On Thursday, February 16, 2017, the Virginia Board of Medicine adopted emergency regulations 18 VAC 85-21-10 et seq. that establish new rules regarding the prescribing of opioids for pain treatment and buprenorphine for addiction treatment. The regulations will become effective spring 2017 after they have been signed by Governor McAuliffe. The information below provides an abbreviated summary of the new regulations. A copy of the full regulations can be found here.

New Requirements for Treating Chronic Pain
(Pain lasting more than 3 months)

**Step 1**
Before prescribing an opioid for chronic pain, complete the following:

- Consider non-pharmacologic and non-opioid treatment for pain
- Perform a medical history, physical examination, including a urine drug screen or serum medication level, and mental status examination and document in the medical record
- Discuss with the patient:
  - The known risks and benefits of opioid therapy
  - The responsibilities of the patient during treatment, including secure storage and proper disposal
  - An exit strategy for the discontinuation of opioids if not effective

**Step 2**
Query the Prescription Monitoring Program (PMP) in accordance with § 54.1-2522.1 of the Virginia Code.

- Query the PMP for opioid prescriptions longer than 7 days and longer than 14 days following surgery or invasive procedures, unless exempted.
  - Effective upon Governor’s signature (Spring 2017)
  - Current law and exceptions can be found here.
- May assign a delegate to query the PMP on your behalf.

**Special Considerations**

**Do** co-prescribe naloxone for patients when the following risk factors exist:

- Prior overdose
- Substance abuse
- Doses in excess of 120 MME/day
- Concomitant benzodiazepine is present

**Do** regularly evaluate for opioid use disorder and initiate treatment, consult with an appropriate healthcare provider, or refer for evaluation for treatment if indicated

**Don’t** co-prescribe an opioid if the patient is already taking these medications*

- Benzodiazepines
- Sedative hypnotics
- Carisoprodol
- Tramadol

*If there is an extenuating circumstance, a prescriber may co-prescribe an opioid. In this case, the prescriber is required to document a tapering plan to achieve the lowest possible effective dose.

Buprenorphine may be prescribed or administered for chronic pain in formulation and dosages that are FDA-approved for that purpose.
Step 3
When choosing the strength of an opioid prescription, follow these guidelines:
- Limits to the prescribed strength:
  - > 50 MME/day, document reasons in the medical record
  - > 120 MME/day, document reasonable justification in the medical record and refer to or consult with a pain management specialist

Step 4
Establish a treatment plan that includes:
- Measures to determine progress in treatment
  - Pain relief and improved physical and psychosocial function
  - Quality of life
  - Daily activities
- Further diagnostic evaluations and the extent to which the pain is associated with physical and psychosocial impairment
- The presence or absence of any indicators for medication misuse, abuse, or diversion and take appropriate action

Step 5
Include informed consent in the medical record:
- Risks
- Benefits
- Alternative approaches

Step 6
Include a written treatment agreement in the medical record that includes:
- Parameters of treatment
- Permission for the practitioner to obtain urine drug screens or serum medication levels, query and receive reports from the PMP, and consult with other prescribers or pharmacists
- Expected outcomes of treatment
- Limitations and side effects
- Patient signature

Step 7
During the course of treatment, complete the following every 3 months:
- Review the course of treatment
- Document the rationale to continue opioid therapy
- Check the Prescription Monitoring Program
- Order and review a urine drug screen or serum medication levels at least every 3 months for the first year of treatment and at least every 6 months thereafter
- If continuing opioid treatment, document the continued benefit in the medical record. If a patient’s progress is unsatisfactory, consider other treatment options

Step 8
Perform additional consultations if needed
- When necessary to achieve treatment goals, refer the patient for additional evaluation and treatment
- When a prescriber makes the diagnosis of opioid use disorder, the prescriber shall:
  - Initiate treatment for opioid use disorder OR
  - Refer the patient for evaluation and treatment

Step 9
Keep detailed medical records that include:
- The medical history and physical examination
- Past medical history
- Applicable records from prior treatment providers and/or any documentation of attempts to obtain
- Diagnostic, therapeutic and laboratory results
- Evaluations and consultations
- Treatment goals
- Discussion of risks and benefits
- Informed consent and agreement for treatment
- Treatments
- Medications (including date, type, dosage, and quantity prescribed and refills)
- Patient instructions
- Periodic reviews
New Requirements for Treating Acute Pain
(Pain lasting less than 3 months)

**Step 1:** Before prescribing an opioid for acute pain, consider the following:
- Consider non-pharmacologic and non-opioid treatments for pain
- If an opioid is necessary for the treatment of acute pain:
  - Prescribe short-acting opioids
  - Give the lowest effective dose for the fewest possible days

**Step 2:** Query the Prescription Monitoring Program (PMP) in accordance with § 54.1-2522.1 of the Virginia Code.
- Query the PMP for opioid prescriptions longer than 7 days and longer than 14 days following surgery or invasive procedures, unless exempted.
  - Effective upon Governor’s signature (Spring 2017)
  - Current law and exceptions can be found here.
- May assign a delegate to query the PMP on your behalf.

**Step 3:** When choosing the strength, length, and pill supply for an opioid prescription, follow these guidelines:
- Limits to the number of days in a supply:
  - Acute pain: 7 days*
  - Emergency department discharge: 7 days*
  - Post-surgical pain: 14 days*
  - *May prescribe longer if extenuating circumstances are clearly documented in the medical record.
- Limits to the number of pills in a supply:
  - Follow the manufacturer’s directions for use*
  - *A prescriber may exceed the manufacturer’s directions for use if extenuating circumstances are clearly documented in the medical record.
- Limits to the prescribed strength:
  - > 50 MME, document reasons in the medical record
  - > 120 MME, document reasonable justification or refer to or consult with a pain management specialist

**Step 4:** Include the following required documentation in the medical record:
- Description of the pain
- Presumptive diagnosis for the origin of the pain
- Examination appropriate to the complaint
- A treatment plan
- The medication prescribed or administered to include the date, type, dosage, and quantity prescribed or administered

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**Special Considerations**

Do co-prescribe naloxone for patients when the following risk factors exist:
- Prior overdose
- Substance abuse
- Doses in excess of 120 MME/day
- Concomitant benzodiazepine is present

Don’t co-prescribe an opioid if the patient is already taking these medications*
- Benzodiazepines
- Sedative hypnotics
- Carisoprodol
- Tramadol

*If there is an extenuating circumstance, a prescriber may co-prescribe an opioid. In this case, the prescriber is required to document a tapering plan to achieve the lowest possible effective dose.

Buprenorphine is not indicated for acute pain in the outpatient setting, except when a waived buprenorphine prescriber is treating pain in a patient whose primary diagnosis is the disease of addiction.
New Requirements for Prescribing of Buprenorphine for Addiction Treatment

**Step 1:** All prescribers must be waivered by the Substance Abuse Mental Health Services Administration (SAMHSA), registered with the Drug Enforcement Administration (DEA), and follow all state and federal laws governing buprenorphine prescribing.

- Nurse Practitioners and Physician Assistants must be waivered and have a practice agreement with a waivered physician

**Step 2:** Before prescribing buprenorphine to treat opioid use disorder, perform and document a patient assessment that includes:

- Comprehensive medical and psychiatric history
- Substance abuse history
- Family history and psychosocial supports
- Appropriate physical examination
- Urine drug screen
- Pregnancy test for women of childbearing age and ability
- Infectious disease testing for HIV, Hepatitis B, Hepatitis C and TB, when clinically indicated

**Step 3:** Query the Prescription Monitoring Program (PMP) before initiating and during treatment

- May assign a delegate to query the PMP on your behalf.

**Step 4:** Establish a treatment plan that includes:

- The practitioner’s rationale for selecting medication assisted treatment
- Patient education
- Written informed consent
- How counseling will be accomplished
- A signed treatment agreement that outlines the responsibilities of the patient and the prescriber

**Step 5:** During the induction phase, follow these guidelines:

- Initiate treatment with no more than 8 mg. buprenorphine, except for medically indicated circumstances as documented in the medical record
- The prescriber shall see the patient at least once a week

**Step 6:** During the stabilization phase, follow these guidelines:

- Increase the daily dosage of buprenorphine in safe and effective increments to achieve the lowest dose that avoids intoxication, withdrawal, or significant drug craving

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**Special Considerations**

**Do** refer the patient to a mental health service provider, as defined by 8.54.1-2400.1 of the Virginia Code, for counseling or provide counseling within the practice and document in the medical record

**Don’t** co-prescribe buprenorphine if the patient is already taking these medications*:

- Benzodiazepines
- Sedative hypnotics
- Carisoprodol
- Tramadol

*If there is an extenuating circumstance, a prescriber may co-prescribe buprenorphine. In this case, the prescriber is required to document a tapering plan to achieve the lowest possible effective dose.
Step 7: During the course of treatment:
- Ensure counseling for the patient (see special considerations for details)
- Limits to strength of prescription:
  - Document in the medical record rationale for prescribed doses exceeding 16 mg. of buprenorphine per day
  - Do not exceed 24 mg. of buprenorphine per day
- Require urine drug screens or serum medication levels at least every 3 months for the first year of treatment and at least every 6 months thereafter
- Take steps to reduce the chances of buprenorphine diversion by:
  - Using the lowest effective dose
  - Appropriate frequency of office visits
  - Pill counts
  - Checks of the Prescription Monitoring Program (PMP)
- Incorporate relapse prevention strategies into counseling or assure that they are addressed by a mental health service provider, as defined by § 54.1-2400.1 of the Virginia Code

Step 8: Include the following required documentation in the medical record
- Records shall be timely, accurate, legible, complete and readily accessible for review
- Treatment agreement and informed consent
- Confidentiality requirements of 42 CFR, Part 2
- Compliance with Board of Medicine Regulations 18VAC85-20-27

Prescribing Limits of Buprenorphine Mono-products:
- Do not prescribe buprenorphine without naloxone (buprenorphine mono-product) unless:
  - The patient is pregnant
  - Converting a patient from methadone to buprenorphine containing naloxone for a period not to exceed 7 days
  - Prescribing in formulations other than tablet form for indications approved by the FDA
- Buprenorphine mono-tablets may be administered directly to patients in federally licensed opioid treatment programs (OTPs), but, with the exception of those conditions listed above, only the buprenorphine product containing naloxone shall be prescribed or dispensed for use offsite from the program
- Document in the medical record evidence for the decision to use buprenorphine mono-product

Special Populations in Addiction Treatment:
- Pregnant women
  - Treat pregnant women with buprenorphine mono-product, usually 16 mg. per day or less
- Patients under 16 years
  - Do not prescribe buprenorphine for addiction treatment unless such treatment is approved by the FDA
- Patients with chronic pain
  - Assess the progress of patients with chronic pain by reduction of pain and functional objectives which can be identified, quantified and independently verified
- Patients with medical comorbidities:
  - Evaluate by history, physical exam, appropriate laboratory studies, and be aware of interactions of buprenorphine with other prescribed medications
- Patients with psychiatric comorbidities and that are not stable
  - Do not undertake buprenorphine treatment
  - Refer the patient for psychiatric evaluation and treatment prior to initiating medication-assisted treatment
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