

# Department of Health Issues New Rules on Opioids and the Prescription Monitoring System

The Vermont Department of Health (VDH) has issued new Rules on two subjects: [Prescribing of Opioids for Chronic Pain](#) and the [Vermont Prescription Monitoring System](#). Effective on August 1, 2015, the Rules reflect and add to the standards established in Vermont statutes on these two subjects. The process to write the Rules included a number of formal reviews, calls for comments, and public hearings. Interested stakeholders, such as the Vermont Medical Society, were notified of the process and participated.

The Rules have the force of law and failure to follow the Rules can constitute a form of unprofessional conduct. Clearly, it is vital for Vermont health care professionals who prescribe opioids for chronic pain or prescribe any DEA Schedule II, III, or IV controlled substances to understand the requirements set forth in these Rules. The following summaries are not comprehensive; they do not substitute for careful review of the Rules themselves.



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

**T**he Board emphasizes that the VDH Rule does not supplant the Board of Medical Practice [Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain](#). The Board's Policy offers guidelines for licensees that cover a broad variety of issues associated with prescribing opioids. Those guidelines constitute a statement of the Board's view as to how to best meet the standard of care when engaged in this aspect of medical practice. In contrast, the VDH Rule is a set of mandatory standards that must be met when a licensee prescribes opioids. An analogy may help to illustrate the distinction. The Board's Policy is the equivalent of a driving manual; the VDH Rule is the equivalent of the traffic laws. The two documents share the goal of good practice and there is much overlap, but the Rule presents a statement of what must be done that does not necessarily include all of the guidance as to what should be done when prescribing opioids for chronic pain.

**T**he requirements of the Rule reflect fundamental principles of sound medical practice and nothing should seem novel. Licensees will note that a number of the mandatory tasks for prescribers constitute only "consideration" of various matters, but the fact that the required consideration took place and the medical professional's analysis must be documented in the chart. These tasks should not be mistaken as "just more charting" – careful, methodical attention to the risks associated with long-term use of opioids and consistent use of the tools available that assist prescribers to manage those risks are essential for providing quality care to patients who are treated with these drugs.

**O**ne notable limitation on the reach of the Rule is that the definition of "chronic pain" excludes pain from cancer and pain during hospice or end-of-life care. Although some of the practices required by the Rule in the chronic pain setting may be equally valuable as part of good care in the exempted instances, the Rule does not mandate procedures for prescribing when treating cancer pain, a hospice patient, or other patient at the end of life.

Prescribers need to review the Rule itself, but some of the mandatory elements set forth in the Rule that apply to all prescribing of opioids for chronic pain are:

- ◆ Conduct and document a thorough medical evaluation/physical exam in the chart.
- ◆ Document the diagnoses that support use of opioids.
- ◆ Evaluate and document benefits and risks, including risk of misuse, diversion, addiction for that individual. "Risk assessment" is defined in the rule.

**B**efore writing any opioid prescription for chronic pain, the prescriber must consider and document:

- ◆ Non-opioid alternatives, including non-pharmacological treatments.
- ◆ Trial use of the opioid.
- ◆ Any required check of the Vermont Prescription Monitoring System.
- ◆ What is learned from a conversation with the patient to ask about receipt of methadone from an OPT or other controlled substance prescriptions, with notice the information is important for the patient's safety and disclosure is required by law.



**I**n addition to the foregoing that apply to all opioid prescriptions for chronic pain, before prescribing opioids for chronic pain for 90 days or more, a prescriber must:

- ◆ Obtain and keep in the chart a signed Informed Consent that covers elements listed in the Rule.
- ◆ Obtain and keep in the chart a signed Controlled Substance Treatment Agreement that covers: functional goals; patient's choice of a single dispensing pharmacy; safe storage and disposal. At the prescriber's discretion, the agreement also covers urine drug screening and pill counts.
- ◆ Ensure follow-up visits/evaluations on a schedule appropriate to the patient's risk factors, dosing, and other clinical considerations. Even for patients who are assessed as stable and achieving effective pain control this must be at least once per year.
- ◆ The prescription must include a maximum daily dose or "not to exceed."

**T**o this point, the requirements listed cover the initiation of opioid therapy. There are also requirements that arise over the course of treatment, based upon signs of a lack of effectiveness or signs that may indicate misuse, abuse or diversion of the treatment. Prescribers must consider referral to an appropriate specialist, such as a pain specialist or substance abuse specialist, when:

- ◆ Treatment goals are not met despite escalating doses.
- ◆ The patient's history and/or a screening indicate high risk for misuse, abuse, diversion, addiction, or overdose.
- ◆ The prescriber knows or suspects based upon reasonable grounds that the patient has engaged in misuse of opioids or other substances.
- ◆ The patient obtains prescriptions from multiple prescribers and/or multiple pharmacies.
- ◆ The patient has been prescribed multiple controlled substances.



**Reevaluation of Treatment** refers to a documented process detailed in the Rule that may be required based upon either of two conditions – continued prescribing for over a year or the prescribing of a dose of opioids, or combination of opioids, that exceeds 120 Morphine Equivalent Daily Dose (MED). The time requirement is a strict year – reevaluation must occur no less frequently than every 365 days. The need to reevaluate arises upon the first prescription above 120 MED, then the requirement for at-least-yearly reevaluations would apply. The elements of the reevaluation process resemble the elements of the process for the initial prescribing of opioids for chronic pain, with the prescriber documenting consideration of the following:

- ◆ Reevaluation of effectiveness and safety of the pain management plan and the patient's adherence to the treatment regimen.
- ◆ Potential for non-opioid/non-pharmacological treatments.
- ◆ Functional status examination of the patient.
- ◆ Review of the Controlled Substance Treatment Agreement and Informed Consent, and any revisions to the conditions.
- ◆ Assessment of co-morbid conditions.
- ◆ Related actions that may prompt adjustments to treatment, including aberrant behavior, early refills, or other factors reasonably suggesting risks associated with misuse, abuse, diversion, addiction, or overdose.

**B**ased on those elements of reevaluation, the prescriber must arrive at and document conclusions as to:

- ◆ Continued treatment with opioids or use of alternatives.
- ◆ Need for pain management, substance abuse, or pharmacological consultation to support pain management, avoidance of dependence or addiction, or taper from opioids.

**A** final element of the reevaluation is to obtain from the patient documented acknowledgment that any violations will result in further reassessment, which could lead to alteration of the treatment plan or additional controls, up to and including tapering or discontinuing the prescription for opioids.



### **Extended Release Hydrocodones and Oxycodones Without Abuse-Deterrent Formulations**

**T**he Rule Governing the Prescribing of Opioids for Chronic Pain also covers the subject of hydrocodones and oxycodones that lack abuse-deterrent features. In 2014, the Health Department issued an emergency Rule On Extended Release Hydrocodones Without Abuse-Deterrent Formulations. A portion of the new Rule replaces that emergency Rule, adding in oxycodones without abuse-deterrent formulations. In recognition that the risks posed by such formulations may be greater than with other opioids, the Rule imposes obligations on the licensee that must be met when prescribing them. These requirements are to:

- ◆ Conduct and document a thorough medical evaluation and physical examination.
- ◆ Document a diagnosis that supports the use of such analgesics.
- ◆ Evaluate and document risks and benefits.
- ◆ Document that the use of such a formulation is required to manage severe pain for which alternative treatments are not adequate.
- ◆ Obtain an Informed Consent.
- ◆ Obtain a Controlled Substance Treatment Agreement.
- ◆ Query VPMS and document it before the first prescription. For higher doses of hydrocodones (40 mg q.d.) or oxycodones (30 mg q.d.) without ADF, no less frequently than every 120 days.
- ◆ Include a maximum daily dose or “not to exceed” on each prescription.
- ◆ Follow-ups for patients on these substances must have follow-up visits and evaluations no less frequently than every 180 days.

**A**s with all government regulations, the Rule has been formally established, but is not necessarily permanent. Prescribers (and others) are free to submit their observations and recommendations for changes to the Rule. The goals for the Rule are to promote safe and effective care and to help prescribers have a clear understanding of what is required of them when prescribing opioids. Please share your thoughts with the Board of Medical Practice and the Department of Health if you believe that changes to the Rule will support either of those goals.

## ***Vermont Prescription Monitoring System Rule***

**O**n the same day that the Rule on Opioids for Chronic Pain was published, the Health Department issued the [Vermont Prescription Monitoring System \(VPMS\) Rule](#). The VPMS is the online system that gathers reports of prescribed controlled substances in DEA Schedules II through IV and makes the information available to prescribers to support good care by allowing verification of the controlled substances history of a patient. By law, all Vermont prescribers who prescribe DEA controlled substances must enroll with VPMS. The focus of this article is on the parts of the Rule that apply to prescribing, but some of the dispensing provisions are of interest to prescribers. First, reports by dispensers are required no less than once every 7 days. Some observe that the seven-day delay presents a window of opportunity for drug seekers. It's true that the seven-day delay in reporting may allow some drug seekers to initially avoid detection, but only for the first instance in which they seek multiple prescriptions.



*T*hat initial delay does not significantly reduce the effectiveness of the system. Second, the Rule is clear that all dispensers must report the same as dispensing pharmacies. The only exceptions are for drugs that are directly administered and hospitals that issue a supply of controlled substances for 48 hours or less. In other words, physician practices that dispense controlled substances must make provision for making VPMS reports.

Of most interest to our licensees are the requirements for checking VPMS. The prescriber or a delegate must query VPMS when:

- ◆ Prescribing an opioid in Schedule II-IV for the first time to treat chronic pain.
- ◆ Prescribing for the first time any Schedule II-IV controlled substance for nonpalliative, long-term pain therapy.
- ◆ Writing any replacement prescription for a Schedule II-IV controlled substance.
- ◆ Prescribing for a patient on ongoing treatment with Schedule II-IV opioids; this must happen at least annually.
- ◆ Prescribing for acute pain for over 21 days.
- ◆ Prescribing an opioid for chronic pain in an Emergency Department or Urgent Care setting in response to patient request for an opioid.
- ◆ Writing a prescription to extend a current prescription of opioids for acute pain in an Emergency Department or Urgent Care setting in response to patient request for an opioid.
- ◆ Prescribing any opioid for over 10 days in an Emergency Department or Urgent Care setting.
- ◆ Prescribing buprenorphine (or any drug containing buprenorphine) for the first time and then at regular intervals, but not less than twice annually.
- ◆ Prescribing buprenorphine (or any drug containing buprenorphine) for a Medicaid patient and the dosage exceeds that set by the Vermont Medicaid Drug Utilization Review Board. In addition, prior approval must be obtained from the Chief Medical Officer or Medical Director of the Department of Vermont Health Access.

*I*n addition to those requirements for when a query must be performed, the Rule addresses when a query may be performed. For prescribers, the important point to remember is that the subject of the query must be a “bona fide” current patient. Delegates are subject to the same limitation. The standard is simple – if the query is not to support care (which includes monitoring for safe use of the prescribed controlled substances), then it is not an appropriate query.

*T*he goals of the VPMS and the Rule on VPMS are the same – safe & effective care and the delivery of clear guidance to prescribers. Prescribers and other delegates are encouraged to submit their observations and recommendations for how the system or the Rule may be improved.