TO: CVMA Board of Directors
FROM: Melanie Marsden, DVM – Chair, Task Force on Pharmacy Issues
DATE: January 6, 2005
RE: Preliminary Task Force Report

The subject of pharmacy issues in the veterinary medical profession is one that is broad, multi-faceted, unclear, and controversial. That said, it has nonetheless been a pleasure for the task force to contribute some knowledge that we hope will assist CVMA members in better understanding the issues.

This report reflects significant progress by the task force in fulfilling its charge, though additional tasks remain to be completed (and some existing material may need revision pending policy clarification from the FDA). With consent from the Board of Directors, the task force is hopeful that the educational materials furnished in this report can be disseminated to members in the first quarter of 2005. The task force anticipates that its final report will be furnished to the board at the Fall Leadership Conference this year.

Position statement on the VCPR

The task force was charged to “Develop a position statement about the veterinarian-client-patient relationship as it relates to prescribing and dispensing medications, and make this position statement available to members.” This was raised in response to a member question about whether the VCPR should include a statement about the time interval between examining the patient and subsequently dispensing or refilling medications.

The task force reviewed VCPR definitions from a number of sources. In no instance did we find such an interval specified in the definitions. Upon reflection, the absence of a specific interval indicates that one solution does not necessarily fit all circumstances. Veterinarians must consider an array of factors to make a complex medical decision when prescribing medications. Dictating an interval might actually serve to diminish the importance of professional discretion.

Accordingly, the task force recommends against amending the VCPR to include a specific time interval between examining an animal patient and subsequently dispensing or refilling medications. However, a discussion of this issue is appropriate to encourage veterinarians to develop a hospital policy on dispensing and refilling medications that includes element such as:

- a discussion with the client about the disease process,
- the appropriate number of refills (if any),
- a schedule for re-check examinations,
consideration of the accelerated rate of animal aging compared to humans, and
potential adverse effects.

This information will be included in materials that the task force is formulating for
dissemination to members.

**Internet pharmacies**

The task force was charged to “Develop a brochure that veterinarians can download from the
CVMA Web site and use to educate clients about pharmacy issues, thereby helping veterinarians
provide optimal patient care, develop a competitive advantage over Internet pharmacies, and
retain clients.” That brochure is attached to this report as Appendix I.

The task force also thought it desirable to provide information to veterinarians on this topic.
That information is attached to this report as Appendix II.

**Drug compounding**

To fully respond to the intent of the above charge, the task force viewed it as desirable to also
address the issue of drug compounding and piracy. The Food and Drug Administration is in the
process of revising the Compliance Policy Guidelines. When FDA releases the updated version,
the task force will amend as appropriate the material for veterinarians that is covered in
Appendix II. The task force may also recommend, following review of the FDA revisions, that
development of a client education brochure could be warranted.

**Sales tax on prescription medications**

After the task force had been formed, another issue surfaced that logically fell to the task force’s
collective lap. The issue was an audit of Boulder veterinary practices for compliance with an
ordinance mandating collection of sales tax on veterinary prescriptions. Thanks to the stellar
leadership of Dr. Sue Patton-Weller, who guided Boulder area veterinarians through a
negotiation process with the City of Boulder, the issue was addressed and CVMA has benefited
by obtaining a clearer view of the rights and responsibilities of veterinarians in regard to sales
and use taxes on veterinary prescriptions and products.

Dr. Patton prepared an article on these topics that was recently published in the Fall 2004 issue
of the CVMA *Voice*. Accompanying that article was a list of home-rule cities, where local
ordinances could create variance from state statute in regard to the collection of sales tax on
veterinary prescription medications, along with a Web link to the Colorado Municipal League
(where sales tax contacts in each home-rule city are identified).

The task force recommends that the articles on sales and use tax and on home rule municipalities
be placed on the CVMA Web site.
Upcoming activity

The task force has made significant progress in addressing its charge by formulating the educational materials contained in this preliminary report. There are additional charges that the task force will now address in its second phase of activity:

- Identify uncertainties or conflicts in Colorado statutes, rules, and regulations governing the prescribing and dispensing of prescription medications.
- Enlist support from the State Board of Veterinary Medicine to approach the Colorado Board of Pharmacy about modifications that would resolve conflicts in statutes, rules and regulations.
- Seek input from members about gaps in information not provided through the pharmacy issues section of the CVMA Web site, and recommend ways to address the knowledge gaps.
- Update educational materials if needed following FDA release of the revised Compliance Policy Guide.
Appendix I – Client education brochure on Internet pharmacies

[Proposed copy for brochure. CVMA staff will incorporate the text into the client education brochure template; add appropriate introductory material, headlines, and graphics; and post to the CVMA Web site.]

- Your veterinarian knows your pet and your family personally, and is familiar with your pet’s specific needs and the environment where you live. Medication prescribed and purchased at your veterinarian’s office comes with the comfort of knowing that you and your pet are individuals and have distinct needs that can best be served within your local community by your veterinarian.

- Each animal is a different and unique individual. Some breeds and species have special needs or sensitivities. Dogs and cats ARE different – some medications that are administered to dogs are not safe (even fatal) for cats. Your veterinarian is aware of these differences, allowing him or her to select the product best suited to your pet.

- There are many medications that should not be administered until your veterinarian determines they are safe to be administered to your pet. For example, heartworm medication should not be given to dogs with active heartworm infections because it can lead to a fatal reaction. Therefore it is important to consult your pet’s veterinarian before administering any medication.

- Medications shipped to your veterinarian are properly packaged, delivered and stored under controlled conditions to avoid temperature extremes, sunlight and moisture, thus ensuring that the safety and efficacy of medications and vaccines is not compromised.

- Some medications require follow-up monitoring for adverse reactions or dosage adjustments. An adjustment to the dosage may need to be made after laboratory test and/or examinations are performed. For example, many arthritis medications require periodic monitoring of vital organ function. IF an adverse reaction does occur, it is important to have established a veterinarian-client-patient relationship to ensure that your pet receives appropriate medical attention on a timely basis.

- You should verify that an Internet pharmacy is properly licensed with the Colorado Board of Pharmacy (go to www.dora.state.co.us/pharmacy/Index.htm and click on Automated License Verification).

- Some pharmacies will try to sell pirated or unapproved “knock-off” drugs (that is, imitations of FDA-approved drugs) to you. When ordering a whole bottle, be sure the original packaging is intact and look for a NADA (New Animal Drug Approval) number on the bottle.

- Be aware that at least two prominent Internet pharmacies selling veterinary medications have been investigated and consented to disciplinary action.

- When talking to an Internet pharmacy:
  - If they do NOT ask for the name, address and telephone number of your pet’s veterinarian, it’s a RED FLAG.
If they suggest you complete a health survey in place of your veterinarian’s examination, it’s a RED FLAG.

If they offer to have a veterinarian online who has never examined your pet provide a prescription, it’s a RED FLAG.

If they do not have a physical address and telephone number, it’s a RED FLAG.

If they require a waiver of rights before drugs are sent, it’s a RED FLAG.

If they say it is advisable to obtain a prescription medication from a foreign country via the Internet, it’s a RED FLAG.

- There are risks to purchasing prescriptions on-line including:
  - The drug manufacturer may not guarantee the medication if a problem arises.
  - Some medications may be foreign drugs that may not have the same quality and purity assurance as US drugs do. It is generally illegal to dispense foreign drugs in the United States, including foreign versions of US products.
  - Some medications may be imitations of approved drugs, and contain incorrect drug amounts. Studies of imitation drugs have found active drug amounts in a 100 mg pill to vary from 5 mg to 200 mg!
  - Many medications must be kept in a controlled environment or refrigerated to ensure potency and effectiveness. You don’t know what happened to your pet’s medication on the delivery truck from the Internet pharmacy.
  - Selling prescription drugs directly to owners without valid prescriptions may pose a health risk to patients and is illegal.
Appendix II – Resource materials for veterinarians on pharmacy issues

Background

Members have expressed confusion and uncertainty in regard to pharmacy issues. In particular, questions have been raised about the time interval between patient examination and subsequent prescribing of medication, Internet pharmacies, and drug compounding and piracy. CVMA has developed the following resources to help answer these questions, and has identified other resources on the Internet for which links are provided. In particular, CVMA suggests visiting the AVMA Web site section on prescribing and dispensing (http://www.avma.org/noah/members/scientific/prescribing/default.asp).

Interval between patient examination and subsequent prescribing of medication

Members have asked whether the veterinarian-client-patient relationship (VCPR), as defined in the Colorado Veterinary Practice Act, should include a statement about the time interval between examining an animal patient and subsequently dispensing or refilling medications.

The CVMA Task Force on Pharmacy Issues reviewed VCPR definitions from a number of sources, and found no instances where such an interval is specified in the definitions. Upon reflection, the absence of a specific interval indicates that one solution does not necessarily fit all circumstances. Veterinarians must consider an array of factors to make a complex medical decision when prescribing medications. Dictating an interval might actually serve to diminish the importance of professional discretion.

CVMA encourages veterinarians to develop a hospital policy on dispensing and refilling medications, and to communicate this policy to clients. This policy should include elements such as:

- a discussion with the client about the disease process, concurrent diseases, and other medications already being administered (if any)
- the appropriate number of refills (if any),
- a schedule for re-check examinations,
- consideration of the accelerated rate of animal aging compared to humans,
- an understanding of appropriate dose and dosing frequency, and
- potential adverse effects.

Internet pharmacies

A client’s request for a written prescription to be filled elsewhere presents an educational opportunity. The discussion should review the medical, legal, and business aspects of complying with the client’s request. To aid this discussion, CVMA has prepared a client education brochure on Internet pharmacies that can be downloaded and duplicated in your practice. Veterinarians should be familiar with, and discuss with clients, the “red flags” and risks associated with Internet pharmacies as presented in the client education brochure.
In addition, the veterinarian should be aware of the following considerations:

- Consider asking client if there is some concern or problem that can be addressed to the client’s satisfaction. For example, an interest in perceived cost savings might be readily addressed by offering to match the Internet pharmacy’s price (including the shipping and handling fees).

- Any medically indicated drug therapy should be initiated by the attending veterinarian in the context of a valid VCPR. It is within the veterinarian’s purview – not the pharmacist’s – to determine the medical criteria whereby a drug is indicated.

- Drugs may be prescribed rather than dispensed. The American Veterinary Medical Association and the Colorado State Board of Veterinary Medicine both recommend that veterinarians honor client requests to prescribe rather than dispense medications. In Colorado, prescriptions are considered to be part of the medical record to which the client has reasonable access.

- When honoring client requests to prescribe rather than dispense medications, veterinarians should provide a written prescription that the client can present to the pharmacy – rather than providing a voice or fax authorization directly to the pharmacy.

- A prescription must be written by the veterinarian who has most recently seen the animal for the medical condition necessitating that particular prescription, since prescriptions require a valid VCPR.

- Review appropriate dose, dosing frequency and number of refills with the client. Consider no refills to encourage client communication.

- As with any prescription, a written record should be maintained. Consider a prescription pad that provides a duplicate copy for the medical record.

- You should suggest the client verify that an Internet pharmacy is properly licensed with the Colorado Board of Pharmacy (go to www.dora.state.co.us/pharmacy/index.htm and click on Automated License Verification).

- Advise the client if he or she purchases a whole bottle of a prescription medication to be sure that the original labeling is intact, including a NADA (New Animal Drug Approval) number.

- When honoring a client’s request for a prescription, the fact that the prescription will be filled elsewhere does not relieve the prescribing veterinarian of the responsibility to discuss proper use, adverse effects, side effects, need for follow-up appointments or blood work, etc.

- Charging for writing a prescription is a gray zone. On one hand, writing a prescription takes time for which the veterinarian should be properly compensated. On the other hand, while Colorado law does not prohibit such a practice, the Colorado Veterinary Practice Act indicates that “obtaining fees for unnecessary services” can be considered unprofessional or unethical.

- If you have a concern about the activities of an Internet pharmacy, the AVMA has developed complaint form (http://www.avma.org/scienact/prescribing/complaint_form.pdf) to convey concerns to the Food and Drug Administration and state authorities.
Compounding and drug piracy

Compounding
Compounding is defined as any manipulation to produce a dosage form a drug other than that manipulation provided for in the directions for use on the label of the approved drug product. A few examples include combining drug agents for anesthesia, incorporating a pill into liquid or capsule forms, or creating certain antidotes.

There is a legitimate need for compounding, which is governed by AMDUCA (since compounding is an extralabel use). Legal compounding can only begin with FDA-approved drugs, yet veterinarians recognize rare instances where unapproved drugs are needed to treat specific non-food animal patients. An excellent brochure explaining veterinary compounding has been produced by AVMA, the Animal Health Institute, and the American Veterinary Distributors Association (http://www.avma.org/??????????).

AVMA has prepared an extensive and helpful collection of Frequently Asked Questions (http://www.avma.org/noah/members/scientific/prescribing/faq_compounding.asp) about compounding. The AVMA Position Statement on Compounding (http://www.avma.org/policies/compounding.htm) provides helpful clarification, such as:

- Use of a compounded drug should be accompanied by the same precautions followed when using a drug in its original form, including counseling the client regarding potential adverse reactions, and the potential for unintended human or animal exposure to the drug
- Use of a compounded drug should be limited to:
  - Those drugs for which safety and efficacy have been demonstrated in the compounded form on target species;
  - Disease conditions for which response to therapy or drug concentrations can be monitored; or
  - Those individual patients for which no other method or route of drug delivery is practical.

There are additional aspects to consider in using a compounded drug, including:
- The flavoring of FDA-approved drugs is acceptable.
- Obtaining or compounding a drug in a quantity for “in-office use” is unacceptable.
- Re-labeling or re-selling compounded drugs is illegal.

Drug piracy
Drug piracy is essentially the wholesaling of unapproved drugs, which are often made from bulk ingredients that do not meet FDA guidelines and which are frequently from foreign sources.
Such drugs circumvent the FDA drug approval and monitoring process. Often pirated drugs are mass-marketed products with little quality control. Pirated drugs mimic approved drugs, but they are not an FDA approved generic that ensures safety, efficacy, quality, stability, and accuracy in packaging and labeling. Some examples of approved drugs that are often pirated include omeprazole, enrofloxacin, praziquantel, and ivermectin formulations.

Why is drug piracy bad?
- It denies the patient treatment with a safe, effective, pure, potent and stable FDA approved drug.
- It exposes the patient to an unapproved drug that may be contaminated, sub- or super-potent, or unstable.
- It exposes all parties, especially the veterinarian, to unnecessary liability. (Even if the client signs a waiver you as veterinarian are still liable if problems arise from a pirated drug.)
- It undermines the incentive for research and development by the drug companies, potentially leading to fewer approved drugs. It takes an average of 8-10 years at a cost of $300 million to get a new drug approved. It costs $2-8 million to add a new species to a drug label. In short, if they can’t sell it they won’t make it!
- Veterinarians may have fewer approved drugs without a healthy animal pharmaceutical industry.
- Bulk ingredients often originate from developing countries that may lack a well-regulated chemical industry, so quality and purity can be questionable. The bulk ingredients may come from countries where there are real threats about bio-terrorism.
- It is illegal.

Remember – when prescribing compounded drugs, it is the veterinarian’s responsibility to:
- Exercise due diligence by determining that the pharmacy is preferentially using FDA-approved products.
- Understand that the veterinarian incurs professional liability if pirated drugs are used in or dispensed from the veterinarian’s practice.
- Inform the client it is never acceptable to use pirated drugs, even if the client desires to sign a waiver.

Other helpful resources:
- AVMA Position Statement on Compounding
  (http://www.avma.org/noah/members/scientific/prescribing/faq_compounding.asp)

[Sidebar – Did you know?]
- According to the Colorado Board of Pharmacy, unless you have a wholesale pharmacy license you may not fill a prescription for a patient from another clinic.
- According to the Colorado Board of Pharmacy, it is technically allowable to borrow and replace a non-controlled prescription medication from another veterinary practice – but it is illegal to sell that same medication to another veterinary practice.