# 2017 Rule Governing the Prescribing of Opioids for Pain


In 2016, the number of accidental (non-suicide) drug deaths in Vermont involving opioids was 106[1], more than doubling the fifty such deaths seen in 2012, just four years earlier. Only 38 of the 106 opioid overdose deaths in 2016 were identified as involving prescription opioids, but research suggests that many who use illicit opioids begin with prescription drugs, whether prescribed to them or obtained improperly. That conclusion is certainly supported by the Vermont statistics. In 2010, there was a total of 41 overdose deaths, with 38 involving prescription opioids and *none* including heroin.[2] The strong connection between prescribed opioids and illicit opioids cannot be denied or ignored.

In 2016, we also saw the General Assembly respond with Act 173, a 27-page law that addressed numerous pieces of the prescription drug aspect of the problem, targeting everything from prescribing, to reporting of prescriptions filled in the VPMS, to disposal, to treatment for addiction to prescription and illicit opioids.[3] Of significant interest to our licensees who prescribe controlled substances was the requirement for the Department of Health to lead a process to revise the regulations regarding the prescribing of opioids. Notably, the law directed establishment of standards for prescribing opioids for acute pain, supplementing the existing rules applicable to chronic pain prescribing. This article will summarize the resulting revision, now called:

Rule Governing the Prescribing of Opioids for Pain, which became effective on July 1, 2017.

There is no substitute for knowing the Rule itself. Also, for every health care profession licensed by the State of Vermont that can prescribe controlled substances, violation of a regulation constitutes a form of unprofessional conduct. Hence, we strongly recommend that all prescribers not only read the Rule, but study it, discuss it with peers and support staff, and consider how the new requirements and limitations will be incorporated into their practice procedures. At a minimum, that will help prescribers avoid being investigated for a possible violation, or accused of failing to comply with the Rule.

At best, if prescribing practices are affected as intended, compliance with the Rule will lead to a reduction in the overall amount of prescription opioids entering Vermont. Fewer patients will be receiving opioid prescriptions, and when they do the dosing and duration will be less. There will be fewer unneeded, unused opioids to be found in Vermont medicine cabinets. Individuals seeking drugs for other than legitimate pain will find it more difficult to scam prescribers. And when patients are on opioids for chronic pain, they will be actively managed with the goal of ensuring that gains of analgesia outweigh the risks. The changes to the Rule are directed at multiple different issues that have all contributed in their own way to getting us to where we are, with so many individuals whose lives are negatively impacted from dependence on or addiction to opioids.

The 2016 law gave the Health Commissioner the task of issuing a revised Rule. It also provided a lot of direction and a process to be followed. It reformed the group that consults on these issues, and renamed it *The Controlled Substances and Pain Management Advisory Council.* The Council is made up of **35 members**, mostly clinicians, who represent diverse perspectives: prescribers, facilities, patients, hospice providers, insurers, psychologists, addiction treatment providers, pharmacists, and regulators.

For any reader concerned that the new Rule will present requirements that cannot be met "in the trenches," you can be assured that the Council included many, many professionals who prescribe opioids on a regular basis.

The law directed the Council to consider several specific topics: temporal and numeric limitations on prescriptions after minor procedures; co-prescribing of naloxone; informed consent from patients of opioid risks; and provision of information on storage and disposal. The law also mandated an expansion of the list of situations in which checking the Vermont Prescription Monitoring System is required before issuing a prescription.

After much deliberation by the Council, and much public input, a revised Rule was put through the final stages of the process to establish regulations and became effective on July 1, 2017. The most obvious change is the deletion of the term "chronic" from the title – it now generally applies to the prescribing of opioids, subject to limited exceptions. Some of the most notable changes include:

- Establishment of Universal Precautions to be used when prescribing opioids.
    - Consideration of non-opioid/non-pharmacological treatments first.
    - Use of VPMS.
    - Patient education and Informed Consent, covering risks, patient education sheets, and a signed Informed Consent with specific warnings.
- Guidelines for prescribing for acute pain, with standards specific to adults and children.
    - Morphine milligram equivalent (MME) guidelines per categories of acute pain level, range from no opioids for minor pain to a maximum of 50 MME for extreme pain. Need to consult tables in Rule.
    - Extended-release/long-acting opioids not indicated for acute pain. Must justify in chart if used.
    - If prescriber is not the PCP, must make effort to contact PCP/provide clear discharge summary with expectations for pain treatment. With children, must make effort to contact PCP before writing opioid for acute pain.
    - The acute pain guidelines do not apply to pts in skilled or intermediate-care nursing facilities, or to pts with severe/extreme trauma.
- Modifications to existing standards for chronic pain prescribing.
    - Addition of universal precautions, which apply to all opioid prescribing other than limited exceptions.

- Ask patient if on buprenorphine, document in record.
- Periodic reevaluation – stable patients not less than every 90 days.
- Must reevaluate if MME level hits 90 MME (was 120).
- Must have in-person discussion with patient of risk of fatal and non-fatal OD
- Co-prescribe naloxone for pts on 90+ MME or concurrent opioid and benzo combination.

*NOTE: the above list is only the changes to the chronic pain standards -most of the standards remain, including guidelines for initiation of opioid prescriptions and requirements for reevaluation.*

The new Rule is not a comprehensive guide with everything you need to know about best practice for prescribing opioids. However, it is a broad statement of many things that a prescriber must do, or cannot do when prescribing opioid analgesics, so it's important to understand the Rule's requirements if you do prescribe opioids. The Board recommends that when you establish practice procedures associated with prescribing, along with the Rule, you consider at a minimum: the Board's Policy on Use of Opioid Analgesics in the Treatment of Chronic Pain, the Vermont Prescription Monitoring System Rule, and the CDC Guideline for Prescribing Opioids for Chronic Pain.[4]

The most frequently heard concern about the *Rule Governing the Prescribing of Opioids for Pain* (or any rule about practice) is that it would impede practice by interfering with the physician being able to exercise professional discretion. The response to that concern is to read and consider the Rule. It includes several specific guidelines, but in most instances where there is a specific guideline, an exception is also included that allows deviation from the guideline based upon the physician's documented exercise of professional discretion. Similarly, many of the requirements of the Rule are not statements of how to prescribe – rather, one focus of the Rule is to present a list of factors that the physician must consider (and document) when initiating or continuing opioids. None of the requirements are in conflict with the Board's Policy on opioids, or with the CDC Guideline. All of the requirements were included with the intent to promote best practice and the safety of patients. As always, the Board is open to hearing your questions and feedback on this important topic.

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[1] As reported by the Office of the Chief Medical Examiner. Statistics regarding opioid abuse and treatment are available on the Health Department website at: http://www.healthvermont.gov/scorecard-opioids.

[2] All from the Vermont Health Department "Opioid Scorecard" at: http://www.healthvermont.gov/scorecard-opioids.

[3] Act 173 of 2016 was summarized in a 2016 article in this newsletter, http://www.healthvermont.gov/sites/default/files/documents/2016/12/BMP_Newsletter_07082016_Act%20173.pdf.

[4] A link to the CDC Guideline and a summary of it are available on the Board's webpage: http://www.healthvermont.gov/sites/default/files/documents/2016/12/BMP_Newsletter_07082016_CDC%20Guidelines.pdf

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