

JOHN R. MCGINLEY, JR., ESQ., CHAIRMAN
ALVIN C. BUSH, VICE CHAIRMAN
ARTHUR COCCODRILLI
ROBERT J. HARBISON, III
JOHN F. MIZNER, ESQ.
ROBERT E. NYCE, EXECUTIVE DIRECTOR
MARY S. WYATTE, CHIEF COUNSEL



PHONE: (717) 783-5417
FAX: (717) 783-2664
irrc@irrc.state.pa.us
<http://www.irrc.state.pa.us>

INDEPENDENT REGULATORY REVIEW COMMISSION
333 MARKET STREET, 14TH FLOOR, HARRISBURG, PA 17101

August 22, 2002

Brian V. Harpster, V.M.D., Chairman
State Board of Veterinary Medicine
116 Pine Street
Harrisburg, PA 17105

Re: Regulation #16A-5712 (IRRC #2276)
State Board of Veterinary Medicine
Professional Conduct; Prescription Drugs

Dear Chairman Harpster:

Enclosed are the Commission's Comments which list objections and suggestions for consideration when you prepare the final version of this regulation. These Comments are not a formal approval or disapproval; however, they specify the regulatory criteria which have not been met.

The Comments will soon be available on our website at www.irrc.state.pa.us. If you would like to discuss them, please contact my office at 783-5417.

Sincerely,

A handwritten signature in black ink that reads "Robert E. Nyce". The signature is written in a cursive style.

Robert E. Nyce
Executive Director
evp
Enclosure

cc: Honorable Mario J. Civera, Jr., Majority Chairman, House Professional Licensure Committee
Honorable William W. Rieger, Democratic Chairman, House Professional Licensure Committee
Honorable Lisa M. Boscola, Minority Chairman, Senate Consumer Protection and Professional Licensure Committee
Honorable C. Michael Weaver, Secretary, Department of State
Honorable Robert C. Jubelirer, President Pro Tempore
Alexandra J. Matthews, Counsel, Senate Consumer Protection and Professional Licensure Committee

Comments of the Independent Regulatory Review Commission

on

State Board of Veterinary Medicine Regulation No. 16A-5712

Professional Conduct; Prescription Drugs

August 22, 2002

We submit for your consideration the following objections and recommendations regarding this regulation. Each objection or recommendation includes a reference to the criteria in the Regulatory Review Act (71 P.S. § 745.5a(h) and (i)) which have not been met. The State Board of Veterinary Medicine (Board) must respond to these Comments when it submits the final-form regulation. If the final-form regulation is not delivered within two years of the close of the public comment period, the regulation will be deemed withdrawn.

Section 31.21. Rules of Professional Conduct for Veterinarians.

Principle 8. Drugs.

1. Subsection (a) - Definitions of “drug” and “prescription drug” - Clarity.

In the version of the proposed rulemaking published in the *Pennsylvania Bulletin*, the definition of “drug” in Subsection (a)(1) includes the phrase “[f]or the purposes of Principle 8, the term ‘drug’ means” The definition of “prescription drug” appears separately in Subsection (a)(2). However, Subsection (a)(2) does not contain the phrase “for the purposes of Principle 8.” In the final-form regulation, the phrase “for the purposes of Principle 8” should be added to Subsection (a)(2).

2. Subsection (b) - “Under the veterinarian’s care” - Clarity.

This subsection contains a definition for the phrase “under the veterinarian’s care.” The second sentence of the subsection defines the phrase and begins with the words: “For the purposes of **this section**...” (emphasis added). The phrase “under the veterinarian’s care” does not appear in the other Principles in Section 31.21. Should the word “section” be replaced with “Principle 8”?

3. Subsection (d)(6) - Cautionary statements required by Federal law - Clarity.

This subsection references “the Federal Food, Drug and Cosmetic Act (21 U.S.C.A. §§ 301 - 397) and 21 CFR (relating to food and drugs).” Title 21 of the CFR contains over 1400 Parts. This reference should identify the specific sections, parts or other provisions that are pertinent to

cautionary statements that must be added to animal drug labels. Federal regulations may be incorporated by reference pursuant to 1 Pa.C.S. § 1937, 45 Pa.C.S. § 727, and 1 Pa. Code § 3.41.

4. Subsection (f) - Written prescriptions - Reasonableness; Need; Clarity.

This subsection requires a veterinarian to provide a client with a written prescription upon request from the client. The subsection includes an exemption from the requirement if the veterinarian has “a good faith belief that the prescription may be misused.”

According to the Preamble, this exemption was included in response to concerns from commentators who work with farm animals. Veterinarians who dispense drugs in large, multiple doses were concerned that unless they dispensed the drugs themselves, it would be “impossible for the veterinarian to have even minimal knowledge or control over the remaining quantity or expiration date of the drug.”

We question the need for the “good faith belief” exemption. The veterinarian determines whether medication is necessary and directs the course of the medication therapy. In the prescription, he or she determines the substance, quantity, dosage and amount of refills, if any. Where the prescription is filled is an unrelated issue. Therefore, unless the Board can justify the need for this exemption, it should delete it from the final-form regulation.

Second, how will clients or consumers be notified that they can request written prescriptions rather than paying for drugs dispensed directly by veterinarians? The final-form regulation should require veterinarians to notify clients that they have the option of receiving a written prescription that can be filled elsewhere.

5. Record-keeping. - Clarity.

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.