### Summary: Progressive Opioid Prescribing Guidelines for a Safer Ohio

	From Emergency Department & Acute Care Facilities	For Chronic, Non-Terminal Pain	For Acute Pain Outside of Emergency Department
Release Date	April 2012	October 2013	January 2016
Specific Goals	Stop inappropriate prescribing from ED & Urgent Care Centers	Ensure long-term patient safety	Limit first use of opioids and decrease availability of unused opioid medications
Prescribing Limitations	<ul><li>No more than 3 days</li><li>No long-acting opioids</li></ul>	<ul> <li>"Press pause" at ≥ 80 mg MED</li> <li>Caution with co-prescribing of benzodiazepines</li> </ul>	<ul> <li>Consider non-pharmacologic and non-opioid therapies</li> <li>Limit pills per script</li> <li>No long-acting opioids</li> </ul>
OARRS Recommendations	Check prior to prescribing	<ul> <li>Check every patient at ≥ 80mg MED</li> <li>By law, OARRS check required for &gt;12 weeks</li> </ul>	<ul> <li>Check prior to prescribing</li> <li>By law, OARRS check required in most cases for ≥ 7 days of use (As of April 2015)</li> </ul>
Key Additional Clinical Steps	Referral to Primary Care	12 weeks a trigger for re-evaluation of pain, function, medication effectiveness & SBIRT	2 weeks a trigger for re-evaluation
TBD: Survey by ODH;     Additional data & trends     through OARRS		<ul> <li># patients at ≥ 80mg MED</li> <li>Proportion of prescriptions ≥ 120 pills/prescription</li> <li>Proportion and # patients on both opioid &amp; benzodiazepines</li> </ul>	<ul> <li><i>#</i> patients receiving <i>new</i> opioid prescription for acute pain</li> <li>See aggregate quarterly measures</li> </ul>
Aggregate Quarterly Measures for all guidelines	<ul> <li>% of prescriptions with associated OARRS check</li> <li># patients receiving opioids per quarter</li> <li>Total opioid pills prescribed per quarter;</li> <li>Average MED per prescription</li> </ul>		
Sample Patient Vignette	Patients who are narcotic- seeking, doctor shopping and/or diverting opioids	Patients with addiction or tolerance to medications; those at greater risk for harm	Patients seeking pain relief following injuries or procedures

Acronyms: ED=Emergency Department; MED=Morphine Equivalent Daily Dose; OARRS=Ohio Automated Rx Reporting System (prescription drug monitoring program); SBIRT=Screening, Brief Intervention, and Referral to Treatment for substance abuse Created December, 2015



#### **EXPANDING OHIO'S OPIOID PRESCRIBING GUIDELINES**

#### Strengthening Our Fight Against Prescription Drug Abuse

In its ongoing efforts to combat drug abuse and save lives, the Governor's Cabinet Opiate Action Team established in 2011 has developed new prescribing guidelines for the outpatient management of acute pain. The acute guidelines follow previous prescribing guidelines for emergency departments and the management of chronic pain. All three guidelines were developed in conjunction with clinical professional associations, healthcare providers, state licensing boards and state agencies. The prescribing guidelines are designed to prevent "doctor shopping" for prescription opioids, to urge prescribers to first consider non-opioid therapies and pain medications, to reduce leftover opioids that can be diverted for abuse, and to encourage prescribers to check Ohio's Automated Rx Reporting System before prescribing opioids to see what other controlled medications a patient might already be taking.

#### OHIO'S OPIOID PRESCRIBING GUIDELINES

- <u>Emergency Department/Acute Care Facility Opioid Prescribing Guidelines</u>: In April 2012, the Governor's Cabinet Opiate Action Team released Emergency and Acute Care Facility Opioid and Other Controlled Substances Prescribing Guidelines to reduce "doctor shopping" for prescription pain medications that could be abused or sold illegally, to encourage emergency department clinicians to check Ohio's Automated Rx Reporting System to see a patient's other prescriptions for controlled medications, to urge prescribers to limit the quantity of opioids prescribed, and to refer patients to a primary care provider or specialist for evaluation, treatment and monitoring of continuing pain.
- <u>Opioid Prescribing Guidelines for Treatment of Chronic Pain</u>: In October 2013, the Governor's Cabinet Opiate Action Team released Opioid Prescribing Guidelines for Treatment of Chronic, Non-Terminal Pain to ensure the safety of patients on high daily doses of opioids for chronic pain lasting longer than 12 weeks, and to urge prescribers to check the Ohio Automated Rx Reporting System to see a patient's other prescriptions for controlled medications.
- Opioid Prescribing Guidelines for Treatment of Acute Pain: In January 2016, the Governor's Cabinet Opiate Action Team released Guidelines for the Management of Acute Pain Outside of Emergency Departments to encourage non-opioid therapies and pain medications - when appropriate - for the management of acute pain expected to resolve within 12 weeks, to urge prescribers to check the Ohio Automated Rx Reporting System to see a patient's other prescriptions for controlled medications, to encourage clinicians to prescribe the minimum quantity of opioid pills needed, to discourage automatic refills of opioid prescriptions, to help reduce the number of leftover opioids that could be diverted or abused, and to recommend the reevaluation of patients prescribed opioids at certain checkpoints.

#### OHIO'S MULTI-PRONGED APPROACH TO FIGHT DRUG ABUSE

Ohio's opioid prescribing guidelines complement its multi-pronged approach to tackling the oversupply of prescription opioids, preventing prescription drug abuse before it starts, treating those who fall prey to prescription drug addiction, and utilizing naloxone to reverse drug overdoses and save lives.

- <u>Cutting the Pill Supply</u>: Too many pills are available on the street for illicit use. From the crack down on pill mills, to the development of acute opioid prescribing guidelines, to enhancements to the Board of Pharmacy's Ohio Automated Rx Reporting System, Ohio is making progress in reducing opioid over-prescribing. From 2012 to 2014, the number of opioid doses dispensed to Ohioans decreased by almost 42 million.
- <u>Preventing Drug Abuse Before it Starts</u>: Research shows that children are 50 percent less likely to use drugs when parents or other trusted adults talk with them about the risks of drug use. Ohio's youth drug prevention program, *Start Talking!*, provides parents, teachers and community leaders with simple tools to have these conversations. Nearly 50,000 parents, 5,000 school principals and administrators, and all of Ohio's school districts, have signed up to receive *Start Talking!* tips.
- <u>Providing Treatment and Recovery Support to Those in Need</u>: Ensuring that Ohioans have access to treatment and recovery support such as stable housing, employment services and relapse prevention is critical to Ohio's efforts to treat addiction as a chronic disease. Ohio has allocated \$2.5 million for recovery housing, an investment that will ultimately result in 900 new beds in treatment facilities. Medication Assisted Treatment is funded in 15 counties as a result of a \$5.5 million annual investment, with the goal of reducing relapses. Ohio is getting prison inmates the help they need to overcome addiction and sustain their recovery after release. By extending Medicaid coverage, 400,000 people with mental health conditions and/or addiction are getting access to the care they need.
- <u>Saving Lives through Naloxone</u>: Gov. Kasich has signed multiple bills into law that increase access to naloxone a drug overdose antidote for use by first responders and families of addicted individuals. Ohio pharmacies with a standing order from a physician can now dispense naloxone over the counter. The 2016-17 state budget dedicates \$1 million to make naloxone available to law enforcement and first responders through Ohio's local health departments.

**<u>BOTTOM LINE</u>**: Ohio's opioid prescribing guidelines will save lives by preventing "doctor shopping" for prescription pain medication, by urging prescribers and patients to consider non-opioid therapies that reduce the potential for addiction and abuse, by reducing overprescribing that leads to leftover pain medication, and by encouraging prescribers to find out what other controlled medications a patient might already be taking.



### **Acute Pain Prescribing Guidelines**

A companion to Ohio's Guidelines for the Management of Acute Pain Outside of Emergency Departments These guidelines are to be used as a clinical tool, but they do not replace clinician judgment.

#### **Patient Presents with Acute Pain**

#### Pain Assessment:

- Medical history and physical examination, including pregnancy status
- Location, intensity, severity; and associated symptoms
- Quality of pain (somatic, visceral or neuropathic)
- Psychological factors, personal/family history of addiction

#### **2**Develop a Plan:

- Educate patient and family and negotiate goals of treatment
- Discuss risks/benefits of non-pharmacologic & pharmacologic therapies
- Set patient expectations for the degree and the duration of the pain GOAL: Improvement of function to baseline as opposed to complete resolution of pain

### Options

#### Non-Pharmacologic Treatment

- Ice, heat, positioning, bracing, wrapping, splints, stretching
- Massage therapy, tactile stimulation, acupuncture/acupressure, chiropractic adjustment, osteopathic neuromusculoskeletal medicine
- Biofeedback
- Directed exercise such as physical therapy

Non-Opioid Pharmacologic Treatment				
Role in Therapy	Somatic (Sharp or Stabbing)	Visceral (Ache or Pressure)	Neuropathic (Burning or Tingling)	
First Line	Acetaminophen, NSAIDs, Corticosetroids		Gabapentin/pregabalin/TCAs/ SNRIs	
Alternatives	Gabapentin/pregabalin, skeletal muscle relaxants, SSRIs/SNRIs/TCAs	SNRIs/TCAs, dicyclomine	Anti-epileptics, baclofen, bupropion, low-concentration capsaicin, SSRIs, topical lidocaine	

#### **Opioid Pharmacologic Treatment**

#### For All Opioids:

- **Complete risk screening** (e.g. age, pregnancy, high-risk psychosocial environment, personal/family history of substance use disorder).
- Provide the patient with the least potent opioid to effectively manage pain (e.g. APAP/codeine instead of oxycodone). Refer to Morphine Equivalence Table.
- Prescribe the minimum quantity needed with no refills.
- **Consider checking OARRS** for all patients who will receive an opioid prescription. (OARRS report is required for most prescriptions of 7 days or more.)
- Avoid prescribing long-acting opioids for acute pain (e.g. methadone, oxycodone).
- Use caution when prescribing opioids with patients on benzodiazepines and sedative-hypnotics or patients known to use alcohol.
- Discuss how to safely and effectively wean patient off opioid medication.
- Remind that it is a unsafe and unlawful to give away or sell their opioids.
- Discuss proper storage and disposal of opioid medications.
- Coordinate care and communication of complex patients with other clinicians.

#### 14 Days (Key Checkpoint)

#### Reassess patient within an appropriate time NOT exceeding 14 days

#### If pain is unresolved, reassess:

- Pain, consider standardized tool (e.g. Oswestry Disability Index for back pain)
- Treatment method
- Context and reason for continued pain
- Additional treatment options, including consultation

## Morphine Equivalence Table Opioid Naive: Morphine Equivalence\* Notable NSAIDS

#### Most Potent

Buprenorphine sublinguam 42:1 Hydromorphone PO 4:1 Oxymorphone 3:1 Hydrocodone 1:1



#### Six Weeks (Key Checkpoint)

- If pain is unresolved:
- Repeat the prior step
- Refer to Chronic Pain Guideline



#### NEW LIMITS ON PRESCRIPTION OPIATES WILL SAVE LIVES AND FIGHT ADDICTION

As the epidemic of opiate abuse and addiction continues to sweep the country, state, local and community leaders constantly look to improve their efforts to combat it by responding with newer, better tools. Ohio is no different. Ohio is investing nearly \$1 billion each year to battle the scourge of drug abuse and addiction. Additionally, Ohio has:

- Shut down dozens of pill mills;
- Taken more than 250 actions against medical licenses because of prescribing issues;
- Increased seizures of illegal drugs resulting in more than 100 percent increase in drug arrests;
- Adopted some of the nation's first policies to reduce opiate prescriptions;
- Strengthened electronic tools that combat doctor shopping and illegal prescriptions;
- Launched a youth drug prevention effort comprised of proven, peer-reviewed strategies; and
- Dramatically increased recovery housing and addiction treatment efforts in local communities.

It is a tough battle, but Ohio's efforts are paying off and have helped the state reduce opiate prescriptions by 20 percent and doctor shopping by 78 percent—that means fewer opiates in circulation for illegal diversion or unauthorized use. Since prescription opiates are often the gateway to heroin use and 74 percent of those who died of a drug overdose in 2015 had a previous controlled substance prescription, we know that shutting down this avenue to addiction it an essential prevention strategy.

#### The Next Step...Implementing New Rules for Acute Pain Prescribing

Ohio is updating its opiate prescribing policies for treating acute pain by giving them the force of law. The state began creating its voluntary guidelines in 2012, together with the medical community, even before the U.S. Centers for Disease Control and Prevention (CDC) issued guidelines last March. After close analysis of the state's electronic prescribing data, Ohio will now take the next step to update its policies to place commonsense limits on opiate prescribing for acute pain. These improvements can lead to an estimated reduction of opiate doses in Ohio by 109 million per year while preserving the ability of clinicians to address pain in a competent and compassionate way.

Highlights of Ohio's new opiate prescribing limits for acute pain include:

- 1. No more than seven days of opiates can be prescribed for adults;
- 2. No more than five days of opiates can be prescribed for minors;
- 3. The total morphine equivalent dose (MED) of a prescription for acute pain cannot exceed an average of 30 MED per day;
- 4. Health care providers can prescribe opiates in excess of the new limits only if they provide a specific reason in the patient's medical record. Unless such a reason is given, a health care provider is prohibited from prescribing opiates that exceed Ohio's limits;
- 5. Prescribers will be required to include a diagnosis or procedure code on every controlled substance prescription, which will be entered into Ohio's prescription monitoring program, OARRS;
- 6. The new limits do not apply to opioids prescribed for cancer, palliative care, end-of-life/hospice care or medication-assisted treatment for addiction;
- 7. The new limits will be enacted through rules passed by the State Medical Board, Board of Pharmacy, Dental Board and Board of Nursing.

**BOTTOM LINE**: Ohio has made significant strides in reducing the amount of opiates prescribed by more than 20 percent since 2012, but more must be done to reduce the supply of prescription opiates available for abuse by establishing limits for the treatment of acute pain. With these new limits, it's estimated that the state could see an additional reduction of 109 million opiate doses. By reducing the availability of unused prescription opiates, fewer Ohioans will be presented with opportunities to misuse these highly addictive medications.



#### Ohio Guideline for the Management of Acute Pain Outside of Emergency Departments

Preface: This guideline provides a general approach to the outpatient management of acute pain. It is not intended to take the place of clinician judgement, which should always be utilized to provide the most appropriate care to meet the unique needs of each patient. This guideline is the result of the work from the Governor's Cabinet Opiate Action Team (GCOAT) and the workgroup on Opioids and Other Controlled Substances (OOCS).

#### Introduction

In 2014, 2,482 individuals in Ohio died from an unintentional opioidrelated overdose – more than a four-fold increase in 10 years<sup>1</sup>. Unintentional opioid overdose has become one of the leading causes of injury-related death in Ohio over the past decade. To respond to this challenge, public health and health care leaders have committed to helping healthcare providers better serve their patients with pain, while reducing the potential for overdose and death. As part of the Governor's Cabinet Opiate Action Team (GCOAT), the workgroup on Opioids and Other Controlled Substances (OOCS) was charged with developing guidelines for the safe, appropriate and effective prescribing of self-administered medications for pain. The two previously released guidelines are:

- Ohio Emergency and Acute Care Facility Opioids and Other Controlled Substances Prescribing Guidelines [Released 2012; Revised 2014]
- Guidelines for Prescribing Opioids for the Treatment of Chronic, Non-Terminal Pain 80mg of a Morphine Equivalent Dose (MED) "Trigger Point" [Released 2013]

#### Purpose

This third guideline is focused on the management of acute pain and the prescribing of self-administered medications for acute pain, delineating a standardized process that includes **key checkpoints** for the clinician to pause and take additional factors into consideration.

#### Definition of Acute Pain

For this guideline, acute pain is defined as pain that normally fades with healing, is related to tissue damage and significantly alters a patient's typical function. Acute pain is expected to resolve within days to weeks; pain present at 12 weeks is considered chronic and should be treated accordingly. This guideline may not apply to acute pain resulting from exacerbations of underlying chronic conditions.

#### Assessment and Diagnosis of Patient Presenting with Pain

For assessing patients presenting with acute pain, in addition to a proper medical history and physical exam, initial considerations should include:

- Location, intensity and severity of the pain and associated symptoms
- Quality of pain e.g. somatic (sharp or stabbing), visceral (ache or pressure) and neuropathic pain (burning, tingling or radiating)<sup>2</sup>
- Psychological factors, including personal and/or family history of substance use disorder

A specific diagnosis should be made, when appropriate, to facilitate the use of an evidence-based approach to treatment.

#### Develop a Plan

Upon determining the symptoms fit the definition of acute pain, both the provider and patient should discuss the risks/benefits of both pharmacologic and non-pharmacologic therapy. The provider should educate and develop a treatment plan together with the patient that includes<sup>3</sup>:

- Measureable goals for the reduction of pain
- Use of both non-pharmacologic and pharmacologic therapies, with a clear path for progression of treatment
- Mutually understood expectations for the degree and the duration of the pain during therapy
- Goal: Improvement of function to baseline or pre-injury status as opposed to complete resolution of pain

#### Treatment of Acute Pain

While these guidelines provide a pathway for the management of acute pain, not every patient will need each option and care should be individualized.

#### Non-Pharmacologic Treatment

Non-pharmacologic therapies should be considered as first-line therapy for acute pain unless the natural history of the cause of pain or clinical judgment warrants a different approach. These therapies often reduce pain with fewer side effects and can be used in combination with non-opioid medications to increase likelihood of success. Examples may include, but are not limited to:

- Ice, heat, positioning, bracing, wrapping, splints, stretching and directed exercise often available through physical therapy
- Massage therapy, tactile stimulation, acupuncture/acupressure, chiropractic adjustment, manipulation, and osteopathic neuromuscular care
- Biofeedback and hypnotherapy

#### Non-Opioid Pharmacologic Treatment

Non-opioid medications should be used with non-pharmacologic therapy. When initiating pharmacologic therapy, patients should be informed on proper use of medication, importance of maintaining other therapies and expectation for duration and degree of symptom improvement. Treatment options, by the quality of pain, are listed below.



#### Somatic Pain

- Acetaminophen
- Non-steroidal anti-inflammatory drugs (NSAIDS)
- Corticosteroids

Alternatives include the following: gabapentin/pregabalin, skeletal muscle relaxants, serotonin-norepinephrine reuptake inhibitors, selective serotonin reuptake inhibitors and tricyclic antidepressants.

#### Visceral Pain

- Acetaminophen
- Non-steroidal anti-inflammatory drugs (NSAIDS)
- Corticosteroids

Alternatives include the following: dicyclomine, skeletal muscle relaxants, serotonin-norepinephrine reuptake inhibitors, topical anesthetics and tricyclic antidepressants.

#### Neuropathic Pain

- Gabapentin/pregabalin
- Serotonin and norepinephrine reuptake inhibitors
- Tricyclic antidepressants

Alternatives include the following: other antiepileptics, baclofen, bupropion, low-concentration capsaicin, selective serotonin reuptake inhibitors and topical lidocaine.

#### **Opioid Pharmacologic Treatment**

In general, reserve opioids for acute pain resulting from severe injuries or medical conditions, surgical procedures, or when alternatives (non-opioid options) are ineffective or contraindicated. Short-term opioid therapy may be preferred as a first line therapy in specific circumstances such as the immediate post-operative period. In most cases, opioids should be used as adjuncts to additional therapies, rather than alone.<sup>4</sup> It is critical that healthcare providers communicate with one another about a patient's care if the patient may be receiving opiate prescriptions from more than one provider to ensure optimum and appropriate pain management. The following are recommendations for the general use of opioids to manage acute pain:

- Appropriate risk screening should be completed (e.g. age, pregnancy, high-risk psychosocial environment, personal or family history of substance use disorder).
- Provide the patient with the least potent opioid to effectively manage pain. A morphine equivalence chart should be used if needed.
- Prescribe the minimum quantity needed with no refills based on each individual patient, rather than a default number of pills.
- Consider checking Ohio Automated Rx Reporting System (OARRS) for all patients who will receive an opiate

prescription. (Note: An OARRS report is required for most prescriptions of seven days or more.)

- Avoid long-acting opioids (e.g. methadone, oxycodone ER, fentanyl).
- Use caution with prescribing opioids with patients on medications causing central nervous system depression (e.g. benzodiazepines and sedative hypnotics) or patients known to use alcohol, as combinations can increase the risk of respiratory depression and death.
- Discuss with the patient a planned wean off opioid therapy, concomitant with reduction or resolution of pain.
- Discuss proper secure storage and disposal of unused medication to reduce risks to the patient and others.
- Remind the patient that it is both unsafe and unlawful to give away or sell opioid medication, including unused or leftover medication.

#### Pain Reevaluation

Key Checkpoint: Reevaluation of patients who receive opioid therapy for acute pain will be considered if opioid therapy will continue beyond 14 days. This reevaluation may be through an office visit or phone call based on the discretion of the provider.

For patients with persisting pain, providers should reevaluate the initial diagnosis and consider the following:

- Pain characteristics (consider using a standardized tool [e.g. Oswestry Disability Index])
- Treatment methods used
- Reason(s) for continued pain
- Additional management options, including consultation with a specialist

#### Additional Checkpoint:

For patients with pain unresolved after 6 weeks, providers should repeat an assessment and determine whether treatment should be adjusted. Referral to guidelines on chronic pain management may be helpful at this point, although chronic pain is defined as pain persisting for longer than 12 weeks.

#### References:

- ODH, Office of Vital Statistics, Analysis by Injury Prevention Program. 2013.
- Institute for Clinical Systems Improvement. Assessment and management of acute pain. Bloomington (MN): Institute for Clinical Systems Improvement; 2008 Mar. 58p.
- Massachusetts Medical Society Opioid Therapy and Physician Communication Guidelines. May 21, 2015.
- 4. Washington State Agency Medical Directors Group. Interagency Guideline on Prescribing Opiates for Pain Washington State Guidance. June 2015.

#### Ohio Guidelines for Prescribing Opioids for the Treatment of Chronic, Non-Terminal Pain 80 mg of a Morphine Equivalent Daily Dose (MED) "Trigger Point"

Preface: These guidelines address the use of opioids for the treatment of chronic, non-terminal pain. "Chronic pain" means pain that has persisted after reasonable medical efforts have been made to relieve the pain or cure its cause and that has continued, either continuously or episodically, for longer than three continuous months. The guidelines are intended to help health care providers review and assess their

approach in the prescribing of opioids. The guidelines are points of reference intended to supplement and not replace the individual prescriber's clinical judgment. The 80 mg MED is the maximum daily dose at which point the prescriber's actions are triggered; however, this 80 mg MED trigger point is not an endorsement by any regulatory body or medical professional to utilize that dose or greater.

#### **Introduction**

Recent analysis by the Centers for Disease Control and Prevention (CDC) shows that "patients with mental health and substance use disorders are at increased risk for nonmedical use and overdose from prescription painkillers as well as being prescribed high doses of these drugs." Drug overdose deaths increased for the 11th consecutive year in 2010. Nearly 60% of the deaths involved pharmaceuticals, and opioids were involved in nearly 75%. Researchers also found that drugs prescribed for mental health conditions were involved in over half. These findings appear consistent with research previously published in the *Annals of Internal Medicine* that concluded that "patients receiving higher doses of prescribed opioids are at an increased risk for overdose, which underscores the need for close supervision of these patients" (Dunn, et al., 2010).

#### Non-Opioid Therapies First

Health care providers are not obligated to use opioids when a favorable risk-benefit balance cannot be documented. Providers should first consider non-pharmacologic and non-opioid therapies. Providers should exercise the same caution with tramadol as with opioids and must take into account the medication's potential for abuse, the possibility the patient will obtain the medication for a nontherapeutic use or distribute it to other persons, and the potential existence of an illicit market for the medication.

#### Avoid Long-Term and Co-Prescribing

Providers must be vigilant to the wide range of potential adverse effects associated with long-term opioid therapy and misuse of extended-release formulations. That vigilance and detailed attention has to be present from the outset of prescribing and continue for the duration of treatment. Providers should avoid starting a patient on long-term opioid therapy when treating chronic pain. Providers should also avoid prescribing benzodiazepines with opioids as it may increase opioid toxicity, add to sleep apnea risk, and increase risk of overdose deaths and other potential adverse effects.

#### Press Pause

Providers can further minimize the potential for prescription drug abuse/misuse and help reduce the number of unintentional overdose deaths associated with pain medications by recognizing times to "press pause" in response to certain "trigger points." This pause allows providers to reassess their compliance with accepted and prevailing standards of care. The 80 mg Morphine Equivalent Daily Dose (MED) "trigger point" is one such time.

#### Ensure Patient Safety

Providers treating chronic, non-terminal pain patients who have received opioids equal to or greater than 80 mg MED for longer than three continuous months should strongly consider doing the following to optimize therapy and help ensure patient safety:

- Reestablish informed consent, including providing the patient with written information on the potential adverse effects of long-term opioid therapy.
- Review the patient's functional status and documentation, including the 4A's of chronic pain treatment
  - Activities of daily living,
  - Adverse effects,
    - o Analgesia; and
    - o Aberrant behavior
- Review the patient's progress toward treatment objectives for the duration of treatment.
- Utilize OARRS as an additional check on patient compliance.
- Consider a patient pain treatment agreement that may include: more frequent office visits, different treatment options, drug screens, use of one pharmacy, use of one provider for the prescription of pain medications, and consequences for non-compliance with terms of the agreement.
- Reconsider having the patient evaluated by one or more other providers who specialize in the treatment of the area, system, or organ of the body perceived as the source of the pain.



#### **Review Treatment Plan**

The 80 MED "trigger point" is an opportunity to review the plan of treatment, the patient's response to treatment, and any modification to the plan of treatment that is necessary to achieve a favorable risk-benefit balance for the patient's care. If opioid therapy is continued, further reassessment will be guided by clinical judgment and decision-making consistent with accepted and prevailing standards of care. The "trigger point" also provides an opportunity to further assess addiction risk or mental health concerns, possibly using Screening, Brief Intervention, and Referral to Treatment (SBIRT) tools, including referral to an addiction medicine specialist when appropriate.

For providers treating acute exacerbation of chronic, nonterminal pain, clinical judgment may not trigger the need for using the full array of reassessment tools.

Providers treating patients with acute care conditions in the emergency department or urgent care center should refer to the Ohio Emergency and Acute Care Facility Opioids and Other Controlled Substances Prescribing Guidelines. <u>http://www.healthy.ohio.gov/ed/guidelines</u>

#### Ohio Guidelines for Emergency and Acute Care Facility Opioid and Other Controlled Substances (OOCS) Prescribing

Preface: These guidelines provide a general approach in the prescribing of OOCS. They are not intended to take the place of clinical judgement, which should always be utilized to provide the most appropriate care to meet the unique needs of each patient. These guidelines are a result of the work from the Governor's Cabinet Opiate Action Team (GCOAT) and the workgroup on Opioids and Other Controlled Substances (OOCS).



- Doses of OOCS for routine chronic pain or acute exacerbations of chronic pain will typically NOT be given in injection (IM or IV) form.
- b. Prescriptions for chronic pain will typically NOT be provided if the patient has either previously presented with the same problem or received an OOCS prescription from another provider within the last month.
- c. IV Demerol (Meperidine) for acute or chronic pain is discouraged.
- 2. Emergency medical clinicians will not routinely provide:
  - a. Replacement prescriptions for OOCS that were lost, destroyed or stolen.
  - b. Replacement doses of Suboxone, Subutex or Methadone for patients in a treatment program.
  - c. Long-acting or controlled-release opioids (such as OxyContin<sup>®</sup>, fentanyl patches, and methadone).
- 3. Prior to making a final determination regarding whether a patient will be provided a prescription for OOCS, the emergency clinician or facility:
  - a. Should search the Ohio Automated Rx Reporting System (OARRS) database (<u>https://www.ohiopmp.gov/portal/Default.asp</u> <u>x</u>) or other prescription monitoring programs, per state rules.
  - b. Reserves the right to request a photo ID to confirm the identity of the patient. If no photo ID is available, the emergency or other acute care facility should photograph the patient for inclusion in the facility medical record.
  - c. Reserves the right to perform a urine drug screen or other drug screening.
- 4. Emergency/acute care facilities should maintain an updated list of clinics that provide primary care and/or pain management services for patients, as needed.

(Released April 2012; Updated January 2014)

- 5. Prior to making a final determination regarding whether a patient will be provided a prescription for an OOCS, the emergency clinician should consider the following options:
  - a. Contact the patient's routine provider who usually prescribes their OOCS.
  - b. Request a consultation from their hospital's palliative or pain service (if available), or an appropriate sub-specialty service.
  - c. Perform case review or case management for patients who frequently visit the emergency/acute care facilities with pain-related complaints.
  - d. Request medical and prescription records from other hospitals, provider's offices, etc.
  - e. Request that the patient sign a pain agreement that outlines the expectations of the emergency clinician with regard to appropriate use of prescriptions for OOCS.
- 6. Emergency/acute care facilities should use available electronic medical resources to coordinate the care of patients who frequently visit the facility, allowing information exchange between emergency/acute care facilities and other community-care providers.
- 7. Except in rare circumstances, prescriptions for OOCS should be limited to a three-day supply. Most conditions seen in the emergency/acute care facility should resolve or improve within a few days. Continued pain needs referral to the primary care physician or appropriate specialist for re-evaluation.
- 8. Each patient leaving the emergency/acute care facility with a prescription for OOCS should be provided with detailed information about the addictive nature of these medications, the potential dangers of misuse and the appropriate storage and disposal of these medications at home. This information may be included in the Discharge Instructions or another handout.
- 9. Following the medical screening, emergency/acute care facilities should provide a patient handout that reflects the above guidelines and clearly states the facility position regarding the prescribing of opioids and other controlled substances.



#### Partners

#### The following organizations were involved in the development of one or more of Ohio's opioid prescribing guidelines.

- Academy of Medicine of Cleveland & Northern Ohio
- BEACON
- Capitol Action Team LLC
- CareSource
- Cleveland Clinic
- Fairfield Medical Center
- Governors Cabinet Opiate Action Team (GCOAT)
- Governor's Office of Health Transformation
- Hospice of Dayton
- Mid-Ohio District Nurses Association
- Midwest Care Alliance
- Nationwide Children's Hospital
- Ohio Academy of Family Physicians
- Ohio Association of Physician Assistants
- Ohio Board of Nursing
- Ohio Bureau of Workers Compensation
- Ohio Chapter, American College of Emergency Physicians
- Ohio Chapter, American College of Surgeons
- Ohio Dental Association
- Ohio Department of Aging
- Ohio Department of Health
- Ohio Department of Job and Family Services
- Ohio Department of Medicaid
- Ohio Department of Mental Health & Addiction Services
- Ohio Department of Public Safety
- Ohio Department of Rehabilitation & Correction
- Ohio Department of Youth Services

- Ohio Foot and Ankle Medical Association
- OhioHealth
- Ohio Healthcare Association
- Ohio Hospice and Palliative Care Organization
- Ohio Hospital Association
- Ohio Nurses Association
- Ohio Orthopaedic Society
- Ohio Osteopathic Association
- Ohio Pain Initiative
- Ohio Pharmacists Association
- Ohio Physical Therapy Association
- Ohio Psychiatric Physicians Association
- Ohio Public Health Association
- Ohio Society of Anesthesiologists
- Ohio Society of Interventional Pain Physicians
- Ohio State Board of Optometry
- Ohio State Chiropractic Association
- Ohio State Dental Board
- Ohio State Medical Association
- Ohio State University College of Dentistry
- Ohio State University College of Nursing
- Ohio State University Wexner Medical Center
- Start Talking!
- State Medical Board of Ohio
- State of Ohio Board of Pharmacy
- Summa Health System
- University Hospitals/Cleveland

#### Opioid Prescribing Guidelines for Oklahoma Health Care Providers in the Office-Based Setting

Note: These guidelines do not replace clinical judgment in the appropriate care of patients. They are not intended as standards of care or as templates for legislation, nor are they meant for patients in palliative care programs or with cancer pain. The recommendations are an educational tool based on the expert opinion of numerous physicians and other health care providers, medical/nursing boards, mental and public health officials, and law enforcement personnel in Oklahoma and throughout the United States. The guidelines are available at http://poison.health.ok.gov.

#### **Opioid Treatment for Acute Pain**

- 1. Opioids should only be used for treatment of acute pain when the severity of the pain warrants that choice and after determining that other non-opioid pain medications or therapies will not provide adequate pain relief.
- 2. Providers should query the Oklahoma Prescription Monitoring Program (PMP) for patients presenting with acute pain, prior to prescribing an opioid medication. In circumstances where a patient's pain is resulting from an objectively diagnosed disease process or injury, a provider may prudently opt not to review the Oklahoma PMP.
- 3. When opioids are prescribed for treatment of acute pain, the number of doses dispensed should be no more than the number of doses needed based on the usual duration of pain severe enough to require opioids for that condition.
- 4. When opioids are prescribed for treatment of acute pain, the patient should be counseled to store the medications securely and never to share with others. In order to prevent non-medical use of the medications, it is also recommended that patients dispose of medications when the pain has resolved.
- 5. Long duration-of-action opioids (e.g., methadone, buprenorphine, fentanyl, extended release oxycodone, and morphine) are rarely indicated for treatment of acute pain.
- 6. The use of opioids should be re-evaluated carefully, including assessing the potential for abuse, if persistent pain suggests the need to continue opioids beyond the anticipated time period of acute pain treatment for that condition. Health care providers should query the Oklahoma PMP as part of this re-evaluation process.
- 7. Health care providers should generally not provide replacement prescriptions for opioids that have been lost, stolen, or destroyed.

#### **Opioid Treatment for Chronic Pain**

- 1. Alternatives to opioid treatment should be tried, or previous attempts documented, before initiating opioid treatment.
- 2. A comprehensive evaluation should be performed before initiating opioid treatment for chronic pain. For chronic pain patients transferring their care to new health care providers, new opioid prescriptions should generally not be written until the previous provider's records have been reviewed or the previous health care provider has been notified of the transfer of care.
- 3. The health care provider should screen for risk of abuse or addiction before initiating opioid treatment.
- 4. Prior to the initial prescribing of opioid medications, health care providers should query the Oklahoma Prescription Monitoring Program (PMP).
- 5. When opioids are used for the treatment of chronic pain, a written treatment plan should be established that includes measurable goals for reduction of pain and improvement of function. One health care provider should coordinate a patient's comprehensive pain care plan and provide all opioid prescriptions required for the plan.

- 6. The patient should be informed of the risks, benefits, and terms for continuation of opioid treatment, ideally using a written and signed treatment agreement.
- 7. Opioids should be initiated as a short-term trial to assess the effects of opioid treatment on pain intensity, function, and quality of life. In most instances, the trial should begin with a short-acting opioid medication.
- 8. Regular visits for evaluation of progress toward goals should be scheduled during the period when the dose of opioids is being adjusted (titration period). During the titration period, and until the patient is clinically stable and judged to be compliant with therapy, it is recommended that the health care provider check the Oklahoma PMP more frequently.
- 9. Once a stable dose has been established (maintenance period), regular monitoring should be conducted at faceto-face visits during which treatment goals, analgesia, activity, adverse effects, and aberrant behaviors are monitored. The Oklahoma PMP should be queried at least once per year for patients receiving opioid treatment for chronic pain.
- 10. Continuing opioid treatment should be a deliberate decision that takes into consideration the risks and benefits of chronic opioid treatment for that patient. Patients and health care providers should periodically reassess the need for continued opioid treatment, weaning whenever possible, as part of the comprehensive pain care plan. A second opinion or consultation may be useful in making that decision.
- 11. Opioid treatment should be discontinued if adverse effects outweigh benefits or if aberrant, dangerous, or illegal behaviors are demonstrated.
- 12. Health care providers treating chronic pain patients with opioids should maintain records, in accordance with state and federal law, documenting patient evaluation, treatment plan, discussion of risks and benefits, informed consent, treatments prescribed, results of treatment, and any aberrant behavior observed.
- 13. Health care providers should consider consultation for patients with complex pain conditions, serious comorbidities and mental illness, a history or evidence of current drug addiction or abuse, or when the provider is not confident of his/her ability to manage the treatment.
- 14. Health care providers should generally not provide replacement prescriptions for opioids that have been lost, stolen, or destroyed.
- 15. The administration of intravenous and intramuscular opioids for the relief of exacerbations of chronic pain is discouraged, except in special circumstances.
- 16. Long-acting opioids are associated with an increased risk of overdose death, and should only be prescribed by health care providers familiar with their indications, risks, and need for careful monitoring.
- 17. When opioids are prescribed for treatment of chronic pain, the patient should be counseled to store the medications securely and never to share with others. In order to prevent non-medical use of the medications, it is also recommended that patients dispose of medications when the pain has resolved.



#### **Oklahoma Society of Interventional Pain Physicians**

#### Background

Prescription drug abuse is Oklahoma's fastest growing drug problem. Of the nearly 3,200 unintentional poisoning deaths in Oklahoma from 2007-2011, 81% involved at least one prescription drug.<sup>1</sup> In 2010, Oklahoma had the fourth highest unintentional poisoning death rate in the nation (17.9 deaths per 100,000 population).<sup>2</sup> Prescription painkillers (opioids) are now the most common class of drug involved in overdose deaths in Oklahoma (involved in 87% of prescription drug-related deaths, with 417 opioid-involved overdose deaths in 2011).1 In a 2010 National Survey on Drug Use and Health report, Oklahoma led the nation in non-medical use of painkillers, with more than 8% of the population age 12 and older abusing/misusing painkillers.<sup>3</sup> Oklahoma is also one of the leading states in prescription painkiller sales per capita.<sup>4</sup>

These guidelines were primarily adapted from the Utah Clinical Guidelines on Prescribing Opioids.<sup>5</sup> The Opioid Prescribing Guidelines for Oklahoma Workgroup also studied other state and national recommendations in an effort to prepare guidelines most relevant to the practice of medicine in Oklahoma. The Workgroup created these guidelines in an effort to help reduce the misuse of prescription opioid analgesics while preserving patient access to needed medical treatment.

#### **Guidelines for Acute Pain**

## 1. Opioids should only be used for treatment of acute pain when the severity of the pain warrants that choice and after determining that other non-opioid pain medications or therapies will not provide adequate pain relief.<sup>6</sup>

Most acute pain is better treated with non-opioid medications [e.g., acetaminophen, non-steroidal antiinflammatory drugs (NSAIDs)] or physical modalities such as therapeutic exercises or stretching. Opioid medications have less desirable adverse effect profiles in acute pain patients. Care should be taken to assure that opioid treatment does not interfere with early implementation of functional restoration programs such as exercise and physical therapy. Non-medical use of opioids is more common among younger people, and these risks should be considered when prescribing to an adolescent.

## 2. Providers should query the Oklahoma Prescription Monitoring Program (PMP) for patients presenting with acute pain, prior to prescribing an opioid medication. In circumstances where a patient's pain is resulting from an objectively diagnosed disease process or injury, a provider may prudently opt not to review the Oklahoma PMP.

The Oklahoma PMP is a real-time database of scheduled prescriptions written to persons who filled a prescription in Oklahoma. The Oklahoma PMP can be accessed at: http://www.ok.gov/obndd/Prescription\_Monitoring\_Program/.

Patients with a history of or current substance abuse are at increased risk of misusing opioids when prescribed.<sup>7,8</sup> Medical providers should ask the patient about a history of substance abuse prior to prescribing an opioid medication for the treatment of acute pain. A non-opioid regimen is preferred for patients presenting with a history of substance abuse who have acute pain. Although this should not exclude a patient from being prescribed opioids for acute pain, it should prompt a discussion with the patient about the potential for addiction. When a patient with a history of opioid addiction presents with acute pain due to an objectively diagnosed clinical or traumatic condition requiring the use of opioids for pain control, very close follow-up is indicated.

## 3. When opioids are prescribed for treatment of acute pain, the number of doses dispensed should be no more than the number of doses needed based on the usual duration of pain severe enough to require opioids for that condition.

Prescribing more medications than necessary can lead to non-medical use, abuse, and diversion of unused

medications. Opioid pain medications should be discontinued when the pain severity no longer requires opioid medications.

## 4. When opioids are prescribed for treatment of acute pain, the patient should be counseled to store the medications securely and never to share with others. In order to prevent non-medical use of the medications, it is also recommended that patients dispose of medications when the pain has resolved.

It is important that patients understand the need to store medications securely. Health care providers should encourage patients to keep medications in a locked environment rather than in easily accessible locations, such as the bathroom or kitchen cabinet, where medications are accessible to children and can be a target for theft. After recovery from pain, leftover medications should be properly disposed of immediately to help protect the medications from being diverted.

Tools to accompany Recommendation 4:

- United States Food and Drug Administration (FDA) Guidelines on Proper Disposal of Prescription Drugs http://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/Under standingOver-the-CounterMedicines/ucm107163.pdf
- Oklahoma Bureau of Narcotics and Dangerous Drugs Take Back Container Locations http://www.ok.gov/obndd/documents/TakeBackBoxes.pdf

### 5. Long duration-of-action opioids (e.g., methadone, buprenorphine, fentanyl, extended release oxycodone, and morphine) are rarely indicated for treatment of acute pain.

Given the epidemiological data showing a significant increase in mortality associated with long-acting opioids, the inherent difficulty in titrating these medications, and the availability of alternative medications and/or treatment modalities, health care providers are advised to refrain from the routine use of long-acting opioids in the acute pain setting.<sup>5,9</sup>

## 6. The use of opioids should be re-evaluated carefully, including assessing the potential for abuse, if persistent pain suggests the need to continue opioids beyond the anticipated time period of acute pain treatment for that condition. Health care providers should query the Oklahoma PMP as part of this re-evaluation process.

Patients with acute pain who fail to recover in a usual timeframe or otherwise deviate from the expected clinical course for their diagnosis should be carefully re-evaluated. The continuation of opioid treatment for acute pain in this setting may represent the initiation of opioid treatment for a chronic pain condition without being recognized as such. At this time, the diagnosis and appropriateness of the treatment plan should be re-evaluated and the patient's medical history should be reviewed for factors that could interfere with treatment and pose a risk for complications during opioid treatment, including substance abuse or history of substance abuse.

Tools to accompany Recommendation 6:

 Oklahoma Prescription Monitoring Program http://www.ok.gov/obndd/Prescription\_Monitoring\_Program/

### 7. Health care providers should generally not provide replacement prescriptions for opioids that have been lost, stolen, or destroyed.

Patients misusing controlled substances frequently report their opioid medications as having been lost or stolen. Pain specialists routinely stipulate in pain agreements with patients that lost or stolen controlled substances will not be replaced. Most written agreements between chronic pain patients and pain management physicians, including the Health Resources and Services Administration (HRSA) toolkit sample pain agreement, state that prescriptions for opioids will not be replaced.<sup>10</sup>

The diversion of prescribed opioids is common. One study looked at completed patient surveys, and found that 45% of respondents reported some form of drug diversion at least once. Stolen medication was the most prevalent method of drug diversion, with 30% of respondents reporting at least one incident of stolen medication.<sup>11</sup> In another survey study, among persons 12 years and older who abused opioid pain medications (2009-2010), 71.2% came from friends or relatives; 55% were given to the abuser, 11.4% were purchased, and 4.8% were stolen.<sup>12,13</sup>

#### **Guidelines for Chronic Pain**

### **1.** Alternatives to opioid treatment should be tried, or previous attempts documented, before initiating opioid treatment.<sup>6,9,13,14,15</sup>

Opioid medications are usually not the most appropriate first line of treatment for patients with chronic pain. Other measures, such as non-opioid pain medications, non-steroidal anti-inflammatory drugs (NSAIDs), antidepressants, antiepileptic drugs, and non-pharmacologic therapies (e.g., therapeutic exercise, physical therapy), should be tried first and the outcomes of those therapies documented. Opioid therapy should be considered only when other potentially safer and more effective therapies prove inadequate. This approach is consistent with the World Health Organization's (WHO) *Pain Relief Ladder*.<sup>16</sup>

**1.1** Clinicians should refer to disease-specific guidelines for recommendations for treatment of chronic pain related to specific diseases or conditions.

Tools to accompany Recommendation 1:

• Non-opioid Pain Management Tool http://health.utah.gov/prescription/tools.html (see *Informational Tools* on website)

# 2. A comprehensive evaluation should be performed before initiating opioid treatment for chronic pain. For chronic pain patients transferring their care to new health care providers, new opioid prescriptions should generally not be written until the previous provider's records have been reviewed or the previous health care provider has been notified of the transfer of care.<sup>13,14,15,17</sup>

There are many reasons to prescribe cautiously when initiating opioid therapy; therefore a comprehensive initial evaluation is necessary to identify patients at high risk for adverse outcomes. The major goal should be to provide the greatest functional benefit while minimizing the potential for harm to patients. The potential for serious harm, including death, exists due either to overdose or to dangerous behaviors that may occur while taking opioids. The patient may be directly harmed, but others may also be harmed through diversion or by acts performed by a person taking opioids.

Initiating opioid treatment often results in short-term relief, which may not be sustainable. Safe long-term use of opioid medications requires the commitment of adequate resources. Patients need to be monitored regularly to evaluate outcomes and identify aberrant behavior or adverse side effects.

The goal of the comprehensive evaluation is to determine the nature of the patient's pain, and to evaluate how the pain is affecting the patient's function and quality of life. The provider should attempt to identify other conditions or circumstances that could adversely affect the treatment plan or the approach to managing the patient's treatment plan. The provider should also re-assess and re-evaluate prior approaches to the patient's pain management to provide a basis for establishing an effective ongoing plan of care.

The evaluation should specifically assess:

A. The character and potential cause(s) of pain, as well as prior treatments.

- The duration of the pain should be considered.
- The character of the pain should be considered. Since certain types of pain, such as neuropathic pain,

might not be best treated with opioids. It is important for the clinician to consider the type and character of pain when prescribing a medication.

- B. Social factors and medical or mental health conditions might influence treatment, especially those that might interfere with appropriate and safe use of opioid therapy.<sup>14</sup>
  - Obtain a history of substance use, addiction, or dependence. (If present, refer to *Recommendations 13.2 and 13.3.*)
  - Consider potential psychiatric conditions, including personality disorders that may affect pain or the treatment of pain. (If present, refer to *Recommendation 13.4.*)
  - Identify use of alcohol and other medications that might interact with opioid medications used to treat pain. Particular attention and caution should be given to alcohol, benzodiazepines, and other sedative medications.
  - Assess the presence of medical conditions that might complicate the treatment of pain, including medication allergy, cardiac or respiratory disease, and sleep apnea or risk factors for sleep apnea.
  - Central sleep apnea is common among persons treated with methadone and other opioid medications, especially at higher dosages. Some experts recommend that all patients who are considered for long-term opioid treatment receive a sleep study prior to therapy or when higher dosages are considered.<sup>14</sup>

C. Effects of pain on the patient's life and function.

• Assess the patient's baseline severity of pain, functional status, and quality of life using a valid, reliable method/instrument that can be used later to evaluate treatment effectiveness.

Tools to accompany Recommendation 2:

- Sheehan Disability Tool http://health.utah.gov/prescription/pdf/guidelines/SheehanDisabilityScale.pdf
- Pain Management Evaluation Tool http://health.utah.gov/prescription/pdf/guidelines/PainManagementWorksheet.pdf

### **3.** The health care provider should screen for risk of abuse or addiction before initiating opioid treatment.

**3.1** Use a screening tool to assess the patient's risk of misuse prior to prescribing an opioid medication for chronic pain.<sup>6</sup>

A number of screening tools have been developed for assessing a patient's risk of misuse of medications. The screening tools are intended to assist the health care provider in determining whether opioid treatment is appropriate and in determining the level of monitoring appropriate for the patient's level of risk.

3.2 Consider performing drug screening before initiating long term opioid treatment for chronic pain.

Drug testing can identify problems, such as use of undisclosed medications, non-use of reported medications (i.e., potential diversion), undisclosed use of alcohol, or the use of illicit substances, not identified without testing.

Health care providers should use a urine drug screen or another laboratory test that can detect the presence of illegal drugs, unreported prescription medications, and/or unreported alcohol use. It is recommended that drug testing be strongly considered and conducted, especially when other factors suggest caution. When screening is limited to situations when there is suspicion of substance misuse, some opportunities may be missed. In one study, testing results upon first admission to a pain clinic did not correlate with reported medication use for nearly one-fourth of patients. Most discrepancies involved substances not reported by the patient; a small minority reported taking medications that were not found on testing.<sup>18</sup>

A positive drug screen indicates the need for caution, but does not preclude opioid use for the treatment of pain. However, consideration should be given to referral for substance abuse counseling and/or a pain management specialist. If an opioid medication is subsequently prescribed, the patient should be more carefully monitored and the conditions under which opioids are being prescribed should be well documented in the treatment plan. (See *Recommendations 5, 6, 8, 12*.)

Inexpensive immunoassays can be performed in the office. These tests can rapidly determine if opioids are present but they do not identify specific substances. When necessary, specific substances can be identified by ordering confirmatory laboratory testing. However, in many cases, candidly going over the results of the initial in-office test with the patient can eliminate the need for confirmatory testing. It is extremely important to keep in mind that immunoassays have both false-positive and false-negative results. Certain over-the-counter medications may cause a positive result. The prescriber should consider confirmatory gas chromatography or mass spectrometry testing or consultation with a certified Medical Review Officer if drug test results are unclear or confirmation is clinically necessary.<sup>9</sup>

Tools to accompany *Recommendation 3*:

- Urine Drug Testing Devices http://health.utah.gov/prescription/pdf/guidelines/CLIADrugTestlist.pdf
- Current Opioid Misuse Measure http://health.utah.gov/prescription/tools.html (see *Tools to Screen for Risk of Complications* on website)
- SOAPP-R http://health.utah.gov/prescription/tools.html (see *Tools to Screen for Risk of Complications* on website)
- Opioid Risk Tool http://health.utah.gov/prescription/pdf/guidelines/ORTwithout\_scoring.pdf
- Signs of Substance Misuse http://health.utah.gov/prescription/pdf/guidelines/signs\_substance\_misuse.pdf
- Checklist for Adverse Effects, Function, and Opioid Dependence http://health.utah.gov/prescription/pdf/guidelines/checklist%20for%20adverse%20effects.pdf

### 4. Prior to the initial prescribing of opioid medications, health care providers should query the Oklahoma Prescription Monitoring Program (PMP).

Most patients who request treatment for pain are legitimately seeking relief of pain. However, subsets of patients seeking treatment for pain are seeking drugs for recreational use, to support an established addiction, or for profit. Information about past patterns of controlled substance prescriptions filled by the patient, such as obtaining medications from multiple providers or obtaining concurrent prescriptions, can alert the provider to potential problems.

The Oklahoma Bureau of Narcotics and Dangerous Drugs Control (OBNDDC) maintains the Oklahoma Prescription Monitoring Program, a real time, searchable database of all controlled substance prescriptions filled in the state. The PMP is used to track and collect data on the dispensing of Schedule II-V drugs by all retail, institutional, and outpatient hospital pharmacies, and in-state/out-of-state mail order pharmacies. Access to the data is provided to authorized individuals and used to identify potential cases of drug over-utilization, misuse, and potential abuse of controlled substances throughout the state. This database is accessible online to all controlled substance prescribers.

Tools to accompany *Recommendation 4:* 

Oklahoma Prescription Monitoring Program
 http://www.ok.gov/obndd/Prescription\_Monitoring\_Program/

#### 5. When opioids are used for the treatment of chronic pain, a written treatment plan should be established that includes measurable goals for reduction of pain and improvement of function. One health care provider should coordinate a patient's comprehensive pain care plan and provide all opioid prescriptions required for the plan.

**5.1** The treatment plan should be tailored to the patient's circumstances and the characteristics and pathophysiology of the pain. The pathophysiology helps to predict whether opioid medication is likely to help reduce pain or to improve function, and should be considered when establishing treatment goals. Non-opioid treatment modalities should be included in the treatment plan, whenever possible, to maximize the likelihood of achieving treatment goals.

**5.2** Goals for the treatment of chronic pain should be measurable and should include improved function and quality of life as well as improved control of pain.<sup>6,9,14</sup>

For most chronic pain conditions, complete elimination of pain is an unreasonable goal. Goals for treatment of chronic pain should include improvement in the tolerability of pain and function.<sup>15</sup> The clinician should counsel the patient on reasonable expectations for treatment outcomes so that agreement is achieved on the goals of addressing pain, function, and quality of life.

The pathophysiologic basis of the pain can help establish a prognosis for future improvement (or worsening) in function and pain and should influence the goals of treatment. Goals for functional improvement and measures to track progress against those goals should be established and documented to serve as a basis of evaluating treatment outcomes.<sup>6,14</sup> These include:

- Objective physical findings obtained by the examining health care provider (e.g., improved strength, range of motion, aerobic capacity);
- Functional status at work (e.g., increase in physical output, endurance, or ability to perform job functions); and
- Functional status at home (e.g., increased ability to perform instrumental activities of daily living, and frequency and intensity of conditioning).

Targets for improved quality of life should also be identified and documented to serve as a basis for evaluating treatment outcomes. These may include:

- Patient rating of quality of life on a measurement scale;
- Psychosocial status (e.g., increased social engagement or decreased emotional distress);
- Familial status (e.g., improved relationships with, or decreased burden, on family members); and
- Physical status (e.g., increased ability to exercise, perform chores, or participate in hobbies).

Health care providers should consider cultural differences in assessing function, quality of life, and pain intensity (see http://prc.coh.org/culture.asp for examples). These measures of improvement could be reported by the patient, family members, and/or the employer. Permission to discuss the patient's condition with these persons should have been previously obtained and documented.

**5.3** Treatment goals should be developed jointly by the patient and health care provider.<sup>15</sup>

Engage patients in their own health care. Health care providers have observed that when patients assume a significant portion of the responsibility for their rehabilitation they are more likely to improve and that when they participate in goal setting they are more likely to achieve the goals. As with any other chronic illness (such as diabetes or heart disease), the health care provider should focus not just on pain control, but also on treating the patient's underlying diseases and encouraging them to engage in ownership of their own health.

Tools to accompany *Recommendation 5*:

- Pain Management Evaluation Tool http://health.utah.gov/prescription/pdf/guidelines/PainManagementWorksheet.pdf
- Patient Pain and Medication Tracking Chart http://health.utah.gov/prescription/pdf/guidelines/PatientPain-FunctionTracking.pdf
- Sheehan Disability Scale http://health.utah.gov/prescription/pdf/guidelines/SheehanDisabilityScale.pdf
- Brief Pain Inventory Form http://health.utah.gov/prescription/pdf/guidelines/BriefPainInvNPEC.pdf
- Sample Treatment Plan for Prescription Opioids http://health.utah.gov/prescription/pdf/guidelines/treatment\_plan.pdf
- Cultural considerations in assessing function, quality of life, and pain intensity http://prc.coh.org/culture.asp

### 6. The patient should be informed of the risks, benefits, and terms for continuation of opioid treatment, ideally using a written and signed treatment agreement.<sup>13</sup>

**6.1** Patients should be informed not to expect complete relief from pain. The excitement and euphoria of initial pain relief that may occur with a potent opioid can lead the patient to expect long-term complete pain relief. Without careful guidance, this may lead the patient to disappointment and to seek excessive doses of opioids.

The patient should be counseled about the appropriate use of opioid medications, possible adverse effects, and the risks of developing tolerance, physical and/or psychological dependence, and withdrawal symptoms.<sup>9,19</sup> Adverse effects can include opioid-induced hyperalgesia, allodynia, abnormal pain sensitivity, and depression.<sup>6,9,20</sup>

Sedation and cognitive impairment may occur when patients are taking opioid medications. Therefore, discuss with patients the need for caution in operating motor vehicles or equipment or performing other tasks where impairment would put them or others at risk.<sup>11</sup>

Ensure the patient does not have any absolute contraindications, and review risks and benefits related to any relative contraindications with the patient.

Absolute contraindications for opioid prescribing:

- Allergy to an opioid agent (may be addressed by using an alternative agent);
- Co-administration of a drug capable of inducing life-threatening drug-drug interaction; and
- Active diversion of controlled substances (providing medication to someone for whom it was not prescribed).

More detail about absolute contraindications is contained in the Guidelines Tools section.

Consider co-prescribing naloxone for high risk patients, and providing training to family/caregivers to reverse potential life-threatening depression of the respiratory and central nervous system. Educate patients and family/caregivers about the danger signs of respiratory depression. Everyone in the household should know to summon medical help immediately if a person demonstrates any of the following signs while on opioids:

- Snoring heavily and cannot be awakened;
- Periods of ataxic (irregular) or other sleep disordered breathing;
- Trouble breathing;

- Exhibiting extreme drowsiness and slow breathing;
- Slow, shallow breathing with little chest movement;
- Increased or decreased heartbeat; and
- Feeling faint, very dizzy, confused or has heart palpitations.

**6.2** The patient and, when applicable, the family or caregiver should be involved in the education process.<sup>14</sup>

Educational material should be provided in written form and discussed in person with the patient and, when applicable, the family or caregiver.<sup>14</sup> Educating the family or caregiver about the signs of opioid overdose may help detect problems before they lead to a serious complication.

It is important to act within the constraints of the Health Insurance Portability and Accountability Act (HIPAA). HIPAA regulates the conditions under which information about the patient can be disclosed to others, such as family members, and under what conditions discussions about the patient with others are allowed.

**6.3** The treatment plan, which defines the responsibilities of both the patient and health care provider, should be documented.  $^{6,9,13,14,15}$ 

Patient responsibilities include properly obtaining, filling, and using prescriptions, and adherence to the treatment plan. Patient responsibilities also include instructions to keep a pain diary, a diary or log of daily activities and accomplishments, and/or instructions on how and when to give feedback to the prescriber.<sup>14</sup>

The prescribing health care provider may consider requiring that the treatment plan be documented in the form of a treatment agreement signed by the patient. Patients should be encouraged to store opioid medications in a secure location to keep the medication away from others who should not have access to them.

**6.4** The treatment plan should contain goals of treatment, guidelines for prescription refills, agreement to submit to urine or serum screening upon request, and reasons for possible discontinuation of drug therapy.9<sup>,13,14,15,17</sup>

The treatment plan (sometimes referred to as a treatment agreement) should contain the items developed jointly by the patient and health care provider, such as follow-up appointments, the pharmacy and health care provider to be used, as well as any non-negotiable demands or limitations the health care provider wishes to make, such as the prohibition of sharing or trading the medication or getting refills early. Specific grounds for immediate termination of the agreement and cessation of prescribing may also be specified, such as forgery or selling of prescriptions or medications or obtaining them from multiple providers as documented by Oklahoma's Prescription Monitoring Program.<sup>14,20</sup>

Optional inclusions in the agreement:

- Pill counts may be required as a means to gauge proper medication use;<sup>14,19</sup>
- Prohibition of use with alcohol or certain other medications;<sup>14</sup>
- Documentation of counseling regarding driving or operating heavy machinery; and <sup>6,14</sup>
- Specific frequencies of urine testing.

Ideally, the patient should be receiving prescriptions from one prescriber only and filling those prescriptions at one pharmacy only.<sup>14,17,19</sup>

It is not necessary to include specific consequences for specific non-compliant behaviors, but it should be documented in the treatment agreement that continuing failure by the patient to adhere to the treatment plan will result in escalating consequences, up to and including termination of the clinician-patient relationship and of opioid prescribing by that clinician.

**6.5** Discuss involvement of family members in the patient's care and request that the patient give written permission to talk with family members about the patient's care.

This is best done before starting to treat the patient because it can be more difficult to obtain consent after an issue occurs. Prior to initiating treatment with opioids, the health care provider may want to consider a family conference to help assess the patient's integrity.<sup>19</sup> Consultation with others, however, must be done within the constraints of HIPAA, as noted above. (See *Recommendation 6.2.*)

Tools to accompany Recommendation 6:

- Absolute Contraindications to Opioid Prescribing http://health.utah.gov/prescription/pdf/guidelines/absolute\_contraindications.pdf
- Sample Treatment Plan for Prescribing Opioids http://health.utah.gov/prescription/pdf/guidelines/treatment\_plan.pdf
- Signs of Substance Misuse http://health.utah.gov/prescription/pdf/guidelines/signs\_substance\_misuse.pdf
- Guidance on HIPAA http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/provider\_ffg.pdf
- Prescription Drug Overdose in Oklahoma Brochure http://www.ok.gov/health2/documents/DrugOverDoseBrochure\_2013.pdf

#### Initiating, Monitoring, and Discontinuing Opioid Treatment

## 7. Opioids should be initiated as a short-term trial to assess the effects of opioid treatment on pain intensity, function, and quality of life. In most instances, the trial should begin with a short-acting opioid medication.

**7.1** The health care provider should clearly explain to the patient that initiation of opioid treatment is not a commitment to long-term opioid treatment and that treatment will be stopped if the trial is determined to be unsuccessful. The trial should be for a specific time period with pre-determined evaluation points. The decision to continue opioid medication treatment beyond the trial period should be based on the balance between benefits, including function and quality of life, and adverse effects experienced. Criteria for cessation should be considered before treatment begins. Refer to *Recommendation 11* for more information on discontinuation of treatment.

**7.2** Short-acting opioid medications are, in general, safer and easier to titrate to an effective dose. If the treatment trial proves successful in achieving the goals established in the treatment plan, the health care provider may consider switching the patient to a long-acting or sustained-release formulation. The patient's individual situation should influence whether the patient is switched from a short-acting medication. Treatment with a long-acting opioid medication before a trial using a short-acting medication has been performed is an option that should be prescribed only by those with considerable expertise in chronic pain management.

Tools to accompany Recommendation 7:

- Dosing Guidelines http://health.utah.gov/prescription/pdf/guidelines/dosing\_guidelines.pdf
- Current Opioid Misuse Measure (COMM) http://health.utah.gov/prescription/tools.html (see *Tools to Screen for Risk of Complications* on website)

#### **Titration Phase of Opioid Treatment**

8. Regular visits for evaluation of progress toward goals should be scheduled during the period when the dose of opioids is being adjusted (titration period). During the titration period, and until the patient is clinically stable and judged to be compliant with therapy, it is recommended that the health care provider check the Oklahoma PMP more frequently.<sup>14</sup>

**8.1** Face-to-face follow-up visits should occur at least every 2-4 weeks during the titration period. More frequent follow-up visits may be advisable and caution should be used when prescribing an opioid medication if the patient has a known addiction problem, suspected drug-behavior problems, or co-existing psychiatric or medical problems. Frequency of visits should also be based on risk stratification (e.g., as determined by a screening tool) and the clinician's judgment (taking into account the volume of the drug being prescribed and how likely it is to be abused).<sup>15</sup>

**8.2** When pain and function have not sufficiently improved on a current opioid dose, a trial of a slightly higher dose could be considered.<sup>14,15</sup>

The rate at which the dosing is increased should balance the risk of leaving the patient in a painful state longer than necessary by increasing too slowly with the risk of causing harm, including fatal overdose, by increasing too fast. Ideally, only one drug at a time should be titrated in an opioid-naïve patient.<sup>14</sup> Age, health, and severity of pain should be taken into consideration when deciding on increments and rates of titration. Particular caution should be used in titrating dosing of methadone.

Evidence and other guidelines are not in agreement regarding the risks and benefits of high daily doses of opioid measured in morphine milligram equivalents (MMEs). It is likely that the risk-benefit ratio is less favorable at higher doses. Clinical vigilance is needed at all dosage levels of opioids, but is even more important at higher doses. Health care providers who are not experienced in prescribing high doses of opioids should consider either referring the patient or obtaining a consultation from a qualified provider for patients receiving high dosages. No clear threshold for a high dose has been established based on evidence. The Washington State guidelines suggest a threshold of 120 MME per day. It is important to increase clinical vigilance at doses exceeding 120 MME per day. Patients receiving 100 MME or more per day had a 9-fold increase in overdose risk. Most overdoses were medically serious, 12% were fatal.<sup>9</sup>

During titration, all patients should be seen frequently until dosing requirements have stabilized. Patients should be instructed to use medication only as directed, that is, not to change doses or frequency of administration without specific instructions from the health care provider.

**8.3** During the titration period, and until the patient is clinically stable and judged to be compliant with therapy, it is recommended that the health care provider check the Oklahoma Prescription Monitoring Program more frequently, such as monthly or quarterly.

Tools to accompany Recommendation 8:

- Dosing Guidelines http://health.utah.gov/prescription/pdf/guidelines/dosing\_guidelines.pdf
- Electronic MME Dosing Calculator http://agencymeddirectors.wa.gov/mobile.html
- Prescription Monitoring Program http://www.ok.gov/obndd/Prescription\_Monitoring\_Program/

#### **Maintenance of Opioid Treatment**

## 9. Once a stable dose has been established (maintenance period), regular monitoring should be conducted at face-to-face visits during which treatment goals, analgesia, activity, adverse effects, and aberrant behaviors are monitored. The Oklahoma PMP should be queried at least once per year for patients receiving opioid treatment for chronic pain.<sup>13,15</sup>

**9.1** The health care provider is advised to consider baseline drug testing at the initiation of opioid treatment, compliance monitoring one to three months later, and random monitoring every 6-12 months. In the event of unexpected drug screens or suspicious patient behavior, additional monitoring can be performed. Health care

providers may consider each of the following four areas of concern at each visit: Analgesia, Activity, Adverse effects, and Aberrant behavior. These assessments can be remembered as the "four A's": <sup>21</sup>

- Analgesia: inquire about level of pain (current, recent, trends, etc.)
- Activity: assess the patient's function and overall quality of life
- Adverse events: determine whether the patient is having medication side effects
- Aberrant behavior: evaluate for possible drug abuse-related behavior

**9.2** During the maintenance period, the Oklahoma Prescription Monitoring Program should be checked at least annually.

After the titration period is complete and the maintenance period is underway, the frequency of checks of the Oklahoma PMP can be based on clinical judgment, but should be done no less than annually. The Oklahoma PMP should be checked more often for high risk patients and patients exhibiting aberrant behavior.

**9.3** Continuation or modification of treatment should depend on the health care provider's evaluation of progress towards stated treatment goals.<sup>13</sup>

Treatment goals include reduction in a patient's pain scores and improved physical, psychological, and social function. If patient compliance with agreed-upon activity levels, are not being achieved despite medication adjustments, the health care provider should re-evaluate the appropriateness of continued treatment with the current medications.<sup>9,17</sup>

A frequent need for dose adjustments after a reasonable time interval of titration is an indication to re-evaluate the underlying condition and consider the possibility the patient has developed opioid hyperalgesia, substantial tolerance, or psychological/physical dependence.

**9.4** Adjustments to previously stable maintenance treatment may be considered if the patient develops tolerance, a new pain-producing medical condition arises or an existing one worsens, or if a new adverse effect emerges or becomes more clinically significant.<sup>14</sup>

Options for adjustment include reducing the medication or rotating opioid medications. If it is documented that the patient is compliant with agreed-upon recommendations such as exercise, working, etc., the addition of supplemental short-acting medications for control of break-through pain (e.g., as related to an increase in activity, end-of-dose pain, weather-related pain exacerbation, or specific medical conditions) can be considered as well. If patients do not achieve effective pain relief with one opioid, rotation to another frequently produces greater success.<sup>22</sup> If rotating among different opioid medications, refer to a standard dosing equivalence table, taking into account the current drug's half-life and potency.

If the patient's situation has changed permanently and consideration is given to the increased risk of adverse events, it is reasonable to consider an ongoing increase in maintenance dosing. In general, if the patient's underlying medical condition is chronic and unchanging, and if opioid-associated problems (hyperalgesia, substantial tolerance, important adverse effects) have not developed, it is recommended that the effective dose achieved through titration not be lowered once the patient has reached a plateau of adequate pain relief and functional level.<sup>14</sup>

**9.5** Dosing changes should generally be made during a clinic visit.<sup>14</sup>

If the patient's underlying, pain-producing, chronic medical condition improves, it is expected that the health care provider will begin tapering the patient off the opioid medication. (See *Recommendation 11* for guidelines on discontinuation.)

Tapering an opioid medication with or without the goal of discontinuation may be performed as described below (*Recommendation 11*) or as described in the *Strategies for Tapering and Weaning Tool*.

Tools to accompany Recommendation 9:

- Checklist for Adverse Effects, Function, and Opioid Dependence http://health.utah.gov/prescription/pdf/guidelines/checklist%20for%20adverse%20effects.pdf
- Signs of Substance Misuse http://health.utah.gov/prescription/pdf/guidelines/signs\_substance\_misuse.pdf
- Pain Management Evaluation Tool http://health.utah.gov/prescription/pdf/guidelines/PainManagementWorksheet.pdf
- Dosing Guidelines http://health.utah.gov/prescription/pdf/guidelines/dosing\_guidelines.pdf
- Strategies for Tapering and Weaning http://health.utah.gov/prescription/pdf/guidelines/Strategies\_tapering\_weaning.pdf

#### Evaluating the Opioid Treatment Trial

# 10. Continuing opioid treatment should be a deliberate decision that takes into consideration the risks and benefits of chronic opioid treatment for that patient. Patients and health care providers should periodically reassess the need for continued opioid treatment, weaning whenever possible, as part of the comprehensive pain care plan. A second opinion or consultation may be useful in making that decision.

The health care provider should clearly explain to the patient that initiation of opioid treatment is not a commitment to long-term opioid treatment and that treatment will be stopped if the trial is determined to be unsuccessful. The trial should be for a specific time period with pre-determined evaluation points. The decision to continue opioid treatment beyond the trial period should be based on the balance between benefits, including function and quality of life, and adverse effects experienced. A second opinion or consult may be useful in making the decision to continue or discontinue opioids after the treatment trial.

#### **Discontinuing Opioid Treatment**

### 11. Opioid treatment should be discontinued if adverse effects outweigh benefits, or if aberrant, dangerous, or illegal behaviors are demonstrated.<sup>9</sup>

**11.1** Discontinuation of opioid treatment is recommended if any of the following occurs:

- Dangerous or illegal behaviors are identified;
- Patient claims or exhibits a lack of effectiveness;
- Pain problem resolves;
- Patient expresses a desire to discontinue therapy; and
- Opioid treatment appears to be causing harm to the patient, particularly if harm exceeds benefit.<sup>14</sup>

The decision to discontinue opioid treatment should ideally be made jointly with the patient and, if appropriate, the family/caregiver.<sup>17</sup> This decision should include careful consideration of the outcomes of ongoing monitoring.

**11.2** When possible, offer to assist patients in safely discontinuing medications, even if they have withdrawn from treatment or been discharged for agreement violations.<sup>14</sup>

The goal is to taper all patients off opioid medications safely. If the patient is discharged, the health care provider is obliged to offer continued monitoring for 30 days post-discharge. Possible complications of opioid

withdrawal should be taken into consideration when discontinuing or tapering opioid medications.

Tools to accompany Recommendation 11:

• Strategies for Tapering and Weaning http://health.utah.gov/prescription/pdf/guidelines/Strategies\_tapering\_weaning.pdf

#### **Documentation and Medical Records**

## **12.** Health care providers treating chronic pain patients with opioids should maintain records, in accordance with state and federal law, documenting patient evaluation, treatment plan, discussion of risks and benefits, informed consent, treatments prescribed, results of treatment, and any aberrant behavior observed. <sup>9,13,14,15,17</sup>

**12.1** A written treatment plan should document objectives that will be used to evaluate treatment success. $9^{,13,14,15,17}$ 

**12.2** Opioid prescriptions should be written on tamper-resistant prescription paper to help reduce the likelihood of prescription fraud or misuse.<sup>15</sup>

To reduce the chance of tampering with the prescription, write legibly, and keep a copy.<sup>15</sup>

**12.3** Assessment of treatment effectiveness should be documented in the medical record.<sup>9,13,15</sup>

Both the underlying medical condition responsible for the pain, if known, and other medical conditions that may affect the efficacy of treatment or risks of adverse events should be assessed and documented at every visit.

Health care providers should consider utilizing a standardized approach such as "The Four A's" or "The SAFE Tool" for medical documentation. The Four A's considers four areas of concern: Analgesia, Activity, Adverse effects, and Aberrant behavior.<sup>21</sup> The SAFE Tool is a numerical five point scoring system that helps to guide the health care provider toward broader views of treatment options.<sup>23</sup> It considers four areas of concern: social functioning (S), analgesia (A), physical function (F), and emotional functioning (E).

The Four A's can be remembered as:

- Analgesia: inquire about level of pain (current, recent, trends, etc.);
- Activity: assess both the patient's function and overall quality of life;
- Adverse events: determine whether the patient is having medication side effects; and
- Aberrant behavior: regularly evaluate for possible drug abuse-related behavior.

The SAFE Tool can be remembered as:

- Social functioning: inquire about family and employment relationships;
- Analgesia: inquire about level of pain (current, recent, trends, etc.);
- Physical functioning: inquire about how well the patient is meeting goals; and
- Emotional functioning: ask about changes in the patient's mental health status.

**12.4** Adherence to the treatment plan, including any evidence of aberrant behavior, should be documented in the medical record.<sup>14</sup>

Specific components of the treatment plan for which adherence should be assessed include:

- Use of opioid analgesics; and
- Follow-up referrals, tests, and other therapies.

Health care providers are encouraged to make use of resources designed to assist them in managing the care of patients with aberrant behavior. Serious non-adherence issues (e.g., illegal, criminal, or dangerous behaviors, including altering of prescriptions) may also warrant immediate discontinuation of opioid treatment.

Tools to accompany Recommendation 12:

- Checklist for Adverse Effects, Function, and Opioid Dependence http://health.utah.gov/prescription/pdf/guidelines/checklist%20for%20adverse%20effects.pdf
- Signs of Substance Misuse http://health.utah.gov/prescription/pdf/guidelines/signs\_substance\_misuse.pdf
- Federal Laws on Prescribing Controlled Substances (21 CFR 1306 et. seq.) http://www.deadiversion.usdoj.gov/21cfr/cfr/
- Osteopathic Rules on Prescribing for Intractable Pain (OAC 510:5-9-1 et. seq.) http://www.ok.gov/osboe/documents/RULES.pdf
- Medical Board Rules on Prescribing for Intractable Pain (OAC 435:10-7-11 et. seq.) http://www.okmedicalboard.org/download/457/MDRULES.pdf

#### **Consultation and Management of Complex Patients**

## **13.** Health care providers should consider consultation for patients with complex pain conditions, serious co-morbidities and mental illness, a history or evidence of current drug addiction or abuse, or when the provider is not confident of his or her ability to manage the treatment.<sup>9,13</sup>

**13.1** Prescribers may wish to consider referring patients if any of the following conditions or situations are present, or if other concerns arise during treatment:

- The patient has a complex pain condition and the clinician wishes verification of diagnosis;
- The patient has significant co-morbidities, including psychiatric illness;
- The patient is at high risk of aberrant behavior or addiction; or
- The clinician suspects the development of significant tolerance, particularly at higher doses.

The main goal of a consultation is for the prescribing clinician to receive recommendations for ongoing treatment.

**13.2** Patients with a history of addiction or substance use disorder or who have positive drug screens indicative of a problem should be closely monitored (e.g., more frequent random drug screens, random pill counts) or considered for referral to an addiction specialist for evaluation of recurrent risk and for assistance with treatment.<sup>9,13,14</sup>

Although this is a desirable approach, it is recognized that following this recommendation may not be feasible in parts of Oklahoma where there is a shortage of readily available addiction specialists.

**13.3** Pain patients addicted to medications/drugs should be referred to a pain management and/or mental health/substance use disorder specialist, if available, for recommendations on the treatment plan and assistance in management.

The health care provider may consider prescribing opioid medications for pain even if the patient has a selfreported or documented previous opioid abuse problem, as long as monitoring is performed during the titration and maintenance phase.

**13.4** Patients with a coexisting psychiatric disorder should receive ongoing mental health support and treatment while receiving an opioid medication for pain control.

Management of patients with a coexisting psychiatric condition may require extra care, monitoring, or documentation.<sup>17,19</sup> Consultation can be obtained to assist in formulating the treatment plan and establishing a

plan for coordinated care of both the chronic pain and psychiatric condition(s).

Tools to accompany Recommendation 13:

• Strategies for Tapering and Weaning http://health.utah.gov/prescription/pdf/guidelines/Strategies\_tapering\_weaning.pdf

### 14. Health care providers should generally not provide replacement prescriptions for opioids that have been lost, stolen, or destroyed.

Patients misusing controlled substances frequently report their opioid medications as having been lost or stolen. Pain specialists routinely stipulate in pain agreements with patients that lost or stolen controlled substances will not be replaced. Most written agreements between chronic pain patients and pain management physicians, including the Health Resources and Services Administration (HRSA) toolkit sample pain agreement, state that prescriptions for opioids will not be replaced.<sup>10</sup>

The diversion of prescribed opioids is common. One study looked at completed patient surveys and determined that 45% of respondents reported some form of drug diversion at least once. Stolen medication was the most prevalent method of drug diversion, and 30% of respondents reported at least one incident of stolen medication.<sup>11</sup> Another survey study found that among persons 12 years and older who abused opioid pain medications (2009-2010), 71.2% came from friends or relatives; 55% were given to the abuser, while 11.4% were purchased, and 4.8% were stolen.<sup>12,13</sup>

### 15. The administration of intravenous and intramuscular opioids for the relief of exacerbations of chronic pain is discouraged, except in special circumstances.

Parenteral opioids should be generally avoided for the treatment of chronic pain because of their short duration and potential for addictive euphoria. For chronic pain, oral opioids are superior to parenteral opioids in duration of action and provide a gradual decrease in the level of pain control. When there is evidence or reasonable suspicion of an acute pathological process causing the acute exacerbation of chronic pain, parenteral opioids may be appropriate.

Tools to accompany Recommendation 15:

- Dosing Guidelines http://health.utah.gov/prescription/pdf/guidelines/dosing\_guidelines.pdf
- Current Opioid Misuse Measure (COMM) http://health.utah.gov/prescription/tools.html (see *Tools to Screen for Risk of Complications*)

#### Methadone and Extended Release/Long-Acting Opioids

## 16. Long-acting opioids are associated with an increased risk of overdose death, and should only be prescribed by health care providers familiar with their indications, risks, and need for careful monitoring.

**16.1** The prescription use of methadone remains controversial due to concerns about its efficacy and safety. During the past two decades methadone-related death rates increased in Oklahoma and the U.S. From 2007-2011, methadone was listed in the cause of death in 21% of prescription drug-related unintentional poisoning deaths in Oklahoma.<sup>1</sup>

The half-life of methadone is long and unpredictable, increasing the risk of inadvertent overdose. The peak respiratory depressant effect of methadone occurs later and lasts longer after treatment initiation or dosage change than does the peak analgesic effect. Conversion tables that have been established to assist with converting a patient from another opioid medication to methadone are considered by many experts to be unreliable.

Methadone metabolism is complicated and varies among individuals. Methadone interacts with several other medications that can alter its metabolism, changing the effects of a given dose on pain and on respiratory depression. Potential for interactions should be considered before starting methadone in a patient taking other medications, and before starting any medication in a patient taking methadone.

Methadone can prolong the rate-corrected QT interval (QTc), increase the risk of Torsades de Pointe, and sudden cardiac death. Caution should be used in prescribing methadone to any patient at risk for prolonged QTc interval, including those with structural cardiac disease, cardiac arrhythmias or cardiac conduction abnormalities and in patients taking another medication associated with QTc interval prolongation.<sup>24</sup> An online reference of such medications is available at: http://www.azcert.org/medical-pros/drug-lists/drug-lists.cfm.

Health care providers should consider obtaining an electrocardiogram (ECG) to measure the QTc interval in patients treated with methadone, especially at higher doses. A recently published consensus guideline recommended that an ECG be performed before prescribing methadone, within the first 30 days, and annually. Additional ECG examinations were recommended if the methadone dose exceeds 100 mg per day or if a patient on methadone has unexplained syncope or seizure. Guidance was provided for actions to be taken at two levels of QTc prolongation (450-500 ms and greater than 500 ms).<sup>25</sup>

Methadone and other opioids have been associated with worsening obstructive sleep apnea and new onset of central sleep apnea. Clinicians should question patients about symptoms and signs of sleep apnea and consider obtaining a sleep study in patients treated with opioids if they develop any signs of sleep-disordered breathing or respiratory depression. This is particularly important for patients receiving higher doses of opioid medications. In a recent study, 92% of patients on opioid doses at or above 200 MMEs had developed ataxic or irregular breathing.<sup>25</sup>

**16.2** If extended release/long-acting opioids are prescribed, consideration should be given to the increased risk of overdose with these medications. Prescribers should consider the current risk evaluation and implement mitigation strategies and close monitoring to reduce the possibility of adverse events.

Tools to accompany Recommendation 16:

- Dosing Guidelines http://health.utah.gov/prescription/pdf/guidelines/dosing\_guidelines.pdf
- The Role of Methadone in the Management of Chronic Non-Malignant Pain http://health.utah.gov/prescription/pdf/guidelines/role\_of\_methadone.pdf
- Electronic MME Dosing Calculator http://agencymeddirectors.wa.gov/mobile.html

#### **Education of Chronic Pain Patients on Using Opioids**

## 17. When opioids are prescribed for treatment of chronic pain, the patient should be counseled to store the medications securely and never to share with others. In order to prevent non-medical use of the medications, it is also recommended that patients dispose of medications when the pain has resolved.

It is important that patients understand the need to store medications securely. Health care providers should encourage patients to keep medications in a locked environment rather than in easily accessible locations, such as the bathroom or kitchen cabinet, where they are accessible to unsuspecting children, curious teenagers, and can be a target for theft. Tell the patient that if they have leftover medications after they have recovered, they should dispose of their medications immediately to help protect them from being a target for theft as well as protect others from getting into the medications.

Tools to accompany Recommendation 17:

- United States Food and Drug Administration (FDA) Guidelines on Proper Disposal of Prescription Drugs http://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/Under standingOver-the-CounterMedicines/ucm107163.pdf
- Oklahoma Bureau of Narcotics and Dangerous Drugs Take Back Container Locations http://www.ok.gov/obndd/documents/TakeBackBoxes.pdf

#### **Guidelines Tools**

#### Tools to use in evaluation and monitoring:

- Pain Management Evaluation Tool http://health.utah.gov/prescription/pdf/guidelines/PainManagementWorksheet.pdf
- Patient Pain and Medication Tracking http://health.utah.gov/prescription/pdf/guidelines/PatientPain-FunctionTracking.pdf
- Sheehan Disability Scale http://health.utah.gov/prescription/pdf/guidelines/SheehanDisabilityScale.pdf
- Brief Pain Inventory Form http://health.utah.gov/prescription/pdf/guidelines/BriefPainInvNPEC.pdf
- Treatment Plan for Prescribing http://health.utah.gov/prescription/pdf/guidelines/treatment\_plan.pdf
- SF-12 http://health.utah.gov/prescription/pdf/guidelines/SF-12v2Standard-Sample.pdf

#### Tools to screen for risk of complications:

- Oklahoma Prescription Monitoring Program http://www.ok.gov/obndd/Prescription\_Monitoring\_Program/
- Current Opioid Misuse Measure (COMM) http://health.utah.gov/prescription/tools.html
- SOAPP-R http://health.utah.gov/prescription/tools.html
- Opioid Risk Tool http://health.utah.gov/prescription/pdf/guidelines/ORTwithout\_scoring.pdf
- Urine Drug Testing Devices http://health.utah.gov/prescription/pdf/guidelines/CLIADrugTestlist.pdf
- Signs of Substance Misuse http://health.utah.gov/prescription/pdf/guidelines/signs\_substance\_misuse.pdf
- Checklist for Adverse Effects, Function, and Opioid Dependence http://health.utah.gov/prescription/pdf/guidelines/checklist%20for%20adverse%20effects.pdf

#### **Informational tools:**

- United States Food and Drug Administration (FDA) Guidelines on Proper Disposal of Prescription Drugs http://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/Understandin gOver-the-CounterMedicines/ucm107163.pdf
- Non-opioid Pain Management Tool http://health.utah.gov/prescription/tools.html
- Absolute Contraindications to Opioid Prescribing http://health.utah.gov/prescription/pdf/guidelines/absolute\_contraindications.pdf
- Strategies for Tapering and Weaning http://health.utah.gov/prescription/pdf/guidelines/Strategies\_tapering\_weaning.pdf
- Information for Patients-Opioid Analgesics for Non-cancer Pain http://health.utah.gov/prescription/pdf/guidelines/Information\_for\_patients.Opioid\_analgesics\_for\_noncancer\_pain.pdf
- The Role of Methadone in the Management of Chronic Non-Malignant Pain http://health.utah.gov/prescription/pdf/guidelines/role\_of\_methadone.pdf
- Dosing Guidelines http://health.utah.gov/prescription/pdf/guidelines/dosing\_guidelines.pdf

- Prescription Drug Overdose in Oklahoma Brochure http://www.ok.gov/health2/documents/DrugOverDoseBrochure\_2013.pdf
- Oklahoma Bureau of Narcotics and Dangerous Drugs Take Back Container Locations http://www.ok.gov/obndd/documents/TakeBackBoxes.pdf
- Electronic MME Dosing Calculator http://agencymeddirectors.wa.gov/mobile.html
- Federal Laws on Prescribing Controlled Substances (21 CFR 1306 et. seq.) http://www.deadiversion.usdoj.gov/21cfr/cfr/
- Osteopathic Rules on Prescribing for Intractable Pain (OAC 510:5-9-1 et. seq.) http://www.ok.gov/osboe/documents/RULES.pdf
- Medical Board Rules on Prescribing for Intractable Pain (OAC 435:10-7-11 et. seq.) http://www.okmedicalboard.org/download/457/MDRULES.pdf

#### **Opioid Prescribing Guidelines for Oklahoma Workgroup Members**

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Clinicians should use their own clinical judgment and not base clinical decisions solely on this document. The recommendations are based on evidence-based research, promising interventions, and expert opinion. Additional research is needed to understand the impact of these interventions on decreasing unintentional drug poisoning and on health care costs. These guidelines should be considered by clinicians, hospitals, administrators, public health entities, and other relevant stakeholders.

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## >> Oregon Opioid Prescribing Guidelines: Recommendations for the Safe Use of Opioid Medications





### Acknowledgments

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### Background

There has been a dramatic increase in Oregon and across the nation in overdose deaths and hospitalizations due to prescription opioid pain medications. The key to reversing the prescription opioid overdose epidemic and associated adverse effects (e.g., increases in heroin use, non-medical use of prescription opioids, opioid use disorder, etc.,) is addressing opioid prescribing practices that lead to misuse, overdose and death. In a March 2016 response, the Centers for Disease Control published the *CDC Guideline for Prescribing Opioids for Chronic Pain*.

The Oregon Public Health Division convened the Oregon Opioid Prescribing Guidelines Task Force in the spring of 2016 to develop statewide guidelines for clinicians and health care organizations. The goal was to address the epidemic of opioid use, misuse and overdose by providing a consistent framework for optimizing care and improving patient safety at the local and regional level.

Task force members met from April through November of 2016, relying on expert review from the varied organizational perspectives to consider endorsement of the CDC Guideline and Oregon-specific additions. Four workgroups were formed and met separately to develop recommendations for these additions and for future work to communicate and implement the Oregon Guidelines.

The task force adopted the CDC Guideline as the foundation for opioid prescribing for Oregon, and developed a brief addendum to address Oregon-specific concerns. The task force encouraged more discussion at state, regional and organizational levels on how the guideline will be disseminated, communicated to patients and providers, and implemented.

### Summary of the recommendations

The task force voted to endorse the 2016 CDC Guideline for Prescribing Opioids for Chronic Pain as the foundation for opioid prescribing in Oregon. The full CDC Guideline can be found at: <u>http://www.cdc.gov/drugoverdose/prescribing/</u>guideline.html.

The task force recognized the need to provide additional clarity to the CDC Guideline and to address Oregon-specific issues. Below are the 12 CDC Guideline abbreviated recommendations, with Oregon additions in shaded text.

## I. Determining when to initiate or continue opioids for chronic pain

- 1. Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate.
- 2. Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and should consider how therapy will be discontinued if benefits do not outweigh risks. Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.
- 3. Before starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy and patient and clinician responsibilities for managing therapy.

## II. Opioid selection, dosage, duration, follow-up and discontinuation

- 4. When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids.
- 5. When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day.
  - Clinicians should strongly consider additional evaluation of the benefits and risks of higher dose opioid therapy, document clinical justification for the higher dose in the medical record, and obtain and document pain management consultation. Options for consultation could include: 1) having a colleague evaluate the patient, 2) presenting and discussing the case to a clinician peer group or multi-disciplinary pain consultation team, 3) referring the patient to a pain specialist who has experience tapering patients off of opioids, or 4) referring the patient to a pain/addictions mental health specialist. (See CDC narrative under recommendation 8.)
  - Refer to Oregon Medical Board Material Risk Notice (required in Oregon when prescribing opioids for chronic pain.): <u>https://www.oregon.gov/omb/</u> <u>OMBFormsl/material-risk-notice.pdf</u>
  - Task force members emphasized the need for compassionate and nondiscriminatory treatment for established (including transferred) patients currently taking higher doses, echoing specific suggestions found in the CDC Guideline narrative supporting this recommendation.
- 6. Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed.
- 7. Clinicians should evaluate benefits and harms with patients within one to four weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every three months or more frequently. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids.

### III. Assessing risk and addressing harms of opioid use

- 8. Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should incorporate strategies into the management plan to mitigate risk, including offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (≥50 MME/day), or concurrent benzodiazepine use, are present.
- 9. Clinicians should review the patient's history of controlled substance prescriptions using state Prescription Drug Monitoring Program (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every three months.
  - The Oregon Prescription Drug Monitoring Program (PDMP) is a tool to help health care providers and pharmacists provide patients better care in managing their prescriptions.
  - Inappropriate behavior identified through the PDMP should lead to discussions about opioid use disorder, but not usually lead to dismissal from practice. While opioids may need to be discontinued, treatment of addiction and other medical comorbidities is still important.
- 10. When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs.
  - If clinicians suspect their patient might be sharing or selling opioids and not taking them, or intentionally misusing opioids, clinicians should consider urine drug testing to consider whether opioids can be discontinued abruptly or tapered, and clinicians should consider referral to substance use disorder (SUD) treatment.
  - Urine drug testing is a tool that can be used to assist providers in assessing whether patients are using opioids as prescribed, using other substances or potentially diverting opioids.

11. Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible.

The task force emphasized two points included in the CDC narrative supporting this recommendation:

- Clinicians should check the PDMP for concurrent controlled medications prescribed by other clinicians (see Recommendation 9 above) and should consider involving pharmacists, pain specialists and/or mental health specialists as part of the management team when opioids are co-prescribed with other central nervous system depressants.
- Clinicians should have an informed discussion with their patient about the serious risks associated with using these medications concurrently, included in recently released FDA boxed warnings.
- 12. Clinicians should offer or arrange evidence-based treatment (usually medicationassisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder.

## IV. Additional considerations: marijuana and safe storage and disposal

#### 1. Marijuana

With Oregon's recent legalization of recreational use of marijuana, its use is relatively prevalent. Current data are limited on the interactions between opioids and marijuana.

- Clinicians should discuss and document the use of marijuana with their patients, including whether they use, if so, amount, type, reasons for use, etc.
- Clinicians and their organizations have an obligation to closely follow the emerging evidence on the use of marijuana for treatment of pain and adopt consistent best practice. Refer to the OHA medical marijuana prescribing guidelines, at <u>https://public.health.oregon.gov/DiseasesConditions/</u> <u>ChronicDisease/MedicalMarijuanaProgram/Pages/Physicians.aspx</u>
- As with all pain treatment, consideration of marijuana use concurrent with opioids should be focused on improving functional status and quality of life, and ensuring patient safety. Clinicians should assess for contraindications and precautions to the concurrent use of marijuana and opioids.

#### 2. Safe storage and disposal

Clinicians should advise patients about safe storage and disposal of all controlled substances. For more information, see "Resources" section.

### Resources

- 1. Additional information is available on the Oregon Public Health Division's website: <a href="http://www.healthoregon.org/opioids">www.healthoregon.org/opioids</a>
- 2. The full version of the CDC Guideline includes specific details and tools for each of the 12 recommendations: <u>http://www.cdc.gov/drugoverdose/prescribing/</u> <u>guideline.html</u>
- 3. Safe and Competent Opioid Prescribing Education: <u>https://www.scopeofpain.org/</u>
- 4. Providers clinical support system for MAT: <u>http://pcssmat.org/</u>
- 5. Providers' clinical support system for opioid therapies: <u>http://pcss-o.org/</u>
- 6. SAMHSA's MAT website: <u>http://www.samhsa.gov/medication-assisted-treatment</u>
- 7. Oregon Marijuana Report, January 2016: Marijuana use, attitudes, and health effects in Oregon: <u>https://public.health.oregon.gov/PreventionWellness/marijuana/</u> <u>Documents/oha-8509-marijuana-report.pdf</u>
- 8. Oregon Medical Marijuana Prescribing Guidelines: <u>https://public.health.oregon.gov/DiseasesConditions/ChronicDisease/MedicalMarijuanaProgram/Pages/Physicians.aspx</u>
- 9. Oregon Prescription Drug Monitoring Program: http://www.orpdmp.com/
- 10. OHA naloxone training protocol: <u>http://public.health.oregon.gov/</u> <u>ProviderPartnerResources/EMSTraumaSystems/Pages/epi-protocol-training.aspx</u>
- 11. Oregon substance use helpline: 1-800-923-4357
- 12. Oregon Pain Guidance website: http://www.oregonpainguidance.org/
- 13. SAMHSA opioid treatment program directory: http://dpt2.samhsa.gov/treatment/directory.aspx
- 14. Oregon Addictions and Mental Health Services: http://www.oregon.gov/oha/amh/Pages/gethelp.aspx
- 15. University of Washington Tele-Pain for health care providers: <u>http://depts.washington.edu/anesth/care/pain/telepain/</u>

- 16. Oregon Drug Take-Back and Disposal: <u>https://public.health.oregon.gov/</u> <u>HealthyEnvironments/DrinkingWater/SourceWater/Pages/takeback.aspx</u>
- 17. Rx Disposal for Pharmacists and Clinics: <u>http://orcrm.oregonpainguidance.org/</u> <u>rx-disposal/rx-disposal-pharmacists-clinics/</u>
- 18. FDA How to dispose of unused medicines: <u>http://www.fda.gov/ForConsumers/</u> <u>ConsumerUpdates/ucm101653.htm</u>



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#### **Rule Governing the Prescribing of Opioids for Pain**

#### 1.0 Authority

This rule is adopted pursuant to 18 V.S.A. § 4289 (e), Sections 14(e) of Act 75 (2013) and Section 2a of Act 173 (2016).

#### 2.0 Purpose

This rule provides legal requirements for the appropriate use of opioids in treating pain in order to minimize opportunities for misuse, abuse, and diversion, and optimize prevention of addiction and overdose. The prescription limits for acute pain only apply to the first prescription written for a given course of treatment, and do not apply to renewals or refills. This rule only applies to Schedule II, III, or IV Controlled Substances.

#### 3.0 Definitions

- 3.1 "Abuse" means a maladaptive pattern of drug use that results in harm or places the individual at risk of harm. Abuse of a prescription medication involves its use in a manner that deviates from approved medical, legal, and social standards, generally to achieve a euphoric state ("high") or to sustain opioid dependence that is opioid addiction or that is other than the purpose for which the medication was prescribed. (Federation of State Medical Boards).
- 3.2 "Abuse-deterrent opioid" means an opioid analgesic medicine determined by the U.S. Food and Drug Administration (FDA) to be expected to result in a meaningful reduction in abuse. These properties may be obtained by: (i) Physical/Chemical barriers that prevent chewing, crushing, cutting, grating, or grinding or chemical barriers that resist extraction using common solvents like water; (ii) Antagonist/Agonist drugs that interfere with, reduce, or defeat the euphoria associated with abuse; (iii) Aversion where substances can be combined to produce an unpleasant effect if the dosage form is manipulated prior to ingestion or a higher dosage than directed is used; (iv) Delivery Systems where drug release designs or the method of drug delivery can offer resistance to abuse; (v) Prodrugs where a formulation lacks opioid activity until transformed in the gastrointestinal system; or (vi) a combination of any of the above methods.
- 3.3 "Administer" or "Administration" means the direct application of a drug by a prescriber to the body of a patient or research subject by injection, inhalation, ingestion, or any other means.
- 3.4 "Acute pain" means pain lasting fewer than 90 days that is a normal and predicted physiological response to a traumatic injury, surgical procedure, or specific disease.



- 3.5 "Addiction" means a primary, chronic, neurobiologic disease, whose development and manifestations are influenced by genetic, psychosocial, and environmental factors. Addiction often is said to be characterized by behaviors that include impaired control over drug use, craving, compulsive use, and continued use despite harm or risk of harm. (Federation of State Medical Boards).
- 3.6 "Chronic Pain" means pain caused by various diseases or abnormal conditions and that continues longer than 90 days.
- 3.7 "Controlled Substance" means a drug, other substance, or immediate precursor, included in Schedules II, III, or IV of the federal Controlled Substances Act (CSA).
- 3.8 "Controlled Substance Treatment Agreement" means a document that is signed and agreed upon by both the prescriber and the patient, acknowledging the rights and responsibilities of being on and prescribing controlled substances, and the treatment expectations.
- 3.9 "Diversion" means the intentional transfer of a controlled substance from authorized to unauthorized possession or channels of distribution including, but not limited to, the sharing or purchasing of drugs between family and friends or individual theft from family and friends. The federal Controlled Substances Act (21 U.S.C. §§ 801 et seq.) establishes a closed system of distribution for drugs that are classified as controlled substances.
- 3.10 "Functional Examination" means an examination used to describe an individual's ability to perform key daily activities and to evaluate changes in the activities of everyday life. It encompasses physical, social, and psychological domains, and covers outcomes from baseline functions through death.
- 3.11 "High-Risk" means a patient at increased risk for misuse, abuse, diversion, addiction, overdose, or other aberrant behaviors as determined by the patient's history and/or the risk assessment tool chosen by the provider.
- 3.12 "MME" means Morphine Milligram Equivalent. The use of MME allows prescribers to equate the dosage of opioid in a given medication. e.g. compare oxycodone with hydromorphone. A MME calculator can be found on the Department of Health website.
- 3.13 "Misuse" means the use of a medication (with therapeutic intent) other than as directed or as indicated whether willful or unintentional, and whether harm results or not.
- 3.14 "OTP" means an Opioid Treatment Program as defined and regulated by federal regulation 42 CFR, Part 8 and DEA regulations related to safe storage and dispensing of OTP's (1301.72). OTP's are specialty addiction treatment programs for dispensing opioid-replacement medication including methadone and



buprenorphine under carefully controlled and observed conditions. In Vermont, OTP's are sometimes referred to as "Hubs."

- 3.15 "Opioid naïve" means a patient who has not used opioids for more than seven consecutive days during the previous 30 days.
- 3.16 "Palliative care" means interdisciplinary care given to improve the quality of life of patients and their families facing the problems associated with a serious medical condition. Palliative care through the continuum of illness involves addressing physical, cognitive, emotional, psychological, and spiritual needs and facilitating patient autonomy, access to information, and choice. Defined in 18 V.S.A. § 2(6).
- 3.17 "Prescriber" means a licensed health care professional with the authority to prescribe controlled substances.
- 3.18 "Prescribe" means to issue an order for a patient made or given by a practitioner. It does not include ordering prescription medication to be administered to the patient in a health care setting.
- 3.19 "Risk Assessment" means a process for predicting a patient's likelihood of misusing or abusing opioids in order to develop and document a level of monitoring for that patient. An example of a screening tool is the Screener and Opioid Assessment for Patients with Pain (SOAPP), but prescribers can use any evidence-based screening tool.

#### 4.0 Universal Precautions when Prescribing Opioids for Pain

Prior to writing a prescription for an opioid Schedule II, III, or IV Controlled Substance for the first time during a course of treatment to any patient, providers shall adhere to the following universal precautions, unless otherwise exempt by this rule.

4.1 Consider Non-Opioid and Non-Pharmacological Treatment

Prescribers shall consider non-opioid and non-pharmacological treatments for pain management and include any appropriate treatments in the patient's medical record. Such treatments may include, but are not limited to:

- Nonsteroidal anti-inflammatory drugs (NSAIDs)
- Acetaminophen
- Acupuncture
- Osteopathic manipulative treatment
- Chiropractic
- Physical therapy
- 4.2 Query the Vermont Prescription Monitoring System according to the Vermont Prescription Monitoring System Rule.



- 4.3 Provide Patient Education and Informed Consent
  - 4.3.1 **Discussion of Risks**: Prior to prescribing an opioid, a prescriber shall have an in-person discussion with the patient regarding potential side effects, risks of dependence and overdose, alternative treatments, appropriate tapering and safe storage and disposal. If the patient is a minor, or lacks legal competence, then the in-person discussion shall take place between the prescriber and the patient's parent, guardian, or legal representative, unless otherwise provided for by law.
  - 4.3.2 **Patient Education Sheet**: Prior to prescribing an opioid, the prescriber shall provide the patient with the Department of Health patient education sheet published on the Department website, or a written alternative provided that the sheet contains all of the topics found in the Department-published sheet and is written in a fifth-grade reading level or lower.
  - 4.3.3 **Informed Consent**: Prior to prescribing an opioid, a prescriber shall receive a signed informed consent from the patient. If the patient is a minor or lacks the capacity to provide informed consent, then the patient's parent, guardian, or legal representative may do so on the patient's behalf, unless otherwise provided for by law.
    - 4.3.3.1 The consent form shall include: Information regarding the drug's potential for misuse, abuse, diversion, and addiction; potential side effects; tolerance; the risks associated with the drug for life-threatening respiratory depression; potentially fatal overdose as a result of accidental exposure, especially in children; neonatal opioid withdrawal syndrome; and potentially fatal overdose when combining with alcohol and/or other psychoactive medication including but not limited to benzodiazepines and barbiturates.

#### 5.0 Prescribing Opioids for Acute Pain

- 5.1 The purpose of this section is to provide prescribers with a framework for prescribing opioids in the smallest doses for the shortest periods of time to be effective in the management of pain.
  - 5.1.1 The limits found in Figures 1.0 and 2.0 are maximums, not therapeutic recommendations.
  - 5.1.2 The daily maximums found in Figure 1.0 and 2.0 are averages, not absolute daily limits. The average daily limit may allow larger doses at the start of the prescription with smaller doses at the end as the patient tapers.



- 5.2 The following limits apply to patients who are opioid naïve and are receiving their first prescriptions not administered in a healthcare setting.
- 5.3 These limits do not prohibit a provider from writing a second prescription (or renewal/refill prescription) for the patient should that be necessary.
- 5.4 The framework provides four categories, each with its own limits, shown in Figure 1.0 for adults ages 18 years old and older and Figure 2.0 for children ages 0-17 years old. The pain category into which a patient is placed is based on the medical judgment of the prescriber.
  - 5.4.1 For adults ages 18 years old and older, should a provider prescribe an average daily dose over 32 morphine milligram equivalents, the reason must be justified in the medical record.

#### Figure 1.0 – Opioid Limits for Adults Ages 18 Years Old or Older

Pain	Average Daily MME (allowing for tapering)	Prescription TOTAL MME based on expected duration of pain	Common average DAILY pill counts	Commonly associated injuries, conditions and surgeries
<b>Minor</b> pain	No Opioids	0 total MME	0 hydrocodone 0 oxycodone 0 hydromorphone	molar removal, sprains, non-specific low back pain, headaches, fibromyalgia, un-diagnosed dental pain
<b>Moderate</b> pain	24 MME/day	0-3 days: <b>72 MME</b> 1-5 days: <b>120 MME</b>	4 hydrocodone 5mg or 3 oxycodone 5mg or 3 hydromorphone 2mg	non-compound bone fractures, most soft tissue surgeries, most outpatient laparoscopic surgeries, shoulder arthroscopy
Severe pain	32 MME/day	0-3 days: <b>96 MME</b> 1-5 days: <b>160 MME</b>	6 hydrocodone 5mg or 4 oxycodone 5mg or 4 hydromorphone 2mg	many non-laparoscopic surgeries, maxillofacial surgery, total joint replacement, compound fracture repair
For patients with severe pain and extreme circumstance, the provider can make a clinical judgement to prescribe				
Extreme Pain	50 MME/day	7 day MAX: 350 MME	10 hydrocodone 5mg or 6 oxycodone 5mg or 6 hydromorphone 2mg	similar to the severe pain category but with complications or other special circumstances



Pain	Average Daily MME (allowing for tapering)	Prescription TOTAL MME based on expected duration of pain	Common average DAILY pill counts	Commonly associated injuries, conditions and surgeries
<b>Minor</b> pain	No Opioids	0 total MME	0 hydrocodone 0 oxycodone 0 hydromorphone	molar removal, sprains, non-specific low back pain, headaches, fibromyalgia, un-diagnosed dental pain
<b>Moderate</b> to <b>Severe</b> pain	24 MME/day	0-3 days: <b>72 MME</b>	4 hydrocodone 5mg or 3 oxycodone 5mg or 3 hydromorphone 2mg	non-compound bone fractures, most soft tissue surgeries, most outpatient laparoscopic surgeries, shoulder arthroscopy

#### Figure 2.0 – Opioid Limits for Children Ages 0-17 Years

#### 5.5 Extended-release/Long-acting Opioids

Long-acting opioids are not indicated for acute pain. Should a provider need to use a long-acting opioid for acute pain for a specific reason, that reason must be justified in the patient's medical record.

#### 5.6 Consultation and Transfer of Patient Care

- 5.6.1 While treating an adult patient for acute pain, and prior to ending a patient's care for acute pain, a prescriber who is not the patient's primary care provider shall ensure a safe transition of care by making a reasonable effort to communicate with the patient's primary care provider with any relevant clinical information concerning the patient's condition, diagnosis and treatment. A clear discharge summary that includes expectations for ongoing pain treatment shall satisfy this requirement.
- 5.6.2 Prior to prescribing an opioid to a child in an Emergency Department, Urgent Care setting or specialty care setting, prescribers shall make a reasonable effort to consult with that child's primary care provider.

#### 5.7 Exemptions

The following conditions, and those similar to them in the medical judgment of the healthcare provider, are exempt from the limits found in this section:

- Patients in skilled and intermediate care nursing facilities
- Pain associated with significant or severe trauma



- Pain associated with complex surgical interventions, such as spinal surgery
- Pain associated with prolonged inpatient care due to post-operative complications
- Medication-assisted treatment for substance use disorders
- Patients who are not opioid naïve
- Other circumstances as determined by the Commissioner of Health

#### 6.0 Prescribing Opioids for Chronic Pain

The following section outlines requirements for prescribing Schedule II, III or IV opioids for chronic pain (pain lasting longer than 90 days). If the provider is prescribing to the patient for the first time during a course of treatment, the Universal Precautions in Section 4.0 also apply. The requirements in this section apply to patients who are receiving an opioid for the treatment of chronic pain.

#### 6.1 Screening, Evaluation, and Risk Assessment

- 6.1.1 The prescriber shall conduct and document a thorough medical evaluation and physical examination as part of the patient's medical record when prescribing opioids for chronic pain.
- 6.1.2 The prescriber shall document in the patient's medical record any diagnoses which support the use of opioids for relief of chronic pain.
- 6.1.3 The prescriber shall evaluate and document benefits and relative risks, including the risk for misuse, abuse, diversion, addiction, or overdose, for the individual patient of the use of opioids prior to writing an opioid prescription for chronic pain. The evaluation shall include but not be limited to a Risk Assessment as defined in Section 3.18 of this rule.
- 6.1.4 Examples of risk assessment screening tools are available on the Department of Health website.

#### 6.2 Initiating an Opioid Prescription for Chronic Pain

- 6.2.1 Prior to prescribing an opioid for the treatment of chronic pain, the prescriber shall consider and document in the patient's medical record:
  - 6.2.1.1 Non-opioid alternatives up to a maximum recommended by the FDA, including non-pharmacological treatments, have been considered;
  - 6.2.1.2 Trial use of the opioid;
  - 6.2.1.3 Any applicable requirements to query the Vermont Prescription Monitoring System;



- 6.2.1.4 That the prescriber has asked the patient if he or she is currently, or has recently been, dispensed methadone or buprenorphine or prescribed and taken any other controlled substance. The prescriber shall explain that this information is important for the patient's safety and that the patient is required by law to disclose this information (18 V.S.A.§4223);
- 6.2.1.5 Receive, and include in the patient's medical record, a signed Controlled Substance Treatment Agreement from the patient, or, if the patient lacks the capacity to provide informed consent, from the patient's legal representative. This agreement must include functional goals for treatment, dispensing pharmacy choice, and safe storage and disposal of medication. It shall include other requirements as determined by the prescriber, such as directly observed urine drug testing and pill counts to reasonably and timely inform the prescriber if the patient is misusing the prescribed substance.
- 6.2.2 For the duration of the patient's treatment of chronic pain with opioids, the provider shall:
  - 6.2.2.1 Schedule and undertake periodic follow-up visits and evaluations at a frequency determined by the patient's risk factors, the medication dose and other clinical indictors. Patients who are stable in terms of the medication dose and its effectiveness in managing chronic pain must be reevaluated no less than once every 90 days; and
  - 6.2.2.2 Write the maximum daily dose or a "not to exceed" equivalent on the prescription for the dispensing pharmacy.
  - 6.2.2.3 Examples of informed consent documents and Controlled Substance Treatment Agreements shall be made available on the Department of Health's website.

#### 6.3 Referrals and Consultations

The prescriber shall consider referring a patient for a consultation with an appropriate specialist (such as a pain specialist or substance abuse specialist) when:

- 6.3.1 The patient is not meeting the goals of treatment despite escalating doses of controlled substances for pain;
- 6.3.2 The patient is at high-risk for substance misuse, abuse, diversion, addiction, or overdose as determined by the patient's history or a screening undertaken pursuant to Section 1 of this rule;



- 6.3.3 The prescriber has reasonable grounds to believe, or confirms, a patient is misusing opioids or other substances;
- 6.3.4 The patient is seeing multiple prescribers and/or utilizing multiple pharmacies;
- 6.3.5 The patient has been prescribed multiple controlled substances; or
- 6.3.6 The patient requests a referral.

#### 6.4 Reevaluation of Treatment

- 6.4.1 Controlled Substance Treatment Agreements for people receiving treatment for chronic pain shall be reviewed by the prescriber and patient no less frequently than once every 365 days to reevaluate the patient. These reviews shall be documented in the patient's medical record.
- 6.4.2 Prior to prescribing a dose of opioids, or a combination of opioids, that exceeds a Morphine Milligram Equivalent Daily Dose of 90 the prescriber shall document in the patient's medical record:
  - 6.4.2.1 A reevaluation of the effectiveness and safety of the patient's pain management plan, including an assessment of the patient's adherence to the treatment regimen;
  - 6.4.2.2 The potential for the use of non-opioid and non-pharmacological alternatives for treating pain;
  - 6.4.2.3 A functional examination of the patient;
  - 6.4.2.4 A review of the patient's Controlled Substance Treatment Agreement and Informed Consent, making any necessary revisions, including pill counts and directly observed urine testing to monitor adherence and possible use of other substances;
  - 6.4.2.5 An assessment of any co-morbid conditions affected by treatment with opioids. This may be best conducted by a mental health or addictions professional; and
  - 6.4.2.6 Any other related actions by the patient that may reasonably lead a prescriber to modify the pain management regimen, including but not limited to aberrant behaviors, early refills of controlled substances, or other known risks associated with misuse, abuse, diversion, addiction, or overdose.
  - 6.4.2.7 Prior to prescribing a patient an average Morphine Milligram Equivalent Daily Dose of 90 or more, a prescriber shall have an



in-person discussion with the patient, regarding the increased risk of fatal and non-fatal overdose, and any precautions the patient should take. If the patient is a minor, or lacks legal competence, then this in-person discussion shall take place between the prescriber and the patient's parent, guardian, or legal representative, unless otherwise provided for by law.

- 6.4.3 Based on the reevaluation the prescriber shall determine and document:
  - 6.4.3.1 Whether to continue the treatment of pain with opioids or if there are available alternatives;
  - 6.4.3.2 The possible need for a pain management, substance abuse or pharmacological consultation to achieve effective pain management, avoidance of dependence or addiction or taper from the prescribed analgesics; and
  - 6.4.3.3 Acknowledgement that a violation of the agreement will result in a re-assessment of the patient's treatment plan and alteration or institution of controls over medication prescribing and dispensing, which may include tapering or discontinuing the prescription. This may occur after consultation with an addictions specialist.

#### 6.5 Exemptions

Patients experiencing chronic pain in the following categories are exempt from the requirements found in this section:

- Chronic pain associated with cancer or cancer treatment
- Patients in skilled and intermediate care nursing facilities

#### 7.0 Co-Prescription of Naloxone

- 7.1 Prescribers shall co-prescribe naloxone for all patients receiving an opioid prescription that exceeds a Morphine Milligram Equivalent Daily Dose of 90.
- 7.2 Prescribers shall co-prescribe naloxone for all patients receiving an opioid prescription if there is a concurrent prescription for benzodiazepines.

### 8.0 Prescription of Extended Release Hydrocodones and Oxycodones without Abuse Deterrent Opioid Formulations

Whereas, extended release hydrocodones and oxycodones that are not manufactured as Abuse-deterrent Opioids are easily misused, abused, diverted, and pose an increased threat to those who unintentionally ingest them, this rule requires specific conditions for their prescription that are in addition to provisions of Sections 4.0 through 7.0 of this rule.



- 8.1 Prior to prescribing an extended release hydrocodone or oxycodone that is not an Abuse-deterrent Opioid, the prescriber shall:
  - 8.1.1 Conduct and document a thorough medical evaluation and physical examination as part of the patient's medical record;
  - 8.1.2 Document in the patient's medical record any diagnoses which support the use of an extended release hydrocodone or oxycodone that is not an Abuse-deterrent Opioid for pain relief;
  - 8.1.3 Evaluate and document benefits and relative risks, including the risk for misuse, abuse, diversion, addiction, or overdose, for the individual patient of the use of extended release hydrocodone or oxycodone that is not an Abuse-deterrent Opioid prior to writing a prescription for such a substance. The evaluation shall include but not be limited to a Risk Assessment as defined in Section 3.0 of this rule;
  - 8.1.4 Document in the patient's medical record that the prescription of an extended release hydrocodone or oxycodone that is not an Abuse-deterrent Opioid is required for the management of pain severe enough to require daily, around-the-clock, long-term, opioid treatment for which alternative treatment options, including non-pharmacological treatments, are ineffective, not tolerated, or are otherwise inadequate to provide sufficient management of pain;
  - 8.1.5 Receive, and include in the patient's medical record a signed Informed Consent from the patient, or, if the patient lacks the capacity to provide informed consent, from the patient's legal representative, that shall include information regarding the drug's potential for misuse, abuse, diversion, and addiction; the risks associated with the drug for life-threatening respiratory depression; potentially fatal overdose as a result of accidental exposure, especially in children; neonatal opioid withdrawal syndrome; and potentially fatal overdose when combining with alcohol;
  - 8.1.6 Receive, and include in the patient's medical record, a signed Controlled Substance Treatment Agreement from the patient, or if the patient lacks the capacity, from the patient's legal representative. This agreement must include functional goals for treatment, dispensing pharmacy choice, safe storage and disposal of medication, and urine testing (no less frequently than annually with the actual frequency to be determined by the clinician on the basis of the patient's risk assessment and ongoing behavior). It shall include other requirements as determined by the prescriber, such as directly observed urine drug testing and pill counts to reasonably and timely inform the prescriber if the patient is misusing the prescribed substance;
  - 8.1.7 Query VPMS and document it in the patient's medical record. The prescriber shall also document in the patient's medical record:



- 8.1.7.1 A review of other controlled substances prescribed to the patient prior to the first prescription of an extended release hydrocodone or oxycodone that is not an Abuse-deterrent Opioid;
- 8.1.7.2 A query no less frequently than once every 120 days for any patient prescribed 40 mg or greater of hydrocodone or 30 mg or greater of oxycodone per day of an extended release hydrocodone or oxycodone that is not an Abuse-deterrent Opioid as long as the patient possesses a valid prescription for that amount; and
- 8.1.7.3 A query no less frequently than as described in the Vermont Prescription Monitoring System rule.
- 8.1.8 Determine and write a maximum daily dose, or a "not to exceed value" for the prescription to be transmitted; and
- 8.1.9 Write a prescription that must be filled within seven (7) days of the date issued and does not exceed a 30-day supply.
- 8.2 Prescribers subject to this section shall schedule and undertake periodic follow-up visits and evaluations (no less frequently than every 90 days), during which the following must be documented in the patient's medical record:
  - 8.2.1 Whether to continue the treatment of pain with an extended release hydrocodone or oxycodone that is not an Abuse-deterrent Opioid or if there are available alternatives;
  - 8.2.2 The possible need for a pain management or substance abuse consultation; and
  - 8.2.3 A provider explanation and a patient acknowledgement that a violation of the agreement will result in a re-assessment of the patient's treatment plan and alteration or institution of controls over medication prescribing and dispensing, which may include tapering or discontinuing the prescription. This may occur after consultation with an addictions specialist.

#### 9.0 Hospice, Palliative Care at End-of-Life, and End-of-Life Care

- 9.1 Hospice services, palliative care services at end-of-life, and end-of-life care services are exempt from Sections 4 7 of this rule.
- 9.2 Prescribers shall comply with the following concerning patient education and informed consent:



- 9.2.1 **Safe Storage and Disposal:** prior to prescribing an opioid, a prescriber shall inform the patient regarding safe storage and disposal for patients receiving an opioid outside of a health care setting. If the patient is a minor, or lacks legal competence, the patient shall inform the patient's patient, guardian, or legal representative, unless otherwise provided for by law.
- 9.2.2 **Patient Education Sheet:** prior to prescribing an opioid, a prescriber shall provide the patient with the Department of Health patient education sheet published on the Department of Health website, or a written alternative provided that the sheet contains all the topics found in the Department-published sheet and is written in a fifth-grade reading level or lower.
- 9.2.3 **Informed Consent:** prior to prescribing an opioid, a prescriber shall receive a signed informed consent from the patient. If the patient is a minor, or lacks the capacity to provide informed consent, then the patient's parent, guardian, or legal representative may do so on the patient's behalf, unless otherwise provided for by law.
  - 9.2.3.1 The consent form shall include the following information: The consent form shall include: Information regarding the drug's potential for misuse, abuse, diversion, and addiction; potential side effects; tolerance; the risks associated with the drug for life-threatening respiratory depression; potentially fatal overdose as a result of accidental exposure, especially in children; and potentially fatal overdose when combining with alcohol and/or other psychoactive medication including but not limited to benzodiazepines and barbiturates.



## INFORMATION FOR HEALTH PROFESSIONALS & PRESCRIBERS

#### Screening, brief intervention & referral to treatment

SBIRT is a public health approach to delivering early intervention and treatment services. It is an evidence-based protocol both for people with substance use disorders and for those at risk of developing them. With SBIRT, screening, intervention and treatment all happen in a medical setting such as a primary care office, hospital emergency department or community clinic. These medical providers in turn form closer relationships with the substance abuse treatment providers in their area, developing a 'warm hand off' protocol for patients who need targeted treatment.

SBIRT providers are helping to integrate health systems to care for the whole individual. The SBIRT website and tools are available to support all health care providers.

#### Vermont prescription monitoring system

VPMS is a highly effective tool to reduce drug abuse and diversion. VPMS collects, monitors and analyzes electronically transmitted prescribing and dispensing data submitted by pharmacies and dispensing practitioners. This information is used to support and coordinate clinical care and substance abuse prevention. It can also help us to understand the patterns of controlled substance prescribing and dispensing in Vermont. VPMS now has data-sharing agreements with New York, Massachusetts, Connecticut and New Hampshire. Find out more and log into VPMS

#### Chronic pain management

A new rule, which goes into effect July 1, 2017, will for the first time ever give guidance to prescribers and set legal limits on the dosage and number of opioid painkillers that may be prescribed. In drafting the rule, the Health Department hosted 19 meetings and conference calls with a range of providers and stakeholders, including physicians, pharmacists and dentists from around the state and around the country.



## Your provider is prescribing an opioid drug to treat pain.

#### Anyone can get addicted to these powerful drugs.

#### Ask your provider: Do I really need this?

Talk with your provider about risks, side effects and other ways to treat your pain. If you decide to take this drug, here's what you need to know:

#### Using this drug may cause addiction.

- Opioid addiction is a lifelong problem. It can start with just one prescription.
- Children and youth have a higher risk of future addiction if they take opioids when they are young.

#### Take only what you need.

• You do not have to use it all.

#### An overdose can happen to anyone.

- Don't take more medication than your provider prescribed.
- Taking too much or taking it with alcohol or other drugs can cause an overdose. You might stop breathing, go into a coma, have brain damage, or die.
- Tell your provider if you use alcohol or other medications or drugs. Tell your provider if you have used alcohol or drugs in the past.
- If you think you are at high risk of an overdose, talk to your provider about your options.

#### Do not drive or use heavy machinery.

• Opioids can slow your reaction time. They can also cause drowsiness and confuse your judgment.

#### Store prescriptions properly.

• Keep prescription drugs locked up. Make sure kids, family, and guests can't get to them. Know where your medication is at all times. Keep it in the original bottle. Make sure the label is clear. Never share or give away your prescription drug, even to family or friends.

#### Dispose of leftover medicine safely.

• Don't flush prescription drugs down the toilet or wash them down the sink. Flushing drugs or throwing them away can harm drinking water, wildlife, pets and people. In Vermont, you can drop off your unused medications at a permanent drug disposal site.

> Go to this website for more information: healthvermont.gov/adap/RxOTCabuse.aspx



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#### **PREVENTING OPIOID ABUSE & ADDICTION**

Everyone has a part to play in preventing opioid abuse and addiction. When we deliver a health curriculum, conduct screenings, run a school or teen program proven to promote mental health and reduce substance abuse, when we mentor, provide family education support groups or work to change conditions in the community – we are doing our part to prevent opioid addiction.

The Health Department has been working to reduce the risks that contribute to addiction while promoting healthy lifestyles and communities, through:

- community education and awareness, parenting programs and youth leadership opportunities
- community partnerships supported with grants and regional prevention consultants
- prescription drug take-back days
- parenting and family resources such as ParentUp and Vermont's Most Dangerous Leftovers

Learn more about community prevention programs (Vermont programs, grants, etc.)

Learn more about family and parenting programs (Vermont targeted PSA for families – "Parent UP VT")

http://www.healthvermont.gov/response/alcohol-drugs/preventing-opioid-abuse-addiction (webpage includes links to pdf briefs "Preventing Opioid Abuse" and "What Communities Can Do"; downloaded)

### Addressing alcohol and drug use in medical settings

Screening, Brief Intervention, and Referral to Treatment **(SBIRT)** is a comprehensive, integrated, public health approach to the delivery of early intervention and treatment services. It is an evidence based protocol both for people with substance use disorders and for those at risk of developing them. In SBIRT, screening, intervention, and treatment all happen in a medical setting such as a primary care office, hospital emergency department, or community clinic. These medical providers in turn form closer relationships with the substance abuse treatment providers in their area, developing a 'warm hand off' protocol for patients who need targeted treatment. SBIRT providers are helping to move toward health systems integration which better cares for the whole person.



<u>Universal Screening</u> – Efficiently screen everyone for risky substance use and depression <u>Initial screening</u> – Includes alcohol, drugs and depression

Secondary screening - Defines level of risk severity and appropriate plan of action

Brief Intervention – Motivational conversation focused on changing risky behavior

Brief Treatment – Embedded behavioral health clinician delivers outpatient treatment

<u>Referral to Specialty Treatment</u> – Linkages in place for referral to intensive levels of treatment

http://sbirt.vermont.gov/



## Facts

#### **Substance Abuse**

**Prevention** is the promotion of healthy lifestyles and norms that reduce the risks associated with use of alcohol, tobacco and other drugs.

#### **Everyone has a part to**

**play.** When we deliver a health curriculum, conduct screenings, run a school or teen program proven to promote mental health and reduce substance abuse, when we mentor, provide family education support groups or work to change conditions in the community — we are doing our part to prevent opioid addiction.

## Preventing opioid addiction can be compared to preventing other chronic diseases.

Community-wide policies that promote health, education and screening are all employed to reduce and prevent other chronic diseases. This is also true of opioid addiction. Preventing opioid addiction takes a comprehensive, long-term approach that includes information, education, early intervention and referral to treatment, community communication and mobilization, and policy setting.

#### Years of research show that effective substance abuse prevention:

- is targeted to reduce risks for addiction, and promote protective factors against addiction
- has multiple and connected interventions in communities, schools, families and individuals
- is sustained over time

### The Health Department supports and funds proven strategies:

- for public information
- in communities
- at schools
- that provide family support and education



ADDRESS 108 Cherry Streeet, Box 70 Burlington, VT 05402 WEB HealthVermont.gov/adap

## Facts

#### Prevention must start young.

Prevention must begin early well before a young person starts engaging in risky behaviors. People admitted and treated for opioid abuse are asked when they started using. 21 is the average age for first use of opioids, somewhat older than 15, the average age for first use of alcohol.

### Treatment is not prevention.

Effective medical treatment for addiction, just like effective medical treatment for any other chronic disease, has high lifelong costs. While we expand the scope of our interventions and treatment options, we must also strengthen proven prevention strategies.

### The cost/benefit of prevention.

Successful prevention strategies save money. Every \$1 invested saves \$3 to \$8 in costs of health care, criminal justice and lost productivity.

- U.S. Substance Abuse & Mental Health Services Administration

### Health Department-funded Strategies EXAMPLES

#### **Public Information**

- VT Alcohol & Drug Information Clearinghouse www.vadic.org
- PARENT www.ParentUpVT.org

#### **Community Coalitions & Regional Partnerships for Success**

- Community Coalitons/Regional Partnerships for Success bring together diverse stakeholders to carry out action plans, educate youth and families, inform the public about proper storage and disposal of prescription drugs, and promote the use of the Vermont Prescription Drug Monitoring System.
- Prevention Consultants from the Health Department's 12 district offices work with coalitions and regional partnerships to provide technical assistance and promote prevention, treatment and recovery resources.

#### **Coordinated School Health Initiatives**

- Substance abuse screening and referral services
- Classroom health curricula that covers substance abuse
- Training for teachers and support staff
- Training for youth empowerment groups
- School-based parent education and support groups

#### **Family Support and Education**

- Parenting education programs
- Project Rocking Horse parenting support group for low-income mothers



### JOIN

a regional partnership or your community coalition.

- Encourage businesses, medical centers and non- profits to join in substance abuse/ intervention work.
- Recognize your community partners for their work.

### **INFORM**

Address 'not in my backyard' concerns by reducing the stigma of addiction:

- Write letters to the editor.
- Post info about treatment and recovery services available in your community.
- Sponsor trainings for partners in law enforcement, health care, education, business, etc.
- Speak up about substance abuse at community events

### ACT

## It takes a community and collective community actions sustained over time, to prevent substance abuse.

- Advocate for family and school programs proven to promote mental health and prevent substance abuse.
- Volunteer to serve as a mentor, or support your community teen center.
- Support the use of screening and brief intervention (SBIRT) and access to addiction treatment.
- Talk with your children. They care what you think. Parental monitoring and supervision are important. Children who learn about the risks of drugs and alcohol from their parents are half as likely to use than those who do not.
- Help your teen stay safe and make healthy choices: Talk and listen. Get directly involved in his everyday world. Make it clear you don't want her to drink or use drugs. Set clear limits.
- Talk with your family about the risks of prescription drug misuse.
- Encourage people who may be struggling with substance abuse to talk with their doctor or treatment professional about what they are experiencing.



ADDRESS 108 Cherry Streeet, Box 70 Burlington, VT 05402 WEB HealthVermont.gov/adap



## **PREVENT** opioid drug deaths

In 2013, the Vermont Legislature authorized the Health Dept. to develop and administer a pilot program to distribute emergency overdose rescue kits to people at risk, and to family, friends and others who may be in a position to help in the event of a opioid drug poisoning. In June 2014, this pilot program is well underway.

The medication in the rescue kit is naloxone, also known by the trade name Narcan<sup>™</sup>. Naloxone is a safe and effective medication that quickly reverses the life-threatening effects of opioid overdose. Naloxone is administered by spraying a fine mist up the person's nostrils. The kit comes with easy to use instructions.

When the Vermont Board of Pharmacy has adopted a policy, naloxone may be dispensed by pharmacists without an individualized prescription.

## **PREVENT** opioid drug misuse or accidents

## If you have medications in your home, store them in a safe, locked place.

Prevent accidental poisoning and misuse by safely storing and disposing of unused or expired prescription medications and over-the-counter drugs. Most people age 12 and older who abused prescription pain relievers got them from friends or relatives.

- Secure your medications at home. Keep out of reach and securely locked to prevent children from taking accidentally, or from being misused or abused by people in your household.
- Safely dispose of your medications. Take advantage of a local drug take back program or follow federal and state guidelines for proper disposal of prescription and over-the-counter medications.
- Know where to take your unused medications. For a listing of places in Vermont that offer drug disposal throughout the year, dial 2-1-1 or visit www.Vermont211.org – or Dept. of Public Safety Drug Diversion website: www.vsp.vermont.gov/drugdiversion

If you can't find a drug take-back or collection program in your area, follow federal and state quidelines available at:

#### State www.healthvermont.gov/adap/documents/RxDisposalGuidelines\_ Nov2013.pdf

Federal www.fda.gov/forconsumers/consumerupdates/ucm101653.htm

For more information healthvermont.gov/adap/treatment/naloxone