconceptions and misinterpretations
6. We can improve care with how we communicate, coordinate and collaborate with patients and professional colleagues, including better documentation
7. CMS is paving the way to compensate for extended services through Chronic Care Management (CCM)
8. We as Health Care Professionals are well positioned to help lead the way
For Further Information Regarding This Program:
Contact David Neff, DO at drneffdo@hotmail.com
or Go To Home (domoa.org)

For Further Information Regarding Pain Management:
Go to - Prescribing Opioids for Pain — The New CDC Clinical Practice Guideline | NEJM and CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022

For Further Information Regarding Medications for Opioid Use Disorder (MOUD):
Go to URL - Medications for Opioid Use Disorder (MOUD) - PCSS (pcssnow.org)
Thank You!!