Regulatory Analysis Form

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INDEPENDENT REGULATORY REVIEW COMMISSION

(1) Agency

Department of State, Bureau of Professional and Occupational Affairs, State Board of Veterinary Medicine

(2) I.D. Number (Governor's Office Use)

16A-5712

IRRC Number: 2276

(3) Short Title

Prescription Drugs

(4) PA Code Cite

49 Pa. Code § 31.21
(Principle 8)

(5) Agency Contacts & Telephone Numbers

Primary Contact: **Teresa Lazo-Miller, Counsel**
State Board of Veterinary Medicine (717) 783-7200
Secondary Contact: **Joyce McKeever, Deputy Chief Counsel, Department of State (717) 783-7200**

(6) Type of Rulemaking (check one)

___**Proposed Rulemaking**
_X_**Final Order Adopting Regulation**
___**Policy Statement**

(7) Is a 120-Day Emergency Certification Attached?

_X_ **No**
___ **Yes: By the Attorney General**
___ **Yes: By the Governor**

(8) Briefly explain the regulation in clear and nontechnical language.

The regulation would: require veterinarians to dispense prescription drugs, other than for food animals, in child resistant or original packaging; require veterinarians to put pertinent information on prescription drug labels; require veterinarians to dispense or administer only current, unexpired medications; provide that a veterinarian will not be disciplined for refusing to issue a written prescription under certain circumstances; and reference the Board's regulations and Federal law relevant to record-keeping related to drugs.

(9) State the statutory authority for the regulation and any relevant state or federal court decisions.

Section 5(2) of the Veterinary Medical Practice Act (Act), Act of December 27, 1974, P.L. 995, No. 326 as amended, 63 P.S. §485.5(2) authorizes the Board to adopt regulations regarding professional conduct.

Regulatory Analysis Form

(10) Is the regulation mandated by any federal or state law or court order, or federal regulation? If yes, cite the specific law, case or regulation, and any deadlines for action.

No. However, federal law contains mandates for packaging and labeling prescription drugs intended for human consumption.

(11) Explain the compelling public interest that justifies the regulation. What is the problem it addresses?

Many drugs dispensed for companion animals are stored in homes with children. The same safety concerns that prompted legislation requiring child resistant packaging for drugs intended for human consumption therefore apply to veterinary drugs that are dispensed for companion animals. In addition, many drugs dispensed for other types of animals may be stored in an area to which children have access. The public interest in requiring child resistant packaging would be addressed by the regulation. Labeling drugs ensures that the drug can be identified.

(12) State the public health, safety, environmental or general welfare risks associated with nonregulation.

Poisoning may result from the accidental ingestion of prescription drugs. This danger is increased if drugs are not packaged in child resistant packaging. The Board's proposed regulation would reduce the risk of accidental poisoning. In addition, the proposed regulation would facilitate treatment by requiring that drugs be labeled.

(13) Describe who will benefit from the regulation. (Quantify the benefits as completely as possible and approximate the number of people who will benefit.)

The general public will benefit from having veterinary drugs dispensed in child resistant packaging. In addition, the general public will benefit from the requirement that veterinarians administer and dispense only current, unexpired medications because these medications are effective in treating diseases of animals. Finally, the general public will benefit from the regulation that veterinarians exercise professional judgment in determining whether or not to provide a prescription to a client because veterinarians serving food-producing animals are better able to monitor the use of drugs in the animals and are, therefore, better able to protect the quality of the food supply.

Regulatory Analysis Form

(14) Describe who will be adversely affected by the regulation. (Quantify the adverse effects as completely as possible and approximate the number of people who will be adversely affected.)

There are approximately 4,700 licensed veterinarians in Pennsylvania who might be adversely affected by the regulation. The adverse effect would be in the form of additional costs to package prescription drugs in child resistant packaging and in labeling prescription drugs. However, many veterinarians already dispense prescription drugs in child resistant packaging. Moreover, veterinarians that dispense prescription drugs only in original packaging will not be affected by the proposed regulatory change. In addition, there is an exception for clients who may have difficulty opening child resistant packaging.

(15) List the persons, groups or entities that will be required to comply with the regulation. (Approximate the number of people who will be required to comply.)

All licensed veterinarians in the Commonwealth of Pennsylvania would be required to comply with the regulation. As stated above, there are approximately 4,700 licensed veterinarians in the Commonwealth of Pennsylvania.

(16) Describe the communications with and input from the public in the development and drafting of the regulation. List the persons and/or groups who were involved, if applicable.

In developing and drafting the regulation, the Board solicited comment from the Pennsylvania Veterinary Medical Association, regional veterinary medical associations, associations of animal health technicians and schools of veterinary medicine.

(17) Provide a specific estimate of the costs and/or savings to the regulated community associated with compliance, including any legal, accounting or consulting procedures which may be required.

The Board projects that the regulated community will experience only minimal additional costs in procuring child resistant packaging over regular packaging and in meeting the requirement of labeling prescription drugs. In addition, many veterinarians in the Commonwealth already dispense prescription medications, particularly for companion animals, in safety closure packaging.

Regulatory Analysis Form

(18) Provide a specific estimate of the costs and/or savings to local governments associated with compliance, including any legal, accounting or consulting procedures which may be required.

There are no specific costs or savings to local governments associated with the regulation.

(19) Provide a specific estimate of the costs and/or savings to state government associated with the implementation of the regulation, including any legal, accounting, or consulting procedures which may be required.

There are no specific costs or savings to the state government associated with implementation of the regulation.

Regulatory Analysis Form

(20) In the table below, provide an estimate of the fiscal savings and costs associated with implementation and compliance for the regulated community, local government, and state government for the current year and five subsequent years.

	Current FY	FY +1	FY +2	FY +3	FY +4	FY +5
SAVINGS:						
Regulated Community	0	0	0	0	0	0
Local Government	0	0	0	0	0	0
State Government	0	0	0	0	0	0
Total Savings						
COSTS:						
Regulated Community	minimal	minimal	minimal	minimal	minimal	minimal
Local Government	0	0	0	0	0	0
State Government	0	0	0	0	0	0
Total Costs						
REVENUE LOSSES:						
Regulated Community	0	0	0	0	0	0
Local Government	0	0	0	0	0	0
State Government	0	0	0	0	0	0
Total Revenue Losses						

(20a) Explain how the cost estimates listed above were derived.

Based on its own members' experience in purchasing child resistant packaging, the Board projects that there will be only a minimal additional cost to the regulated community to comply with the regulation.

Regulatory Analysis Form

(20b) Provide the past three year expenditure history for programs affected by the regulation.

N/A	FY 99-00	FY 00-01	FY 01-02	FY 02-03
Program	**FY -3**	**FY -2**	**FY -1**	**Current FY**
Veterinary Board	**197,487.51**	**348,088.02**	**341,658.88**	**300,000.00**

(21) Using the cost-benefit information provided above, explain how the benefits of the regulation outweigh the adverse effects and costs.

The benefits outweigh the minimal costs of the regulation in protecting the safety of the population, particularly that of children who are especially vulnerable to accidental poisoning.

(22) Describe the nonregulatory alternatives considered and the costs associated with those alternatives. Provide the reasons for their dismissal.

Because Section 5(2) of the Act, 63 P.S. § 485.5(2) provides that the Board is to adopt rules of professional conduct by promulgating regulations, the Board considered no nonregulatory alternatives to achieve the goals.

(23) Describe alternative regulatory schemes considered and the costs associated with those schemes. Provide the reasons for their dismissal.

The Board considered numerous alternative regulatory schemes including requiring that all medications rather than just prescription drugs be placed in safety closure packaging, and requiring that veterinarians release a prescription to any client who requests one. The Board restricted its regulation to the packaging of prescription drugs, which is consistent with federal law. In addition, the Board determined that a veterinarian should be permitted to exercise professional judgment in determining whether or not to provide a client with a written prescription rather than a dispensed medication, based on numerous comments from farm and food animal practitioners warning of dangers to the food supply should the regulation require a veterinarian to provide a prescription.

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(24) Are there any provisions that are more stringent than federal standards? If yes, identify the specific provisions and the compelling Pennsylvania interest that demands stronger regulation.

None of the provisions of the regulation are more stringent than federal standards.

(25) How does this regulation compare with those of other states? Will the regulation put Pennsylvania at a competitive disadvantage with other states?

This regulation is similar to that in some of the states surrounding Pennsylvania and will not put Pennsylvania at a competitive disadvantage. Maryland requires that veterinarians dispense only unexpired medications. (Code of Maryland Regulations 15.14.01.12). West Virginia requires veterinarians to dispense repackaged drugs for companion animals in approved child resistant packaging, except upon the specific request of the client. (West Virginia Code of State Rules, tit. 26, §4-3.5(D). West Virginia also requires veterinarians to include information on the label of a dispensed drug, similar to the information required by the regulation. (West Virginia Code of State Rules, tit. 26 §6-3.5(D)). New Jersey's Veterinary Board regulations also require specific information on the label of a dispensed veterinary drug. (New Jersey Administrative Code, tit. 13:44, §4.1(a)). Delaware and New York do not specifically address labeling, packaging, or dispensing requirements.

(26) Will the regulation affect existing or proposed regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations.

This regulation will not effect any existing or proposed regulations of the Board or other state agencies.

(27) Will any public hearings or informational meetings be scheduled? Please provide the dates, times, and locations, if available.

The Board holds public meetings on a monthly basis and public comment at the meetings is invited. The 2003 meetings of the State Board of Veterinary Medicine are as follows: March 13, May 22, July 17, September 4, October 23 and December 4, 2003.

Regulatory Analysis Form

(28) Will the regulation change existing reporting, record keeping, or other paperwork requirements? Describe the changes and attach copies of forms or reports which will be required as a result of implementation, if available.

The Board anticipates no reporting, record keeping or other paperwork requirements associated with this regulation.

(29) Please list any special provisions which have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, elderly, small businesses, and farmers.

The Board has identified no affected groups whose needs must be considered in this regulation.

(30) What is the anticipated effective date of the regulation; the date by which compliance with the regulation will be required; and the date by which any required permits, licenses or other approvals must be obtained?

The Board anticipates that the regulation will be effective upon final publication in the Pennsylvania Bulletin. Veterinarians will be expected to be in full compliance with the regulation within one month of its final publication date.

(31) Provide the schedule for continual review of the regulation.

The Board continuously reviews regulations at its monthly meetings.

141), known as the Teacher Certification Law] (act) (24 P. S. § [12-1225(a)(11) (act)] 2070.9b) and this section, a document certified by the clerk of court or other judicial officer designated by law as the official custodian of criminal court records or certified by the official custodian of the appropriate licensing authority in another state, territory or nation will be treated by the Commission as a certified copy of the document.

(e) *Indictment.* Indictment under section [5(a)(11)] 9.2 of the act includes a criminal complaint, criminal information or other similar document filed in a court of competent jurisdiction.

(f) *Conviction.* The term conviction under section [5(a)(11)] 9.2 of the act is defined to mean the [entry of a judgment of sentence] verdict, judgment or sentence or the entry of an order which constitutes a final order by the sentencing court. [Judgment of sentence following a] A plea of guilty or nolo contendere constitutes a conviction for purposes of this section.

§ 237.10. Surrender in lieu of discipline.

A professional educator's teaching certificate or a charter school staff member's eligibility to teach will be considered surrendered in lieu of discipline whenever the certificate or eligibility is surrendered to the Department after a local school entity furnishes the educator or charter school staff member with a written statement of charges for dismissal under section 1127 of the Public School Code of 1949 (24 P. S. § 11-1127), or after the educator or charter school staff member is discharged for cause by a local school entity, or after the Department receives a report concerning the educator or charter school staff member under section 9.1 of the Professional Educator Discipline Act (24 P. S. § 2070.9b) (act), or after the Department receives a complaint concerning the educator or charter staff member under section 9 of the act (24 P. S. § 2070.9).

[Pa.B. Doc. No. 02-1097. Filed for public inspection June 21, 2002, 9:00 a.m.]

STATE BOARD OF VETERINARY MEDICINE

[49 PA. CODE CH. 31]

Professional Conduct; Prescription Drugs

The State Board of Veterinary Medicine (Board) proposes to amend § 31.21 (relating to Rules of Professional Conduct for Veterinarians) to read as set forth in Annex A. The proposed amendment would require veterinarians to dispense prescription drugs in child resistant or manufacturer's original packaging; require veterinarians to place certain information on the label of dispensed prescription drugs; require veterinarians to dispense or administer prescription drugs and other medications only if they are within the manufacturer's expiration date; and provide that a veterinarian will not be disciplined for refusing to issue a written prescription, rather than dispensing a prescription drug, if the veterinarian has a good faith belief that a written prescription may be misused.

Effective Date

The rulemaking would be effective upon publication of the final-form regulation in the *Pennsylvania Bulletin*.

Statutory Authority

Section 5(2) of the Veterinary Medicine Practice Act (act) (63 P. S. § 485.5(2)) authorizes the Board to adopt rules and regulations of professional conduct appropriate to establish and maintain a high standard of integrity, skills and practice in the profession of veterinary medicine.

Background and Need for Amendment

The Board currently has no regulations addressing the issues of dispensing, packaging and labeling of drugs by a veterinarian. Several inquiries have been addressed to the Board regarding the proper packaging of veterinary drugs. In the past, it was common for veterinarians to dispense prescription drugs in paper envelopes. However, both professionals and the public have become more aware of the dangers inherent in having prescription drugs in the home.

Current Federal regulations require drugs dispensed for human consumption to be packaged in child resistant packaging. Approximately 60% of the drugs used by a small animal veterinary practitioner are also prescribed for humans. In the interest of public safety, the Board believes it is appropriate to address the issue of packaging of prescription drugs dispensed by veterinarians. Requiring child resistant or manufacturer's original packaging, except in limited circumstances, would promote the safety of children who may come into contact with prescription drugs dispensed for animals in their home environments. In addition, public safety demands that a prescription drug be readily identified by its label. In the case of an accidental ingestion, that information may be life saving.

In a disciplinary context, the Board has determined that a veterinarian's use of outdated prescription drugs is a violation of the act, because that conduct fails to conform to the standards of acceptable and prevailing veterinary medical practice. However, there are no regulations that specifically restrict a veterinarian to dispensing and administering only prescription drugs and other drugs that are not date-expired. Some of the states surrounding this Commonwealth have adopted regulations specifically precluding the use of outdated prescription drugs or drugs. The proposed prohibition on the use of outdated prescription drugs or drugs would be purposefully broader than the packaging and labeling requirements. The packaging and labeling requirements of the proposed rulemaking would apply only to prescription drugs (those determined by the United States Food and Drug Administration to be limited to use on the order of a veterinarian or other medical doctor); in contrast, the prohibition on the use of outdated prescription drugs or drugs would apply to all drugs, whether or not a prescription is required for their use.

Finally, there are no current regulations addressing the provision of written prescriptions to clients. Both veterinarians and consumers have questioned the Board about proper veterinary practice related to providing a written prescription for veterinary drugs. The Board therefore proposes this amendment to establish the standard of professional conduct of a veterinarian with regard to written prescriptions.

Description of Proposed Amendment

The Board proposes to amend its professional conduct regulations in § 31.21 to add a new Principle 8 related to prescription drugs and drugs. The proposed amendment would, with just three exceptions, require a veterinarian to dispense prescription drugs in child resistant packaging. The amendment would set forth requirements for the proper labeling of prescription drugs dispensed by a veterinarian. The amendment would mandate that veterinarians dispense or administer only currently dated drugs. Finally, the amendment would provide that a veterinarian will not be disciplined for refusing to issue a written prescription to a client if the veterinarian has a good faith belief that the prescription may be misused.

Definitions

Subsection (a) would define "drug" as that term is defined in both the Federal Food, Drug, and Cosmetic Act, 21 U.S.C.A. § 321(g), and section 102 of The Controlled Substance, Drug Device and Cosmetic Act (35 P. S. § 780-102). "Prescription drug" would be defined as any drug, except for blood and blood components intended for transfusion, required by Federal law, including Federal regulation, to be dispensed only by a prescription. This definition encompasses both the definition of prescription drug and veterinary prescription drug in 21 U.S.C.A. § 353(b) and (f) and is consistent with the definition of "prescription drug" used in 21 CFR 203.3(y) (relating to definitions).

Prescribing Limited to Animals under the Care of the Veterinarian

Subsection (b) would limit veterinarians to prescribing prescription drugs for animals that are under the veterinarian's care. This provision would require that the veterinarian or an authorized licensed associate have personal, first-hand knowledge of, and medical responsibility for, the animal for which the drug is prescribed. This provision is designed to ensure the safety of animals and prevent unscrupulous persons from obtaining prescription drugs by misrepresenting information to a veterinarian. As an alternative, a veterinarian may also prescribe prescription drugs for an animal if the veterinarian has made medically appropriate and timely visits to the premises where the animal is kept. This alternative would set forth the appropriate criteria for a veterinarian who works with herd animals.

Packaging Requirements

Subsection (c) would require veterinarians to dispense prescription drugs, other than for food animals, in child resistant or manufacturer's original packaging. The draft sent to interested parties used the term "safety closure packaging" instead of "child resistant packaging." Several commentators asked the Board to clarify what was intended by "safety closure" packaging. The Board determined that the standard language in use in the Federal regulations for the appropriate type of packaging is "child resistant" packaging and has adopted this term for its regulation. See 16 CFR 1700.15 (relating to poison prevention packaging standards).

The proposed amendment would allow a veterinarian to dispense a prescription drug in the manufacturer's original packaging for several reasons. First, this type of packaging is often inherently child resistant. For example, manufacturers sometimes package pills and single dose topical preparations in a sheet of individually separated, sealed plastic containers. Second, it may be impractical for a veterinarian to repackage certain types of prescription drugs. For example, tubes of an ointment would be impossible to repackage and, depending on the size of the tube, it might be impractical or costly to place the entire tube inside a child resistant package. Finally, some drugs used by veterinarians are dispensed in a quantity that would be difficult for the veterinarian to obtain safety closure packaging to accommodate the medication. Moreover, this exemption for manufacturer's original packaging would not exempt medications with a high risk of accident, such as syringes prefilled with the correct dosage of a drug because the syringe does not come prefilled from the manufacturer. No hardship would be created for the veterinarian, because safety closure packaging for syringes is readily available.

The following two exceptions would be permitted: (1) when dispensing for food animals; and (2) when the client specifically requests alternate packaging. Dispensing for food animals is exempted for three reasons. First, the drugs are not normally kept within the reach of children, thus lessening the danger of accidental ingestion. Second, laypersons administering drugs to food animals are generally familiar with safe handling procedures because administration of drugs is a common part of animal husbandry. Third, because drugs dispensed for food animals are often dispensed on a "per herd" basis, their quantity would make meeting the general requirement impractical and costly.

Finally, an exemption is permitted under a client's request to allow a veterinarian to dispense drugs to a person who has difficulty opening child resistant packaging in a container that is more easily opened by that person. This exemption mirrors the exemption to the child resistant packaging requirement for human drugs in Federal law. See 16 CFR 1701.1(d) (relating to definitions).

Labeling Requirements

Subsection (d) would address labeling requirements for prescription drugs dispensed by veterinarians. Requiring information about the prescribing or dispensing, or both, veterinarian on the medication's label would serve the public interest by allowing consumers immediate access to veterinarian contact information in the case of questions or concerns about the prescription drug or its effects and in case of an emergency accidental ingestion. The proposed amendment would require the name, address and telephone number of the prescribing veterinarian and the name and telephone number of the dispensing veterinarian, if different. The address of the dispensing veterinarian, if a different veterinarian than the veterinarian who prescribed the drug, is unnecessary because the client would already know the address of the dispensing veterinarian because the client would have to go to the dispensing veterinarian to pick up the medication. The information required would enable the two veterinarians to more easily communicate with each other and would allow the client ready access to the contact information of the prescribing veterinarian, who is in the best position to answer questions or concerns about the drug prescribed.

The information regarding the name, potency, quantity of the drug and date dispensed would permit a veterinarian, medical doctor or poison control center to more accurately provide the appropriate treatment in the case of accidental ingestion and would provide important information to enable a veterinarian to answer a client's questions. Requiring directions for use and cautionary statements would aid the veterinary client in proper administration of the drug. The reference to cautionary

statements required by law encompasses Federal law that requires the statement that the drug may only be dispensed on the prescription of a veterinarian and any other cautionary statements that Federal law may require to be placed on specific drugs. Providing the expiration date of the drug would identify the drug as either within the expiration date or expired and requiring disposal. Other information required would include the number of refills allowed and the name of the patient, if applicable, that is, when not prescribed for a herd.

Requirement that Veterinarians Administer and Dispense only Currently Dated Medications

Section 21(11) of the act (63 P. S. § 485.21(11)) authorizes the Board to discipline licensees who depart from, or fail to conform to, the standards of acceptable and prevailing veterinary medical practice. The Board's regulations currently do not address the issue of whether a veterinarian departs from the standards of acceptable and prevailing veterinary medical practice by prescribing, administering or dispensing a medication that is expired. The Board has reviewed the issue and found that the acceptable and prevailing standards of veterinary medical practice demand that veterinarians administer or dispense only medications that are within the date set by the manufacturer as the drug's effective date. The determination of this expiration date has been given thorough review by the United States Food and Drug Administration and the Board finds that it is the date that shall determine whether a drug is current or expired.

The Board uses the term "drugs" in this section of the proposed amendment rather than using the term "prescription drugs." The Board intends to require that all drugs administered or dispensed by a licensed veterinarian, whether or not the drug is a prescription drug, shall be current, within the date as determined by the manufacturer. The Board believes that the safety and efficacy of outdated drugs, as well as prescription drugs, could negatively impact the health and safety of animals and their human custodians.

Issuance of Written Prescriptions

Finally, the amendment as submitted for predraft commentary required a veterinarian to provide the client with a prescription if one was requested, rather than dispensing the medication. A number of commentators who work with farm animals voiced strong objections to the draft language. Because these veterinarians often dispense drugs in large, multiple dose quantities, providing a prescription rather than the drug itself would make it impossible for the veterinarian to have even minimal knowledge or control over the remaining quantity or expiration date of the drug. This could be particularly dangerous to humans when food animals are involved. The Board determined that its regulation should leave the decision of whether to provide a prescription upon request of a client to the professional judgment of the veterinarian. However, the proposed amendment requires that a veterinarian have a good faith reason for refusing a client's request for a prescription. This provision clarifies the Board's position that a veterinarian should not be motivated solely by profit in determining whether to issue a prescription rather than dispense a medication.

Compliance with Executive Order 1996-1

In accordance with "Regulatory Review and Promulgation," Executive Order 1996-1 in drafting and promulgating the proposed amendment, the Board sent the text of the proposed amendment to interested parties, including State and regional veterinary medical associations, associations of animal health technicians and schools of veterinary medicine. Several persons submitted comments. One commentator suggested that the Board clarify the term "food animal" to specifically include or exclude equines. The Board determined that it would not further define the term because equines are not intended for human food consumption in this country. Another commentator suggested that the amendment provide that "hazardous or potentially toxic medications are recommended to be dispensed in" child resistant packaging. The Board rejected this suggestion for two reasons. First, if the amendment sets forth a recommendation rather than a requirement, the amendment would be impossible to enforce. Second, the Board rejected the suggestion that the packaging requirements be limited to hazardous medications because virtually any prescription drug can be hazardous if accidentally ingested. Comments also suggested requiring the veterinarian's telephone number, method of administration, number of refills authorized and the name of the patient on the drug label. The Board adopted all of these suggestions.

Fiscal Impact and Paperwork Requirements

The proposed amendment should have only a minimal financial impact on licensees, who will be required to purchase child resistant packaging for some of the drugs they dispense. The proposed amendment should have no fiscal impact on the Board, the private sector, the general public or political subdivisions. In addition, the proposed amendment should not create additional paperwork for licensees, the Board, State government or the private sector.

Sunset Date

The Board continuously monitors its regulations. Therefore, no sunset date has been assigned.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on June 10, 2002, the Board submitted a copy of this proposed amendment to the Independent Regulatory Review Commission (IRRC), the Senate Consumer Protection and Professional Licensure Committee (SCP/PLC) and the House Professional Licensure Committee (HPLC). In addition to submitting the proposed amendment, the Board has provided IRRC, the SCP/PLC and the HPLC with a copy of a detailed Regulatory Analysis Form prepared by the Board in compliance with Executive Order 1996-1. A copy of this material is available to the public upon request.

Under section 5(g) of the Regulatory Review Act (71 P. S. § 745.5(g)), if IRRC has objections to any portion of the proposed rulemaking, it will notify the Board within 10 days of the close of the SCP/PLC's and HPLC's review period. The notification shall specify the regulatory review criteria that have not been met. The Regulatory Review Act specifies detailed procedures for review of objections by the Board, the General Assembly and the Governor prior to publication of the regulations.

Public Comment

Interested persons are invited to submit written comments, suggestions or objections regarding this proposed amendment to Robert Kline, State Board of Veterinary Medicine, P. O. Box 2649, Harrisburg, PA 17105-2649, www.dos.state.pa.us, within 30 days following publication of this proposed rulemaking in the *Pennsylvania Bulletin*.

BRIAN V. HARPSTER, V.M.D.,
Chairperson

Fiscal Note: 16A-5712. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 31. STATE BOARD OF VETERINARY MEDICINE

PROFESSIONAL CONDUCT

§ 31.21. Rules of Professional Conduct for Veterinarians.

Preamble

The Board is empowered under section 5(2) of the act (63 P. S. § 485.5(2)) to adopt rules and regulations of professional conduct appropriate to establish and maintain a high standard of integrity, skill and practice in the profession of veterinary medicine. In accordance with this authority, the Board has determined that the following rules are necessary in the public interest to protect the public against unprofessional conduct on the part of veterinarians. The Board therefore adopts this professional conduct code for veterinarians practicing veterinary medicine in this Commonwealth. Some of the rules of conduct are imperatives, cast in the terms, "shall" or "may not." Veterinarians who fail to adhere to these rules will be subject to professional discipline. Other rules, generally cast in the terms "may" or "should," are intended as aspirational goals and define areas under which the veterinarian has professional discretion. No disciplinary action will be taken when a veterinarian acts within the bounds of discretion. References throughout this professional conduct code to imperative conduct on the part of veterinarians [shall] also apply to applicants for licensure and temporary permit holders where these persons render services under qualified supervision.

* * * * *

Principle 8. Drugs.

(a)(1) For purposes of Principle 8, the term "drug" means:

(i) Substances recognized in the official United States Pharmacopoeia, official National Formulary, or Federal Food and Drug Administration Approved Animal Drug Products or any supplement to them.

(ii) Substances intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals.

(iii) Substances (other than food) intended to affect the structure or any function of the human body or other animal body.

(iv) Substances intended for use as a component of any substance specified in subparagraph (i), (ii) or (iii), but not including devices as that term is defined in section 2 of The Controlled Substance, Drug, Device and Cosmetic Act (35 P. S. § 780-102).

(2) The term "prescription drug" means any drug required by Federal law, including Federal regulation, to be dispensed only by a prescription.

(b) A veterinarian shall only prescribe prescription drugs to animals that are under the veterinarian's care. For purposes of this section, "under the veterinarian's care" means that the veterinarian or one of the veterinarian's licensed associates has examined the animal or has made medically appropriate and timely visits to the premises where the animal is kept.

(c) Prescription drugs dispensed by a veterinarian, other than drugs for food animals, shall be dispensed in child resistant packaging or in the manufacturer's original packaging, except when the client specifically requests other packaging.

(d) Prescription drugs dispensed by a veterinarian shall be labeled with, at a minimum, the following information:

(1) The name, address and telephone number of the prescribing veterinarian and the name and telephone number of the dispenser, if different;

(2) The brand or generic name of the drug.

(3) The potency and the quantity of the drug.

(4) The number of refills allowed, if any.

(5) Adequate directions for use, which shall include quantity of dose, frequency of administration or application, duration of administration or application and route or method of administration or application.

(6) Any cautionary statements specified by the veterinarian or required by Federal law, including the Federal Food, Drug and Cosmetic Act (21 U.S.C.A. §§ 301—397) and 21 CFR (relating to food and drugs).

(7) The name of the patient, if applicable.

(8) The date the drug was dispensed.

(9) The expiration date of the drug.

(e) Veterinarians shall dispense or administer only drugs, including prescription drugs, that are within the expiration date specified by the manufacturer and shall dispense or administer only drugs that will not expire within the prescribed treatment period.

(f) Upon request, a veterinarian shall provide a client with a written prescription for an animal that is under the veterinarian's care, except that a veterinarian may refuse to do so without being subject to discipline if the veterinarian has a good faith belief that the prescription may be misused.

[Pa.B. Doc. No. 02-1098. Filed for public inspection June 21, 2002, 9:00 a.m.]

CDL-1

FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU

(Pursuant to Commonwealth Documents Law)

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BY: _____
(DEPUTY ATTORNEY GENERAL)

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DATE OF APPROVAL

Copy below is hereby certified to be a true and correct copy of a document issued, prescribed or promulgated by:

State Board of Veterinary Medicine
(AGENCY)

DOCUMENT/FISCAL NOTE NO. 16A-5712

DATE OF ADOPTION: _____

BY: Brian V. Harpster, V.M.D.
Brian V. Harpster, V.M.D.

TITLE: Chairperson
(EXECUTIVE OFFICER, CHAIRMAN OR SECRETARY)

Copy below is approved as to form and legality. Executive or Independent Agencies.

BY: John V. Cox

5/9/03
DATE OF APPROVAL

(Deputy General Counsel
(Chief Counsel,
Independent Agency
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title)

[ ] Check if applicable
Copy not approved.
Objections attached.

[ ] Check if applicable. No Attorney General approval or objection within 30 day after submission.

FINAL RULEMAKING
COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
STATE BOARD OF VETERINARY MEDICINE
49 PA. CODE, CHAPTER 31
PROFESSIONAL CONDUCT, PRESCRIPTION DRUGS

The State Board of Veterinary Medicine (Board) adopts an amendment to 49 Pa.Code § 31.21 (relating to Rules of Professional Conduct for Veterinarians) as set forth in Annex A.

Notice of Proposed Rulemaking was published at 32 Pa.B. 2997 (June 22, 2002). Publication was followed by a 30-day public comment period during which the Board received one comment. On August 9, 2002, the House Professional Licensure Committee (HPLC) informed the Board that it would not be submitting comments to the proposed rulemaking. The Senate Consumer Protection and Professional Licensure Committee made no comments. The Independent Regulatory Review Commission (IRRC) submitted comments to the proposed rulemaking on August 22, 2002.

Summary of Comments and Responses to Proposed Rulemaking

IRRC Comments

IRRC pointed out an inconsistency in the introductory language to definitions for "drug," "prescription drug" and "under the veterinarian's care." On some occasions, the Board prefaced the definition by stating the definition was applicable only for a particular subsection of the regulation. The Board finds that these definitions are generally applicable to all of §31.21, and strikes the prefatory language "for purposes of this section" in final rulemaking.

Regarding proposed § 21(d)(6), IRRC requested the Board's references to the Federal Food, Drug and Cosmetic Act (21 U.S.C.A. §§ 301 – 397) and 21 C.F.R. (relating to food and drugs) be made more specific as to what sections of the law and what parts of the Code of Federal Regulations apply. Upon review of IRRC's comments and concerns, the Board has determined that this subsection should be revised. First, veterinarians have an affirmative duty as practitioners to comply with federal and state laws and regulations pertaining to all aspects of drug dispensing including labeling. Thus, as suggested by IRRC, the subsection would not provide necessary or useful information to the practicing veterinarian. Additionally, the specificity suggested by IRRC would impose additional administrative costs on the Board by creating the need to continually revise its regulations as the Federal government makes changes. Veterinarians receive training in both state and federal drug labeling requirements and the Board's regulation does not need to specify the multitude of state and federal laws and regulations in this area. Therefore, the Board strikes all references to federal laws and regulations.

Subsection (f) of the Board's proposed rulemaking would have required a veterinarian to provide a client with a written prescription, rather than dispensing a drug, if the client requested a prescription, and provided that the veterinarian would not be subject to discipline if the veterinarian refused to do so because the veterinarian had a good faith belief that the prescription may be misused. IRRC questioned "the need for the 'good faith belief' exemption," and opined

that where a prescription is filled is an unrelated issue to whether the medication is necessary. In the veterinary profession, a veterinarian prescribes for an animal but the animal's owner takes control of the prescription or drug. A pharmacist filling a veterinary prescription has no duty to the animal patient as the pharmacist has to a human patient. The special duty of a veterinarian to attend to the welfare of both the animal patient and the human client is unique to the practice of veterinary medicine. The common logic of relationship between where a prescription is filled and whether a medication is necessary that may apply where a prescription is written or filled for a human patient does not apply in the veterinary medical context. In the judgment of the professional members of the Board regarding the prescribing, dispensing and use of drugs in veterinary medicine, a veterinarian must have the ability to refuse to issue a prescription where in the veterinarian's professional judgment it would be detrimental to the health of the animal or the public welfare. The responsibility of a veterinarian goes beyond the duty to the animal patient and the owner-client. For example, veterinarians who work with farm animals have a duty to protect the Commonwealth's milk and meat supply, and all veterinarians have a duty to protect the public health and welfare. Moreover, every practitioner who prescribes or dispenses drugs has the ethical obligation and legal authority to refuse to prescribe or dispense a drug. The Board's regulation does not change the current state of the law or acceptable and prevailing standard of veterinary medical practice and ethics. The Board declines to strike the good faith exemption as proposed by IRRC.

IRRC further commented that the Board should add a provision to its final rulemaking that would require a veterinarian to inform his or her clients that the client may request a written prescription rather than a dispensed drug. IRRC's comment appears to be aimed at providing the consumer of veterinary services with options regarding treatment choices for the provision of drugs. While the suggestion is interesting, the Board is not convinced that it falls within the scope of proposed rulemaking. Also, such a requirement would not be appropriate or safe under certain circumstances. For example, veterinarians, unlike pharmacies, are prohibited from merchandising, or selling professional veterinary products without a veterinarian/client relationship. See 49 Pa. Code §§ 31.1 and 31.21, Principle 3(d). Also, the Board's regulations, like those of other professional licensing boards, do not contain provisions requiring professionals to explain the rules governing the practice of the profession to clients. For these reasons, the Board declines to impose such a requirement on its licensees.

Finally, IRRC suggests that the regulation should reference the record-keeping requirements in Section 31.22 and the specific record-keeping requirements for controlled substances in federal regulations at 21 CFR part 1304. The Board has no objection to adding a new section to its rulemaking specifying the duty of the veterinarian to keep appropriate records relating to drugs and prescription drugs and has added a new subsection (g) to its proposed Principle 8.

Public Comment

The Board received one comment from the public to its proposed rulemaking, from the Pennsylvania Society for Biomedical Research (Society). The Society opined that the proposed regulations "would not and cannot apply to" persons exempted from the Veterinary Medical Practice Act (Act) by section 32(5) of the Act (63 P.S. §485.32(5)) and that "no rule or regulation issued by the State Board of Veterinary Medicine under 49 Pa. Code Ch. 31 applies to" any persons exempted from the Act by section 32(5) of the Act (63 P.S. §485.32(5)). The Board concurs that none of its regulations are enforceable against unlicensed persons exempted by this section of the Act. However, if persons exempted from the Act choose to be licensees of the Board, the Board believes that the Act and its regulations would apply to those persons.

Statutory Authority

The regulation is authorized under Sections 5(2) of the Veterinary Medicine Practice Act, the Act of December 27, 1974, P.L. 995, No. 326, as amended, 63 P.S. §§ 485.5(2). Section 5(2) of the Act empowers the Board to adopt regulations regarding professional conduct.

Fiscal Impact and Paperwork Requirements

The regulation will have no fiscal impact on the Commonwealth or its political subdivisions. The regulation will create no additional paperwork for the Board or the private sector.

Compliance with Executive Order 1996-1

The Board reviewed this rulemaking and considered its purpose and likely impact on the public and the regulated population under the Directives of Executive Order 1996-1. This final-form rulemaking addresses or compelling public interest and otherwise complies with Executive Order 1996-1.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), the Board submitted a copy of the Notice of Proposed Rulemaking, published at 32 Pa.B. 2997 (June 22, 2002), to the Independent Regulatory Review Commission and to the Chairpersons of the House

Committee on Professional Licensure and the Senate Committee on Consumer Protection and Professional Licensure. In compliance with section 5(c) (71 P.S. § 745.5(c)), the Board also provided the Commission and the committees with copies of all comments received, as well as other documents.

Publication of the Notice of Proposed Rulemaking was followed by a 30-day public comment period during which the Board received one comment from the public. The Board also received comments from IRRC. In preparing this final-form regulation, the Board has considered all comments received from IRRC and the public.

This final form regulation was (deemed) approved by the House Professional Licensure Committee and the Senate Consumer Protection and Professional Licensure Committee on June 17, 2003. IRRC met on _____, 2003, and (deemed) approved the regulation in accordance with section 5.1(e) of the Regulatory Review Act.

Additional Information

Individuals who need information about the regulation may contact Robert Kline, Administrative Assistant, State Board of Veterinary Medicine, P.O. Box 2649, Harrisburg, PA 17105-2649.

Findings

The State Board of Veterinary Medicine finds:

(1) That public notice of intention to adopt a regulation at 49 Pa.Code, Chapter 31, was given under sections 201 and 202 of the Commonwealth Documents Law, 45 P.S. §§ 1201- 1202, and the regulations promulgated under those sections at 1 Pa. Code §§ 7.1-7.2.

(2) A public comment period was provided as required by law and all comments were considered.

(3) That the regulation of the State Board of Veterinary Medicine is necessary and appropriate for the administration of the Veterinary Medicine Practice Act.

(4) The amendments to this final rulemaking do not enlarge the original purpose of the proposed regulation published at 32 Pa. B. 2997.

Order

The Board therefore ORDERS that:

(A) The regulations of the State Board of Veterinary Medicine, 49 Pa.Code Chapter 31, are amended to read as set forth in the attached Annex.

(B) The Board shall submit the Order and a copy of the Annex to the Office of Attorney General and the Office of General Counsel for approval as required by law.

(C) The Board shall certify this Order and Annex and shall deposit them with the Legislative Reference Bureau as required by law.

(D) This Order and regulation shall take effect upon publication in the Pennsylvania Bulletin.

Brian V. Harpster, V.M.D.
Chairman, State Board of Veterinary Medicine

Annex A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS
PART I. DEPARTMENT OF STATE
Subpart A. Professional and Occupational Affairs
CHAPTER 31. STATE BOARD OF VETERINARY MEDICINE
PROFESSIONAL CONDUCT

§ 31.21. Rules of Professional Conduct for Veterinarians.

Preamble

The Board is empowered under Section 5(2) of the act (63 P.S. § 485.5(2)) to adopt rules and regulations of professional conduct appropriate to establish and maintain a high standard of integrity, skill and practice in the professional of veterinary medicine. In accordance with this authority, the Board has determined that the following rules are necessary in the public interest to protect the public against unprofessional conduct on the part of veterinarians. The Board therefore adopts this professional conduct code for veterinarians practicing veterinary medicine in this Commonwealth. Some of the rules of conduct are imperatives, cast in the terms, "shall" or "may not." Veterinarians who fail to adhere to these rules will be subject to professional discipline. Other rules, generally cast in the terms "may" or "should," are intended as aspirational goals and define areas under which the veterinarian has professional discretion. No disciplinary action will be taken when a veterinarian acts within the bounds of discretion. References throughout this professional conduct code to imperative conduct on the part of veterinarians **[shall]** also apply to applicants for licensure and temporary permit holders where these persons render services under qualified supervision.

* * *

Principle 8. Drugs.

(a) (1) ~~For purposes of Principle 8, t~~The term "drug" means:

(i) Substances recognized in the official United States Pharmacopoeia, official National Formulary, or Federal Food and Drug Administration Approved Animal Drug Products, or any supplement to them.

(ii) Substances intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals.

(iii) Substances (other than food) intended to affect the structure or any function of the human body or other animal body.

(iv) Substances intended for use as a component of any substance specified in subparagraph (i), (ii), or (iii), but not including devices as that term is defined in section 2 of the Controlled Substance, Drug, Device and Cosmetic Act (35 P.S. § 780-102).

(2) The term "prescription drug" means any drug required by Federal law, including Federal regulation, to be dispensed only by a prescription.

(b) A veterinarian shall only prescribe prescription drugs to animals that are under the veterinarian's care. ~~For purposes of this section,~~ "~~u~~Under the veterinarian's care" means that the veterinarian or one of the veterinarian's licensed associates has examined the animal or has made medically appropriate and timely visits to the premises where the animal is kept.

(c) Prescription drugs dispensed by a veterinarian, other than drugs for food animals, shall be dispensed in child resistant packaging or in the manufacturer's original packaging, except when the client specifically requests other packaging.

(d) Prescription drugs dispensed by a veterinarian shall be labeled with, at a minimum, the following information:

(1) The name, address and telephone number of the prescribing veterinarian and the name and telephone number of the dispenser, if different.

(2) The brand or generic name of the drug.

(3) The potency and the quantity of the drug.

(4) The number of refills allowed, if any.

(5) Adequate directions for use, which shall include quantity of dose, frequency of administration or application, duration of administration or application, and route or method of administration or application.

(6) Any cautionary statement specified by the veterinarian or required by ~~Federal~~ law~~, including the Federal Food Drug and Cosmetic Act (21 U.S.C.A. §§ 301—397) and 21 CFR (relating to food and drugs.)~~.

(7) The name of the patient, if applicable.

(8) The date the drug was dispensed.

(9) The expiration fate of the drug.

(e) Veterinarians shall dispense or administer only drugs, including prescription drugs, that are within the expiration date specified by the manufacturer, and shall dispense or administer only drugs that will not expire within the prescribed treatment period.

(f) Upon request, a veterinarian shall provide a client with a written prescription for an animal that is under the veterinarian's care, except that a veterinarian may refuse to do so without being subject to discipline if the veterinarian has a good faith belief that the prescription may be missed.

(G) VETERINARIANS SHALL MAINTAIN RECORDS RELATED TO DRUGS IN ACCORDANCE WITH §31.22 (RELATING TO RECORD KEEPING RATIONALE.)

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
STATE BOARD OF VETERINARY MEDICINE
Post Office Box 2649
Harrisburg, Pennsylvania 17105-2649
(717) 783-7134

June 17, 2003

The Honorable John R. McGinley, Jr., Chairman
INDEPENDENT REGULATORY REVIEW COMMISSION
14th Floor, Harristown 2, 333 Market Street
Harrisburg, Pennsylvania 17101

Re: Final Regulation
State Board of Veterinary Medicine
16A-5712: Professional Conduct, Prescription Drugs

Dear Chairman McGinley:

Enclosed is a copy of a final rulemaking package of the State Board of Veterinary Medicine pertaining to professional conduct and prescription drugs.

The Board will be pleased to provide whatever information the Commission may require during the course of its review of the rulemaking.

Sincerely,

Brian V. Harpster, VMD

Brian V. Harpster, V.M.D., Chairperson
State Board of Veterinary Medicine

BVH/TLM:kmh
Enclosure
cc: Scott J. Messing, Deputy Commissioner
Bureau of Professional and Occupational Affairs
Andrew Sislo, Chief Counsel
Department of State
Joyce McKeever, Deputy Chief Counsel
Department of State
Cynthia Montgomery, Regulatory Counsel
Department of State
Herbert Abramson, Senior Counsel in Charge
Department of State
Teresa Lazo-Miller, Counsel
State Board of Veterinary Medicine
State Board of Veterinary Medicine

TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

I.D. NUMBER:	16A-5712
SUBJECT:	State Board of Veterinary Medicine - Professional Conduct, Prescription Drugs
AGENCY:	DEPARTMENT OF STATE

TYPE OF REGULATION

Proposed Regulation

X Final Regulation

Final Regulation with Notice of Proposed Rulemaking Omitted

120-day Emergency Certification of the Attorney General

120-day Emergency Certification of the Governor

Delivery of Tolled Regulation
a. With Revisions b. Without Revisions

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
6/17/03	Sandra J. Harper S	HOUSE COMMITTEE ON PROFESSIONAL LICENSURE
6/17/03	Mary Walmer	SENATE COMMITTEE ON CONSUMER PROTECTION & PROFESSIONAL LICENSURE
6/17/03	J. Talbot	INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL (for Final Omitted only)
		LEGISLATIVE REFERENCE BUREAU (for Proposed only)