

**COMMONWEALTH OF MASSACHUSETTS
DEPARTMENT OF INDUSTRIAL ACCIDENTS**

**OPIOID/CONTROLLED SUBSTANCE PROTOCOL
May 2016**

INTRODUCTION

This Protocol is intended to

- Promote the delivery of safe, quality health care to injured workers;
- Ensure patient pain relief and functional improvement;
- Be used in conjunction with other treatment guidelines, not in lieu of other recommended treatment;
- Prevent and reduce the number of complications caused by prescription medication, including addiction; and
- Recommend opioid prescribing practices that promote functional restoration.

The protocol does not apply to patients with cancer, end of life/hospice patients, or inpatients of hospitals, nursing homes, and skilled nursing facilities. The protocol is not intended to be a substitute for appropriate medical judgment and should allow for philosophical and practice differences among health care practitioners who provide care to injured workers. On a rare occasion, a case may fall outside of this protocol and may be reviewed, and prescription medication approved, on an individual basis. Ongoing use of medication, as with all other interventions, should be guided by objective evidence of functional improvement and include an active treatment program. Before prescribing opioids, the prescribing practitioner must be cognizant of synergism and drug interactions which affect the respiratory and central nervous systems; as well as the patient's age, metabolic capacity, and any potentially co-morbid medical conditions. Generic medication should be used if possible.

TIME FRAMES

Acute Pain: Up to 4 weeks from onset

Subacute Pain: 4-12 weeks from onset

Post-operative Pain: Up to 4 weeks from date of surgery

Chronic Pain: Greater than 12 weeks from onset

RECOMMENDATION FOR ACUTE, SUBACUTE, AND POST-OPERATIVE PAIN

1. Opioid medication should only be used when the severity of the pain warrants that choice, and after determining that other non-opioid pain medication or non-pharmacological therapies, including but not limited to home exercise, chiropractic treatment, physical therapy, and psychological treatment, will not provide adequate pain relief. Increased activity should be encouraged if medically indicated. This recommendation is not intended to mandate a trial of non-opioid medication and/or complementary therapies prior to prescribing opioids when opioids are necessary for relief of severe pain or non-opioid medication is contraindicated.

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May 2016**

2. When opioid medications, including other controlled substances, are prescribed:

- Assess for risk factors including current and past addiction or misuse, and factors affecting patient adherence.
POTENTIAL RISK FACTORS – Medical and psychiatric co-morbidities, emotional/physical trauma, declines other adjunctive treatments, inconsistency in prescription monitoring, personal or family history of substance abuse, positive score on screening questionnaires, conflicting or non-specific medical diagnoses, patient deception, complex pain conditions, and smoking. No single risk factor is predictive of a problematic course, and decisions about patient care should be balanced with a thorough assessment of patient strengths and coping skills.
- Adhere to federal and state laws and regulations regarding prescription of medication, including but not limited to state Prescription Monitoring Program regulations.
- Start with the lowest possible effective dose.
- Prescribe no more than the number of doses needed based on usual duration of pain severe enough to require opioids for that condition.
- Counsel the patient on risks of overdose, dependence, addiction, the importance of using medications as prescribed for effective pain relief, as well as safe storage and proper disposal of unused medication.
- The use of opioids can present serious safety concerns. Review job requirements and provide guidance regarding safe use of medication while performing safety sensitive activities such as operating machinery and driving. Discuss possible dangers associated with psychomotor effects related to dosage and timing.
- Consider psychological assessment when risk factors are present.

3. Do not initiate treatment of acute pain, including post-operative pain, with long acting or extended release opioid analgesics.

4. The use of opioids, including controlled substances, should be re-evaluated if persistence of pain suggests the need to continue these medications beyond the anticipated time period of pain treatment for the condition.

5. When issuing a prescription for an opiate to an adult patient for outpatient use for the first time, a practitioner shall not issue a prescription for more than a 7-day supply. A practitioner shall not issue an opiate prescription to a minor for more than a 7-day supply at any time and shall discuss with the parent

**COMMONWEALTH OF MASSACHUSETTS
DEPARTMENT OF INDUSTRIAL ACCIDENTS**

**OPIOID/CONTROLLED SUBSTANCE PROTOCOL
May 2016**

or guardian of the minor the risks associated with opiate use and the reasons why the prescription is necessary. Notwithstanding the aforesaid, if, in the professional medical judgment of a practitioner, more than a 7-day supply of an opiate is required to treat the adult or minor patient's acute medical condition or is necessary for the treatment of chronic pain management, then the practitioner may issue a prescription for the quantity needed to treat such acute medical condition or chronic pain. The condition triggering the prescription of an opiate for more than a 7-day supply shall be documented in the patient's medical record and the practitioner shall indicate that a non-opiate alternative was not appropriate to address the medical condition. See M.G.L. Chapter 94C Section 19D.

6. 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 considering 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. If the patient's dosage is increased to 90 MME/day without substantial improvement in function and pain, seek a consult with a pain specialist. A consult may be considered at an earlier time period if there are risk factors related to opioid treatment.

7. Exercise caution when prescribing opioid analgesics to patients currently taking benzodiazepines, barbiturates, centrally acting muscle relaxants, other central nervous system depressants, and/or other opioids; and consider conferring with co-treating health care provider to coordinate care and formulate a treatment plan which minimizes the effects of polypharmacy. Treatment with a combination of opioids and scheduled sedatives should be discouraged.

8. Medical record should document evaluation, current medication list, and the clinical rationale for prescribing opioids and other controlled substances if any, along with the functional benefit from continued use. Documentation should include a discussion regarding a safe return to work plan and safety issues pertaining to change of medication dose.

9. The use of an opioid treatment agreement is recommended after 4 weeks, or when risk factors for opioid misuse are present, in order to document patient understanding, acknowledgement of potential adverse effects, and agreement with the expectations of opioid use.

RECOMMENDATION FOR CHRONIC PAIN

MA Chronic Pain Treatment Guideline Section V.D. MEDICATIONS

Control of chronic non-malignant pain often involves the appropriate use of various medications. Ongoing effort to gain improvement in activities of daily living, and social and physical function as a result of pain relief should be a primary goal with the use of any medication. Consultation or referral to a pain specialist should be considered when the pain persists beyond the expected time for tissue healing of the injury. Consider consultation to a pain specialist if suffering and pain behaviors are

**COMMONWEALTH OF MASSACHUSETTS
DEPARTMENT OF INDUSTRIAL ACCIDENTS**

**OPIOID/CONTROLLED SUBSTANCE PROTOCOL
May 2016**

present and the patient continues to request medication, or when standard treatment measures have not been successful or are not indicated. Opioids may only provide limited pain reduction and improvement in function, and increase the risk of dependence and addiction. As such, other non-opioid/or non-pharmacological options may be superior to opioids. If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate. 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 opioid 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.

It is recommended that use of opioid analgesic and sedative hypnotic medications in chronic pain patients be used in a very limited manner, with total elimination desirable whenever clinically feasible and/or resolution of the underlying cause of the pain. Tapering or a detoxification program may be necessary and this may include inpatient detoxification. Medical management should be part of an overall interdisciplinary treatment plan and return to work must be a treatment goal if medically possible.

On-Going, Long-Term Opioid Management – Actions should include:

- A) Prescriptions from a single practitioner, and one pharmacy when possible. 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 3 months. The Massachusetts Prescription Monitoring Program may be accessed at www.mass.gov/dph/dcp/onlinepmp.
- B) Ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Visits initially at least every 2-4 weeks for the first 2-4 months of the trial, then at least once every 6-8 weeks while receiving opioids. If there has not been an overall improvement in function, opioids should be tapered and discontinued.
- C) Patient Physician Agreement – All patients on long term opioids must have a written, informed agreement. The agreement should discuss side effects of opioids, results of use in pregnancy, inability to refill lost or missing medication/prescription, withdrawal symptoms, requirement for drug testing, necessity of tapering, and reasons for termination of prescription.
- D) A baseline initial drug screen should be performed before starting opioid therapy, and the use of random drug screening at least twice and up to 4 times per year, or more if clinically indicated, for the purpose of improving patient care.
- E) If more than two opioids are prescribed for long-term use; and/or the total daily dose of opioids is above 90 MME/day; and/or opioids with central nervous system depressants are prescribed, then a second opinion from a Pain Medicine Specialist is strongly recommended.
- F) Inpatient treatment may be appropriate in complex cases as well as referral to a Pain Specialist.
- G) Laboratory monitoring as indicated.
- H) The total daily dose of opioids should not be increased above 90 MME/day. In some instances, the patient may benefit from a higher dose if there is documented objective improvement in function

**COMMONWEALTH OF MASSACHUSETTS
DEPARTMENT OF INDUSTRIAL ACCIDENTS**

**OPIOID/CONTROLLED SUBSTANCE PROTOCOL
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and pain, and a lack of significant opioid side effects.

- I) Multidisciplinary treatment including non-opioid pain medication and non-pharmacological therapies, including but not limited to home exercise, chiropractic treatment, physical therapy, and psychological treatment may be beneficial.
- J) Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should incorporate into the management plan strategies to mitigate risk, including considering 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.
- K) Clinicians should, if possible, offer or arrange evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder. Prescribing practitioners should be mindful of the impact of prescribing opioids relative to safety sensitive positions.

GENERAL GUIDELINES FOR OPIOID DISCONTINUATION AND TAPERING

Patients should not be abandoned

After determining that the failure of the pain treatment plan was not due to opioid under-dosing and/or inadequate medication time schedules, discontinue opioids when:

Pain resolution;
Lack of functional improvement;
Decrease in functioning;
Aberrant drug screening result and/or diversion;
Serious non-adherence;
Intolerance or severe adverse side effects;
Hyperalgesia; and
Decreased effects from opioid.

- Patients treated for acute pain who are opioid-naïve should generally require no tapering.
- Patients with acute pain treated with continuous opioids over 50mg MED for longer than 3 weeks duration may benefit from brief tapering over three to seven days.
- Tapering plan for patients treated with opioids for subacute and chronic pain varies depending on prior opioid dose and duration.
- Consultation with an addiction/pain medicine specialist or behavioral health specialist with expertise in pain management is recommended for complex patients.
- Multidisciplinary treatment including non-opioid pain medication and non-pharmacological therapies, including but not limited to home exercise, chiropractic treatment, physical therapy, and psychological treatment may be beneficial during the tapering process.

LINKS: www.agencymeddirectors.wa.gov/opioiddosing.asp
www.massmed.org/opioid-guidelines/
www.cdc.gov/drugoverdose/prescribing/guideline.html

SAMPLE

PATIENT UNDERSTANDING FOR OPIOID TREATMENT

Patient Name: _____

Doctor Name: _____

I am taking a pain medicine called **OPIOIDS** to help reduce my pain.

I agree (the patient must initial each box to show agreement):

- | | |
|--------------------------|--|
| <input type="checkbox"/> | I will take my pain medicine exactly the way my doctor tells me to. That means I will take the right amount of pain medicine at the right time. |
| <input type="checkbox"/> | I will tell my doctor about any new medical problems. |
| <input type="checkbox"/> | I will tell my doctor about all medicine I take, and will tell my doctor if I am given any new medicines. |
| <input type="checkbox"/> | I will tell my doctor if I treat with another medical provider, or if I go to the Emergency Room. |
| <input type="checkbox"/> | I will only get my pain medicine prescription from this doctor. My doctor's name is listed on the top of this page. |
| <input type="checkbox"/> | If my doctor is away, I will only get medicine from the doctor who is in charge while my doctor is away. |
| <input type="checkbox"/> | I will only get my pain medicine from one pharmacy (drug store). |
| <input type="checkbox"/> | I will follow my doctor's directions about therapy, exercises and physical things to do so I can learn to function with my pain and have the best outcome. |
| <input type="checkbox"/> | I understand the dangers to myself and others when driving and participating in safety sensitive activities while taking opioids. |

- | | |
|--------------------------|---|
| <input type="checkbox"/> | When I am asked, I will get lab tests to see if I am taking my medicines the right way. |
| <input type="checkbox"/> | If the lab tests show that I am not taking the medicines the way I should, my doctor may cut down or stop my medicine or send me to a specialist or special program to help care for me. |
| <input type="checkbox"/> | I will store my pain medicine in a safe place where other people cannot take it. |
| <input type="checkbox"/> | I will keep my scheduled appointments. If I must miss an appointment, I will call my doctor to cancel at least 24 hours before the appointment. |
| <input type="checkbox"/> | My doctor may stop giving me pain medicine if: <ul style="list-style-type: none">• I do not follow this agreement.• The pain medicine is not helping me.• I'm not meeting my goals in active therapy.• My pain or my functions do not improve.• I have bad side effects from the pain medicine.• I become addicted to the pain medicine.• I give or sell the pain medicine to someone else. |
| <input type="checkbox"/> | I am not pregnant and I will call my doctor as soon as possible if I think I may be pregnant. |
| <input type="checkbox"/> | I understand that alcohol use when taking opioid medication is extremely dangerous. I will not take any other drugs unless I am told to do so by my doctor. |

Patient Signature:

Date:

I attest that this form was reviewed by me with the patient and all questions were answered.

Prescriber Signature:

Date:

SAMPLE

PATIENT INFORMED CONSENT FOR OPIOID TREATMENT

Patient Name: _____

Doctor Name: _____

I plan to take a pain medicine called OPIOIDS. This pain medicine may help reduce my pain but it may also cause some serious problems. The problems may be worse if I mix the pain medicine with alcohol or other drugs.

I understand that the pain medicine I will be taking may cause serious problems including:

- ⇒ Confusion
- ⇒ Poor judgment
- ⇒ Nausea/Vomiting
- ⇒ Stomach ache
- ⇒ Constipation (hard stools that may be painful to push out).
- ⇒ Sleepy or drowsy feeling
- ⇒ Poor coordination and balance (such as feeling unsteady, tripping, and falling)
- ⇒ Slow reaction time
- ⇒ Slow breathing or I can stop breathing - which could cause me to die
- ⇒ More depression (such as feeling sad, hopeless, or unable to do anything)
- ⇒ Dry mouth
- ⇒ Increased feeling of pain (hyperalgesia)
- ⇒ Addiction (it may be very hard to stop taking the pain medicine when I'm ready to quit)
- ⇒ For men: the pain medicine may lead to less interest in sex and poor sexual performance
- ⇒ For pregnant women, the pain medicine may hurt my unborn child and may cause my child to be born addicted to the pain medicine

- I will tell my doctor if I have any of the problems listed here.
- I understand there may be other problems caused by the pain medicine, in addition to the problems listed here.
- I understand that these problems may get better when I stop taking the pain medicine.
- I understand that my physician will be checking the Prescription Monitoring Program as required by state law.
- My doctor has reviewed the serious problems that this pain medicine may cause with me.
- My doctor has answered all questions that I have about this pain medicine and the serious problems it may cause.

Patient Signature:

Date:

I attest that this form was reviewed by me with the patient and all questions were answered.

Prescriber Signature:

Date