



Opioid and Buprenorphine Prescriber Regulations Guide

The Virginia Board of Medicine has adopted final regulations 18 VAC 85-21-10 et seq. that establish rules regarding the prescribing of opioids for pain treatment and buprenorphine for addiction treatment. The final regulations became effective August 8, 2018 and replace the March 2017 emergency regulations. We have published an abbreviated summary of the new regulations for your reference. To view a full copy of the regulations, please visit [the Virginia Board of Medicine website](#).

These regulations do **NOT** apply to:

- 1 the treatment of acute or chronic pain related to cancer, sickle cell, a patient in hospice care, or a patient in palliative care
- 2 the treatment of acute or chronic pain during an inpatient hospital admission or in a nursing home or assisted living facility
- 3 a patient enrolled in a clinical trial as authorized by state or federal law

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. If an opioid is necessary for acute pain treatment, prescribe short-acting opioids at the lowest effective dose and frequency

Step 2

Perform a history and physical examination appropriate to the complaint.

Step 3

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

- ▶ Query the PMP for opioid prescriptions longer than 7 days, unless exempted.
 - Current exceptions can be found [here](#).
- ▶ Assign [delegate](#) to query the PMP on your behalf.

Step 4

Conduct an assessment of the patient's history and risk of substance misuse.

Step 5

Follow these guidelines when choosing the strength, length, and pill supply:

- ▶ Limits to the number of days in a supply:
 - Acute: 7 days*
 - Emergency department discharge: 7 days*
 - Post-surgical: 14 days*
- ▶ Limits to the number of pills in a supply:
 - Follow manufacturer's directions for use*
- ▶ 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

**May prescribe longer and/or exceed the manufacturer's directions for use if extenuating circumstances are clearly documented in the medical record.*

Special Considerations

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

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

Don't co-prescribe an opioid if these medications are currently prescribed:*

- ▶ 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 outpatient setting, except when a waived buprenorphine prescriber is treating pain in a patient whose primary diagnosis is the disease of addiction.

Step 6

Include the following required documentation in the medical record:

- ▶ Description of the pain
- ▶ Presumptive diagnosis for the pain origin
- ▶ Examination appropriate to the complaint
- ▶ Treatment plan
- ▶ The medication prescribed or administered and include the date, type, dosage, and quantity

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 and physical examination, to include a mental status examination, and document in the medical record, including:
 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 misuse history of the patient and any family history of addiction or substance misuse
 6. A urine drug screen or serum medication level
 7. A query of the Prescription Monitoring Program as set forth in § 54.1-2522.1 of the Code of Virginia (see step 2)
 8. An assessment of the patient's history and risk of substance misuse
 9. A request for prior applicable records
- ▶ 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, unless exempted.
 - 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 when the following risk factors exist:

- ▶ Prior overdose
- ▶ Substance misuse
- ▶ 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.*

Don't prescribe buprenorphine mono-product in the tablet form for chronic pain.

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 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:

- ▶ Review the course of treatment every 3 months
- ▶ Document the rationale to continue opioid therapy every 3 months
- ▶ Check the Prescription Monitoring Program every 3 months
- ▶ Order and review a urine drug screen or serum medication levels at the initiation of chronic pain management and thereafter randomly at the discretion of the practitioner, but at least once a year.
- ▶ 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:

- ▶ 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 Prescribing of Buprenorphine for Addiction Treatment

Step 1

All prescribers must be waived 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 waived and have a practice agreement with a waived 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 misuse 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

Special Considerations

Do refer the patient to a mental health service provider, as defined by § 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 5

During the induction phase, follow these guidelines:

- ▶ Initiate treatment with no more than 8 mg./day 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

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, who has the education and experience to provide substance misuse counseling

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 or buprenorphine mono-product 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
 - Prescribing for patients who have demonstrated intolerance to naloxone. Such prescriptions 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.
- ▶ 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
 - May be treated 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

Contact Information

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