

JOHN R. MCGINLEY, JR., ESQ., CHAIRMAN ALVIN C. BUSH, VICE CHAIRMAN DANIEL F. CLARK, ESQ. ARTHUR COCCODRILLI MURRAY UFBERG, ESQ. ROBERT E. NYCE, EXECUTIVE DIRECTOR MARY S. WYATTE, CHIEF COUNSEL

INDEPENDENT REGULATORY REVIEW COMMISSION COMMONWEALTH OF PENNSYLVANIA 333 MARKET STREET 14TH FLOOR HARRISBURG. PA 17101

irre@irre.state.pa.w http://www.irre.state.pa.ws (717) 783-5417 Fax (717) 783-2664

September 29, 2003

Brian V. Harpster, V.M.D., Chairman State Board of Veterinary Medicine 2601 North 3rd Street Harrisburg, PA 17110

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

Dear Chairman Harpster:

On September 25, 2003, the Independent Regulatory Review Commission approved the State Board of Veterinary Medicine's report and revised regulation, submitted pursuant to Section 7(c) of the Regulatory Review Act. A copy of the Order is enclosed.

Since the regulation was initially disapproved, any subsequent action must undergo concurrent resolution review. Therefore, final publication of this regulation is barred for at least 14 days to allow the committees the opportunity to review the Board's report and the Commission's action. The committee review period begins on September 30, 2003. If either the House Professional Licensure Committee or Senate Consumer Protection and Professional Licensure Committee reports a concurrent resolution, the bar will continue pursuant to Section 7(d) of the Act.

If you have any questions about this action, please contact me at 783-5506.

Sincerely,

Robert E. Nyce Executive Director

evp

Enclosure

cc: Honorable Thomas P. Gannon, Majority Chairman, House Professional Licensure Committee Honorable William W. Rieger, Democratic Chairman, House Professional Licensure Committee Honorable Robert M. Tomlinson, Chairman, Senate Consumer Protection and Professional Licensure Committee

Honorable Lisa M. Boscola, Minority Chairman, Senate Consumer Protection and Professional Licensure Committee

Honorable Pedro A. Cortes, Secretary, Department of State

INDEPENDENT REGULATORY REVIEW COMMISSION APPROVAL ORDER

Commissioners Voting:

Public Meeting Held September 25, 2003

John R. McGinley, Jr., Esq., Chairman, by Phone Alvin C. Bush, Vice Chairman Daniel F. Clark, Esq. Arthur Coccodrilli Murray Ufberg, Esq.

Regulation No. 16A-5712 State Board of Veterinary Medicine Professional Conduct; Prescription Drugs

On June 10, 2002, the Independent Regulatory Review Commission (Commission) received this proposed regulation from the State Board of Veterinary Medicine (Board). This rulemaking amends 49 Pa. Code § 31.21. The proposed regulation was published in the June 22, 2002 *Pennsylvania Bulletin* with a 30-day public comment period. The final-form regulation was submitted to the Commission on June 17, 2003. At its July 24, 2003 public meeting, the Commission voted to disapprove the final-form regulation. On September 5, 2003, the Board submitted its report containing the revised final-form regulation to the Commission.

The final-form regulation establishes requirements and standards for prescribing and dispensing both prescription and non-prescription drugs. In acting on our disapproval order, dated July 24, 2003, the Board deleted a provision that required veterinarians to provide written prescriptions upon request except when a veterinarian has a good faith belief that the prescription may be misused.

The revised regulation contains beneficial provisions relating to drugs and dispensing including requirements for child-resistant packaging, detailed labeling, adequate directions for use, and precautions concerning expiration dates. Even though we support these provisions in the regulation and believe they are in the public interest, we are disappointed by the deletion of the written prescription provision that was in both the proposed rulemaking and the original final-form version of this regulation.

When the Commission voted to disapprove this regulation on July 24, 2003, we noted one issue. In explaining this concern, our order stated:

One issue, which we raised in our comments, remains a concern. Our comments suggested that the final-form regulation require veterinarians to inform clients that they have the option of receiving a written prescription that can be filled elsewhere. The Board did not include such a requirement in the final-form regulation.

We believe that notification to the consumer of the opportunity to request a written prescription is in the public interest and will not impose an unreasonable burden upon veterinarians (71 P.S. §§ 745.5b(b)(1)(i) and (ii), and (b)(3)).

In its report, the Board misrepresents the Commission's position on this regulation. It asserts that the Commission concluded it was unreasonable to require a veterinarian to give a

written prescription at the client's request "if the Board did not also require the veterinarian to notify clients that the clients could obtain a written prescription." This is an erroneous interpretation of our order.

Nothing in our comments or order on this regulation supports this interpretation of the Commission's position. At the public meeting on July 24, 2003, Commissioners expressed support for the entire regulation including the written prescription option. However, the order, as stated above, affirmed that notification to clients of this option is also in the public interest. The vote to disapprove provided an opportunity for the Board to improve the regulation by adding a public notice provision. Such a provision would expand the economic benefits of the written prescription option by insuring greater public awareness of the option. In this light, it would be cost effective, reasonable and in the public interest. The vote on July 24, 2003, was not a rejection of any part of the regulation.

We must assert that we are very displeased with the deletion of the written prescription provision. As stated above, we were looking for further improvement of this provision, not its deletion. Even though we are dismayed by this action, the Board did state in its report that it will review the written prescription provision and public notice issue. Furthermore, the Board counsel advised the Commission that the written prescription provision will be the subject of a rulemaking in the very near future and that the public notice issue will also be considered at that time. We note that the American Veterinary Medical Association and consumer organizations, such as Consumer Reports magazine, have studied the written prescription issue. The Board should take advantage of this research. We urge the Board to expedite its review and to publish a proposed rulemaking addressing the written prescription and public notice issues at the earliest possible opportunity.

Finally, the Commission believes that the General Assembly should review these issues pursuant to Section 5.2(b)(4) of the Regulatory Review Act (71 P.S. § 745.5b(b)(4)).

Having considered all the criteria of the Regulatory Review Act, we find promulgation of this regulation is in the public interest.

BY ORDER OF THE COMMISSION:

This regulation is approved.



Alvin C. Bush, Vice Chairman