New Virginia Laws and Regulations on the Prescribing of Opioid and Buprenorphine

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On February 16, 2017 the Virginia Board of Medicine (“The Board”) adopted regulations entitled “Governing Opioid Prescribing for Pain and Prescribing of Buprenorphine.” The regulations were adopted under the Board’s emergency authority given that State Health Commissioner Marissa Levine declared on November 20, 2016 an opioid addiction crisis as a public health emergency. The regulations quickly advanced through the approval process by the Virginia Attorney General’s Office, the Virginia Department of Planning and Budget and were signed by the Governor on March 13, 2017. The regulations became effective March 15, 2017.

Coupled with these regulations, at least ten pieces of legislation were introduced during the 2017 Session of the Virginia General Assembly dealing with the prescribing of opioids and buprenorphine. This Advisory will provide an overview the legislation and new regulations regarding the treatment of acute pain, chronic pain and treatment with buprenorphine.

Two identical pieces of legislation passed by the 2017 General Assembly Session directed the Board to promulgate regulations on the treatment of acute pain and/or chronic pain with opioids and the prescription of buprenorphine. House Bill 2167, patroned by Delegate Todd Pillion (R, Dickenson) and Senate Bill 1180, patroned by Senator Ben Chafin (R, Bland) directed Board action. Both bills included emergency clauses making them effective upon signature of the Governor. The Governor signed HB 2167 on March 3, 2017 and signed SB 1180 on March 27, 2017. After the bills were filed, stakeholders stressed to the members of the General Assembly that it would be more appropriate to use the physician experts at the Board to address the issue of prescribing practices through regulations, as opposed to addressing by statute. The Board relied on expertise from a regulatory advisory panel, the Board’s legislative committee and the full Board, to revise and hone the regulations throughout January and February.

General Provisions

The regulations apply to Doctors of Medicine, Osteopathic Medicine, Podiatry and Physician Assistants. The Board of Nursing has adopted identical regulations that will govern Nurse Practitioners with prescriptive authority who are licensed through the Joint Boards of Medicine and Nursing. These regulations have been approved and are effective on May 8, 2017.

1. Both pieces of legislation also direct the Board of Dentistry to promulgate regulations for the prescribing of opioids for acute and chronic pain. The Board of Dentistry has already approved regulations that are proceeding through regulatory process to final approval.

2. 18 VAC 85-21-10

With regard to exclusions, the regulations do not apply to the following:
1. “The treatment of acute or chronic pain related to cancer, a patient in hospice care or a patient in palliative care;

2. The treatment of acute or chronic pain during an inpatient hospital admission, in a nursing home or an assisted living facility that uses a sole source pharmacy; or

3. A patient enrolled in a clinical trial as authorized by state or federal law.”

The regulations define acute pain and chronic pain as follows:

Acute pain “shall mean pain that occurs within the normal course of a disease or condition or as the result of surgery for which controlled substances may be prescribed for no more than three months.” [emphasis added]

Chronic pain “means non-malignant pain that goes beyond the normal course of a disease or condition for which controlled substances may be prescribed for a period greater than three months.” [emphasis added]

Management of Acute Pain

The first section of the Regulations outlines requirements to prescribe opioids for the treatment of acute pain. Prescribers are required to give consideration to non-pharmacologic and non-opioid treatment of pain prior to initiating treatment with opioids. In addition, prescribers are required to perform a history and physical examination, query the Prescription Monitoring Program (“PMP”) as required by Virginia Code § 54.1-2522.1 and conduct an assessment of the patient’s history and risk of abuse.

Of note, three pieces of legislation were introduced in the 2017 Session of the Virginia General Assembly that would have limited, by statute, the ability to prescribe controlled substances containing opioids in acute pain settings. Specifically, Senate Bill 1232, patroned by Senator Siobhan S. Dunnavant (R, Henrico) and House Bill 1885, patroned by Delegate Tim Hugo (R, Fairfax), sought to achieve seven-day prescribing limits. Both SB1232 and HB1885 were amended during the General Assembly Session to instead revise the requirements for a prescriber to check the PMP. Current law requires a prescriber to check the PMP for prescription at the onset of treatment lasting more than 14 consecutive days. This was revised to require a check for opioids prescribed for more than seven days. In addition, the current law exempts a prescriber from the requirement to check the PMP as part of treatment for surgical or invasive procedure. This requirement was amended to require a check of the PMP as part of treatment for a surgical invasive procedure if the prescription for an opioid is for more than 14 consecutive days. Both bills were signed by the Governor on Friday, February 24, 2017 and become law July 1, 2017. Finally, the General Assembly included a sunset clause on both bills that will sunset on January 1, 2022, absent further action.

Similarly, House Bill 1898 was introduced by Delegate John Bell (D, Loudoun). This bill would have limited controlled substances contained in opioids to a three-day supply upon discharge from an emergency department. This legislation

5 18 VAC-85-21-10-B
6 18 VAC 85-21-10
5 18 VAC 85-21-20
6 18 VAC 85-21-30
was not advanced during the 2017 Session. Delegate Bell championed the package of legislation introduced given his son’s battle with addiction that stemmed from opioids prescribed after presenting to an emergency room.

**Treatment of Acute Pain with Opioids**

The Board regulations also require numerous treatment requirements on prescribers. First, a prescriber treating acute pain shall begin opioid treatment with short acting opioids as opposed to those that are long acting. The Board heard testimony that risks of addiction increase with initial prescriptions of long acting opioids. If the prescriber determines the opioids are required, the quantity shall not exceed a seven-day supply, unless “extenuating circumstances are clearly documented in the medical record.” Finally, opioids prescribed as part of a surgical procedure shall be for no more than 14 consecutive days “unless extenuating circumstances are clearly documented in the patient’s medical record.”

Many states have considered tracking and monitoring the mean morphine milligram equivalent (“MME”) for patients receiving controlled substances containing opioids. Prescribers are encouraged to download the Centers for Disease Control (CDC) application from Apple or to consult the CDC website, as both have an MME calculator that enables prescribers to enter the opioids and have the MME calculated. Also, the Virginia PMP automatically calculates an MME for patients and this is available to any prescriber who checks the PMP on a patient. Three requirements surrounding MME evaluation of patients are required by the regulations. First, a prescriber shall document in the medical record any reason to exceed 50 MME/day; second, prior to exceeding 120 MME/day, the prescriber is required to document the justification for the dosages or refer or consult with pain management specialists on behalf of the patient; finally, Naloxone shall be prescribed for any patient when “risk factors for overdose, substance abuse, doses in excess of 120 MME/day, or concomitant benzodiazepine are present.”

Due to a higher risk of overdose when opioids are prescribed with benzodiazepines and other medications, prescribers are required to document in the medical record a tapering plan to achieve the lowest effective dose if other medications are prescribed.

**Medical Records for Acute Pain**

The Board included in regulations very specific documentation requirements for treatment of acute pain with controlled substances containing opioids. Recent Board disciplinary cases have revealed a number of instances of inadequate medical records surrounding the prescribing of opioids.

**Management of Chronic Pain**

The second section of the regulations address prescribing opioids for chronic pain. When a patient transitions from acute pain to chronic pain, the regulations include numerous requirements that a prescriber must honor before beginning management of chronic pain with controlled substances containing opioids. These requirements fall into the general

7 18 VAC 85-21-40
8 18 VAC 85-21-40
9 18 VAC 85-21-40
10 [www.cdc.gov/drugoverdose/prescribing/app.html](http://www.cdc.gov/drugoverdose/prescribing/app.html)
11 18 VAC 85-21-40-B
categories of evaluation, treatment, treatment planning, informed consent, therapy consultation, and additional requirements for medical record documentation.

In evaluating a patient with chronic pain, a medical history and physical examination must be performed, including a mental status examination and the following nine specific items must be documented in the patient’s medical record:

1. “The nature and intensity of the pain;
2. Current and past treatments for pain;
3. Underlying or coexisting diseases or conditions;
4. The effect of the pain on physical and psychological function, quality of life and activities of daily living;
5. Psychiatric, addiction and substance abuse history of the patient and any family history of addiction or substance abuse;
6. A urine drug screen or serum medication level;
8. An assessment of the patient’s history and risk of substance abuse; and
9. A request for prior applicable records.”

The Board was also concerned that chronic pain patients be advised of the appropriate safe storage and disposal of controlled substances containing opioids; and therefore, a requirement on prescribers to discuss this information with patients was included in the regulation, as well, as a requirement for prescribers to discuss an exit strategy for the discontinuation of opioid use if they are not effective.

With regard to treatment requirements for chronic pain, prescribers again should consider the use of non-pharmacologic and non-opioid treatment prior to initiating treatment with opioids. Prescribers similar to acute pain, are required to consider and document reasons to exceed 50 MME/day. Prescribers who exceed 120 MME/day shall document the justification for the dose or refer or consult with a pain management specialist. Similarly, a requirement to prescribe Naloxone is imposed for any patient who’s risk factors indicate or who is receiving greater than 120 MME/day.

In an effort to make sure chronic pain patients are routinely reviewed, the Board requires prescribers to document the rationale for continued opioid therapy every three months. Likewise, for patients who receive opioids in addition to benzodiazepine and other medications, a tapering plan must be documented in the patient’s chart “to achieve the lowest possible effective dose of these medications . . .”
Finally, prescribers are required to regularly evaluate for opioid use disorder. If opioid use disorder is present, the prescriber “shall initiate specific treatment for opioid use disorder, consult with an appropriate healthcare provider, or refer the patient for evaluation and treatment, if indicated.”

The Board requires the existence of a treatment plan for patients receiving controlled substances containing opioids for chronic pain. This treatment plan has specific requirements, including measurements that are going to be used to document progress with treatment, diagnostic evaluations and indications for misuse, abuse or diversion with appropriate steps to be taken.

Informed consent and a signed treatment agreement are required of prescribers for chronic pain, as well. The informed consent shall be documented in the medical record and include, “risks, benefits and alternative approaches, prior to the initiation of opioids for chronic pain.”

The written treatment agreement must be signed by the patient and must address parameters of treatment, behaviors necessitating referral, cessation of treatment or dismissal from care. Specifically, the treatment agreement is required to include permission of the prescriber to obtain urine drug screens or serum medication levels, query the PMP, and consult other prescribers or dispensing pharmacies.

The Board imposed requirements to include periodic review of the treatment. Prescribers are to review the course of pain treatment, the etiology of the pain and the patient’s state of health, at least every three months after initiation.

Next, the prescriber has to document the continued benefit from continuation of treatment being prescribed. If the patient’s response has been unsatisfactory, the prescriber has to document the rationale for continued use, or consider the use of other therapeutic modalities.

Prescribers are required to check the PMP at least every three months after initiation of treatment. Urine drug screens or serum medication levels are required to be ordered at the “initiation of chronic pain management and at least every three months from the first year of treatment, and at least every six months, thereafter.” Finally, the prescriber is required to continue to evaluate for opioid use disorder and take appropriate action if such disorder develops.

Next, the Board addressed the requirements for additional consultations. Prescribers are required to refer patients for additional evaluation and treatment when needed; and if a chronic pain patient is determined to have developed an opioid use disorder, “treatment for opioid use disorder shall be initiated or the patient shall be referred for evaluation and treatment.”

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15 18 VAC 85-21-60-B  
16 18 VAC-85-21-70  
17 18 VAC-85-21-70-D  
18 18 VAC-85-21-70-E  
19 18 VAC-85-21-80  
20 18 VAC-85-21-90  
21 18 VAC-85-21-90-C  
22 www.msv.org  
23 18 VAC-85-21-90  
24 www.MagMutual.com
Finally, the Board has imposed 12 specific requirements for inclusion in the medical records of chronic pain patients. Of note, the Board requires that not only this documentation be included in the medical record, but it be readily available for review. The specific items are as follows:

1. “The medical history and physical examination;
2. Past medical history;
3. Applicable records from prior treatment providers and/or any documentation of attempts to obtain;
4. Diagnostic, therapeutic and laboratory results;
5. Evaluations and consultations;
6. Treatment goals;
7. Discussion of risks and benefits;
8. Informed consent and agreement for treatment;
9. Treatments;
10. Medications (including date, type, dosage and quantity prescribed and refills);
11. Patient instructions; and
12. Periodic reviews.”

**Prescribing of Buprenorphine**

The final section of the regulations addresses the prescribing of buprenorphine. Buprenorphine is an opioid medication that is most commonly used to treat opioid addiction; but, it also has a role in the treatment of chronic pain. The Board regulations address the appropriateness of the prescribing of buprenorphine in three settings. Specifically, for acute pain, the Board regulations indicate that buprenorphine is not indicated for acute pain in the outpatient setting. However, the Board included an exception for when a prescriber has obtained a waiver from the Substance Abuse Mental Health Services Administration and DEA, that such prescriber may use buprenorphine to treat acute pain in a patient whose primary diagnosis is a disease of addiction.

For example, if a patient has been diagnosed with the disease of addiction and breaks his ankle, the patient commonly will present to the emergency room. If the emergency room physician prescribes an opioid such as Percocet for the patient, the chance of interfering with the patient’s addiction treatment is greatly enhanced. If the patient, instead, is referred back to their prescriber, who was prescribing the buprenorphine pursuant to a waiver, that prescriber will have the ability to treat the acute pain by increasing the buprenorphine dose; therefore, managing the pain and preserving the course for addiction treatment.
With regards to chronic pain, buprenorphine may be prescribed and administered in formulations and dosages that are “FDA approved for that purpose.” At this time, FDA has given approval for two formulations to be used to treat chronic pain, which includes a buprenorphine patch and a buprenorphine mucosal strip. Of note, prescribers of buprenorphine for chronic pain need not obtain a waiver from the Substance Abuse Mental Health Services Administration and DEA.

Part four of the Board regulations address the prescribing of buprenorphine as part of addiction treatment. The Board imposed general provisions and requirements on prescribing buprenorphine and then went on to address requirements for patient assessment and treatment. The treatment itself has considerations for special populations and requirements for medical records.

The general provisions regarding prescribing buprenorphine include a requirement that prescribers of buprenorphine in the addiction treatment setting obtain a waiver from the Substance Abuse Mental Health Services Administration and the DEA. This is commonly referred to as a DEA X-number. Virginia currently has approximately 385 prescribers who hold waivers. Physician Assistants and Nurse Practitioners are able to obtain waivers, as are Doctors of Medicine and Osteopathic Medicine. The Board, through regulations, clarified that only physician assistants and nurse practitioners, who have obtained waivers, may prescribe buprenorphine for opioid addiction if they have entered into a practice agreement with a waivered Doctor of Medicine or Osteopathic Medicine.

The Board focused on the medical evidence indicating that the success of addiction treatment is largely enhanced if it involves, not only the prescription of buprenorphine, but also a counseling component. Accordingly, the Board requires prescribers to refer patients to a mental health provider for counseling or provide the counseling in their practice and document that in the patient’s medical record.

Initially, the Board looked to limit the referrals to “licensed mental health providers,” but given the current shortage of a sufficient number of these providers in various areas across the Commonwealth, the Board was concerned that continuing to limit referral to that specific provider category would do more harm than good. Accordingly, the Board decided to rely upon a definition of mental health service provider as contained in 54.1-2400.1, which includes: “[i] a person who provides professional services as a certified substance abuse counselor, clinical psychologist, clinical social worker, licensed substance abuse treatment practitioner, licensed practical nurse, marriage and family therapist, mental health professional, physician, professional counselor, psychologist, registered nurse, school psychologist, or social workers. . .”

With regard to patient assessment and treatment, many of the requirements for opioid prescribers, as far as history and physical and evaluations, are also required of prescribers of buprenorphine. In addition, at the outset of treatment, urine drug screens, pregnancy tests for women of child bearing age and ability, and a check of the PMP are required given the high risk of Hepatitis C and other communicable diseases (i.e., when clinically indicated, “testing must be performed for HIV, Hepatitis B, Hepatitis C, and TB.”)
Southwest Virginia has seen extensive diversion and misuse of buprenorphine, which does not contain Naloxone. This product is commonly referred to as buprenorphine mono-product. The buprenorphine mono-product is often referred to by the drug name, Subutex®, whereas the buprenorphine product that contains Naloxone is commonly referred to as Suboxone®.

Both, by legislation passed in the 2017 Session (which is effective July 1, 2017) and by the Board regulations (which became effective March 15, 2017), the prescription of the buprenorphine mono-product is limited. Specifically, House Bill 2163, patroned by Delegate Todd Pillion (R, Dickenson) and Senate Bill 1178, patroned by Senator Ben Chafin (R, Bland), limit the prescription of buprenorphine mono-products to the following: patients who are pregnant; patients converting from methadone to buprenorphine, containing Naloxone, for a period not exceeding seven days; or as permitted by regulations of the Board.

The General Assembly placed emergency clauses on both pieces of legislation and also placed sunset clauses of July 1, 2022. The Governor has until March 27, 2017 to act on both bills. The Board regulations reflect the exception for patients who are pregnant and the patients converting from methadone and also add the ability to prescribe the buprenorphine mono-product in formulations other than tablets for indications that are approved by the FDA.

The Board heard testimony that the street value of Subutex® in Southwest Virginia is $75.00/tablet, where the street value of Suboxone® is $25.00/tablet. Through feedback from Commonwealth’s attorneys and judges in Southwest Virginia, the immediate concern is reducing the amount of Subutex® on the street, as patients will crush the tablet formulations and divert them, or will sell them as a way to make a living and sustain their habit.

Other states also permit the prescription of the buprenorphine mono-product in cases where there is a documented allergy as confirmed by a Board Certified allergist, or in cases where a patient has failed a course of treatment in a category commonly referred to as medical necessity. The Board chose not to adopt either of those exceptions out of concern that they would be abused and be difficult to enforce.

As with other opioids, a tapering plan is required when patients receiving buprenorphine are also co-prescribed other benzodiazepines or other medications. The prescriber of buprenorphine for all patients in addiction treatment must check the PMP at the outset of treatment.

The Board also addressed the issue of the appropriate dosages of buprenorphine on induction. Specifically, the regulations require that patients should be starting on no more than 8mg/day of buprenorphine, and seen weekly by the prescriber. If the prescriber documents that a patient requires a dosage higher than 8mg/day, that medical indication must be documented in the patient’s medical record.
The Board also addressed the rationale for total dosages per day, and, in particular requires that any total dosage per day exceeding 16mg have the medical indication documented in the medical record. "Dosages exceeding 24mg/day of buprenorphine shall not be prescribed." [emphasis added]  

During stabilization, the prescribers are directed to increase dosages of buprenorphine in safe and effective increments with a goal of obtaining the lowest dose that "avoids intoxication, withdrawal or significant drug craving."  

With regard to urine drug screens or serum medication levels, similar to what the Board required of those prescribers treating chronic pain, requirements are placed on those prescribing buprenorphine for addiction treatment to require screens "at least every three months for the first year of treatment, and at least every six months thereafter."  

Finally, as the Board did with the management of chronic pain, prescribers of buprenorphine and addiction treatment are required to incorporate, relapse prevention strategies in their counseling or refer the patient to "mental health service provider, as defined in § 54.1-2400.1."  

The Board regulations next addressed special populations and considerations that must be followed by prescribers. Specifically, patients should be treated with buprenorphine mono-product in doses 16mg per day or less. Patients under the age of 16 shall not be prescribed buprenorphine as part of addiction treatment until such time as the FDA grants approval. Patients receiving buprenorphine as part of addiction treatment also have to be monitored for the reduction of their chronic pain and functionality.  

Finally, "practitioner shall not undertake buprenorphine treatment with a patient who has psychiatric comorbidities and that is not stable," For patients determined to be unstable, they shall be referred for psychiatric evaluation and treatment prior to the prescriber initiating buprenorphine treatment. Discussion at the Board of this requirement clarified that only the referral need be made before buprenorphine treatment is initiated as opposed to the psychiatric evaluation and treatment having been completed. The Board was concerned that if the evaluation and treatment had to be completed, that the patient would deteriorate in the interim.  

The medical recordation requirements for buprenorphine treatment was addressed by the Board to ensure that the medical records were accurate; preserved the necessary confidentiality under Federal law; and prohibited unauthorized disclosure.  

Conclusion

Rarely has the Commonwealth seen such a health tragedy give rise to such prompt action by the Board and the General Assembly in tandem. Prescribers are recommended to quickly review patients currently being treated for acute pain, chronic pain or for addiction treatment to ensure compliance with the new laws and regulations. There is no grandfathering of existing patients, nor any grace period to achieve compliance once the regulations are published in the

56 18 VAC-85-21-150-I  
57 18 VAC-85-21-150-G  
58 18 VAC-85-21-150-H  
59 18 VAC-85-21-150-J  
60 18 VAC-85-21-160  
61 18 VAC-85-21-160-E  
62 18 VAC-85-21-170
Virginia Register. For questions regarding these new laws and regulations, please contact your MagMutual Patient Safety Consultant or Nichole Lydon (nlydon@magmutual.com).

**Next Steps**

The Board of Medicine has conveyed a Regulatory Advisory Panel (RAP) to review the regulations on opioids and buprenorphine to determine if any revisions need to be made. Examples to be discussed include potential exemptions or exclusions for documented intolerance or allergic reactions to Suboxone®. The RAP is scheduled to meet May 15, 2017.

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