

## 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
Minor 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
Moderate 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
<b>For patients with severe pain and extreme circumstance, the provider can make a clinical judgement to prescribe up to 7 days so long as the reason is documented in the medical record.</b>				
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

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

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
Minor 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
Moderate to Severe 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

**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 indicators. 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 parent, 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.