VERMONT
DEPARTMENT OF HEALTH

2017 Rules for Prescribing of Opioids for Pain and Vermont Prescription Monitoring System Frequently Asked Questions: For Providers

PRESCRIBING OF OPIOIDS FOR PAIN RULE

- **What is this rule and what does it do?**
  The rule sets conditions for the prescribing of opioids to treat pain in certain circumstances. A primary purpose of the rule is to use universal precautions for prescribing. Anyone can become addicted to opioids. The rule is intended to assist prescribers and patients by providing structures such that patients will be prescribed opioids only when needed and to determine whether the risks associated with the drugs are outweighed by the expected benefits.

- **When did the rule take effect?**
  The chronic pain section of the rule took effect in 2015, the acute pain and universal precaution section took effect on July 1, 2017.

- **Will this prevent a health care provider from prescribing opioids to a patient in pain?**
  No, nothing in the rule prevents a provider from prescribing opioids as a part of pain treatment.

- **What does an informed consent and patient information sheet look like?**
  An example informed consent and the patient information sheet can be found here: http://www.healthvermont.gov/sites/default/files/documents/pdf/ADAP_EXAMPLE%20Acute%20Opioid%20Rx%20Informed%20Consent.pdf

  This is only an example. This version of an informed consent does not need to be used in a provider's practice. The law requires, however, that all the elements found in this sample be present in a practice-specific informed consent.

- **How do I calculate morphine milligram equivalents (MME)?**
  There are multiple MME calculators available electronically. The Health Department has an example available on the website here: http://www.pdmpassist.org/pdf/NYDOHMH_OpioidCalc_a.pdf

- **How often do I need to document informed consent?**
  Providers must obtain informed consent from the patient prior to writing a new prescription for opioids during a course of acute or chronic pain treatment. Informed consent should be completed no less frequently than once a year for a patient prescribed opioids for chronic pain.

- **Can someone on the medical team complete the patient education and informed consent?**
  Yes. The prescriber is responsible for making sure the universal precautions in Section 4 of the rule are met, but they can be completed by a team member.

- **What does the rule mean by "opioid naïve"?**
  Opioid naïve means a patient who has not used opioids for more than seven consecutive days during the previous 30 days.

- **If a patient is not opioid naïve, then what parts of the rule apply?**
  For patients who are not opioid naïve, all sections of the rule apply except Section 5.

- **If I am covering for another provider in my practice who has prescribed an opioid to a patient, and I prescribe an opioid to the patient (who is not opioid naïve), do the requirements associated with an initial opioid prescription apply?**
  If you have access to the patient's medical record so that you can confirm that the provider you are covering met the requirements for an initial prescription, then this would not be considered an initial prescription. Thus, the initial prescription requirements need not be met.

- **What happens if I have a patient who is traveling a long distance to be treated? How do I make sure they can get a second prescription if they need one?**
  E-prescribing may be the best solution for long-distance patients, especially if the provider has many patients traveling a significant distance. This way a provider can check in with the patients after the initial prescription and if they need a second one, can electronically prescribe that at the patient's local pharmacy. When interacting with a patient who is out-of-state, a provider must be licensed in the state where the patient is located at the time the prescriber has that interaction and writes the prescription.

- **How often do patients who have pain associated with an ongoing condition or chronic disease, but only use opioids on occasion, need to be reassessed?**
  The prescriber may determine to treat the patient under the Chronic Pain section or the Acute Pain section of rule. Either course of treatment would benefit from the provider working with the patient annually to assess the current pain treatment plan and to identify other options for pain management.

- **Do I have to follow the rules when I see a patient in Vermont who is from out of state?**
  Yes. These rules are based on where the provider is practicing and licensed and are not determined by the patient's residence.

- **I practice and am licensed in New Hampshire but not Vermont, and I am treating Vermont residents. Do I have to follow the rules?**
  No. A provider is required to adhere to the governing rules of the state where the provider is practicing and licensed, and not the patient's residence, assuming you are seeing the patient in New Hampshire and not through technology or telemedicine with the patient located in Vermont at the time of the visit.

  Regardless of where you practice, if your patient fills their prescription in another state, the pharmacy may refuse to fill it if it is inconsistent with that state's rules for opioids.

- **If my patient lives part of the year in another state, do they need to come back to Vermont for a reassessment every 90 days for the provider to be in compliance with this rule?**
  Unless the provider also has a medical license for the state where the patient resides the other part of the year, the patient would need to return to Vermont for the provider to reassess the patient at least every 90 days for the Vermont provider to issue the prescription. If the provider is licensed in the state where the patient is located, and it is possible to assess the patient in accordance with the standard of care using technology, then the prescription could be issued remotely.

  Providers must be sure to adhere to the DEA requirements for Schedule II drugs. As of November 26, 2018 these included a prohibition on refills, the requirement that an "individual practitioner may issue multiple prescriptions authorizing the patient to receive a total of up to a 90-day supply of a schedule II controlled substance" provided specific conditions are met.

- **What happens to me if I do not follow the Rules?**
  Like all rules relevant to the practice of medicine, the licensing boards are the enforcement mechanism. In the case of allopathic physicians and physician assistants, the Vermont Board of Medical Practice (BMP) enforces these rules. For all other prescribing providers, boards within the Office of Professional Regulation (OPR) enforce these rules.

  Separately, the Health Department will be providing education and quality improvement outreach to providers based on prescribing analysis described in this memo. This will not have regulatory repercussions – the intent is to ensure that providers whose prescribing practices fall outside the normal range for their specialty have access to resources should they be interested.

- **Whose responsibility is it to educate patients about these new Rules?**
  The Health Department is supporting a multi-faceted public education campaign regarding the risks of opioid use and exploring non-opioid and non-pharmacological treatment options. Health care providers, however, are the most critical points of contact. Providers may explain to patients that the new requirements come from the Health Department during doctor-patient discussion.

- **Are cancer patients exempt?**
  Cancer patients are exempt from the *chronic pain* (Section 6) prescribing requirements only. Providers should use their clinical judgment and include precautions described in the chronic pain section as they see appropriate.

- **Why are the prescribing limits for patients under the age of 18 based on age and not weight?**
  The rules are focused on preventing unnecessary exposure to opioids to reduce the incidence of dependence. Many studies have shown that the developing brain is more susceptible to opioids, and that the risk of long-term dependence is much higher for those exposed at an early age, regardless of weight.

- **What information can I provide to patients concerning appropriate disposal of excess medications?**
  There are many drop-off centers across the state. They can be found here:
  http://www.healthvermont.gov/alcohol-drugs/services/prescription-drug-disposal

- **What about prescriptions that are dispensed to patients from a pharmacy but are meant to be observed or administered directly to a patient by a physician? For example, a patient picks up a prescription for a benzodiazepine prior to a procedure but takes the medication at the time of the procedure in a clinical setting.**
  Because the prescription is being dispensed at a pharmacy and the patient will be in possession of that prescription outside of a medical facility, and not dispensed by the facility, the rules apply.

- **Do I have to prescribe naloxone even if a patient has a prescription for it or has it in his or her possession?**
  No. The provider must verify that the patient has a prescription for naloxone or the naloxone itself and document that in the patient's medical record. The provider does not need to prescribe naloxone or guarantee that the patient has filled the prescription for naloxone.

  Licensed Nursing homes, residential care homes, assisted living residences, and therapeutic community residences should have a facility policy that describes how naloxone will be made available to a resident with a physician order for naloxone, i.e. contained in a facility emergency kit, or describes the facility protocol in the event of a suspected overdose.

- **How often does naloxone need to be prescribed?**
  After the initial naloxone prescription, the provider should check-in with patients regularly about the prescription, but only needs to write another prescription if the initial one has expired or if the patient reports having used the naloxone and continues to meet the requirements for co-prescribing.

- **What if my patient cannot afford naloxone?**
  The Health Department maintains a statewide naloxone distribution system at sites across the state. If a patient cannot afford a co-pay or cannot afford the prescription, then they can obtain a free kit from one of the sites. Here is a link to information on where kits can be found:
  http://www.healthvermont.gov/response/alcohol-drugs/narcan-naloxone-overdose-rescue

- **Who is responsible for educating patients and their supports around the administration of naloxone?**
  Naloxone is available as an intra-nasal spray application that comes with simplified step-by-step instructions that can be used easily by contacts of the patient. Providers and pharmacists are responsible for discussing the use of naloxone with the patients but are not required to discuss it with anyone else.

  Providers may also distribute step-by-step administration instructions published by the Department:
  http://www.healthvermont.gov/sites/default/files/documents/pdf/RESP_Narcan_HowToGiveBrochure2016.pdf

- **Does my patient have to fill the naloxone prescription? Am I responsible for that?**
  No. Like all prescriptions, patients can choose whether to fill that prescription.

  Licensed nursing homes, residential care homes, assisted living residences, and therapeutic community residences may stock naloxone onsite under a lawful prescription or order. While providers must ensure that patients living in such facilities have valid prescriptions for naloxone, these patients may not need to fill those prescriptions to be sufficiently protected. Providers prescribing to patients living in such facilities should discuss the facility protocols with the patient and a facility manager or designated facility personnel.

- **Is Tramadol treated as an opioid?**
  Yes. Tramadol is a "centrally acting opioid analgesic" and a Schedule IV drug as determined by the Drug Enforcement Agency and Health and Human Services, and therefore the rules apply.

- **Can I still prescribe to patients at 90 MME or more under this rule?**
  Yes. For chronic pain management, 90 MME is not a ceiling for prescribing, but rather an indicator that requires the prescriber to take additional precautions. Strong evidence shows a significantly increased risk of overdose for patients receiving 90 MME or more.

- **For patients undergoing surgery, we complete most paperwork at an appointment well before the patient is admitted for the procedure. Can I have the patient sign the informed consent sheet for a potential opioid prescription at that time?**
  Yes. But at the time of surgery there should be another copy of the Patient Education Sheet provided to the patient with the prescription.

- **For patients in residential health care settings, can a nurse or other provider be the one to conduct the steps in Section 4.0 of this rule?**
  It is ultimately the responsibility of the prescriber for the steps to be completed in order for the prescriber to be in compliance with the rule, but the rule allows for the delegation of some of the tasks to a nurse or other provider.

- **Are long term care facilities regulated by these rules?**
  No. Prescribers, not facilities, are responsible for compliance with the rule; long-term care facilities do not prescribe and are not responsible for ensuring the rule is followed. However, long-term care facilities may have a role to play in supporting the providers who care for their residents in their efforts to comply with the rule.

VERMONT PRESCRIPTION MONITORING SYSTEM (VPMS) RULE

- **What is the VPMS?**
  The Vermont Prescription Monitoring System is a database established by the Vermont Legislature and run by the Vermont Department of Health. When a Schedule II, III, or IV controlled substance is dispensed from a Vermont licensed pharmacy, the VPMS collects a standard set of information on the patient, the prescriber, and the drug. This information is held in a central database for six years and can be used by prescribers and pharmacists to improve patient care. Information in the System is confidential and can only be accessed under very strict parameters.

  As of November 15, 2013, all health care providers who prescribe Schedule II-IV substances are required to have registered with VPMS.

  VPMS allows approved users to access the prescription monitoring programs in Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York and Rhode Island.

- **What is its purpose?**
  A primary purpose of VPMS is to promote the public's health by providing health care providers and dispensers with a tool to help them assess and monitor controlled substances prescribed to their patients. The goal is to enhance treatment and prevent the abuse of controlled substances without interfering with the medical use of those substances.

- **Am I required to register for VPMS?**
  If you have a Vermont license and you write prescriptions for a controlled substance (regardless of the number of prescriptions you write), then you are required to register with VPMS. If you are a Vermont-licensed pharmacist who dispenses controlled substances, you are also required to register for VPMS.

- **Do I actually have to check VPMS for even one benzodiazepine pill?**
  Yes. Even though one benzodiazepine pill may not be a danger on its own, there is an increased risk of overdose if a patient has been prescribed an opioid or other contraindicated medication at the same time.

- **What does the 10-pill exemption apply to?**
  The 10-pill exemption ONLY applies to checking VPMS. All other parts of the rule remain in effect. There is no exemption for liquid formulas.

- **What is a delegate in the VPMS context?**
  A delegate is anyone in the provider office (with HIPAA clearance) who is authorized by the prescriber to look up the prescriber's patients on their behalf for the purposes of patient care.

- **What do I have to do if a pharmacist calls me with concerns?**
  Pharmacists are required to query the VPMS under certain circumstances that may indicate a possible concern of risk or diversion. While there are no required actions from reviewing the results, this additional information provides an opportunity to coordinate care between the prescriber(s) and pharmacist(s).

- **How do I document that I looked a patient up in VPMS?**
  You do not have to document that you looked up a patient in VPMS. The VPMS tracks all queries conducted in the system.

- **How do I sign up for VPMS?**
  To register for VPMS visit: https://vermont.pmpaware.net
  User tutorials are available through the system and online at:
  http://www.healthvermont.gov/vpms

- **What do I do as a provider if a VPMS query raises concerns about a patient?**
  Querying VPMS can provide additional information about a patient's prescription history that a provider may not have known. A query that raises concerns about patient safety or diversion should be considered when prescribing or dispensing to that patient.

  A provider may also choose to use this information to:
  - Contact the patient's other providers to coordinate care
  - Contact the other pharmacies to coordinate care
  - Use the information to have a conversation with the patient about possible diversion or misuse risks and other options for care or treatment

- **What about checking the Vermont Prescription Monitoring System (VPMS) if my patient fills their prescription out of state?**
  VPMS only has information on prescriptions that are dispensed from Vermont licensed pharmacies. However, by checking the state boxes at the bottom of the Patient Query page, certain user types can include data about prescriptions dispensed in CT, ME, MA, NH, NJ, NY and RI. These queries must have an exact name match to be pulled into the patient report.

Contact information for further questions

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