

Adverse impact notification sent to Joint Commission on Administrative Rules, House Committee on Appropriations, and Senate Committee on Finance (COV § 2.2-4007.04.C): Yes Not Needed

If/when this economic impact analysis (EIA) is published in the *Virginia Register of Regulations*, notification will be sent to each member of the General Assembly (COV § 2.2-4007.04.B).



Virginia Department of Planning and Budget Economic Impact Analysis

18 VAC 150-20 – Regulations Governing the Practice of Veterinary Medicine
Department of Health Professions
Town Hall Action/Stage: 4808/8041
October 18, 2017

Summary of the Proposed Amendments to Regulation

The Board of Veterinary Medicine (Board) proposes to amend its regulations to set rules for the prescribing of opioids other than buprenorphine for animals in need of acute or chronic pain treatment. Separately, the Board proposes to set rules for the prescription of buprenorphine for animals. This proposed regulation will replace an emergency regulation that became effective June 26, 2017 and will expire December 25, 2018.

Result of Analysis

There is insufficient information to ascertain whether benefits will outweigh costs for these regulatory changes.

Estimated Economic Impact

Board's Purpose:

The agency background document (ABD) states that the Board's purpose for promulgating these regulatory changes is to establish the "requirements for prescribing of controlled substances containing opioids to address the overdose and addiction crisis in the Commonwealth." The ABD also notes that the proposed regulation's "primary benefit is a reduction in the amount of opioid medication that is available in our communities."

Proposed Regulatory Requirements:

Prior to the promulgation of the expiring emergency regulation, there were no specific laws or regulations that set requirements for veterinarians' prescribing of opioids. In this proposed regulation, and the emergency regulation it will replace, the Board now proposes to require that veterinarians consider nonpharmacologic¹ and non-opioid² treatments for pain before considering an opioid. Veterinarians will also be required to perform a history and physical exam, as well as assess the patient animal's history as part of an initial evaluation. If an opioid medication is prescribed for the treatment of acute pain, the Board proposes to require that it be prescribed in the lowest effective dose appropriate to the size and species of the animal patient and for the least amount of time possible. For acute pain, the Board proposes to limit any prescriptions for opioids to a 14-day supply.

The Board proposes to specify that treatment with opioids past an initial 14-day supply may only occur if that prescribing is within the accepted standard of care and is for the treatment of chronic pain, end-of-life pain, or for certain chronic conditions.³ The Board proposes to require that animal patients being treated for chronic or end-of-life conditions be seen and evaluated for the continued need for opioid treatment after the initial 14-day prescription. For any opioid treatment that will last longer than 14 days, veterinarians will be required to develop a treatment plan that includes "measures to be used to determine progress, further diagnostic evaluations or modalities that might be necessary, and the extent to which the pain or condition is associated with physical impairment." Thereafter, the Board proposes to require re-evaluation of the patient animal every six months and that justification for continued prescribing of opioid medication be documented in the patient animal's records.

The Board also proposes to limit the prescribing of buprenorphine (for out-patient administration) to (1) a dosage, quantity and formulation appropriate for the patient animal, (2) an initial prescription of seven days, with any extension requiring a re-examination of the patient animal. The veterinarian will be required to document in the patient animal's records the re-

¹ Board staff reports that nonpharmacologic treatments can include such treatments as acupuncture, physical therapy, hydrotherapy and heat therapy.

² Board staff and other sources reports that non-opioid treatments include ibuprofen, acetaminophen and aspirin.

³ The proposed regulation lists chronic heart failure, chronic bronchitis, collapsing trachea "or other related conditions" as chronic conditions that would allow a veterinarian to prescribe opioids.

examination, and that continued treatment with buprenorphine is consistent with an appropriate standard of care.

Prior to prescribing any opioid medications, the Board proposes to require veterinarians discuss with pet owners the known risks and benefits of opioid therapy, the owners' responsibility to secure opioid medications while in use, and how to properly dispose of any unused medication. Veterinarians will be required to document these discussions. The Board also proposes to specify that "continuation of treatment with controlled substances shall be supported by documentation of continued benefit from the prescribing." If a patient animal's progress is unsatisfactory, the Board proposes to require that veterinarians assess the appropriateness of continued opioid therapy and consider the use of other treatments. Additionally, the Board proposes to require that any medical record for prescribing controlled substances include "signs or presentation of pain or condition, a presumptive diagnosis of 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."

Benefits and Costs for Proposed Regulatory Requirements:

As noted above, the primary benefit identified by the Board is a reduction in the amount of opioid medication available in Virginia communities. Other benefits identified in the ABD include:

- the "potential reduction in the number of persons addicted to opioids and deaths from overdoses;"
- providing "veterinarians with definitive rules to follow so they may feel more assured of their ability to treat pain in an appropriate manner to avoid underprescribing or over-prescribing;" and
- to "discourage pet owners from using their animals to obtain drugs."

The magnitude of the opioid crisis in Virginia is described in the ABD, which notes 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. (This includes heroin and fentanyl.) Moreover, 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. The ABD also notes that many individuals who become addicted to heroin started with an addiction to prescription drugs, and the federal Drug

Enforcement Administration observes that “fentanyl can serve as substitute for heroin in opioid dependent individuals.”⁴ Therefore, in order to stem the tide of addiction, the Board states that practitioners need enforceable rules for proper prescribing of opioids.

Analysis of Regulatory Effects Is Hindered by Lack of Key Information. The ABD appears to suggest that the opioid crisis substantially results from prescription opioids. The harm the regulation is intended to address occurs either directly, from misuse of prescription opioids, or indirectly, wherein misuse of prescription opioids leads to misuse of other substances. No data appear to exist, however, that could be used to analyze the magnitude to which this may occur in Virginia. As noted below, available data indicate that prescription opioids are a leading cause or contributing factor in overdoses in Virginia. On the other hand, data indicate that the driver of fatal drug overdoses in Virginia is illicit fentanyl, not prescription opioids. Moreover, no data appear to exist that indicate the number of Virginians who misuse a prescription opioid and then become addicted to, or fatally overdose on, a non-prescription opioid. To the extent that the regulation reduces the amount of opioids in Virginia communities, and the number of persons addicted to opioids or deaths from overdoses, a benefit would be conferred. However, given the lack of data available to measure these outcomes, DPB staff were not able to calculate the extent to which this benefit may result.

Most of the drug-related deaths in Virginia since 2015 have resulted from sources other than prescription opioids. The Office of the Chief Medical Examiner (OCME) reports that “there has not been a significant increase or decrease in fatal prescription opioid overdoses” in the nine-year period from 2007 to 2016.⁵ Instead, the OCME notes that fentanyl “has caused the significant rise in all fatal opioid overdoses in the Commonwealth since 2012.” More specifically, OCME data indicate that prescription opioids (excluding fentanyl) caused or contributed to, on average, 443 deaths each year during this time period. In contrast, during 2015 to 2016 alone the OCME reports that “fatal fentanyl overdoses increased by 176.4 percent,” accounting for 622 deaths in 2016, an increase from 225 in 2015.⁶

⁴ https://departments.arlingtonva.us/wp-content/uploads/sites/6/2017/06/heroin_fentanyl_brochure.pdf

⁵ http://www.vdh.virginia.gov/content/uploads/sites/18/2016/04/Fatal-Drug-Overdoses-Quarterly-Report-Q1-2017_Updated.pdf

⁶ OCME data indicate that more than 90 percent of fentanyl-related deaths result from illicit fentanyl.

These drug-related deaths, however, are often caused by more than one drug. Accordingly, the data reported by OCME on the number of deaths from a given drug frequently include deaths where more than one drug was “on board.” As noted by the OCME, a single cocaine, heroin, and alprazolam overdose death will be counted three times: once under each class of drug. Because of the frequency of these “polypharmacy” results, no specific data exist on the number of deaths in Virginia that result from just one drug, such as prescription opioids.

DPB staff were not able to identify any data indicating the number of persons in Virginia who have become addicted or died to opioids as a result of diversion or misuse of opioids, including prescriptions to animals. In part this results from the presence of the polypharmacy results noted above, which hinder an assessment of the actual number of people who die from prescription opioids. And though national survey data⁷ and other studies indicate that 65 to 75 percent of heroin abusers began with prescription opioids,⁸ no discrete data appear to exist on the number of Virginians who become addicted or the deaths that may occur.

Regulatory Requirements Affecting the Commonwealth. According to the ABD, there is sufficient evidence to indicate that a small percentage of opioids prescribed by veterinarians for animals are being diverted for human use. Although not specifically stated in the ABD, it appears that the kind of diversion the regulation is intended to address would occur outside of the veterinarian’s office, by either the pet’s owner or other persons who gain access to the prescribed opioid. DPB staff were able to identify an instance of “veterinarian shopping” that occurred in Fairfax County in 2016. According to a brochure published by the Franconia District, *Drug Diversion Information for Veterinarians*,⁹ a dog owner brought his pet to six different veterinarians and received multiple prescriptions for Xanax and Tramadol (an opioid).

Regulatory Requirements Affecting Veterinarians. The ABD also indicates that veterinarians will benefit from the presence of definitive rules for prescribing opioids. Any benefit that might be realized from this proposed regulation would have to be weighed against costs that may be incurred by veterinarians. To the extent that veterinarians’ current record

⁷ <https://www.drugabuse.gov/publications/research-reports/relationship-between-prescription-drug-heroin-abuse/prescription-opioid-use-risk-factor-heroin-use>

⁸ *Fentanyl in the US heroin supply: A rapidly changing risk environment*, International Journal of Drug Policy 46 (2017) 107–111.

⁹ https://www.washingtonpost.com/r/2010-2019/WashingtonPost/2017/08/30/Health-Environment-Science/Graphics/Drug-Diversion-Brochure.pdf?tid=a_inl

keeping and drug consultation practices differ from the requirements proposed by the Board, they will likely incur time and record keeping costs on account of the proposed regulation. Some veterinarians may also incur costs defending against Board disciplinary actions regarding their decisions to prescribe opioids, their record keeping, or other practices.

Regulatory Requirements Affecting Pet Owners. The benefits accruing to pet owners appear to be mixed, depending upon the species, the nature of their health concerns, and the efficacy of non-opioid treatments. The ABD notes that because of a bill passed during the 2017 Session,¹⁰ “without these regulations, Virginia law would prohibit all prescribing of buprenorphine mono-product for animals.” Accordingly, the regulation would confer a benefit by allowing prescriptions for buprenorphine mono-product. Board staff report, in the Board’s answer to a commenter at the emergency stage of this regulation, that the most common use of buprenorphine in veterinary medicine is to treat pain in cats.¹¹ Board staff further reports that the dosages typically prescribed for felines are small and are unlikely to be abused by humans.

As noted by the Board in the ABD, some other pet owners, whose animals are prescribed opioids other than buprenorphine, may incur additional fees for additional office visits.¹² These fees are most likely for owners of pets with chronic or end-of-life conditions, or whose otherwise need a prescription that exceeds 14 days. DPB staff obtained one estimate of approximately \$50 for a simple office visit¹³ with no tests ordered or vaccines given. Costs incurred at any individual veterinarian’s office may vary from that estimate.

In addition, to the extent that this proposed regulation leads veterinarians to order more nonpharmacologic treatments rather than, or in addition to, prescribing opioids, pet owners will likely incur increased costs for those treatments. The potential exists for any reduction in medication to result in unrelieved pain in animal patients, but the extent to which this may occur could not be determined. DPB staff obtained several estimates for the cost of animal

¹⁰ <https://lis.virginia.gov/cgi-bin/legp604.exe?171+ful+CHAP0794>

¹¹ According to the agency background document, small doses of a trans-mucosal (liquid) formulation of buprenorphine are prescribed for cats.

¹² DPB called several veterinarians’ offices and found that re-examination policies varied from office to office with some offices already having policies similar to those in the Board’s proposed regulation and some only requiring annual re-examination if an animal is doing well on their opioid prescription.

¹³ Most re-examinations would likely be simple office visits with no additional charges.

acupuncture¹⁴ that ranged from \$146 to \$160 for initial consultation and approximately \$85 for each treatment thereafter.¹⁵ Again, costs incurred at any individual veterinarian's office may vary from these estimates.¹⁶

Businesses and Entities Affected

These changes will affect all veterinarians in Virginia as well as all pet owners who use their services. Board staff reports that there are 4,342 veterinarians licensed by the Board, and that almost all veterinarians work for veterinary practices that would be considered small businesses.

Localities Particularly Affected

No localities will be particularly affected by this proposed change.

Projected Impact on Employment

This regulatory action is unlikely to have any effect on employment in the Commonwealth.

Effects on the Use and Value of Private Property

This proposed regulatory change is unlikely to affect the use or value of private property in the Commonwealth.

Real Estate Development Costs

These proposed regulatory changes are unlikely to affect real estate development costs in the Commonwealth.

Small Businesses:

Definition

Pursuant to § 2.2-4007.04 of the Code of Virginia, small business is defined as “a business entity, including its affiliates, that (i) is independently owned and operated and

¹⁴ DPB also obtained cost estimates for laser treatments from one veterinarian's office. Those treatments at that office are \$52 per treatment or a bundle of six treatments for \$277. Another veterinarian's office that offers underwater treadmill treatments reported that the initial consultation for those treatments is \$160 with additional charges for each treatment thereafter.

¹⁵ One source also reported that frequency of required visits would vary. Treatment for acute conditions would usually require a series of treatments over several weeks and treatment for chronic conditions would usually require less frequent treatments which could be once a month or once every several months.

¹⁶ These costs would likely be incurred either in addition to, or instead of, the costs for opioid medications. DPB obtained an estimate of \$20 for the cost of filling a prescription for 100 tablets of tramadol of a dosage appropriate for an 85-pound dog. This cost would likely vary for different medications, dosages and number of pills dispensed and may vary by veterinarian's office or pharmacy.

(ii) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.”

Costs and Other Effects

Small businesses veterinarians will likely incur additional time and record keeping costs on account of this proposed regulation.

Alternative Method that Minimizes Adverse Impact

There are likely no alternative methods that would both further minimize costs for affected small businesses and meet the Board’s aims in promulgating this regulation.

Adverse Impacts:

Businesses:

Veterinary practices will likely incur additional time and record keeping costs on account of this proposed regulation.

Localities:

No locality is likely to suffer adverse impacts on account of this proposed regulatory change.

Other Entities:

Some affected pet owners are likely to incur additional office visit costs for their pets on account of the proposed regulation’s requirement that (1) pets being treated for chronic pain with opioids other than buprenorphine be seen by their veterinarian after 14 days and every six months thereafter, and (2) that animals being treated with buprenorphine be re-examined after seven days. Pet owners may also incur additional costs for nonpharmacologic treatments for their pets if this proposed regulation causes veterinarians to order those treatments more frequently. Cat owners may be disproportionately affected by the limitations on prescription of buprenorphine.

Legal Mandates

General: The Department of Planning and Budget has analyzed the economic impact of this proposed regulation in accordance with § 2.2-4007.04 of the Code of Virginia (Code) and Executive Order Number 17 (2014). Code § 2.2-4007.04 requires that such economic impact analyses determine the public benefits and costs of the proposed amendments. Further the report should include but not be limited to: (1) the projected number of businesses or other entities to whom the proposed regulatory action would apply, (2) the identity of any localities and types of businesses or other entities particularly affected, (3) the projected number of persons and employment positions to

be affected, (4) the projected costs to affected businesses or entities to implement or comply with the regulation, and (5) the impact on the use and value of private property.

Adverse impacts: Pursuant to Code § 2.2-4007.04(C): In the event this economic impact analysis reveals that the proposed regulation would have an adverse economic impact on businesses or would impose a significant adverse economic impact on a locality, business, or entity particularly affected, the Department of Planning and Budget shall advise the Joint Commission on Administrative Rules, the House Committee on Appropriations, and the Senate Committee on Finance within the 45-day period.

If the proposed regulatory action may have an adverse effect on small businesses, Code § 2.2-4007.04 requires that such economic impact analyses include: (1) an identification and estimate of the number of small businesses subject to the proposed regulation, (2) the projected reporting, recordkeeping, and other administrative costs required for small businesses to comply with the proposed regulation, including the type of professional skills necessary for preparing required reports and other documents, (3) a statement of the probable effect of the proposed regulation on affected small businesses, and (4) a description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed regulation. Additionally, pursuant to Code § 2.2-4007.1, if there is a finding that a proposed regulation may have an adverse impact on small business, the Joint Commission on Administrative Rules shall be notified.