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Final Regulation
Agency Background Document

Agency name	Board of Medicine, Department of Health Professions
Virginia Administrative Code (VAC) citation(s)	18VAC85-21
Regulation title(s)	Regulations Governing Prescribing of Opioids and Buprenorphine
Action title	Replacement of emergency regulations
Date this document prepared	2/19/18

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

Please provide a brief summary of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

Regulations Governing Opioid Prescribing for Pain and Prescribing of Buprenorphine were promulgated as emergency regulations to address the opioid abuse crisis in Virginia; this action is to replace the emergency regulation with permanent regulations.

The regulations establish the practitioners to whom the rules apply and the exceptions or non-applicability. Regulations for the management of acute pain include requirements for the evaluation of the patient, limitations on quantity and dosage, and medical record-keeping. Regulations 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 record-keeping. Regulations 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.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

CDC – Centers for Disease Control
FDA = Food and Drug Administration
PMP = Prescription Monitoring Program

Statement of final agency action

Please provide a statement of the final action taken by the agency including:1) the date the action was taken;2) the name of the agency taking the action; and 3) the title of the regulation.

On February 15, 2018, the Board of Medicine took final action to promulgate 18VAC85-21-10 et seq., Regulations Governing the Prescribing of Opioids and Buprenorphine.

Legal basis

Please identify the (1) the agency (includes any type of promulgating entity) and (2) the state and/or federal legal authority for the proposed regulatory action, including the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable. Your citation should include a specific provision, if any, authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency's overall regulatory authority.

Regulations are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400, which provides the Board of Medicine the authority to promulgate regulations to administer the regulatory system:

§ 54.1-2400 -General powers and duties of health regulatory boards
The general powers and duties of health regulatory boards shall be:
...
6. To promulgate regulations in accordance with the Administrative Process Act (§ 9-6.14:1 et seq.) which are reasonable and necessary to administer effectively the regulatory system. Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 (§ 54.1-100 et seq.) and Chapter 25 (§ 54.1-2500 et seq.) of this title. ...

In addition, the Board was mandated to adopt regulations by passage of HB2167 and SB1180 in the 2017 General Assembly:

§ 54.1-2928.2. Board to adopt regulations related to prescribing of opioids and buprenorphine.

The Board shall adopt regulations for the prescribing of opioids and products containing buprenorphine. Such regulations shall include guidelines for:

1. The treatment of acute pain, which shall include (i) requirements for an appropriate patient history and evaluation, (ii) limitations on dosages or day supply of drugs prescribed, (iii) requirements for appropriate documentation in the patient's health record, and (iv) a requirement that the prescriber request and review information contained in the Prescription Monitoring Program in accordance with § 54.1-2522.1;

2. The treatment of chronic pain, which shall include, in addition to the requirements for treatment of acute pain set forth in subdivision 1, requirements for (i) development of a treatment plan for the patient, (ii) an agreement for treatment signed by the provider and the patient that includes permission to obtain urine drug screens, and (iii) periodic review of the treatment provided at specific intervals to determine the continued appropriateness of such treatment; and

3. The use of buprenorphine in the treatment of addiction, including a requirement for referral to or consultation with a provider of substance abuse counseling in conjunction with treatment of opioid dependency with products containing buprenorphine.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Describe the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

The purpose of the regulatory action is the establishment of requirements for prescribing of controlled substances containing opioids or buprenorphine to address the overdose and addiction crisis in the Commonwealth. The goal is to provide prescribers with definitive rules to follow so they may feel more assured of their ability to treat pain in an appropriate manner to avoid under-prescribing or over-prescribing.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both.

The regulations establish the practitioners to whom the rules apply and the exceptions or non-applicability. Regulations for the management of acute pain include requirements for the evaluation of the patient, limitations on quantity and dosage, and medical record-keeping. Regulations 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 record-keeping. Regulations 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.

Issues

Please identify the issues associated with the proposed regulatory action, including: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, please indicate.

1) The primary advantage to the public is a reduction in the amount of opioid medication that is available in our communities. A limitation on the quantity of opioids that may be prescribed should result in fewer people becoming addicted to pain medication, which sometimes leads them to turn to heroin and other illicit drugs. Persons who are receiving opioids for chronic pain should be more closely monitored to ensure that the prescribing is appropriate and necessary. A limitation on prescribing the buprenorphine mono-product should result in a reduction in the number of tablets that are sold on the street. The primary disadvantage to the public has been the cost of urine drug screens (made less burdensome in final regulations) and physicians who have not read or who do not understand the rules who have chosen not to manage chronic pain patients in their practice.
2) The primary advantage to the Commonwealth is the potential reduction in the number of persons addicted to opioids and deaths from overdoses. If physicians follow the regulations, there are no disadvantages.
3) The Director of the Department of Health Professions has reviewed the proposal and performed a competitive impact analysis. The Board is authorized under § 54.1-2400 to "*To promulgate regulations in accordance with the Administrative Process Act (§ 2.2-4000 et seq.) which are reasonable and necessary to administer effectively the regulatory system. Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 (§ 54.1-100 et seq.) and Chapter 25 (§ 54.1-2500 et seq.) of this title*." There is no restraint on competition as a result of promulgating this regulation; all prescribers must follow the same rules for prescribing of opioids or buprenorphine.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

There regulations for prescribing of buprenorphine are consistent with the rules of the federal Substance Abuse and Mental Health Services Administration (SAMHSA).

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

There are no localities particularly affected.

Family impact

Please assess the impact of this regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

The institution of the family and family stability is being severely impacted by the opioid addiction crisis in the Commonwealth. The impact of this action is intended to empower and instruct practitioners in the appropriate prescribing of opioids to manage pain in such a manner as to prevent addiction and diversion.

Changes made since the proposed stage

*Please list all changes that made to the text since the proposed regulation was published in the Virginia Register of Regulations and the rationale for the changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. *Please put an asterisk next to any substantive changes.*

Section number	Requirement at proposed stage	What has changed	Rationale for change
10	Subsection B establishes the exceptions to the requirements of the chapter	Added sickle cell disease to the exceptions.	Board responded to testimony and public comment requesting the change
40, 70, 150	Sets out a requirement for co-prescribing opioids or buprenorphine with certain other drugs	Clarification that tramadol is an atypical opioid	Board addressed confusion or lack of knowledge by some practitioners about the nature of tramadol as an atypical opioid
100	Sets out the requirement in subsection D for urine drug screens or serum medication level testing	Deleted the requirement for drug testing every three months in the first year following initiation of chronic pain management and	Board responded to public comment and adopted a rule consistent with the CDC Guidelines

		substituted "thereafter randomly at the discretion of the practitioner but at least once a year"	

Public comment

Please summarize all comments received during the public comment period following the publication of the proposed stage, and provide the agency response. If no comment was received, please so indicate. Please distinguish between comments received on Town Hall versus those made in a public hearing or submitted directly to the agency or board.

Proposed regulations for prescribing of opioids and buprenorphine were published on November 27, 2017 with comment accepted through January 26, 2018. A public hearing was conducted on December 1, 2017.

Comment received at the Public Hearing were:

- Dionne BoBo addressed the Committee saying that she has two children who have sickle cell disease. She asked the Committee to consider adding an exemption in the proposed opioid regulations to ensure that prescribers that treat patients with sickle cell disease know that they can provide adequate doses of opioids to control the pain.
- Tiffany Dews, with Statewide Sickle Cell Chapters of Virginia and mother of two children with sickle cell, asked the Committee to exempt this population from the opioid regulations.
- George Carter, with Statewide Sickle Cell Chapters of Virginia, requested an amendment to 18VAC85-21-10(B) that would include a fourth exception to the guidelines for "patients diagnosed with Sickle Cell Disease".

  Board response: The Board added sickle cell disease to the list of exceptions to adherence to prescribing regulations.

- Ajay Manhapra, MD provided his perspective regarding the difficulty of opioid tapering in high-dose patients. He stated that restricting the writing of opioid prescriptions is not the solution and that the other side of this action is an alarming rate of suicide. Dr. Manhapra said that the policy seems based on feelings and not science. Regarding buprenorphine, it is not a detox medication or substitute therapy. The principle is that buprenorphine saves lives, and the lack of buprenorphine does not. He quoted a recent study that showed the use of buprenorphine mono-product nationwide was 8.8%. Dr. Manhapra also noted that the section about co-prescribing of opioids and benzodiazepine is outdated. The FDA advises that it is not appropriate to deny OUD patients buprenorphine treatment simply because they are on benzodiazepines. (Statement from FDA provided)

  Board response: The Board considered the information provided by Dr. Manhapra and weighed it against literature on intolerance to suboxone. Given the lack of scientific research on the subject of intolerance and the ongoing concerns from law enforcement and legislators about the abuse of mono-product (particularly in

Southwest Virginia), the Board elected to retain the percent of allowance for prescribing the mono-product at 3%.

The following comments were received through the Virginia Regulatory Townhall:

Commenter	Comment	Board response
5 persons	Commented about the cost and burden of doing urine drug screens	The Board has eliminated the mandatory testing for chronic pain prescribing every three months to allow the prescriber discretion for testing, provided tests are performed at the initiation of chronic pain management and at least annually thereafter. The Board will also try to educate practitioners about less expensive test options.
13 persons	Requested an exemption from the regulatory requirements for management of pain for patients with sickle cell disease.	See response above.
Medical Society of Virginia	Supports the multi-faceted approach to opioid and buprenorphine prescribing. These efforts and others have already produced results in the decline of opioid prescriptions. Supports the enactment of new chapter, 18VAC85-21.	The Board appreciates the support of the Medical Society.

The following legislators sent letters in support of including sickle cell disease in the exceptions from the opioid regulations: Delegates James and McQuinn and Senator McClellan

Board response: See response above.

Comments by email were sent from the following:

Commenter	Comment	Board response
Va. Academy of Physician Assistants	Supports the proposed regulations	The Board appreciates the support of the Virginia Academy.
William O'Keefe	Class 4 opioids like Tramadol do not have the same risk for abuse and addiction as other drugs, but the impact of regulations on patients is significant. For many such patients, they are burdensome, costly and unreasonable. Should not treat all opioids the same.	The Board amended regulations to identify and clarify that tramadol is an opioid. It did not choose to treat tramadol differently from other opioids; changes to the drug screen requirements should reduce some of the costs
William & Sara Ballard	There is a disconnect between the law and practitioners, who believe there is a "government prohibition" on prescribing pain medications, so many patients are suffering	The Board agrees that some practitioners are not well-informed about the actual language in the regulation and will repeat its efforts to educate licensees.
Dr. Eduardo Fraifeld	CDC recommendations are Guidelines, not prescription standards. There is now a restriction to patient care;	The Board acknowledges that CDC guidelines are not standards, so those guidelines that should be

	many 3rd party payors are restricting payment for pain medications beyond 7 days There is an increase burden on documentation which is required by payors resulting in delayed treatment for patients There are increased costs due to a lack of risk stratification; there needs to be more flexibility	imposed and enforced for patient safety are included in the regulation. The Board cannot manage the expectation and requirements for third-party payors.

There was also a petition on Change.org in opposition to the restriction on prescribing of buprenorphine mono-product.

Board response: There were no changes to the restriction on prescribing the mono-product.

All changes made in this regulatory action

Please list all changes that are being proposed and the consequences of the proposed changes. Describe new provisions and/or all changes to existing sections. Explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale

Section number	Proposed requirements	Intent and likely impact of proposed requirements
10	Subsection A sets out the practitioners to whom this chapter applies - doctors of medicine, osteopathic medicine, and podiatry and to physician assistants. Subsection B specifies that the chapter does 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, 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.	Rather than inserting regulations into existing chapters for the licensure of doctors (Chapter 20) and physician assistants (Chapter 50), a new chapter is promulgated that applies to all prescribers solely licensed by the Board. Nurse practitioners, who are dually licensed by Medicine and Nursing, will have similar regulations included in the chapter on prescriptive authority. Exclusions specified in subsection B were requested by physician groups and are reasonable exceptions to requirements for managing pain. **Change from proposed regulations:** **Sickle cell disease was added to exceptions listed in subsection B. Sickle cell is a chronic disease that may require excessive dosages of pain medication to manage. Current regulations do not prohibit such prescribing provided the rationale is**

		documented, but sickle cell advocates believe they may be a detriment to physicians in managing pain.
20	Section 20 sets out definitions for words and terms used in this chapter. They include a definition for acute pain to mean pain that occurs within the normal course of a disease or condition or as the result of surgery for which controlled substances may be prescribed for no more than three months. The definition for chronic pain means non-malignant pain that goes beyond the normal course of a disease or condition for which controlled substances may be prescribed for a period greater than three months.	There are various definitions for acute and chronic pain. The Federation of State Medical Boards guidance defines "acute" pain as generally lasting six weeks or less. Since requirements for the management of chronic pain are more burdensome on prescribers and patients, the Board adopted a more generous definition for acute pain, as no more than three months.
30	Section 30 sets out the rules for evaluation of a patient. Subsection A requires that non-pharmacologic 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. Subsection B requires that prior to initiating treatment with a controlled substance for a complaint of acute pain, the prescriber must perform a history and physical examination appropriate to the complaint, query the Prescription Monitoring Program as set forth in the Code of Virginia and conduct an assessment of the patient's history and risk of substance abuse.	The intent of this section is to ensure that practitioners prescribe opioids only when absolutely necessary, rather than as a routine treatment and that the prescription be limited in quantity and dosage. Prior to prescribing a controlled substance for pain, the practitioner has legal obligations in the establishment of a practitioner/patient relationship and in checking the PMP and also a professional obligation to assess the patient's risk.
40	Section 40 establishes the requirements for treatment of acute pain with opioids. Subsection A specifies that initiation of opioid treatment for patients with acute pain shall be with short-acting opioids. When prescribing a controlled substance containing an opioid, a practitioner is limited to a quantity that do not exceed a **seven-day** supply as determined by the manufacturer's directions for use**,** unless extenuating circumstances are clearly documented in the medical record. The 7-day limit also applies to prescriptions of a controlled substance containing an opioid upon discharge from an emergency department. When an opioid is 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. Subsection B sets the following limits on dosages: 1. The practitioner must carefully consider and	Legislation introduced in the General Assembly would have limited prescribing for acute pain to 7 days and for emergency room discharge to 3 days. The medical community requested that the Board make the decision about prescribing limitation through regulation, and the Board determined that a consistent 7-day limit was advisable. If post-surgical pain is being treated, the limitation is 14 days. In each case, the prescriber can document circumstances that would warrant prescribing outside the limits. A specified limitation on days of prescribing will reduce the amount of unused or unnecessary opioids available for abuse or diversion. It will also encourage practitioners to prescribe non-opioid controlled substances that may be just as effective but not addictive. Since there are many controlled substances containing opioids, the acceptable limitation on dosage is translated into morphine

	document in the medical record the reasons to exceed 50 MME/day. 2. Prior to exceeding 120 MME/day, the practitioner must 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 abuse, doses in excess of 120 MME/day, or concomitant benzodiazepine is present. Subsection C limits co-prescribing of certain substances. Due to a higher risk of fatal overdose when opioids are prescribed with benzodiazepines, sedative hypnotics, carisoprodol, and tramadol, 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. Subsection D provides that buprenorphine is not indicated for acute pain in the outpatient setting, except when a waivered buprenorphine prescriber is treating pain in a patient whose primary diagnosis is the disease of addiction.	milligram equivalency (MME). Typically, a patient should not be prescribed a dosage in excess of 50 MME per day. If a prescriber exceeds 120 MME per day for a patient, there must be a clear justification or consultation with or referral to a pain specialist. Naloxone, an overdose antidote, should always be prescribed under the conditions listed in subsection B. A specified standard in regulation should assist practitioners in determining dosages that are consistent with the standard of care in prescribing for pain. Subsection C lists drugs, for which there is a high risk of overdose if co-prescribed with an opioid. Regulations require documentation of the circumstances necessitating co-prescribing and the tapering plan in place. **Change from proposed:** **The phrase (an atypical opioid) was added after "tramadol" to clarify and educate prescribers that it is considered an opioid, and they should treat it as such.** Buprenorphine is not allowed for treatment of pain outside of the practice of a waivered prescriber because of a high risk of abuse.
50	Section 50 requires that the medical record 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.	Requirements for the medical record in the treatment of a patient with are consistent with the establishment of a bona fide practitioner-patient relationship and Board regulations for complete records.
60	Section 60 sets out the requirements for evaluation of the chronic pain patient. Subsection A provides that, 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, must 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 abuse history of the patient and any family history of addiction or substance abuse; 6. A urine drug screen or serum medication level; 7. A query the Prescription Monitoring Program as	Prescribing for chronic pain with a substance containing an opioid (longer than 30 days) requires a more in-depth evaluation of the patient because of the high risk of addiction. In addition to a thorough evaluation of the patient's physical and mental status, the prescribed must obtain a urine drug screen or serum medication level to determine what drugs (illicit or prescribed) are in the patient's system and must check with PMP to determine what other drugs may have been prescribed. A urine drug screen may cost as little as $50, but it is an essential test to determine the risk of abuse or addiction if a practitioner is going to initiate prescribing of opioids for chronic pain. Subsection B requires the practitioner to discuss risks and benefits, the responsibilities of the patient, and an exit strategy for

	set forth in § 54.1-2522 of the Code of Virginia; 8. An assessment of the patient's history and risk of substance abuse; and 9. A request for prior applicable records. Subsection B specifies that 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. The practitioner shall also discuss with the patient an exit strategy for the discontinuation of opioids in the event they are not effective	discontinuation if necessary. Those patient responsibilities should include securely the drug and properly disposing of any unwanted or unused drug to prevent affecting our people or the environment.
70	A. Non-pharmacologic and non-opioid treatment for pain shall be given consideration prior to treatment with opioids. B. In initiating and treating with opioids, the practitioner shall: 1. 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 and refer to or consult with a pain management specialist. 3. Prescribe naloxone for any patient when risk factors of prior overdose, substance abuse, doses in excess of 120 MME/day, or concomitant benzodiazepine is 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, 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 regularly screen for opioid use disorder and shall initiate specific treatment for opioid use disorder or refer the patient for evaluation and treatment if indicated	Board members carefully considered guidelines for treating with opioids from the Center for Disease Control and other sources familiar with pain management to determine that the equivalent of 50 MME/day was a reasonable dosage for chronic pain. However, the practitioner may still exercise his/her professional judgment based on factors unique to a patient and may exceed the dosage if documented and justified in the medical record. Board members discussed simply referencing CDC guidelines but determined that prescribers need the Board regulation as a standard by which to base prescribing decisions. Likewise, any decision to exceed 120 MME/day should be documented and justified and the prescriber should refer to or consult with a pain management specialist. The Board recognizes that most chronic pain is going to be managed by primary care physicians, so they are not required to refer patients for chronic pain but are required to consult with practitioners who have expertise in managing pain with opioids. Any prescribing of doses in excess of 120 MME/day or concomitant benzos heightens the risk of overdose, so the rules require prescribing of naloxone in addition to the opioid. Subsection C recommended that the buprenorphine mono-product (without naloxone) cannot be used for chronic pain. FDA does not approve such usage, but there seemed to be some confusion in that regulation, so specificity was recommended. Subsection D notes the higher risk of fatal

		overdose when an opioid is co-prescribed with certain other drugs and requires the prescriber to document the extenuating circumstances for such co-prescribing and a tapering plan for achieving the lowest possible effective doses. **Change from proposed:** **The phrase (an atypical opioid) was added after "tramadol" to clarify and educate prescribers that it is considered an opioid, and they should treat it as such.** Subsection E requires evaluating for opioid use disorder and for initiation or referral for treatment if indicated.
80	Section 80 sets out the requirements for a treatment plan as documented in the medical record to include: 1) measures to be used to determine progress in treatment, including but not limited to pain relief and improved physical and psychosocial function, quality of life, and daily activities; 2) 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; and 3) the presence or absence of any indicators for medication misuse, abuse or diversion and the action taken by the prescriber.	This section details what a practitioner should include in a treatment plan and what should be documented in the patient record, included the presence or absence of indicators for medication abuse, misuse, abuse or diversion. The intent is to have documentation that the practitioner has a plan for monitoring the effectiveness of his prescribing and for being alert to signs of abuse, diversion, misuse, or addiction. A patient who is compliant with the plan should not have to be concerned about being denied his/her pain medication, and a prescriber who is fully documenting and monitoring should not have to be concerned about compliance with law and regulation.
90	Section 90 sets out the requirements for informed consent and the treatment agreement. Subsection A requires the prescriber to document in the medical record informed consent, to include risks, benefits and alternative approaches, prior to the initiation of opioids for chronic pain. Subsection B requires there to be a written treatment agreement, signed by the patient, in the medical record that addresses the parameters of treatment, including those behaviors which will result in referral to a higher level of care, cessation of treatment, or dismissal from care. C. The treatment agreement shall include, but not be limited to permission for the practitioner to: 1) Obtain urine drug screens or serum medication levels, when requested; 2) Query and receive reports from the Prescription Monitoring Program; and 3) Consult with other prescribers or dispensing	The intent of section 90 is protection for both the patient and the practitioner. With a clearly documented treatment plan and informed consent, the patient should know the expectation for continued treatment with opioids and the practitioner has a roadmap to follow in the management of chronic pain.

	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.	
100	Section 100 establishes requirements for opioid therapy for chronic pain. Subsection A requires the prescriber to 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. Subsection B specifies that continuation of treatment with opioids shall be supported by documentation of continued benefit from such prescribing. If the patient's progress is unsatisfactory, the prescriber 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. 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~~ thereafter randomly at the discretion of the practitioner, ~~and~~ but] at least [~~every six months thereafter~~ once a year. E. The practitioner shall regularly screen for opioid use disorder and shall initiate specific treatment for opioid use disorder or refer the patient for evaluation for treatment if indicated.	Requirements in section 100 for opioid therapy for chronic pain are intended to ensure that the practitioner is carefully considering the effects of the prescribing, evaluating the patient's progress, considering other modalities for pain control, monitoring the patient's prescribing history to check for evidence of drugs from other sources, and evaluating for opioid use disorder. The evaluation needs to occur at least every 3 months so problems can be detected before addiction or diversion is evidenced. The only method of assurance that the drug is being taken by the patient as prescribed and that there are no other drugs in the patient's system is by the use of a urine drug screen or serum medication level. The type of screen will be determined by the prescriber. The proposed regulation requires testing every three months for the first year and every six months thereafter. **Change from proposed regulation:** **Rather than requiring a urine drug screen every three months in the first year, the Board has adopted a more flexible regulation that allows the practitioner to determine when additional screens are necessary and to require them randomly, which is more effective than on a set schedule. A drug screen is required at the initiation of prescribing opioids for chronic pain and at least annually thereafter, but interim drug screens are at the discretion of the physician. The revised regulation is consistent with CDC guidelines.**
110	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	Section 110 has the regulation for achieving the treatment goals as set in the treatment plan, which may include referral or, if there is a diagnosis of opioid use disorder, refers initiation of treatment or referral to address the condition.

	evaluation and treatment.	
120	Section 120 specifies the content of a medical record when a practitioner is prescribing opioids for chronic pain, including the requirement that records be accurate and complete and in an accessible manner readily available for review. The content shall include: 1.The medical history and physical examination; 2. Past medical history; 3. Applicable records from prior treatment providers and/or any documentation of attempts to obtain; 4. Diagnostic, therapeutic and laboratory results; 5. Evaluations and consultations; 6. Treatment goals; 7. Discussion of risks and benefits; 8. Informed consent and agreement for treatment; 9. Treatments; 10. Medications (including date, type, dosage and quantity prescribed and refills). 11. Patient instructions; and 12. Periodic reviews.	Requirements for the medical record in the treatment of a patient with are consistent with the establishment of a bona fide practitioner-patient relationship and Board requirements for a complete record of the treatment plan and goals, informed consent, evaluations and consultations and periodic reviews as specified in other sections of this chapter.
130	Section 130 sets out the general provisions for the prescribing of buprenorphine for addiction treatment. Subsection A. Prescribers engaged in office-based opioid addiction treatment with buprenorphine shall have obtained a waiver from the Substance Abuse Mental Health Services Administration and the appropriate Drug Enforcement Administration registration. B. Prescribers 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 waiver from the Substance Abuse Mental Health Services Administration, shall only prescribe buprenorphine for opioid addiction pursuant to a practice agreement with a waivered doctor of medicine or doctor of osteopathic medicine. D. Practitioners engaged in medication-assisted treatment shall refer the patient to a mental health provider for counseling or provide counseling in their practice and document such in the medical record.	The general provisions set out the required qualifications for practitioners who are authorized to engage in office-based opioid addiction treatment with buprenorphine. They must have training and a SAMHSA waiver, and they are required to either provide counseling in their practice or refer for counseling as documented in the patient record. The intent is to ensure that these programs are truly treating the disease of addiction and not just prescribing buprenorphine.
140	Patient assessment and treatment planning. A. A practitioner shall perform and document an assessment that includes a comprehensive medical and psychiatric history, substance abuse history, family history and psychosocial supports, appropriate physical examination, urine drug screen, pregnancy test for women of childbearing age and ability, a check of the Prescription Monitoring Program, and, when clinically indicated, infectious	The intent of section 140 is to require an appropriate and comprehensive assessment and a plan for treating the patient with medication. There must be a signed agreement that outlines the responsibilities of the two parties and written informed consent so the patient understands the expectations and limitations.

	disease testing for HIV, Hepatitis B, Hepatitis C and TB. 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 prescriber.	
150	Section 150 sets out the requirements for 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 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% 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 treatment programs (OTPs). With the exceptions, listed in subsection A, only the buprenorphine product containing naloxone shall be prescribed or dispensed for use offsite 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, 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 8 mg. of buprenorphine. 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	Buprenorphine mono-product has become a frequently abused drug in Southwest Virginia. Legislation introduced in the 2017 General Assembly would have limited the use of the mon-product for pregnant women only. Legislators were convinced to amend those bills to allow the Medical Board to determine appropriate use for the mono-product, and rules adopted are a compromise between those who wanted very restricted availability and those who want access to the mono-product for general prescribing for addiction treatment. The Board believes that the rules set forth in subsection A will allow appropriate access with minimal risk of diversion and abuse. The additional formulations (other than tablets) are available as transdermal patches, mucosal adhesives and implantable devices; the FDA is in the process of also approving an injectable formulation. The mono-product tablet may still be administered in an opioid treatment program but not dispensed or prescribed for use offsite. According to numerous comments and testimony from patients and physicians, the restriction on prescribing the mono-product was highly problematic to a small number of patients who have demonstrated an intolerance to naloxone. While the literature does not validate the existence of allergies to naloxone, physicians on the RAP and others have observed the physical manifestations of intolerance, estimated to be within 3% of their patients. To provide these patients with access to buprenorphine in the treatment of substance abuse as soon as possible, it was determined that the Board should readopt the emergency regulations to include this allowance for prescribing. Additional requirements in this section specify a check of the PMP and the appropriate dosage for initiating and

	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 mg. of buprenorphine per day shall be placed in the medical record. Dosages exceeding 24 mg. 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 licensed mental health professional.	maintaining a patient on buprenorphine. While 4 mg. of buprenorphine is usually adequate for induction, regulations allow a prescriber to start a patient on 8 mg. During induction, the patient has to be seen at the program at least once a week. As with management of chronic pain, a urine drug screen or serum mediation level must be obtained every 3 months for the first year and every 6 months thereafter. While a practitioner is allowed to prescribe dosages of 16 mg. per day, any prescribing above that level must be documented and justified. Dosages exceeding 24 mg. per day are not FDA-approved and are prohibited. Requirements in this section also include steps to reduce the chance of diversion and relapse strategies that must be employed.
160	Establishes requirements for prescribing of buprenorphine to special populations. A. Pregnant women may be treated with the buprenorphine mono-product, usually 16 mg. per day or less. B. Patients under 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 which can be identified, quantified and independently verified. D. Practitioners shall evaluate patients with medical comorbidities by history, physical exam, appropriate laboratory studies, and 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 that 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.	Because of the risk associated with addiction treatment with buprenorphine, this section has specific rules for special populations of patients, including pregnant women, children under age 16, patients with a diagnosis of chronic pain in addition to addiction, and other medical or psychiatric comorbidities. The second RAP noted that a small number of pregnant women who have a history of substance misuse may need to have buprenorphine with naloxone. Therefore, in subsection A, the word "shall" was changed to "may" to allow such prescribing based on the medical history of the patient and the professional judgment of the prescriber. **Change from proposed:** **The phrase (an atypical opioid) was added after "tramadol" to clarify and educate prescribers that it is considered an opioid, and they should treat it as such.**
170	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	In addition to the requirements for complete medical records, this section specifies confidentiality relating to substance abuse treatment in federal rules and the confidentiality provisions of Board regulations.

	which prohibits release of medical records, re-disclosure or other information without the patient's consent or a court order, or in cases of a bona fide medical emergency, or in the mandatory reporting of child abuse, shall be followed. D. Compliance with Board of Medicine Regulation 18VAC85-20-27, which prohibits willful or negligent breach of confidentiality or unauthorized disclosure of confidential Prescription Monitoring Program information, shall be maintained.	