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Emergency Regulation and Notice of Intended Regulatory Action
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	4/24/17

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 of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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

Emergency regulations for veterinarians prescribing of controlled substances containing opioids are being promulgated as emergency regulations to address 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 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

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" was adoption of emergency regulations by the Boards of Medicine and Nursing setting out rules for prescribing of opioids and buprenorphine, and by the Board of Dentistry adoption of regulations for prescribing of opioids for acute pain. To ensure that opioids are not being abused and diverted for sale through veterinary prescribing, the Board of Veterinary Medicine has also adopted emergency regulations.

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 Dentistry 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 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 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.

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

Regulations in this chapter were drafted by a Regulatory Advisory Panel (RAP), comprised of two board members with different areas of practice, 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. To the extent consistent with public health and safety, recommendations from interested parties were incorporated into the regulations.

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
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	§ 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.

	clearly documented in the patient's record. 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.		The Boards of Dentistry and Medicine determined that a consistent 7-day limit was advisable. In each case, the prescriber can document circumstances that would warrant prescribing outside the limits. A specified limitation on days of prescribing will reduce the amount of unused or unnecessary opioids available for abuse or diversion. It will also encourage practitioners to prescribe non-opioid controlled substances that may be just as effective but not addictive. 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		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.

	record.		
	C. Prior to prescribing or dispensing a controlled substance, the veterinarian 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.		The intent of this provision is to ensure that the veterinarian has 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.

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.

The Board has an obligation to participate in the efforts to combat opioid addiction. There are no alternatives to the essential purpose of this 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 veterinarians in the appropriate prescribing of opioids to manage pain in animals in such a manner as to prevent diversion by human owners or others who have contact with such animals.