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 waivered physician's office, a clinic staffed by a waivered 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