

---DRAFT UNAPPROVED---

Virginia Board of Medicine
Regulatory Advisory Panel on Opioids and Buprenorphine

Friday, March 31, 2023

Department of Health Professions

Henrico, VA 23223

CALL TO ORDER: Mr. Marchese called the meeting to order at 9:10 a.m.

MEMBERS PRESENT: Blanton Marchese - Board President & Chair
Albert Arias, MD - VCU
Mark Blackwell - DBHDS
Ashley Carter - PMP
Ashley Harrel - DMAS
Kathrin Hobron - OCME
Lynn Kohan, MD - UVA
Tony McDowell - OAA
Sarah Melton, PharmD - ETSU
Antonio Quidgley-Nevares, MD
Gilbert Schmidt, Jr., MD
Pat Selig, NP
Justin Wood - DEA

MEMBERS ABSENT: None

STAFF PRESENT: William L. Harp, MD - Executive Director
Colanthia Morton Opher - Deputy Exec. Director for Administration
Deirdre Brown - Administrative Assistant

OTHERS PRESENT: Ben Traynham, JD - MSV
Marti Williams, - Into the Neighborhood
Chauncie Beaston - Where You're At Foundation
Blake Williams - Imagine the Freedom Recovery Foundation
Tess Bettles - Indivior
Jason Love - DMAS
Bart Devon - Eggleston
Amanda Reeves - You Matter

EMERGENCY EGRESS INSTRUCTIONS

Mr. Marchese announced the emergency egress instructions.

INTRODUCTION OF PANEL MEMBERS AND SPEAKERS

Mr. Marchese asked all the participants to introduce themselves.

PUBLIC COMMENT

Mr. Marchese opened the floor for public comment. There being none, the floor was closed.

NEW BUSINESS

1. Charge of the Work Group – Mr. Marchese

Mr. Marchese advised that in March of 2017, Governor McAuliffe signed emergency regulations for prescribing opioids for pain and buprenorphine for opioid use disorder. 18VAC85-21-10 et seq became effective immediately upon his signing. The emergency regulations had to be replaced by final regulations which became effective in August 2018. It is now time for the current regulations to be reviewed, given that more data and literature on these topics exist.

2. Speakers

- Kathrin Hobron – Office of the Chief Medical Examiner
 - Presentation Title: “Overdose Deaths Due to Prescription Opioids and Buprenorphine”
- Ashley Carter – Prescription Monitoring Program
 - Presentation Title: “Analysis of Data from Virginia's Prescription Monitoring Program”
- Justin Wood – Drug Enforcement Administration
- Anthony McDowell – Opioid Abatement Authority
 - Presentation Title: “Update on the Opioid Abatement Authority and Opioid Settlement Funds”

3-4. Section-by-Section Review and Discussion of the Regulations to Reach Consensus on Recommended Changes

Dr. Harp led the Panel members through a review of the current regulations with suggested amendments. After discussion of each section, the Panel unanimously agreed to the proposed changes as indicated below.

Part I. General Provisions

18VAC85-21-10. 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 may be prescribed for no more than three months.~~

“Acute pain” is pain of any origin which has existed < 1 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 > 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**.

DEA means the U.S. Drug Enforcement Administration

"DMAS" means the Department of Medical Assistance Services.

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

"Induction" with buprenorphine means the initial 7-14 days of treatment.

"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.

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

"Subacute pain" is that which has existed for 1-3 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.

18VAC85-21-20. 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.

C. A practitioner shall not request payment from a DMAS recipient for services involving the prescription of an opioid for pain management of opioid use disorder. The prohibition on payment shall not apply to the recipient's cost-sharing amounts set by DMAS.

D. Practitioners that participate or do not participate in DMAS shall provide written notice to DMAS recipients that the services described in 18VAC85-21-20(C) will be covered by DMAS if medical necessity criteria are met.

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.

18VAC85-21-21. 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.

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.

C. A practitioner may prescribe to a patient via telemedicine Schedule II-V drugs if a prior in-person evaluation has been done or if the patient is referred by a practitioner who has conducted a prior in-person evaluation.

D. A practitioner may prescribe to a patient via telemedicine Schedule III-V drugs for up to 30 days who has not previously been evaluated in-person. To prescribe past 30 days, the patient must be seen in-person.

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.

Part II. Management of Acute Pain

18VAC85-21-30. Evaluation of the acute 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, 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, 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.

18VAC85-21-40. 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 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/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. ~~Naloxone~~ **A 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.

~~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.~~

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.

18VAC85-21-50. 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 Subacute Pain

18VAC85-21-60. Evaluation of the 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 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, 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.

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

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

1. A prescriber providing treatment for acute pain shall not prescribe a controlled substance containing an opioid in a quantity that exceeds a fourteen-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/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. ~~Naloxone~~ A 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.

D. The practitioner shall continually assess the need for treatment with opioids to reduce the risk of opioid use disorder and other health conditions.

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.

18VAC85-21-80. Medical records for subacute pain.

The medical record shall include a description of the pain, a diagnosis for the origin of the pain, a thorough history and examination appropriate to the patient's complaint, a treatment plan including informed consent and a treatment agreement, the medications 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.

Part IV. Management of Chronic Pain

18VAC85-21-90. Evaluation of the chronic pain patient.

A. Nonpharmacologic and non-opioid treatment for pain shall be given consideration prior to treatment with opioids. To support the decision to initiate management of chronic pain with a controlled substance containing an opioid, a medical history, physical examination, mental status examination, assessment of the patient's history and risk of substance misuse, and consideration of potentially reversible causes for the pain ~~and~~ shall be 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 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;

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.

18VAC85-21-100. 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 ~~naloxone~~ a 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 (i) shall regularly evaluate the patient for opioid use disorder and (ii) shall 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.

18VAC85-21-110. 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 ~~or absence~~ of any indicators of **and any efforts taken to address** medication misuse or diversion. ~~and shall take appropriate action.~~

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. 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.

18VAC85-21-130. 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. **If the treatment plan includes opioid tapering, the rate should be individualized based on the patient's clinical situation.**
- C. The practitioner 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 thereafter randomly at the discretion of the practitioner but at least once a year.
- E. The practitioner (i) shall regularly evaluate the patient for opioid use disorder and (ii) 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.

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.

18VAC85-21-140. 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.

18VAC85-21-150. 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 V. Prescribing of Buprenorphine for ~~Addiction Treatment~~ Opioid Use Disorder

18VAC85-21-160. General provisions pertaining to prescribing of buprenorphine

~~for addiction treatment~~ **opioid use disorder.**

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

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

~~C. Physician assistants and nurse practitioners who have obtained a SAMHSA waiver shall only prescribe buprenorphine for opioid~~ **use disorder** ~~addiction~~ pursuant to a practice agreement with a ~~waivered~~ **patient care team** doctor of medicine or doctor of osteopathic medicine.

D. Practitioners shall encourage patients to seek counseling as an adjunct to medications for opioid use disorder. ~~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.

18VAC85-21-170. Patient assessment and treatment planning for addiction treatment.

A. A practitioner shall perform and document an assessment that includes a comprehensive medical and psychiatric history, substance misuse history including fentanyl exposure, 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 ~~medication-assisted treatment,~~ **medications for opioid use disorder,** patient education, written informed consent, how ~~counseling will be accomplished,~~ 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.

18VAC85-21-180. 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 ~~medication-assisted treatment~~, **medications for opioid use disorder**, 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.~~ **consideration shall be given to dose based upon the patient's history and current status, including recent exposure to high-potency opioids.** 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 **avoid** ~~reduce the chances of~~ buprenorphine diversion 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 ~~16~~ **24** 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 **inform patients of the benefit of** ~~incorporate~~ **seeking counseling inclusive of 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 misuse counseling.~~

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.

18VAC85-21-190. Special populations in **medication for opioid use disorder**

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

B. **A.** 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. **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.

D. **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.

~~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 prescriber to be psychiatrically unstable shall be referred for psychiatric evaluation and treatment prior to initiating medication-assisted 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.

18VAC85-21-200. 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.
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5. Next Steps

Mr. Marchese advised the Panel that staff will forward a copy of the regulations with their proposed recommendations for review after which they will be presented to the Full Board on June 22, 2023.

Adjournment

Mr. Marchese provided the travel reimbursement instructions to the Panel. With no other business to conduct, the meeting adjourned at 1:40 p.m.

William L. Harp, MD
Executive Director