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Final Regulation
Agency Background Document

Agency name	Board of Veterinary Medicine, Department of Health Professions
Virginia Administrative Code (VAC) citation(s)	18VAC150-20-10 et seq.
Regulation title(s)	Regulations Governing the Practice of Veterinary Medicine
Action title	Prescribing of opioids
Date this document prepared	3/15/18

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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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.

The Board proposes to replace emergency regulations for veterinarians prescribing of controlled substances containing opioids, including tramadol and buprenorphine, in response to the opioid abuse crisis in Virginia. Regulations for the management of pain include requirements for the evaluation of the patient, limitations on quantity and dosage, and record-keeping. Regulations provide requirements for prescribing an opioid beyond 14 days for pain, terminal illness, and certain chronic conditions, and allow for prescribing of in a dosage, quantity, and formulation appropriate for an animal species and size. Finally, there are requirements for continuation of treatment and for the content of the medical record.

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.

N/A

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 March 15, 2018, the Board of Veterinary Medicine adopted amendments to 18VAC150-20-10 et seq., Regulations Governing the Practice of Veterinary Medicine.

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 Veterinary 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 is required to adopt regulations by passage of HB2163 and SB1178 in the 2017 General Assembly in order for veterinarians to be able to prescribe buprenorphine:

54.1-3408.4. Prescription of buprenorphine without naloxone; limitation.

Prescriptions for products containing buprenorphine without naloxone shall be issued only (i) for patients who are pregnant, (ii) when converting a patient from methadone to buprenorphine containing naloxone for a period not to exceed seven days, or (iii) as permitted by regulations of the Board of Medicine, the Board of Nursing, or the Board of Veterinary Medicine.

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 to address the overdose and addiction crisis in the Commonwealth. The goal is to provide veterinarians 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 and to discourage pet owners from using their animals to obtain drugs.

Substance

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

Regulations specify that non-pharmacologic and non-opioid treatment for pain should be considered, but if an opioid is necessary, it should be prescribed in the lowest effective dose for the shortest period of time, not to exceed 14 days. Regulations for management of pain beyond 14 days and for terminal illnesses or chronic conditions include requirements for evaluation and treatment, including a treatment plan, consultation with an owner about storage and security, and record-keeping.

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. Although veterinarians prescribe opioids for animals, there is sufficient evidence to indicate that a small percentage of opioids are being diverted for human use. Therefore, 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. The primary disadvantage to the public may be that

more explicit rules for prescribing may result in some owners having to bring their animals for more frequent visits in order to continue receiving opioid medication.

2) The primary advantage to the Commonwealth is the potential reduction in the number of persons addicted to opioids and deaths from overdoses. 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.

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 are no applicable federal requirements.

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.

There is no impact on the family.

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
174 A 1	Defines a controlled substance for the purpose of this section	Addition of "to include tramadol and buprenorphine" after the word "opioid"	To clarify for practitioners that tramadol is an opioid and is therefore covered by these regulations and to include buprenorphine in the category of an opioid rather than separately regulated in subsection E.
174 A 3	Sets out requirements for prescribing for "acute" pain	Deletion of the word "acute" before pain Addition of the word "initial" before dose	There was confusion among practitioners about the distinction between acute and chronic pain, so those descriptive words were deleted. The word "initial" was added to clarify that the first dose could not exceed 14 days. Subsequently, the veterinarian can write for a longer period provided he follows the requirements in subsection B.
174 B	Sets out requirements for continuance of prescribing for a variety of reasons	Deletion of the word "chronic" before pain	See rationale above
174 B1	Requires a veterinarian prescribing for pain beyond 14 days to see and evaluate the patient	Addition of a sentence to clarify that continued prescribing beyond 14 days for terminal illnesses or certain chronic conditions does not require the veterinarian to see and re-evaluate the patient at the end of 14 days.	The revisions to #1 in subsection B were made in response to comment. If the prescribing is for palliative care in a terminal illness or to manage certain chronic conditions, there isn't a need to re-evaluate at the end of 14 days because the condition of the animal will not change in that time period.
174 B 2	Requires the veterinarian to assess the extent to which the pain or condition is associated with physical impairment	Deletion of the word "physical" before impairment	The revision was made in response to comment that the impairment in an animal may be behavioral rather than physical.
174 C	Requires the veterinarian to document a discussion about the risks and benefits of opioid therapy	Deletion of risks and benefits, but retention of responsibility for security and proper disposal of the drug	The revision was made in response to comment that "risks and benefits" are not necessarily applicable to animals.
174 E	Sets out the specific requirements for prescribing of	Deletion of the entire subsection	The revision was made in response to comment that the seven-day limitation was too restrictive. Rather than modify

	buprenorphine		the limit to 14 days, the Board determined that the general rules for prescribing opioids could be applicable to buprenorphine and a separate subsection was unnecessary.

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.

A public comment period on proposed regulations on prescribing opioids was open between December 11, 2017 and February 9, 2018.

There was a public hearing conducted before the Board on February 8, 2018, at which Dr. Barnett spoke in support of the requirement to prescribe opioids in the lowest effective dose appropriate to the size and species of the animal for the least amount of time and for the dose not to exceed a 14-day supply.

Public comment received by email or regular mail included:

Commenter	Comment	Board response
Maurice Casey, DVM	Any animal on long-term opioids should be rechecked and evaluated at a minimum of every 3 months or even monthly for the first 6 months. Other modalities should be included in long-term pain management.	The Board did not revise the requirement for an animal to be rechecked every six months with the exception for prescribing for pain, and in that case, the requirement is re-evaluation at the end of 14 days.
S. D. Foley, DVM	Does not believe regulations are necessary for veterinarians – imply that they do not use good judgment. Current protocols for managing pain without opioids; regs are aimed at post-operative pain management, which is always short term. Should set up a CE course to education veterinarians about the consequences of dispensing opioids and red flags to look for.	The Board has determined that regulations are necessary for public health and safety. The Board did not choose to require continuing education or to create a course; CE is provided by approved entities, which may choose to create such a course.
Eagle's Nest Animal Hospital	Commented in opposition to allowing national corporations to purchase veterinary practices	The comment is not applicable to the regulatory action
Jerry Hinn, DVM	Need a database similar to PMP for veterinary prescribing; Need to have a template of drug regulations incorporated into practice document to be signed by the client and practitioner Need to not make veterinary prescribers held to a more stringent standard than physicians	Recent legislation will require reporting to the PMP for any dispensing of a covered substance for more than seven days. There is no requirement for a "form" to be signed, so the Board has not created a template for documentation. Each practice may decide how to document.

		The veterinary regulations for prescribing of opioids are less stringent than those for human medicine.
Lori Leonard, DVM	• No mention of extenuating circumstances allowing prescribing beyond initial 14-day supply • Not clear when patient must be seen and evaluated (B1) • Question about intermittent pain therapy – how it is recorded and managed • Physical impairment should be expanded to include mental and general impairment (B2) • No opioids are approved for animal use, so it is unknown how a vet can discuss risks and benefits • Recommends 14 days or more for prescribing buprenorphine, as determined by vet • Comments on proper disposal of drugs doesn't really give options; pharmacies and law enforcement don't take back drugs. Questions who has responsibility if drugs are dispensed by a pharmacy • Questions the VVMA and the AAHA and malpractice carriers positions on regs • Questions position of Board of Pharmacy – these regs mandate certain actions when dispensing drugs, which is what pharmacists do; questions why vets are made to follow rules for handling, storage & dispensing of controlled substances • Asks about the penalty for not following the regulations • Asks about the re-evaluation – whether it must be in person or by electronic means • Asks about continuation of treatment beyond 14 days – Part B does not specify number of days for continuation of treatment • Asks about extenuating circumstances mentioned in A3 • Asks about the reference for standard of care • Putting this burden on practicing veterinarians is unfair, as well as abdicating responsibility and accountability where it belongs	Changes were made to several of the regulations in response to this comment. Other comments were general questions rather than comment on the regulation.
Lauri Fauss	Question about information provided to owners if more than one pet in a household is receiving opioid medication and about who signs forms	There is no requirement for forms; the veterinarian may document in the medical record in whatever format such record is maintained.
Va. Veterinary Medical Association	• Referenced legislation in 2018 General Assembly relating to requiring prescriptions in excess of 7 days to be dispensed by pharmacy; may need amendment to regs • A member requested clarification on prescribing buprenorphine over 7 days – is a	An amendment relating to reporting to the PMP will be added as an exempt action after the legislation becomes effective. The request about extending the limitation for prescribing of

	reexamination required every 7 days or reevaluation (by phone) • Appreciate the need to limit the potential for human abuse while allowing vets to provide appropriate pain management	buprenorphine was answered in the deletion of subsection E.

Public comment received through the Virginia Regulatory Townhall included:

Commenter	Comment	
Tyler Carmack, DVM	Asks for amendment to buprenorphine section allowing for the use of buprenorphine for a period of longer than 7 days if being used for chronic, palliative care. All clients sign a pain management contract, modeled on similar contracts in human medicine, discussing the risks and benefits of opioid therapy, the responsibility for the security of the drug, and proper disposal of any unused drug.	Amendments are consistent with the comment.
Theresa Gray, LVT	Supports the changes in regulation	The Board appreciates the comment.
Megan Kees, DVM	Appreciated changing the prescribing standard from 7 to 14 days (emergency regs to proposed regs). Regs appear to be reasonable for management of chronic conditions.	The Board appreciates the comment.
Kelly Gottschalk, DVM	Situations in which buprenorphine is indicated for chronic use, so there should be extenuating circumstances beyond 7 days within a re-examination	Amendment to delete subsection E
Julie Carlisle	Questions whether pets should be microchipped to prevent owner from taking pet to multiple veterinarians for opioid medications	The Board does not agree with the suggestion
Danielle Russ, LVT	Agree with Dr. Carmack's comment – 14 days is more reasonable.	The Board appreciates the comment.
Elizabeth Arguelles, DVM	Provide an exception to the 7-days rule for buprenorphine for chronic pain and for hospice patient, allowing for a 14-day supply as long as a treatment plan is in place; require re-examination every 6 months	Amendments will allow longer prescribing for chronic conditions and terminal illnesses.
Sarah Sheafor, DVM	Same comment as above – allow exemption for cats with chronic/terminal illnesses with monthly recheck exams	Amendments will allow longer prescribing for chronic conditions and terminal illnesses.
Kathy Kallay, DVM	Requests waiver of limitation of days for prescribing if pet has a terminal condition (palliative care)	Amendments will allow longer prescribing for chronic conditions and terminal illnesses.
Caroline Pattie	Mandatory day 7-14 day limit on opiates is impractical for cats and large dogs with mobility issues. Have not had concerns about diversion issues with owners	Amendments will allow longer prescribing after an initial dose for chronic conditions and terminal illnesses without having to see the animal.
Jason Bollenbeck, DVM	Supports tightening regulations but does not believe vets are part of the reason for the opioid crisis. Agrees with other comments about prescribing buprenorphine for cats, especially those chronically ill. Should be able to give a 30-day supply	Amendments will allow longer prescribing for chronic conditions and terminal illnesses.
Lori Leonard,	Comments summarized above	

DVA		
Lauri Fauss	Comment summarized above	

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.

Section number	Proposed requirements	Intent and likely impact of proposed requirements
174	Subsection A: 1. Establishes the definition for controlled substance as used in the section as a drug that contains an opioid. 2. Requires that non-pharmacologic and non-opioid treatment for pain be given consideration prior to treatment with opioids. Requires that, prior to initiating treatment with a controlled substance, as defined, the prescriber must perform a history and physical examination appropriate to the complaint and conduct an assessment of the patient's history as part of the initial evaluation. 3. Requires that, if a controlled substance is necessary for treatment of pain, the veterinarian must prescribe it in the lowest effective dose appropriate to the size and species of the animal for the least amount of time. The initial dose cannot exceed a 14-day supply.	In the Code of Virginia, controlled substances is defined as drugs in Schedules I through VI. For the purposes of requirements in this section, only the prescribing of drugs that contain an opioid is regulated. *Change to proposed:* *Addition of "to include tramadol and buprenorphine" after the word "opioid" to clarify for practitioners that tramadol is an opioid and is therefore covered by these regulations and to include buprenorphine in the category of an opioid rather than separately regulated in subsection E.* There is a requirement for an appropriate history and physical, and a limitation of a 14-day supply. 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 for animals but not addictive to humans. The intent of this subsection is to ensure that veterinarians prescribe opioids only when absolutely necessary, rather than as a routine treatment and that the prescription be limited in quantity and dosage.
174	Subsection B provides that a veterinarian may prescribe a controlled substance beyond 14 days for management of pain, terminal illnesses,	Regulations for veterinarians allow for prescribing beyond 14 days under certain conditions. If appropriate doses and quantities

	and certain chronic conditions, such as chronic heart failure, chronic bronchitis, osteoarthritis, collapsing trachea or related conditions, consistent with the accepted standard of care. For treatment of pain or a chronic condition with an opioid beyond 14 days, there must be a treatment plan that includes measures to be used to determine progress in treatment, further diagnostic evaluations or modalities that might be necessary, and the extent to which the pain or condition is associated with impairment.	are prescribed, such prescribing would be the accepted standard of care. For pain that extends beyond 14 days, the veterinarian must see and re-evaluate the patient to determine and document why it is necessary to continue prescribing an opioid. If the veterinarian is prescribing for a terminal illness or for certain chronic conditions, it is not necessary to re-evaluate at the end of 14 days. All patients on opioids must be seen at least every six months to ensure that the patient is still alive and that he still suffers from the same illness or condition.
	C. Prior to prescribing or dispensing a controlled substance, the veterinarian must document a discussion with the owner about the responsibility for the security of the drug and proper disposal of any unused drug.	The intent of this provision is to ensure that the veterinarian has discussed the responsibility of the owner of the animal for the safety and security of the medication to avoid opioids intended for animal use being abused or diverted for human use.
	D. Continuation of treatment with controlled substances shall be supported by documentation of continued benefit from the prescribing. If the patient's progress is unsatisfactory, the veterinarian shall assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.	The intent is to have documentation that the practitioner has a plan for monitoring the effectiveness of his prescribing. A veterinarian who is fully documenting and monitoring should not have to be concerned about compliance with law and regulation.
	Subsection E is deleted in the final action	According to § 54.1-3408.4, buprenorphine mono-product may only be prescribed by veterinarians in accordance with regulations adopted by the Board. Typically, it is prescribed for felines in small dosages and in trans-mucosal formulations, so it unlikely to be abused by humans. In response to comment on proposed regulation, it was determined that the requirements of subsections A and B could be applicable to buprenorphine, so a separate subsection was unnecessary.
	E. The medical record for prescribing controlled substances shall include signs or presentation of the pain or condition,	Requirements for the patient record in the treatment of a patient are consistent with the establishment of a bona fide veterinarian-patient-

	a presumptive diagnosis for the origin of the pain or condition, an examination appropriate to the complaint, a treatment plan and the medication prescribed to include the date, type, dosage, and quantity prescribed.	owner relationship and Board regulations for complete records.