

Virginia Board of Medicine

Frequently Asked Questions about the Prescribing of Buprenorphine for Addiction

1. Can I continue to prescribe mono-product for my patients that have a demonstrated intolerance to naloxone –containing products?

The amended emergency regulations that became effective August 24, 2017 read as follows: *For patients who have a demonstrated intolerance to naloxone; such prescriptions for the mono-product shall not exceed 3% of the total prescriptions for buprenorphine written by the prescriber, and the exception shall be clearly documented in the patient's medical record. So 3% of buprenorphine prescriptions that will be administered off-site can be for mono-product, and the rest must be for naloxone-containing products. The 3% restriction does not apply to injectable formulations of buprenorphine mono-product administered directly to patients in a waived physician's office, a clinic staffed by a waived provider, or in a federally licensed opioid treatment program or to mono-product tablets administered directly to patients in federally licensed opioid treatment programs.*

2. What alternatives to buprenorphine mono-product are there that contain no or low-dose naloxone?

This is not an endorsement for a particular medication, and there may be other alternatives unknown to the Board at this time. The only other mono-products currently FDA-approved for the treatment of addiction are the Probuphine implant and Sublocade extended-release injection. Formulations with low-dose naloxone include Zubsolv sublingual tablets and Bunavail buccal film. Methadone and Vivitrol are also options.

3. Is there a grace period for switching patients to a naloxone-containing product?

It is lawful to prescribe up to 7 days of mono-product in the switching of a patient from methadone to a naloxone-containing product or for 7 days in switching a patient from the mono-product to a naloxone-containing product.

4. Is there a grace period for tapering patients off the mono-product if they choose not to take a naloxone-containing product?

There is no grace period in the regulations, other than what is stated above. The Board does expect that sound medical judgement and safety of the patient will be paramount in the tapering process.

5. Are buprenorphine and naloxone safe for mothers and their breastfeeding infants?

The American Society of Addiction Medicine National Practice Guideline adopted June 2015 stated, "It was shown that the amount of buprenorphine metabolites secreted in breastmilk are so low that they pose little risk to breastfeeding infants." In the May 11, 2016 issue of the ASAM Magazine, a question about breastfeeding was

addressed by a Providers' Clinical Support System expert, "While buprenorphine levels transfer to breastmilk in very low levels, naloxone is even much less detectable, if at all." An August 2016 article from the Journal of Human Lactation confirmed that infant plasma levels were low or undetectable. A consultant to the Board, an OB-GYN who provides MAT, opines that naloxone-containing products prescribed to the mother can be considered safe for breastfeeding infants.

6. Is the prescribing of tramadol subject to these regulations?

YES, tramadol is an opioid and is therefore subject to these regulations.

7. Can I use the mono-product for induction and then switch to the naloxone-containing product?

The regulations do not speak to induction with the mono-product and then switching to a naloxone-containing product. The regulations state that 7 days of mono-product can be written in the switching from mono-product to a naloxone containing product.

8. Can a pharmacist dispense a prescription of the mono-product for a non-pregnant individual after March 15, 2017?

A pharmacist should dispense mono-product in keeping with the 3% rule for prescribers described in #1.

9. Can my staff see the patient during the induction phase?

The regulations require that the patient be seen "by the prescriber" at least once a week during induction.

10. Does the Board have a list of "sedative hypnotics"?

No.

11. Can I continue to prescribe benzodiazepines with buprenorphine?

The regulations allow for benzodiazepines in the lowest effective dose required for the treatment of co-morbid conditions. Extenuating circumstances must be documented in the medical record to support the prescriber's rationale.

12. Is there an exception for financial hardship that allows a patient to take Subutex instead of Suboxone?

NO. There is no such exception in the regulations. However, the Medical Society of Virginia has developed the following list of resources for patients that may need help with the expenses of treatment with naloxone-containing products.
https://www.msv.org/sites/default/files/patient_assistance_resources.pdf

Virginia Board of Medicine

Frequently Asked Questions about the Prescribing of Opioids for Pain

1. Do I need to refer a patient being treated for chronic pain to a pain management specialist before exceeding 120 MME/day?

The regulations require the prescriber to document the reasonable justification for the increase OR refer to or consult with a pain management specialist.

2. If a patient being treated for chronic pain admits to occasional marijuana use or has a positive screen, what should I do?

This issue is not addressed in the regulations. The Board of Medicine expects physicians to use good judgement in their care of patients and fully document what you do and why in the chart.

3. If a patient I am treating for chronic pain is on a benzodiazepine from another provider, must I prescribe naloxone?

YES. The regulations are meant to save lives. There would need to be coordination with the other practitioner so that you are on the same page. Controlled substances from more than one prescriber could lead to an inadvertent overdose. There is a provision for “extenuating circumstances” in the regulations, in case the benzo is absolutely essential to the patient’s well-being.

4. What if the benzodiazepine is only PRN?

The Board of Medicine cannot recommend deviation from the regulations.

5. What formulation of naloxone do I prescribe?

The prescribing of naloxone required by these regulations is intended to rescue those who are in the midst of an overdose or anticipated to be in overdose. The regulations do not require a specific formulation. Here are the options in the Pharmacy guidance document. <http://www.dhp.virginia.gov/Pharmacy/guidelines/110-44.docx>

6. Do I have to ensure that a patient fills the prescription for naloxone?

NO, the prescriber’s responsibility is to prescribe the naloxone, but the regulations do not require that the prescriber ensures that the patient gets it filled. However, a prescriber may wish to revisit the dose of opioid prescribed, if warranted.

7. Can a pharmacist fill an opioid prescription exceeding 120 MME/day, or with concomitant benzodiazepine, if a patient does not present a naloxone prescription?

The answer is YES, but it would be within your discretion to call the prescriber to ask if that is what he/she intended.

8. Must naloxone be prescribed for lower doses of opioids in the presence of benzodiazepines?

YES, the regulations state that is the case.

9. Must I drug screen all patients that I will be putting on opioids for chronic pain?

YES, a drug screen is required initially upon beginning chronic pain management, and at least once a year thereafter.

10. What is the Board's policy on PRN pain medications?

The regulations require drug screens for patients on chronic opioid medications. The Board cannot recommend deviation from the regulations. The Board would make the determination about the standard of care in such a case, based upon the documentation of the treatment.

11. Is it true that I can only prescribe 1 week of opioid for acute pain?

Prescribing is limited to a 7-day supply unless "extenuating circumstances are clearly documented in the medical record."

12. Can I write for more than 14 days for post-operative pain?

Prescribing is limited to a 14-day supply unless "extenuating circumstances are clearly documented in the medical record."

13. Is tramadol an opioid?

YES. It is an opioid and a Schedule IV drug.

14. Is tramadol subject to these regulations?

YES.

15. How can a pharmacist determine that a physician is prescribing for acute pain, post-op pain, or chronic pain?

It has been suggested that prescribers put a notation on the prescription as to whether the drug is for acute pain, post-op pain, or chronic pain. The Board sees this as an excellent communication between professionals involved in the patient's care.

16. Does the Board of Medicine have a list of "sedative hypnotics"?

NO

17. Must patients that have been stable on their current dose of opioid analgesic for a long time be drug tested?

YES, the regulations require testing at least once a year.

18. Can I use Subutex and Suboxone off-label for the treatment of pain?

The amended emergency regulations that became effective August 24, 2017 allow Suboxone, or any naloxone-containing tablet, to be used to treat chronic pain. Subutex cannot be used for chronic pain. Buprenorphine products are not indicated for acute pain.

19. Does the physician have to see pain patients every 3 months or can a nurse practitioner or a physician assistant see a patient, assess the opioid therapy, evaluate for opioid use disorder and document findings in the medical record?

The regulations use the term “practitioner” and state these issues need to be addressed every 3 months. Nurse practitioners and physician assistants can perform acts of medicine through a practice agreement with a physician. As long as the NP and PA are trained and competent to accomplish the assessments required, and the physician maintains responsibility for patient care, it would appear that the requirements of the law would be met.

20. If a patient is held in the ED or other part of the hospital for 24-48 hours, do the regulations apply?

The regulations do not apply to pain treated during an inpatient hospital admission. Observation is an administrative status for a patient that is under clinical watch and care within the hospital, therefore the regulations would not apply. However, when the patient is discharged, the regulations would apply in regards to the 7-day limit of opioid or more if extenuating circumstances are documented.

21. Are there any exemptions to the requirements of these regulations?

Yes, patients with cancer, sickle cell, and those in hospice and palliative care are exempt from these regulations.