

PROPOSED RULEMAKING

ENVIRONMENTAL QUALITY BOARD

[25 PA. CODE CH. 93]

Oysterville Creek, et al. Stream Redesignations; Public Meeting, Hearing and Extension of Public Comment Period

The Environmental Quality Board (Board) will hold a public meeting and hearing to discuss and accept comments on its proposal to redesignate portions of Oysterville Creek and West Branch Perkiomen Creek in Berks County as High Quality (HQ) and Exceptional Value (EV) Waters. The Board's proposal is based on specific segments of the basins meeting the biological test for HQ or EV designation as specified by the antidegradation regulations in 25 Pa. Code Chapter 93 (relating to water quality standards).

For Oysterville Creek, the proposed EV segment includes the upper reaches of the basin (source to T-634). The remainder of the basin (T-634 to mouth) qualifies for HQ, with the exception of Unnamed Tributary 01680, which would retain its Cold Water Fishes (CWF) designation. For West Branch Perkiomen Creek, the proposed EV segment includes the lower portion of the basin (SR 1022 to SR 2069). The remainder of the basin would retain its CWF designation.

The Board's proposal to redesignate portions of Oysterville Creek and West Branch Perkiomen Creek was published at 32 Pa.B. 2219 (May 4, 2002) and in the *Reading Eagle Times* on May 4, 2002, with a public comment period that closed on June 18, 2002. During the public comment period, the Board received a request to conduct a public hearing on the proposed redesignations. As a result of this request, a public meeting and hearing has been scheduled for August 7, 2002, in Topton, PA. In addition, the public comment period has been extended until August 21, 2002.

Public Meeting and Hearing

The public meeting and hearing will be held as follows:

August 7, 2002 Brandywine Heights High School
Auditorium
200 West Weis Street
Topton, PA 19562

The meeting segment will begin at 6:30 p.m. with staff from the Department of Environmental Protection (Department) providing a brief overview of the proposed redesignations and responding to questions. The public hearing will follow and begin at approximately 7:30 p.m.

Persons interested in presenting testimony at the hearing are requested to contact Debra Failor, Environmental Quality Board, P. O. Box 8477, Harrisburg, PA 17105-8477, (717) 787-4526, at least 1 week in advance of the hearing to reserve a time to present testimony. It is not necessary to preregister for the public meeting. Oral testimony is limited to 5 minutes for each witness. Witnesses are requested to submit three written copies of their statement at the hearing. Each organization is limited to designating one witness to present testimony on its behalf.

Persons with a disability who wish to attend a hearing and require an auxiliary aid, service or other accommoda-

tion to participate should contact Debra Failor at (717) 787-4526 or through the Pennsylvania AT&T Relay Service at (800) 654-5984 (TDD) to discuss how their needs may be accommodated.

Written Comments

Written comments will be accepted and must be sent to Environmental Quality Board, P. O. Box 8477, Harrisburg, PA 17105-8477 (express mail: Rachel Carson State Office Building, 15th Floor, 400 Market Street, Harrisburg, PA 17101-2301). Comments on the proposal must be received by August 21, 2002. Comments may also be submitted via e-mail to RegComments@state.pa.us and must also be received by August 21, 2002. Comments submitted by facsimile will not be accepted.

Availability of the Proposed Redesignations

Copies of the proposed redesignations are available from Roxy Naugle, Bureau of Water Supply and Wastewater Management, P. O. Box 8467, Harrisburg, PA 17105-8467, (717) 787-9031, e-mail rnaugle@state.pa.us. The proposed redesignations are also available on the Department website at <http://www.dep.state.pa.us> (Public Participation Center/Proposals Open for Comment).

DAVID E. HESS,
Chairperson

[Pa.B. Doc. No. 02-1096. Filed for public inspection June 21, 2002, 9:00 a.m.]

PROFESSIONAL STANDARDS AND PRACTICES COMMISSION

[22 PA. CODE CH. 237]

Definitions of Statutory Terms

The Professional Standards and Practices Commission (Commission) proposes to amend Chapter 237 (relating to definitions of statutory terms) to read as set forth in Annex A. The proposed amendments are made under the authority of sections 5(a)(11) and 9.2 of the Professional Educator Discipline Act (act) (24 P. S. §§ 2070.5(a)(11) and 2070.9b).

The Commission was created by the act of December 12, 1973 (P. L. 397, No. 141) as amended by the act of November 21, 2000 (P. L. 918, No. 123) (Act 123). By virtue of the act, the General Assembly has empowered the Commission to discipline professional educators and charter school staff members. In addition, the General Assembly directed the Commission to establish definitions consistent with its authority to discipline under sections 5(a)(11) and 9.2 of the act. Accordingly, the Commission did promulgate definitions in May of 1994.

Purpose

This chapter establishes definitions under sections 5(a)(11) and 9.2 of the act. The act recently was amended by Act 123 and this proposed rulemaking reflects the amendments to the act.

Requirements of the Propose Amendments

The most significant new requirements under the proposed amendments to this chapter are:

1. The recognition of the extended jurisdiction of the Commission to discipline charter school staff members, as well as professional educators, as contemplated by the recent amendments to the act.

2. The standard for "morals of a community" within the definition of immorality has been changed from a local standard to a Statewide standard to comport with the overall mission of the Commission.

3. A definition for the term "surrender in lieu of discipline" has been added to this chapter to reflect the recent amendments to the act, which designated a surrender in lieu of discipline as a specific type of discipline. The most significant impact of this designation is that surrenders in lieu of discipline are now considered public under the act.

Affected Parties

This chapter primarily affects professional educators who have been certified by the Department of Education (Department) as well as charter school staff members who are employed by a charter school in a position for which Pennsylvania certification would be required in a public school other than a charter school but who are not required to hold State certification under section 1724-A of the School Code of 1949 (24 P. S. § 17-1724-A).

Cost and Paperwork Estimates

It is not anticipated that the proposed amendments will engender any additional costs or paperwork for affected parties, which include professional educators, charter school staff members, local school districts and the Department.

Effective Date

This proposed rulemaking would become effective upon final-form publication in the *Pennsylvania Bulletin*.

Sunset Date

The Commission will review the effectiveness of Chapter 237 on an ongoing basis. Thus, no sunset date is necessary.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on June 11, 2002, the Commission submitted a copy of this proposed rulemaking to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the House and Senate Committees on Education. In addition to submitting the proposed rulemaking, the Commission has provided IRRC and the Committees with a copy of a detailed Regulatory Analysis Form prepared by the Board in compliance with Executive Order 1996-1, "Regulatory Review and Promulgation." A copy of this material is available to the public upon request.

Under section 5(g) of the Regulatory Review Act, if IRRC has objections to any portion of the proposed rulemaking, it will notify the Commission within 10 days of the close of the Committees' review period. The notification shall specify the regulatory review criteria which have not been met by that portion of the proposed rulemaking. The Regulatory Review Act specifies detailed procedures for review, prior to final publication of the amendments, by the Commission, the General Assembly and the Governor of objections raised.

Public Comments and Contact Person

Interested persons are invited to submit written comments, suggestions or objections regarding this proposal to Carolyn Angelo, Executive Director, Professional Standards and Practices Commission, 333 Market Street, Harrisburg, PA 17126-0333 within 30 days following publication in the *Pennsylvania Bulletin*. Persons needing additional information regarding this proposal may contact Carolyn Angelo at (717) 787-6576.

Persons with disabilities who need an alternative means of providing public comment may make arrangements by calling Carolyn Angelo at (717) 787-6576. Alternative formats of this proposed rulemaking (such as, Braille, large print, cassette tape) can be made available to members of the public upon request to Carolyn Angelo at the telephone number previously listed.

CAROLYN ANGELO,
Executive Director

Fiscal Note: 6-274. No fiscal impact; (8) recommends adoption.

Annex A**TITLE 22. EDUCATION****PART XIV. PROFESSIONAL STANDARDS AND PRACTICES COMMISSION****CHAPTER 237. DEFINITIONS OF STATUTORY TERMS****Subchapter A. DEFINITIONS****§ 237.1. Purpose**

(a) Under [**section**] **sections 5(a)(11) and 9.2** of the [**act of December 12, 1973 (P. L. 397, No. 141) (act) (24 P. S. § 12-1255(a)(11)), known as the Teacher Certification Law**] **Professional Educator Discipline Act (act) (24 P. S. §§ 2070.5(a)(11) and 2070.9b)**, the Professional Standards and Practices Commission (Commission) is vested with the duty and granted the power to discipline professional educators [**charged with or convicted of certain criminal offenses or found guilty by the Commission, after hearing, of certain statutory offenses**] and **charter school staff members and to consider the reinstatement applications of professional educators and charter school staff members who seek to have previously revoked or suspended certificates or eligibility reinstated.**

(b) Under section 5(a)(11) of the act, the Commission has adopted this subchapter to define terms in [**section 5(a)(11) of**] the act which describe the conduct for which discipline of a professional educator **or charter school staff member** might be imposed by the Commission.

(c) This subchapter is not the sole authority for defining terms under [**section**] **sections 5(a)(11) and 9.2** of the act. Judicial interpretations and adjudications of the Commission will authoritatively define the statutory terms. Judicial decisions **and decisions of the Secretary** under Article XI, Part C of the Public School Code of 1949 (24 P. S. §§ 11-1121—11-1133) [—], known as the Teachers' Tenure Act [—], and decisions of the Secretary under the Teachers' Tenure Act are not binding upon the Commission but [**will**] **may** be regarded as persuasive authority.

(d) The standards and conduct expected of a professional educator **or charter school staff member** are also prescribed by Chapter 235 (relating to Code of Professional Practice and Conduct for Educators), the violation of which may be grounds for discipline.

(e) **The definitions found in section 1.1 of the act (24 P. S. § 2070.1b) are incorporated herein by reference.**

§ 237.2. Scope and effect.

(a) *Applicability.* This subchapter applies to the terms in **[section] sections 5(a)(11) and 9.2 of the [act of December 12, 1973 (P. L. 397, No. 141) (act), known as the Teacher Certification Law] Professional Educator Discipline Act (24 P. S. §§ 2070.5(a)(11) and 2070.9b)**, and proceedings before the Commission. This subchapter does not apply to similar or identical terms used in other regulations or statutes, including section 1122 of the Public School Code of 1949 (24 P. S. § 11-1122), or to proceedings before a board of school directors or the Secretary under Article XI of the Public School Code of 1949 (24 P. S. §§ 11-1121—11-1133), known as Teachers Tenure Act, or to proceedings before the Secretary under **[sections] section 2(i) and (j) of the act of May 29, 1931 (P. L. 210, No. 126)**, and section 1211 of the Public School Code of 1949, which were partially preserved from repeal by section 2 of the act of April 26, 1990 (P. L. 122, No. 33).

(b) *Statewide effect.* The act and this subchapter will be construed and applied by the Commission in the context of the Commission's power and duty to determine the present, continuing and future fitness and ability of a person to properly perform in this Commonwealth the duties and responsibilities of a professional educator **[in the area of the person's certification] or charter school staff member.**

§ 237.3. Immorality.

[(a) Definition.] Immorality is conduct which offends the morals of **[a community] the Commonwealth** and is a bad example to the youth whose ideals a professional educator **or a charter school staff member** has a duty to foster and elevate.

[(b) Morals of a community. For purposes of the definition of the term "immorality" set forth in subsection (a), the "morals of a community" means the morals of the community in which the professional educator is employed.]

§ 237.4. Incompetency.

Incompetency is a continuing or persistent mental or intellectual inability or incapacity to perform the services expected of a professional educator **or a charter school staff member.**

§ 237.6. [Habitual use of drugs or narcotics] (Reserved).

[(a) Definition. Habitual use of drugs or narcotics is the illegal or improper use of drugs or narcotics on a frequent or regular basis.

(b) *Drugs and narcotics.* The terms "drug or narcotics" as used in section 5(a)(11) of the act of December 12, 1973 (P. L. 397, No. 141), known as the Teacher Certification Law (24 P. S. § 12-1225(a)(11)) are defined as the terms "drug" and "narcotic" are defined in section 2 of The Controlled Substance,

Drug, Device and Cosmetic Act (35 P. S. § 780-102), and as the term "drug" is defined by section 2 of the Pennsylvania Drug and Alcohol Abuse Control Act (71 P. S. § 1690.102).]

§ 237.8. Negligence.

(a) *Definition.* Negligence is a continuing or persistent **[actions] action or [omissions] omission** in violation of a duty.

(b) *Duty.* A duty may be established by law, by **[duly]** promulgated school rules, **policies** or procedures, by express direction from superiors or by duties of professional responsibility, including duties prescribed by Chapter 235 (relating to Code of Professional Practice and Conduct for Educators).

§ 237.9. Crimes [and misdemeanors] involving moral turpitude.

(a) *Definition.* Moral turpitude includes the following:

(1) That element **[and]** of personal misconduct in the private and social duties which a person owes to his fellow human beings or to society in general, which characterizes the act done as an act of baseness, vileness or depravity, and contrary to the accepted and customary rule of right and duty between two human beings.

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(b) *Elements of the crime [or misdemeanor].* A determination of whether a crime **[or misdemeanor]** involves moral turpitude will be determined based solely upon the elements of the crime **[or misdemeanor]**. The underlying facts or details of an individual criminal charge, indictment or conviction **[is]** are not relevant to the issue of moral turpitude. **[The actual guilt or professed innocence of the charged, indicted or convicted professional educator is not relevant.]**

(c) *Specific crimes [or misdemeanors].* Crimes **[or misdemeanors]** involving moral turpitude **per se** include the following:

(1) An offense under 18 Pa.C.S. (relating to crimes and offenses) listed in section 111(e)(1) of the Public School Code of 1949 (24 P. S. § 1-111(e)(1)). **At any time subsequent to the adoption of this chapter if section 111(e)(1) is amended to add or delete crimes, the Commission will consider each additional or deleted crime to determine if the crime involves moral turpitude per se and will vote at a public meeting whether the crime will be designated as involving moral turpitude per se for purposes of cases coming before the Commission under section 9.2 of the Professional Educator Discipline Act (24 P. S. § 2070.9.2) (act).**

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(3) An offense of a criminal law of the Commonwealth, the Federal government or another state or territory of the United States, **or another nation**, an element of which offense is delivery of a controlled substance or possession of a controlled substance with intent to deliver.

(4) A State offense, out-of-State offense or Federal offense **or an offense of another nation** similar in nature to crimes **[listed]** in paragraphs (1)—(3).

(d) *Certified copy.* For purposes of section **[5(a)(11)] 9.2 of the [act of December 12, 1973 (P. L. 397, No.**

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, asso-

ciations 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.

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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.

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