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Fast-Track Regulation
Agency Background Document

Agency name	Board of Medicine, Department of Health Professions
Virginia Administrative Code (VAC) Chapter citation(s)	18VAC85-21
VAC Chapter title(s)	Regulations Governing Prescribing of Opioids and Buprenorphine
Action title	Amendments of opioid and buprenorphine prescribing regulations following updated federal guidance
Date this document prepared	July 7, 2023

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 19 (2022) (EO 19), any instructions or procedures issued by the Office of Regulatory Management (ORM) or the Department of Planning and Budget (DPB) pursuant to EO 19, the Regulations for Filing and Publishing Agency Regulations (1 VAC 7-10), and the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code.*

Brief Summary

Provide a brief summary (preferably no more than 2 or 3 paragraphs) of this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation). Alert the reader to all substantive matters. If applicable, generally describe the existing regulation.

These amendments update regulations which govern practitioner prescribing of opioids and buprenorphine. These regulations were promulgated pursuant to a directive by the General Assembly and became effective in 2018. Since that time, medical research and Centers for Disease Control and Prevention guidelines surrounding opioid and buprenorphine prescribing has changed. The Board of Medicine determined that these regulations should be revised to reflect those changes.

Acronyms and Definitions

Define all acronyms used in this form, and any technical terms that are not also defined in the "Definitions" section of the regulation.

CDC = Centers for Disease Control and Prevention
SAMHSA = Substance Abuse and Mental Health Services Administration

Statement of Final Agency Action

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 June 22, 2023, the Board of Medicine voted to amend 18VAC85-21, the Regulations Governing Prescribing of Opioids and Buprenorphine, by fast-track regulatory action.

Mandate and Impetus

Identify the mandate for this regulatory change and any other impetus that specifically prompted its initiation (e.g., new or modified mandate, petition for rulemaking, periodic review, or board decision). For purposes of executive branch review, "mandate" has the same meaning as defined in the ORM procedures, "a directive from the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part."

Consistent with Virginia Code § 2.2-4012.1, also explain why this rulemaking is expected to be noncontroversial and therefore appropriate for the fast-track rulemaking process.

The impetus for these changes were the issuance in late 2022 of new CDC guidelines concerning opioid and buprenorphine prescribing, along with the pending release of other opioid reversal agents aside from naloxone.

This rulemaking is expected to be noncontroversial because the Board has received comments for several years of the need for these changes. Additionally, the Board convened a regulatory advisory panel of 12 stakeholders from a variety of backgrounds to provide assistance in drafting these changes. These amendments have been the subject of substantial public participation.

Legal Basis

Identify (1) the promulgating agency, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia and Acts of Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the promulgating agency to regulate this specific subject or program, as well as a reference to the agency's overall regulatory authority.

Regulations of the Board of Virginia are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Virginia Code § 54.1-2400(6) specifically states that the general powers and duties of health regulatory boards shall be "[t]o promulgate regulations in accordance with the Administrative Process Act (§ 2.2-4000 et seq.) that are reasonable and necessary to administer effectively the regulatory system."

Virginia Code § 54.1-2928.2 directs the Board of Medicine to promulgate regulations governing the prescribing of opioids and buprenorphine.

Purpose

Explain the need for the regulatory change, including a description of: (1) the rationale or justification, (2) the specific reasons the regulatory change is essential to protect the health, safety or welfare of citizens, and (3) the goals of the regulatory change and the problems it is intended to solve.

These regulations need to be amended to account for current federal guidance regarding prescription of opioids and buprenorphine and to reflect current practice, which has changed since these regulations were initially promulgated as emergency regulations in 2017. The regulations are still necessary to protect the health, safety and welfare of patients because they guide practitioners in use of opioids and buprenorphine, which are addictive and often abused drugs. Similarly, the failure to appropriately prescribe these medications to the pain management or opioid use disorder populations can harm the public. The regulatory changes are intended to address the discrepancies between the Board's initial regulations in 2017 and current federal and medical practice regarding prescription of opioids and buprenorphine.

Substance

Briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the "Detail of Changes" section below.

These amendments make the following general changes:

- Include other FDA-approved opioid reversal agents where "naloxone" is currently used;
- Change references to addition treatment to opioid use disorder;
- Update prescribing guidelines based on patient population or type of pain treated;
- Clarify tapering;
- Include subacute pain as a pain management category along with acute and chronic;
- Remove references to the SAMHSA waiver to prescribe buprenorphine, as that is no longer issued by SAMHSA or required for buprenorphine prescribing;
- Clarify use of telemedicine for prescription of opioids; and
- Increase the recommended quantity for initial prescription of opioids.

Issues

Identify the issues associated with the regulatory change, 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, include a specific statement to that effect.

1) The primary advantages to the public are updated guidelines for practitioners regarding prescription of opioids and buprenorphine. There are no disadvantages to the public.
2) There are no primary advantages or disadvantages to the agency or the Commonwealth.
3) The Director of the Department of Health Professions has reviewed the proposal and performed a competitive impact analysis. Any restraint on competition as a result of promulgating these regulations is a foreseeable, inherent, and ordinary result of the statutory obligation of the Board to protect the safety and health of citizens of the Commonwealth and a foreseeable, inherent,

and ordinary result of the General Assembly's directive to the Board to regulate opioid and buprenorphine prescribing. The Board is authorized under § 54.1-2400 "[t]o 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." The promulgated regulations do not conflict with the purpose or intent of Chapters 1 or 25 of Title 54.1.

Requirements More Restrictive than Federal

Identify and describe any requirement of the regulatory change which is more restrictive than applicable federal requirements. Include a specific citation for each applicable federal requirement, and 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 specific statement to that effect.

There are no applicable federal requirements.

Agencies, Localities, and Other Entities Particularly Affected

Consistent with § 2.2-4007.04 of the Code of Virginia, identify any other state agencies, localities, or other entities particularly affected by the regulatory change. Other entities could include local partners such as tribal governments, school boards, community services boards, and similar regional organizations. "Particularly affected" are those that are likely to bear any identified disproportionate material impact which would not be experienced by other agencies, localities, or entities. "Locality" can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulation or regulatory change are most likely to occur. If no agency, locality, or entity is particularly affected, include a specific statement to that effect.

Other State Agencies Particularly Affected – none

Localities Particularly Affected – none

Other Entities Particularly Affected – none

Economic Impact

Consistent with § 2.2-4007.04 of the Code of Virginia, identify all specific economic impacts (costs and/or benefits), anticipated to result from the regulatory change. When describing a particular economic impact, specify which new requirement or change in requirement creates the anticipated economic impact. Keep in mind that this is the proposed change versus the status quo.

Impact on State Agencies

For your agency: projected costs, savings, fees or revenues resulting from the regulatory change, including: a) fund source / fund detail; b) delineation of one-time versus on-going expenditures; and	The Department of Health Professions is a Special Fund agency. All operating costs for the regulatory boards are taken from fees for licensing and renewal of regulated professions. This will not affect costs, savings, fees, or revenues for the agency.

c) whether any costs or revenue loss can be absorbed within existing resources	
For other state agencies: projected costs, savings, fees or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.	There are no costs to other state agencies.
For all agencies: Benefits the regulatory change is designed to produce.	There are no benefits to state agencies.

Impact on Localities

If this analysis has been reported on the ORM Economic Impact form, indicate the tables (1a or 2) on which it was reported. Information provided on that form need not be repeated here.

Projected costs, savings, fees or revenues resulting from the regulatory change.	No impact on localities.
Benefits the regulatory change is designed to produce.	No benefit to localities.

Impact on Other Entities

If this analysis has been reported on the ORM Economic Impact form, indicate the tables (1a, 3, or 4) on which it was reported. Information provided on that form need not be repeated here.

Description of the individuals, businesses, or other entities likely to be affected by the regulatory change. If no other entities will be affected, include a specific statement to that effect.	Individual practitioners that prescribe opioids and buprenorphine as part of pain management, opioid use disorder treatment, or surgery will be affected.
Agency's best estimate of the number of such entities that will be affected. Include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	The agency has no data regarding the number of practitioners that prescribe opioids and buprenorphine as part of pain management, opioid use disorder treatment, or surgery. As of March 31, 2023, the agency reported a total of 53,127 prescribers under the Board of Medicine (42,132 medical doctors, 4,941 doctors of osteopathy, and 6,054 physician assistants). The number of these practitioners affected by the regulatory amendments would likely be a minority of that number.
All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. Be specific and include all costs including, but not limited to: a) projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the regulatory change; c) fees; d) purchases of equipment or services; and e) time required to comply with the requirements.	There are no projected costs.
Benefits the regulatory change is designed to produce.	There are no monetary benefits the amendments are designed to produce.

Alternatives to Regulation

Describe any viable alternatives to the regulatory change that were considered, and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the regulatory change. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulatory change.

There is no alternative to a regulatory amendment as these are existing regulations required to be promulgated by Virginia Code § 54.1-2928.2.

Regulatory Flexibility Analysis

Consistent with § 2.2-4007.1 B of the Code of Virginia, describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) establishing less stringent compliance or reporting requirements; 2) establishing less stringent schedules or deadlines for compliance or reporting requirements; 3) consolidation or simplification of compliance or reporting requirements; 4) establishing performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the regulatory change.

These amendments do establish less stringent prescribing requirements; there are no schedules for reporting or compliance requirements to consider; there are no compliance or reporting requirements to consolidate; there are no operational standards to consider and businesses are not regulated by the Board; businesses are not regulated by the Board, and exempting any practitioner from safety requirements due to size or income shirks the Board's duty to protect the public.

Public Participation

Indicate how the public should contact the agency to submit comments on this regulation, and whether a public hearing will be held, by completing the text below.

Consistent with § 2.2-4011 of the Code of Virginia, if an objection to the use of the fast-track process is received within the 30-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall: 1) file notice of the objections with the Registrar of Regulations for publication in the Virginia Register and 2) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

If you are objecting to the use of the fast-track process as the means of promulgating this regulation, please clearly indicate your objection in your comment. Please also indicate the nature of, and reason for, your objection to using this process.

The Board of Medicine is providing an opportunity for comments on this regulatory proposal, including but not limited to (i) the costs and benefits of the regulatory proposal and any alternative approaches, (ii) the

potential impacts of the regulation, and (iii) the agency's regulatory flexibility analysis stated in this background document.

Anyone wishing to submit written comments for the public comment file may do so through the Public Comment Forums feature of the Virginia Regulatory Town Hall web site at: https://townhall.virginia.gov. Comments may also be submitted by mail to Erin Barrett, 9960 Mayland Drive, Suite 300, Henrico, Virginia 23233; by email to erin.barrett@dhp.virginia.gov; by fax to (804) 527-4434. In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

Detail of Changes

List all regulatory changes and the consequences of the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. For example, describe the intent of the language and the expected impact. Describe the difference between existing requirement(s) and/or agency practice(s) and what is being proposed in this regulatory change. Use all tables that apply, but delete inapplicable tables.

If an existing VAC Chapter(s) is being amended or repealed, use Table 1 to describe the changes between existing VAC Chapter(s) and the proposed regulation. If existing VAC Chapter(s) or sections are being repealed and replaced, ensure Table 1 clearly shows both the current number and the new number for each repealed section and the replacement section.

Table 1: Changes to Existing VAC Chapter(s)

Current chapter-section number	New chapter-section number, if applicable	Current requirements in VAC	Change, intent, rationale, and likely impact of new requirements
21-20		Contains definitions	The definition of “acute pain” is amended to include pain of any origin that has existed less than one month. This definition is consistent with the CDC 2022 guidelines. A definition is added for DMAS. A definition is added for “induction phase.” A definition of “subacute pain” is added, consistent with the CDC 2022 guidelines. The definition of SAMHSA is deleted. These changes will conform to CDC guidelines and, regarding the elimination of SAHMSA, will conform to elimination of the federal waiver that was previously required for practitioners prescribing buprenorphine. Please see information included regarding changes to 21-40 D and 21-130, below.

21-21		Governs electronic prescribing.	The start date for the application of subsection A is deleted, as that date has passed.
	21-22		Section 22 is added to clarify that DMAS members should not pay for services involving prescription of an opioid for pain management related to opioid use disorder. DMAS addressed this prohibition in a 2018 memorandum available here.
21-30		Sets out guidelines for evaluation of acute pain patients.	Amendments in A and B include subacute pain patients in existing requirements for evaluation of acute pain patients consistent with CDC guidelines.
21-40		Provides requirements for treatment of acute pain patients with opioids.	Subsection A is amended to include subacute pain, consistent with CDC guidelines. A 1 is amended to include subacute pain and to change the limit on prescription for acute or subacute pain from 7 days to 14. These changes are consistent with CDC 2022 guidelines and current practice. The 7 day limitation is too restrictive in practice for acute and subacute pain. A 1 is also amended to remove the statement that the limitation applies to discharge from an emergency department. This language is not necessary and causes confusion. The provision applies to all situations where acute and subacute pain is treated with an opioid. Singling out the emergency department has led to confusion among practitioners who believed that acute pain patients should be sent to the emergency department, when most acute pain can be handled in an office-based setting. A 2 is amended to delete the phrase “in accordance with manufacturer’s direction.” Not all opioids are prescribed immediately following surgery, and the use of opioids for off-label uses may not need to be or should be in accordance with manufacturer directions for post-surgical care. B 3 is amended to replace the reference to naloxone with “an FDA-approved opioid reversal agent.” This is in response to the approval by the FDA of opioid reversal agents that are not

			naloxone. These other opioid reversal agents should be available to practitioners and the public in late 2023. The use of this phrase will still allow naloxone to be used, but will also allow use of new opioid reversal agents as they become available. Subsection D is deleted. SAMHSA no longer issues waivers for buprenorphine prescribing, known as "X-waivers." Therefore the limitation to use of buprenorphine to individuals who possess a waiver from SAMHSA is obsolete.
21-50		Contains medical record requirements for acute pain patients.	The only change to this regulation is the caption, which will now include a reference to subacute pain as well as acute pain. This change is consistent with CDC 2022 guidelines.
21-60		Provides evaluation requirements of chronic pain patients.	Subsection A is amended to include the phrase "or continuing management." This is intended to clarify that the requirements in the section apply to those continuing management treatment of a patient that previously worked with another practitioner. A 5 is amended to remove the term "addiction" and replace it with "substance use disorder." Clinically, "substance use disorder" includes addiction. The term is amended to remove stigmatizing language around substance use disorder and treatment for substance use disorder, consistent with other changes made within this action.
21-70		Treatment of chronic pain with opioids.	B 3 is amended to replace the reference to naloxone with "an FDA-approved opioid reversal agent." This is in response to the approval by the FDA of opioid reversal agents that are not naloxone. These other opioid reversal agents should be available to practitioners and the public in late 2023. The use of this phrase will still allow naloxone to be used, but will also allow use of new opioid reversal agents as they become available.
21-80		Provides requirements for a treatment plan for chronic pain management.	Subsection C is amended to delete the requirement that the practitioner note the absence of indicators for medication misuse or diversion. In other disciplines of medicine, practitioners are not required to document the absence of symptoms. It was viewed as

			unnecessarily burdensome and stigmatizing to include the requirement in these regulations. C is also amended to remove the requirement that a prescriber "take appropriate action" upon documenting in the medical record the presence of indicators of medication misuse or diversion. This requirement placed practitioners in a difficult position when working with a vulnerable population. It is additionally difficult to enforce.
21-100		Opioid therapy for chronic pain.	New subsection C is added that addresses tapering plans. The amendment provides requirements for determining tapering rates for individual patients. The new subsection additionally states that no opioid patient should have treatment stopped without a tapering plan without documentation of extenuating circumstances. This is a direct result of complaints and communications the Board has received regarding practitioners stopping opioid treatment without any tapering at all, resulting in severe consequences for patients. The Board does, however, recognize that extenuating circumstances may exist, such as if the practitioner receives evidence in the form of drug tests that indicate the patient is not taking the drugs as prescribed. In that example the patient may be providing drugs to third parties or selling the medication, and continuing to provide prescription medication under such conditions is inadvisable.
21-130		General provisions for prescribing buprenorphine for addiction treatment	Subsection A is deleted because the federal government no longer requires practitioners to obtain a waiver to prescribe buprenorphine. New subsection B (former subsection C) also deletes references to SAMHSA waivers. Additionally, the reference to nurse practitioners is deleted because nurse practitioners prescribing buprenorphine is covered under regulations of the Board of Nursing (18VAC90-40-250).
21-140		Patient assessment and treatment planning for addiction treatment	References to addiction treatment and medication assisted treatment are changed to opioid use disorder. This is to reflect current terminology.

			Subsection A adds “liver function tests” to the required portions of an assessment of a patient. The Board feels that liver function tests are an important component of assessing risk of medication assisted treatment for any practitioner. Subsection B is amended to use the phrase “medications for opioid use disorder” in place of “medication assisted treatment,” consistent with current federal and practice terminology. Additionally, the phrase “how counseling will be accomplished” is replaced with “referral for counseling.” The Board, following the recommendation of the regulatory advisory panel, felt the requirement to document how counseling would be accomplished was too burdensome. The new requirement to include a referral for counseling in the treatment plan addresses the need to incorporate counseling into treatment while not holding the prescriber to unreasonable standards.
21-150		Sets out requirements for treating opioid use disorder with buprenorphine	“Addiction” is replaced with “opioid use disorder” and “medication assisted treatment” is replaced with “medications for opioid use disorder.” These changes occur in the caption and subsection E. These changes are intended to reflect current terminology and use less stigmatizing language. Subsection F is amended to remove the limit of 8mg of buprenorphine per day during the induction phase. Language is added stating that the dose during the induction phase should be individual to the patient, based on the patient’s history and current usage. This change is intended to allow practitioners to make clinical decisions based on the patient that presents before them rather than be limited to a set dosage amount. This practitioner-driven dosing is consistent with the CDC’s 2022 guidelines. Subsection H is amended to require practitioners to take steps to reduce chances of buprenorphine misuse, as well as diversion, by using the lowest effective dose, scheduling frequent office visits, performing pill counts, and checking the Prescription Monitoring

			Program. This addition is intended to clearly state that the intent of these safeguards is not simply to prevent diversion, but to ensure that the patient is appropriately using buprenorphine as it is prescribed. Subsection I is amended to increase the threshold at which rationale must be included in the medical record from 16 mg/day to 24 mg/day. Additionally, the ban on prescribing more than 24 mg/day is deleted. These changes are consistent with CDC 2022 guidelines and current medical practice. Subsection J is amended to change the requirement that a practitioner "assure that [relapse prevention strategies] are addressed by" a mental health service provider to "document referral to" a mental health services provider. Practitioners have no way to "assure" strategies are addressed by another health professional. Documentation of referral to a mental health service provider is a reasonable requirement that is attainable for prescribers. Additionally, the regulatory advisory panel and the Board felt that the limitation of a referral to only certain mental health providers was unnecessarily limiting. This is particularly true in the current environment, in which it is difficult to obtain appointments with any mental health practitioner.
21-160		Provides requirements for treating special populations with buprenorphine	Subsection A, which stated that pregnant women may be treated with the buprenorphine mono product usually at 16m/day or less, is deleted. CDC guidelines state that buprenorphine or methadone is the preferred treatment for pregnant women, not the buprenorphine mono product. Therefore this limitation and reference is deleted. Subsection E is deleted. The Board determined that eliminating patients with psychiatric comorbidities was unnecessarily limiting. Many patients who need treatment for opioid use disorder present psychiatric comorbidities, but those comorbidities are resolved with successful treatment for opioid use disorder. Excluding those

			patients from treatment keeps those patients from getting needed treatment.