

BEHAVIORAL HEALTH GUIDELINE

OPIOID MANAGEMENT OF CHRONIC (NON-CANCER) PAIN GUIDELINE

Guideline History

Date Approved	05/03
Date Revised	10/03, 10/05, 10/07, 11/09, 3/10, 10/12, 9/13, 09/15, 9/17, 9/19, 9/21, 9/23, 9/26
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Next Review Date	9/28

These Guidelines are promulgated by Sentara Healthcare (SHC) as recommendations for the clinical Management of specific conditions. Clinical data in a particular case may necessitate or permit deviation from these Guidelines. The SHC Guidelines are institutionally endorsed recommendations and are not intended as a substitute for clinical judgment.

Virginia Administrative Code
Title 18. Professional And Occupational Licensing
Agency 85. Board Of Medicine
Chapter 21. Regulations Governing Prescribing of Opioids and Buprenorphine

Part I. General Provisions

18VAC85-21-10. Applicability.

A. This chapter shall apply to doctors of medicine, osteopathic medicine, and podiatry and to physician assistants.

B. This chapter shall not apply to:

1. The treatment of acute or chronic pain related to (i) cancer, (ii) sickle cell, (iii) a patient in hospice care, or (iv) a patient in palliative care;

2. The treatment of acute or chronic pain during an inpatient hospital admission or 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.

Statutory Authority
§§ 54.1-2400 and 54.1-2928.2 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 34, Issue 23, eff. August 8, 2018.

18VAC85-21-20. Definitions.

The following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise:

"Acute pain" means pain of any origin that has existed less than one month.

"Board" means the Virginia Board of Medicine.

"Chronic pain" means nonmalignant 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.

"Controlled substance" means drugs listed in The Drug Control Act (§ 54.1-3400 et seq. of the Code of Virginia) in Schedules II through IV.

"DMAS" means the Virginia Department of Medical Assistance Services.

"FDA" means the U.S. Food and Drug Administration.

"Induction phase" means the initial seven to 14 days of treatment with buprenorphine.

"MME" means morphine milligram equivalent.

"Prescription Monitoring Program" means the electronic system within the Department of Health Professions that monitors the dispensing of certain controlled substances.

"Subacute pain" means pain that has existed for one to three months.

Statutory Authority

§§ 54.1-2400 and 54.1-2928.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 34, Issue 23, eff. August 8, 2018; amended, Virginia Register Volume 41, Issue 7, eff. January 2, 2025.

18VAC85-21-21. Electronic prescribing.

A. A prescription for a controlled substance that contains an opioid shall be issued as an electronic prescription consistent with § 54.1-3408.02 of the Code of Virginia, unless the prescription qualifies for an exemption as set forth in subsection C of § 54.1-3408.02.

B. Upon written request, the board may grant a one-time waiver of the requirement of subsection A of this section for a period not to exceed one year due to demonstrated economic hardship, technological limitations that are not reasonably within the control of the prescriber, or other exceptional circumstances demonstrated by the prescriber.

Statutory Authority

§§ 54.1-2400 and 54.1-2928.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 37, Issue 19, eff. June 9, 2021; amended, Virginia Register Volume 41, Issue 7, eff. January 2, 2025.

18VAC85-21-21. Electronic prescribing.

A. A prescription for a controlled substance that contains an opioid shall be issued as an electronic prescription consistent with § 54.1-3408.02 of the Code of Virginia, unless the prescription qualifies for an exemption as set forth in subsection C of § 54.1-3408.02.

B. Upon written request, the board may grant a one-time waiver of the requirement of subsection A of this section for a period not to exceed one year due to demonstrated economic hardship, technological limitations that are not reasonably within the control of the prescriber, or other exceptional circumstances demonstrated by the prescriber.

Statutory Authority

§§ 54.1-2400 and 54.1-2928.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 37, Issue 19, eff. June 9, 2021; amended, Virginia Register Volume 41, Issue 7, eff. January 2, 2025.

Part II. Management of Acute Pain

18VAC85-21-30. Evaluation of the acute pain or subacute pain patient.

A. Nonpharmacologic and non-opioid treatment for pain shall be given consideration prior to treatment with opioids. If an opioid is considered necessary for the treatment of acute pain or subacute pain, the practitioner shall give a short-acting opioid in the lowest effective dose for the fewest possible days.

B. Prior to initiating treatment with a controlled substance containing an opioid for a complaint of acute pain or subacute pain, the prescriber shall perform a history and physical examination appropriate to the complaint, query the Prescription Monitoring Program as set forth in § 54.1-2522.1 of the Code of Virginia, and conduct an assessment of the patient's history and risk of substance misuse.

Statutory Authority

§§ 54.1-2400 and 54.1-2928.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 34, Issue 23, eff. August 8, 2018; amended, Virginia Register Volume 41, Issue 7, eff. January 2, 2025.

18VAC85-21-40. Treatment of acute pain and subacute pain with opioids.

A. Initiation of opioid treatment for patients with acute pain and subacute pain shall be with short-acting opioids.

1. A prescriber providing treatment for acute or subacute pain shall not prescribe a controlled substance containing an opioid in a quantity that exceeds a 14-day supply, unless extenuating circumstances are clearly documented in the medical record.

2. An opioid prescribed as part of treatment for a surgical procedure shall be for no more than 14 consecutive days and within the immediate perioperative period, unless extenuating circumstances are clearly documented in the medical record.

B. Initiation of opioid treatment for all patients shall include the following:

1. The practitioner shall carefully consider and document in the medical record the reasons to exceed 50 MME/day.

2. Prior to exceeding 120 MME/day, the practitioner shall document in the medical record the reasonable justification for such doses or refer to or consult with a pain management specialist.

3. An FDA-approved opioid reversal agent shall be prescribed for any patient when risk factors of prior overdose, substance misuse, doses in excess of 120 MME/day, or concomitant benzodiazepine are present.

C. Due to a higher risk of fatal overdose when opioids are prescribed with benzodiazepines, sedative hypnotics, carisoprodol, and tramadol (an atypical opioid), the prescriber shall only co-prescribe these substances when there are extenuating circumstances and shall document in the medical record a tapering plan to achieve the lowest possible effective doses if these medications are prescribed.

Statutory Authority

§§ 54.1-2400 and 54.1-2928.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 34, Issue 23, eff. August 8, 2018; amended, Virginia Register Volume 41, Issue 7, eff. January 2, 2025.

18VAC85-21-50. Medical records for acute pain.

The medical record shall include a description of the pain, a presumptive diagnosis for the origin of the pain, an examination appropriate to the complaint, a treatment plan, and the medication prescribed or administered to include the date, type, dosage, and quantity prescribed or administered.

Statutory Authority

§§ 54.1-2400 and 54.1-2928.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 34, Issue 23, eff. August 8, 2018.

Part III. Management of Chronic Pain

18VAC85-21-60. Evaluation of the chronic pain patient.

A. Prior to initiating management or continuing management of chronic pain with a controlled substance containing an opioid, a medical history and physical examination, to include a mental status examination, shall be performed and documented 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 and substance use disorder or misuse history of the patient and any family history of substance use disorder or 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;

8. An assessment of the patient's history and risk of substance misuse; and

9. A request for prior applicable records.

B. Prior to initiating opioid treatment for chronic pain, the practitioner shall discuss with the patient the known risks and benefits of opioid therapy and the responsibilities of the patient during treatment to include securely storing the drug and properly disposing of any unwanted or unused drugs. The practitioner shall also discuss with the patient an exit strategy for the discontinuation of opioids in the event they are not effective.

Statutory Authority

§§ 54.1-2400 and 54.1-2928.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 34, Issue 23, eff. August 8, 2018; amended, Virginia Register Volume 41, Issue 7, eff. January 2, 2025.

18VAC85-21-70. Treatment of chronic pain with opioids.

A. Nonpharmacologic and non-opioid treatment for pain shall be given consideration prior to treatment with opioids.

B. In initiating and treating with an opioid, the practitioner shall:

1. Carefully consider and document in the medical record the reasons to exceed 50 MME per day;

2. Prior to exceeding 120 MME per day, the practitioner shall document in the medical record the reasonable justification for such doses or refer to or consult with a pain management specialist;

3. Prescribe an FDA-approved opioid reversal agent for any patient when risk factors of prior overdose, substance misuse, doses in excess of 120 MME per day, or concomitant benzodiazepine are present; and *

4. Document the rationale to continue opioid therapy every three months.

C. Buprenorphine mono-product in tablet form shall not be prescribed for chronic pain.

D. Due to a higher risk of fatal overdose when opioids, including buprenorphine, are given with other opioids, benzodiazepines, sedative hypnotics, carisoprodol, and tramadol (an atypical opioid), the prescriber shall only co-prescribe these substances when there are extenuating circumstances and shall document in the medical record a tapering plan to achieve the lowest possible effective doses of these medications if prescribed.

E. The practitioner shall (i) regularly evaluate the patient for opioid use disorder and (ii) initiate specific treatment for opioid use disorder, consult with an appropriate health care provider, or refer the patient for evaluation and treatment if indicated.

Statutory Authority

§§ 54.1-2400 and 54.1-2928.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 34, Issue 23, eff. August 8, 2018; amended, Virginia Register Volume 41, Issue 7, eff. January 2, 2025.

18VAC85-21-80. Treatment plan for chronic pain.

A. The medical record shall include a treatment plan that states measures to be used to determine progress in treatment, including pain relief and improved physical and psychosocial function, quality of life, and daily activities.

B. The treatment plan shall include further diagnostic evaluations and other treatment modalities or rehabilitation that may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

C. The prescriber shall document in the medical record the presence of any indicators for medication misuse or diversion.

Statutory Authority

§§ 54.1-2400 and 54.1-2928.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 34, Issue 23, eff. August 8, 2018; amended, Virginia Register Volume 41, Issue 7, eff. January 2, 2025.

18VAC85-21-90. Informed consent and agreement for treatment for chronic pain.

A. The practitioner shall document in the medical record informed consent, to include risks, benefits, and alternative approaches, prior to the initiation of opioids for chronic pain.

B. There shall be a written treatment agreement signed by the patient in the medical record that addresses the parameters of treatment, including those behaviors that will result in referral to a higher level of care, cessation of treatment, or dismissal from care.

C. The treatment agreement shall include notice that the practitioner will query and receive reports from the Prescription Monitoring Program and permission for the practitioner to:

1. Obtain urine drug screens or serum medication levels when requested; and

2. Consult with other prescribers or dispensing pharmacists for the patient.

D. Expected outcomes shall be documented in the medical record including improvement in pain relief and function or simply in pain relief. Limitations and side effects of chronic opioid therapy shall be documented in the medical record.

Statutory Authority

§§ 54.1-2400 and 54.1-2928.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 34, Issue 23, eff. August 8, 2018.

18VAC85-21-100. Opioid therapy for chronic pain.

A. The practitioner shall review the course of pain treatment and any new information about the etiology of the pain and the patient's state of health at least every three months.

B. Continuation of treatment with opioids shall be supported by documentation of continued benefit from such prescribing. If the patient's progress is unsatisfactory, the practitioner shall assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.

C. If the treatment plan includes opioid tapering, the taper rate shall be individualized based on the patient's clinical situation. A practitioner should not abruptly stop opioid treatment without tapering unless the prescriber documents extenuating circumstances.

D. The practitioner shall check the Prescription Monitoring Program at least every three months after the initiation of treatment.

E. The practitioner shall 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.

F. The practitioner shall (i) regularly evaluate the patient for opioid use disorder and (ii) initiate specific treatment for opioid use disorder, consult with an appropriate health care provider, or refer the patient for evaluation for treatment if indicated.

Statutory Authority

§§ 54.1-2400 and 54.1-2928.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 34, Issue 23, eff. August 8, 2018; amended, Virginia Register Volume 41, Issue 7, eff. January 2, 2025.

18VAC85-21-110. Additional consultations.

A. When necessary to achieve treatment goals, the prescriber shall refer the patient for additional evaluation and treatment.

B. When a prescriber makes the diagnosis of opioid use disorder, treatment for opioid use disorder shall be initiated or the patient shall be referred for evaluation and treatment.

Statutory Authority

§§ 54.1-2400 and 54.1-2928.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 34, Issue 23, eff. August 8, 2018.

18VAC85-21-120. Medical records for chronic pain.

The prescriber shall keep current, accurate, and complete records in an accessible manner readily available for review to include:

1. The medical history and physical examination;

2. Past medical history;

3. Applicable records from prior treatment providers or any documentation of attempts to obtain those records;

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.

Statutory Authority

§§ 54.1-2400 and 54.1-2928.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 34, Issue 23, eff. August 8, 2018.

Part IV. Prescribing of Buprenorphine for Addiction Treatment

18VAC85-21-130. General provisions pertaining to prescribing of buprenorphine for opioid use disorder.

A. Practitioners shall abide by all federal and state laws and regulations governing the prescribing of buprenorphine for the treatment of opioid use disorder.

B. Physician assistants shall prescribe buprenorphine for opioid use disorder pursuant to a practice agreement with a patient care team doctor of medicine or doctor of osteopathic medicine.

C. Practitioners engaged in medication-assisted treatment shall either provide counseling in their practice or refer the patient to a mental health service provider, as defined in § 54.1-2400.1 of the Code of Virginia, who has the education and experience to provide substance misuse counseling. The practitioner shall document provision of counseling or referral in the medical record.

Statutory Authority

§§ 54.1-2400 and 54.1-2928.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 34, Issue 23, eff. August 8, 2018; amended, Virginia Register Volume 41, Issue 7, eff. January 2, 2025.

18VAC85-21-140. Patient assessment and treatment planning for opioid use disorder.

A. A practitioner shall perform and document an assessment that includes a 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, a check of the Prescription Monitoring Program, and, when clinically indicated, infectious disease testing for human immunodeficiency virus, hepatitis B, hepatitis C, tuberculosis, and liver function tests.

B. The treatment plan shall include the practitioner's rationale for selecting medications for opioid use disorder, patient education, written informed consent, referral for counseling, and a signed treatment agreement that outlines the responsibilities of the patient and the prescriber.

Statutory Authority

§§ 54.1-2400 and 54.1-2928.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 34, Issue 23, eff. August 8, 2018; amended, Virginia Register Volume 41, Issue 7, eff. January 2, 2025.

18VAC85-21-150. Treatment with buprenorphine for opioid use disorder.

A. Buprenorphine without naloxone (buprenorphine mono-product) shall not be prescribed except:

1. When a patient is pregnant;

2. When converting a patient from methadone or buprenorphine mono-product to buprenorphine containing naloxone for a period not to exceed seven days;

3. In formulations other than tablet form for indications approved by the FDA; or

4. For patients who have a demonstrated intolerance to naloxone; such prescriptions for the mono-product shall not exceed 3.0% of the total prescriptions for buprenorphine written by the prescriber, and the exception shall be clearly documented in the patient's medical record.

B. Buprenorphine mono-product tablets may be administered directly to patients in federally licensed opioid treatment programs. With the exception of those conditions listed in subsection A of this section, only the buprenorphine product containing naloxone shall be prescribed or dispensed for use off site from the program.

C. The evidence for the decision to use buprenorphine mono-product shall be fully documented in the medical record.

D. Due to a higher risk of fatal overdose when buprenorphine is prescribed with other opioids, benzodiazepines, sedative hypnotics, carisoprodol, and tramadol (an atypical opioid), the prescriber shall only co-prescribe these substances when there are extenuating circumstances and shall document in the medical record a tapering plan to achieve the lowest possible effective doses if these medications are prescribed.

E. Prior to starting medications for opioid use disorder, the practitioner shall perform a check of the Prescription Monitoring Program.

F. During the induction phase, dosage shall be based on the patient's history and current usage, including exposure to high-potency opioids. The patient shall be evaluated by the prescriber at least once a week.

G. During the stabilization phase, the prescriber shall increase the daily dosage of buprenorphine in safe and effective increments to achieve the lowest dose that avoids intoxication, withdrawal, or significant drug craving.

H. Practitioners shall take steps to reduce the chances of buprenorphine diversion and misuse by using the lowest effective dose, appropriate frequency of office visits, pill counts, and checks of the Prescription Monitoring Program. The practitioner shall also require urine drug screens or serum medication levels at least every three months for the first year of treatment and at least every six months thereafter.

I. Documentation of the rationale for prescribed doses exceeding 24 milligrams of buprenorphine per day shall be placed in the medical record.

J. The practitioner shall incorporate relapse prevention strategies into counseling or document referral to a mental health service provider, as defined in § 54.1-2400.1 of the Code of Virginia.

Statutory Authority

§§ 54.1-2400 and 54.1-2928.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 34, Issue 23, eff. August 8, 2018; amended, Virginia Register Volume 41, Issue 7, eff. January 2, 2025.

18VAC85-21-160. Special populations in treatment for opioid use disorder.

A. Patients younger than 16 years of age shall not be prescribed buprenorphine for addiction treatment unless such treatment is approved by the FDA.

B. The progress of patients with chronic pain shall be assessed by reduction of pain and functional objectives that can be identified, quantified, and independently verified.

C. Practitioners shall (i) evaluate patients with medical comorbidities by history, physical exam, and appropriate laboratory studies and (ii) be aware of interactions of buprenorphine with other prescribed medications.

Statutory Authority

§§ 54.1-2400 and 54.1-2928.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 34, Issue 23, eff. August 8, 2018; amended, Virginia Register Volume 41, Issue 7, eff. January 2, 2025.

18VAC85-21-170. Medical records for opioid addiction treatment.

A. Records shall be timely, accurate, legible, complete, and readily accessible for review.

B. The treatment agreement and informed consent shall be maintained in the medical record.

C. Confidentiality requirements of 42 CFR Part 2 shall be followed.

D. Compliance with 18VAC85-20-27, which prohibits willful or negligent breach of confidentiality or unauthorized disclosure of confidential Prescription Monitoring Program information, shall be maintained.

Statutory Authority

§§ 54.1-2400 and 54.1-2928.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 34, Issue 23, eff. August 8, 2018.

* Clinical Note for Guideline Committee Consideration

Sentara Health Plan supports aligning opioid prescribing practices with the CDC's 2022 Clinical Practice Guideline for Prescribing Opioids for Pain to improve patient safety and reduce overdose risk. (Centers for Disease Control and Prevention. *CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022*. MMWR Recommendations and Reports. 2022;71(3):1-95 (https://www.cdc.gov/mmwr/volumes/71/rr/rr7103a1.htm)

Clinicians should consider offering or prescribing naloxone to patients receiving opioid dosages of ≥50 MME/day, consistent with CDC recommendations. Additionally, naloxone should be considered regardless of opioid dosage when other overdose risk factors are present, including:

- Concurrent use of benzodiazepines or other CNS depressants
- Diagnosis of sleep apnea or other sleep-disordered breathing
- History of opioid overdose
- Diagnosis of opioid use disorder
- Reduced opioid tolerance following a period of abstinence

These recommendations supplement Virginia regulations, which require prescribing an FDA-approved opioid reversal agent for patients with specified overdose risk factors, including those receiving opioid dosages >120 MME/day.

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TITLE 18. PROFESSIONAL AND OCCUPATIONAL LICENSING

BOARD OF MEDICINE

Chapter 21

Final

Title of Regulation: **18VAC85-21. Regulations Governing Prescribing of Opioids and Buprenorphine (adding 18VAC85-21-21**).

Statutory Authority: §§ 54.1-2400 and 54.1-2928.2 of the Code of Virginia.

Effective Date: June 9, 2021.

Agency Contact: William L. Harp, M.D., Executive Director, Board of Medicine, 9960 Mayland Drive, Suite 300, Richmond, VA 23233, telephone (804) 367-4558, FAX (804) 527-4429, or email william.harp@dhp.virginia.gov.

Summary:

The amendments (i) require a prescription for a controlled substance that contains an opioid to be issued as an electronic prescription unless the prescriber qualifies for an exemption set out in the law and (ii) provide a one-time waiver of this requirement for a maximum of one year if a practitioner

can demonstrate economic hardship, technological limitations, or other exceptional circumstances beyond the practitioner's control.

Summary of Public Comments and Agency's Response: A summary of comments made by the public and the agency's response may be obtained from the promulgating agency or viewed at the office of the Registrar of Regulations.

18VAC85-21-21. Electronic prescribing.

A. Beginning July 1, 2020, a prescription for a controlled substance that contains an opioid shall be issued as an electronic prescription consistent with § 54.1-3408.02 of the Code of Virginia [, unless the prescription qualifies for an exemption as set forth in subsection C of § 54.1-3408.02 1.:.

B. Upon written request, the board may grant a one-time waiver of the requirement of subsection A of this section for a period not to exceed one year due to demonstrated economic hardship, technological limitations that are not reasonably within the control of the prescriber, or other exceptional circumstances demonstrated by the prescriber.

VA.R. Doc. No. R20-6085; Filed April 12, 2021

VIRGINIA
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TITLE 18. PROFESSIONAL AND OCCUPATIONAL LICENSING
BOARD OF NURSING
Chapter 30
Final Regulation

Titles of Regulations: 18VAC90-30. Regulations Governing the Licensure of Nurse Practitioners (amending 18VAC90-30-220).

18VAC90-40. Regulations for Prescriptive Authority for Nurse Practitioners (amending 18VAC90-40-10; adding 18VAC90-40-150 through 18VAC90-40-290).

Statutory Authority: §§ 54.1-2400 and 54.1-2957 of the Code of Virginia.

Effective Date: July 10, 2019.

Agency Contact: Jay P. Douglas, R.N., Executive Director, Board of Nursing, 9960 Mayland Drive, Suite 300, Richmond, VA 23233-1463, telephone (804) 367-4520, FAX (804) 527-4455, or email jay.douglas@dhp.virginia.gov.

Summary:

The amendments establish the practitioners to whom the regulations apply and exceptions or nonapplicability. Provisions for the management of acute pain include requirements for the evaluation of the patient, limitations on quantity and dosage, and recordkeeping. Provisions for management of chronic pain include requirements for evaluation and treatment, including a treatment plan, informed consent and agreement, consultation with other providers, and medical recordkeeping. Provisions for prescribing of buprenorphine include requirements for patient assessment and treatment planning, limitations on prescribing the buprenorphine mono-product (without naloxone), dosages, co-prescribing of other drugs, consultation, and medical records for opioid addiction treatment. The amendments replace emergency regulations currently in effect.

Changes to the proposed regulation (i) add sickle cell disease to the exceptions, (ii) clarify that tramadol is an atypical opioid, (iii) replace the requirement for drug testing every three months in the first year following initiation of chronic pain management with testing that is "randomly at the discretion of the practitioner" at least once a year, and (iv) provide that a nurse practitioner who has been authorized by the boards for autonomous practice isn't limited to prescribing buprenorphine for opioid addiction per a practice agreement.

Summary of Public Comments and Agency's Response: A summary of comments made by the public and the agency's response may be obtained from the promulgating agency or viewed at the office of the Registrar of Regulations.

18VAC90-30-220. Grounds for disciplinary action against the license of a licensed nurse practitioner.

The boards may deny licensure or relicensure, revoke or suspend the license, or take other disciplinary action upon proof that the nurse practitioner:

1. Has had a license or multistate privilege to practice nursing in this Commonwealth or in another jurisdiction revoked or suspended or otherwise disciplined;

2. Has directly or indirectly represented to the public that the nurse practitioner is a physician, or is able to, or will practice independently of a physician;

3. Has exceeded the authority as a licensed nurse practitioner;

4. Has violated or cooperated in the violation of the laws or regulations governing the practice of medicine, nursing or nurse practitioners;

5. Has become unable to practice with reasonable skill and safety to patients as the result of a physical or mental illness or the excessive use of alcohol, drugs, narcotics, chemicals or any other type of material;

6. Has violated or cooperated with others in violating or attempting to violate any law or regulation, state or federal, relating to the possession, use, dispensing, administration or distribution of drugs; or

7. Has failed to comply with continuing competency requirements as set forth in 18VAC90-30-105;

8. Has willfully or negligently breached the confidentiality between a practitioner and a patient. A breach of confidentiality that is required or permitted by applicable law or beyond the control of the practitioner shall not be considered negligent or willful; or

9. Has engaged in unauthorized use or disclosure of confidential information received from the Prescription Monitoring Program, the electronic system within the Department of Health Professions that monitors the dispensing of certain controlled substances.

Part I
General Provisions

18VAC90-40-10. Definitions.

The following words and terms when used in this chapter shall have the following meanings, unless the context clearly indicates otherwise:

"Acute pain" means pain that occurs within the normal course of a disease or condition or as the result of surgery for which controlled substances containing an opioid may be prescribed for no more than three months.

"Boards" means the Virginia Board of Medicine and the Virginia Board of Nursing.

"Certified nurse midwife" means an advanced practice registered nurse who is certified in the specialty of nurse midwifery and who is jointly licensed by the Boards of Medicine and Nursing as a nurse practitioner pursuant to § 54.1-2957 of the Code of Virginia.

"Chronic pain" means nonmalignant pain that goes beyond the normal course of a disease or condition for which controlled substances containing an opioid may be prescribed for a period greater than three months.

"Committee" means the Committee of the Joint Boards of Nursing and Medicine.

"FDA" means the U.S. Food and Drug Administration.

"MME" means morphine milligram equivalent.

"Nonprofit health care clinics or programs" means a clinic organized in whole or in part for the delivery of health care services without charge or when a reasonable minimum fee is charged only to cover administrative costs.

"Nurse practitioner" means an advanced practice registered nurse who has met the requirements for licensure as a nurse practitioner as stated in 18VAC90-30.

"Practice agreement" means a written or electronic agreement jointly developed by the patient care team physician and the nurse practitioner for the practice of the nurse practitioner that also describes the prescriptive authority of the nurse practitioner, if applicable. For a nurse practitioner licensed in the category of certified nurse midwife, the practice agreement is a statement jointly developed with the consulting physician.

"Prescription Monitoring Program" means the electronic system within the Department of Health Professions that monitors the dispensing of certain controlled substances.

"SAMHSA" means the federal Substance Abuse and Mental Health Services Administration.

Part V
Management of Acute Pain

18VAC90-40-150. Evaluation of the patient for acute pain.

A. The requirements of this part shall not apply to:

1. The treatment of acute pain related to (i) cancer, (ii) [sickle cell, (iii)] a patient in hospice care, or [(iii) (iv)] a patient in palliative care;

2. The treatment of acute pain during an inpatient hospital admission or 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.

B. Nonpharmacologic and non-opioid treatment for pain shall be given consideration prior to treatment with opioids. If an opioid is considered necessary for the treatment of acute pain, the practitioner shall give a short-acting opioid in the lowest effective dose for the fewest possible days.

C. Prior to initiating treatment with a controlled substance containing an opioid for a complaint of acute pain, the prescriber shall perform a history and physical examination appropriate to the complaint, query the Prescription Monitoring Program as set forth in § 54.1-2522.1 of the Code of Virginia, and conduct an assessment of the patient's history and risk of substance misuse as a part of the initial evaluation.

18VAC90-40-160. Treatment of acute pain with opioids.

A. Initiation of opioid treatment for patients with acute pain shall be with short-acting opioids.

1. A prescriber providing treatment for a patient with acute pain shall not prescribe a controlled substance containing an opioid in a quantity that exceeds a seven-day supply as determined by the manufacturer's directions for use, unless extenuating circumstances are clearly documented in the medical record. This shall also apply to prescriptions of a controlled substance containing an opioid upon discharge from an emergency department.

2. An opioid prescribed as part of treatment for a surgical procedure shall be for no more than 14 consecutive days in accordance with manufacturer's direction and within the immediate perioperative period, unless extenuating circumstances are clearly documented in the medical record.

B. Initiation of opioid treatment for all patients shall include the following:

1. The practitioner shall carefully consider and document in the medical record the reasons to exceed 50 MME per day.

2. Prior to exceeding 120 MME per day, the practitioner shall document in the medical record the reasonable justification for such doses or refer to or consult with a pain management specialist.

3. Naloxone shall be prescribed for any patient when risk factors of prior overdose, substance misuse, doses in excess of 120 MME per day, or concomitant benzodiazepine are present.

C. Due to a higher risk of fatal overdose when opioids are used with benzodiazepines, sedative hypnotics, carisoprodol, and tramadol [(an atypical opioid)], the prescriber shall only co-prescribe these substances when there are extenuating circumstances and shall document in the medical record a tapering plan to achieve the lowest possible effective doses if these medications are prescribed.

D. Buprenorphine is not indicated for acute pain in the outpatient setting, except when a prescriber who has obtained a SAMHSA waiver is treating pain in a patient whose primary diagnosis is the disease of addiction.

18VAC90-40-170. Medical records for acute pain.

The medical record shall include a description of the pain, a presumptive diagnosis for the origin of the pain, an examination appropriate to the complaint, a treatment plan, and the medication prescribed or administered to include the date, type, dosage, and quantity prescribed or administered.

Part VI
Management of Chronic Pain

18VAC90-40-180. Evaluation of the chronic pain patient.

A. The requirements of this part shall not apply to:

1. The treatment of chronic pain related to (i) cancer, (ii) [sickle cell, (iii)] a patient in hospice care, or [(iii) (iv)] a patient in palliative care;

2. The treatment of chronic pain during an inpatient hospital admission or 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.

B. Prior to initiating management of chronic pain with a controlled substance containing an opioid, a medical history and physical examination, to include a mental status examination, shall be performed and documented 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 histories 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;

8. An assessment of the patient's history and risk of substance misuse; and

9. A request for prior applicable records.

C. Prior to initiating opioid analgesia for chronic pain, the practitioner shall discuss with the patient the known risks and benefits of opioid therapy and the responsibilities of the patient during treatment to include securely storing the drug and properly disposing of any unwanted or unused drugs. The practitioner shall also discuss with the patient an exit strategy for the discontinuation of opioids in the event they are not effective.

18VAC90-40-190. Treatment of chronic pain with opioids.

A. Nonpharmacologic and non-opioid treatment for pain shall be given consideration prior to treatment with opioids.

B. In initiating opioid treatment for all patients, the practitioner shall:

1. Carefully consider and document in the medical record the reasons to exceed 50 MME per day;

2. Prior to exceeding 120 MME per day, the practitioner shall document in the medical record the reasonable justification for such doses or refer to or consult with a pain management specialist;

3. Prescribe naloxone for any patient when risk factors of prior overdose, substance misuse, doses in excess of 120 MME per day, or concomitant benzodiazepine are present; and

4. Document the rationale to continue opioid therapy every three months.

C. Buprenorphine mono-product in tablet form shall not be prescribed for chronic pain.

D. Due to a higher risk of fatal overdose when opioids, including buprenorphine, are given with other opioids, benzodiazepines, sedative hypnotics, carisoprodol, and tramadol [(an atypical opioid)], the prescriber shall only co-prescribe these substances when there are extenuating circumstances and shall document in the medical record a tapering plan to achieve the lowest possible effective doses if these medications are prescribed.

E. The practitioner shall regularly evaluate for opioid use disorder and shall initiate specific treatment for opioid use disorder, consult with an appropriate health care provider, or refer the patient for evaluation for treatment if indicated.

18VAC90-40-200. Treatment plan for chronic pain.

A. The medical record shall include a treatment plan that states measures to be used to determine progress in treatment, including pain relief and improved physical and psychosocial function, quality of life, and daily activities.

B. The treatment plan shall include further diagnostic evaluations and other treatment modalities or rehabilitation that may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

C. The prescriber shall record in the medical records the presence or absence of any indicators for medication misuse or diversion and take appropriate action.

18VAC90-40-210. Informed consent and agreement for treatment of chronic pain.

A. The practitioner shall document in the medical record informed consent, to include risks, benefits, and alternative approaches, prior to the initiation of opioids for chronic pain.

B. There shall be a written treatment agreement, signed by the patient, in the medical record that addresses the parameters of treatment, including those behaviors that will result in referral to a higher level of care, cessation of treatment, or dismissal from care.

C. The treatment agreement shall include notice that the practitioner will query and receive reports from the Prescription Monitoring Program and permission for the practitioner to:

1. Obtain urine drug screen or serum medication levels, when requested; and

2. Consult with other prescribers or dispensing pharmacists for the patient.

D. Expected outcomes shall be documented in the medical record including improvement in pain relief and function or simply in pain relief. Limitations and side effects of chronic opioid therapy shall be documented in the medical record.

18VAC90-40-220. Opioid therapy for chronic pain.

A. The practitioner shall review the course of pain treatment and any new information about the etiology of the pain or the patient's state of health at least every three months.

B. Continuation of treatment with opioids shall be supported by documentation of continued benefit from the prescribing. If the patient's progress is unsatisfactory, the practitioner shall assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.

C. Practitioners shall check the Prescription Monitoring Program at least every three months after the initiation of treatment.

D. The practitioner shall order and review a urine drug screen or serum medication levels at the initiation of chronic pain management and [at least every three months for the first year of treatment and thereafter randomly at the discretion of the practitioner but] at least [every six months thereafter once a year].

E. The practitioner shall regularly evaluate for opioid use disorder and shall initiate specific treatment for opioid use disorder, consult with an appropriate health care provider, or refer the patient for evaluation for treatment if indicated.

18VAC90-40-230. Additional consultation.

A. When necessary to achieve treatment goals, the prescriber shall refer the patient for additional evaluation and treatment.

B. When a practitioner makes the diagnosis of opioid use disorder, treatment for opioid use disorder shall be initiated or the patient shall be referred for evaluation and treatment.

18VAC90-40-240. Medical records.

The prescriber shall keep current, accurate, and complete records in an accessible manner and readily available for review to include:

1. The medical history and physical examination;

2. Past medical history;

3. Applicable records from prior treatment providers or any documentation of attempts to obtain those records;

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.

Part VII
Prescribing of Buprenorphine

18VAC90-40-250. General provisions.

A. Practitioners engaged in office-based opioid addiction treatment with buprenorphine shall have obtained a waiver from SAMHSA and the appropriate U.S. Drug Enforcement Administration registration.

B. Practitioners shall abide by all federal and state laws and regulations governing the prescribing of

buprenorphine for the treatment of opioid use disorder.

C. Nurse practitioners who have obtained a SAMHSA waiver shall only prescribe buprenorphine for opioid addiction pursuant to a practice agreement with a SAMHSA-waivered doctor of medicine or doctor of osteopathic medicine [unless the nurse practitioner has been authorized by the boards for autonomous practice].

D. Practitioners engaged in medication-assisted treatment shall either provide counseling in their practice or refer the patient to a mental health service provider, as defined in § 54.1-2400.1 of the Code of Virginia, who has the education and experience to provide substance misuse counseling. The practitioner shall document provision of counseling or referral in the medical record.

18VAC90-40-260. Patient assessment and treatment planning.

A. A practitioner shall perform and document an assessment that includes a 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, a check of the Prescription Monitoring Program, and, when clinically indicated, infectious disease testing for human immunodeficiency virus, hepatitis B, hepatitis C, and tuberculosis.

B. The treatment plan shall include the practitioner's rationale for selecting medication assisted treatment, patient education, written informed consent, how counseling will be accomplished, and a signed treatment agreement that outlines the responsibilities of the patient and the practitioner.

18VAC90-40-270. Treatment with buprenorphine.

A. Buprenorphine without naloxone (buprenorphine mono-product) shall not be prescribed except:

1. When a patient is pregnant;

2. When converting a patient from methadone or buprenorphine mono-product to buprenorphine containing naloxone for a period not to exceed seven days;

3. In formulations other than tablet form for indications approved by the FDA; or

4. For patients who have a demonstrated intolerance to naloxone; such prescriptions for the mono-product shall not exceed 3.0% of the total prescriptions for buprenorphine written by the prescriber, and the exception shall be clearly documented in the patient's medical record.

B. Buprenorphine mono-product tablets may be administered directly to patients in federally licensed [opiate opioid] treatment programs. With the exception of those conditions listed in subsection A of this section, only the buprenorphine product containing naloxone shall be prescribed or dispensed for use off site from the program.

C. The evidence for the decision to use buprenorphine mono-product shall be fully documented in the medical record.

D. Due to a higher risk of fatal overdose when buprenorphine is prescribed with other opioids, benzodiazepines, sedative hypnotics, carisoprodol, and tramadol [(an atypical opioid)], the prescriber shall only co-prescribe these substances when there are extenuating circumstances and shall document in the medical record a tapering plan to achieve the lowest possible effective doses if these medications are prescribed.

E. Prior to starting medication-assisted treatment, the practitioner shall perform a check of the Prescription Monitoring Program.

F. During the induction phase, except for medically indicated circumstances as documented in the medical record, patients should be started on no more than eight milligrams of buprenorphine per day. The patient shall be seen by the prescriber at least once a week.

G. During the stabilization phase, the prescriber shall increase the daily dosage of buprenorphine in safe and effective increments to achieve the lowest dose that avoids intoxication, withdrawal, or significant drug craving.

H. Practitioners shall take steps to reduce the chances of buprenorphine diversion by using the lowest effective

dose, appropriate frequency of office visits, pill counts, and checks of the Prescription Monitoring Program. The practitioner shall also require urine drug screens or serum medication levels at least every three months for the first year of treatment and at least every six months thereafter.

I. Documentation of the rationale for prescribed doses exceeding 16 milligrams of buprenorphine per day shall be placed in the medical record. Dosages exceeding 24 milligrams of buprenorphine per day shall not be prescribed.

J. The practitioner shall incorporate relapse prevention strategies into counseling or assure that they are addressed by a mental health service provider, as defined in § 54.1-2400.1 of the Code of Virginia, who has the education and experience to provide substance [abuse misuse] counseling.

18VAC90-40-280. Special populations.

A. Pregnant women may be treated with the buprenorphine mono-product, usually 16 milligrams per day or less.

B. Patients younger than the age of 16 years shall not be prescribed buprenorphine for addiction treatment unless such treatment is approved by the FDA.

C. The progress of patients with chronic pain shall be assessed by reduction of pain and functional objectives that can be identified, quantified, and independently verified.

D. Practitioners shall (i) evaluate patients with medical comorbidities by history, physical exam, and appropriate laboratory studies and (ii) be aware of interactions of buprenorphine with other prescribed medications.

E. Practitioners shall not undertake buprenorphine treatment with a patient who has psychiatric comorbidities and is not stable. A patient who is determined by the practitioner to be psychiatrically unstable shall be referred for psychiatric evaluation and treatment prior to initiating medication-assisted treatment.

18VAC90-40-290. Medical records for opioid addiction treatment.

A. Records shall be timely, accurate, legible, complete, and readily accessible for review.

B. The treatment agreement and informed consent shall be maintained in the medical record.

C. Confidentiality requirements of 42 CFR Part 2 shall be followed.

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