Virginia Regulatory Town Hall

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Fast Track Proposed Regulation
Agency Background Document

Agency name	Board of Veterinary Medicine, Department of Health Professions
Virginia Administrative Code (VAC) citation	18VAC150-20-10 et seq.
Regulation title	Regulations Governing the Practice of Veterinary Medicine
Action title	Drug destruction
Date this document prepared	8/12/10

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

Please provide a brief summary (no more than 2 short 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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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.

Currently, regulations specify that veterinarian must follow the instructions contained in the drug destruction packet available from the board office which provides the latest U.S. Drug Enforcement Administration (DEA) approved drug destruction guidelines. However, the DEA no longer has a "drug destruction packet." Therefore, amended regulations set out the guidance of the DEA for drug destruction, which includes transferring drugs to another entity or destroying by incineration which meets local, state and federal requirements.

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.

The Board of Veterinary Medicine amended 18VAC150-20-10 et seq., Regulations Governing the Practice of Veterinary Medicine on July 20, 2010.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., the agency, board, or person. Describe the scope of the legal authority and the extent to which the authority is mandatory or discretionary.

Chapter 24 of Title 54.1 establishes the general powers and duties of health regulatory boards including the responsibility of the Board of Veterinary Medicine to promulgate regulations. and administer a licensure and renewal program.

§ 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 and Chapter 25 of this title.

Chapter 38 of Title 54.1 establishes the specific powers of Board:

In addition to the powers granted in § 54.1-2400, the Board shall have the following specific powers and duties:

1. To establish essential requirements and standards for approval of veterinary programs.

2. To establish and monitor programs for the practical training of qualified students of veterinary medicine or veterinary technology in college or university programs of veterinary medicine or veterinary technology.

3. To regulate, inspect and register all establishments and premises where veterinary medicine is practiced.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail 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 amended regulation is to update requirements for drug destruction, consistent with current DEA policies and rules. Proper destruction of drugs is essential to protect the health and safety of citizens who may be affected by improper flushing, incineration or disposal in a landfill. Use of expired drugs that may be ineffective could affect the health and welfare of animals, who are patients of veterinarians.

Rationale for using fast track process

Please explain the rationale for using the fast track process in promulgating this regulation. Why do you expect this rulemaking to be noncontroversial?

This regulation is appropriate for the fast-track process because the agency does not have the option of continuing the current regulation, which calls for following instructions in a DEA package that no longer exists. The amendment states the guidance of the DEA for drug destruction and is identical to the regulation for drug destruction by other entities that stock drugs.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (Provide more detail about these changes in the "Detail of changes" section.)

The amendments to section 190 delete the requirement that Schedule II through V drugs be destroyed by following the instructions contained in the drug destruction packet available from the board office which provides the latest U.S. Drug Enforcement Administration approved drug destruction guidelines. The amendments specify that the drugs can be destroyed by: 1) transferring the drugs to another entity authorized to possess or provide for proper disposal of such drugs; or 2) destroying the drugs by burning in an incinerator that is in compliance with applicable local, state, and federal laws and regulations. Regulations further provide that if Schedule II through V drugs are to be destroyed, a DEA drug destruction form shall be fully completed and used as the record of all drugs to be destroyed. A copy of the destruction form shall be retained at the veterinarian practice site with other inventory records.

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 would be the timely and effective destruction of stocks of unused, expired or adulterated prescription drugs that could find their way into illegal distribution or abuse. For those reasons, the DEA has a drug destruction form that should be completed by any entity that has the legal authority to maintain a stock of controlled substances. There are no disadvantages to the public, which is better protected by the proper destruction of prescription drugs.
2) There are no advantages or disadvantages to the agency;

3) There are no other pertinent matters of interest.

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.

The requirements are not more restrictive than federal requirements for destruction of drugs.

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.

Regulatory flexibility analysis

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 were no alternative regulatory methods; the current regulations are ineffective and inaccurate and needed to be updated.

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 some one-time costs (less than $1,000) for mailings to the Public Participation Guidelines mailing lists, conducting a public hearing, and sending notice of final regulations to regulated entities. Every effort will be made to incorporate those into anticipated mailings and Board meetings already scheduled. There are no additional on-going costs relating to these regulations.
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*.	The entities that are likely to be affected by these regulations would be veterinary establishments that have a stock of expired or tainted drugs that must be destroyed.
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 (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	There are 709 full service veterinary facilities and 240 restricted service veterinary facilities. Most of the facilities would be classified as 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. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses. 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.	Since use of a reverse distributor is currently the common method for drug disposal, there are no projected costs for the amended regulations. According to board members who use reverse distributors, costs typically average $125 to $150 per year for a contract with a reverse distributor.
Beneficial impact the regulation is designed to produce.	Specific rules for legal destruction of drugs prevent unused drugs from being abused or diverted.

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.

Since the regulation is clearly outdated and a "drug destruction package" from the DEA no longer exists, there was no alternative other than puts the current guidance of the DEA in regulations for consistency with other entities that maintain a stock of drugs.

The amendments reflect current policies and DEA rules. In the "Practitioner's Manual" issued by the Office of Diversion Control of the U. S. Department of Justice, Drug Enforcement Administration, the disposal of controlled substances is in Section IV or Recordkeeping Requirements. It advised that a practitioner may "dispose of out-of-date, damaged or otherwise unusable or unwanted controlled substances, including samples, by transferring them to a registrant who is authorized to receive such materials. These registrants are referred to as "Reverse Distributors." The practitioner should contact the local DEA field office for a list of authorized Reverse Distributors."

DEA further specifies that Schedule II should be transferred via the DEA Form 222 and that Schedule III-V drugs may be transferred via invoice. The practitioner should maintain copies of the records documenting the transfer and disposal of controlled substances for a period of two years.

Family impact

Please assess the impact of the proposed 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 or family stability.

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact in each section. Please describe the difference between the requirements of the new provisions and the current practice or if applicable, the requirements of other existing regulations in place.

If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all provisions of the new regulation or changes to existing regulations between the pre-emergency regulation and the proposed regulation, and (2) only changes made since the publication of the emergency regulation.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
190	n/a	Sets out requirements for drug storage, dispensing, destruction and records for veterinary establishments.	Subsection E is amended to eliminate the requirement that Schedule II, III, IV and V drugs be destroyed by following the instructions contained in the drug destruction packet available from the board office which provides the latest U.S. Drug Enforcement

			Administration approved drug destruction guidelines and to replace with rules for destruction by: 1) transferring the drugs to another entity authorized to possess or provide for proper disposal of such drugs; or 2) destroying the drugs by burning in an incinerator that is in compliance with applicable local, state, and federal laws and regulations. *The entity that is authorized to possess and provide for proper disposal of drugs is known as a reverse distributor; such entities are commonly used by pharmacies and hospitals for drug destruction and are available for use by veterinary establishments as well.* If Schedule II through V drugs are to be destroyed, a DEA drug destruction form shall be fully completed and used as the record of all drugs to be destroyed. A copy of the destruction form shall be retained at the veterinarian practice site with other inventory records. *A record of drug destruction is absolutely essential for the establishment's accountability for the drugs in its inventory. DHP inspectors check drug records for administration, dispensing or destruction to reconcile the stock of drugs ordered by an establishment. Subsection H of section 190 requires:* *"Original invoices for all Schedule II, III, IV and V drugs received shall be maintained in chronological order on the premises where the stock of drugs is held and actual date of receipt is noted. Invoices for Schedule II drugs shall be maintained separately from other records. All drug records shall be maintained for a period of two years from the date of transaction."*