# SENATE COMMITTEE ON BUSINESS, PROFESSIONS AND ECONOMIC DEVELOPMENT

Senator Jerry Hill, Chair 2017 - 2018 Regular

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Author: Hill

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Urgency: No Fiscal: Yes

Consultant: Bill Gage

Subject: Veterinary medicine

**SUMMARY:** Clarifies that the Veterinary Medical Board (VMB) shall inspect at least 20 percent of veterinary premises within one year of being issued a premises permit; clarifies the exemption for students from the requirement for licensure who are participating in specified accredited veterinary medical programs; changes the period of time for reinstatement of a surrendered or revoked license and to petition for termination or modification of probation; requires, in nonemergency situations and outpatient settings, that each time a veterinarian prescribes, administers, dispenses, or furnishes a dangerous drug or prescription medicine, unless in conjunction with surgery during an anesthetic procedure or emergency services, that the veterinarian offer to provide the client with a consultation that includes specified information and also requires a veterinarian to provide pharmaceutical literature or written information, when available, if requested by the client and to provide a poster which reflects these requirements.

# Existing law, the Veterinary Medicine Practice Act (Act):

- 1) Provides for the licensing and regulation of veterinarians and registered veterinary technicians (RVTs) by the VMB within the Department of Consumer Affairs (DCA). (Business and Professions Code (BPC) § 4800 et seq.)
- 2) Provides that protection of the public shall be the highest priority for the VMB in exercising its licensing, regulatory, and disciplinary functions. Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount. (BPC § 4800.1)
- 3) Specifies that the VMB may, in accordance with the provisions of the Administrative Procedure Act, adopt, amend, or repeal rules and regulations that are reasonably necessary to carry into effect the provisions of the Act. (BPC § 4808)
- 4) Provides that the VMB may, at any time, inspect the premises in which veterinary medicine, veterinary dentistry, veterinary surgery is being practiced. (BPC § 4809.5)
- 5) Requires the VMB to establish a regular inspection program which will provide for random, unannounced inspections. Provides that the VMB shall make every effort to inspect at least 20 percent of veterinary premises on an annual basis. (BPC § 4809.7)
- 6) Provides that the practice of veterinary medicine includes the diagnosing, prescribing, or administering of a drug, medicine, appliance, application, or treatment

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- for the prevention, cure, or relief of a wound, fracture, bodily injury, or disease of animals. (BPC § 4826)
- 7) Permits a licensed veterinarian or a RVT under the supervision of a licensed veterinarian to compound drugs for animal use as specified. (BPC § 4826.5)
- 8) Provides that certain veterinarians and other persons are exempt from the Act and that these exempt persons include students in the School of Veterinary Medicine of the University of California or the College of Veterinary Medicine of the Western University of Health Services who participate in diagnosis and treatment as part of their educational experience, as specified. (BPC § 4830)
- 9) Authorizes a RVT technician or a veterinary assistant (VA) to administer a drug, including a drug that is a controlled substance, under the direct or indirect supervision of a licensed veterinarian when done pursuant to the order, control, and full professional responsibility of a licensed veterinarian. (BPC § 4836.1 (a))
- 10) Authorizes a VA to obtain or administer a controlled substance pursuant to the order, control, and full professional responsibility of a license veterinarian under specified conditions. (BPC § 4836.1)
- 11)Permits a person, whose license or registration has been surrendered while under investigation, revoked or who has been placed on probation to petition the VMB for reinstatement for modification of penalty after a period of not less than one year has elapsed from the effective date of the decision ordering the disciplinary action. (BPC § 4887)

### **Existing law, the Pharmacy Law:**

- 1) Defines "dangerous drug" as any drug unsafe for self-use in humans or animals, and includes: (BPC § 4022)
  - a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without a prescription," "Rx only," or words of similar import.
  - b) Any drug that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant regulations of the Board of Pharmacy since unrestricted retail sale of the drug would be dangerous to the public health or safety.
- 2) Provides that veterinarians may personally furnish any dangerous drug prescribed by them to the patient for whom prescribed, provided that the drug is properly labeled to show all the information required pursuant to the labeling requirements as specified in BPC § 4076. (BPC § 4077).

# Existing California Code of Regulations (CCR) for the Board of Pharmacy:

1) Requires a pharmacist to provide oral consultation to his or her patient or the patient's agent in all care settings upon request, or whenever the pharmacist deems

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it warranted in the exercise of his or her professional judgment. (CCR § 1707.2 (a))

2) Provides that, in addition to the obligation to consult above, a pharmacist shall provide oral consultation to his or her patient, or the patient's agent, in any care setting in which the patient or agent is present whenever the prescription drug has not been dispensed to a patient, or whenever the patient or agent is not present, a pharmacy shall ensure that the patient receives written notice of his or her right to request consultation and a telephone number from which the patient may obtain oral consultation from a pharmacist. (CCR § 1707.2 (b))

- 3) Provides that the oral consultation provided shall include at least directions for the use and storage and the importance of compliance with directions and precautions and relevant warnings, including common severe side or adverse effects or interactions that may be encountered. (CCR § 1707.2 (c))
- 4) Provides that whenever a pharmacist deems it warranted in the exercise of his or her professional judgment, the oral consultation shall include additional information as specified. (CCR § 1707.2 (d))
- 5) Specifies that a pharmacist is not required to provide oral consultation when a patient or the patient's agent refuses such consultation. (CCR § 1707.2 (e))

#### This bill:

- 1) Requires the VMB to inspect at least 20 percent of veterinary premises within one year of being issued a premises permit.
- 2) Exempts students of an American Veterinary Medical Association Council on Education accredited veterinary medical program who participate, as part of their formal curriculum, in diagnosis and treatment with direct supervision or in surgery with immediate supervision and who meet other specified requirements from the Act.
- 3) Specifies that if an accredited veterinary medical program provides formal curriculum at an off-campus or distributive site, a memorandum of understanding (MOU) between the accredited veterinary medical program as specified above and in current law must be in place that provides for a description of the educational objectives expected to be achieved at the site, a review conducted by the accredited veterinary medical program to ensure the educational programs is being delivered in accordance with the MOU, and a mechanism for assessing training outcomes of the educational process.
- 4) Extends the period to petition the VMB for reinstatement of a surrendered or revoked license to 3 years and extends the period to petition the VMB for early termination or modification of probation to 2 years, unless otherwise authorized by the VMB in the revocation or surrender order or order imposing probation.
- 5) Requires, in nonemergency situations and outpatient settings, that each time a veterinarian prescribes, administers, dispenses, or furnishes a dangerous drug or prescription medicine, unless in conjunction with surgery during an anesthetic procedure or emergency services, the veterinarian offer to provide the client with a

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consultation that includes specified information.

6) Requires a veterinarian to provide, along with the consultation, pharmaceutical literature or written information, when available, if requested by the client.

- 7) Authorizes a veterinarian to delegate the task of providing the consultation and literature or written information to a RVT or VA who is employed by and working under the supervision of the veterinarian.
- 8) Requires in every veterinarian practice, a poster notifying clients about the following consumer rights:
  - a) The right to be offered a drug or medicine consultation.
  - b) The right to ask for basic pharmaceutical and drug and medicine interaction information.
  - c) The right to have a choice to obtain either the medication or a written prescription and to not be charged for the written prescription as specified.

**FISCAL EFFECT:** Unknown. This bill has been keyed "fiscal" by Legislative Counsel.

#### **COMMENTS:**

Purpose. This measure is sponsored by the <u>Author</u>. According to the Author, the
primary purpose of this bill is to require veterinarians to provide consultation to their
clients (pet owners) regarding dangerous drugs or prescription medicines they
provide to their animal patients. During the 2016 sunset review oversight of the
VMB, there was testimony provided regarding information and consultation that
should be provided by veterinarians when prescribing or furnishing drugs and
medicines.

It was indicated that veterinarians generally provide some counseling voluntarily or when requested, and provide some written information regarding the drug or medicines they prescribe or furnish when asked. However, it does not appear that it is always a consistent practice for all veterinarians. Obviously, some of these drugs provided are considered as "dangerous drugs" (prescription medicines) and some are designated as controlled substances and could be very harmful to the animal patient if provided incorrectly or if there is overmedication. It could potentially lead to needless suffering of the patient animal or even death of a beloved pet.

As argued, pet owners are consumers covered by consumer protection laws and have the right to be fully informed about the care being provided to their animal(s). The veterinarian is actually standing in the shoes of a pharmacist. Pharmacists are required to fully inform their patients of the type of medication being provided and the potential risks and side effects associated with the drug provided. They do this by counseling and providing consultation to the patients as well as providing pharmaceutical literature with all prescription medications provided. Therefore,

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veterinarians who prescribe, supply and administer medications for pets should at least offer to provide certain information regarding the drugs they provide such as details for the administration of a drug, the correct dosage to administer and for how long, directions for proper use and storage, precautions and relevant warnings regarding severe adverse effect or interactions of the drugs with other medications being provided and what might happen if the drug is being provided on a long-term basis. They should also provide important pharmaceutical literature when requested by the client and when it is available.

Veterinarians are in a unique position both as the prescriber and usually the dispenser of these dangerous drugs or prescription medicines to provide this important information regarding the drugs they provide. Consistently providing consultation to clients of the veterinarian, similar to the consultation that patients currently receive from pharmacists for prescription medication, is a reasonable and simple preventative approach that is missing from the practice of veterinary medicine.

There is also concern that the practice of veterinary medicine is changing rapidly. There are advances in both veterinary clinics or hospitals in the diagnosis and treatments provided for animal patients including use of MRI and CAT scans, echocardiograms and other technologies and techniques that were normally available only to human patients, and in the new drugs being provided by pharmaceutical companies and utilized by veterinarians. There also is the change from the independent veterinarian practice to that of the corporate model with major companies buying up independent practices and shifting to an emphasis of having more services provided and offered, such as more use of vaccines and expensive specialized drugs. With this in mind, consumers of veterinarian care being better informed about the services and drugs they receive, becomes ever more critical.

Other changes in this bill are considered as important to the VMB and provide clarification regarding inspection of veterinarian premises, student exemption from licensure when participating in surgery as part of their formal instruction, and extending the time frame for reinstatement of a surrendered or revoked license or for termination or modification of probation.

2. **Background.** Created in 1893, the VMB licenses and regulates veterinarians, RVTs, RVT schools and programs, and veterinary premises and hospitals through the enforcement of the Act.

The veterinary medical profession provides health care to livestock, poultry, and pets from birds, fish, rabbits, hamsters, and snakes to dogs, cats, goats, pigs, horses, and llamas. The quality of health care is on a par with that of human medicine. Currently there are 36 recognized specialties in veterinary medicine such as surgery, internal medicine, pathology, and ophthalmology. In some cases, drugs and procedures are identical in human and animal medicine. Frequently, techniques and procedures are developed in veterinary medical research prior to their use in human medicine.

Every day, Californians are protected by the veterinary profession through its responsibilities for food safety and control of zoonotic diseases (diseases spread

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from animals to people). Early recognition of symptoms, aggressive vaccination campaigns, and accompanying education by veterinarians have significantly reduced the public health threat of rabies, the most well-known disease that is transmitted between animals and people. Although there are fluctuations in numbers of occurrences of other diseases such as tuberculosis, brucellosis, Eastern and Western encephalomyelitis, and West Nile virus, the overall low incidence rate of these diseases is due to the competency of veterinarians who diagnose and supervise preventive medicine programs. In addition, veterinary medicine is on the front line of defense against bio-terrorism threats such as anthrax, foot and mouth disease, and food and water resource contamination.

The services veterinarians and RVTs provide to the food, agricultural, pharmaceutical, research, horse racing, and pet care industries have a major impact on the State's economy. According to the American Veterinary Medical Association (AVMA), veterinary services are a \$1.2 billion industry in the state. Based on 2010 statistics from the California Department of Food and Agriculture, livestock and poultry products alone generate over \$9.8 billion in sales, with dairy as the leading commodity.

In a pet ownership survey based on data from 2011, the AVMA shows that 56 percent of all American households own at least one pet. A national average shows that dog owners spend approximately \$19.1 billion and cat owners spend approximately \$7.4 billion for veterinary health care maintenance. Ninety percent of dog owners use veterinary services at least once per year and make 2.2 repeat visits, while 75 percent of cat owners use veterinary services with 1.2 repeat visits per year.

The VMB protects the public from the incompetent, unprofessional, and unlicensed practice of veterinary medicine. The VMB requires adherence to strict licensure requirements for California veterinarians and RVTs. The pet-owning public expects that the providers of their pet's health care are well-trained and are competent to provide these services. The VMB assures the public that veterinarians and RVTs possess the level of competence required to perform these services by developing and enforcing standards for examinations, licensing, and hospital and school inspection. The VMB also conducts regular practice analyses to validate the licensing examinations for both veterinarians and RVTs. Additional eligibility pathways have also been approved for licensure of internationally trained veterinary graduates and certification of RVTs to allow qualified applicants from other states in the U.S. and countries around the world to come to California and to improve the provision of veterinary health care for consumers and their animals.

To meets this mission, the VMB: (1) promotes legal and ethical standards of professional conduct, conducts background checks for all applicants; (2) promotes a national examination reflective of the current practice of veterinary medicine, in addition to a jurisprudence examination focused specifically on California laws and regulation; (3) provides for an examination for RVTs, both a state laws and regulations examination and the National Veterinary Technician Examination; licenses veterinarians and RVTs and maintains oversight responsibility for others working within veterinarian offices and hospitals such as veterinarian assistants; (4) establishes animal health care tasks and the appropriate degree of supervision

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required for those tasks that may be performed by a licensed veterinarian, RVT, or a veterinarian assistant; investigates complaints on veterinarians, RVTs, and unlicensed veterinary medicine practice; (5) takes disciplinary action and issues citations when appropriate; conducts various outreach activities to provide the public, licensees, and potential licenses the most comprehensive and current information and; routinely develops a Strategic Plan to establish goals and objectives for the VMB. The VMB's goals, as stated in its Strategic Plan, include decreased enforcement cycle times, enhanced quality and training of hospital inspectors, inspecting existing hospitals within one year of registration, and working with DCA to reduce the amount of unlicensed activity occurring in the marketplace.

The VMB is composed of eight members: four veterinarians, one RVT, and three public members. The VMB has one statutorily mandated advisory committee, the Multidisciplinary Advisory Committee (MDC). The VMB's MDC was created in 2009 by the Legislature to assist, advise, and make recommendations for the implementation of rules and regulations necessary to ensure proper administration and enforcement of the VMB's laws and regulations and to assist the VMB in its examination, licensure, and registration programs. It was also created to address the various practices of the profession and address veterinarian, RVT, and veterinarian assistant issues. The composition of the MDC is nine members: five licensed veterinarians, three registered veterinary technicians, and one public member.

3. Provisions Related to Student Exemption from Licensure. As indicated by the VMB, the MDC and VMB spent a great deal of time discussing the provisions authorizing veterinary students to participate in surgery as part of their formal instruction under the immediate supervision of a licensed veterinarian. Clearly, it is imperative for veterinary students to be trained in surgical procedures and have instruction by a supervising veterinarian who is present and monitoring the students while in a learning the new skills. The public's animals are best served by well-trained and competent veterinarians and facilitating these learning opportunities in a safe educational environment prepares graduates for entry level practice. The provisions include a safeguard to prevent new veterinary students from engaging in surgical procedures until such time as the students have been trained in the activity as part of the program's formal curriculum.

The current exemption under BPC Section 4830(a)(4) mentions *off-campus educational programs,* but the provisions do not specify the requirements for the off-campus sites, in terms of providing an appropriate learning environment for the student. As such, the learning environments and educational objectives at the sites may not be consistent with the training standards required of the veterinary medical program. It is important for the program to formulate an agreement with each site that defines the educational objectives and the learning outcomes for the student. In this way, training standards may be measured and students are afforded relevant and consistent learning opportunities with appropriate supervision at various off-campus veterinary practices.

4. Consideration of Reinstatement of Licensure or Modification of Terms of **Probation.** The VMB indicated that the hearing of a petition for reinstatement and/or modification of penalty is one year after the effective date of the decision is

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problematic. This is because a period of one year is often insufficient to show evidence of rehabilitation and compliance with the terms and conditions of the order to an extent sufficient to ensure remediation and ultimately public protection. The VMB believes that staggered timeframes of eligibility to file a petition will provide sufficient opportunity for the VMB to assure compliance with probation terms or orders and sufficient time to observe rehabilitation of the person whose license has been surrendered or revoked.

- 5. MDC of the VMB Currently Considering Drug Counseling and Disclosure for Veterinarians. At a recent meeting, the MDC began the process of reviewing potential language regarding consultation to be provided by a veterinarian when furnishing a dangerous drug to a client, or his or her representative. The following is the information that would be provided if made part of regulations promulgated by the VMB:
  - a) the name and description of the drug;
  - b) details for preparation and administration to the animal patient by the client, or his or her representative;
  - c) route of administration, dosage form, dosage, and duration of drug therapy;
  - d) directions for proper use and storage;
  - e) precautions and relevant warnings provided by the drug's manufacturer, including common severe adverse effects or interactions that may be encountered and adverse interactions with other medications including those available with or without a prescription;
  - f) drug prescription refill information; and,
  - g) actions to be taken in the event of a missed dose.

The VMB also provided for the following:

- a) A veterinarian may delegate the task of providing the consultation to a registered veterinary technician or veterinary assistant under his or her supervision, and the required information may be provided in written form.
- b) The provisions of subdivision (a) shall not apply if the client, or his or her representative, declines or refuses the consultation or elects to have a prescription filled at a location other than at registered veterinary premises. If a consultation is not provided, that fact shall be recorded in the patient's records.
- c) A registered veterinary premise where dangerous drugs are furnished shall post a sign in a conspicuous location, with the form to be specified by the board, indicating that the consultation specified in subdivision (a) must be offered to the client, or his or her representative.

The process for MDC to recommend language to the VMB for discussion and

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debate, and then for the VMB to formally adopt and then move forward with possible regulations to be approved by the Office of Administrative Law could take up to two years or more. The Author believes that a statutory requirement for consultation should go into place much sooner (January 1, 2018) and that the veterinarian profession seems willing to move forward with consideration of language and the requirements in this measure.

4. Arguments in Support. Mr. Salomon Stupp, Author of the "Lizzie Initiative for Veterinary Pharmacy" whose proposal was presented to this Committee during its sunset review oversight of VMB in March of 2016, urged the Committee to consider the need for veterinarians to provide information to consumers about the drugs furnished or administered to pets. He believes that information about potential side effects or adverse events is basic consumer protection information that is essential to making informed decisions about the health or treatment options of a pet. He indicates that many veterinarians are very responsible and aware of this issue and inform their clients, but not all veterinarians provide pharmaceutical information to consumers - which is not only inconsistent with general medical practice, but also ignores the basic consumer protection right to be informed.

He further states that, "the absence of pharmaceutical information exposes pets, pet owners, guardians, caretakers and veterinarian themselves to a flawed and mislead decision-making process, because decisions for treatment may be made based upon incomplete or limited information. This can and does result in the needless suffering or even the painful death of a beloved pet.

"The need for consistent pharmaceutical information is reinforced by the fact that drugs are furnished and administered at veterinary clinics or hospitals where there are not veterinary pharmacists. These veterinary clinics or hospitals where there are no veterinary pharmacists. These veterinary clinics or hospitals in reality operate as drug stores that diagnose, label, furnish and administer medicines. Consequently, veterinarians must consistently assume the informational and preventative role of the pharmacist through counseling and by providing printed literature explaining the type of medication and the potential risks and side effects associated with the specific treatment. Additionally, the growing number of new drugs being developed by laboratories and the inherent risks for dangerous drug interactions argues for the need for pharmaceutical information."

"The established protocol of preventative disclosure about potential risks and side effects of drugs is absolutely justified in veterinary medicine. This is not only true because of it is how modern medicine is practiced, but also because when consumers protect the health of their pets and service animals they are also protecting their own health and welfare. In fact, pets are often an integral part of the family structure."

"Consumers need the pharmaceutical information about the drugs prescribed to pets in order to make responsible and intelligent decisions."

The <u>Veterinary Medical Board</u> (VMB) as of April 19, 2017, took a "support if amended" position on the measure. There are only two minor issues that the VMB has with the measure. They want to clarify that the drug counseling does not pertain

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to inpatient treatment, which the bill is intended not to effect or require, and clarify under what circumstance drug consultation would have to be provided for refill of drugs by the client.

5. Arguments in Opposition. The <u>California Veterinary Medical Association</u> (CVMA) has taken an "oppose/work with Author" position on this measure. As indicated by CVMA, recent amendments strike several major provisions which would have been difficult for veterinary professionals to comply with. CVMA believes the continued conversations with the Author may result in additional amendments that will further tighten the intent of the measure, while preserving the overarching goal of the legislation.

CVMA was concerned with the bill as introduced and believed it would have put undue pressure on the veterinarian to provide volumes of printed drug information to a client and this information is not universally available to veterinarians at this time. The recent amendments strike several references in the bill related to providing this printed drug material requirements. To assure that when the client does request information and because of the difficulty in obtaining certain drug information, CVMA wants to clarify that it will provide the information "when available" or "when applicable."

CVMA is also concerned that they would have to offer consultation to a client each time a drug is dispensed at the veterinary hospital, which could include every time the prescription is refilled. CVMA recommends that the word "initially" be added so it states: "each time a veterinarian *initially* prescribes." Also, there is concern that consultation would still have to be provided even though the client chooses to take their prescription to a standard pharmacy to be filled where consultation would be provided.

CVMA would also like some clarification on the recordkeeping related to the consultation and that the posting requirement only be provided at a "fixed" veterinary premise.

#### **SUPPORT AND OPPOSITION:**

## Support:

Salomon Stupp (Author of the "Lizzie Initiative for Veterinary Pharmacy")
American Society for the Prevention of Cruelty to Animals (ASPCA)
Humane Society Veterinary Medical Association
Social Compassion in Legislation
Veterinary Medical Board (Support if Amended)

## Opposition:

California Veterinary Medical Association (Oppose/Work with Author)