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Emergency Regulation
Agency Background Document

Agency name	Board of Medicine, Department of Health Professions
Virginia Administrative Code (VAC) citation(s)	18VAC85-21-10 et seq.
Regulation title(s)	REGULATIONS GOVERNING OPIOID PRESCRIBING FOR PAIN AND PRESCRIBING OF BUPRENORPHINE FOR ADDICTION TREATMENT
Action title	New chapter - Emergency
Date	2/17/17

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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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 are being promulgated as emergency regulations to address the opioid abuse crisis in Virginia. 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.

PMP = Prescription Monitoring Program

Emergency Authority

The APA (Code of Virginia § 2.2-4011) states that agencies may adopt emergency regulations in situations in which Virginia statutory law or the appropriation act or federal law or federal regulation requires that a regulation be effective in 280 days or less from its enactment, and the regulation is not exempt under the provisions of subdivision A. 4. of § 2.2-4006. Please explain why this is an emergency situation as described above, and provide specific citations to the Code of Virginia or the Appropriation Act, if applicable.

On November 16, 2016, State Health Commissioner Marissa Levine declared the opioid addiction crisis to be a public health emergency in Virginia. In his news conference about the opioid crisis, Governor McAuliffe noted that the Declaration would "provide a framework for further actions to fight it, and to save Virginians' lives." One of those "further actions" is adoption of emergency regulations by the Board of Medicine setting out rules for prescribing of opioids and buprenorphine.
The authority in § 2.2-4011 authorizes an agency to adopt emergency regulations when they "are necessitated by an emergency situation." The Declaration by Commissioner Levine is indeed evidence that such an emergency situation exists in the Commonwealth.

Legal basis

Other than the emergency authority described above, please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and 2) the promulgating entity, i.e., agency, board, or person.

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 has been 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.

Both bills have emergency enactments that provide: *That an emergency exists and this act is in force from its passage.*

Purpose

Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.

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.

Need

Please describe the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, delineate any potential issues that may need to be addressed as the regulation is developed.

As noted above, the opioid addiction crisis was declared to be a public health emergency in Virginia on November 21, 2016. In the declaration announcement, it was noted that by the end of 2016, the numbers of fatal opioid overdose deaths were expected to increase by 77 percent, compared to five years ago. In 2014, for the first time in Virginia, more people died from opioid overdoses than fatal car accidents. Emergency department visits for heroin overdose for January-September 2016 increased 89 percent, compared to the same nine-month period in 2015. In the first half of 2016, the total number of fatal drug overdoses in Virginia increased 35 percent, when compared to the same time period in 2015, and in 2013, fatal drug overdoses became the number one cause of unnatural death. In addition to overdoses from opioids, overdoses from heroin and other illicit drugs continue to soar. Many of those who become addicted to heroin started with an addiction to prescription drugs. In order to stem the tide of addiction, practitioners need enforceable rules for proper prescribing of drugs containing opioid in treatment of pain to protect the public health and safety.

Regulations in this chapter were drafted by a Regulatory Advisory Panel (RAP), comprised of four specialists in addiction medicine. Extensive comment, both in writing and oral, was received by the RAP, the Legislative Committee of the Board, and the full Board of Medicine prior to adoption of emergency regulations. Additionally, a 14-member workgroup held two lengthy meeting and received comment on guidance for buprenorphine prescribing. To the extent consistent with public health and safety, recommendations from interested parties were incorporated into the document adopted as 18VAC85-21-10 et seq.

Substance

Please describe any changes that are proposed. Please outline new substantive provisions, all substantive changes to existing sections, or both where appropriate. Set forth the specific reasons the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of Virginians.

Section number	Proposed requirements	Other regulations and law that apply	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, a patient in hospice care or a patient in palliative care; 2) The treatment of acute or chronic pain	§ 54.1-100	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

	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.		prescriptive authority. Exclusions specified in subsection B were requested by physician groups and are reasonable exceptions to requirements for 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.	§§ 54.1-3303 and 54.1-2522.1	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	§§ 54.1-2915 (13) and 54.1-3408	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

	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 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.		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 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. 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.	§§ 54.1-3303 and 32.1-127.1:03 18VAC85-20-26	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	§§ 54.1-3303 and 54.1-2522.1	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

	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 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		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 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	§§ 54.1-2915 (3) (13) and 54.1-3408	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

	4. Document the rationale to continue opioid therapy every three months. C. Buprenorphine may be prescribed or administered for chronic pain in formulation and dosages that are FDA-approved for that purpose. 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		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 specifies that buprenorphine must be prescribed for chronic pain in formulations and dosages consistent with FDA approval, which calls for a delivery method that is effective but not at high risk for diversion – such as a transdermal patch. 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. 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	§ 54.1-3408 18VAC85-20-28	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

	the prescriber.		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 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.	§ 54.1-3408 18VAC85-20-28	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.
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	§§ 54.1-2915 (3) (13) and 54.1-3408	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

	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 and at least every six months thereafter. 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.		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, but the regulation requires testing every three months for the first year and every six months thereafter.
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 evaluation and treatment.	§ 54.1-2915 (3)	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.
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.	§§ 54.1-3303 and 32.1-127.1:03 18VAC85-20-26	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.	§ 54.1-3408	The general provisions set out the required qualifications for

	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.		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 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.	§§ 54.1-3303 and 54.1-3408	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.
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; or 3) In formulations other than tablet	§§ 54.1-2915 (3) (13) and 54.1-3408	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

	form for indications approved by the FDA. 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 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		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. Additional requirements in this section specify a check of the PMP and the appropriate dosage for initiating and 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.

	prevention strategies into counseling or assure that they are addressed by a licensed mental health professional.		
160	Establishes requirements for prescribing of buprenorphine to special populations. A. Pregnant women shall 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.	§§ 54.1-2915 (3) (13) and 54.1-3408	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.
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 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	42 CFR, Part 2 § 32.1-127.1:03. 18VAC85-20-27	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.

	Program information, shall be maintained.		

Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been considered to meet the essential purpose of the action. Also describe the process by which the agency has considered or will consider other alternatives for achieving the need in the most cost-effective manner.

In 2004, the Virginia Board of Medicine adopted the Federation of State Medical Boards' *Model Policy on the Use of Controlled Substances in the Treatment of Pain* as Board Guidance Document 85-24. It served as a guide to licensees who accepted the challenge of treating chronic pain, informed the Board members of the essential aspects of good pain management, and also provided the public with perspective on this sometimes controversial field of medicine.

As the thinking about chronic pain management evolved, the Federation of State Medical Boards revisited the issue in 2012-2013 and produced a subsequent version of the Model Policy. At its October 24, 2013 meeting, the Board voted to replace the 2004 version with the 2013 *Model Policy for the Use of Opioid Analgesics in the Treatment of Chronic Pain* to serve as its guidance in this matter.

While guidance is helpful to practitioners, Guidance Document 85-24 is not enforceable and does not offer specific limitations on prescribing or rules for management of acute and chronic pain. Likewise, it did not address issues relating to prescribing of buprenorphine.

Numerous measures have been introduced in the General Assembly to set limitations on prescribing, but the medical community has advocated for specification on the practice of medicine to come from the medical board rather than from the legislators. Accordingly, the Medical Society and other physician groups have supported and been involved in the development of these emergency regulations.

To ensure that regulations were adopted in accordance with the standard of care and acceptable practices for management of pain and buprenorphine for addiction, the Board of Medicine convened a Regulatory Advisory Panel (RAP), chaired by the Board president and including two addiction specialists, a pain management specialist, and the Chief Medical Officer for the Department of Medical Assistance Services - Stephen Long, MD; Hughes Melton, MD; Katherine Neuhausen, MD; and Paul Spector, DO. The RAP met on January 6, 2017 to draft regulations, which were then discussed and recommended by the Legislative Committee of the Board on January 27, 2017.

The draft regulations were posted on the Board's website prior to its meeting on February 16, 2017 in order to allow interested parties an opportunity to address the Board in public comment in advance of the regulatory action.

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.