

#### BUSINESS. CONSUMER SERVICES, AND HOUSING AGENCY . GOVERNOR EDMUND G. BROWN IR

# **Veterinary Medical Board**

1747 N. Market Boulevard, Suite 230, Sacramento, CA 95834 Telephone: 916-515-5220 Fax: 916-928-6849 | www.vmb.ca.gov



### **MEETING MINUTES**

Multidisciplinary Advisory Committee 1747 N. Market Blvd. – Hearing Room Sacramento, California

# 9:00 a.m. Tuesday, January 19, 2016

# 1. Call to Order- Establishment of a Quorum

Multidisciplinary Advisory Committee (MDC) Vice Chair, Dr. Allan Drusys, called the meeting to order at 9:07 a.m. Veterinary Medical Board (Board) Executive Officer, Annemarie Del Mugnaio, called roll; six members of the MDC were present and thus a quorum was established.

#### 2. Introductions

### Members Present

Jon A. Klingborg, DVM, Chair Allan Drusys, DVM, Vice Chair William A. Grant II, DVM Diana Woodward Hagle, Public Member David F. Johnson, RVT Kristi Pawlowski, RVT Jeff Pollard, DVM Richard Sullivan, DVM, Board Liaison

# Staff Present

Annemarie Del Mugnaio, Executive Officer, Veterinary Medical Board Elizabeth Bynum, Associate Enforcement Analyst Nina Galang, Administrative Program Coordinator Bryce Penney, DCA Television Specialist Kurt Heppler, Legal Counsel Candace Raney, Enforcement Manager

### **Guests Present**

Nancy Ehrlich, RVT, California Registered Veterinary Technician Association Mark Nunez, DVM, Veterinary Medical Board Dan Segna, DVM, California Veterinary Medical Association Cheryl Waterhouse, DVM, Veterinary Medical Board Erin Troy, DVM Jessica Waldmen, DVM Nicole Bellington, Senate Fellow, Senate Business Professions and Economic Development Committee

Jonathan Burke, DCA

Kathy Bowler, DVM, Veterinary Medical Board

- 3. Review and Approval of July 20, 2015 Meeting Minutes
- Dr. William Grant made a clerical change to page three of the meeting minutes.
  - Dr. William Grant motioned and Dr. Richard Sullivan seconded the motion to approve the July 20, 2015 meeting minutes. The motion carried 6-0.

Dr. Klingborg and Mr. Johnson were not present for this portion of the agenda and therefore, were unable to vote.

4. Discuss Draft Statutory Language Authorizing Veterinarians to Compound Drugs; Potential Recommendation to Full Board

Ms. Del Mugnaio reviewed the background and intent of the drug compounding statutory language discussion, which originated from deficiencies of expired or mislabeled drugs found during hospital inspections. Federal rule allows for limited compounding on the part of veterinarians if there are no other Food and Drug Administration (FDA) approved drug or other compounded formula in an appropriate strength for a particular animal patient. However, there is currently no specific grant of authority in the Veterinary Medicine Practice Act that includes drug compounding in the scope of veterinary medicine. The MDC's charge is to discuss what statutory changes the Board should consider to provide the authority for veterinarians to compound drugs in limited circumstances.

Dr. Sullivan provided a summary of the minutes from the meeting with the California Board of Pharmacy regarding allowing veterinarians to compound drugs. The discussion included the issue of compounding intra-venous (IV) injectable products, which the Board of Pharmacy currently refers to as "tabletop compounding," which can legally be performed by a prescriber or dispenser based on current regulations, as long as the compounding mixture is administered immediately. The Board ultimately learned that the Board of Pharmacy regulations relating to dispensing a compounding drug apply only to the compounding pharmacists, not to dispensers.

The MDC discussed the start and completion time of administration of an injectable compound. Ms. Del Mugnaio clarified that we do not have the authority to go beyond Federal rule, which restricts compounded drugs administered to be used on individual patients only, as opposed to batch administration.

The MDC made the following changes to the proposed language: add "anesthesia" to section 4826.3 (a), change "used" to "administer," and remove "properly" from the language, as it does not add anything of value. The MDC also agreed to add a new section, (h), which states that any deviation from this statute will be considered a violation of the veterinary medicine practice act.

The MDC agreed that if the drug is to be used for immediate administration, it needs only a label stating "for immediate use only." If the drug is to be used within one hour from the time that the drug has been compounded, the drug must be labeled with patient identification information, name and amount of all ingredients, name or initials of the person who prepared the compounded sterile preparation, and the exact one-hour beyond use date and time.

Legal Counsel, Kurt Heppler, suggested that 1751.8 (f) should be handled through regulations, which may need specialized rulemaking authority in order to do so.

Nancy Ehrlich requested clarity regarding the level of supervision of a Registered Veterinary Technician who is following a written protocol. Dr. Sullivan clarified that the intention is for the RVT to follow a

written protocol under indirect supervision of a licensed veterinarian. If the drug is administered as an IV product, it should be under direct supervision. The MDC agreed to clarify this point.

- Dr. Richard Sullivan motioned and Mrs. Diana Woodward-Hagle seconded the motion to forward the Drug Compounding draft statutory language to the Veterinary Medical Board for action at the next Board meeting (on January 20-21, 2016). The motion carried 8-0.
- 5. Discuss Draft Regulatory Language Regarding Animal Rehabilitation [California Code of Regulations, Title 16, Division 20, Section 2038.5]; Potential Recommendation to Full Board

Dr. Klingborg reported that the MDC was tasked with reviewing the Animal Rehabilitation draft regulatory language, including the supplemental packet provided by the Board and the video testimony provided by the public and various interested parties at the Board meeting on October 20, 2015.

Kristi Pawlowski shared the following concerns regarding the language:

- subsection (a) could be interpreted to include surgery
- unclear definition of "wellness modality"

Language was provided from the Physical Therapy Practice Act to use as a model, however, the MDC discussed that we cannot simply use the Physical Therapy Practice Act language and add "animal rehabilitation."

Mr. Heppler reminded the MDC and the public that the purpose of regulations is to implement, interpret, or make specific the statute. The test of a good regulation is that it should be consistent with, and not in conflict with, existing statute, and reasonably necessary to effectuate the purpose. Mr. Heppler advised the MDC to determine if the language satisfies that obligation.

Ms. Del Mugnaio clarified that the current statute does not provide the authority to exempt other licensed health care practitioners (e.g. physical therapists) from the Practice Act. Ms. Del Mugnaio identified two possible approaches: 1) expand statutory authority to exempt other health care practitioners from the Practice Act and only allow the practice of animal rehabilitation to those specifically named in statute, or 2) develop regulations to allow the practice of animal rehabilitation, regardless of who is performing the service, provided they meet minimum standards set by the Board, including supervision. Minimum standards can be defined through regulations.

Ms. Del Mugnaio added that a hearing was held in 2013 and again in 2015, and comments from the Board and the public were considered when developing the proposed language. Ms. Del Mugnaio noted that the MDC has options, which include: proceed with formulating language for Board consideration, recommending to the Board that animal rehabilitation cases be handled through enforcement based on unlicensed activity or unprofessional conduct on the part of a veterinarian, or tabling the discussion until Legislative recommendations are revealed during Sunset Review.

Dr. Klingborg identified the following points of discussion:

- Is animal rehabilitation the practice of veterinary medicine?
- Should we stipulate what is and what is not animal rehabilitation?
- Supervision must be considered
- Location (i.e. premises) must be considered
- "Competency" in animal rehabilitation must be determined.

The MDC discussed the difficulty in certifying animal rehabilitation schools without also requiring Board oversight.

Comments from the public included the following:

- support for supervision by a veterinarian
- support for direct supervision by a veterinarian
- support for defining animal rehabilitation as the practice of veterinary medicine and requiring certification in animal rehabilitation
- the Practice Act, as it stands today, is already set up to support animal rehabilitation if it is considered the practice of veterinary medicine, as the liability falls on the licensed veterinarian who is delegating tasks
- in urban areas, it can be difficult to have a veterinarian on-site
- suggestion to develop a veterinary rehabilitation license program
- proposed language does not include Board directive to consider education and competency standards for all of those who practice animal rehabilitation
- must determine what training is necessary and how many hours are required to be considered competent
- support regarding establishing a Veterinarian-Client-Patient Relationship (VCPR) prior to referring animal rehabilitation services
  - o length of clearance from veterinarian would need to be determined
- veterinarians do not have the competency to perform animal rehabilitation without a certification
- support for another task force
- recommendation for two separate definitions: "animal rehabilitation" and "animal physical therapy"
- identify whose license is at stake (i.e. physical therapist, veterinarian) and what entity has the regulatory authority for disciplinary action of license (i.e. Physical Therapy Board, Veterinary Medical Board)
- the animal rehabilitation regulations work in other states and there has been no evidence of animal harm

The MDC asked follow-up questions to Dr. Jessica Waldmen and Dr. Erin Troy, two veterinarians with a certification in animal rehabilitation. Dr. Waldmen and Dr. Troy expressed support for direct supervision since animal patients often come to their office without a diagnosis and the health status may continually change even after the initial examination. Based on their experience, they have witnessed animals come in for rehabilitation who are found to have non-rehabilitation related conditions or illnesses, such as cancer, and the owner is unaware of the condition. In their opinion, an RVT would not have the competency to perform animal rehabilitation without specialized training.

Mrs. Ehrlich noted that the Board's job is not to set the highest standard, only a minimum standard. Mrs. Ehrlich expressed concern that requiring direct supervision increases costs and decreases access to those who cannot afford it. If indirect supervision is allowed, Mrs. Ehrlich expressed that the individual performing animal rehabilitation should be certified.

Dr. Sullivan expressed concern regarding decreasing the level of supervision from "direct" to "indirect," but noted that the Board's goal to increase hospital inspections may compensate for the lower level of supervision.

Ms. Del Mugnaio noted that the Board can provide numbers of unlicensed activity complaints; however, the complaints are not currently tracked by the type of service being provided.

• Dr. William Grant motioned and Dr. Allan Drusys seconded the motion to suspend discussion until recommendations are known through the Sunset Review process. The motion carried 8-0.

6. Review and Consider Recommendations from the Complaint Process Audit Task Force Report; Potential Recommendation to Full Board

The Complaint Process Audit Task Force, Dr. Grant and Dr. Jeff Pollard, reported on the issue of consistency and quality of the reports written by expert witnesses with regards to the complaint process. More specifically, there appeared to be an inconsistent application of law by which different experts came to their conclusions. In-house experts appeared to be more consistent when compared with external experts.

The Task Force felt that additional training must be provided to expert witnesses. Dr. Pollard suggested that a template should be created to standardize how expert reports are written, as well as a suggestion to have more than one expert review a case. Mrs. Diana Woodward-Hagle shared her experience with giving expert witness seminars and noted that it can be harder to draft an accusation when there are two expert witnesses, as they may be in conflict with one another.

Dr. Sullivan noted that there does not seem to be oversight over expert witnesses. Ms. Del Mugnaio added that the Medical Board of California will be speaking at the Veterinary Medical Board meeting the next day, January 20, 2016 to share their experience with how expert witnesses are vetted, evaluated, and monitored. Mr. Heppler provided an overview on the internal process for monitoring expert witnesses within the Medical Board of California based on his experience as Legal Counsel.

Enforcement Manager, Candace Raney, added that two expert witness trainings were conducted by Diann Sokoloff last year, one in April (Sacramento) and the other in October (San Diego). Most of the information covered during the training addressed how to testify in court.

Ms. Del Mugnaio suggested having expert witnesses submit a sample report using a test case, before evaluating a real case. Mrs. Raney added that the Board currently has 16 expert witnesses, of which 12 are actively being used.

- Dr. Allan Drusys motioned and Dr. William Grant seconded the motion to forward the recommendation to continue the Complaint Audit Task Force to the full Board. The motion carried 8-0.
- 7. Update on Report for Shelter Medicine Minimum Standards & Protocols

The Shelter Medicine Subcommittee, Dr. Allan Drusys and Mr. Johnson, reported on the Shelter Medicine standards and protocols that need clarity and require guidance by Legal Counsel in terms of existing statutory authority. The first goal of the Subcommittee was to identify statutes that may need revisions and then determine if statutory changes are needed versus handling the changes through regulations. More specifically, Ms. Del Mugnaio noted that we need to determine if the statute, as defined today, allows for the authority of shelters to operate based on veterinary guidelines intended as written orders that RVTs may follow when providing services without a veterinarian on site.

The MDC discussed the difficulty in having a veterinarian look at each animal prior to the delegation of a health care task due to the sheer volume of animals coming into animal shelters, and also discussed the need for an RVT to immediately perform certain tasks on animals upon intake, as failure to do so may be considered harm or neglect for an animal that requires immediate care.

The MDC noted that there is a question regarding the purpose of sedation and who has control over the purchase and possession of controlled substances in a shelter where there are no on-site veterinarians. The Subcommittee expressed strong support regarding the requirement for animal shelters providing service to the public to obtain a premises permit to promote consumer protection.

The Subcommittee noted that there is a potential conflict regarding the inability to treat "owned" animals without the owner's consent.

Mr. Johnson noted that RVTs may receive a 2N classification Drug Enforcement Administration (DEA) license, which only allows for the purchase of the controlled substance, pentobarbital, for the purposes of euthanasia. The 2N classified DEA license does not authorize the traditional level of controlled substances authorized to DEA licensed veterinarians.

Ms. Del Mugnaio noted that the California Veterinary Medical Association (CVMA) has also developed a Task Force to identify minimum standards for shelter premises types. The next CVMA Task Force meeting will be February 10, 2016.

Mr. Johnson noted that the next step would be to obtain guidance from Legal Counsel regarding what the statute provides for in terms of the written order exemption.

Dr. Klingborg identified three options: 1) define written order, 2) continue developing language regarding the RVT's role within the shelter, and 3) hold a public hearing to gather additional input.

Mr. Johnson noted that there is an open forum at the Animal Care Conference coming up in March, whose attendees include the Board of the State Humane Association, the Animal Control Directors, and other stakeholders. Ms. Del Mugnaio suggested that the Subcommittee should attend the conference to ask the questions regarding the shelter environment and the relevant staffing challenges, and bring information back to the MDC.

Mr. Heppler suggested having an "interested parties" meeting, in order to allow staff and the public to meet and discuss ideas.

- David Johnson motioned to: 1) direct Legal Counsel to review and provide guidance on section 4840 that allows RVTs to work under a written order in an animal shelter environment, 2) direct the Subcommittee continue to develop minimum standards on the practice of veterinary medicine in the shelter community, and 3) direct the Subcommittee attend the Animal Care Conference on behalf of the MDC. Dr. William Grant seconded the motion. The motion carried 8-0.
- 8. Public Comments on Items Not on the Agenda

There were no comments from public/outside agencies/associations.

9. Agenda Items and Next Meeting Dates – April 19, 2016; Los Angeles

The MDC agreed to meet on April 19, 2016 for the next meeting (proposed location is Los Angeles), and also agreed to meet on July 19, 2016 and October 18, 2016 in Sacramento for the remaining 2016 quarterly MDC meetings.

A. Multidisciplinary Advisory Committee Assignment Priorities

Dr. Klingborg reviewed the items on MDC assignment priority list that have been discussed and may be ongoing:

- Animal Rehabilitation Regulations
- Drug Compounding Statutory Language
- Complaint Audit Task Force Report
- Minimum Standards for Premises

• Veterinary Student Exemption.

Other assignments that have moved up on the priority list include: "Extended Duty" for RVTs and Standard of Care for Animal Dentistry.

Ms. Del Mugnaio noted that there may be more assignments delegated to the MDC based on Sunset Review.

B. Agenda Items for Next Meeting – Veterinary Student Exemption [Duties and Supervision at University Hospitals]

Mrs. Woodward-Hagle provided an overview of her research which addresses what animal health care tasks a veterinary student may perform off campus under the direct supervision of a veterinarian and in what off campus settings a veterinary student may perform these tasks. Mrs. Woodward-Hagle identified issues regarding "exemptions" versus "tasks." Mrs. Woodward-Hagle also recommended looking at the free-standing clinic at University of California, Davis, which advertises services to the public, as a potential premises requiring registration with the Board.

The MDC will discuss this item at length at the next meeting.

C. Multidisciplinary Advisory Committee Meetings – 2016 Schedule

10. Adjournment

The MDC adjourned at 2:58 p.m.