

Rule Governing the Prescribing of Opioids for Chronic Pain

1.0 Authority

This rule is adopted pursuant to Act No. 75 of the Acts of the 2013 Sess. (2013) (An act relating to strengthening Vermont's response to opioid addiction and methamphetamine abuse), Sections 14(e) and 11(e).

2.0 Purpose

This rule provides legal requirements for the appropriate use of opioids in treating chronic pain in order to minimize opportunities for misuse, abuse, and diversion, and optimize prevention of addiction and overdose.

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 "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).

- 3.2 “Chronic Pain” means pain caused by various diseases or abnormal conditions and that continues longer than 90 days. For the purposes of this rule, chronic pain does not include pain from cancer or pain experienced during hospice or end-of-life care.
- 3.3 “Controlled Substance” means a drug, other substance, or immediate precursor, included in Schedules II, III, or IV of the federal Controlled Substances Act (CSA).
- 3.4 “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.
- 3.5 “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.
- 3.6 “Functional Status 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.
- 3.7 “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.
- 3.8 “MED” means Morphine Equivalent Daily Dose.
- 3.9 “Prescriber” means a licensed health care professional with the authority to prescribe controlled substances.
- 3.10 “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.
- 3.11 “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”.

- 3.12 “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 Screening, Evaluation, and Risk Assessment

- 4.1 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.
- 4.2 The prescriber shall document in the patient’s medical record any diagnoses which support the use of opioids for relief of chronic pain.
- 4.3 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 3.11 of this rule.

Examples of risk assessment screening tools are available on the Department of Health website.

5.0 Prescribing Opioids for Chronic Pain

- 5.1 Prior to prescribing an opioid for the treatment of chronic pain, the prescriber shall consider and document in the patient’s medical record:
- 5.1.1 Non-opioid alternatives up to a maximum recommended by the FDA, including non-pharmacological treatments, have been considered;
- 5.1.2 Trial use of the opioid;
- 5.1.3 Any applicable requirements to query the Vermont Prescription Monitoring System;
- 5.1.4 That the prescriber has asked the patient if he or she is currently, or has recently been, dispensed methadone from an OTP 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).
- 5.2 The prescribing of opioids for chronic pain for permanent residents of skilled and intermediate care nursing facilities is excluded from the provisions of this rule.

- 5.3 For patients prescribed opioids for 90 days or more for chronic pain, the prescriber shall:
- 5.3.1 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 and/or other psychoactive medication including but not limited to benzodiazepines and barbiturates
 - 5.3.2 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;
 - 5.3.3 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 year.
 - 5.3.4 Write the maximum daily dose or a "not to exceed" equivalent on the prescription for the dispensing pharmacy.
- 5.4 Examples of Informed consent documents and controlled substance Treatment agreements are available on the Department of Health's website.

6.0 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:

- 6.1. The patient is not meeting the goals of treatment despite escalating doses of controlled substances for pain;
- 6.2. 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 4.0 of this rule.

- 6.3 The prescriber has reasonable grounds to believe, or confirms, a patient is misusing opioids or other substances;
- 6.4 The patient is seeing multiple prescribers and/or utilizing multiple pharmacies;
- 6.5 The patient has been prescribed multiple controlled substances.

7.0 Reevaluation of Treatment

- 7.1 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.
- 7.2 Prior to prescribing a dose of opioids, or a combination of opioids, that exceeds 120 MED/day the prescriber of opioids to treat chronic pain shall document in the patient's medical record:¹
 - 7.2.1 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;
 - 7.2.2 The potential for the use of non-opioid and non-pharmacological alternatives for treating pain;
 - 7.2.3 A functional status examination of the patient;
 - 7.2.4 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;
 - 7.2.5 An assessment of any co-morbid conditions affected by treatment with opioids. This may be best conducted by a mental health or addictions professional;
 - 7.2.6 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.

¹ The Department of Health will post several MED calculators on its website.

- 7.3 Based on the reevaluation required by 7.1, the prescriber shall determine and document:
- 7.3.1 Whether to continue the treatment of pain with opioids or if there are available alternatives;
 - 7.3.2 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
 - 7.3.3 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.

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 enacts 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 to provide consent, 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 the Vermont Prescription Monitoring System (VPMS) and document it 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 Opioids;
- 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 Opioids as long as the patient possesses a valid prescription for that amount.
- 8.1.7.3 A query no less frequently than as described in Section 6.2 of Vermont Prescription Monitoring System rule.

- 8.1.8 A determination of a maximum daily dose, or a “not to exceed value” for the prescription to be transmitted;
- 8.1.9 The writing of 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 180 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 Opioids or if there are available alternatives;
 - 8.2.2 The possible need for a pain management or substance abuse consultation;
 - 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.