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Proposed 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	8/24/17

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 (preferably no more than 2 or 3 paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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 in response to the opioid abuse crisis in Virginia. Regulations for the management of acute 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 terminal illness, chronic pain and certain chronic conditions, and allow for prescribing of buprenorphine 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

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable; and 2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person'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. A more detailed discussion is provided in the "Detail of changes" section below.

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 chronic pain, terminal illness, or chronic conditions beyond 14 days include requirements for evaluation and treatment, including a treatment plan, consultation with an owner about storage and security, and record-keeping. Regulations for prescribing of buprenorphine include a limitation of a seven-day supply with a re-examination required to prescribe beyond that period.

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 or buprenorphine.

Requirements more restrictive than federal

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

There 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.

Public participation

Please include a statement that in addition to any other comments on the proposal, the agency is seeking comments on the costs and benefits of the proposal and the impacts of the regulated community.

In addition to any other comments, the Board of Veterinary Medicine is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the agency/board is seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit written comments for the public comment file may do so by mail, email or fax to Elaine Yeatts at elaine.yeatts@dhp.virginia.gov or at 9960 Mayland Drive, Henrico, VA 23233 or by fax at (804) 527-4434.. Comments may also be submitted through the Public Forum feature of the Virginia Regulatory Town Hall web site at: http://www.townhall.virginia.gov. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

A public hearing will be held following the publication of this stage and notice of the hearing will be posted on the Virginia Regulatory Town Hall website (**http://www.townhall.virginia.gov**) and on the Commonwealth Calendar website

(https://www.virginia.gov/connect/commonwealth-calendar). Both oral and written comments may be submitted at that time.

Economic impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact.

Projected cost to the state to implement and enforce the proposed regulation, including: **a) fund source / fund detail; and** **b) a delineation of one-time versus on-going expenditures**	a) As a special fund agency, the Board must generate sufficient revenue to cover its expenditures from non-general funds, specifically the renewal and application fees it charges to practitioners for necessary functions of regulation; b) The agency will incur no additional costs for mailings to the Public Participation Guidelines mailing lists, conducting a public hearing, and sending notice of final regulations to regulated entities. Since most mailings to the PPG list are handled electronically, there is very little cost involved. Every effort will be made to incorporate those into anticipated mailings and Board meetings already scheduled. There are no on-going expenditures.
Projected cost of the new regulations or changes to existing regulations on localities.	None
Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.	Licensed veterinarians
Agency's best estimate of the number of such entities that will be affected. Please 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.	There are 4342 veterinarians licensed in Virginia. Almost all are employees of veterinary practices which would be considered small businesses.
All projected costs of the new regulations or changes to existing regulations for affected individuals, businesses, or other entities. Please be specific and include all costs including: **a) the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; and** **b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.**	The Board does not believe there are any additional costs associated with these proposed amendments.

Beneficial impact the regulation is designed to produce.	The primary benefit is a reduction in the amount of opioid medication that is available in our communities. Veterinarians should ensure that the prescribing of opioids is appropriate and necessary.

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. 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 regulation.

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 an opioid in the treatment of pain to protect the public health and safety.

The emergency regulations in this chapter, which are being replaced in this action, were drafted by a Regulatory Advisory Panel (RAP), comprised of veterinarians with different areas of practice and included two board members, the President of the Virginia Veterinary Medical Association (VVMA), a veterinarian recommended by the VVMA, and an assistant professor of anesthesiology at the VA-MD College of Veterinary Medicine. The Board considered comments on the NOIRA and to the extent consistent with public health and safety, recommendations from interested parties were incorporated into the proposed regulations.

Regulatory flexibility analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, please 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) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of 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 proposed regulation.

There are no alternative regulatory methods consistent with public health and safety, as demonstrated by the adoption of this regulation as an emergency action.

Public comment

Please summarize all comments received during the public comment period following the publication of the NOIRA, and provide the agency response.

Commenter	Comment	Agency response
Dianne Webb	Asks for consideration of a pet with chronic pain and kidney failure	There is no regulation that would prohibit a veterinarian from treating an animal with tramadol and gabapentin, the drugs the commenter mentioned.
Luke DelPo, DVM	Veterinarians are not significant contributors to the opioid crisis; opposes "ineffective" regulations	There is evidence that veterinarians are already being used by persons seeking opioids. Regulations have been modified and are reasonable. If followed, regulations will be effective in reducing amount of drugs unnecessarily prescribed.
David Morris, DVM	Requiring vets to inform clients of potential abuse may actually encourage abuse	The regulation requires discussion about the known risks and benefits; the Board does not agree that such a discussion will encourage abuse.
Miranda Ertel, DVM	Limiting a prescription to 7-day supply will leave patients inadequately managed; requiring a "re-check" after 7 days would lead to animal not receiving adequate medication. Concern about measuring progress in prescribing for chronic pain.	The seven-day limitation was modified in the proposed regulation. Regulations require a veterinarian to include in a treatment plan certain measures to determine the patient's progress and continued benefit from prescribing.
Tripp Stewart	Veterinarians are not responsible for the opioid crisis; opposes "reactionary" regulations	The Board does not agree.
Jan Larsen, DVM	Regulations will not solve the problem.	The Board understands that veterinary regulations will not solve the problem, but the intent is to ensure that veterinary prescribing does not contribute to the problem.
Nathan Higgins, DVM	Agreed with previous comments	See above
Danielle Russ, LVT	Agreed with comment above	See above
Dr. Kathy Kallay	Has owners resisting getting tramadol or buprenorphine because they have to come back in a week.	There is no requirement for the animal to be seen in one week in order to get a refill prescription.
Richard Godline, DVM	Agreed with previous comments; unnecessary burden on professionals that are not part of the opioid epidemic. No long term opioids are prescribed.	The veterinarian should not have a problem if he does not prescribe "long-term" opioids. The time limit was extended from 7 to 14 days in the proposed regulations.

Joseph May, DVM	Regulations are not necessary; veterinarians are already in compliance. Regulations not necessary for prescribing the buprenorphine. People who write regulations should use common sense about how changes affect practice.	Veterinarians already in compliance should not be concerned about regulation; emergency regulations were drafted by a panel of veterinarians who are very aware of how they affect practice. The Code of Virginia, as amended in 2017, prohibits prescribing of the mono-product except for pregnant women or as specified in regulations adopted by the Boards on Medicine, Dentistry and Veterinary Medicine. Without the proposed regulations, a veterinarian would not be allowed to prescribe buprenorphine mono-product for a cat, which is the most common use of the drug in veterinary care.
Stephanie Chmiel, DVM	Agreed with regulations except requirement to return after 7 days	Proposed regulations follow the commenter's recommendation to be able to prescribe a 14-day supply, with a recheck after 14 days for continuation of the prescription, and required rechecks every 6 months.
Sandy Christmus, DVM	Agreed with comment above	See above
Kelly Gottschalk, DVM	Regulations delineate best practices. Concern about the term "reevaluation" and whether that could be clarified	The Board has amended the emergency regulation accordingly.
Maggie Doran	Concern that she would have to bring her dog into the office every 6 months.	The Board does not believe it is appropriate to continue an animal on an opioid without an evaluation at least every 6 months.
Stefani Olsen	Opposed to regulations; does not stop drug diversion by practitioners and staff. Regulations will lead to unintended consequences	The Board has other regulations for drug security and takes action if there is evidence of diversion.
Geoff Stone	Should not use this as an opportunity to make more money	Reevaluation after a seven-day supply has been eliminated, but an animal on an opioid for more than 14 days needs to be rechecked.
Mark Johnson	Not a solution; a lack of understanding of drugs in veterinary practice	Regulations were drafted by veterinarians.
Mark Held, LVT	Same comment; negatives outweigh the positives	The Board does not agree. Without these regulations, Virginia law would prohibit all prescribing of buprenorphine mono-product for animals.
Chris Hussion, DVM	Same comment	See above

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.

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action. If the proposed regulation is intended to replace an emergency regulation, please follow the instructions in the text following the three chart templates below.

Section number	Proposed requirements	Other regulations and law that apply	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. 3. 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. 4. Requires that, if a controlled substance is necessary for treatment of acute 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 dose cannot exceed a seven-day supply, unless extenuating circumstances are clearly documented in the patient's record.	§ 54.1-3408.4 and 18VAC150-20-190	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. The requirements in numbers 2, 3 and 4 are similar to those in regulations for doctors of medicine, osteopathic medicine, and podiatry, nurse practitioners, physician assistants, and dentists. There is a requirement for an appropriate history and physical, and a limitation of a seven-day supply unless there are extenuating circumstances documented in the patient record. Prescribing beyond seven days requires a re-evaluation of the animal. The Boards of Dentistry and Medicine determined that a consistent 7-day limit was advisable. In each case, the

	5. Allows the veterinarian to prescribe a controlled substance for an additional seven days if it is medically necessary and consistent with an appropriate standard of care, and after a re-evaluation of the patient has been documented in the patient record.		prescriber can document circumstances that would warrant prescribing outside the limits. A specified limitation on days of prescribing will reduce the amount of unused or unnecessary opioids available for abuse or diversion. It will also encourage practitioners to prescribe non-opioid controlled substances that may be just as effective but not addictive. 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 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 chronic 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 physical impairment. For any prescribing of a controlled substance beyond 14 days, the patient must be seen and re-evaluated at least every six months, and the justification for such prescribing documented in the patient record.		Regulations for veterinarians allow for prescribing beyond 14 days for certain chronic conditions as listed. If appropriate doses and quantities are prescribed, such prescribing would be the accepted standard of care. For chronic pain that extends beyond 14 days, the veterinarian must re-evaluate the patient at least every 6 months and determine and document why it is necessary to continue prescribing an opioid.
	C. Prior to prescribing or dispensing a controlled substance, the veterinarian		The intent of this provision is to ensure that the veterinarian has

	must document a discussion with the owner about the known risks and benefits of opioid therapy, the responsibility for the security of the drug, and proper disposal of any unused drug.		discussed risks and benefits associated with opioids and 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.
	E. Prescribing of buprenorphine for out-patient administration shall only occur in accordance with the following: 1. The dosage, quantity, and formulation shall be appropriate for the patient; and 2. The prescription shall not exceed a seven-day supply. Any prescribing beyond seven days shall be consistent with an appropriate standard of care and only after a re-evaluation of the patient as documented in the patient record.		According to § 54.1-3408.4, buprenorphine mono-product may only be prescribed by veterinarians in accordance with regulations adopted by the Board. After consultation with members of the RAP and the VVMA, the Board determined that such prescribing should be appropriate to the species and size of the animal. Typically, it is prescribed for felines in small dosages and in trans-mucosal formulations, so it unlikely to be abused by humans.
	F. The medical record for prescribing controlled substances shall include signs or presentation of the pain or condition, 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.		Requirements for the patient record in the treatment of a patient are consistent with the establishment of a bona fide veterinarian-patient-owner relationship and Board regulations for complete records.

Current section number	Current requirement	Change from the emergency regulation
174	Sets out the requirements for	Subsection A 3 is amended to delete "seven-day" supply

Subsection A 3 and 4	evaluation of the patient and the need for prescribing. *3. If a controlled substance is necessary for treatment of acute pain, the veterinarian shall prescribe it in the lowest effective dose appropriate to the size and species of the animal for the least amount of time. The dose shall not exceed a seven-day supply, unless extenuating circumstances are clearly documented in the patient's record.* *4. The veterinarian may prescribe a controlled substance for an additional seven days if medically necessary and consistent with an appropriate standard of care, and after a reevaluation of the patient as documented in the patient record.*	and the phrase "unless extenuating circumstances area clearly documented in the patient's record. An amendment substitutes "14-day" supply of controlled substances for treatment of acute pain. *Some veterinarians found the time periods and the language about "extenuating circumstances" confusing and expressed concern about the Board's interpretation. In response, the Board amended the section to allow up to a 14-day supply, after which time the veterinarian may prescribe in accordance with rules for managing chronic pain or conditions.* Subsection A 4 is deleted to eliminate the requirement for "reevaluation" after seven days; many veterinarians raised questions about whether that necessitated a physical examination or reevaluation by telephone. By allowing an initial prescription up to 14 days, there is no need for reevaluation after seven days.
174 Subsection B	Sets out the requirements for prescribing and management of chronic pain and conditions with opioid treatment	Subsection B is amended to reorganize the provisions to make the regulation clearer. An amendment also added "terminal illnesses" to conditions for which a veterinarian may prescribe controlled substances beyond 14 days.
174 Subsection E	Sets out the rules for prescribing of buprenorphine	The word "reevaluation" is deleted and substituted with the word "reexamination" to clarify the meaning intended. Any prescribing of buprenorphine beyond seven days (which would be very unusual) necessitates a reexamination of the patient.