STATE OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS

BUSINESS, CONSUMER SERVICES, AND HOUSING AGENCY • GOVERNOR EDMUND G. BROWN JR.

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 AGENDA

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
2. Introductions
3. Review and Approval of July 20, 2015 Meeting Minutes
4. Discuss Draft Statutory Language Authorizing Veterinarians to Compound Drugs; Potential Recommendation to Full Board
5. Discuss Draft Regulatory Language Regarding Animal Rehabilitation [California Code of Regulations, Title 16, Division 20, Section 2038.5]; Potential Recommendation to Full Board
6. Review and Consider Recommendations from the Complaint Process Audit Task Force Report; Potential Recommendation to Full Board
7. Update on Report for Shelter Medicine Minimum Standards & Protocols
8. Public Comments on Items Not on the Agenda
   Note: The board may not discuss or take action on any matter raised during this public comment section, except to decide whether to place the matter on the agenda of a future meeting. (Government Code Sections 11125 and 11125.7(a)).
9. Agenda Items and Next Meeting Dates – April 19, 2016; Los Angeles
   A. Multidisciplinary Advisory Committee Assignment Priorities
   B. Agenda Items for Next Meeting – Veterinary Student Exemption [Duties and Supervision at University Hospitals]
   C. Multidisciplinary Advisory Committee Meetings – 2016 Schedule
10. Adjournment

This agenda can be found on the Veterinary Medical Board website at www.vmb.ca.gov. Times stated are approximate and subject to change. This meeting will conform to the Open Meeting Act. Agenda discussions and report items are subject to action being taken on them during the meeting by the Board at its discretion. The Board provides the public the opportunity at meetings to address each agenda item during the Board's discussion or consideration of the item. Total time allocated for public comment may be limited.

The Board plans to webcast items 1-10 at this meeting on its website at www.vmb.ca.gov. Webcast availability cannot, however, be guaranteed due to limitations on resources or technical difficulties that may arise. If you wish to participate or to have a guaranteed opportunity to observe, please plan to attend at a physical location.

The meeting locations are accessible to the physically disabled. Other disability-related accommodations or modifications can be provided upon request. Please make your request for disability-related accommodations by contacting the Board at (916) 515-5220 or sending a written request to 1747 N. Market St., Suite 230, Sacramento, CA 95834. Provide at least five (5) business days' notice prior to the meeting to help ensure availability of requested accommodations.

MISSION

The mission of the Veterinary Medical Board is to protect consumers and animals by regulating licensees, promoting professional standards and diligent enforcement of the practice of veterinary medicine.

STATE OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS

BUSINESS, CONSUMER SERVICES, AND HOUSING AGENCY • GOVERNOR EDMUND G. BROWN JR.

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
The Waterfront Hotel
10 Washington Street
Oakland, CA

10:00 a.m. Monday July 20, 2015

1. Call to Order- Establishment of a Quorum

Multidisciplinary Advisory Committee (MDC) Chair, Dr. William Grant II, called the meeting to order at 10:04 a.m. Veterinary Medical Board (Board) Executive Officer, Annemarie Del Mugnaio, called roll; nine members of the MDC were present and thus a quorum was established.

2. Introductions

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

Staff Present
Annemarie Del Mugnaio, Executive Officer, Veterinary Medical Board
Nina Galang, Administrative Program Coordinator
Lou Galiano, DCA Television Specialist
Sabina Knight, Legal Counsel
Ethan Mathes, Administrative Program Manager

Guests Present
Nancy Ehrlich, California Registered Veterinary Technician Association
Mark Nunez, DVM, Veterinary Medical Board
John Pascoe, University of California, Davis
Cindy Savely, Sacramento Valley Veterinary Technician Association
Dan Segna, DVM, California Veterinary Medical Association
Ron Terra, Western University of Health Sciences, College of Veterinary Medicine
Linda Tripp, University of California, Davis and Sacramento Valley Veterinary Technician Association

3. Swearing in of New Multidisciplinary Advisory Committee Members

Ms. Del Mugnaio swore in Kristi Pawlowski as a new member, and Diana Woodward Hagle, Dr. William Grant, David Johnson, and Dr. Jon Klingborg as returning members on the MDC.

4. Election of Officers

- Dr. Richard Sullivan nominated Dr. Jon Klingborg for the new position of MDC Chair. Dr. Jon Klingborg accepted the nomination and the remaining members of the MDC voted 8-0 to elect Dr. Jon Klingborg as the new MDC Chair.

- Dr. Richard Sullivan nominated Dr. Allan Drusys for the new position of Vice Chair. Dr. Allan Drusys accepted the nomination and the remaining members of the MDC voted 8-0 to elect Dr. Allan Drusys as the new MDC Vice-Chair.

5. Review and Approval of February 19, 2015 Meeting Minutes

Public guest, Nancy Ehrlich, noted that the minutes regarding interactive versus non-interactive components should be corrected to be in reference to academic experience, instead of the practical experience. The minutes are also missing information regarding the eligibility for candidates who are pursuing the Alternate Route adhoc pathway for licensure, which the MDC agreed would be eliminated, and the effective date of when the alternate route pathway expires and the new requirements for Board approved programs must be included in the proposed regulations.

- Dr. Klingborg motioned and David Johnson seconded the motion to approve the February 19, 2015 meeting minutes as amended. Kristi Pawlowski was not in attendance at the February 19, 2015 meeting and therefore, was not allowed to vote. The motion carried 8-0.

6. Discuss and Possible Action on Proposed RVT Student Exemption Regulation (California Code of Regulations Title 16, Division 20, section 2064)

Ms. Del Mugnaio clarified that the MDC agreed to move forward with the regulations regarding the AVMA and California-approved schools; however, since there are no regulations currently in place to approve the Alternate Route program, the student exemption will be folded in once an established format has been developed.

The MDC reviewed and discussed the revised Registered Veterinary Technician (RVT) student exemption regulatory language prepared by Diana Woodward Hagle. The definition for "immediate supervision," is a new definition and the language was added to provide additional clarification since the enabling statute does not include RVTs as supervisors.

The approved veterinary technician program will retain responsibility of all training in the program, including assessing that the student is qualified to participate in a clinical externship and will be responsible for arranging the externship sites.

The MDC agreed that it is inappropriate to redefine the definition of "final year" to a percent-of-program-completion. Alternatively, the MDC agreed that the responsibility should lie with the program to assess the competency of the student and determine when the student has the knowledge and familiarity of the RVT animal health care tasks sufficient to perform these tasks under immediate supervision. The MDC agreed to revise section 2036.6 (4) and (4)(b) by removing the percentages and re-wording it to be at the program's discretion.

- Dr. Richard Sullivan motioned and David Johnson seconded the motion to approve the proposed RVT Student Exemption regulations as amended and forward to the Board for discussion. Motion carried 9-0.

7. Discuss and Possible Action on University Licensure

Guest speaker, Dr. John Pascoe, spoke on behalf of University of California, Davis (UCD) to provide feedback on the proposed University Licensure issue. Dr. Pascoe shared the experience of the university to self-regulate its faculty of those veterinarians employed by UCD practicing veterinary medicine outside of the university, including cases of litigation and the non-reappointment of faculty whose competency did not meet the university's standards. In the opinion of UCD, a University License requirement would be acceptable; however, the language should be flexible enough to account, for example, for varying lengths of residency programs.

Guest speaker, Dr. Ron Terra, representing Western University of Health Sciences (WUHS) also shared support for the University License requirement.

Ms. Del Mugnaio emphasized that one of the main functions of a government agency is to provide protection and recourse for consumers. The Board can provide mediation, restitution, and transparency to the public, among other things.

The MDC discussed the option to remove, keep, or modify the standing exemption as put forth in the Practice Act. Dr. Sullivan recommended adding the phrase "except for those veterinarians working on private animals" to the exemption. The MDC expressed the desire to modify the language to protect the consumer, include the veterinary law exam and regionally specific diseases examination, and to reaffirm that the Board has the authority to investigate complaints. Diana Woodward Hagle and Jeff Pollard expressed concern regarding the potential for universities to compete with private practices.

Ms. Del Mugnaio reviewed the options presented before the MDC for possible consideration:
1) modifying the existing exemption, BPC section 4830(a)(4) to provide for an exemption to licensure only when individuals are practicing on the public's animals and 2) modifying 4830(a)(4) to state that this section does not apply to veterinarians employed by the universities while engaged in the performance of duties in connection with the universities, if and only if that veterinarian obtains a limited license to practice as issued by the Board. Ms. Del Mugnaio also explained the option to have a Grandfather clause, which attaches a date to the exemption.

Dr. Pascoe shared that he favors the modification that allows the Board to provide recourse to consumers and recommended calling it a University License, as opposed to a Faculty License.

Ms. Del Mugnaio clarified that the proposed language is modeled after section 4848 regarding temporary licenses and would also necessitate an additional statute, as proposed BPC section 4848.1 to require individuals to obtain a University License and a definition of the requirements for eligibility of the license.

Dr. Sullivan suggested breaking down the requirements into three categories (interns/residents, existing faculty, and new faculty) to create a clear distinction between interns/residents and faculty staff.

The MDC discussed amending the language to strike the word "temporary," create a new category for university licenses, and add language which would prevent a person with a fitness to practice issues to obtain the license.

- Dr. Jon Klingborg motioned and Dr. Allan Drusys seconded the motion to approve the proposed University Licensure language as amended and forward to the Board for discussion. The motion carried 6-0. Dr. Richard Sullivan opposed. Jennifer Loredo and Kathy Bowler abstained.

8. Discuss Shelter Medicine Protocols

The MDC discussed the need for training for RVTs in order to provide care in an animal shelter in the absence of a supervising veterinarian. There are currently no minimum standards for shelter medicine.

Jennifer Loredo shared her experience working at a clinic where there are many RVTs and only one veterinarian. Dr. Drusys shared his research regarding animals being vaccinated and euthanized in animal shelters by unlicensed persons, such as animal control officers.

Ms. Del Mugnaio noted that current statute provides the authority for RVTs to perform services based on orders received telephonically from veterinarians, but clarified that these orders are on a case-by-case basis. This per patient orders may not work for shelter medicine.

Mr. Johnson discussed the low percentage of animals that are claimed by their owners upon intake and are therefore known as "owner relinquished animals". In the case of an owner relinquished animal, the shelter is considered the repository, and therefore, the animal has no client owner with whom to establish a Veterinary-Client-Patient-Relationship (VCPR). The MDC discussed when it is appropriate to establish a VCPR. Ms. Del Mugnaio suggested that in a shelter environment, the requirement for a VCPR to be established after the animal is triaged.

Mr. Johnson shared that, in his experience, only mid-level practitioners order and maintain controlled substances, and if an animal is taken to the emergency veterinary hospital, euthanasia is only performed if the animal is truly suffering. Drugs are then logged electronically.

Dr. Dan Segna updated that the California Veterinary Medical Association (CVMA) is working to put together a task force to propose minimum standards per shelter medicine among other premise types. Ms. Del Mugnaio requested to have a subcommittee created to deal only with shelter medicine issues, separate from the task force that is already being created to cover other premise types, equine medicine, etc. Shelter medicine needs to be a priority to establish a protocol for RVTs. Dr. Segna shared that the task force will meet in September 2015.

Ms. Del Mugnaio clarified that the only thing that can be brought before the MDC is the minimum standards for public and private animal shelters from a premise permit standpoint. Dr. Grant noted that the new Chair can appoint a subcommittee at a future date, after the scheduled Board meeting tomorrow.

9. Review Board Strategic Action Plan 2015-2019
   A. Review Proposed Multidisciplinary Advisory Committee Action Items

The Board is scheduled to meet tomorrow and will prioritize the issues they would like the MDC to address at its next meeting.

10. Comments from Public/Outside Agencies/Associations on Items Not on the Agenda

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

11. Agenda Items and Next Meeting Dates
   A. Agenda Items for Next Meeting

The MDC noted that the Board is scheduled to meet July 21, 2015 and may decide what items will be on the agenda for the next MDC meeting.

B. Multidisciplinary Advisory Committee Meetings – 2015 Schedule

12. Adjourn

The MDC meeting adjourned at 2:06 p.m.

STATE OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS

BUSINESS, CONSUMER SERVICES, AND HOUSING AGENCY • GOVERNOR EDMUND G. BROWN JR.

Veterinary Medical Board
1747 N. Market Blvd., Ste. 230, Sacramento, CA 95834
Telephone: 916-515-5222 Fax: 916-928-6582 | www.vmb.ca.gov

MEMORANDUM

DATE	January 1, 2016
TO	MDC
FROM	Annemarie Del Mugnaio, Executive Officer DCA/Veterinary Medical Board
SUBJECT	**Compounded Medications and Veterinary Practice**

Background:

At its October 20, 2014 meeting, the MDC reviewed the issue of drug compounding by veterinarians for their animal patients. The issue, as raised by Board Counsel, was that there is no explicit grant of authority in the Veterinary Medicine Practice Act authorizing licensed veterinarians to compound drugs pursuant to federal law. Board Counsel advised that provisions for veterinarians to compound drugs for animal patients would need to be added to the veterinary medicine scope of practice. The MDC examined the lack of statutory guidance for veterinarians and ultimately recommended that the Board consider a legislative proposal to grant veterinarians the authority to compound drugs for their animal patients under the existing limitations of CFR Title 21 Part 530.13. The VMB agreed to pursue a statutory change, but ultimately referred the matter back to the MDC to work with the Board of Pharmacy and stakeholders on a statutory framework.

On November 12, 2015, an MDC Subcommittee of Dr. Klingborg and Dr. Sullivan joined me in a meeting with Virginia Herold, the Executive Officer of the Board of Pharmacy and Deputy Attorney General (DAG) Joshua Room to discuss a statutory proposal that would provide for limited drug compounding by veterinarians, and also address necessary compliance issues provided for in Pharmacy laws and regulations. At the meeting, the Subcommittee learned that the historical interpretation of CCR Section 1735.2 regarding restrictions on dispensing a 72-hour supply to a client/patient was not intended to be a dispensing restriction imposed on a veterinarian. Instead, the regulation defines a "reasonable quantity" of a compounded medication that may be furnished by a pharmacy to a veterinarian for in office use, or to dispense to their client/patient. Thus, the "reasonably quantity" is a formula used by pharmacies to supply prescribers and dispensers.

Shortly after the meeting, DAG Room prepared a draft proposal for review and consideration by the MDC (attached).

Issues:

Historically, the VMB has advised licensed veterinarians that it is only permissible to compound an oral or injectable medication if:

- There is no approved animal or human drug available that is labeled for, and in a concentration or form appropriate for, treating the condition diagnosed.

- *The compounding is performed by a licensed veterinarian within the scope of a professional practice.*
- Adequate measures are followed to ensure the safety and effectiveness of the compounded product.
- The quantity of compounding is commensurate with the established need of the identified patient.
- There is legitimate need for the drug when non-treatment would result in either suffering or death.

However, based on legal guidance, we understand that regulating drug compounding by veterinarians must be codified in statute.

The following issues must be considered in pursuing a legislative solution:

- FDA Guidance for Industry #230 Compounding Animal Drugs from Bulk Drug Substances
- The animal drugs that may or may not be available through Outsourcing Facilities & Compounding Pharmacies?
- Implementing regulations may be necessary to further address immediate use sterile injectable drugs

Attachments:

- Proposed Statutory Language – Business & Professions Code Sections 4825.1& 4826.3
- Proposed California Code of Regulations Title 16, Sections 1735-1735.8 & 1751 et seq. – Regulations Regarding Compounding
- Code of Federal Regulations Title 21, Part 530.13
- Summary of FDA Guidance #230 – AVMA
- AVMA Letter to FDA- Nov. 16, 2015 (Including attached Bulk Drug Nominations)
- UPS Comments to FDA Guidance

Action:

- Review draft statutory language as proposed and recommend action to the VMB.

Veterinary Compounding

Draft Statutory Proposal

SDAG Joshua A. Room – November 18, 2015

§ 4825.1. Definitions – ADD

(e) "Compounding," for the purposes of veterinary medicine, shall have the same meaning as that given in California Code of Regulations, title 16, section 1735, except that every reference therein to "pharmacy" and "pharmacist" shall be replaced by "veterinary premises" and "veterinarian," and except that only a licensed veterinarian or a licensed RVT (following the written protocol of a licensed veterinarian) may perform compounding, and may not delegate to or supervise any part of the performance of compounding by any other person.

§ 4826.3. Veterinary Compounding

(a) Notwithstanding section 4051, a veterinarian RVT with a current and active license may compound a drug for the prevention, cure, or relief of a wound, fracture, bodily injury, or disease of an animal, in a premises currently and actively registered with the board, only under the following conditions:

(1) Where there is no FDA-approved animal or human drug that can be used as labeled or in an appropriate extralabel manner to properly treat the disease, symptom, or condition for which the drug is being prescribed;

(2) Where the compounded drug is not available from a compounding pharmacy, outsourcing facility, or other compounding supplier, in a dosage form and concentration to appropriately treat the disease, symptom, or condition for which the drug is being prescribed;

(3) Where the need and prescription for the compounded medication has arisen within an established veterinarian-client-patient relationship, as a means to treat a specific occurrence of a disease, symptom, or condition observed and diagnosed by the veterinarian in a specific animal which threatens the health of the animal or will cause suffering or death if left untreated;

(4) Where the quantity compounded does not exceed a quantity demonstrably needed to treat patients with which the veterinarian has a current veterinarian-client-patient relationship; and

(5) Except as specified in (c), where the compound is prepared only with commercially available FDA-approved animal or human drugs as active ingredients.

(b) A compounded veterinary drug may be prepared from an FDA-approved animal or human drug for extralabel use only when there is no approved animal or human drug that, when used as labeled or in an appropriate extralabel manner will, in the available dosage form and concentration, properly treat the

disease, symptom, or condition. Compounding from an approved human drug for use in food-producing animals is not permitted if an approved animal drug can be used for compounding.

(c) A compounded veterinary drug may be prepared from bulk drug substances only when:

(1) The drug is compounded and dispensed by the veterinarian to treat an individually identified animal patient under his or her care;

(2) The drug is not intended for use in food-producing animals;

(3) If the drug contains a bulk drug substance that is a component of any marketed FDA-approved animal or human drug, there is a change between the compounded drug and the comparable marketed drug made for an individually identified animal patient that produces a clinical difference for that individually identified animal patient, as determined by the veterinarian prescribing the compounded drug for his or her patient;

(4) There are no FDA-approved animal or human drugs that can be used as labeled or in an appropriate extralabel manner to properly treat the disease, symptom, or condition for which the drug is being prescribed;

(5) All bulk drug substances used in compounding are manufactured by an establishment registered under 21 U.S.C. § 360 and are accompanied by a valid certificate of analysis;

(6) The drug is not sold or transferred by the veterinarian compounding the drug, except that the veterinarian shall be permitted to administer the drug to a patient under his or her care, or dispense it to the owner or caretaker of an animal under his or her care;

(7) Within fifteen (15) days of becoming aware of any product defect or serious adverse event associated with any drug compounded by the veterinarian from bulk drug substances, the veterinarian reports it to the FDA on Form FDA 1932a; and

(8) In addition to other requirements, the label of any veterinary drug compounded from bulk drug substances indicates the species of the intended animal patient, the name of the animal patient, and the name of the owner or caretaker of the patient.

(d) Each compounded veterinary drug preparation shall meet the labeling requirements of section 4076, and of California Code of Regulations, title 16, sections 1707.5 and 1735.4, except that every reference therein to “pharmacy” and “pharmacist” shall be replaced by “veterinary premises” and “veterinarian,” and any reference to “patient” shall be understood to refer to the animal patient. In addition, each label on a compounded veterinary drug preparation shall include withdrawal/holding times, if needed, and the disease, symptom, or condition for which the drug is being prescribed. Any compounded veterinary drug preparation that is intended to be sterile, including for injection, administration into the eye, or inhalation, shall in addition meet the labeling requirements of California Code of Regulations, title 16, section 1751.2, except that every reference therein to “pharmacy” and

"pharmacist" shall be replaced by "veterinary premises" and "veterinarian," and any reference to "patient" shall be understood to refer to the animal patient.

(e) Any veterinarian and veterinary premises engaged in compounding shall meet the compounding requirements for pharmacies and pharmacists stated by the following sections and subdivisions of Article 4.5 of Title 16 of the California Code of Regulations, except that every reference therein to "pharmacy" and "pharmacist" shall be replaced by "veterinary premises" and "veterinarian," and any reference to "patient" shall be understood to refer to the animal patient:

(1) Section 1735.1;

(2) Section 1735.2, subdivisions (d), (e), (f), (g), (h), (i), (j), (k), and (l);

(3) Section 1735.3, except that only a licensed veterinarian or RVT may perform compounding, and may not delegate to or supervise any part of the performance of compounding by any other person.

(4) Section 1735.4;

(5) Section 1735.5;

(6) Section 1735.6;

(7) Section 1735.7; and

(8) Section 1735.8.

(f) Any veterinarian and veterinary premises engaged in sterile compounding shall meet the sterile compounding requirements for pharmacies and pharmacists stated by Article 7 of Title 16 of the California Code of Regulations (sections 1751 through 1751.8, inclusive), except that every reference therein to "pharmacy" and "pharmacist" shall be replaced by "veterinary premises" and "veterinarian," and any reference to "patient" shall be understood to refer to the animal patient. Section 1751.8 (e) allows a veterinarian or RVT to compound a "sterile IV product" outside of an ISO class 5 PEC or under conditions that do not meet all of the requirements for sterile compounding if the preparation is labeled "for immediate use only," and is used within one hour by the individual that has compounded the preparation.

(g) The California State Board of Pharmacy shall have authority with the Veterinary Medical Board to ensure compliance with this section, and shall have the right to inspect any veterinary premises engaged in compounding, along with or separate from the Veterinary Medical Board, to ensure compliance. The Veterinary Medical Board is specifically charged with enforcing this section with regard to its licensees.

Title 16. Board of Pharmacy

Second Modified Text

Changes made to the originally proposed language are shown by ~~double strike-through~~ for deleted language and double underline for added language. (The changes are also indicated in red font)

Changes made to the modified proposed language are shown by ~~double strike-through/bold underline~~ for deleted language and curved underline for added language. (The changes are also indicated in blue font)

To Amend § 1735 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735. Compounding in Licensed Pharmacies.

(a) "Compounding" means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:

(1) Altering the dosage form or delivery system of a drug

(2) Altering the strength of a drug

(3) Combining components or active ingredients

(4) Preparing a compounded drug ~~product~~ preparation from chemicals or bulk drug substances

(b) "Compounding" does not include reconstitution of a drug pursuant to a manufacturer's direction(s) ~~for oral, rectal, topical, or injectable administration~~, nor does it include the sole act of tablet splitting or crushing, capsule opening, or the addition of flavoring agent(s) to enhance palatability.

~~(c) "Compounding" does not include, except in small quantities under limited circumstances as justified by a specific, documented, medical need, preparation of a compounded drug product that is commercially available in the marketplace or that is essentially a copy of a drug product that is commercially available in the marketplace~~

~~(d)~~(c) The parameters and requirements stated by ~~this~~ Article 4.5 (Section 1735 et seq.) apply

to all compounding practices. Additional parameters and requirements applicable solely to sterile ~~injectable~~ compounding are stated by Article 7 (Section 1751 et seq.).

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1735.1 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.1. Compounding Definitions.

(a) "Ante-area" means an area with ISO Class 8 or better air quality where personnel hand hygiene and garbing procedures, staging of components, and other high-particulate-generating activities are performed, that is adjacent to the area designated for sterile compounding. It is a transition area that begins the systematic reduction of particles, prevents large fluctuations in air temperature and pressures in the ~~buffer area or~~ cleanroom, and maintains air flows from clean to dirty areas. ISO Class 7 or better air quality is required for ante-areas providing air to a negative pressure room.

(b) "Beyond use date" means the date, or date and time, after which administration of a compounded drug preparation shall not ~~be begun~~ begin, the preparation shall not be dispensed, and the preparation shall not be stored (other than for quarantine purposes).

(c) "Biological Safety Cabinet (BSC)" means a ventilated cabinet for compounding~~ed~~ sterile drug preparations, having an open front with inward airflow for personnel protection, downward HEPA-filtered laminar airflow for product protection, and HEPA-filtered exhausted air for environmental protection. Where hazardous drugs are prepared, the exhaust air from the biological safety cabinet ~~should~~ shall be appropriately removed by properly designed external building ventilation. This external venting should be dedicated to one BSC or CACI.

~~(d) "Buffer area" means an area which maintains segregation from the adjacent ante-area by means of specific pressure differentials. The principle of displacement airflow shall be employed. This concept utilizes a low pressure differential, high airflow principle. Using displacement airflow typically requires an air velocity of 40 ft per minute or more from the~~

~~buffer area across the line of demarcation into the ante-area. The displacement concept may not be used to maintain buffer area requirements for sterile compounds which originate from any ingredient that was at any time non-sterile, regardless of intervening sterilization of the ingredient, for hazardous compounds, or for chemotherapy compounds.~~

~~(c)~~(d) "Bulk drug substance" means any substance that, when used in the preparation of a compounded drug preparation, processing, or packaging of a drug, ~~becomes~~ is an active ingredient or a finished dosage form of the drug, but the term does not include any intermediate used in the synthesis of such substances.

~~(f)~~(e) "Cleanroom or clean area or buffer area" means a ~~physically separate~~ room or area ~~with walls and doors~~ with HEPA-filtered air that provides ~~at least an~~ ISO Class 7 or better air quality where the primary engineering control (PEC) is physically located.

(1) For nonhazardous compounding a ~~A minimum differential~~ positive pressure differential of 0.02- to 0.05-inch water column relative to all adjacent spaces is required.

(2) For hazardous compounding at least 30 air changes per hour of HEPA-filtered supply air and a negative pressure of between ~~at least~~ 0.01 to 0.03 inches of water column relative to all adjacent spaces is required.

~~(h)~~(f) "Compounding Aseptic Containment Isolator (CACI)" means a unidirectional HEPA-filtered airflow compounding aseptic isolator (CAI) designed to provide worker protection from exposure to undesirable levels of airborne drug throughout the compounding and material transfer processes and to provide an aseptic environment for compounding sterile preparations. Air exchange with the surrounding environment should not occur unless the air is first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Where ~~volatile~~ hazardous drugs are prepared, the exhaust air from the isolator ~~should~~ shall be appropriately removed by properly designed external building ventilation. This external venting should be dedicated to one BSC or CACI. Air within the CACI shall not be re-circulated nor turbulent.

(g) "Compounding Aseptic Isolator (CAI)" means a form of isolator specifically designed for non-hazardous compounding of pharmaceutical ingredients or preparations while bathed with

unidirectional HEPA-filtered air. It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes. Air exchange into the isolator from the surrounding environment should not occur unless the air has first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Air within the CAI shall not be re-circulated nor turbulent.

~~(i)~~(h) "Controlled cold temperature" means 2 degrees to 8 degrees C (35~~-6~~ degrees to 46~~-4~~ degrees F).

~~(j)~~(i) "Controlled freezer temperature" means -25 degrees to -10 degrees C (-13 degrees to 14 degrees F) or at a range otherwise specified by the pharmaceutical manufacturer(s) for that product.

~~(k)~~(j) "Controlled room temperature" means 20 degrees to 25 degrees C (68 degrees to 77 degrees F).

~~(l)~~(k) "Copy or essentially a copy" of a commercially available drug product includes all preparations that are comparable in active ingredients to commercially available drug products, except that it does not include any preparations in which there has been a change, made for an identified individual patient, which produces for that patient a clinically significant difference, as determined by a prescribing practitioner, between that compounded preparation and the comparable commercially available drug product.

~~(m)~~(l) "Daily" means occurring every day ~~that a~~ the pharmacy is operating, except when daily monitoring of refrigerator and freezer temperature are required, then daily means every 24 hours.

~~(n)~~(m) "Displacement airflow method"~~:~~ means a concept which utilizes a low pressure differential, high airflow principle to maintain segregation from the adjacent ante-area by means of specific pressure differentials. This principle of displacement airflow shall require an air velocity of 40 ft per minute or more, from floor to ceiling and wall to wall, from the clean area across the line of demarcation into the ante-area. The displacement concept may not be used to maintain clean area requirements for sterile compounds which originate from any ingredient that was at any time non-sterile, regardless of intervening sterilization of the

ingredient, or for hazardous compounds.

~~(n)~~~~(o)~~(n) "Dosage unit" means a quantity sufficient for one administration to one patient~~,~~ ~~except that for self-administered ophthalmic drops, a quantity sufficient for 30 days or less shall be considered one dosage unit~~.

~~(a)~~~~(c)~~~~(p)~~(o) "Equipment" means items that must be calibrated, maintained or periodically certified.

~~(p)~~~~(q)~~(p) "First air" means the air exiting the HEPA filter in a unidirectional air stream that is essentially particle free.

~~(q)~~~~(r)~~(q) "Gloved fingertip sampling" means a process whereby compounding personnel lightly press each fingertip and thumb of each hand onto appropriate growth media, which are then incubated at a temperature and for a time period conducive to multiplication of microorganisms, and then examined for growth of microorganisms.

~~(r)~~~~(s)~~(r) "Hazardous" means all anti-neoplastic agents identified by the National Institute for Occupational Safety and Health (NIOSH) as meeting the criteria for a hazardous drug and any other drugs, compounds, or materials identified as hazardous by the pharmacist-in-charge.

~~(b)~~~~(c)~~~~(t)~~(s) "Integrity" means retention of potency until the ~~expiration~~ beyond use date ~~noted~~ provided on the label, so long as the preparation is stored and handled according to the label directions ~~after it is dispensed~~.

~~(t)~~~~(u)~~(t) "Lot" means one or more compounded drug preparation(s) prepared during one uninterrupted continuous cycle of compounding from one or more common active ingredient(s).

~~(u)~~~~(v)~~(u) "Media-fill test" means a test used to measure the efficacy of compounding personnel in aseptic techniques whereby ~~that mimics~~ compounding procedures are mimicked using a growth-based media and then the resulting preparation is evaluated for sterility. ~~to demonstrate the competency of compounding personnel in aseptic techniques.~~ The media-fill test must mimic the most complex compounding procedures performed by the pharmacy ~~that aseptic techniques of compounding personnel or processes routinely employed do not result in microbial contamination. To be valid, media-fill tests must be conducted on both the most routine and the most challenging compounding procedures performed~~.

~~(v)~~~~(w)~~(v) "Non-sterile-to-sterile batch" means any compounded drug preparation containing two (2) or more dosage units with any ingredient that was at any time non-sterile, regardless of intervening sterilization of that ingredient.

~~(w)~~~~(x)~~(w) "Parenteral" means a preparation of drugs administered in a manner other than through the digestive tract. ~~This includes, but is not limited to, injection through one or more layers of skin, administration into the eye, and by inhalation.~~ It does not include topical, sublingual, rectal or buccal routes of administration.

~~(x)~~~~(y)~~(x) "Personal protective equipment" means clothing or devices that protect the employee from exposure to ~~drug products~~ compounding ingredients and/or potential toxins and minimize the contamination of compounded preparations. These include shoe covers, head and facial hair covers, face masks, gowns, and gloves.

~~(c)~~~~(y)~~~~(z)~~(y) "Potency" means active ingredient strength within +/- 10% (or the range specified in USP37-NF32, 37th Revision, Through 2nd Supplement Effective December 1, 2014) of the labeled amount. Sterile injectable products compounded solely from commercially manufactured sterile pharmaceutical products in a health care facility licensed under section 1250 of the Health and Safety Code are exempt from this definition. For those exempt, the range ~~may~~ shall be calculated and defined in the master formula.

~~(z)~~~~(aa)~~(z) "Preparation" means a drug or nutrient compounded in a licensed pharmacy; the preparation may or may not be sterile.

~~(aa)~~~~(ab)~~(aa) "Prescriber's office" or "prescriber office" means an office or suite of offices in which a prescriber regularly sees patients for outpatient diagnosis and treatment. This definition does not include any hospital, pharmacy, or other facility, whether or not separately licensed, that may be affiliated with, adjacent to, or co-owned by, the prescriber's practice environment.

~~(ab)~~~~(ac)~~(ab) "Primary Engineering Control (PEC)" means a device that provides an ISO Class 5 or better environment through the use of non-turbulent, unidirectional HEPA-filtered first air for ~~the exposure of critical sites when~~ compounding sterile preparations. Examples of PEC devices include, but are not limited to, laminar airflow workbenches, biological safety cabinets, sterile compounding automated robots, compounding aseptic isolators, and compounding aseptic

containment isolators.

~~(ac)~~~~(ad)~~(ac) "Process validation" means demonstrating that when a process is repeated within specified limits, the process will consistently produce preparations complying with predetermined requirements. If any aspect of the process is changed, the process would need to be revalidated.

~~(ad)~~~~(ae)~~(ad) "Product" means a commercially manufactured drug or nutrient evaluated for safety and efficacy by the FDA.

~~(d)~~~~(ae)~~~~(af)~~(ae) "Quality" means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, ~~and~~ the absence of active ingredients other than those listed on the label, and the absence of inactive ingredients other than those listed on the master formula ~~record~~ document.

~~(af)~~~~(ag)~~(af) "Segregated sterile compounding area" means a designated space for sterile-to-sterile compounding where a PEC is located within either a demarcated area (at least three foot perimeter) or in a separate room. Such area or room shall not contain and shall be void of activities and materials that are extraneous to sterile compounding. The segregated sterile compounding area shall not be in a location that has unsealed windows or doors that connect to the outdoors, in a location with high traffic flow, or in a location that is adjacent to construction sites, warehouses, or food preparation. The segregated sterile compounding area shall not have a sink, other than an emergency eye-washing station, located within three feet of a PEC. The segregated sterile compounding area shall be restricted to preparing ~~non-hazardous~~ of sterile-to-sterile compounded preparations.

(1) The BUD of a sterile drug preparation made in a segregated sterile compounding area is limited to 12 hours or less as defined by section 1751.8(d).

(2) When the PEC in the segregated sterile compounding area is a CAI or a CACI and the documentation provided by the manufacturer shows its meeting the requirements listed in section 1751.4(f)(1)-(3), the assigned BUD shall comply with section 1751.8(a-b) or (d) ~~(b)~~.

~~(e)~~(ag) "Strength" means amount of active ingredient per unit of a compounded drug ~~product~~ preparation.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1735.2 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.2. Compounding Limitations and Requirements; Self-Assessment.

(a) Except as specified in (b) and (c), no drug ~~product~~ preparation shall be compounded prior to receipt by a pharmacy of a valid prescription for an individual patient where the prescriber has approved use of a compounded drug ~~product~~ preparation either orally or in writing. Where approval is given orally, that approval shall be noted on the prescription prior to compounding.

(b) A pharmacy may prepare and store a limited quantity of a compounded drug ~~product~~ preparation in advance of receipt of a patient-specific prescription where and solely in such quantity as is necessary to ensure continuity of care for an identified population of patients of the pharmacy based on a documented history of prescriptions for that patient population.

(c) A "reasonable quantity" ~~as used in~~ that may be furnished to a prescriber for office use by the prescriber as authorized by Business and Professions Code section 4052, subdivision (a)(1), means that amount of compounded drug ~~product~~ preparation that:

(1) ~~I~~Is ordered by the prescriber or the prescriber's agent ~~and paid for by the prescriber at a price that fairly reflects the fair market value of each drug preparation,~~ using a purchase order or other documentation received by the pharmacy prior to furnishing that lists the number of patients seen or to be seen in the prescriber's office for whom the drug is needed or anticipated, and the quantity for each patient that is sufficient for ~~either~~ office administration ~~or application to patients in the prescriber's office, or for distribution of not more than~~ ~~or~~ ~~furnishing of a 72-hour supply~~ ~~to the prescriber's patients, as estimated by the prescriber~~; and

(2) Is delivered to the prescriber's office and signed for by the prescriber or the prescriber's agent; and

(3) Is sufficient for administration or application to patients solely in the prescriber's office, or for furnishing of not more than ~~a 72-hour supply for human medical practices, or~~ a 120-hour

supply for veterinary medical practices, solely to the prescriber's own veterinary patients seen as part of regular treatment in the prescriber's office, as fairly estimated by the prescriber and documented on the purchase order or other documentation submitted to the pharmacy prior to furnishing; and

~~(2)~~(4) That the pharmacist has a credible basis for concluding it is a reasonable quantity for office use ~~the quantity provided for office use is reasonable~~ considering the intended use of the compounded medication and the nature of the prescriber's practice; and

~~(3)~~ (5) ~~for~~ With regard to any individual prescriber to whom the pharmacy furnishes, and with regard to ~~for~~ all prescribers to whom the pharmacy furnishes, ~~taken as a whole,~~ is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug ~~product~~ preparation; and

(6) Does not exceed an amount the pharmacy can reasonably and safely compound.

(d) No pharmacy or pharmacist shall compound a drug preparation that:

(1) Is classified by the FDA as demonstrably difficult to compound;

(2) Appears on an FDA list of drugs that have been withdrawn or removed from the market because such drugs or components of such drugs have been found to be unsafe or not effective; or

(3) Is a copy or essentially a copy of one or more commercially available drug products, unless that drug product appears on an ASHP (American Society of Health-System Pharmacists) or FDA list of drugs that are in short supply at the time of compounding and at the time of dispense, and the compounding of that drug preparation is justified by a specific, documented medical need made known to the pharmacist prior to compounding. The pharmacy shall retain a copy of the documentation of the shortage and the specific medical need in the pharmacy records for three years from the date of receipt of the documentation.

~~(d)~~(e) A drug ~~product~~ preparation shall not be compounded until the pharmacy has first prepared a written master formula ~~record~~ document that includes at least the following elements:

(1) Active ingredients to be used.

(2) Equipment to be used.

(3) ~~Expiration dating requirements.~~ The maximum allowable beyond use date for the preparation, and the rationale or reference source justifying its determination.

(4) Inactive ingredients to be used.

(5) ~~Process and/or procedure~~ Specific and essential compounding steps used to prepare the drug.

(6) Quality reviews required at each step in preparation of the drug.

(7) Post-compounding process or procedures required, if any.

(8) Instructions for storage and handling of the compounded drug preparation.

~~(e)~~(f) Where a pharmacy does not routinely compound a particular drug ~~product~~ preparation, the master formula record for that ~~product~~ preparation may be recorded on the prescription document itself.

~~(f)~~(g) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug ~~product~~ preparation until ~~it~~ the beyond use date indicated on the label, so long as label instructions for storage and handling are followed after the preparation is dispensed.

~~(g)~~(h) All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendia~~l~~ and other applicable requirements to maintain their integrity, potency, quality, and labeled strength.

~~(h)~~(i) Every compounded drug ~~product~~ preparation shall be given a~~n expiration~~ beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, ~~.~~ and determined based on the professional judgment of the pharmacist performing or supervising the compounding. ~~, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used, stored, transported, or administration begun.~~

(1) For non-sterile compounded drug preparation(s), the beyond use date ~~This "beyond use date" of the compounded drug product preparation~~ shall not exceed any of the following: ~~180 days from preparation or~~

(A) the shortest expiration date or beyond use date of any ~~component~~ ingredient in the compounded drug ~~product~~ preparation, ~~nor shall it exceed 180 days~~

(B) the chemical stability of any one ingredient in the compounded drug preparation;

(C) the chemical stability of the combination of all ingredients in the compounded drug preparation,

(D) 180 days for non-aqueous formulations,

(E) 14 days for water-containing oral formulations, and

(F) 30 days for water-containing topical/dermal and mucosal liquid and semisolid formulations.

~~from preparation~~

(2) For sterile compounded drug preparations, the beyond use date shall not exceed any of the following:

(A) The shortest expiration date or beyond use date of any ingredient in the sterile compounded drug product preparation,

(B) The chemical stability of any one ingredient in the sterile compounded drug preparation,

(C) The chemical stability of the combination of all ingredients in the sterile compounded drug preparation, and

(D) The beyond use date assigned for sterility in section 1751.8.

(3) Extension of a beyond use date is only allowable when supported by the following:

(A) Method Suitability Test,

(B) Container Closure Integrity Test, and

(C) Stability Studies

~~unless a longer later date is supported by stability studies of~~

(4) In addition to the requirements of paragraph three (3), the ~~finished~~ drugs or compounded drug ~~products~~ preparations tested and studied shall be ~~using~~ ~~the same~~ identical ~~components~~ in ingredients, specific and essential compounding steps, quality reviews, and packaging as the finished drug or compounded drug preparation.

(5) Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

~~(i)~~(j) The pharmacist performing or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug ~~product~~ preparation.

~~(j)~~ (k) Prior to allowing any drug product preparation to be compounded in a pharmacy, the

pharmacist-in-charge shall complete a self-assessment for compounding pharmacies developed by the board (Incorporated by reference is "Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment" Form 17M-39 Rev. 02/12.) as required by Section 1715 of Title 16, Division 17, of the California Code of Regulations. That form contains a first section applicable to all compounding, and a second section applicable to sterile injectable compounding. The first section must be completed by the pharmacist-in-charge before any compounding is performed in the pharmacy. The second section must be completed by the pharmacist-in-charge before any sterile ~~injectable~~ compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of each odd-numbered year, within 30 days of the start date of a new pharmacist-in-charge or change of location, and within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

~~(k)~~(l) Packages of ingredients, both active and inactive, that lack a supplier's expiration date are subject to the following limitations:

(1) such ingredients cannot be used for any non-sterile compounded drug preparation more than three (3) years after the date of receipt by the pharmacy. ~~unless either appropriate and documented inspection or analytical testing indicates that the ingredient has retained its purity and quality for use in compounded drug preparations, considering the container in which it is packaged and the storage conditions, and~~

(2) such ingredients cannot be used for any sterile compounded drug preparation more than one (1) year after the date of receipt by the pharmacy~~, unless either appropriate and documented inspection or analytical testing indicates that the ingredient has retained its purity and quality for use in compounded drug preparations, considering the container in which it is packaged and the storage conditions~~.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code, Sections 1735, 1735.1, 1735.8, and 1751.1-1751.8 of Title 16, Division 17, of the California Code of Regulations.

To Amend § 1735.3 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.3. ~~Records~~ Recordkeeping ~~of~~ for Compounded Drug ~~Products~~ Preparations.

(a) For each compounded drug ~~product~~ preparation, ~~the~~ pharmacy records shall include:

(1) The master formula ~~record~~ document.

(2) A compounding log consisting of a single document containing all of the following: ~~The compounding document shall include the following:~~

(A) Name and Strength of the compounded drug preparation.

~~(2)~~(A)(B) The date the drug ~~product~~ preparation was compounded.

~~(3)~~(B)(C) The identity of ~~the~~ any pharmacy personnel ~~who compounded the~~ engaged in compounding the drug ~~product~~ preparation.

~~(4)~~(C)(D) The identity of the pharmacist reviewing the final drug ~~product~~ preparation.

~~(5)~~(D)(E) The quantity of each ~~component~~ ingredient used in compounding the drug ~~product~~ preparation.

~~(6)~~(E)(F) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. If the manufacturer does not supply an expiration date for any component, the records shall include the date of receipt of the component in the pharmacy, and the limitations of section 1735.2, subdivision (k) shall apply.

(i) Exempt from the requirements in this paragraph (1735.3(a)(2)(E)) are sterile ~~products~~ preparations compounded ~~on a one-time basis~~ in a single lot for administration within seventy-two (72) hours to a~~n in~~patient in a health care facility licensed under section 1250 of the Health and Safety Code and stored in accordance with standards for "Redispensed CSPs" found in Chapter 797 of the United States Pharmacopeia – National Formulary (USP37-NF32) Through 2nd Supplement (~~35~~ 37th Revision, Effective ~~May~~ December 1, ~~2012~~ 2014), hereby incorporated by reference~~, to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code~~.

~~(7)~~~~(F)~~(G) A pharmacy-assigned unique reference or lot number for the compounded drug ~~product~~ preparation.

~~(8)~~~~(G)~~(H) The ~~expiration~~ beyond use date or beyond use date and time of the final compounded drug ~~product~~ preparation, expressed in the compounding ~~record~~ document in a standard date and time format.

~~(9)~~~~(H)~~(I) The final quantity or amount of drug ~~product~~ preparation compounded for dispensing.

(J) Documentation of quality reviews and required post-compounding process and procedures.

(b) Pharmacies shall maintain records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products, and components used in compounding.

(c) Active ingredients shall be obtained from a supplier registered with the Food and Drug Administration (FDA). All other ~~C~~chemicals, bulk drug substances, and drug products~~, and components~~ used to compound drug ~~products~~ preparations shall be obtained, whenever possible, from ~~reliable~~ FDA- registered suppliers. The pharmacy shall acquire and retain ~~any available~~ certificates of purity or analysis, either written in English or translated into English, for chemicals, bulk drug substances, and drug products~~, and components~~ used in compounding. Certificates of purity or analysis are not required for drug products that are approved by the FDA. Any certificates of purity or analysis acquired by the pharmacy shall be matched to the corresponding ~~product~~ chemical, bulk drug substance, or drug products received.

(d) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was ~~created~~ last in effect. If only recorded and stored electronically, on magnetic media, or in any other computerized form, the records shall be maintained as specified by Business and Professions Code section 4070 subsection (c).

Authority cited: Sections 4005, 4127, and 4169, Business and Professions Code.

Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1735.4 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.4. Labeling of Compounded Drug ~~Products~~ Preparations.

(a) Each compounded drug preparation shall be affixed with a container label prior to dispensing that contains at least:

(1) Name of the compounding pharmacy and dispensing pharmacy (if different);

(2) Name (brand or generic) and strength, volume, or weight of each active ingredient. For admixed IV solutions, the intravenous solution utilized shall be included;

(3) Instructions for storage, handling, and administration. For admixed IV solutions, the rate of infusion shall be included;

(4) The beyond use date for the drug preparation;

(5) The date compounded; and

(6) The lot number or pharmacy reference number.

~~In addition to the labeling information required under Business and Professions Code section 4076 and under California Code of Regulations section 1707.5, the label of a compounded drug product preparation shall contain the generic or brand name(s) of the principal all active ingredient(s)~~.

(b) Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient shall also include on the label the information required under Business and Professions Code section 4076 and California Code of Regulations, title 16, section 1707.5.

~~A statement that the drug has been compounded by the pharmacy shall be included on the container or on the receipt provided to the patient. Exempt from the requirements of this paragraph are those sterile drug preparations compounded within a health care facility solely for administration, by a licensed health care professional, to a patient of the facility. To be treated as such, the "health care facility" must be licensed under Health and Safety Code section 1250.~~

(c) Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient shall also include, on the container label or on a receipt provided to the patient, a

statement that the drug has been compounded by the pharmacy. ~~Drug products preparations compounded into unit-dose containers that are too small or otherwise impractical for full compliance with subdivisions (a) and (b) shall be labeled with at least the name of the compounding pharmacy and dispensing pharmacy, if different, the name(s) of the active ingredient(s), concentration or strength, volume or weight of the preparation, pharmacy reference or lot number, and expiration beyond use date and shall not be subject to minimum font size requirements.~~

(d) Prior to dispensing drug preparations compounded into unit-dose containers that are too small or otherwise impractical for full compliance with subdivisions (a), (b), and (c) shall be labeled with at least the name of the compounding pharmacy and dispensing pharmacy, if different, the name(s) of the active ingredient(s), strength, volume or weight of the preparation, pharmacy reference or lot number, and beyond use date, and shall not be subject to minimum font size requirements. Once dispensed, outer packaging must comply with 1735.4(a) – (c).

(e) All hazardous agents shall bear a special label which states "Chemotherapy - Dispose of Properly" or "Hazardous – Dispose of Properly."

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4076 and 4127, Business and Professions Code.

To Amend § 1735.5 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.5. Compounding Policies and Procedures.

(a) Any pharmacy engaged in compounding shall maintain ~~a~~written policy~~y~~ies and procedures ~~manual~~ for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for

disciplinary action.

(b) The policy~~y~~ies and procedures ~~manual~~ shall be reviewed and such review shall be documented on an annual basis by the pharmacist-in-charge. ~~and~~ The policies and procedures ~~manual~~ shall be updated whenever changes in policies and procedures ~~processes~~ are implemented.

(c) The policy~~y~~ies and procedures ~~manual~~ shall include at least the following:

(1) Procedures for notifying staff assigned to compounding duties of any changes in ~~processes or to the~~ policy~~y~~ies or procedures ~~manual~~.

(2) ~~Documentation of a~~ A written plan for recall of a dispensed compounded drug ~~product~~ preparation where subsequent ~~verification~~ information demonstrates the potential for adverse effects with continued use ~~of a compounded drug product~~. The plan shall ensure that all affected doses can be accounted for during the recall and shall provide steps to identify which patients received the affected lot or compounded drug preparation(s).

(3) ~~The p~~Procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency evaluation process.

(4) ~~The p~~Procedures for evaluating, maintaining, certifying, cleaning, and disinfecting the facility (physical plant) used for compounding, and for training on these procedures as part of the staff training and competency evaluation process.

(~~4~~5) Documentation of the methodology used to ~~test~~ validate integrity, potency, quality, and labeled strength of compounded drug ~~products~~ preparations. The methodology must be appropriate to compounded drug preparations.

(~~5~~6) Documentation of the methodology and rationale or reference source used to determine appropriate ~~expiration~~ beyond use dates for compounded drug ~~products~~ preparations.

(7) Dates and signatures reflecting all annual reviews of the policies and procedures ~~manual~~ by the pharmacist-in-charge.

(8) Dates and signatures accompanying any revisions to the policies and procedures ~~manual~~ approved by the pharmacist-in-charge.

(9) Policies and procedures for storage of compounded drug preparations in the pharmacy and

daily documentation of all room, refrigerator, and freezer temperatures within the pharmacy.

(10) Policies and procedures regarding ensuring appropriate functioning of refrigeration devices, monitoring refrigeration device temperatures, and actions to take regarding any out of range temperature variations within the pharmacy.

(11) Policies and procedures for proper garbing when compounding with hazardous products. This shall include when to utilize double shoe covers.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, ~~and~~ 4127, and 4301, Business and Professions Code.

To Amend § 1735.6 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.6. Compounding Facilities and Equipment.

(a) Any pharmacy engaged in compounding shall maintain written documentation regarding the facilities and equipment necessary for safe and accurate compounding of ~~ed~~ compounded drug ~~products~~ preparations. This shall include records of maintenance and cleaning of the facilities and equipment. Where applicable, this shall also include records of certification(s) of facilities or equipment.

(b) Any equipment used to compound drug ~~products~~ preparations shall be stored, used, ~~and~~ maintained, and cleaned in accordance with manufacturers' specifications.

(c) Any equipment that weighs, measures, or transfers ingredients used to compound drug ~~products~~ preparations for which calibration or adjustment is appropriate shall be calibrated prior to use, on a schedule and by a method determined by the manufacturer's specifications, to ensure accuracy. Documentation of each such calibration shall be recorded ~~in writing~~ in a form which is not alterable and these records of calibration shall be maintained and retained in the pharmacy.

(d) Any pharmacy engaged in any hazardous drug compounding shall maintain written documentation regarding appropriate cleaning of facilities and equipment to prevent cross-

contamination with non-hazardous drugs.

(e) Hazardous drug compounding shall be completed in an externally vented physically separate room with the following requirements:

(1) Minimum of ~~12~~30 air changes per hour except that 12 air changes per hour are acceptable for segregated compounding areas with a BSC or CACI when products are assigned a BUD of 12 hrs or less or when non sterile products are compounded; and

(2) Maintained at a negative pressure of ~~at least~~ 0.01 to 0.03 inches of water column relative to all adjacent spaces (rooms, above ceiling, and corridors); and

(3) Each PEC in the room shall also be externally vented; and

(4) All surfaces within the room shall be smooth, seamless, impervious, and non-shedding.

(f) Where compliance with the [insert effective date upon adoption] amendments to Article 4.5 or Article 7, requires physical construction or alteration to a facility or physical environment, the board or its designee may grant a waiver of such compliance for a period of time to permit such physical change(s). Application for any waiver shall be made by the licensee in writing, and the request shall identify the provision(s) requiring physical construction or alteration, and the timeline for any such change(s). The board or its designee may grant the waiver when, in its discretion, good cause is demonstrated for such waiver.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code.
Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code.

To Amend § 1735.7 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.7. Training of Compounding Staff.

(a) A pharmacy engaged in compounding shall maintain documentation ~~that demonstrates~~ demonstrating that personnel involved in compounding have the skills and training required to properly and accurately perform their assigned responsibilities and documentation ~~that~~ demonstrating that all personnel involved in compounding ~~was~~ are trained in all aspects of

policies and procedures. This training shall include but is not limited to support personnel (e.g. institutional environmental services, housekeeping), maintenance staff, supervising pharmacist and all others whose jobs are related to the ~~sterile~~ compounding process. ~~Any pharmacy engaged in compounding shall maintain written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding. Additionally, documentation demonstrating that staff have been trained on all policies and procedures shall be maintained.~~

(b) The pharmacy shall develop and maintain an ongoing competency evaluation process for pharmacy personnel involved in compounding, and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel.

(c) Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug ~~product~~ preparation.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code.

To Amend § 1735.8 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.8. Compounding Quality Assurance.

(a) Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug ~~products~~ preparations.

(b) The quality assurance plan shall include written procedures for verification, monitoring, and review of the adequacy of the compounding processes and shall also include written documentation of review of those processes by qualified pharmacy personnel.

(c) The quality assurance plan shall include written standards for qualitative and quantitative analysis of compounded drug preparations to ensure integrity, potency, quality, and labeled

strength, including the frequency of testing~~, analysis of compounded drug products preparations~~. All qualitative and quantitative analysis reports for compounded drug ~~products~~ preparations shall be retained by the pharmacy and ~~collated~~ maintained along with the compounding log ~~record document~~ and master formula document. The quality assurance plan shall include a schedule for routine testing and analysis of specified compounded drug preparations to ensure integrity, potency, quality, and labeled strength, on at least an annual basis.

(d) The quality assurance plan shall include a written procedure for scheduled action in the event any compounded drug ~~product~~ preparation is ever discovered to be ~~below~~ outside minimum standards for integrity, potency, quality, or labeled strength.

(e) The quality assurance plan shall include a written procedure for responding to out-of-range temperature variations within the pharmacy ~~or~~ and within patient care areas of a hospital where furnished drug is returned for redispensing.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code.

To Amend § 1751 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

Article 7. Sterile ~~Injectable~~ Compounding

1751. Sterile ~~Injectable~~ Compounding; Compounding Area; Self-Assessment.

(a) Any pharmacy engaged in compounding sterile ~~injectable~~ drug ~~products~~ preparations shall conform to the parameters and requirements stated by Article 4.5 (Section 1735 et seq.), applicable to all compounding, and shall also conform to the parameters and requirements stated by this Article 7 (Section 1751 et seq.), applicable solely to sterile ~~injectable~~ compounding.

(b) Any pharmacy compounding sterile ~~injectable~~ drug ~~products~~ preparations shall have a ~~designated~~ compounding area designated for the preparation of sterile ~~injectable~~ drug ~~products~~ preparations that is in a restricted location where traffic has no impact on the

performance of the PEC(s). The ~~buffer area or~~ cleanroom, including the walls, ceilings, and floors, shall be constructed in accordance with Section 1250.4 of Title 24, Part 2, Chapter 12, of the California Code of Regulations. The pharmacy shall be ventilated in a manner in accordance with Section 505.5 of Title 24, Part 4, Chapter 5 of the California Code of Regulations. ~~which shall meet the following standards:~~ The environments within the pharmacy shall meet the following standards:

(1) ~~Clean Room and Work Station Requirements, shall be in accordance with Section 1250 of Title 24, Part 2, Chapter 12, of the California Code of Regulations.~~

~~(2) Walls, ceilings and floors shall be constructed in accordance with Section 1250 of Title 24, Part 2, Chapter 12, of the California Code of Regulations.~~

~~(3) Be ventilated in a manner in accordance with Section 505.12 of Title 24, Chapter 5 of the California Code of Regulations.~~

~~(4) Be~~ Each ISO environment shall be certified ~~annually~~ at least every six months by a qualified technician ~~who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with standards adopted by the United States General Services Administration~~ in accordance with Section 1751.4. Certification records must be retained ~~for at least 3 years~~ in the pharmacy.

~~(5)~~ (2) ~~The pharmacy shall be arranged in accordance with Section 1250 of Title 24, Part 2, Chapter 12, of the California Code of Regulations.~~ Items related to the compounding of sterile ~~injectable~~ drug ~~products~~ preparations within the compounding area shall be stored in such a way as to maintain the integrity of an aseptic environment.

~~(6)~~ (3) A sink shall be included in accordance with Section 1250.4 of Title 24, Part 2, Chapter 12, of the California Code of Regulations. Sinks and drains shall not be present in any ISO Class 7 or better ~~buffer area or~~ cleanroom, nor in a segregated sterile compounding area within three feet of an ISO Class 5 or better PEC, with the exception of emergency eye-rinsing stations. A sink may be located in an ante-area. ~~(A)~~ When the PEC in the segregated sterile compounding area is a CAI or CACI and the documentation provided by the manufacturer shows it meets the requirements listed in 1751.4(f)(1)-(3) ~~they~~ the sterile compounding area is ~~are~~ exempt from the room requirement listed in 1751(b)(3).

~~(7)~~ (4) There shall be a refrigerator and, ~~/or~~ where appropriate, a freezer, of sufficient capacity to meet the storage requirements for all material requiring refrigeration or freezing, and a backup plan to ensure continuity of available compounded drug preparations in the event of a power outage.

~~(c) Any pharmacy compounding a sterile injectable drug product preparation from one or more non-sterile ingredients shall comply with Business and Professions Code section 4127.7.~~

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127 ~~and 4127.7~~, Business and Professions Code; Sections 1735, 1735.1-1735.8., and 1751.1-1751.8. of Title 16, Division 17, of the California Code of Regulations; and Section 18944, Health and Safety Code.

To Amend § 1751.1 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.1. Sterile ~~Injectable~~ Compounding Recordkeeping Requirements.

(a) ~~Pharmacies compounding sterile injectable products for future use pursuant to section 1735.2 shall, in addition to those records required by section 1735.3, make and keep records indicating the name, lot number, amount, and date on which the products were provided to a prescriber.~~

~~(b)~~ In addition to the records required by section 1735.3 ~~and subdivision (a)~~, any pharmacy engaged in any compounding of ~~for~~ sterile drug ~~products~~ preparations ~~compounded from one or more non-sterile~~ ~~ingredients~~, shall ~~make and~~ ~~keep~~ maintain the following records, which must be ~~must be made and kept by~~ readily retrievable, within the pharmacy:

(1) ~~The~~ Documents evidencing training and competency evaluations of employees in sterile ~~product~~ drug preparation policies and procedures.

(2) Results of hand hygiene and garbing assessments with integrated gloved fingertip testing.

(3) Results of assessments of personnel for aseptic techniques including results of media-fill tests and gloved fingertip testing performed in association with media-fill tests.

(4) Results of viable ~~volumetric~~ air and surface sampling.

(5) Video of smoke studies in all ISO certified spaces.

~~(2)~~ ~~(5)~~(6) Documents indicating daily ~~recordation~~ documentation of room, ~~R~~ refrigerator, and freezer temperatures appropriate for sterile compounded drug preparations consistent with the temperatures listed in section 1735.1 for:

(A) Controlled room temperature.

(B) Controlled cold temperature.

(C) Controlled freezer temperature.

~~(3)~~ ~~(6)~~(7) Certification(s) of the sterile compounding environment(s).

~~(7)~~(8) Documents indicating daily documentation ~~recordation~~ of air pressure differentials or air velocity measurements between all adjoining ISO rooms or areas, including those associated with compounding aseptic (containment) isolators, and air pressure differentials or air velocity measurements between all rooms or spaces with an immediate entry or opening to ISO rooms or areas.

~~(4)~~ ~~(9)~~(9) Other facility quality control ~~logs~~ records specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment).

~~(5)~~ ~~(9)~~(10) Logs or other documentation of ~~I~~inspections for expired or recalled ~~pharmaceutical products or raw ingredients~~ chemicals, bulk drug substances, drug products, or other ingredients.

~~(6)~~ ~~(10)~~(11) Preparation records including the master formula document ~~work sheet~~, the preparation compounding log ~~document~~~~work sheet~~, and records of end-product evaluation testing and results.

(b) Pharmacies compounding sterile drug preparations for future use pursuant to section 1735.2 shall, in addition to those records required by section 1735.3, make and keep records indicating the name, lot number, and amount of any drug preparation compounded for future use, the date on which any preparation was provided to a prescriber, and the name, address, ~~and~~ license type and number of the prescriber.

(c) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created. If only

recorded and stored electronically, on magnetic media, or in any other computerized form, the records shall be maintained as specified by Business and Professions Code section 4070 subsection (c).

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1751.2 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.2. Sterile ~~Injectable~~ Compounding Labeling Requirements.

In addition to the labeling information required under Business and Professions Code section 4076 and California Code of Regulations, title 16, sections 1707.5 and 1735.4, a pharmacy ~~which~~ that compounds sterile ~~injectable~~ drug ~~products~~ preparations shall include the following information on the label~~s~~ for each such ~~those products~~ preparation:

(a) The ~~T~~telephone number of the pharmacy. ~~, except~~ The telephone number is not required on the label for sterile ~~injectable~~ drug ~~products~~ preparations ~~dispensed~~ administered ~~for~~ to inpatients ~~of a~~ within the hospital ~~pharmacy~~.

~~(b) Name (brand or generic) and concentration strength, volume, or weight of each active ingredients contained in the sterile injectable drug product preparation.~~

(~~c~~b) Instructions for storage, ~~and~~ handling, and administration.

(~~d~~c) All ~~cytotoxic~~ hazardous agents shall bear a special label which states "Chemotherapy - Dispose of Properly" or "~~Cytotoxic~~ Hazardous – Dispose of Properly."

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4076 and 4127, Business and Professions Code.

To Amend § 1751.3 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.3. Sterile ~~Injectable~~ Compounding Policies and Procedures.

(a) Any pharmacy engaged in compounding sterile drug preparations shall maintain ~~a~~ written policies and procedures ~~manual~~ for compounding. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action. In addition to the elements required by section 1735.5, there shall be written policies and procedures regarding the following:

(1) Action levels for colony-forming units (CFUs) detected during viable surface sampling, glove fingertip, and viable air sampling~~.~~ and actions to be taken when the levels are exceeded.

(2) Airflow considerations and pressure differential monitoring.

(3) An environmental sampling plan and procedures specific to viable air, surface and gloved fingertip sampling as well as nonviable particle sampling.

(4) Cleaning and maintenance of ISO environments and segregated compounding areas.

(5) Compounded sterile drug preparation stability and beyond use dating.

(6) Compounding, filling, and labeling of sterile drug preparations.

(7) Daily and monthly cleaning and disinfection schedule for the controlled areas and any equipment in the controlled area as specified in section 1751.4.

(8) Depyrogenation of glassware (if applicable)

~~(8)~~(9) Facility management including certification and maintenance of controlled environments and related equipment.

~~(9)~~(10) For compounding aseptic isolators and compounding aseptic containment isolators, documentation of the manufacturer's recommended purge time.

~~(10)~~(11) Hand hygiene and garbing.

~~(11)~~(12) Labeling of the sterile compounded drug preparations based on the intended route of administration and recommended rate of administration.

~~(12)~~(13) Methods by which the supervising pharmacist will fulfill his or her responsibility to ensure the quality of compounded drug preparations. ~~Media-fill testing procedure~~.

~~(13)~~(14) Orientation, training, and competency evaluation of staff in all aspects of the

preparation of sterile drug preparations including didactic training and knowledge/competency assessments that include at minimum: hand hygiene and garbing; decontamination (where applicable); cleaning and disinfection of controlled compounding areas; and proper aseptic technique, demonstrated through the use of a media-fill test performed by applicable personnel; and aseptic area practices.

~~(14)~~(15) Preparing sterile compounded drug preparations from non-sterile components (if applicable). This shall include sterilization method suitability testing for each master formula document.

~~(15)~~(16) Procedures for handling, compounding and disposal of hazardous agents. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.

~~(16)~~(17) Procedures for handling, compounding and disposal of infectious materials. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.

~~(17)~~(18) Proper use of equipment and supplies.

~~(18)~~(19) Quality assurance program compliant with sections 1711, 1735.8 and 1751.7.

~~(19)~~(20) Record keeping requirements.

~~(20)~~(21) Temperature monitoring in compounding and controlled storage areas.

~~(21)~~(22) The determination and approval by a pharmacist of ingredients and the compounding process for each preparation before compounding begins.

~~(22)~~(23) Use of automated compounding devices (if applicable).

~~(23)~~(24) Visual inspection and other final quality checks of sterile drug preparations.

~~(a) Any pharmacy engaged in compounding sterile injectable drug products~~ preparations ~~shall maintain a written policyies and procedures manual for compounding. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action, that includes, i~~In addition to the elements required by section 1735.5, ~~written policies and procedures regarding the following:~~

~~(1) Compounding, filling, and labeling of sterile injectable compounds~~ drug preparations.

~~(2) Labeling of the sterile injectable product~~ compounded drug preparations ~~based on the~~

~~intended route of administration and recommended rate of administration.~~

~~(3) Proper use of E equipment and supplies.~~

~~(4) Training of staff in the preparation of sterile injectable drug products Hand hygiene and garbing.~~

~~(5) Procedures for handling cytotoxic agents Media-fill testing procedure.~~

~~(6) Quality assurance program.~~

~~(7) Record keeping requirements.~~

~~(8) Compounded sterile drug preparation stability and beyond-use dating.~~

~~(9) Visual inspection and other final quality checks of sterile drug preparations.~~

~~(10) Use of automated compounding devices (if applicable).~~

~~(11) Preparing sterile compounded drug preparations from non-sterile components (if applicable). This shall include sterilization method suitability testing for each master formula document.~~

~~(12) Orientation, training, and competency evaluation of staff in all aspects of the preparation of sterile drug preparations including didactic training and knowledge/competency assessments that include at minimum: hand hygiene and garbing; decontamination (where applicable); cleaning and disinfection of controlled compounding areas; and proper aseptic technique.~~

~~(13) Airflow considerations and pressure differential monitoring.~~

~~(14) Cleaning and maintenance of ISO environments and segregated compounding areas.~~

~~(15) An environmental sampling plan and procedures specific to viable air, surface and gloved fingertip sampling as well as nonviable particle sampling.~~

~~(16) For compounding aseptic isolators and compounding aseptic containment isolators, documentation of the manufacturer's recommended purge time.~~

~~(17) Temperature monitoring in compounding and controlled storage areas.~~

~~(18) Facility management including certification and maintenance of controlled environments and related equipment.~~

~~(19) Action levels for colony forming units (CFUs) detected during viable surface testing, sampling, glove fingertip, and volumetric viable air sampling.~~

~~(b)(20) The determination and approval by a pharmacist of~~ The ingredients and the ~~compounding process for each preparation must be determined in writing before compounding begins and must be reviewed by a pharmacist.~~

~~(c)(21)~~ ~~Pharmacies compounding sterile injectable drug products preparations shall have written policies and procedures for the disposal of infectious materials and/or materials containing cytotoxic hazardous residues.~~ ~~Procedures for handling, compounding and disposal of hazardous agents.~~ ~~The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.~~

~~(22) Procedures for handling, compounding and disposal of infectious materials. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.~~

~~(23) Daily and monthly cleaning and disinfection schedule for the controlled areas and any equipment in the controlled area as specified in section 1751.4.~~

(b) For lot compounding, the pharmacy shall maintain ~~a~~written policies and procedures ~~manual~~ that includes, in addition to the elements required by section 1735.5 and 1751.3(a), written policies and procedures regarding the following:

(1) Use of master formula~~s~~ documents and compounding logs ~~documents work sheets~~.

(2) Appropriate documentation.

(3) Appropriate sterility and potency testing.

(c) For non-sterile-to-sterile batch compounding, the pharmacy shall maintain ~~a~~written policies and procedures ~~manual~~ for compounding that includes, in addition to the elements required by section 1735.5, ~~and~~ 1751.3(a), and 1751.7(e), written policies and procedures regarding the following:

(1) Process validation for chosen s~~S~~terilization methods ~~and shall include sterilization method suitability testing for each master formula document~~.

(2) End-product evaluation, quantitative, and qualitative testing.

(d)~~(1) All written p~~Policies and procedures ~~manuals and materials~~ shall be immediately available to all personnel involved in ~~these~~ compounding activities and to board inspectors.

~~(d)(2)~~(e) All personnel involved must read the policies and procedures before compounding

sterile ~~injectable products~~ drug preparations. ~~, and any~~ All personal involved must read all additions, revisions, and deletions to the written policies and procedures ~~must be communicated to all personnel involved in sterile compounding~~. ~~This~~ Each review must be documented by a signature and date.

~~(3) Policies and procedures must address at least the following:~~

~~(A) Competency evaluation.~~

~~(B) Storage and handling of products and supplies.~~

~~(C) Storage and delivery of final products.~~

~~(D) Process validation.~~

~~(E) Personnel access and movement of materials into and near the controlled area~~

~~(F) Use and maintenance of environmental control devices used to create the critical direct compounding area for manipulation of sterile products (e.g., laminar-airflow workstations, biological safety cabinets, class 100 cleanrooms, and barrier isolator workstations).~~

~~(G) Regular cleaning schedule for the controlled areas and any equipment in the controlled area and the alternation of disinfectants. Pharmacies subject to an institutional infection control policy may follow that policy as it relates to cleaning schedules and the alternation of disinfectants in lieu of complying with this subdivision.~~

~~(H) Disposal of packaging materials, used syringes, containers, and needles to enhance sanitation and avoid accumulation in the controlled area.~~

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1751.4 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.4. Facility and Equipment Standards for Sterile ~~Injectable~~ Compounding.

(a) No sterile ~~injectable~~ drug ~~product~~ preparation shall be compounded if it is known, or

reasonably should be known, that the compounding environment fails to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile ~~injectable~~ drug ~~products~~ preparations.

(b) During the compounding of ~~preparation of~~ sterile ~~injectable~~ drug ~~products~~ preparations, access to the areas designated ~~area or cleanroom~~ for compounding must be limited to those individuals who are properly attired.

(c) All equipment used in the areas designated ~~area or cleanroom~~ for compounding must be made of a material that can be easily cleaned and disinfected.

(d) ~~Cleaning and disinfecting surfaces in the ISO Class 5 PEC shall occur frequently, including:~~ Cleaning shall be done using a germicidal detergent and sterile water. The use of a sporicidal agent is required to be used at least monthly.

(1) All ISO Class 5 surfaces, work table surfaces, carts, counters, and the cleanroom floor shall be cleaned at least daily. After each cleaning, disinfection using a suitable sterile agent shall occur on all ISO Class 5 surfaces, work table surfaces, carts, and counters.

(2) Walls, ceilings, storage shelving, tables, stools, and all other items in the ISO Class 7 or ISO Class 8 environment shall be cleaned at least monthly.

(3) Cleaning shall also occur after any unanticipated event that could increase the risk of contamination.

(4) All cleaning materials, such as wipers, sponges, and mops, shall be non-shedding and dedicated to use in the cleanroom, or ante-area, and segregated sterile compounding areas and shall not be removed from these areas except for disposal.

(e) Disinfection, using a suitable sterile agent, shall also occur on all surfaces in the ISO Class 5 PEC frequently ~~(at least every 30 minutes)~~, including:

(1) At the beginning of each shift;

(2) At least every 30 minutes when compounding involving human staff is occurring or ~~B~~before ~~and after~~ each lot;

(3) After each spill; and

(4) When surface contamination is known or suspected.

~~(d) (e) Exterior workbench surfaces and other hard surfaces in the designated area, such as~~

~~walls, floors, ceilings, shelves, tables, and stools, must be disinfected weekly and after any unanticipated event that could increase the risk of contamination. Counters, cleanable work surfaces and floors shall be cleaned with a germicidal detergent and water and disinfected with a suitable agent daily. Walls, ceilings, storage shelving, tables and stools shall be cleaned with a germicidal detergent and water and disinfected with a suitable agent monthly. Cleaning and disinfecting shall occur after any unanticipated event that could increase the risk of contamination.~~

~~(e)~~ (f) Pharmacies preparing sterile compounded preparations require the use of a PEC that provides ISO Class 5 air or better air quality. Certification and testing of primary and secondary engineering controls shall be performed no less than every six months and whenever the device or area designated for compounding is relocated, altered or a service to the facility is performed that would impact the device or area. Certification must be completed by a qualified technician who is familiar with certification methods and procedures in accordance with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-13~~1~~, Revised ~~January 31, 2012~~May 20, 2015). Certification records must be retained for at least 3 years. Unidirectional ~~C~~compounding aseptic isolators or compounding aseptic containment isolators may be used outside of an ISO Class 7 ~~buffer area or~~ cleanroom if the isolator is certified to meet~~s~~ the following criteria:

(1) Particle counts sampled approximately 6-12 inches upstream of the critical exposure site shall maintain ISO Class 5 levels during compounding operations.

(2) Not more than 3520 particles (0.5 um and larger) per cubic meter shall be counted during material transfer, with the particle counter probe located as near to the transfer door as possible without obstructing transfer.

(3) Recovery time to achieve ISO Class 5 air quality shall be documented and internal procedures developed to ensure that adequate recovery time is allowed after material transfer before and during compounding operations.

Compounding aseptic isolators ~~or compounding aseptic containment isolators~~ that do not meet the requirements as outlined in this subdivision or are not located within an ISO Class 7 ~~buffer area~~ cleanroom may only be used to compound preparations that meet the criteria specified in accordance with subdivision (d) of Section 1751.8 of Title 16, Division 17, of the

California Code of Regulations.

(g) Pharmacies preparing ~~parenteral cytotoxic~~ sterile hazardous agents shall do so in accordance with Section 505.~~12~~5.1 of Title 24, Chapter 5, of the California Code of Regulations, requiring a ~~laminar air flow hood~~ negative pressure PEC. Additionally, each PEC used to compound hazardous agents shall be externally vented.The ~~hood~~ negative pressure PEC must be certified ~~annually~~ every six months by a qualified technician who is familiar with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-1~~3~~1, Revised ~~January 31, 2012~~May 20, 2015). ~~the methods and procedures for certifying laminar air flow hoods and cleanroom requirements, in accordance with National Sanitation Foundation Standard 49 for Class II (Laminar Flow) Biohazard Cabinetry, as revised May, 1983 (available from the National Sanitation Foundation, 3475 Plymouth Road, P.O. Box 1468, Ann Arbor, Michigan 48106, phone number (313) 769-8010) or manufacturer's specifications. Certification records must be retained for at least 3 years.~~ Any drug preparation that is compounded in a PEC where hazardous drugs are prepared must be labeled as hazardous, regardless of whether the drug ingredients are considered hazardous.

(1) During the hazardous drug compounding that is performed in a compounding aseptic containment isolator, full hand hygiene and garbing must occur~~, complete with~~. Garbing shall include hair cover, facemask, beard cover (if applicable), polypropylene or low shedding gown that closes in the back, shoe covers, and ~~two layers of gloves with the outermost glove tested to meet~~ two pairs of sterile ASTM D6978-05 standard gloves. ~~Where the documentation provided by CACI manufacturer does not require garbing, only the two glove requirement shall apply.~~

(h) If a compounding aseptic isolator is certified by the manufacturer to maintain ISO Class 5 air quality during dynamic operation conditions during compounding as well as during the transfer of ingredients into and out of the compounding aseptic isolator, then it may be placed into a non-ISO classified room. Individuals that use compounding aseptic isolators in this manner must ensure appropriate garbing, which consists of donning sterile gloves over the isolator gloves immediately before non-hazardous compounding. These sterile gloves must be changed by each individual whenever continuous compounding is ceased and before

compounding starts again.

(i) Compounding aseptic isolator and compounding aseptic containment isolator used in the compounding of sterile drug preparations shall use non-turbulent unidirectional air flow patterns. A smoke patterned test shall be used to determine air flow patterns.

~~(i)~~(j) Viable surface sampling shall be done at least ~~quarterly~~ every six months for all sterile-to-sterile compounding and ~~monthly~~ quarterly for all non-sterile-to-sterile compounding. ~~Volumetric~~ Viable air sampling shall be done by ~~impaction~~ volumetric air sampling procedures which test a sufficient volume of air (400 to 1,000 liters) at each location and shall be done at least once every six months. Viable surface and ~~volumetric~~ viable air sampling shall be performed by a qualified individual who is familiar with the methods and procedures for surface testing and air sampling. Viable air sampling is to be performed under dynamic conditions that simulate actual production. Viable s~~S~~urface sampling is to be performed under dynamic conditions of actual compounding. When the environmental monitoring action levels are exceeded, the pharmacy shall identify the CFUs at least to the genus level in addition to conducting an investigation pursuant to its policies and procedures. Remediation shall include, at minimum, an immediate investigation of cleaning and compounding operations and facility management.

~~(j)~~(k) The sterile compounding area ~~is~~in the pharmacy shall have a comfortable and well-lighted working environment, which includes a room temperature of 20-2~~3~~4 degrees Celsius (68-75 degrees Fahrenheit) or cooler to maintain comfortable conditions for compounding personnel when attired in the required compounding garb.

(l) A licensee may request a waiver of these provisions as provided in section 1735.6(f).

Note: Authority Cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code; and Section 18944, Health and Safety Code.

To Amend § 1751.5 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.5. Sterile ~~Injectable~~ Compounding Attire.

~~(a) When preparing cytotoxic agents, gowns and gloves shall be worn.~~

~~(b)~~ (a) When compounding sterile drug ~~products~~ preparations ~~from one or more non-sterile ingredients~~ the following standards must be met:

(1) ~~Cleanroom garb~~ Personal protective equipment consisting of a ~~low~~ non-shedding ~~coverall~~ gown, head cover, face mask, facial hair covers (if applicable), and shoe covers must be worn inside the designated area at all times~~, unless the compounding aseptic isolator or compounding aseptic containment isolator manufacturer can provide written documentation, based on validated environmental testing, that any component of the personal protective equipment or personnel cleansing is not required~~. For hazardous compounding double shoe covers are required.

(2) ~~Cleanroom garb~~ Personal protective equipment must be donned and removed ~~outside the designated area~~ in an ante-area or immediately outside the segregated compounding area.

(3) Personnel shall don personal protective equipment in an order that proceeds from those activities considered the dirtiest to those considered the cleanest. The following order is to be followed unless the pharmacy has a procedure in place that documents a method equivalent to or superior to the method described here: The donning of shoe covers or dedicated shoes, head and facial hair covers and face masks shall be followed by the washing of hands and forearms up to the elbows for 30 seconds with soap and water, drying hands, and then the donning of a non-shedding gown.

~~(3)~~ (4) Compounding personnel shall not wear any wrist, ~~H~~hand, finger, ~~and~~ or ~~wrist~~ other visible ~~jewelry or piercing must be eliminated~~ jewelry, piercing, headphones, earbuds, or personal electronic device. ~~If jewelry cannot be removed then it must be thoroughly cleaned and covered with a sterile glove.~~

~~(4) Head and facial hair must be kept out of the critical area or be covered.~~

(5) ~~Gloves made of low-shedding materials are required.~~ Sterile gloves that have been tested for

compatibility with disinfection with isopropyl alcohol are required. Hand cleansing with a persistently active alcohol-based product followed by the donning of sterile gloves may occur within the ante or ~~buffer area or~~ cleanroom. Gloves are to be routinely disinfected with sterile 70 percent isopropyl alcohol before entering or re-entering the PEC and after contact with non-sterile objects. Gloves shall also be routinely inspected for holes, punctures, or tears and replaced immediately if such are detected.

(6) Individuals experiencing exposed rashes, sunburn, weeping sores, conjunctivitis, active respiratory infections or other communicable disease, or those wearing cosmetics, nail polish, or artificial nails shall be excluded from the ISO Class 5 and ISO Class 7 compounding areas until their conditions are remedied.

~~(c) The requirements of subdivision (b) do not apply if a barrier isolator is used to compound sterile injectable products from one or more non-sterile ingredients.~~

(b) When preparing hazardous agents, appropriate gowns and personal protective equipment shall be worn regardless of the PECs used (e.g., biological safety cabinet and compounding aseptic containment isolator). ~~Exceptions are as listed in 1751.4(g).~~

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1751.6 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.6 ~~Training of Sterile Injectable Compounding Staff, Patient, and Caregiver.~~ **Sterile Compounding Consultation; Training of Sterile Compounding Staff**.

(a) Consultation shall be available to the patient and/or primary caregiver concerning proper use, storage, handling, and disposal of sterile ~~injectable~~ drug ~~products~~ preparations and related supplies furnished by the pharmacy.

(b) The pharmacist-in-charge shall ~~be responsible to~~ ensure that all pharmacy personnel engaging in compounding sterile ~~injectable~~ drug ~~products~~ preparations ~~shall~~ have training and

demonstrated competence in the safe handling and compounding of sterile ~~injectable~~ drug ~~products~~ preparations, including ~~cytotoxic~~ hazardous agents if the pharmacy compounds products with ~~cytotoxic~~ hazardous agents.

(c) Records of training and demonstrated competence shall be available for each individual and shall be retained for three years beyond the period of employment.

(d) The pharmacist-in-charge shall be responsible to ensure the continuing competence of pharmacy personnel engaged in compounding sterile ~~injectable~~ drug ~~products~~ preparations.

(e) Pharmacies that compound sterile drug ~~products from one or more non-sterile ingredients~~ preparations must comply with the following training requirements:

(1) The pharmacy must establish and follow a written program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. This program of training and performance evaluation must address at least the following:

(A) Aseptic technique.

(B) Pharmaceutical calculations and terminology.

(C) Sterile ~~product~~ preparation compounding documentation.

(D) Quality assurance procedures.

(E) Aseptic preparation procedures ~~using media-fill tests which are as complicated as the most complex manipulations performed by staff and which contain the same amount or greater of volume transferred during the selected manipulations~~.

(F) Proper hand hygiene, gowning and gloving technique.

(G) General conduct in the controlled area (aseptic area practices).

(H) Cleaning, sanitizing, and maintaining of the equipment and ~~used in~~ the controlled area.

(I) Sterilization techniques for compounding sterile drug preparations from one or more non-sterile ingredients.

(J) Container, equipment, and closure system selection.

(2) Each person ~~assigned to the controlled area~~ engaged in sterile compounding must successfully complete practical skills training in aseptic technique and aseptic area practices using models that are comparable to the most complex manipulations to be performs by the

individual. Each pharmacist responsible for, or directly supervising and controlling, aseptic techniques or practices, must demonstrate the skills needed to ensure the sterility of compounded drug preparations. Evaluation must include written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures. Each person's proficiency and continuing training needs must be reassessed at least every 12 months. Results of these assessments must be documented and retained in the pharmacy for three years.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1751.7 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.7. Sterile ~~Injectable~~ Compounding Quality Assurance and Process Validation.

(a) Any pharmacy engaged in compounding sterile ~~injectable~~ drug ~~products~~ preparations shall maintain, as part of its written policies and procedures, a written quality assurance plan including, in addition to the elements required by section 1735.8, a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities. The end product shall be examined on a periodic sampling basis as determined by the pharmacist-in-charge to assure that it meets required specifications. The ~~Q~~quality ~~A~~assurance ~~P~~program shall include at least the following:

(1) Procedures for ~~C~~cleaning and sanitization of the ~~parenteral medication~~ sterile preparation area.

~~(2) The storage of compounded sterile injectable products in the pharmacy and periodic documentation of refrigerator temperature.~~

~~(3)~~(2) Actions to be taken in the event of a drug recall.

~~(4)~~(3) ~~Written justification of~~ Documentation justifying the chosen ~~expiration~~ beyond use dates for compounded sterile ~~injectable~~ drug ~~products~~ preparations.

(b)(1) The pharmacy and each individual involved in the compounding of sterile drug preparations must successfully demonstrate competency on aseptic technique and aseptic area practices before being allowed to prepare sterile drug preparations. The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be representative of the types of manipulations, products and batch sizes the individual is expected to prepare and include a media-fill test. The validation process shall be as complicated as the most complex manipulations performed by staff and contain the same amount or greater amount of volume transferred during the compounding process. The same personnel, procedures, equipment, and materials must be used in the testing. Media used must have demonstrated the ability to support and promote growth. Completed medium samples must be incubated in a manner consistent with the manufacturer's recommendations. If microbial growth is detected, then each individual's sterile preparation process must be evaluated, corrective action taken and documented, and the validation process repeated.

(2) Each individual's competency must be revalidated at least every twelve months for sterile to sterile compounding and at least every six months for individuals compounding sterile preparations from non-sterile ingredients.

(3) The pharmacy's validation process on aseptic technique and aseptic area practices must be revalidated whenever:

(A) the quality assurance program yields an unacceptable result,

(B) there is any change in the compounding process, the Primary Engineering Control (PEC), or the compounding environment. For purposes of this subsection, a change includes, but is not limited to, when the PEC is moved, repaired or replaced, when the facility is modified in a manner that affects airflow or traffic patterns, or when improper aseptic techniques are observed.

(4) The pharmacy must document the validation and revalidation process.

~~Each individual involved in the preparation of sterile injectable drug products preparations must first successfully demonstrate competency by successfully performing aseptic media-fill~~

~~tests complete a validation process on technique before being allowed to prepare sterile injectable drug products preparations. The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be representative of all types of manipulations, products and batch sizes the individual is expected to prepare. The media-fill testing process shall be as complicated as the most complex manipulations performed by staff and contain the same amount or greater of volume transferred during the compounding process. The same personnel, procedures, equipment, and materials must be involved. Media used must have demonstrated the ability to support and promote growth. Completed medium media samples must be incubated in a manner consistent with the manufacturer's recommendations. If microbial growth is detected, then the employee's sterile preparation process must be evaluated, corrective action taken and documented, and the validation process media-fill testing repeated. Personnel competency must be revalidated at least every twelve months for sterile to sterile compounding and at least every six months for individuals compounding sterile products from non-sterile ingredients. Aseptic work practice assessments via media-fill tests must be revalidated, as appropriate to the circumstance or personnel found to be deficient, whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile injectable drug products preparations is repaired or replaced, the facility is modified in a manner that affects airflow or traffic patterns, or whenever improper aseptic techniques are observed. Revalidation must be documented~~.

(c) All sterile compounding personnel must successfully complete an initial competency evaluation. In addition, immediately following the initial hand hygiene and garbing procedure, ~~all compounding personnel~~ each individual who may be required to do so in practice must successfully complete a gloved fingertip (all fingers on both hands) sampling procedure (zero colony forming units for both hands) at least three times before initially being allowed to compound sterile drug preparations.

(d) Re-evaluation of garbing and gloving competency shall occur at least every 12 months for personnel compounding products made from sterile ingredients and at least every six months

for personnel compounding products from non-sterile ingredients.

~~(c)~~ (e)(1) Batch-produced sterile ~~injectable~~ drug preparations compounded from one or more non-sterile ingredients, except as provided in paragraph (2), ~~non-sterile-to-sterile batch drug preparations~~ shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens. Sterility testing shall be USP chapter 71 compliant and pyrogens testing shall confirm acceptable levels of pyrogen~~,~~ per USP chapter 85 limits~~,~~ before dispensing. This requirement of end product testing confirming sterility and acceptable levels of pyrogens prior to dispensing shall apply regardless of any sterility or pyrogen testing that may have been conducted on any ingredient or combination of ingredients that were previously non-sterile. Exempt from pyrogen testing are ~~non-injectable~~ topical ophthalmic and inhalation preparation.

(~~1~~2) The following non-sterile-to-sterile batch drug preparations do not require end product testing for sterility and pyrogens:

(A) Preparations for self-administered ophthalmic drops in a quantity sufficient for administration to a single patient for 30 days or less pursuant to a prescription.

(B) Preparations for self-administered inhalation in a quantity sufficient for administration to a single patient for 5 days or less pursuant to a prescription.

~~Batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients Non-sterile-to-sterile batch drug preparations shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens, per USP chapter 85 limits, before dispensing. This requirement of end product testing confirming sterility and acceptable levels of pyrogens prior to dispensing shall apply regardless of any sterility or pyrogen testing that may have been conducted on any ingredient or combination of ingredients that were previously non-sterile.~~

~~(d) Batch-produced sterile to sterile transfers shall be subject to periodic testing through process validation for sterility as determined by the pharmacist-in-charge and described in the written policies and procedures.~~

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1751.8 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.8. Beyond Use Dating for Sterile Compounded Drug Preparations.

In conformity with and in addition to the requirements and limitations of section 1735.2, subdivision (h), every sterile compounded drug preparation shall be given and labeled with a beyond use date that does not exceed the shortest expiration date or beyond use date of any ingredient in sterile compounded drug preparation, nor the chemical stability of any one ingredient in the sterile compounded drug preparation, nor the chemical stability of the combination of all ingredients in the sterile compounded drug preparation ~~the expiration date or beyond use date provided by the manufacturer for any component in the preparation~~, and that, in the absence of passing a sterility test in accordance with standards for sterility testing found in Chapter 797 of the United States Pharmacopeia – National Formulary (USP37-NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014), hereby incorporated by reference, that would justify ~~a more~~ an extended beyond use date, conforms to the following limitations:

(a) The beyond use date shall specify that storage and exposure periods cannot exceed 48 hours at controlled room temperature, 14 days at controlled cold temperature, and 45 days ~~at controlled freezer temperature~~ in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply:

(1) The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 ~~buffer area or~~ cleanroom with an ante-area or compounded entirely within a CAI ~~or CACI~~ which meets the requirements in 1751.4(f)(1)-(3), using only sterile ingredients, products, components, and devices; and

(2) The compounding process involves transferring, measuring, and mixing manipulations using not more than three commercially manufactured packages of sterile preparations and

not more than two entries into any one sterile container or package of sterile preparations or administration containers/devices to prepare the drug preparation; and

(3) Compounding manipulations are limited to aseptically opening ampules, penetrating disinfected stoppers on vials with sterile needles and syringes or spiked transfer devices, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile preparations, and containers for storage dispensing.

(b) The beyond use date shall specify that storage and exposure periods cannot exceed 30 hours at controlled room temperature, 9 days at controlled cold temperature, and 45 days ~~at controlled freezer temperature~~ in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply:

(1) The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 ~~buffer area or~~ cleanroom with an ante-area or compounded entirely within a CAI ~~or CACI~~ which meets the requirements in 1751.4(f)(1)-(3), using multiple individual or small doses of sterile preparations combined or pooled to prepare a compounded sterile preparation that will be administered either to multiple patients or to one patient on multiple occasions; and

(2) The compounding process involves complex aseptic manipulations other than the single-volume transfer; and

(3) The compounding process requires unusually long duration such as that required to complete dissolution or homogenous mixing.

(c) The beyond use date shall specify that storage and exposure periods cannot exceed 24 hours at controlled room temperature, 3 days at controlled cold temperature, and 45 days ~~at controlled freezer temperature~~ in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations using non-sterile ingredients, regardless of intervening sterilization of that ingredient and the following applies: ~~including manufactured preparations not intended for sterile routes of administration, or non-sterile devices, before terminal sterilization, or where the sterile compounded drug preparation lacks effective antimicrobial preservatives.~~

~~For the purposes of this subdivision, "non-sterile" includes sterile contents of commercially manufactured preparations, sterile surfaces of devices, and containers for the preparation,~~

~~transfer, sterilization, and packaging of compounded sterile preparations, that are exposed to worse than ISO Class 5 air quality for more than one hour.~~

(1) The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI ~~or CACI~~ which meets the requirements in 1751.4(f)(1)-(3).

(d) The beyond use date shall specify that storage and exposure periods cannot exceed 12 hours where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply:

(1) The preparation was compounded entirely within an ISO Class 5 PEC that is located in a segregated sterile compounding area and restricted to sterile compounding activities, using only sterile ingredients, components, and devices, by personnel properly cleansed and garbed; and

(2) The compounding process involves simple transfer of not more than three commercially manufactured packages of sterile nonhazardous preparations or diagnostic radiopharmaceutical preparations from the manufacturer's original containers; and

(3) The compounding process involves not more than two entries into any one container or package (e.g., bag, vial) of sterile infusion solution or administration container/device.

(e) Where any sterile compounded drug preparation was compounded either outside of an ISO class 5 PEC or under conditions that do not meet all of the requirements for any of subdivisions (a) through (e), the sterile compounded drug preparation shall be labeled "for immediate use only" and administration shall begin no later than one hour following the start of the compounding process. Unless the "immediate use" preparation is immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the preparation shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the compounded sterile preparation, and the exact one-hour beyond use date and time. If administration has not begun within one hour following the start of the compounding process, the compounded sterile preparation shall be promptly, properly, entirely, and safely discarded. This provision does not preclude the use of a PEC to compound an "immediate use"

preparation. A PEC used solely to compound 'immediate use' preparations need not be placed within an ISO Class 7 ~~buffer area or~~ cleanroom, with an ante-area. ~~(1)~~ Such "immediate use" preparations shall be compounded only in those limited situations where there is a need for immediate administration of a sterile preparation compounded outside of an ISO class 5 environment and where failure to administer could result in loss of life or intense suffering. Any such compounding shall be only in such quantity as is necessary to meet the immediate need and the circumstance causing the immediate need shall be documented in accordance with policies and procedures.

(f) The beyond use date for any compounded allergen extracts shall be the earliest manufacturer expiration date of the individual allergen extracts.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Add § 1751.9 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.9 Single-Dose and Multi-Dose Containers; Limitations on Use

(a) Single-dose ampules are for immediate use only, and once opened shall not be stored for any time period.

(b) Unless otherwise specified by the manufacturer, any single-dose container of a compounded sterile drug preparation other than an ampule, such as a bag, bottle, syringe or vial, shall be used in its entirety or its remaining contents shall be labeled with a beyond use date ~~BUD~~ and discarded within the following time limit, depending on the environment:

(1) When needle-punctured in an environment with air quality worse than ISO Class 5, within one (1) hour;

(2) When needle-punctured in an environment with ISO Class 5 or better air quality, within six (6) hours. A container must remain within the ISO Class 5 or better air quality to be used for the full six hours, unless otherwise specified by the manufacturer.

(3) If the puncture time is not noted on the container, the container must immediately be discarded.

(c) Unless otherwise specified by the manufacturer, a multi-dose container stored according to the manufacturer's specifications shall be used in its entirety or its remaining contents shall be labeled with a beyond use date ~~BUD~~ and discarded within twenty eight (28) days from initial opening or puncture. Any multi-dose container not stored according to the manufacturer's specifications shall be discarded immediately upon identification of such storage circumstance. If any open container is not labeled with a beyond use date or the beyond use date is not correct, the container must immediately be discarded.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1751.10 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

~~1751.8.~~ 1751.10. Sterile ~~Injectable~~ Compounding Reference Materials.

In any pharmacy engaged in compounding sterile ~~injectable~~ drug ~~products~~ preparations, there shall be current and appropriate reference materials regarding the compounding of sterile ~~injectable~~ drug ~~products~~ preparations located in or immediately available to the pharmacy.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Add Article 7.5 of Division 17 of Title 16 of the California Code of Regulations to read as follow

Article 7.5 Furnishing for Home Administration

To Amend § 1751.10 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

~~1751.10.~~ 1752. Furnishing to Parenteral Patient at Home.

Subject to all provisions of this article, a pharmacist may carry and furnish to a patient at home dangerous drugs, other than controlled substances, and devices for parenteral therapy when the dangerous drug or device is one currently prescribed for the patient.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.

To Amend § 1751.11 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

~~1751.11.~~ 1753. Furnishing to Home Health Agencies and Licensed Hospices.

Subject to the following conditions, a licensed pharmacy may furnish to a home health agency licensed under provisions of Chapter 8 (commencing with section 1725 of Division 2 of the Health and Safety Code) or to a hospice licensed under provisions of Chapter 8.5 (commencing with section 1745 of Division 2 of the Health and Safety Code) dangerous drugs for parenteral therapy other than controlled substances, in a portable container for furnishing to patients at home for emergency treatment or adjustment of parenteral drug therapy by the home health agency or licensed hospice.

(a) The pharmacy, having ownership and responsibility for the portable containers, shall ensure that each portable container is:

(1) furnished by a registered pharmacist;

(2) sealed in such a manner that a tamper-proof seal must be broken to gain access to the drugs;

(3) under the effective control of a registered nurse, pharmacist or delivery person at all times

when not in the pharmacy;

(4) labeled on the outside of the container with a list of the contents;

(5) maintained at an appropriate temperature according to United States Pharmacopeia Standards (1995, 23rd Revision), and protected at all times from extreme temperatures that could damage the contents.

(b) The portable container may contain up to:

(1) 1000mL of 0.9% sodium chloride intravenous infusion in containers of a size determined by the pharmacy;

(2) 1000mL of 5% dextrose in water injection in containers of a size determined by the pharmacy;

(3) two vials of urokinase 5000 units;

(4) Each of the following items shall be in sealed, unused containers; the furnishing pharmacy may select any or all of these dangerous drugs in up to five dosage units for inclusion in the sealed, portable container:

(A) heparin sodium lock flush 100 units/mL;

(B) heparin sodium lock flush 10 units/mL;

(C) epinephrine HCl solution 1:1,000;

(D) epinephrine HCl solution 1:10,000;

(E) diphenhydramine HCl 50mg/mL;

(F) methylprednisolone 125mg/2mL;

(G) normal saline, preserved, up to 30 mL vials;

(H) naloxone 1mg/mL 2 mL;

(I) droperidol 5mg/2mL;

(J) prochlorperazine 10mg/2mL;

(K) promethazine 25mg/mL;

(L) dextrose 25gms/50mL;

(M) glucagon 1mg/mL;

(N) insulin (human) 100 units/mL;

(O) bumetamide 0.5mg/2mL;

(P) furosemide 10mg/mL;

(Q) EMLA Cream 5 gm tube;

(R) Lidocaine 1 percent 30mL vials.

(5) The pharmacy shall ensure that the specific dangerous drugs and quantities to be included in the portable container are listed in the home health agency's or licensed hospice's policyies and procedures.

(c) The pharmacy shall not supply a portable container to a home health agency or licensed hospice which does not:

(1) implement and maintain policies and procedures for:

(A) the storage, temperature stability and transportation of the portable container;

(B) the furnishing of dangerous drugs from the portable container upon the written or oral authorization of a prescriber; and

(C) a specific treatment protocol for the administration of each medication contained in the portable container.

(2) have the policies, procedures and protocols reviewed and revised (as needed) annually by a group of professional personnel including a physician and surgeon, a pharmacist and a registered nurse.

(d) A copy of these policies, procedures and protocols shall be maintained by the furnishing pharmacy from each home health agency or licensed hospice for which the pharmacy furnishes portable containers.

(e) In cases where a drug has been administered to a patient pursuant to the oral order of a licensed prescriber, the pharmacy shall ensure that the oral order is immediately written down by the registered nurse or pharmacist and communicated by copy or fax within 24 hours to the furnishing pharmacy, with a copy of the prescriber-signed document forwarded to the dispensing pharmacy within 20 days.

(f) The pharmacy shall ensure that within seven days (168 hours) after the seal has been broken on the portable container, the home health agency's director of nursing service or a registered nurse employed by the home health agency or licensed hospice returns the container to the furnishing pharmacy. The furnishing pharmacy shall then perform an

inventory of the drugs used from the container, and if the container will be reused, must restock and reseal the container before it is again furnished to the home health agency or licensed hospice.

(g) The furnishing pharmacy shall have written policies and procedures for the contents, packaging, inventory monitoring, labeling and storage instructions of the portable container. (h) The furnishing pharmacy shall ensure that the home health agency or licensed hospice returns the portable containers to the furnishing pharmacy at least every 60 days for verification of product quality, quantity, integrity and expiration dates, or within seven days (168 hours) after the seal has been broken.

(i) The furnishing pharmacy shall maintain a current inventory and record of all items placed into and furnished from the portable container.

Note: Authority cited: Sections 4005 and ~~and~~ 4057, Business and Professions Code. Reference: Sections 4040, 4057, 4081 and 4332, Business and Professions Code.

To Amend § 1751.12 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

~~1751.12~~ 1754. Obligations of a Pharmacy Furnishing Portable Containers.

(a) A licensed pharmacy shall not issue portable containers to any home health agency or licensed hospice unless the home health agency or licensed hospice complies with provisions of section ~~1751.11~~ 1753.

(b) A licensed pharmacy shall cease to furnish portable containers to a home health agency or licensed hospice if the home health agency or licensed hospice does not comply with provisions of section ~~1751.11~~ 1753.

Note: Authority cited: Sections 4005 and 4057, Business and Professions Code. Reference: Sections 4040, 4057, 4081 and 4332, Business and Professions Code.

CODE OF FEDERAL REGULATIONS:

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER E--ANIMAL DRUGS, FEEDS, AND RELATED PRODUCTS

PART 530 EXTRALABEL DRUG USE IN ANIMALS

Sec. 530.13 Extralabel use from compounding of approved new animal and approved human drugs.

(a) This part applies to compounding of a product from approved animal or human drugs by a veterinarian or a pharmacist on the order of a veterinarian within the practice of veterinary medicine. Nothing in this part shall be construed as permitting compounding from bulk drugs.

(b) Extralabel use from compounding of approved new animal or human drugs is permitted if:

(1) All relevant portions of this part have been complied with;

(2) There is no approved new animal or approved new human drug that, when used as labeled or in conformity with criteria established in this part, will, in the available dosage form and concentration, appropriately treat the condition diagnosed. Compounding from a human drug for use in food-producing animals will not be permitted if an approved animal drug can be used for the compounding;

(3) The compounding is performed by a licensed pharmacist or veterinarian within the scope of a professional practice;

(4) Adequate procedures and processes are followed that ensure the safety and effectiveness of the compounded product;

(5) The scale of the compounding operation is commensurate with the established need for compounded products (e.g., similar to that of comparable practices); and

(6) All relevant State laws relating to the compounding of drugs for use in animals are followed.

(c) Guidance on the subject of compounding may be found in guidance documents issued by FDA.

FDA Proposed Guidance Document
Compounding Animal Drugs from Bulk Drug Substances
May 19, 2015

Overview

Current law does not permit compounding of animal drugs from bulk drug substances, but the Food and Drug Administration recognizes that there are limited circumstances when an animal drug compounded from bulk drug substances may be an appropriate treatment option. According to the FDA, a "bulk drug substance" applies to "any substance that is represented for use in a drug and that, when used in manufacturing, processing or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug."

On May 19, 2015, the FDA released a draft guidance document that proposes a new enforcement policy related to the compounding of veterinary preparations using bulk ingredients. This draft document, FDA's Guidance for Industry #230, "Compounding Animal Drugs from Bulk Drug Substances," outlines specific conditions under which the agency generally does not intend to take action against state-licensed pharmacies, veterinarians, and facilities registered as outsourcing facilities when drugs are compounded for animals from bulk drug substances.

GFI #230 will not become enforceable or official until a public comment period has closed and a final version is issued. Even then, it only represents the FDA's current thinking on this topic, which the agency will use as a baseline for determining whether to pursue enforcement action against undesirable compounding activities.

The veterinary profession and other stakeholders have 90 days to review and submit comments and questions to the FDA. The comment period for feedback on the overall guidance document is scheduled to close Aug. 17. The FDA is accepting nominations of bulk drug substances which can be used by outsourcing facilities through Nov. 16.

The AVMA has prepared the following summary for you, which contains key information on GFI #230. While the AVMA prepares to file formal comments on behalf of its members, we strongly encourage you to read through the draft guidance document and consider how its contents may affect your practice and how you care for your patients. Also, please review the questions at the end of this document and be sure to share your concerns and/or comments on those via e-mail with the AVMA or directly to the FDA.

By reading through GFI #230 and submitting your comments, you have an opportunity to shape how the FDA regulates compounding from bulk ingredients in the future. If you have

Deadlines:

Aug. 17, 2015: The comment period closes for feedback on the overall guidance document.

Nov. 16, 2015: The comment period closes for nominations of bulk drug substances which can be used by outsourcing facilities on FDA's proposed list.

Web Resources:

- FDA's draft Guidance for Industry #230, "Compounding Animal Drugs from Bulk Drug Substances"
- The Federal Register notice from May 19, 2015
- Information on how to nominate bulk ingredients to the 503B outsourcing facility "positive list" of animal drugs
- AVMA's policies on compounding

American Veterinary Medical Association Governmental Relations Division
1910 Sunderland Place, NW, Washington, DC 20036-1642 / Phone: 800.321.1473

Overview of FDA's Proposed Guidance for Industry #230

Bulk Ingredient Compounding In a State-Licensed Pharmacy

Pages 3-5 of the Proposed Guidance Document Policy III (A) (1-11)

Highlights

- Compounding must be done by or under the direct supervision of a pharmacist.
- Any bulk ingredient used to compound must come from an FDA-registered manufacturer and have a valid certificate of analysis (COA).
- All compounding must follow the standards of USP <795> for non-sterile preparations and USP <797> for sterile preparations.
- All product defects or serious adverse events associated with a bulk-compounded veterinary preparation must be reported on Form 1932a within 15 days to the FDA.
- The preparation label must include: the name of the animal patient, the name of the owner/caretaker, and the species of the animal.
- The compounded product may not be sold or transferred by any other entity—meaning that the product cannot be wholesaled. This does not prevent a pharmacy from dispensing an order related to a patient-specific prescription.
- No compounding from bulk ingredients is permitted for food-producing animals.
- **The prescription and/or documentation from the veterinarian must have the following statement**: "This patient is not a food-producing animal."
  - "Food-producing animals" are defined as all cattle, swine, chickens, turkeys, sheep, goats, and non-ornamental fish, regardless of whether the specific animal or food from the animal is intended to be introduced into the human or animal food chain (e.g. pet pot-bellied pigs, pet chicks).
  - The definition also includes any other animal which the veterinarian designates on the prescription as a food-producing animal regardless of species (e.g. rabbits, captive elk and deer).

No Office-Use Compounding Permitted

- Compounding with bulk ingredients must be patient-specific. Dispensing to the patient is permitted only after a valid prescription has been received by the pharmacy.

Compounding "Marketed" Drugs

- If an FDA-approved animal or human drug exists, the pharmacy may compound a preparation using bulk ingredients of the same active ingredient only if there is a change between the compounded drug and the comparable FDA-approved animal or human drug made for an individually identified animal patient that produces a clinical difference for the individual patient as determined by the veterinarian prescribing the compounded drug.

Documentation and Mandatory Statements

- The species of the animal being treated must be documented either on the prescription or other materials and be recorded by the pharmacist.
- If an FDA-approved animal or human drug with the same active ingredients exists and the pharmacist determines that the compound cannot be made using those ingredients, the pharmacist must document the reasoning for that (e.g., sterile injectable guafenisin for equine use cannot be made from an over-the-counter cough syrup).
- **On the prescription or other documentation, the following statement must be included by the veterinarian**: "There are no FDA-approved animal or human drugs that can be used as labeled or in an extra-label manner under section 512(a)(4) or (5) and 21 CFT part 530 to appropriately treat the disease, symptom, or condition for which this drug is being prescribed."
- If bulk ingredients are used to prepare a compound that contains the same active ingredient as an FDA-approved animal or human drug, it must be for a specific individual animal patient under the prescribing veterinarian's care. **The prescription or documentation must be accompanied by a statement from the veterinarian stating** that the compounded preparation "produces a clinical difference for the individually identified animal patient" with an explanation of what that difference is.

Overview of FDA's Proposed Guidance for Industry #230

Bulk Ingredient Compounding By a Licensed Veterinarian

Pages 5-6 of the Proposed Guidance Document Policy III (B) (1-9)

Highlights

- Compounding must be done by the veterinarian for an individual patient under his or her care.
- No compounding for food-producing animals by a veterinarian is permitted. (See the definition above for what constitutes a food-producing animal.)
- If an FDA-approved animal or human drug exists, the veterinarian may compound a preparation with the same active ingredient as the approved product using bulk ingredients *only if there is a change made that produces a clinical difference* for that individually identified animal patient under the veterinarian's care.
- Bulk ingredient compounding is not permitted if there is any FDA-approved animal or human drug that can be used as labeled or in an extra-label manner to appropriately treat the disease, symptom or condition.
- All veterinarians engaged in compounding must follow the standards of USP <795> for non-sterile preparations and USP <797> for sterile preparations.
- Any bulk ingredient used to compound must come from an FDA-registered manufacturer and have a valid certificate of analysis.
- All product defects or serious adverse events associated with a compounded veterinary preparation from a bulk ingredient must be reported on Form 1932a within 15 days to the FDA.
- The preparation label must include the name of the animal patient, the name of the owner/caretaker, and the species of the animal.
- The veterinarian may not sell or transfer any compound prepared using bulk ingredients (e.g., to another clinic or another veterinarian). The veterinarian is permitted to use those compounds for administration to the individual animal patient or dispensing to that animal patient's owner or caretaker.

Bulk Ingredient Compounding By a 503B Outsourcing Facility

Pages 6-8 of the Proposed Guidance Document Policy III (C) (1-10)

Highlights

- Outsourcing facilities registered with the FDA are permitted to compound and distribute non-patient-specific veterinary preparations (i.e., office stock), but only using bulk drug substances which will appear on Appendix A of the guidance.
- Compounding must be done by or under the direct supervision of a pharmacist.
- Any bulk ingredient used to compound must come from an FDA-registered manufacturer and have a valid certificate of analysis.
- All compounding (sterile and non-sterile) conducted by a 503B outsourcing facility must comply with cGMP standards that the FDA is developing specifically for outsourcing.
- All product defects or serious adverse events associated with a bulk ingredient-compounded veterinary preparation must be reported on Form 1932a within 15 days to the FDA.
- No bulk ingredient-based compounding for food producing animals is permitted. **The prescription, order or other documentation from the veterinarian must have the following statement**: "This drug will not be dispensed for or administered to food-producing animals." (See for the definition above for what constitutes a food-producing animal.)
- The compounded product may not be sold or transferred by any other entity—meaning that the product cannot be wholesaled. This does not prevent an outsourcing facility from filling an order from a veterinarian (i.e., office stock) for administration of the product to a patient in his or her care.
- All drugs compounded for animals must be reported by a 503B outsourcing facility on its biannual report to the FDA. It must list: the active ingredients; bulk ingredient source; assigned National Drug Code (NDC), where available; strength per unit; dosage form; route of administration; package description; and the quantity of units produced. The report must clearly designate which products were

intended for animal use.

- **All orders from veterinarians, including prescriptions, must include a statement** confirming that the product is to be used in a manner and on a species that complies with the list of permitted bulk ingredient uses under Appendix A.

Positive List

Because Section 503B of the Drug Quality and Security Act of 2013 restricts the "what" and "when" of using a bulk ingredient by an outsourcing facility, the FDA is proposing a new process for nominating bulk substances that may be used by an outsourcing facility in compounding drugs for use in animals.

- The FDA issued a request for nominations of bulk ingredients at the same time the draft guidance document was released. The deadline for nominations is **Nov. 16, 2015**.
- Nominated bulk ingredients for animal compounding by 503B outsourcing facilities will need to provide information that shows:
  - No marketed, conditionally approved or index-listed animal drug is available to treat the specific condition.
  - No marketed, approved or human drug exists that could be used to treat the condition.
  - The drug cannot be compounded using an approved animal or human-finished manufactured drug product.
  - Use of a bulk ingredient compound is needed to prevent animal death or suffering.
  - No significant safety concerns exist that are associated with using a bulk ingredient for compounding.
- The FDA will review the nominated bulk list on a rolling basis and periodically update Appendix A. The actual frequency of the review and update timeline is not specified in the guidance document.

Labeling Requirements

- The labeling of animal drugs compounded using bulk ingredients by outsourcing facilities must include:
  - Active ingredients, inactive ingredients, dosage form, strength, flavoring (if any), directions for use, quantity/volume, lot/batch number, date of compounding, Beyond-Use-Date, name of veterinarian who ordered or prescribed the drug, address and phone number of the outsourcing facility.
- A clear statement that says, "Not for resale."
- A statement, "For use in [species, condition, and limitations]."
- The statement, "Compounded by [name of 503B outsourcing facility]."
- The statement, "Adverse events associated with this compounded drug should be reported to the FDA on Form FDA1932a."
- If the drug is being dispensed based upon the receipt of patient specific prescription, the name of the animal, the animal owner/caretaker's name, and the species must be included.

Overview of FDA's Proposed Guidance for Industry #230

Specific Veterinary-Related Questions Posed in the Guidance Notice

The FDA specifically seeks comments from the public on a number of questions, including the following:

- Should the final guidance address the issue of FDA-approved animal and human drugs that are in shortage or are otherwise unavailable? If so:
  - How should these situations be addressed in the final guidance?
  - How should the final guidance define "shortage" and "unavailable?"
  - What criteria should the FDA use to determine if an approved animal drug is in shortage or otherwise unavailable?
- Should licensed veterinarians be able to sell or transfer an animal drug compounded from bulk drug substances by a state-licensed pharmacy or an outsourcing facility to owners or caretakers of animals under the veterinarian's care?
- Is additional guidance needed to address the compounding of animal drugs from approved animal or human drugs under sections 512(a)(4) or (a)(5) of the FFDCA and 21 CFR Part 530?
- Is additional guidance needed to address the compounding of animal drugs from bulk drug substances for food-producing animals?
- Do United States Pharmacopeia and National Formulary (USP–NF) chapters <795> and <797> provide suitable standards for animal drugs compounded by veterinarians, and if not, what standards of safety, purity, and quality should apply to animal drugs compounded by veterinarians?
- How should the FDA apply the condition to identify an individual patient when it is not possible to identify an individual animal (e.g., koi in a koi pond)?
- Should facilities registered as "outsourcing facilities" be able to compound animal drugs from bulk drug substances that do not appear on Appendix A for an individually identified animal patient under conditions similar to those applicable to state-licensed pharmacies?
- The FDA is proposing that licensed pharmacies and veterinarians report any product defect or serious adverse event within 15 days of becoming aware of the product defect or serious adverse event.
  - How many licensed veterinarians compound animal drugs from bulk drug substances and would potentially be reporting product defects and serious adverse events to the FDA?
  - Are veterinarians reporting the same or similar information to any state regulatory agency?
  - If so, how many reports on average does each veterinarian submit each year?
  - How should the FDA define the terms "product defect" and "serious adverse event"?
- Can the FDA achieve the same objective of identifying and tracing the source of injuries or disease associated with an animal drug compounded from bulk substance through means other than product defect and serious adverse event reporting and if so, what other means?
- Is additional guidance needed to address the repackaging of drugs for animal use?
  - How widespread is the practice of repackaging drugs for animal use?
  - What types of drugs are repackaged for animal use, and why are they repackaged?
  - Have problems been identified with repackaged drugs for animal use?

AVMA
Our Passion. Our Profession.

November 16, 2015

Dr. Neal Bataller
Center for Veterinary Medicine
Director, Division of Surveillance
FDA Center for Veterinary Medicine
7519 Standish Pl
Rockville, MD 20852

Re: Docket No. FDA-2015-N-1196 - List of Bulk Drug Substances That May Be Used by an Outsourcing Facility To Compound Drugs for Use in Animals; Request for Nominations

Dear Dr. Bataller:

The American Veterinary Medical Association recognizes that the List of Bulk Drug Substances That May Be Used by an Outsourcing Facility To Compound Drugs for Use in Animals [Docket No. FDA-2015-N-1196] proposes that outsourcing facilities compound animal drugs only from bulk drug substances that will be listed in Appendix A of the final guidance, either pursuant to a veterinarian's order or pursuant to a patient-specific prescription. We understand that when a facility registered as an outsourcing facility under section 503B of the Federal Food, Drug, & Cosmetic Act uses the listed bulk drug substances to make the specified drug products pursuant to an order from a licensed veterinarian without a prescription for an individually identified animal, the FDA does not intend to take action under sections 512(a), 501(a)(5) (21 U.S.C. 351(a)(5)), 502(f), and 501(a)(2)(B) as long as such compounding is done in accordance with any associated conditions described in GFI #230.

We continue to have reservations related to creation of a "list" of bulk drug substances, even considering that the Appendix A list is focused upon in-office use, which is a subset of wider needs to compound from bulk drug substances. In lieu of a list, the AVMA continues to believe that there are three circumstances wherein compounding from bulk drug substances may be medically necessary in nonfood animals and should be allowable within the confines of a Veterinarian-Client-Patient Relationship, specifically when:

- the approved product is not commercially available,
- the needed compounded preparation cannot be made from the approved product, or
- there is no approved product from which to compound the needed preparation.

We have a number of concerns related to the use of a list of bulk drug substances that can be used to create compounded preparations for in-office emergent needs:

- In species including, but not limited to zoo animals, laboratory animals, exotic pets, wildlife, aquaria animals, and nonfood aquacultural animals, the use of compounded preparations is unquestionably

necessary. Although significant time and resources went into the development of our nominations, the bibliographies required for each submission are lacking because of the sometimes limited numbers of studies showing safety and efficacy of the needed dosage forms across the various species and conditions seen by veterinarians. Many of the compounding needs in these species are due to requirements to limit stress in the animals, promote worker safety, and diminish the need for lethal methods of wildlife and zoo immobilization in a dangerous public setting. For example, a zoo and wildlife veterinarian's use of a consistently produced compounded immobilization preparation to dart an escaped animal is more desirable in the eyes of the public than the use of a firearm, even if the substance used to prepare the medication has been subject to only limited research studies illustrating safety and efficacy.

- How will the list be maintained in an up-to-date, clinically relevant way? We contend that the FDA should provide for an immediate, nimble mechanism to consider and allow for changes to the list. Patients in need of emergency care cannot afford to wait for a response to a citizen's petition each time a new need arises. To preserve the FDA's drug approval process, we ask that the FDA also ensure the immediate removal of a bulk drug substance when it is no longer necessary.
- The FDA's request for information on "safety concerns" of nominated bulk drug substances is difficult, if not impossible, to fulfill. Any substance can be toxic in certain scenarios (e.g., used at a toxic dose or used in a patient with an idiosyncratic response). Substances that have known, serious safety concerns in the target species have not been included in our nominations.
- We understand the FDA seeks to mirror veterinary compounding enforcement to that of human compounding. However, veterinary bulk drug substance nominations are required to illustrate needs above and beyond those required for human compounding. Specifically, veterinary compounding nominations must illustrate why immediate treatment with the compounded preparation is necessary to avoid animal suffering or death. Why is there this discrepancy? Any delay in treatment of an animal's medical condition inherently endangers animal health and welfare. We again contend that the FDA should instead use the AVMA's three circumstances for compounding from bulk drug substances, as bulleted above.

Despite our reservations related to the feasibility of a list of bulk drug substances for outsourcing facilities to prepare compounded preparations for in-office use, we are submitting nominations for the list on behalf of our members. We wish to help ensure the list is fitting with the needs of our patients as much as possible; see our attachment.

Extensive consideration was given to preparations that are compounded from bulk drug substances and needed for in-office use for emergent and urgent situations. Our list of nominations is based on existing availability of FDA-approved drug products. As we have stressed in previous communications, backorders and shortages of FDA-approved drug products make access to compounded preparations even more important. Some of these medications are needed for in-office use. How will the FDA address access to these substances during the short- and long-term breaks in availability? If the FDA mirrors the human framework by allowing outsourcing facilities to compound using substances on a shortage list, will outsourcing facilities be able to respond appropriately and in a timely fashion during these periods? As stated in our letter dated August 14, 2015, we appreciate that the use of outsourcing facilities in the preparation of office stock is intended to increase safety of compounded preparations, yet we caution that use of outsourcing facilities might have the unintended consequence that some preparations of critical importance to animal health may no longer be available because of economic or other business considerations. We contend that before any list is finalized, the FDA must engage in further discussions

with the pharmacy, veterinary, and drug manufacturing communities to determine how the Agency will address this issue.

Additionally, we recognize that food-animal compounding is not permissible within the draft Guidance For Industry #230 nor its Appendix A. We reiterate our previous request that the FDA develop a separate guidance document specific to compounding from bulk drug substances in food animals and limited to euthanasia, depopulation, and poison antidote preparations.

The AVMA, founded in 1863, is one of the oldest and largest veterinary medical organizations in the world, with more than 86,500 member veterinarians worldwide engaged in a wide variety of professional activities and dedicated to the art and science of veterinary medicine. Thank you for your time and consideration of our comments and nominations. For questions or concerns regarding the AVMA's request, please contact Dr. Lynne White-Shim at (800) 248-2862 ext. 6784 or at lwhite@avma.org and Dr. Ashley Morgan at (202) 289-3210 or at amorgan@avma.org.

Respectfully,

W. Ron DeHaven, DVM, MBA
Executive Vice President and CEO

	Chemical grade	UNII	Description of the strength, quality, stability, and purity of the ingredient	Ingredient format	Recognition in Pharmacopeias	Presence of USP monograph?	Final compounded formulation dosage form(s)	Final compounded formation strength(s)	Final compounded formulation route(s) of administration	Species and condition(s)	Bibliographies on safety and efficacy data	Why necessary (why approved drug is not suitable for patients)
Amlodipine	**3,5-Pyridinedicarboxylic acid, 2-[(2-aminoethoxy)methyl]-4-(2-chlorophenyl)-1,4-dihydro-6-methyl-, 3-ethyl 5-methyl ester, (±)-, monobenzenesulfonate. 3-Ethyl 5-methyl (±)-2-[(2-aminoethoxy)methyl]-4-(o-chlorophenyl)-1,4-dihydro-6-methyl-3,5-pyridinedicarboxylate, monobenzenesulfonate**	**1J444QC288**	USP	Neat	yes	Yes Amlodipine Oral Suspension	Gel	12.5 mg/ml	Transdermal	Feline treatment of systemic hypertension	Helms SR. Treatment of Feline Hypertension With Transdermal Amlodipine: A Pilot Study. J Amer Anim Hospital Assoc. 2007; 43:149-156.	oral dosing can be very difficult in cats
Apomorphine	**4H-Dibenzo[de,g]quinoline-10,11-diol, 5,6,6a,7-tetrahydro-6-methyl-, hydrochloride, hemihydrate, (R)-; 6a-Aporphine-10,11-diol hydrochloride hemihydrate**	**N21FAR7B4S**	USP	Neat	Yes	No	Solution	3.125-6.25 mg/ml	solution for subconjunctival administration	Canine, induction of emesis	Khan etal. Effectiveness and adverse effects of the use of apomorphine and 3% hydrogen peroxide solution to induce emesis in dogs. *J Am Vet Med Assoc* 2012;241:1179-1184.	no FDA approved injectable, capsule or powder available
Budesonide	**Pregna-1,4-diene-3,20-dione, 16,17-[1R-butylidenebis(oxy)]-11,21-dihydroxy and pregna-1,4-diene-3,20-dione,16,17-[1S-butylidenebis(oxy)]-11,21-dihydroxy; (RS)-11,16,17,21-Tetrahydroxypregna-1,4-diene-3,20-dione cyclic 16,17-acetal with butyraldehyde**	**Q3OKS62Q6X**	USP	Neat	Yes	No	1 mg/cat	1 mg/cat	Oral capsule/tab and oral suspension,	Feline, IBD	Plumb's Veterinary Handbook, 8th Ed, 2015	No veterinary approved product, Human product is too large for most cats (FDA product 3 mg capsule - most cats need 0.5 - 2 mg)
Chloramphenicol	**Acetamide, 2,2-dichloro-N-[2-hydroxy-1-(hydroxymethyl)-2-(4-nitrophenyl)ethyl]-, [R-(R*,R*)]-D-threo-()-2,2-Dichloro-N-[-hydroxy--(hydroxymethyl)-p-nitrophenethyl]acetamide**	**66974FR9Q1**	USP	Neat	Yes	No	Ophthalmic ointment or solution	1% (both solution and ointment)	Conjunctival	Equine	Limited data due to recent unavailability of commercial preparations	No opthalmic ointment or solutions available as approved product

	Literature review to determine whether FDA-approved animal or human drugs that could be prescribed as an extra-label use	Explanation supported by scientific data of why drug cannot be compounded from approved drug	Final compounded formulation clinical rationale and history of past use	Why immediate treatment is needed	Safety concerns
Amlodipine	Buoncompagni S, Bowles MH. Treatment of systemic hypertension associated with kidney disease in the dog and cat. Tierarztl Prax Ausg K Kleintiere Heimtiere 2014;42(3):194-201. Jepson RE, Syme HM, Elliott J. Plasma renin activity and aldosterone concentrations in hypertensive cats with and without azotemia and in response to treatment with amlodipine besylate. J Vet Intern Med. 2014 Jan-Feb;28(1):144-53. doi: 10.1111/jvim.12240. Epub 2013 Nov 13. Trepanier LA. Pharmacologic management of feline hyperthyroidism. Vet Clin North Am Small Anim Pract. 2007 Jul;37(4):775-88, vii. Helms SR. Treatment of feline hypertension with transdermal amlodipine: a pilot study. J Am Anim Hosp Assoc. 2007 May-Jun;43(3):149-56. Mathur S, Syme H, Brown CA, Elliot J, Moore PA, Newell MA, Munday JS, Cartier LM, Sheldon SE, Brown SA. Effects of the calcium channel antagonist amlodipine in cats with surgically induced hypertensive renal insufficiency. Am J Vet Res. 2002 Jun;63(6):833-9. Elliott J, Barber PJ, Syme HM, Rawlings JM, Markwell PJ. Feline hypertension: clinical findings and response to antihypertensive treatment in 30 cases. J Small Anim Pract. 2001 Mar;42(3):122-9. Snyder PS, Sadek D, Jones GL. Effect of amlodipine on echocardiographic variables in cats with systemic hypertension. J Vet Intern Med. 2001 Jan-Feb;15(1):52-6. Snyder PS. Amlodipine: a randomized, blinded clinical trial in 9 cats with systemic hypertension. J Vet Intern Med. 1998 May-Jun;12(3):157-62. Henik RA, Snyder PS, Volk LM. Treatment of systemic hypertension in cats with amlodipine besylate. J Am Anim Hosp Assoc. 1997 May-Jun;33(3):226-34.	The binders and excipients in amlodipine tablets occupy more space that the typical 0.1ml volume of dose that is applied. If bulk API is used then a 0.625mg dose can easily be solubilized into 0.1ml TD dose.	Less stress to patients	Emergency treatment of systemic hypertension	No known minimal safety risk to cats and horses
Apomorphine	Plumb's Veterinary Handbook, 8th Ed, 2015	There is no approved formulation for apomorphine available, Human injectable is no longer marketed.	Described in Plumb's Veterinary Handbook, 8th Ed, 2015	Emergency emesis induction	Described in Plumb's Veterinary Handbook, 8th Ed, 2015
Budesonide	Plumb's Veterinary Handbook, 8th Ed, 2015	enteric coated beads prevent compounding, Plumb's Veterinary Handbook, 8th Ed, 2015	Described in Plumb's Veterinary Handbook, 8th Ed, 2015	Emergency treatment of acute inflammatory gastrointestinal conditions	Known Safety information described in Plumb's Veterinary Handbook, 8th Ed, 2015
Chloramphenicol	Must be compounded, no human or animal preparation available. Labelle A. Therapy of the Eye. In: C Cole, B Bentz, L Maxwell, eds. Equine Pharmacology: Wiley Blackwell, 2015: 254-268. Matthews AG. Ophthalmic antimicrobial therapy in the horse. Equine Vet Ed, 2009; 36(5): 271-280. Brooks D, Kzallberg M, Utter M, et al. Survival Methods for the Equine Practitioner in Equine Ophthalmology. AAEP Proceedings 2007; 53:374-396.	No approved ointments, solutions or sterile injectable products on the market for ophthalmic use.	No approved product available for ophthalmic use. Urgent need for emergency antimicrobial ophthalmic use in the horse. Extensive number of references citing rationale and history of past use in the horses. Labelle A. Therapy of the Eye. In: C Cole, B Bentz, L Maxwell, eds. Equine Pharmacology: Wiley Blackwell, 2015: 254-268. Brooks D, Kzallberg M, Utter M, et al. Survival Methods for the Equine Practitioner in Equine Ophthalmology. AAEP Proceedings 2007; 53:374-396. Matthews AG. Ophthalmic antimicrobial therapy in the horse. Equine Vet Ed, 2009; 36(5): 271-280.	Emergency antibiotic treatment	No known minimal safety risk to horses

	Chemical grade	UNII	Description of the strength, quality, stability, and purity of the ingredient	Ingredient format	Recognition in Pharmacopeias	Presence of USP monograph?	Final compounded formulation dosage form(s)	Final compounded formation strength(s)	Final compounded formulation route(s) of administration	Species and condition(s)	Bibliographies on safety and efficacy data	Why necessary (why approved drug is not suitable for patients)
Cisapride	**Benzamide, 4-amino-5-chloro-N-[1-[3-(4-fluorophenoxy)propyl]-3-methoxy-4-piperidinyl]-2-methoxy-, cis- cis-4-Amino-5-chloro-N-[1-[3-(p-fluorophenoxy)propyl]-3-methoxy-4-piperidyl]-o-anisamide**	**UVL329170W**	USP	Neat	Yes	Yes - Veterinary Clinical Drug Information Monograph (available on AAVPT.org)	Oral suspension, IV solution. See available data in Veterinary Clinical Drug Information Monograph	See available data in Veterinary Clinical Drug Information Monograph	oral capsule/tab and oral suspension, GI motility disorders	Feline	USP Clinical Drug Information Monograph, Plumb's Veterinary Handbook, 8th Ed, 2015, Can Vet Jv.36(2); 1995 Feb, Equine Veterinary Education Volume 3, Issue 3, pages 143–145, September 1991 Volume 3, Issue 3, pages 138–142, September 1991 Volume 21, Issue S7, pages 52–55, June 1989	no FDA product available
Dexamethasone	**Pregna-1,4-diene-3,20-dione, 9-fluoro-11,17,21-trihydroxy-16-methyl-, (11,16)-. 9-Fluoro-11,17,21-trihydroxy-16-methylpregna-1,4-diene-3,20-dione**	**7S5I7G3JQL**	USP	Neat	yes	Yes - Veterinary Clinical Drug Information Monograph (available on AAVPT.org)	Powder	Packets of 10 mg	Oral	Equine	Detailed info on USP Clinical Drug Monograph. Willis-Goulet HS, Schmidt, BA, Nicklin CF, et al. Comparison of serum dexamethasone	Azium product off the market; dex injetable available but not useable
Dipyrone	**sodium;[(1,5-dimethyl-3-oxo-2-phenylpyrazol-4-yl)-methylamino]methanesulfonate**	VSU62Z74ON	USP	Neat	yes	No	Injectable solution	250-500 mg/dog	Subcutaneous	Canine	Shimada SG, Otterness IG, Stitt JT. A study of the mechanism of action of the mild analgesic dipyrone. Agents Actions 1994; 41: 188–192. Jasiecka A, Maslanka T, Jaroszewski JJ. Pharmacological characteristics of metamizole. Polish J Vet Sci 2014; 17:207-214. Imagawa VH, Fantoni DT, Tatarunas AC, Mastrocinque S, Almeida TF, Ferreira F, Posso IP. The use of different doses of metamizole for post-operative analgesia in dogs. Vet Anaesth Analg. 2011 Jul;38(4):385-93.	Shar Pei Fever

	Literature review to determine whether FDA-approved animal or human drugs that could be prescribed as an extra-label use	Explanation supported by scientific data of why drug cannot be compounded from approved drug	Final compounded formulation clinical rationale and history of past use	Why immediate treatment is needed	Safety concerns
Cisapride	Must be compounded, no human or animal drug available. See USP Clinical Drug Information Monograph for complete review of efficacy/safety data. Boothe DM. Digestive drugs. In: Small animal clinical pharmacology and therapeutics. 2nd ed. Saint Louis: Elsevier, 2011; 672-744.	Must be compounded, no human or animal drug available.	Must be compounded, no human or animal drug available. See USP Clinical Drug Information Monograph for complete review of efficacy/safety data	Emergency treatment of GI motility disorders: constipation, esophagitis, megacolon, Esophogeal reflux during surgery, Ileus in horses	Appears to be safe at recommended doses, QT issues seen in humans, not been reported in dogs or cats. See USP Clinical Drug Information Monograph for complete review of efficacy/safety data
Dexamethasone	See response in Column Q	Approved oral product no longer available	Approved oral product is no longer available.	Emergency treatment of histaminergic reactions	Detailed info on USP Clinical Drug Monograph. Willis-Goulet HS, Schmidt, BA, Nicklin CF, et al.
Dipyrone	Boothe DM. Antiinflammatory drugs. In: Small animal clinical pharmacology and therapeutics. 2nd ed. Saint Louis: Elsevier, 2011; 1045-1118. Rivas AL, et al. A primary immunodeficiency syndrome in Shar-Pei dogs. Clin Immunol Immunopathol. Mar;74(3):243-51. 1995. Zhang Y, Wang X, Baranov SV, et al. Dipyrone inhibits neuronal cell death and diminishes hypoxic/ischemic brain injury. Neurosurgery 2011; 69:942–956.	Shar Pei Fever	No approved product available. Urgent need in some Shar Pei patients.	Emergency treatment of Shar Pei Fever	No known minimal safety risk to dogs

	Chemical grade	UNII	Description of the strength, quality, stability, and purity of the ingredient	Ingredient format	Recognition in Pharmacopeias	Presence of USP monograph?	Final compounded formulation dosage form(s)	Final compounded formation strength(s)	Final compounded formulation route(s) of administration	Species and condition(s)	Bibliographies on safety and efficacy data	Why necessary (why approved drug is not suitable for patients)
Doxycycline	**2-Naphthacenecarboxamide, 4-(dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,5,10,12,12a-pentahydroxy-6-methyl-1,11-dioxo-, [4S-(4,4a,5,5a,6,12a)]-, monohydrate; 4-(Dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,5,10,12,12a-pentahydroxy-6-methyl-1,11-dioxo-2-naphthacenecarboxamide monohydrate**	**N12000U13O**	USP	Neat	yes	Yes (Vet Compounding Monograph for oral Suspension)	Reformulated capsule, pill, solution	Equine: 10 mg/kg	Oral	Equine	Plumb's Veterinary Handbook, 8th Ed, 2015	inappropriate mg strength for equine use
Gabapentin	**Cyclohexaneacetic acid, 1-(aminomethyl)-; 1-(Aminomethyl)cyclohexaneacetic acid**	**6CW7F3G59X**	USP	Neat	yes	No	Oral suspension, capsules	100 mg/ml	Oral	Feline	Plumb's Veterinary Handbook, 8th Ed, 2015. Muller G. Compounded gabapentin suspension for lower back pain in an older cat: a case report. Int J Pharm Compd. 2010;14(3):215-7.	Smallest FDA product too high mg for most feline patients
Idoxuridine	**Uridine, 2¢-deoxy-5-iodo-; 2¢-Deoxy-5-iodouridine**	**LGP81V5245**	USP	Neat	yes	No	Ophthalmic ointment or solution	0.1%.	Ophthalmic	Feline	Maggs, DJ. Update on pathogenesis, diagnosis and treatment of feline herpesvirus type 1. Clin Techniques Small Anim Practice. 2005; 20:94-101.	Human product is only injectable; no ophthalmic producst on market
Itraconazole	**3H-1,2,4-Triazol-3-one, 4-[4-[4-[[2-(2,4-dichlorophenyl)-2-(1H-1,2,4-triazol-1-ylmethyl)-1,3-dioxolan-4-yl]methoxy]phenyl]-1-piperazinyl]phenyl]-2,4-dihydro-2-(1-methylpropyl)-; (±)-1-sec-Butyl-4-[p-[4-[p-[[(2R*,4S*)-2-(2,4-dichlorophenyl)-2-(1H-1,2,4-triazol-1-ylmethyl)-1,3-dioxolan-4-yl]methoxy]phenyl]-1-piperazinyl]phenyl]-D2-1,2,4-triazolin-5-one**	**304NUG5GF4**	USP	Neat	yes	No	Ophthalmic ointment or solution	1%	Ophthalmic	Equine	Plumb's Veterinary Handbook, 8th Ed, 2015. Ball MA, Rebhun WC, Trepanier L. Corneal concentrations and preliminary toxicological evaluation of an itraconazole/dimethyl sulphoxide ophthalmic	No approved products; for ophthalmic indiction is okay; would not reference any oral at all
Metronidazole benzoate	**2-(2-Methyl-5-nitroimidazol-1-yl)ethyl benzoate**	**A355C835XC**	USP	Neat	yes	Yes Metronidazole Benzoate Compounded Oral Suspension	oral suspension, tabs or capsules	80 mg/ml	oral	Canine, feline	Plumb's Veterinary Handbook, 8th Ed, 2015; Davidson, G. To benzoate or not to benzoate: Cats are the question. Int J Pharm Compounding 2001; 5: 89-90. Scorza AV, Lappin MR. Metronidazole for the treatment of feline giardiasis. J feline Med Surg 2004; 6: 157-160.	FDA tab (250) mg too high mg to split accurately for many cats that require 30-40 mg; benzoate liquid lacks bitter metallic taste of HCl salt

	Literature review to determine whether FDA-approved animal or human drugs that could be prescribed as an extra-label use	Explanation supported by scientific data of why drug cannot be compounded from approved drug	Final compounded formulation clinical rationale and history of past use	Why immediate treatment is needed	Safety concerns
Doxycycline	Davis JL, Papich MG. Antimicrobial therapy. In: Equine Infectious Diseases. 2nd ed. Saint Louis: Elsevier, 2014; 514-584.	Question for Gigi: Do you think that there are enough approved strengths to compound for cats adequately instead of using bulk?	USP Compounding Monograph	Emergency antibiotic treatment	Plumb's Veterinary Handbook, 8th Ed, 2015
Gabapentin	Boothe DM. Anticonvulsants and other neurologic therapies in small animals. In: Small animal clinical pharmacology and therapeutics. 2nd ed. Saint Louis: Elsevier, 2011; 932-991. KuKanich B. Outpatient oral analgesics in dogs and cats beyond nonsteroidal antiinflammatory drugs: an evidence-based approach. Vet Clin North Am Small Anim Pract. 2013; 43(5):1109-1125.	Compounding by emptying approved capsules is inaccurate. Commercially available soutions contain xylitol, which presents safety concerns for dogs. Compounding with the bulk allows for more precise and safe dosing.	Nahata (1999) Development of two stable oral suspensions for gabapentin. Pediatric Neurol 20 (3): 195-7	emergency control of severe neuropathic pain in cats	Plumb's Veterinary Handbook, 8th Ed, 2015
Idoxuridine	Plummer CE, Colitz CMH, Kuonen V. Ocular infections. In: Equine Infectious Diseases. 2nd ed. Saint Louis: Elsevier, 2014; 109-118.	Human product has been discontinued	Human product has been discontinued	Emergency treatment of viral keratitis	No known minimal safety risk to cats and horses
Itraconazole	Plummer CE, Colitz CMH, Kuonen V. Ocular infections. In: Equine Infectious Diseases. 2nd ed. Saint Louis: Elsevier, 2014; 109-118. i. Labelle A. Therapy of the Eye. In: C Cole, B Bentz, L Maxwell, eds. Equine Pharmacology: Wiley Blackwell, 2015: 254-268.	No approved opthalmic products	J Vet Pharmacol Ther. 1997 Apr;20(2):100-4.	Emergency treatment of fungal keratomycosis	No known minimal safety risk to horses
Metronidazole benzoate	Willard MD. Feline inflammatory bowel disease: a review. J Feline Med Surg. 1999 Sep; 1(3):155-64.	HCl product is very bitter and cannot be taste masked, benzoate salt is more palatble	Described in Plumb's Veterinary Handbook, 8th Ed, 2015	Emergency treatment of acute infectious disease	Plumb's Veterinary Handbook, 8th Ed, 2015

	Chemical grade	UNII	Description of the strength, quality, stability, and purity of the ingredient	Ingredient format	Recognition in Pharmacopeias	Presence of USP monograph?	Final compounded formulation dosage form(s)	Final compounded formation strength(s)	Final compounded formulation route(s) of administration	Species and condition(s)	Bibliographies on safety and efficacy data	Why necessary (why approved drug is not suitable for patients)
Miconazole nitrate	**1H-Imidazole, 1-[2-(2,4-dichlorophenyl)-2-[(2,4-dichlorophenyl)methoxy]ethyl]-, mononitrate; 1-[2,4-Dichloro--[(2,4-dichlorobenzyl)oxy]phenethyl]imidazole mononitrate**	**VW4H1CYW1K**	USP	Neat	yes	No	Miconazole in solution, Miconazole in petroleum	1%, 2%	Ophthalmic	Equine	Plumb's Veterinary Handbook, 8th Ed, 2015	Ophthalmic solution not commercially available; commercially available ones not suitable for the eye
Potassium bromide	**Potassium bromide**	**OSD78555ZM**	USP	Neat	yes	Yes (Vet Compounding Monograph for Oral Solution)	solution, capsules	250 mg/ml	oral	canine, equine	Plumb's Veterinary Handbook, 8th Ed, 2015	Not available any other way than the compounded formulation or a manufactured unapproved drug
		OSD78555ZM										

	Literature review to determine whether FDA-approved animal or human drugs that could be prescribed as an extra-label use	Explanation supported by scientific data of why drug cannot be compounded from approved drug	Final compounded formulation clinical rationale and history of past use	Why immediate treatment is needed	Safety concerns
Miconazole nitrate	Plummer CE, Colitz CMH, Kuonen V. Ocular infections. In: Equine Infectious Diseases. 2nd ed. Saint Louis: Elsevier, 2014; 109-118. i. Labelle A. Therapy of the Eye. In: C Cole, B Bentz, L Maxwell, eds. Equine Pharmacology: Wiley Blackwell, 2015: 254-268.i.	**Solution:** Miconazole in solution is administered onto the corneal surface via a subpalpebral lavage tube. There is no approved drug available in solution format. **Ointment**: A majority of horses will not tolerate eyedrop instillation of liquids without a lavage tube; they require an ointment for topical therapy.	Ophthalmic solution not commercially available; commercially available ones not suitable for the eye	Emergency treatment of fungal keratomycosis	No known minimal safety risk to horses
Potassium bromide	March PA, Podell M, Sams RA. Pharmacokinetics and toxicity of bromide following high-dose oral potassium bromide administration in healthy Beagles. J Vet Pharmacol Therap 2002; 25:425-432. Podell M, Fenner WR. Bromide therapy in refractory canine idiopathic epilepsy. J Vet Int Med 2003; 7: 318-327. Schwartz-Porsche D, U. Jurgens. Wirksamkeit von Bromid bei den therapieresistenten Epilepsien des Hundes. Tierarztl Prax 1991; 19:395-401. Baird-Heinz, HE, Van Schoick AL, Pelsor FR, et al. A systematic review of the safety of potassium bromide in dogs. J Am Vet Med Assoc 2012; 240:705-715.Pharmacokinetics and toxicity of bromide following high-dose oral potassium bromide administration in healthy Beagles. J Vet Pharmacol Therap 2002; 25:425-432. Podell M, Fenner WR. Bromide therapy in refractory canine idiopathic epilepsy. J Vet Int Med 2003; 7: 318-327. Schwartz-Porsche D, U. Jurgens. Wirksamkeit von Bromid bei den therapieresistenten Epilepsien des Hundes. Tierarztl Prax 1991; 19:395-401. Trepanier LA, Babish JGwell PJ. Feline hypertension: clinical findings and response to antihypertensive treatment in 30 cases. J Small Anim Pract. 2001 Mar;42(3):12	No approved product available	USP Compounding Monograph	Emergency control of seizures	Plumb's Veterinary Handbook, 8th Ed, 2015

	Chemical name	Common name	UNII Code	Chemical grade	Description of the strength, quality, stability, and purity of the ingredient	Ingredient format(s)	Recognition in Pharmacopeias	Final compounded formulation dosage form(s)	Final compounded formation strength(s)	Final compounded formulation route(s) of administration	Species and condition(s)	Bibliographies on safety and efficacy data	Why necessary (why approved drug is not suitable for patients)	Literature review to determine whether FDA-approved animal or human drugs that could be prescribed as an extra-label use	Explanation supported by scientific data of why drug cannot be compounded from approved drug	Final compounded formulation clinical rational and history of past use	Why immediate treatment is needed	Safety concerns	
ACTH	Acth (4-11); Cosyntropin, Corticotropin 4-11; AC1L4XVG; Acth 4-11; AR-1J3349; AM006795; (2S)-6-amino-2-[[2-[[(2S)-2-[[(2S)-2-[[(2S)-2-[[(2S)-2-[[(2S)-2-[[(2S)-2-amino-4-methylsulfanylbutanoyl]amino]-4-carboxybutanoyl]amino]-3-(4H-imidazol-4-yl)propanoyl]amino]-3-phenylpropanoyl]amino]-5-(diaminomethylideneamino)pentanoyl]amino]-3-(1H-indol-3-yl)propanoyl]amino]acetyl]amino]hexanoic acid	Corticotropin	J48AU3I790	USP (synthetic cosyntropin)	USP	neat	USP	Gel	As specified by clinician	Topical or oral	Zoo animals (sea otters) NB: this could apply to any species needing this treatment; and increasing endocrine evaluations could present this situation as a future need	see below	frequently unavailable	see below	not typical product at this time	gel - reported by front line clinicians as effecive use for species	Addisonian crises	None known	
Albuterol	Salbutamol; Albuterol; Proventil; 18559-94-9; Sultanol; Aerolin; 4-[2-(tert-butylamino)-1-hydroxyethyl]-2-(hydroxymethyl)phenol	Albuterol	021SEF3731	USP	USP	neat	USP	Solution	As specified by clinician	Inhalant or oral	Zoo animals any exotic species which presented with need of brochodilation; in particular, this product is used in nebulizing solutions with mucolytics and or antibiotics - such as for chelonians with upper respiratory disease	Mader Reptile Medicine and Surgery; Carpenter Formulary	variable concentration of this product maximizes the flexiblity of its application throughout the exotic animal discipline	see below	specific concentration formulation would be needed from bulk drug	solution - personal use of the product for clinical cases in nebulization	to alleviate potentially serious captive and free-ranging wild animal health and welfare, or public safety, problems or emergencies when exotic species require nebulization, marked respiratory impact often is present which is a life-threatening concern; this product woudl permit a clinician to intervene and provide deeper penetration into the respiratory tree of other therapeutic agents specific to treat the issue presented.	None known	

	Chemical name	Common name	UNII Code	Chemical grade	Description of the strength, quality, stability, and purity of the ingredient	Ingredient format(s)	Recognition in Pharmacopeias	Final compounded formulation dosage form(s)	Final compounded formation strength(s)	Final compounded formulation route(s) of administration	Species and condition(s)	Bibliographies on safety and efficacy data	Why necessary (why approved drug is not suitable for patients)	Literature review to determine whether FDA-approved animal or human drugs that could be prescribed as an extra-label use	Explanation supported by scientific data of why drug cannot be compounded from approved drug	Final compounded formulation clinical rational and history of past use	Why immediate treatment is needed	Safety concerns	
Atipamezole	Atipamezole; 104054-27-5; Antisedan; MPV-1248; Atipamezol [Spanish]; Atipamezolum [Latin]; 5-(2-ethyl-1,3-dihydroinden-2-yl)-1H-imidazole	Atipamezole	03N9U5JAF6	ACS	neat	No	no information	Sterile Injectable	25 mg/ml	parenteral - IV, SC, IM	any and all exotic species (such as captive and free ranging mammals, birds, reptiles and elasmobranchs) for which alpha-2 agonist anesthesia is utilized; which is considered standard of care within the zoo and wildlife community for balance anesthetic efforts, reduced quantities of more potent anesthetics, and improved quality of anesthetic episodes	Throughout JZWM, Fowler, and West, repeated documentation of the use and efficacy of the alpha-2 agonist for which this product reverses the effects - older generation of reversals are not as effective or potentially as concentrated for delivery by projectile when supplementaiton is needed.	Variable concentration of this product maximizes the flexiblity of its application throughout the exotic animal discipline. Injection volume necessary for effect is not possible by dart delivery or hand injection in many species.	see below	approved formulation too dilute to use in large hoofstock	explained in other blocks	more concentrated solution is needed, so cannot use FDA-approved drug	None known	
Azaperone	Azaperone; Fluoperidol; Stresnil; Suicalm; 1649-18-9; Azaperon; 1-(4-fluorophenyl)-4-(4-pyridin-2-ylpiperazin-1-yl)butan-1-one	Azaperone	19BV78AK7W	USP	USP	neat	USP	Solution	30 and 50 mg/ml	parenteral - IV, SC, IM	Captive and free ranging mammals, birds and reptiles and elasmobranchs	throughout JZWM, Fowler, and West, repeated documentation of the use of this product for tranquilization especially in transport situations of hoofstock and charismatic megavertebrates and acclimination of anxious species. Previously held NADA.	variable concentration of this product maximizes the flexiblity of its application throughout the exotic animal discipline	see below	Not available	explained in other blocks	tranquilization	None known	

	Chemical name	Common name	UNII Code	Chemical grade	Description of the strength, quality, stability, and purity of the ingredient	Ingredient format(s)	Recognition in Pharmacopeias	Final compounded formulation dosage form(s)	Final compounded formation strength(s)	Final compounded formulation route(s) of administration	Species and condition(s)	Bibliographies on safety and efficacy data	Why necessary (why approved drug is not suitable for patients)	Literature review to determine whether FDA-approved animal or human drugs that could be prescribed as an extra-label use	Explanation supported by scientific data of why drug cannot be compounded from approved drug	Final compounded formulation clinical rational and history of past use	Why immediate treatment is needed	Safety concerns	
Buprenorphine	Buprenorphine; Buprenex; Temgesic; Subutex; Buprenorfina; Buprenorphinum;	Buprenorphine	40D3SCR4GZ	USP	USP	neat	USP	Sterile Injectable	3 mg/ml and slow release	parenteral - IV, SC, IM - generally and IM for slow release; has been used orally	Captive and free ranging mammals and birds	exceptional analgesia and part of balanced anesthetic plans; thorughout JZWM, West, Fowler, and AAZV proceedings, this product has been idenified as useful and beneficial to multitudes of species. Article Citation: Christine M. Molter, Lorraine Barbosa, Shawn Johnson, Heather K. Knych, Sathya K. Chinnadurai, and Raymund F. Wack (2015) PHARMACOKINETICS OF A SINGLE SUBCUTANEOUS DOSE OF SUSTAINED RELEASE BUPRENORPHINE IN NORTHERN ELEPHANT SEALS (MIROUNGA ANGUSTIROSTRIS). Journal of Zoo and Wildlife Medicine: March 2015, Vol. 46, No. 1, pp. 52-61.	More concentrated solution is critical to release dart and administration volume for a variety of patients. Injection volume necessary for effect is not possible by dart delivery or hand injection in many species.	see below	specific concentration formulation would be needed from bulk drug	pain management, improved animal welfare	analgesic; to alleviate potentially serious captive and free-ranging wild animal health and welfare, or public safety, problems or emergencies and in treatment situations, reduced handling needs by higher concentrations with smaller volumes.	None known	

	Chemical name	Common name	UNII Code	Chemical grade	Description of the strength, quality, stability, and purity of the ingredient	Ingredient format(s)	Recognition in Pharmacopeias	Final compounded formulation dosage form(s)	Final compounded formation strength(s)	Final compounded formulation route(s) of administration	Species and condition(s)	Bibliographies on safety and efficacy data	Why necessary (why approved drug is not suitable for patients)	Literature review to determine whether FDA-approved animal or human drugs that could be prescribed as an extra-label use	Explanation supported by scientific data of why drug cannot be compounded from approved drug	Final compounded formulation clinical rational and history of past use	Why immediate treatment is needed	Safety concerns	
Butorphanol	Butorphanol; Butorfanol; Beforal; Moradol; Butorphanol tartrate; Levo-BC-2627;	Butorphanol	QV897JC36D	USP	USP	neat	USP	Sterile Injectable	30 and 50 mg/ml	parenteral - IV, SC, IM	Captive and free ranging mammals and birds	exceptional analgesia and part of balanced anesthetic plans; thorughout JZWM, West, Fowler, and AAZV proceedings, this product has been idenified as useful and beneficial to multitudes of species. Michele Miller, Peter Buss, Jenny Joubert, Nomkhosi Mathebula, Marius Kruger, Laura Martin, Markus Hofmeyr, and Francisco Olea-Popelka (2013) USE OF BUTORPHANOL DURING IMMOBILIZATION OF FREE-RANGING WHITE RHINOCEROS (CERATOTHERIUM SIMUM). Journal of Zoo and Wildlife Medicine: March 2013, Vol. 44, No. 1, pp. 55-61.	More concentrated solution is critical to release dart and administration volume for a variety of patients. Injection volume necessary for effect is not possible by dart delivery or hand injection in many species.	see below	specific concentration formulation would be needed from bulk drug	Combined with potent alpha 2 for immobilization	sedation; to alleviate potentially serious captive and free-ranging wild animal health and welfare, or public safety, problems or emergencies; and in treatment situations, for analgesia, reduced handling needs by higher concentrations with smaller volumes, or less dart impact.	None known	

	Chemical name	Common name	UNII Code	Chemical grade	Description of the strength, quality, stability, and purity of the ingredient	Ingredient format(s)	Recognition in Pharmacopeias	Final compounded formulation dosage form(s)	Final compounded formation strength(s)	Final compounded formulation route(s) of administration	Species and condition(s)	Bibliographies on safety and efficacy data	Why necessary (why approved drug is not suitable for patients)	Literature review to determine whether FDA-approved animal or human drugs that could be prescribed as an extra-label use	Explanation supported by scientific data of why drug cannot be compounded from approved drug	Final compounded formulation clinical rational and history of past use	Why immediate treatment is needed	Safety concerns	
Calcium edetate	EDTA; Ethylenediaminetetraacetic acid; Edetic acid; 60-00-4; Edathamil; Endrate; 2-[2-[bis(carboxymethyl)amino]ethyl-(carboxymethyl)amino]acetic acid	Calcium EDTA	9G34HU7RV0	USP	USP	neat	USP	Solution	As specified by clinician	parenteral - IV or IM	Zoo animals (raptors)- any zoo species with heavy metal poisoning - esp lead; but particularly - galliforms, raptors, penguins; additionally, wildlife rehabilitation raptors (esp concern California condors); water birds (such as loons); cranes.	Of note, publications are available in JZWM on lead intoxication in sea ducks as wildlife concern; galliforms in zoo setting (Bronx Zoo); penguins from personal experience and proceedings documentation AAZV; California condor medicine in Fowler ZAWAM and AAZV proceedings cite lead intoxication as one of primary medical concerns in free-ranging/released condors; cranes also listed in Fowler as species of major concern.	cost prohibitive human formulation that has true acquisition potential issues when emergency arises for this treatment as it is preferentially provided for humans; concentration of product can produce painful injection concerns	see below	specific concentration formulation would be needed from bulk drug	necessary product that is currently used in formulation available but needed for more species specific flexiblity in compounded form	emergency intoxications need rapid response; high profile endangered species release program	None known	
Carfentanil	methyl 4- (1-oxopropyl) phenylaminol-1-(2 phenylethyl)-4-piperidinecarboxylate-2 hydroxy-1, 2, 3-propanetricarboxylate (1:1).	Wildnil	LA9DTA2L8F	ACS	ACS	Carfentanil citrate 4.46 mg (equivalent to 3 mg Carfentanil), sodium chloride 8 mg, methyl paraben 1.8 mg, propyl paraben 0.2 mg in water for injection.	no information	Sterile Injectable	3 mg/ml	Intramuscular	Captive and free ranging mammals, birds and elasmobranchs	Common in current text books	not available	see below	not available	In published literature	anesthesia	None known	

	Chemical name	Common name	UNII Code	Chemical grade	Description of the strength, quality, stability, and purity of the ingredient	Ingredient format(s)	Recognition in Pharmacopeias	Final compounded formulation dosage form(s)	Final compounded formation strength(s)	Final compounded formulation route(s) of administration	Species and condition(s)	Bibliographies on safety and efficacy data	Why necessary (why approved drug is not suitable for patients)	Literature review to determine whether FDA-approved animal or human drugs that could be prescribed as an extra-label use	Explanation supported by scientific data of why drug cannot be compounded from approved drug	Final compounded formulation clinical rational and history of past use	Why immediate treatment is needed	Safety concerns	
Cisapride	(±)-*cis* -4-amino-5-chloro-*N* -(1-[3-(4-fluorophenoxy)propyl]-3-methoxypiperidin-4-yl)-2-methoxybenzamide		UVL329170W	no information	no information	no information	no information	Suspension	Variable 1-10 mg/ml based on size of species	Oral	Zoo species: GI motility disorders	see below	Not currently commerciall y available	see below	No available FDA approved drug	Literature supports its effectiveness	Gastrointestinal motility disorders can result in death	None known	
Clotrimazole	Clotrimazole; Lotrimin; Canesten; Mycelex; Empecid; Mycosporin. 1-[(2-chlorophenyl)-diphenylmethyl]imidazole	Clotrimazole	G07GZ97H65	USP	USP	neat; 10 mg/ml in propylene glycol	USP	Nebulization	10 mg/ml	Inhalant	Zoo animals	see below	Formulation for nebulization not commerciall y available	see below	Appropriate formulation not commercially availabe.	In published literature	Birds will die quickly from respiratory aspergillosis	None known	
Dexmedetomidine	DEXMEDETOMIDINE; Dexmedetomidina; Dexmedetomidinum; MPV 1440; 113775-47-6; CHEMBL778; 5-[(1S)-1-(2,3-dimethylphenyl)ethyl]-1H-imidazole	Dexmedetomidine	67VB76HONO	USP	USP	Neat	USP	not available	not available	not available	Captive and free ranging mammals, birds, reptiles, fish and elasmobranchs	see below	not available	see below	not available	not available	not available	None known	
Diazepam	Diazepam; Valium; Ansiolisina; Diazemuls; Apaurin; Faustan; 7-chloro-1-methyl-5-phenyl-3H-1,4-benzodiazepin-2-one	Diazepam	Q3JTX2Q7TU	USP	USP	neat	USP	not available	10 mg/ml	not available	Captive and free ranging mammals, birds, reptiles, fish and elasmobranchs	see below	see below	see below	not available	not available	tranquilization	None known	
Enrofloxacin	Enrofloxacin; Baytril; 93106-60-6; Enrofloxacine; CFPQ; Bay-Vp-2674;1-cyclopropyl-7-(4-ethylpiperazin-1-yl)-6-fluoro-4-oxoquinoline-3-carboxylic acid	Enrofloxacin	3DX3XEK1BN	USP	USP	neat	USP	Suspension	Variable; greater than 200 mg/ml	Oral	Zoo animals; treatment of bacterial infections. Once daily dosing is advantageous.	see below	Concentrated formualtion facilitates delivery of feasible	see below	High concentration formulations not commerci	Routinely used by zoo clinicians	Delayed treatment of bacterial diseases can result in death.	None known	
Etorphine	6,14-Ethenomorphinan-7-methanol, 4,5-epoxy-3-hydroxy-6-methoxy-ά,17-dimethyl-ά-propyl-, (5ά,7á-(R))- hydrochloride.	M99	8CBE01N748	ACS	ACS	Etorphine Hcl, citric acid, propylene glycol and WFI		Sterile Injectable	10 mg/ml and 1 mg/ml	Intramuscular	Captive and free ranging mammals and reptiles	Common in current text books	not available	see below	not available	Common in published literature	anesthesia	None known	
Famcyclovir	Famciclovir; Famvir; 104227-87-4; Famciclovirum; BRL-42810; Oravir; [2-(acetyloxymethyl)-4-(2-aminopurin-9-yl)butyl] acetate	Famciclovir	QIC03ANI02	USP	USP	neat	USP	not available	not available	not available	Zoo animals	see below	not available	see below	not available	not available	not available	None known	
Fentanyl	N-(1-(2-phenylethyl)-4-piperidinyl)-N-phenylpropanamide	Duragesic,Sublimase 50 mcg/ml	UF599785JZ	USP	USP	neat	Yes	Sterile Injectable	not available	not available	Captive and free ranging mammals	see below	not available	see below	not available	not available	not available	None known	

	Chemical name	Common name	UNII Code	Chemical grade	Description of the strength, quality, stability, and purity of the ingredient	Ingredient format(s)	Recognition in Pharmacopeias	Final compounded formulation dosage form(s)	Final compounded formation strength(s)	Final compounded formulation route(s) of administration	Species and condition(s)	Bibliographies on safety and efficacy data	Why necessary (why approved drug is not suitable for patients)	Literature review to determine whether FDA-approved animal or human drugs that could be prescribed as an extra-label use	Explanation supported by scientific data of why drug cannot be compounded from approved drug	Final compounded formulation clinical rational and history of past use	Why immediate treatment is needed	Safety concerns	
Fluphenazine	FLUPHENAZINE; Triflumethazine; Fluorophenazine; Fluorfenazine; Fluorphenazine; Siqualine; 2-[4-[3-[2-(trifluoromethyl)phenothiazin-10-yl]propyl]piperazin-1-yl]ethanol	Fluphenazine	S79426A41Z	USP	USP	neat	USP	not available	not available	not available	Zoo animals	see below	not available	see below	not available	not available	not available	None known	
Guaifenesin	Glycerol guaiacolate; Guaiacol glyceryl ether; 93-14-1;	Guaifenesin	495W7451VQ	USP	USP	neat	USP	not available	not available	not available	Zoo animals	see below		see below	not available	not available	not available	None known	
Haloperidol	Haloperidol; Haldol; Eukystol; Serenace; Aloperidin; Aloperidol;4-[4-(4-chlorophenyl)-4-hydroxypiperidin-1-yl]-1-(4-fluorophenyl)butan-1-one	Haloperidol	J6292F8L3D	USP	USP	neat	USP	Sterile Injectable	20 mg/ml	Intramuscular	Captive and free ranging mammals	see below	Injection volume necessary for effect is not possible by dart delivery or hand injection in many species.	see below	not available	not available	long term tranquilization	None known	
Hyaluronidase	Hyaluronidase/; Apaziquone/; Cetuximab/; Desloratadine/; Prucalopride/; Rosuvastatin/; 6-(3,3-dimethyl-2-methylideneindol-1-yl)hexanoic acid;hydrobromide	Hyaluronidase	8KOG53Z5EM	USP	USP	neat	USP	not available	not available	not available	Zoo animals	see below	not available	see below	not available	not available	not available	None known	
Isoxsuprine	Isoxsuprine; Vasodilian; Dilavase; Vasosurpine; 395-28-8; Isoxsuprine [INN:BAN]; 4-[1-hydroxy-2-(1-phenoxypropan-2-ylamino)propyl]phenol	Isoxsuprine	R15UI3245N	USP	USP	neat	USP	not available	not available	not available	Zoo animals	see below	not available	see below	not available	not available	not available	None known	

	Chemical name	Common name	UNII Code	Chemical grade	Description of the strength, quality, stability, and purity of the ingredient	Ingredient format(s)	Recognition in Pharmacopeias	Final compounded formulation dosage form(s)	Final compounded formation strength(s)	Final compounded formulation route(s) of administration	Species and condition(s)	Bibliographies on safety and efficacy data	Why necessary (why approved drug is not suitable for patients)	Literature review to determine whether FDA-approved animal or human drugs that could be prescribed as an extra-label use	Explanation supported by scientific data of why drug cannot be compounded from approved drug	Final compounded formulation clinical rational and history of past use	Why immediate treatment is needed	Safety concerns	
Itraconazole	Itraconazole; Sporanox; Oriconazole; Itraconazolum; Itraconazol; Itrizole (TN); 2-butan-2-yl-4-[4-[4-[4-[[(2R,4S)-2-(2,4-dichlorophenyl)-2-(1,2,4-triazol-1-ylmethyl)-1,3-dioxolan-4-yl]methoxy]phenyl]piperazin-1-yl]phenyl]-1,2,4-triazol-3-one	Itraconazole	304NUG5GF4	USP	USP	neat	USP	not available	40 mg capsules	not available	zoo birds, primarily penguins (aspergillosis)	see below	not available	see below	API is not bioavailable in penguins	not available	not available	None known	
Ketamine	Ketamine; Ketaject; Ketalar; DI-Ketamine; Ketanest; CI 581 base; 2-(2-chlorophenyl)-2-(methylamino)cyclohexan-1-one	Ketamine	690G0D6V8H	USP	USP	neat	USP	not available	200 mg/ml	not available	Captive and free ranging mammals, birds, reptiles, fish and elasmobranchs	see below	not available	see below	not available	not available	anesthesia	None known	
Large-volume parenteral fluids	not available	not available	not available	not available	not available	not available	not available	Sterile injectable	not available	not available	Zoo animals	see below	not available	not available	not available	not available	not available	None known	
Leuprolide acetate	Leuprolide acetate; Leuprorelin acetate; Enantone; Abbott-43818; CHEBI:63597; TAP-144;acetic acid;(2S)-N-[(2S)-1-[[(2S)-1-[[(2S)-1-[[(2S)-1-[[(2R)-1-[[(2S)-1-[[(2S)-5-(diaminomethylideneamino)-1-[(2S)-2-(ethylcarbamoyl)pyrrolidin-1-yl]-1-oxopentan-2-yl]amino]-4-methyl-1-oxopentan-2-yl]amino]-4-methyl-1-oxopentan-2-yl]amino]-3-(4-hydroxyphenyl)-1-oxopropan-2-yl]amino]-3-hydroxy-1-oxopropan-2-yl]amino]-3-(1H-indol-3-yl)-1-oxopropan-2-yl]amino]-3-(1H-imidazol-5-yl)-1-oxopropan-2-yl]-5-oxopyrrolidine-2-carboxamide	Leuprolide acetate	37JNS02E7V	USP	USP	neat	USP	not available	not available	not available	Zoo animals	see below	not available	see below	human product might/might not be right	not available	not available	None known	

	Chemical name	Common name	UNII Code	Chemical grade	Description of the strength, quality, stability, and purity of the ingredient	Ingredient format(s)	Recognition in Pharmacopeias	Final compounded formulation dosage form(s)	Final compounded formation strength(s)	Final compounded formulation route(s) of administration	Species and condition(s)	Bibliographies on safety and efficacy data	Why necessary (why approved drug is not suitable for patients)	Literature review to determine whether FDA-approved animal or human drugs that could be prescribed as an extra-label use	Explanation supported by scientific data of why drug cannot be compounded from approved drug	Final compounded formulation clinical rational and history of past use	Why immediate treatment is needed	Safety concerns	
Medetomidine	-4-[1-(2,3-dimethylphenyl) ethyl] -1H-imidazole monohydrochloride.	Domitor 1 mg/ml	MR15E85MQM	ACS	ACS	neat	not available	Sterile Injectable	10, 20, and 40 mg/ml	Intramuscular	Captive and free ranging mammals, birds, reptiles, fish and elasmobranchs	see below	Injection volume necessary for effect is not possible by dart delivery or hand injection in many species.	see below	Too dilute	not available	sedation/anesthesia, animal welfare, public safety	None known	
Melengestrol acetate	MELENGESTROL ACETATE; 2919-66-6; UNII-4W5HDS3936; CHEBI:34831; 17-Hydroxy-6-methyl-16-methylenepregna-4,6-diene-3,20-dione acetate; NSC-70968; [(8R,9S,10R,13S,14S,17R)-17-acetyl-6,10,13-trimethyl-16-methylidene-3-oxo-1,2,8,9,11,12,14,15-octahydrocyclopenta[a]phenanthren-17-yl] acetate	Melegestrol acetate	4W5HDS3936	ACS	ACS	neat	not available	Sterile implant or feed additive	Variable based on individual weight	SQ or in feed	Contraception for primates, carnivores, hoofstock species	see below	There is no approved formulation	see below	There is no approved formulation	Common contraceptive in use in the zoo community for 25 + years	Population management	None known	
Meloxicam	Meloxicam; Mobic; 71125-38-7; Metacam; Movalis; Meloxicamum; 4-hydroxy-2-methyl-N-(5-methyl-1,3-thiazol-2-yl)-1,1-dioxo-1$l^{6},2-benzothiazine-3-carboxamide	Meloxicam	VG2QF83CGL	USP	USP	neat	USP	not available	2 mg/ml	not available	Captive and free ranging mammals, birds, reptiles	see below	not available	see below	comes as 5 mg/ml solution	not available	analgesic	None known	
Midazolam	Midazolam; Versed; Dormicum; Midazolamum; 59467-70-8; Midazolamum [INN-Latin]; 8-chloro-6-(2-fluorophenyl)-1-methyl-4H-imidazo[1,5-a][1,4]benzodiazepine	Midazolam	R60L0SM5BC	USP	USP	Neat	USP	not available	20 mg/ml	not available	Captive and free ranging mammals, birds, reptiles	see below	not available	see below	not available	not available	tranquilization	None known	

	Chemical name	Common name	UNII Code	Chemical grade	Description of the strength, quality, stability, and purity of the ingredient	Ingredient format(s)	Recognition in Pharmacopeias	Final compounded formulation dosage form(s)	Final compounded formation strength(s)	Final compounded formulation route(s) of administration	Species and condition(s)	Bibliographies on safety and efficacy data	Why necessary (why approved drug is not suitable for patients)	Literature review to determine whether FDA-approved animal or human drugs that could be prescribed as an extra-label use	Explanation supported by scientific data of why drug cannot be compounded from approved drug	Final compounded formulation clinical rational and history of past use	Why immediate treatment is needed	Safety concerns	
Nalbuphine	–)-17-(cyclobutylmethyl)- 4,5α-epoxymorphinan- 3,6α,14-triol hydrochloride	Nubain (human) 10 mg/ml	L2T84IQI2K	USP	USP	neat	USP	Sterile Injectable	50 mg/ml	Intramuscular	Captive and free ranging mammals	Published use combined with Med and Azaperone in Bears and Cervids	Injection volume necessary for effect is not possible by dart delivery or hand injection in many species.	see below	not available	not available	long term sedation, animal welfare and public safety	None known	
Naloxone	Naloxone; L-Naloxone; Narcan; N-Allylnoroxymorphone; Naloxona; Naloxonum; (4R,4aS,7aR,12bS)-4a,9-dihydroxy-3-prop-2-enyl-2,4,5,6,7a,13-hexahydro-1H-4,12-methanobenzofuro[3,2-e]isoquinoline-7-one	Naloxone	36B82AMQ7N	USP	USP	neat	usp	not available	10 mg/ml	not available	Wildlife	see below		see below			human reversal for narcotic exposure	None known	
Naltrexone	17-(cyclopropylmethyl)-4,5-epoxy-3,14 dihydroxy-morphinan-6-one hydrochloride.	Revia 50 mg tablet for human use	5S6W795CQM	USP	USP	neat	USP	Sterile Injectable	50 mg/ml	not available	Captive and free ranging mammals, birds and elasmobranchs	Previously a FDA approved product	Currently not commerciall y available	see below	Revia is an oral tablet	Previously an approved NADA	reversal of narcotics	None known	
Ponazuril	Toltrazuril sulfone; Ponazuril; 69004-04-2; UNII-JPW84AS66U; NCGC00182044-01; 1-methyl-3-[3-methyl-4-[4-(trifluoromethylsulfonyl)phenoxy]phenyl]-1,3,5-triazinane-2,4,6-trione; 1-methyl-3-[3-methyl-4-[4-(trifluoromethylsulfonyl)phenoxy]phenyl]-1,3,5-triazinane-2,4,6-trione	Ponazuril	JPW84AS66U	ACS	ACS	neat	?	Solution or suspension	Variable based on species	not available	Zoo species suscpetible to protozoal diseases such as Sarcocystis, Coccidiosis, Atoxoplasmosis, Toxoplasmosis	see below	Paste formulation not ammendable for oral suspensions or for treatment of groups of birds in the water	see below	not available	not available	Protozoal diseases left untreated will result in death	None known	

	Chemical name	Common name	UNII Code	Chemical grade	Description of the strength, quality, stability, and purity of the ingredient	Ingredient format(s)	Recognition in Pharmacopeias	Final compounded formulation dosage form(s)	Final compounded formation strength(s)	Final compounded formulation route(s) of administration	Species and condition(s)	Bibliographies on safety and efficacy data	Why necessary (why approved drug is not suitable for patients)	Literature review to determine whether FDA-approved animal or human drugs that could be prescribed as an extra-label use	Explanation supported by scientific data of why drug cannot be compounded from approved drug	Final compounded formulation clinical rational and history of past use	Why immediate treatment is needed	Safety concerns	
Praziquantel	Praziquantel; Biltricide; 55268-74-1; Droncit; Cesol; Pyquiton; 2-(cyclohexanecarbonyl)-3,6,7,11b-tetrahydro-1H-pyrazino[2,1-a]isoquinolin-4-one	Praziquantel	6490C9U457	USP	USP	neat	USP	not available	not available	not available	Zoo animals	see below	not available	see below	not available	not available	not available	None known	
Primaquine	PRIMAQUINE; Neo-Quipenyl; Primachin; 90-34-6; 8-(4-Amino-1-methylbutylamino)-6-methoxyquinoline; Primaquin; 4-N-(6-methoxyquinolin-8-yl)pentane-1,4-diamine	Primaquine	MVR3634GX1	USP	USP	neat	USP	Suspension	Variable based on species	Oral	Zoo species suscpetible to protozoal diseases such as Sarcocystis, Coccidiosis, Atoxoplasmosis, Toxoplasmosis	see below	Inability to accurately get concentrations needed for the treatment of small patients	see below	not available	not available	Protozoal diseases left untreated will result in death	None known	
Pyrimethamine	Pyrimethamine; 58-14-0; Daraprim; Chloridine; Ethylpyrimidine; Chloridin;	Pyrimethamine	Z3614QOX8W	USP	USP	Neat	USP	Suspension	Variable based on species	Oral	Zoo species suscpetible to protozoal diseases such as Sarcocystis, Malaria, Atoxoplasmosis, Toxoplasmosis	see below	Inability to accurately get concentrations needed for the treatment of small patients	see below	not available	not available	Protozoal diseases left untreated will result in death	None known	

	Chemical name	Common name	UNII Code	Chemical grade	Description of the strength, quality, stability, and purity of the ingredient	Ingredient format(s)	Recognition in Pharmacopeias	Final compounded formulation dosage form(s)	Final compounded formation strength(s)	Final compounded formulation route(s) of administration	Species and condition(s)	Bibliographies on safety and efficacy data	Why necessary (why approved drug is not suitable for patients)	Literature review to determine whether FDA-approved animal or human drugs that could be prescribed as an extra-label use	Explanation supported by scientific data of why drug cannot be compounded from approved drug	Final compounded formulation clinical rational and history of past use	Why immediate treatment is needed	Safety concerns	
Pyrimethamine-Trimethoprim sulfa	not available	not available	not available	not available	not available	not available	not available	Suspension	480mg/ml	parenteral - IM or SC	generally zoo species but also could apply to pet exotics	repeated mention in Carpenter's formularies; JZWM in clinical settings	frequently unavailable	currently off market	not available	parenteral suspension	broad-spectrum antibiotic use which needs administration at time of sedation while other diagnostics are ongoing; in particular, it is a front line treatment for amoebic meningoencephalitis in great ape/non-human primate species which would need administration for more rapid onset to therapeutic drug concentrations rather than oral; additionally, many ill animals will not consume medications until after infection was considered more controlled; product needs to be available on shelf for immediate use.	None known	
Terbinafine	Terbinafine; 91161-71-6; Lamisil; Lamasil; SF-86-327; Lamisil Tablet;(E)-N,6,6-trimethyl-N-(naphthalen-1-ylmethyl)hept-2-en-4-yn-1-amine	Terbinafine	G7RIW8S0XP	USP	USP	Neat	USP	not available	not available	not available	Zoo animals	see below	not available	see below	not available		not available	None known	
Thiafentanil	4-methoxycarbonyl-4(*N*-phenyl-methoxyacetamido)-1-[2'-(2"-thienyl)ethyl]-piperidinium oxalate	Thianil (under review as a MUMS Indexed drug)	no information	no information	no information	no information	no information	Sterile Injectable	10 mg/ml	Intramuscular	Captive and free ranging mammals	see below	Currently not commerciall y available	see below	not available	Field results superior to other potent opiates (Carfentanil and Etorphine)	anesthesia	None known	

	Chemical name	Common name	UNII Code	Chemical grade	Description of the strength, quality, stability, and purity of the ingredient	Ingredient format(s)	Recognition in Pharmacopeias	Final compounded formulation dosage form(s)	Final compounded formation strength(s)	Final compounded formulation route(s) of administration	Species and condition(s)	Bibliographies on safety and efficacy data	Why necessary (why approved drug is not suitable for patients)	Literature review to determine whether FDA-approved animal or human drugs that could be prescribed as an extra-label use	Explanation supported by scientific data of why drug cannot be compounded from approved drug	Final compounded formulation clinical rational and history of past use	Why immediate treatment is needed	Safety concerns	
Tolazoline hydrochloride (concentrated)	1H-imidazole,4,5-dihydro-2-(phenylmethyl)-monohydrochlroide	CHH9H12AQ3	USP	USP	Neat	USP	no information	sterile injectable	200 mg/ml	IM, IV, SC	aptive and free ranging mammals	see below	Concentrated form to antagonize concentrated xylazine hydrochloride	see below	approved formulation too dilute to use in large hoofstock		anesthetic antagonist	None known	
MS-222 or Tricaine methanesulfonate	Tricaine methanesulfonate	Finquel, MS222, Tricaine-S	no information	no information	no information	no information	no information	no information	aqueous	no information	Bath	Aquatic animals (large fish such as sharks)	see below	Used as an aqueous anesthetic and aqutic animal euthanasia solution; concentrated form for large aquatic animals (e.g., sharks)	see below	approved formulation too dilute to use in large hoofstock		sedation, anesthesia	None known	
Trimethoprim sulfadiazine paste	not available	not available	no information	no information	no information	no information	no information	no information	oral paste	400 mg/ml	Oral	Zoo animals (e.g., large ungulates)	see below	FDA-approved product requently backordered from manufacturer	see below	approved formulation too dilute to use in large hoofstock		antibiotic for large ungulates	None known	

	Chemical name	Common name	UNII Code	Chemical grade	Description of the strength, quality, stability, and purity of the ingredient	Ingredient format(s)	Recognition in Pharmacopeias	Final compounded formulation dosage form(s)	Final compounded formation strength(s)	Final compounded formulation route(s) of administration	Species and condition(s)	Bibliographies on safety and efficacy data	Why necessary (why approved drug is not suitable for patients)	Literature review to determine whether FDA-approved animal or human drugs that could be prescribed as an extra-label use	Explanation supported by scientific data of why drug cannot be compounded from approved drug	Final compounded formulation clinical rational and history of past use	Why immediate treatment is needed	Safety concerns	
Vitamin K1 (phytonadione)	Phytomenadione; Konakion; Phytonadione; Phylloquinone; Phytylmenadione; Aquamephyton; 2-methyl-3-[(E)-3,7,11,15-tetramethylhexadec-2-enyl]naphthalene-1,4-dione	Phytonadione	S5Z3U87QHF	USP	USP	neat	USP	injectable	not available	SC, IV, Oral	Large zoo animals	see below	Concentrated form for larger animals; used for coagulopathies, rodenticide toxicities, newborn hemorrhagic disease,	see below	approved formulation too dilute to use in large hoofstock		coagulopathies, rodenticide toxicities, newborn hemorrhagic disease	None known	
Voriconazole	Voriconazole; Vfend; 137234-62-9; UK-109496; UK 109496; Voriconazol; (2R,3S)-2-(2,4-difluorophenyl)-3-(5-fluoropyrimidin-4-yl)-1-(1,2,4-triazol-1-yl)butan-2-ol	Voriconazole	JFU09I87TR	USP	USP	Neat	USP	oral suspension	300 mg/ml	Oral	Zoo animals, exotic pets, aquaria, wildlife	see below	Concentrated formulations for treating fungal infections in a variety of species	see below	approved formulation too dilute to use in large hoofstock		antifungal	None known	
Xylazine (concentrated)	2- (2,6-dimethylphenylamino) -4H-5,6-dihydro-1,3-thiazine hydrochloride	Cervizine	2KFG9TP5V8	USP	USP	neat	USP	sterile injectable	300 and 450 mg/ml	IM, IV, SC	Captive and free ranging mammals, birds, reptiles	see below	Injection volume necessary for effect is not possible by dart delivery or hand injection in many species.	see below	approved formulation too dilute to use in large hoofstock		sedation	None known	

	Chemical name	Common name	UNII Code	Chemical grade	Description of the strength, quality, stability, and purity of the ingredient	Ingredient format(s)	Recognition in Pharmacopeias	Final compounded formulation dosage form(s)	Final compounded formation strength(s)	Final compounded formulation route(s) of administration	Species and condition(s)	Bibliographies on safety and efficacy data	Why necessary (why approved drug is not suitable for patients)	Literature review to determine whether FDA-approved animal or human drugs that could be prescribed as an extra-label use	Explanation supported by scientific data of why drug cannot be compounded from approved drug	Final compounded formulation clinical rational and history of past use	Why immediate treatment is needed	Safety concerns	
Yohimbine (concentrated)	Yohimban-16-carboxylic acid, 17-hydroxy-, methyl ester, hydrochloride	Antagonil	not available	no information	no information	no information	no information	sterile injectable	10 mg/ml, 30 ml/ml	IM, IV, SC	Captive and free ranging mammals, birds, reptiles	see below	Concentrated form to antagonize concentrated xylazine hydrochloride	see below	approved formulation too dilute to use in large hoofstock		anesthetic antagonist	None known	
References																			
West, G., Heard, D., & Caulkett, N. (Eds.). (2007). Zoo animal and wildlife immobilization and anesthesia. Blackwell Publishing.																			
West, G., Heard, D., & Caulkett, N. (Eds.). (2014). Zoo animal and wildlife immobilization and anesthesia, second edition. John Wiley & Sons, Inc.																			
Handbook of Wildlife Chemical Immobilization. Terry J. Kreeger and Jon M. Arnemo. T. Kreeger. Published by Author. 2012. 448 pp																			
Michele Miller, Peter Buss, Jenny Joubert, Nomkhosi Mathebula, Marius Kruger, Laura Martin, Markus Hofmeyr, and Francisco Olea-Popelka (2013) USE OF BUTORPHANOL DURING IMMOBILIZATION OF FREE-RANGING WHITE RHINOCEROS (CERATOTHERIUM SIMUM). Journal of Zoo and Wildlife Medicine: March 2013, Vol. 44, No.																			
Kurt K. Sladky, Lisa Krugner-Higby, Elizabeth Meek-Walker, Timothy D. Heath, Joanne Paul-Murphy. Serum concentrations and analgesic effects of liposome-encapsulated and standard butorphanol tartrate in parrots. American Journal of Veterinary Research May 2006, Vol. 67, No. 5, Pages 775-781.																			
Corrine S. Brown, Joanne Luebbert, Daniel Mulcahy, Jason Schamber, and Daniel H. Rosenberg. 2006. BLOOD LEAD LEVELS OF WILD STELLER'S EIDERS (POLYSTICTA STELLERI) AND BLACK SCOTERS (MELANITTA NIGRA) IN ALASKA USING A PORTABLE BLOOD LEAD ANALYZER. Journal of Zoo and Wildlife Medicine 37(3):361-365.																			
Christine M. Molter, Lorraine Barbosa, Shawn Johnson, Heather K. Knych, Sathya K. Chinnadurai, and Raymund F. Wack (2015) PHARMACOKINETICS OF A SINGLE SUBCUTANEOUS DOSE OF SUSTAINED RELEASE BUPRENORPHINE IN NORTHERN ELEPHANT SEALS (MIROUNGA ANGUSTIROSTRIS). Journal of Zoo and Wildlife Medicine: M																			
CISAPRIDE																			

	Chemical name	Common name	UNII Code	Chemical grade	Description of the strength, quality, stability, and purity of the ingredient	Ingredient format(s)	Recognition in Pharmacopeias	Final compounded formulation dosage form(s)	Final compounded formation strength(s)	Final compounded formulation route(s) of administration	Species and condition(s)	Bibliographies on safety and efficacy data	Why necessary (why approved drug is not suitable for patients)	Literature review to determine whether FDA-approved animal or human drugs that could be prescribed as an extra-label use	Explanation supported by scientific data of why drug cannot be compounded from approved drug	Final compounded formulation clinical rational and history of past use	Why immediate treatment is needed	Safety concerns	
Therapeutic Review: Cisapride K Wangen - Journal of Exotic Pet Medicine, 2013 - Elsevier																			
The anatomy, physiology, and diseases of the avian proventriculus and ventriculus. I Langlois - Veterinary Clinics of North America: Exotic Animal ..., 2003 - Elsevier																			
Compounds for avian and exotic patients: regulation and science. G Davidson, L Powers - Proc Annu Conf Assoc Avian Vet, 2011 - Citeseer																			
Ferrets, Rabbits, and Rodents: Clinical Medicine and Surgery. 3rd Edition. Eds. Quesenberry KE, Carpenter JW. 2007. Elsevier																			
CLOTRIMAZOLE																			
Conference Proceedings : Assoc Avian Vet (AC) & Unusual/Exotic Pets : AAVC & UEP 2008. Doug Black																			
Antifungal drug therapy in avian species SE Orosz - Veterinary Clinics of North America: Exotic Animal ..., 2003 - Elsevier																			
Joseph V, Pappagianis D, Reavill dR. Clotrimazole nebulization for the treatment of respiratory aspergillosis. Proc Annu conf Assoc Avian Vet 1994; 301-306.																			
Tully TN. Psittacine Therapeutics. Vet Clin North Am Exotic Anim Pract 2003;3:59-90.																			
MELENGESTROL ACETATE																			
Wildlife Contraception: Issues, Methods, and Applications. Editors Cheryl Asa & Ingrid Porrton. 2004. Smithsonian Books																			
Zoo Biology 2007 26(4) Special Issue on Contraception																			
PRIMAQUINE																			
Clinical signs and response to primaquine in falcons with Haemoproteus tinnunculi infection. Vet Rec. August 2007;161(6):204-6.																			
Smith SA. Parasites of birds of prey: their diagnosis and treatment. Semin Avian Exotic Pet Med 1996;5:97-105.																			
PYRIMETHAMINE																			
Diagnosis and Treatment of Sarcocystis neurona in a Captive Harbor Seal (Phoca vitulina). Natalie D. MylniczenkoM.S., D.V.M., Karen S. KearnsD.V.M., Dipl. A.C.Z.M., Ann C. MelliB.A., B.S. Journal of Zoo and Wildlife Medicine June 2008 : Vol. 39, Issue 2 (Jun 2008), pg(s) 228-235																			
Clyde VL., Patton S. Diagnosis, treatment, and control of common parasites in companion and aviary birds. Semin Avian Exotic Pet Med 1996;5:75-84.																			
PONAZURIL																			
Vet Clin North Am Exot Anim Pract. 2009 Sep;12(3):491-517, Table of Contents. doi: 10.1016/j.cvex.2009.06.006.																			
Management of select bacterial and parasitic conditions of raptors. Willette M1, Ponder J, Cruz-Martinez L, Arent L, Bueno Padilla I, de Francisco ON, Redig P. Vet Clinics N Am: Exotic Anim Pract. 2009 12(3):491-517																			

Global Expertise
Trusted Standards
Improved Health

November 16, 2015

Submitted electronically to http://www.regulations.gov

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Subject: USP's Comments on Compounding Animal Drugs from Bulk Drug Substances; Draft Guidance for Industry, Docket No. FDA-2015-D-1176

Dear Sir/Madam:

The United States Pharmacopeial Convention (USP) appreciates the opportunity to provide comments to the Food and Drug Administration (FDA) on the "Compounding Animal Drugs from Bulk Drug Substances Draft Guidance for Industry" (Draft Guidance). USP's standards for animal drugs support access to customized therapies designed for animal patients. We appreciate FDA's efforts in continuing to support standards for animal health, including recognizing the critical role of USP's compounding chapters. We look forward to working with FDA and other stakeholders on these important issues.

Similar to existing statutory and FDA requirements governing traditional compounding of human drug preparations, the Draft Guidance stipulates that licensed pharmacies and licensed veterinarians comply with *USP General Chapters <795> Pharmaceutical Compounding—Nonsterile Preparations and <797> Pharmaceutical Compounding—Sterile Preparations*, and meet other conditions, if they want to compound animal drugs from bulk substances and be aligned with FDA's enforcement policy set forth in the Draft Guidance. USP fully supports this stipulation.

Related to FDA's intent to handle traditional animal compounding in this manner, the Agency has specifically requested comments on whether *United States Pharmacopeia and National Formulary (USP-NF) General Chapters <795> and <797> provide suitable standards for animal drugs compounded by veterinarians, and if not, what standards of safety, purity, and quality should apply to animal drugs compounded by veterinarians.* **USP fully supports full compliance with both <795> and <797> when compounding extemporaneous preparations for animal patients as suitable standards.**

I. USP Position

USP standards provide compounders with guidance on applying good compounding practices for extemporaneously compounded preparations. USP General Chapters <795> and <797> provide practice and quality standards for compounding preparations for human and animal patients. General Chapter <795> also provides specific information on compounding for animal patients. USP continues to encourage regulators to adopt USP General Chapters to help ensure the quality and benefit of compounded preparations for all patients. **USP's public standards on compounding protect animal patients—an important commitment to USP—and we are prepared to help ensure the utilization of General Chapters <795> and <797> as well as consider additional animal compounding-specific standards by working closely with FDA, States, practitioners, pharmacists, veterinarians, and other stakeholders.**

USP–U.S.
12601 Twinbrook Parkway
Rockville, MD 20852–1790, USA
+1-301-881-0666

USP–Switzerland
Basel

USP–India
Hyderabad

USP–China
Shanghai

USP–Brazil
São Paulo

USP–Ghana
Accra

USP–Ethiopia
Addis Ababa

USP–Indonesia
Jakarta

II. USP's Standards-Setting Role

USP is a scientific nonprofit organization that sets public standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements. USP develops its standards through Expert Committees, consisting of leading scientific expert volunteers, which are the ultimate decision-making bodies that approve USP standards, including monographs and general chapters. Consistent with our commitment to provide public standards, USP is advancing its animal health standards, including those devoted to veterinary drug products, whether in the form of a manufactured product or compounded preparation.

Animal-specific standards for drug substances and manufactured products are the responsibility of one of USP's six Chemical Medicines (CHM) Expert Committees, with support from two liaisons from the FDA Center for Veterinary Medicine (CVM). USP's compounding standards are developed through USP's Compounding Expert Committee, whose work is supported by eight FDA liaisons (including two from CVM) and two liaisons from the Centers for Disease Control (CDC). USP has been active in setting standards for animal drugs for many years including supporting the public's access to customized drug therapy for animal patients. For animal drug compounding, similar to human compounding, three types of standards add value by assuring quality for compounders, regulators, and animal patients:

1. Monographs for drug articles

   Under the Federal Food, Drug, and Cosmetic Act, USP monographs for drug articles are legally enforceable by FDA. Monographs for drug articles include standards of identity, quality, purity, strength, packaging and labeling and are applicable to both human drugs and animal drugs. There are more than 190 veterinary-specific monographs for FDA approved drug substances and drug products.

2. Veterinary-specific compounded preparation monographs

   There are currently more than 10 veterinary-specific compounded preparation monographs providing standardized formulas and beyond-use dates.

3. General Chapters

   General Chapters may serve as introductory overviews of test or of analytical methods or provide more specific techniques or detailed procedures. In the case of <795> and <797>, they provide practice standards such as those for personnel and environments to ensure quality compounded preparations.

   By way of information, General Chapters (in addition to <795> and <797>) relevant to Animal Drugs include:

   - General Chapter <1151> *Pharmaceutical Dosage Forms* discusses general principles related to the manufacture or compounding of drug products, or dosage forms, commonly used to administer the drug substance (active pharmaceutical

ingredient, API) including general descriptions and definitions for these dosage forms.

- General Chapter <1152> Animal Drugs for Use in Animal Feeds provides important information and general principles involved in the manufacture, packaging, and labeling of animal drugs and drug products intended to be delivered in animal feeds.

We appreciate FDA's work in this area and look forward to continued collaboration with the Agency and other stakeholders.

Thank you for your consideration of this matter. For more information please feel free to contact Morgan Puderbaugh, Scientific Liaison, Science-Chemical Medicines, at (301) 998-6833 or mxp@usp.org; or Rick Schnatz, Pharm. D., Senior Manager, HQS and Compounding, Science-Healthcare Quality Standards, at (301) 816-8526 or rxs@usp.org.

Sincerely,

Jaap Venema, Ph.D.
Executive Vice President and Chief Science Officer

STATE OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS

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

MEMORANDUM

DATE	January 4, 2016
TO	MDC
FROM	Annemarie Del Mugnaio, Executive Officer DCA/Veterinary Medical Board
SUBJECT	Animal Rehabilitation Regulations

At its October 20, 2015 meeting, the Board voted to withdraw its regulatory action on Animal Rehabilitation (AR) from the Office of Administrative Law and delegate to the MDC, the task of revising the proposed regulation in light of the numerous challenges raised by interested parties. The Board provided specific direction to the MDC to formulate language that would: define that AR is the practice of veterinary medicine, describe the practice of AR and eliminate the laundry list of modalities, address whether minimal education or training requirements should be specified, explore the option of an indirect supervision parameter, and include the requirement that the settings where AR is performed is subject to holding a premises registration with the oversight of a Licensee Manager (BPC Section 4853).

As MDC Chair, Dr. Klingborg appointed himself and Dr. Sullivan to serve on the AR Task Force. The AR Task Force drafted language for the Committee's consideration (attached). Also, the complete record of the VMB's AR meeting materials of October 20, 2015 is attached for the Committee's reference.

Attachment

- Proposed Animal Rehabilitation Language – MDC – January 2016
- VMB October 20, 2015 Board Meeting Materials and Background Regarding Animal Rehabilitation

Animal Rehabilitation

(a) Animal Rehabilitation is defined as the art and science of physical or corrective rehabilitation or of physical or corrective treatment of any physical condition of an animal patient.

(b) Animal Rehabilitation requires diagnosis and prescriptive treatment of an animal patient, and it therefore is the practice of veterinary medicine as defined in Section 4826 of the code.

(c) For the purposes of this section, Animal Rehabilitation does not include relaxation, recreational or wellness modalities, such as massage, athletic training or exercise.

(d) Nothing in this section is restricts or amends section 2038 regarding the provision of Musculoskeletal Manipulation modalities.

(e) Prior to performing or authorizing Animal Rehabilitation, a veterinarian shall establish a valid-client-patient relationship as defined in section 2032.1 or section 2032.15.

(1) The veterinarian who established the valid-client-patient relationship may authorize treatment by an R.V.T or an unlicensed veterinary assistant.

(2) The veterinarian shall determine the appropriate level of supervision.

(f) Pursuant to Section 4853 of the code, all premises where Animal Rehabilitation is being performed shall be registered by the Board and shall have on record with the Board a responsible Licensee Manager.

Animal Rehabilitation - Table of Contents

STATE OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS

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

MEMORANDUM

DATE	October 13, 2015
TO	Veterinary Medical Board
FROM	Annemarie Del Mugnaio, Executive Officer DCA/Veterinary Medical Board
SUBJECT	Animal Rehabilitation Regulations

Background:

Around February 2011, the MDC identified the issues before the Board regarding the regulation of animal rehabilitation (AR), including defining AR and considering exclusions, identifying who may engage in AR, appropriate supervision parameters, and available AR training. In March 2012, the MDC Task Force prepared an issues memo (attached) that outlined its recommendations before the MDC. Ultimately, the Board adopted some of the recommendations, by including certain provisions in the proposed regulations, but did not adopt the indirect supervision standards or require any specialized training in order to perform AR.

In June 2015, the Board filed its regulatory proposal for AR. The Notice of regulatory action and associated Initial Statement of Reasons, set forth the 45-day public comment period and public hearing on September 10, 2015. The Board received several hundred comments (thousands signed petitions), and received testimony from over sixty (60) interested parties at the September 10, 2015, hearing. The testimony included opposition similar to that which was raised in public meetings in 2012/2013 as follows: complementary therapy, such as massage, should not be defined as AR; supervision parameters are overly restrictive; the lack of specific training in AR for all providers poses a consumer protection problem; this is an attempt by the Board to restrict business competition; and the definition of AR in the Board's proposal is too broad. The following reflects some of the more common concerns and feedback from interested parties:

1. AR should be regulated to protect animal patients from incompetent providers.
2. Specifically state that MSM, 16 C.C.R. Section 2038 is not being modified by the regulatory proposal.
3. Since animals are deemed property, the consumer should have a right to choose complementary services for their animals.
4. Significant negative impact to jobs and businesses would result if the regulations were to take effect.
5. The supervision requirement is far too restrictive; change direct supervision requirement to indirect supervision.
6. The level of supervision should be determined by the referring veterinarian.
7. Lack of clarity in the supervision requirement for AR
8. The VMB has an incomplete understanding of the application of AR.
9. Remove massage from the definition of AR.

10. Exercise for the prevention of disease is not medicine and should be excluded.
11. Horse trainers are not licensed and yet provide most of the exercise therapy for race horses.
12. Both Colorado and Nevada have workable models.
13. There are not enough veterinarians to oversee AR services and thus the regulations present a barrier to access for the consumer.
14. The regulations will drive up consumer costs for AR.

Issues:

Although this issue has been considered by the Board for some time, since the time the Board began its discussion, several policy and legal issues have been raised. Initially, the Board must consider the definition of the practice of veterinary medicine. If the modalities or interventions defined in the AR regulations, then constitute the practice of veterinary medicine pursuant to Bus. & Prof. Code section 4825, those modalities or interventions can only be practiced by a person licensed by the Board. It is questionable whether the Board can adopt regulations that define other practitioners who are not licensed by the Board to engage in those aspects of veterinary medicine.

If those modalities or interventions do not constitute the practice of veterinary medicine, it is questionable whether the Board can adopt regulations to govern areas outside its scope of practice.

In either case, concerns have been raised that the Board is attempting to limit business competition and protect the profession's financial interests, not to further its consumer protection board's mandate, and the Board must address this concern. The attached Office of Attorney General Opinion15-402 issued September 10, 2015, states, in part, *State agencies are immune from antitrust challenge if their conduct is undertaken pursuant to a "clearly articulated" and "affirmatively expressed" state policy to displace competition. A state policy is sufficiently clear when displacement of competition is the "inherent, logical, or ordinary result" of the authority delegated by the state legislature.*

Clearly, the Board may adopt regulations that govern the competent practice of aspects of veterinary medicine in a manner that serves to protect animal patients within the Board's authority. However, to the extent that the proposed AR regulations attempt to act as a waiver of the requirement for license, restrict services that are not clearly identified as the practice of veterinary medicine, or restrict services that do not pose a reasonable threat in term of patient safety, the Board will likely be challenged.

Also, since the practice of AR is deemed the practice of veterinary medicine, the settings where such services are rendered would require registration with the Board and the oversight of a Licensee Manager (BPC Section 4853). Such oversight would provide another layer of consumer protection as the Board would be authorized to inspect the premises where AR services are provided.

Both the Colorado and Nevada models include flexibility regarding the oversight of a veterinarian referring to a non-veterinarian providing AR. Many of the commenters suggested these models as reasonable and appropriate models for regulating AR. Both states, however, have specific language in their respective Physical Therapy and Veterinary Medicine practice acts allowing for the practice of physical therapy on animals. The Board must be prepared to respond to such comments.

Action Requested:

Consider legal issues that have been raised, and the comments received during the public comment period regarding the proposed AR regulations, and determine an appropriate course of action. If the Board decides to continue with this rulemaking process, it will need to respond to all of the comments and determine whether any of the proposed text should be modified, or express the rationale(s) for rejecting modifications. However, if the Board decides to not pursue the regulations, it should consider other avenues at its disposal for enforcing violations of the Practice Act.

Attachment

- Proposed Animal Rehabilitation Language – VMB January 2015
- MDC 2012 Report
- Office of the Attorney General Legal Opinion 15-402, dated September 10, 2015
- Public Comments Received in Response to the Proposed Regulations
- Colorado Regulations for Physical Therapists to Perform Physical Therapy on Animals
- Nevada Provisions on Animal Physical Therapy
- Utah Provision on Anima Physical Therapy
- Nebraska Regulations on Animal Therapists
- Maryland Rules on Animal Acupuncture
- Minnesota Statutes on Equine Teeth Floating Services
- JAVMA News – Pet Rehab Becoming Mainstream Practice, October 1, 2009
- JAVMA News – Scope of Practice Laws Draw Attacks, October 15, 2008
- Model Standards for Veterinary Physical Rehabilitation Practice- American Association of Rehabilitation Veterinarians

Veterinary Medical Board
Proposed Language

New text is shown in underline.

ADOPT SECTION 2038.5 OF ARTICLE 4 OF DIVISION 20 OF TITLE 16 OF THE CALIFORNIA CODE OF REGULATIONS TO READ AS FOLLOWS:

§ 2038.5. Animal Rehabilitation.

(a) The term "animal rehabilitation" (AR) is the use of the physical, chemical, and other properties of thermal, magnetic, biofeedback technology, hydrotherapy (such as underwater treadmills), electricity, sound, therapeutic massage, manual therapy, and active, passive, and resistive exercise for the prevention, cure, or relief of a wound, fracture, bodily injury, or disease of animals. AR includes evaluation, treatment, instruction, and consultative services.

(b) AR may be performed only by the following persons:

(1) A veterinarian who has examined the animal patient and has sufficient knowledge to make a diagnosis of the medical condition of the animal, has assumed responsibility for making clinical judgments regarding the health of the animal and the need for medical treatment, including a determination that AR will not be harmful to the animal patient, discussed with the owner of the animal or the owner's authorized representative a course of treatment, and is readily available or has made arrangements for follow-up evaluation in the event of adverse reactions or failure of the treatment regimen. The veterinarian shall ensure that accurate and complete records of AR treatments are maintained in the patient's veterinary medical record.

(2) A California licensed physical therapist (PT) or registered veterinary technician (RVT) working under the direct supervision of a veterinarian. A PT or a RVT shall be deemed to be working under the direct supervision of a veterinarian where the following protocol has been followed:

(A) The supervising veterinarian shall comply with the provisions of subsection (b)(1) prior to authorizing a PT or RVT to complete an initial evaluation of and/or perform treatment upon an animal patient.

(B) The supervising veterinarian shall be physically present wherever the AR is being performed.

(C) A veterinarian shall conform to the provisions of this section when supervising a PT or RVT who is performing AR treatments upon an animal. Failure to conform to these provisions shall be deemed unprofessional conduct or aiding and abetting the unlicensed practice of veterinary medicine pursuant to section 4826 of the Code.

(D) After the PT or RVT has completed an initial evaluation of and/or treatment upon the animal patient, the PT or RVT shall consult with the supervising veterinarian

to confirm that the AR care is appropriate, and to coordinate complementary treatment, to assure proper patient care.

(E) A PT or RVT shall conform to the provisions of this section when performing AR upon an animal. Failure to conform to these provisions shall be deemed the unlicensed practice of veterinary medicine pursuant to section 4826 of the Code.

(c) If at any time either the supervising veterinarian or the PT or RVT terminates the supervisory relationship as defined above, the PT or RVT shall immediately cease AR treatment.

Note: **Authority Cited**: Sections 4808 and 4836 of the Business and Professions Code.

Reference: Sections 4825, 4826, and 4883 of the Business and Professions Code.

VMB MDC

Animal Rehabilitation Task Force Report

Jon Klingborg, DVM & Jennifer Boyle, RVT

1) A California licensed DVM may provide animal rehabilitation services.

2) A California licensed DVM may provide animal rehabilitation services *on a referral basis* when:

   A. The referring veterinarian has previously examined the animal patient and has provided a differential diagnosis if appropriate.

   B. The referring veterinarian has cleared the animal for physical rehabilitation.

      (i) The animal patient's record must include a notation of verbal or written veterinary medical clearance. If verbal clearance is given, the veterinarian providing physical rehabilitation services (henceforth called the ***"rehab veterinarian"***) must document the verbal clearance in the animal patient's record, including the name of the referring veterinarian, date and time clearance was received.

   C. The rehab veterinarian is responsible for developing and implementing the plan of care for the animal patient's physical rehabilitation, and will appropriately record the plan and progress of the patient. The referring veterinarian must approve and sign off on the rehabilitation plan before it can be implemented. Any significant changes in the plan by the rehab veterinarian must also receive prior approval from the referring veterinarian, unless there is an emergency or reason to believe that continuing with the plan would be detrimental to the patient.

   D. It is expected that the rehab veterinarian and the referring veterinarian will continue professional collaboration and communication as necessary and appropriate for the well being of the animal patient. While the patient is undergoing physical rehabilitation, the rehab veterinarian will provide a written update of the animal patient's plan and progress to the referring veterinarian within 72 hours of a treatment.

   E. It is expected that the referring veterinarian will review the progress reports from the rehab veterinarian, and communicate in writing or verbally any questions, concerns or recommendations for modification of the rehabilitation program.

   F. Ultimately, cessation of physical rehabilitation will be decided by the referring veterinarian.

3) An RVT can provide physical rehabilitation services under the *direct* supervision of a DVM.

4) If a California certified RVT wishes to provide rehab services under *Indirect* supervision, then the RVT meet all of the following standards:

A) become certified by one of these two programs:

University of Tennessee (CCRP)

or

Canine Rehabilitation Institute (CCRA)

B) Spend 120 hours working with a veterinarian who provides Rehabilitation services, and who will sign off that the RVT demonstrates the skill and meets the appropriate standards at the conclusion of the internship period. At this point, the RVT will receive a credential from the VMB to provide animal rehabilitation services.

C) For a patient to be referred from a DVM to an appropriately credentialed RVT:

(i) The referring veterinarian has previously examined the animal patient and has provided a differential diagnosis if appropriate.

(ii) The referring veterinarian has cleared the animal for physical rehabilitation.

(iii) The animal patient's record must include a notation of verbal or written veterinary medical clearance. If verbal clearance is given, the RVT providing physical rehabilitation services (henceforth called the "rehab RVT") must document the verbal clearance in the animal patient's record, including the name of the veterinarian, date and time clearance was received.

(iv) The referring veterinarian and the rehab RVT are jointly responsible for developing and implementing the plan of care for the animal patient's physical rehabilitation. The rehab RVT will appropriately document the plan and progress of the patient. Any suggested changes in the plan by the rehab RVT must also receive prior authorization from the referring veterinarian, unless there is an emergency or reason to believe that continuing with the plan would be detrimental to the patient.

(v) It is expected that the rehab RVT and the referring veterinarian will continue professional collaboration and communication as necessary and appropriate for the well being of the animal patient. The rehab RVT will provide a written update of the animal patient's plan and progress to the referring veterinarian within 72 hours of a treatment.

(vi) It is expected that the referring veterinarian will review the progress reports from the rehab RVT, and communicate in writing or verbally any questions, concerns or recommendations for modification of the rehabilitation program.

(vii) Ultimately, cessation of physical rehabilitation will be decided by the referring veterinarian.

(viii) In the advent of an unexpected complication with treatment or animal emergency, the RVT will have established a protocol and a relationship with a nearby DVM to provide necessary and timely treatment.

5) A California Licensed Physical Therapist can provide rehab services under *direct* supervision.

Explanation:

1) This is consistent with the MSM language.

2) The VMB has no regulatory authority over the Physical Therapists. If this situation changes in regards to animal rehabilitation, then it is recommended by this task force that PTs with the certifications references in 4A be allowed to perform rehab under indirect supervision and conform with the standards as set forth in Section 4.

6) Unregistered Assistants may provide Physical Rehabilitation services under the *immediate* supervision of a DVM.

7) Unregistered Assistants who have become certified by the following programs may provide rehab under *direct* supervision.

University of Tennessee (CCRP)

or

Canine Rehabilitation Institute (CCRA)

TO BE PUBLISHED IN THE OFFICIAL REPORTS

OFFICE OF THE ATTORNEY GENERAL
State of California

KAMALA D. HARRIS
Attorney General

OPINION	:	No. 15-402
of	:	September 10, 2015
KAMALA D. HARRIS Attorney General	:	
SUSAN DUNCAN LEE Deputy Attorney General	:	

THE HONORABLE JERRY HILL, MEMBER OF THE STATE SENATE, has requested an opinion on the following question:

What constitutes "active state supervision" of a state licensing board for purposes of the state action immunity doctrine in antitrust actions, and what measures might be taken to guard against antitrust liability for board members?

CONCLUSIONS

"Active state supervision" requires a state official to review the substance of a regulatory decision made by a state licensing board, in order to determine whether the decision actually furthers a clearly articulated state policy to displace competition with regulation in a particular market. The official reviewing the decision must not be an active member of the market being regulated, and must have and exercise the power to approve, modify, or disapprove the decision.

Measures that might be taken to guard against antitrust liability for board members include changing the composition of boards, adding lines of supervision by state officials, and providing board members with legal indemnification and antitrust training.

ANALYSIS

In *North Carolina State Board of Dental Examiners v. Federal Trade Commission*,[1] the Supreme Court of the United States established a new standard for determining whether a state licensing board is entitled to immunity from antitrust actions.

Immunity is important to state actors not only because it shields them from adverse judgments, but because it shields them from having to go through litigation. When immunity is well established, most people are deterred from filing a suit at all. If a suit is filed, the state can move for summary disposition of the case, often before the discovery process begins. This saves the state a great deal of time and money, and it relieves employees (such as board members) of the stresses and burdens that inevitably go along with being sued. This freedom from suit clears a safe space for government officials and employees to perform their duties and to exercise their discretion without constant fear of litigation. Indeed, allowing government actors freedom to exercise discretion is one of the fundamental justifications underlying immunity doctrines.[2]

Before *North Carolina Dental* was decided, most state licensing boards operated under the assumption that they were protected from antitrust suits under the state action immunity doctrine. In light of the decision, many states—including California—are reassessing the structures and operations of their state licensing boards with a view to determining whether changes should be made to reduce the risk of antitrust claims. This opinion examines the legal requirements for state supervision under the *North Carolina Dental* decision, and identifies a variety of measures that the state Legislature might consider taking in response to the decision.

---

[1] *North Carolina State Bd. of Dental Examiners v. F. T. C.* (2015) ___ U.S. ___, 135 S. Ct. 1101 (*North Carolina Dental*).

[2] See *Mitchell v. Forsyth* (1985) 472 U.S. 511, 526; *Harlow v. Fitzgerald* (1982) 457 U.S. 800, 819.

I. *North Carolina Dental* Established a New Immunity Standard for State Licensing Boards

A. The *North Carolina Dental* Decision

The North Carolina Board of Dental Examiners was established under North Carolina law and charged with administering a licensing system for dentists. A majority of the members of the board are themselves practicing dentists. North Carolina statutes delegated authority to the dental board to regulate the practice of dentistry, but did not expressly provide that teeth-whitening was within the scope of the practice of dentistry.

Following complaints by dentists that non-dentists were performing teeth-whitening services for low prices, the dental board conducted an investigation. The board subsequently issued cease-and-desist letters to dozens of teeth-whitening outfits, as well as to some owners of shopping malls where teeth-whiteners operated. The effect on the teeth-whitening market in North Carolina was dramatic, and the Federal Trade Commission took action.

In defense to antitrust charges, the dental board argued that, as a state agency, it was immune from liability under the federal antitrust laws. The Supreme Court rejected that argument, holding that a state board on which a controlling number of decision makers are active market participants must show that it is subject to "active supervision" in order to claim immunity.[3]

B. State Action Immunity Doctrine Before *North Carolina Dental*

The Sherman Antitrust Act of 1890[4] was enacted to prevent anticompetitive economic practices such as the creation of monopolies or restraints of trade. The terms of the Sherman Act are broad, and do not expressly exempt government entities, but the Supreme Court has long since ruled that federal principles of dual sovereignty imply that federal antitrust laws do not apply to the actions of states, even if those actions are anticompetitive.[5]

This immunity of states from federal antitrust lawsuits is known as the "state action doctrine."[6] The state action doctrine, which was developed by the Supreme Court

---

[3] *North Carolina Dental*, *supra*, 135 S.Ct. at p. 1114.

[4] 15 U.S.C. §§ 1, 2.

[5] *Parker v. Brown* (1943) 317 U.S. 341, 350-351.

[6] It is important to note that the phrase "state action" in this context means something

in *Parker v. Brown*,[7] establishes three tiers of decision makers, with different thresholds for immunity in each tier.

In the top tier, with the greatest immunity, is the state itself: the sovereign acts of state governments are absolutely immune from antitrust challenge.[8] Absolute immunity extends, at a minimum, to the state Legislature, the Governor, and the state's Supreme Court.

In the second tier are subordinate state agencies,[9] such as executive departments and administrative agencies with statewide jurisdiction. State agencies are immune from antitrust challenge if their conduct is undertaken pursuant to a "clearly articulated" and "affirmatively expressed" state policy to displace competition.[10] A state policy is sufficiently clear when displacement of competition is the "inherent, logical, or ordinary result" of the authority delegated by the state legislature.[11]

The third tier includes private parties acting on behalf of a state, such as the members of a state-created professional licensing board. Private parties may enjoy state action immunity when two conditions are met: (1) their conduct is undertaken pursuant to a "clearly articulated" and "affirmatively expressed" state policy to displace competition, and (2) their conduct is "actively supervised" by the state.[12] The

---

very different from "state action" for purposes of analysis of a civil rights violation under section 1983 of title 42 of the United States Code. Under section 1983, *liability* attaches to "state action," which may cover even the inadvertent or unilateral act of a state official not acting pursuant to state policy. In the antitrust context, a conclusion that a policy or action amounts to "state action" results in *immunity* from suit.

[7] *Parker v. Brown*, *supra*, 317 U.S. 341.

[8] *Hoover v. Ronwin* (1984) 466 U.S. 558, 574, 579-580.

[9] Distinguishing the state itself from subordinate state agencies has sometimes proven difficult. Compare the majority opinion in *Hoover v. Ronwin*, *supra*, 466 U.S. at p. 581 with dissenting opinion of Stevens, J., at pp. 588-589. (See *Costco v. Maleng* (9th Cir. 2008) 522 F.3d 874, 887, subseq. hrg. 538 F.3d 1128; *Charley's Taxi Radio Dispatch Corp. v. SIDA of Haw., Inc.* (9th Cir. 1987) 810 F.2d 869, 875.)

[10] See *Town of Hallie v. City of Eau Claire* (1985) 471 U.S. 34, 39.

[11] *F.T.C. v. Phoebe Putney Health Systems, Inc.* (2013) ___ U.S. ___, 133 S.Ct. 1003, 1013; see also *Southern Motor Carriers Rate Conference, Inc. v. U.S.* (1985) 471 U.S. 48, 57 (state policy need not compel specific anticompetitive effect).

[12] *Cal. Retail Liquor Dealers Assn. v. Midcal Aluminum, Inc.* (1980) 445 U.S. 97, 105 (*Midcal*).

fundamental purpose of the supervision requirement is to shelter only those private anticompetitive acts that the state approves as actually furthering its regulatory policies.[13] To that end, the mere possibility of supervision—such as the existence of a regulatory structure that is not operative, or not resorted to—is not enough. "The active supervision prong . . . requires that state officials have and exercise power to review particular anticompetitive acts of private parties and disapprove those that fail to accord with state policy."[14]

C. State Action Immunity Doctrine After *North Carolina Dental*

Until the Supreme Court decided *North Carolina Dental*, it was widely believed that most professional licensing boards would fall within the second tier of state action immunity, requiring a clear and affirmative policy, but not active state supervision of every anticompetitive decision. In California in particular, there were good arguments that professional licensing boards[15] were subordinate agencies of the state: they are formal, ongoing bodies created pursuant to state law; they are housed within the Department of Consumer Affairs and operate under the Consumer Affairs Director's broad powers of investigation and control; they are subject to periodic sunset review by the Legislature, to rule-making review under the Administrative Procedure Act, and to administrative and judicial review of disciplinary decisions; their members are appointed by state officials, and include increasingly large numbers of public (non-professional) members; their meetings and records are subject to open-government laws and to strong prohibitions on conflicts of interest; and their enabling statutes generally provide well-guided discretion to make decisions affecting the professional markets that the boards regulate.[16]

Those arguments are now foreclosed, however, by *North Carolina Dental*. There, the Court squarely held, for the first time, that "a state board on which a controlling

---

[13] *Patrick v. Burget* (1988) 486 U.S. 94, 100-101.

[14] *Ibid*.

[15] California's Department of Consumer Affairs includes some 25 professional regulatory boards that establish minimum qualifications and levels of competency for licensure in various professions, including accountancy, acupuncture, architecture, medicine, nursing, structural pest control, and veterinary medicine—to name just a few. (See http://www.dca.gov/about_ca/entities.shtml.)

[16] Cf. 1A Areeda & Hovenkamp, *supra*, ¶ 227, p. 208 (what matters is not what the body is called, but its structure, membership, authority, openness to the public, exposure to ongoing review, etc.).

number of decisionmakers are active market participants in the occupation the board regulates must satisfy *Midcal*'s active supervision requirement in order to invoke state-action antitrust immunity."[17] The effect of *North Carolina Dental* is to put professional licensing boards "on which a controlling number of decision makers are active market participants" in the third tier of state-action immunity. That is, they are immune from antitrust actions as long as they act pursuant to clearly articulated state policy to replace competition with regulation of the profession, *and* their decisions are actively supervised by the state.

Thus arises the question presented here: What constitutes "active state supervision"?[18]

D. Legal Standards for Active State Supervision

The active supervision requirement arises from the concern that, when active market participants are involved in regulating their own field, "there is a real danger" that they will act to further their own interests, rather than those of consumers or of the state.[19] The purpose of the requirement is to ensure that state action immunity is afforded to private parties only when their actions actually further the state's policies.[20]

There is no bright-line test for determining what constitutes active supervision of a professional licensing board: the standard is "flexible and context-dependent."[21] Sufficient supervision "need not entail day-to-day involvement" in the board's operations or "micromanagement of its every decision."[22] Instead, the question is whether the review mechanisms that are in place "provide 'realistic assurance'" that the anticompetitive effects of a board's actions promote state policy, rather than the board members' private interests.[23]

---

[17] *North Carolina Dental*, *supra*, 135 S.Ct. at p. 1114; *Midcal*, *supra*, 445 U.S at p. 105.

[18] Questions about whether the State's anticompetitive policies are adequately articulated are beyond the scope of this Opinion.

[19] *Patrick v. Burget*, *supra*, 486 U.S. at p. 100, citing *Town of Hallie v. City of Eau Claire*, *supra*, 471 U.S. at p. 47; see *id.* at p. 45 ("A private party . . . may be presumed to be acting primarily on his or its own behalf").

[20] *Patrick v. Burget*, *supra*, 486 U.S. at pp. 100-101.

[21] *North Carolina Dental*, *supra*, 135 S.Ct. at p. 1116.

[22] *Ibid.*

[23] *Ibid.*

The *North Carolina Dental* opinion and pre-existing authorities allow us to identify "a few constant requirements of active supervision":[24]

- The state supervisor who reviews a decision must have the power to reverse or modify the decision.[25]
- The "mere potential" for supervision is not an adequate substitute for supervision.[26]
- When a state supervisor reviews a decision, he or she must review the substance of the decision, not just the procedures followed to reach it.[27]
- The state supervisor must not be an active market participant.[28]

Keeping these requirements in mind may help readers evaluate whether California law already provides adequate supervision for professional licensing boards, or whether new or stronger measures are desirable.

II. Threshold Considerations for Assessing Potential Responses to *North Carolina Dental*

There are a number of different measures that the Legislature might consider in response to the *North Carolina Dental* decision. We will describe a variety of these, along with some of their potential advantages or disadvantages. Before moving on to those options, however, we should put the question of immunity into proper perspective.

---

[24] *Id. at* pp. 1116-1117.

[25] *Ibid.*

[26] *Id.* at p. 1116, citing *F.T.C. v. Ticor Title Ins. Co.* (1992) 504 U.S. 621, 638. For example, a passive or negative-option review process, in which an action is considered approved as long as the state supervisor raises no objection to it, may be considered inadequate in some circumstances. (*Ibid.*)

[27] *Ibid.*, citing *Patrick v. Burget, supra,* 486 U.S. at pp. 102-103. In most cases, there should be some evidence that the state supervisor considered the particular circumstances of the action before making a decision. Ideally, there should be a factual record and a written decision showing that there has been an assessment of the action's potential impact on the market, and whether the action furthers state policy. (See *In the Matter of Indiana Household Moves and Warehousemen, Inc.* (2008) 135 F.T.C. 535, 555-557; see also Federal Trade Commission, Report of the State Action Task Force (2003) at p. 54.)

[28] *North Carolina Dental*, *supra,* 135 S.Ct. at pp. 1116-1117.

There are two important things keep in mind: (1) the loss of immunity, if it is lost, does not mean that an antitrust violation has been committed, and (2) even when board members participate in regulating the markets they compete in, many—if not most—of their actions do not implicate the federal antitrust laws.

In the context of regulating professions, "market-sensitive" decisions (that is, the kinds of decisions that are most likely to be open to antitrust scrutiny) are those that create barriers to market participation, such as rules or enforcement actions regulating the scope of unlicensed practice; licensing requirements imposing heavy burdens on applicants; marketing programs; restrictions on advertising; restrictions on competitive bidding; restrictions on commercial dealings with suppliers and other third parties; and price regulation, including restrictions on discounts.

On the other hand, we believe that there are broad areas of operation where board members can act with reasonable confidence—especially once they and their state-official contacts have been taught to recognize actual antitrust issues, and to treat those issues specially. Broadly speaking, promulgation of regulations is a fairly safe area for board members, because of the public notice, written justification, Director review, and review by the Office of Administrative Law as required by the Administrative Procedure Act. Also, broadly speaking, disciplinary decisions are another fairly safe area because of due process procedures; participation of state actors such as board executive officers, investigators, prosecutors, and administrative law judges; and availability of administrative mandamus review.

We are not saying that the procedures that attend these quasi-legislative and quasi-judicial functions make the licensing boards altogether immune from antitrust claims. Nor are we saying that rule-making and disciplinary actions are per se immune from antitrust laws. What we are saying is that, assuming a board identifies its market-sensitive decisions and gets active state supervision for those, then ordinary rule-making and discipline (faithfully carried out under the applicable rules) may be regarded as relatively safe harbors for board members to operate in. It may require some education and experience for board members to understand the difference between market-sensitive and "ordinary" actions, but a few examples may bring in some light.

North Carolina Dental presents a perfect example of a market-sensitive action. There, the dental board decided to, and actually succeeded in, driving non-dentist teeth-whitening service providers out of the market, even though nothing in North Carolina's laws specified that teeth-whitening constituted the illegal practice of dentistry. Counter-examples—instances where no antitrust violation occurs—are far more plentiful. For example, a regulatory board may legitimately make rules or impose discipline to prohibit license-holders from engaging in fraudulent business practices (such as untruthful or

deceptive advertising) without violating antitrust laws.[29] As well, suspending the license of an individual license-holder for violating the standards of the profession is a reasonable restraint and has virtually no effect on a large market, and therefore would not violate antitrust laws.[30]

Another area where board members can feel safe is in carrying out the actions required by a detailed anticompetitive statutory scheme.[31] For example, a state law prohibiting certain kinds of advertising or requiring certain fees may be enforced without need for substantial judgment or deliberation by the board. Such detailed legislation leaves nothing for the state to supervise, and thus it may be said that the legislation itself satisfies the supervision requirement.[32]

Finally, some actions will not be antitrust violations because their effects are, in fact, pro-competitive rather than anti-competitive. For instance, the adoption of safety standards that are based on objective expert judgments have been found to be pro-competitive.[33] Efficiency measures taken for the benefit of consumers, such as making information available to the purchasers of competing products, or spreading development costs to reduce per-unit prices, have been held to be pro-competitive because they are pro-consumer.[34]

III. Potential Measures for Preserving State Action Immunity

A. Changes to the Composition of Boards

The *North Carolina Dental* decision turns on the principle that a state board is a group of private actors, not a subordinate state agency, when "a controlling number of decisionmakers are active market participants in the occupation the board regulates."[35]

---

[29] See generally *California Dental Assn. v. F.T.C.* (1999) 526 U.S. 756.

[30] See *Oksanen v. Page Memorial Hospital* (4th Cir. 1999) 945 F.2d 696 (*en banc*).

[31] See *324 Liquor Corp. v. Duffy* (1987) 479 U.S. 335, 344, fn. 6.

[32] 1A Areeda & Hovenkamp, Antitrust Law, *supra*, ¶ 221, at p. 66; ¶ 222, at pp. 67, 76.

[33] See *Allied Tube & Conduit Corp. v. Indian Head, Inc.* (1988) 486 U.S. 492, 500-501.

[34] *Broadcom Corp. v. Qualcomm Inc.* (3rd Cir. 2007) 501 F.3d 297, 308-309; see generally Bus. & Prof. Code, § 301.

[35] 135 S.Ct. at p. 1114.

This ruling brings the composition of boards into the spotlight. While many boards in California currently require a majority of public members, it is still the norm for professional members to outnumber public members on boards that regulate healing-arts professions. In addition, delays in identifying suitable public-member candidates and in filling public seats can result in de facto market-participant majorities.

In the wake of *North Carolina Dental*, many observers' first impulse was to assume that reforming the composition of professional boards would be the best resolution, both for state actors and for consumer interests. Upon reflection, however, it is not obvious that sweeping changes to board composition would be the most effective solution.[36]

Even if the Legislature were inclined to decrease the number of market-participant board members, the current state of the law does not allow us to project accurately how many market-participant members is too many. This is a question that was not resolved by the *North Carolina Dental* decision, as the dissenting opinion points out:

> What is a "controlling number"? Is it a majority? And if so, why does the Court eschew that term? Or does the Court mean to leave open the possibility that something less than a majority might suffice in particular circumstances? Suppose that active market participants constitute a voting bloc that is generally able to get its way? How about an obstructionist minority or an agency chair empowered to set the agenda or veto regulations?[37]

Some observers believe it is safe to assume that the *North Carolina Dental* standard would be satisfied if public members constituted a majority of a board. The

---

[36] Most observers believe that there are real advantages in staffing boards with professionals in the field. The combination of technical expertise, practiced judgment, and orientation to prevailing ethical norms is probably impossible to replicate on a board composed entirely of public members. Public confidence must also be considered. Many consumers would no doubt share the sentiments expressed by Justice Breyer during oral argument in the *North Carolina Dental* case: "[W]hat the State says is: We would like this group of brain surgeons to decide who can practice brain surgery in this State. I don't want a group of bureaucrats deciding that. I would like brain surgeons to decide that." (*North Carolina Dental*, *supra*, transcript of oral argument p. 31, available at http://www.supremecourt.gov/oral_arguments/argument_transcripts/13-534_l6h1.pdf (hereafter, Transcript).)

[37] *North Carolina Dental*, *supra*, 135 S.Ct. at p. 1123 (dis. opn. of Alito, J).

obvious rejoinder to that argument is that the Court pointedly did not use the term "majority;" it used "controlling number." More cautious observers have suggested that "controlling number" should be taken to mean the majority of a quorum, at least until the courts give more guidance on the matter.

North Carolina Dental leaves open other questions about board composition as well. One of these is: Who is an "active market participant"?[38] Would a retired member of the profession no longer be a participant of the market? Would withdrawal from practice during a board member's term of service suffice? These questions were discussed at oral argument,[39] but were not resolved. Also left open is the scope of the market in which a member may not participate while serving on the board.[40]

Over the past four decades, California has moved decisively to expand public membership on licensing boards.[41] The change is generally agreed to be a salutary one for consumers, and for underserved communities in particular.[42] There are many good reasons to consider continuing the trend to increase public membership on licensing boards—but we believe a desire to ensure immunity for board members should not be the decisive factor. As long as the legal questions raised by *North Carolina Dental* remain unresolved, radical changes to board composition are likely to create a whole new set of policy and practical challenges, with no guarantee of resolving the immunity problem.

B. Some Mechanisms for Increasing State Supervision

Observers have proposed a variety of mechanisms for building more state oversight into licensing boards' decision-making processes. In considering these alternatives, it may be helpful to bear in mind that licensing boards perform a variety of

---

[38] *Ibid*.

[39] Transcript, *supra*, at p. 31.

[40] *North Carolina Dental*, *supra*, 135 S.Ct. at p. 1123 (dis. opn. of Alito, J). Some observers have suggested that professionals from one practice area might be appointed to serve on the board regulating another practice area, in order to bring their professional expertise to bear in markets where they are not actively competing.

[41] See Center for Public Interest Law, A Guide to California's Health Care Licensing Boards (July 2009) at pp. 1-2; Shimberg, Occupational Licensing: A Public Perspective (1982) at pp. 163-165.

[42] See Center for Public Interest Law, *supra*, at pp. 15-17; Shimberg, *supra*, at pp. 175-179.

distinct functions, and that different supervisory structures may be appropriate for different functions.

For example, boards may develop and enforce standards for licensure; receive, track, and assess trends in consumer complaints; perform investigations and support administrative and criminal prosecutions; adjudicate complaints and enforce disciplinary measures; propose regulations and shepherd them through the regulatory process; perform consumer education; and more. Some of these functions are administrative in nature, some are quasi-judicial, and some are quasi-legislative. Boards' quasi-judicial and quasi-legislative functions, in particular, are already well supported by due process safeguards and other forms of state supervision (such as vertical prosecutions, administrative mandamus procedures, and public notice and scrutiny through the Administrative Procedure Act). Further, some functions are less likely to have antitrust implications than others: decisions affecting only a single license or licensee in a large market will rarely have an anticompetitive effect within the meaning of the Sherman Act. For these reasons, it is worth considering whether it is less urgent, or not necessary at all, to impose additional levels of supervision with respect to certain functions.

Ideas for providing state oversight include the concept of a superagency, such as a stand-alone office, or a committee within a larger agency, which has full responsibility for reviewing board actions de novo. Under such a system, the boards could be permitted to carry on with their business as usual, except that they would be required to refer each of their decisions (or some subset of decisions) to the superagency for its review. The superagency could review each action file submitted by the board, review the record and decision in light of the state's articulated regulatory policies, and then issue its own decision approving, modifying, or vetoing the board's action.

Another concept is to modify the powers of the boards themselves, so that all of their functions (or some subset of functions) would be advisory only. Under such a system, the boards would not take formal actions, but would produce a record and a recommendation for action, perhaps with proposed findings and conclusions. The recommendation file would then be submitted to a supervising state agency for its further consideration and formal action, if any.

Depending on the particular powers and procedures of each system, either could be tailored to encourage the development of written records to demonstrate executive discretion; access to administrative mandamus procedures for appeal of decisions; and the development of expertise and collaboration among reviewers, as well as between the reviewers and the boards that they review. Under any system, care should be taken to structure review functions so as to avoid unnecessary duplication or conflicts with other agencies and departments, and to minimize the development of super-policies not

adequately tailored to individual professions and markets. To prevent the development of "rubber-stamp" decisions, any acceptable system must be designed and sufficiently staffed to enable plenary review of board actions or recommendations at the individual transactional level.

As it stands, California is in a relatively advantageous position to create these kinds of mechanisms for active supervision of licensing boards. With the boards centrally housed within the Department of Consumer Affairs (an "umbrella agency"), there already exists an organization with good knowledge and experience of board operations, and with working lines of communication and accountability. It is worth exploring whether existing resources and minimal adjustments to procedures and outlooks might be converted to lines of active supervision, at least for the boards' most market-sensitive actions.

Moreover, the Business and Professions Code already demonstrates an intention that the Department of Consumer Affairs will protect consumer interests as a means of promoting "the fair and efficient functioning of the free enterprise market economy" by educating consumers, suppressing deceptive and fraudulent practices, fostering competition, and representing consumer interests at all levels of government.[43] The free-market and consumer-oriented principles underlying *North Carolina Dental* are nothing new to California, and no bureaucratic paradigms need to be radically shifted as a result.

The Business and Professions Code also gives broad powers to the Director of Consumer Affairs (and his or her designees)[44] to protect the interests of consumers at every level.[45] The Director has power to investigate the work of the boards and to obtain their data and records;[46] to investigate alleged misconduct in licensing examinations and qualifications reviews;[47] to require reports;[48] to receive consumer complaints[49] and to initiate audits and reviews of disciplinary cases and complaints about licensees.[50]

---

[43] Bus. & Prof. Code, § 301.

[44] Bus. & Prof. Code, §§ 10, 305.

[45] See Bus. & Prof. Code, § 310.

[46] Bus. & Prof. Code, § 153.

[47] Bus. & Prof. Code, § 109.

[48] Bus. & Prof. Code, § 127.

[49] Bus. & Prof. Code, § 325.

[50] Bus. & Prof. Code, § 116.

In addition, the Director must be provided a full opportunity to review all proposed rules and regulations (except those relating to examinations and licensure qualifications) before they are filed with the Office of Administrative Law, and the Director may disapprove any proposed regulation on the ground that it is injurious to the public.[51] Whenever the Director (or his or her designee) actually exercises one of these powers to reach a substantive conclusion as to whether a board's action furthers an affirmative state policy, then it is safe to say that the active supervision requirement has been met.[52]

It is worth considering whether the Director's powers should be amended to make review of certain board decisions mandatory as a matter of course, or to make the Director's review available upon the request of a board. It is also worth considering whether certain existing limitations on the Director's powers should be removed or modified. For example, the Director may investigate allegations of misconduct in examinations or qualification reviews, but the Director currently does not appear to have power to review board decisions in those areas, or to review proposed rules in those areas.[53] In addition, the Director's power to initiate audits and reviews appears to be limited to disciplinary cases and complaints about licensees.[54] If the Director's initiative is in fact so limited, it is worth considering whether that limitation continues to make sense. Finally, while the Director must be given a full opportunity to review most proposed regulations, the Director's disapproval may be overridden by a unanimous vote of the board.[55] It is worth considering whether the provision for an override maintains its utility, given that such an override would nullify any "active supervision" and concomitant immunity that would have been gained by the Director's review.[56]

---

[51] Bus. & Prof. Code, § 313.1.

[52] Although a written statement of decision is not specifically required by existing legal standards, developing a practice of creating an evidentiary record and statement of decision would be valuable for many reasons, not the least of which would be the ability to proffer the documents to a court in support of a motion asserting state action immunity.

[53] Bus. & Prof. Code, §§ 109, 313.1.

[54] Bus. & Prof. Code, § 116.

[55] Bus. & Prof. Code, § 313.1.

[56] Even with an override, proposed regulations are still subject to review by the Office of Administrative Law.

C. Legislation Granting Immunity

From time to time, states have enacted laws expressly granting immunity from antitrust laws to political subdivisions, usually with respect to a specific market.[57] However, a statute purporting to grant immunity to private persons, such as licensing board members, would be of doubtful validity. Such a statute might be regarded as providing adequate authorization for anticompetitive activity, but active state supervision would probably still be required to give effect to the intended immunity. What is quite clear is that a state cannot grant blanket immunity by fiat. "[A] state does not give immunity to those who violate the Sherman Act by authorizing them to violate it, or by declaring that their action is lawful . . . ."[58]

IV. Indemnification of Board Members

So far we have focused entirely on the concept of immunity, and how to preserve it. But immunity is not the only way to protect state employees from the costs of suit, or to provide the reassurance necessary to secure their willingness and ability to perform their duties. Indemnification can also go a long way toward providing board members the protection they need to do their jobs. It is important for policy makers to keep this in mind in weighing the costs of creating supervision structures adequate to ensure blanket state action immunity for board members. If the costs of implementing a given supervisory structure are especially high, it makes sense to consider whether immunity is an absolute necessity, or whether indemnification (with or without additional risk-management measures such as training or reporting) is an adequate alternative.

As the law currently stands, the state has a duty to defend and indemnify members of licensing boards against antitrust litigation to the same extent, and subject to the same exceptions, that it defends and indemnifies state officers and employees in general civil litigation. The duty to defend and indemnify is governed by the Government Claims Act.[59] For purposes of the Act, the term "employee" includes officers and uncompensated servants.[60] We have repeatedly determined that members of a board,

---

[57] See 1A Areeda & Hovenkamp, Antitrust Law, *supra*, 225, at pp. 135-137; e.g. *A1 Ambulance Service, Inc. v. County of Monterey* (9th Cir. 1996) 90 F.3d 333, 335 (discussing Health & Saf. Code, § 1797.6).

[58] *Parker v. Brown, supra,* 317 U.S. at 351.

[59] Gov. Code, §§ 810-996.6.

[60] See Gov. Code § 810.2.

commission, or similar body established by statute are employees entitled to defense and indemnification.[61]

A. Duty to Defend

Public employees are generally entitled to have their employer provide for the defense of any civil action "on account of an act or omission in the scope" of employment.[62] A public entity may refuse to provide a defense in specified circumstances, including where the employee acted due to "actual fraud, corruption, or actual malice."[63] The duty to defend contains no exception for antitrust violations.[64] Further, violations of antitrust laws do not inherently entail the sort of egregious behavior that would amount to fraud, corruption, or actual malice under state law. There would therefore be no basis to refuse to defend an employee on the bare allegation that he or she violated antitrust laws.

B. Duty to Indemnify

The Government Claims Act provides that when a public employee properly requests the employer to defend a claim, and reasonably cooperates in the defense, "the public entity shall pay any judgment based thereon or any compromise or settlement of the claim or action to which the public entity has agreed."[65] In general, the government is liable for an injury proximately caused by an act within the scope of employment,[66] but is not liable for punitive damages.[67]

One of the possible remedies for an antitrust violation is an award of treble damages to a person whose business or property has been injured by the violation.[68] This raises a question whether a treble damages award equates to an award of punitive damages within the meaning of the Government Claims Act. Although the answer is not

---

[61] E.g., 81 Ops.Cal.Atty.Gen. 199, 200 (1998); 57 Ops.Cal.Atty.Gen. 358, 361 (1974).

[62] Gov. Code, § 995.

[63] Gov. Code, § 995.2, subd. (a).

[64] Cf. *Mt. Hawley Insurance Co. v. Lopez* (2013) 215 Cal.App.4th 1385 (discussing Ins. Code, § 533.5).

[65] Gov. Code, § 825, subd. (a).

[66] Gov. Code, § 815.2.

[67] Gov. Code, § 818.

[68] 15 U.S.C. § 15(a).

entirely certain, we believe that antitrust treble damages do *not* equate to punitive damages.

The purposes of treble damage awards are to deter anticompetitive behavior and to encourage private enforcement of antitrust laws.[69] And, an award of treble damages is automatic once an antitrust violation is proved.[70] In contrast, punitive damages are "uniquely justified by and proportioned to the actor's particular reprehensible conduct as well as that person or entity's net worth . . . in order to adequately make the award 'sting' . . . ."[71] Also, punitive damages in California must be premised on a specific finding of malice, fraud, or oppression.[72] In our view, the lack of a malice or fraud element in an antitrust claim, and the immateriality of a defendant's particular conduct or net worth to the treble damage calculation, puts antitrust treble damages outside the Government Claims Act's definition of punitive damages.[73]

C. Possible Improvements to Indemnification Scheme

As set out above, state law provides for the defense and indemnification of board members to the same extent as other state employees. This should go a long way toward reassuring board members and potential board members that they will not be exposed to undue risk if they act reasonably and in good faith. This reassurance cannot be complete, however, as long as board members face significant uncertainty about how much litigation they may have to face, or about the status of treble damage awards.

Uncertainty about the legal status of treble damage awards could be reduced significantly by amending state law to specify that treble damage antitrust awards are not punitive damages within the meaning of the Government Claims Act. This would put them on the same footing as general damages awards, and thereby remove any uncertainty as to whether the state would provide indemnification for them.[74]

---

[69] *Clayworth v. Pfizer, Inc.* (2010) 49 Cal.4th 758, 783-784 (individual right to treble damages is "incidental and subordinate" to purposes of deterrence and vigorous enforcement).

[70] 15 U.S.C. § 15(a).

[71] *Piscitelli v. Friedenberg* (2001) 87 Cal.App.4th 953, 981-982.

[72] Civ. Code, §§ 818, 3294.

[73] If treble damages awards were construed as constituting punitive damages, the state would still have the option of paying them under Government Code section 825.

[74] Ideally, treble damages should not be available at all against public entities and public officials. Since properly articulated and supervised anticompetitive behavior is

As a complement to indemnification, the potential for board member liability may be greatly reduced by introducing antitrust concepts to the required training and orientation programs that the Department of Consumer Affairs provides to new board members.[75] When board members share an awareness of the sensitivity of certain kinds of actions, they will be in a much better position to seek advice and review (that is, active supervision) from appropriate officials. They will also be far better prepared to assemble evidence and to articulate reasons for the decisions they make in market-sensitive areas. With training and practice, boards can be expected to become as proficient in making and demonstrating sound market decisions, and ensuring proper review of those decisions, as they are now in making and defending sound regulatory and disciplinary decisions.

V. Conclusions

North Carolina Dental has brought both the composition of licensing boards and the concept of active state supervision into the public spotlight, but the standard it imposes is flexible and context-specific. This leaves the state with many variables to consider in deciding how to respond.

Whatever the chosen response may be, the state can be assured that *North Carolina Dental*'s "active state supervision" requirement is satisfied when a non-market-

---

permitted to the state and its agents, the deterrent purpose of treble damages does not hold in the public arena. Further, when a state indemnifies board members, treble damages go not against the board members but against public coffers. "It is a grave act to make governmental units potentially liable for massive treble damages when, however 'proprietary' some of their activities may seem, they have fundamental responsibilities to their citizens for the provision of life-sustaining services such as police and fire protection." (*City of Lafayette, La. v. Louisiana Power & Light Co.* (1978) 435 U.S. 389, 442 (dis. opn. of Blackmun, J.).)

In response to concerns about the possibility of treble damage awards against municipalities, Congress passed the Local Government Antitrust Act (15 U.S.C. §§ 34-36), which provides that local governments and their officers and employees cannot be held liable for treble damages, compensatory damages, or attorney's fees. (See H.R. Rep. No. 965, 2nd Sess., p. 11 (1984).) For an argument that punitive sanctions should never be levied against public bodies and officers under the Sherman Act, see 1A Areeda & Hovenkamp, *supra*, ¶ 228, at pp. 214-226. Unfortunately, because treble damages are a product of federal statute, this problem is not susceptible of a solution by state legislation.

[75] Bus. & Prof. Code, § 453.

participant state official has and exercises the power to substantively review a board's action and determines whether the action effectuates the state's regulatory policies.

*****

Public Comments on CCR Section 2038.5, Animal Rehabilitation

A. Comments in Support of Proposed Regulations

Comment 1: The CVMA is in support of the proposed regulations. CVMA is pleased that the proposed language defines animal rehabilitation, clarifies who may render treatment, and provides an increased level of safety for animal patients. It will allow for greater enforcement of unlicensed activity in veterinary medicine and afford a greater level of protection for pet owners in California.
No. of Commenters: 1, representing membership of CVMA.

Comment 2: Animal rehabilitation has become a rapidly expanding veterinary specialty and the necessity for stricter oversight and enforcement has been justified at many meetings. CVMA veterinarians have testified to the need for an accurate diagnosis in order to develop an effective treatment plan and prognosis, that consideration must be given to existing medical problems, and that drug regimens must be balanced with the physical modalities of treatment. Additionally, many of these patients may develop new medical issues and may be in a fragile condition, such as with senior pets. Only veterinarians have the education and experience to manage these cases and are the only licensed professionals allowed to diagnose and treat or supervise treatment of these animals.
No. of Commenters: 1, representing membership of CVMA.

Comment 3: Commenter expresses a strong endorsement of the proposed regulation. He considers animal rehabilitation to be part of veterinary practice and its implementation should be under the supervision of a licensed veterinarian. Without VMB oversight, it would allow unlicensed people to practice veterinary medicine, and the consumer would have little recourse if there are problems.
No. of Commenters: 1.

Comment 4: Commenter has two dogs that are currently in physical rehabilitation with a RVT that is directly supervised by a veterinarian on the premises. This supervision is critical to her dogs care and successful recovery. Based on her experience, it would not be safe for her dogs to be treated in an unsupervised environment since (1) urgent care would not be available if there was an emergency, (2) immediate adjustments to appropriate medications could not be made, (3) medical questions could not be answered at the time of treatment, (4) additional testing (i.e., radiographs or diagnosis of a new medical condition) could not be made, and (5) a treatment plan and decisions could not be discussed before being implemented or adjusted, and (6) advanced pain management strategies, including stem cell, join injections, and extracorporeal shockwave, would not be available. Animals deserve to be treated in a safe environment with direct supervision by a veterinarian.
No. of Commenters: 408 (including Erin Troy petition).

Comment 5: Commenters fully support the regulations to keep animal physical rehab by PTs and RVTs under direct supervision of a veterinarian. They expect their pets, while receiving physical therapy treatments, to be treated in an environment that can immediately respond to any urgent medical needs.

No. of Commenters: 6.

Comment 6: Commenter supports the proposed regulations. It is in the best interests of the patient animal that therapeutic physical rehabilitation be administered only by veterinarians, or California licensed physical therapists or registered veterinary technicians under the direct supervision of the animal's veterinarian as proposed. These professionals are the only providers sufficiently trained and regulated to administer appropriate therapies to animals in need of rehabilitation.
No. of Commenters: 412 (including Erin Troy petition).

Comment 7: Commenters support the proposed language that veterinarians directly supervise pet rehabilitation. They do not think it is fair for the pets that non-veterinarians be asked medical questions or be responsible for the overall health of the pet, especially as all pets do have medical issues.
No. of Commenters: 5.

Comment 8: Commenters support the proposed regulations as they are written. They want the very best professional care that can be provided.
No. of Commentators: 25.

Comment 9: Commenter supports the proposed regulations. Commenter believes that in order to oversee the proper rehabilitation on animals, a veterinarian should be within the building to ensure proper techniques are available if something occurs.
No. of Commenters: 16.

Comment 10: Commenters support the proposed regulations. Commenter works at a busy canine rehabilitation center. She cannot imagine a physical therapist or RVT being capable of or having the legal authority to diagnose and/or treat all of the additional medical issues that come with the patients.
No. of Commenters: 9.

Comment 11: Commenter's patients/pets have had medical emergencies while in the practice's rehabilitation department that necessitated a quick medical response. There was no veterinary 911 to call in these emergencies. It is doubtful that PTs and RVTs are legally able to administer lifesaving procedures.
No. of Commenters: 8.

Comment 12: Veterinary patients are unable to speak for themselves, sometimes requiring a veterinarian to assess and intervene.
No. of Commenters: 4.

Comment 13: The proposed regulatory change in no way puts PTs out of business; they simply have to work to partner with DVMs by working with them or for them at the same facility.
No. of Commenters: 1, plus 406 from Erin Troy petition.

Comment 14: Without direct supervision from trained veterinarians, it is too easy for treatment errors to be made. Commenter wants to make sure that the work (non-veterinarian staff) do with her animals has oversight from a medically trained eye.
No. of Commenters: 1.

Comment 15: The synergy between the rehabilitation therapists and the veterinarians is essential for the animals to receive the best care possible.
No. of Commenters: 1.

Comment 16: Commenter supports the proposed regulation. She does not feel that a physical therapist or a veterinary technician can safely or adequately perform animal rehabilitation without the direct guidance and supervision of a veterinarian. Veterinarians have undergone years of schooling that cover the health and function of the animal's entire body. This education and experience is essential to the safety and recovery of animal rehabilitation patients.
No. of Commenters: 1.

Comment 17: Commenter supports the inclusion of manual therapy in the definition of animal rehabilitation and the barring of all non-DVMs from offering it. Commenter suggests we need to go further and ban all chiropractic techniques on children and animals based on a complete lack of quality evidence for efficacy and significant potential for harm from such techniques being used on innocents.
No. of Commenters: 1.

Comment 18: The direct supervision model works. Commenter currently has such a practice, and she knows it's viable. Direct supervision is necessary to attend to things like acute pain issues, wounds, and diseases that can only be diagnosed by a DVM.
No. of Commenters: 1.

Comment 19: AR is veterinary medicine. It should not be parallel to human rehabilitation. Clients have an expectation of a broader set of care with a vet. Medical issues tend to come up during AR, for which a vet needs to see the animal. The vet may need to handle many issues at once. This can only be achieved by a veterinarian.
No. of Commenters: 1.

B. <u>Comments Suggesting Concrete Language Changes</u>:

Comment 20: Instead of "a licensed PT", the regulation should say "a licensed veterinary PT" to remove the possibility of a human PT practicing AR on an animal without proper licensure.
No. of Commenters: 1.

Comment 21: The language stating that the supervising vet shall be physically present wherever the AR is performed suggests being in the room /area where the AR is being performed versus the usual definition of direct supervision, which is: "'Direct supervision' means a licensed veterinarian is readily available on the premises where the patient is being treated and has assumed responsibility for the veterinary care given to the patient by a person working under his or her direction." (Definition taken from the AVMA's Model Veterinary Practice Act, January 2013

edition, Section 2.18.a.) Commenter is concerned that the proposed language could be "overly interpreted".
No. of Commenters: 1.

Comment 22: The list of what AR includes in Section 2038.5(a) is vague. It will be very difficult to determine the scope of this regulation and, as written, it leaves too much interpretation for the board consultants and/or those practicing in the field. Is there language that can be taken from another regulation, such as a regulation pertaining to human medicine that can be used?
No. of Commenters: 1.

Comment 23: Why not tie Section 2038.5(b)(1) in with the definition of a VCPR in CCR , Title 16, Section 2032.1? It appears that the intent is to require a VCPR before a veterinarian can perform AR. If that is the case, commenter strongly suggests that "has established a VCPR as defined in section 2032.1" after "A veterinarian who" should be added. Either a VCPR is required or not, but the way the proposed regulation is written, it is unclear whether all of the provisions of the VCPR must be met or that this regulation is proposing a new definition of what is required prior to performing AR. This lack of clarity will cause a lot of problems with interpretation of this regulation.
No. of Commenters: 1.

Comment 24: Strongly recommends adding "who has established a VCPR as defined in section 2032.1" after "under the direct supervision of a veterinarian" in Section 2038.5(b)(2).
No. of Commenters: 1.

Comment 25: Strongly recommends adding "as direct supervision is defined in section 2034(e)" after "deemed to be working under the direct supervision of a veterinarian" in Section 2038.5(b)(2).
No. of Commenters: 1.

Comment 26: Strongly recommends that Section 2038.5(b)(2)(A) refers back to the definitions of "VCPR" and "direct supervision" that are already defined in regulations in order to avoid confusion or deliberate efforts to skirt the requirements. Recommends changing this section to say "The supervising veterinarian shall establish a VCPR as defined in section 2032.1 and comply with the provisions of subsection (b)(1) prior to authorizing a PT or RVT…"
No. of Commenters: 1.

Comment 27: Need to clarify the meaning of an "initial" evaluation by the PT or RVT. This is true for 2038.5(b)(2)(A) and 2038.5(b)(2)(D).
No. of Commenters: 1.

Comment 28: What is the meaning of "physically present wherever the AR is being performed"? Strongly recommends the use of the definition of "direct supervision" from Section 2034(e) of the CCR. Alternatively, if the intent is to require the veterinarian to be in the room or immediate vicinity rather than "physically present at the location" as required in section 2034, then this section should clearly state that. The way it is currently written, it is not clear whether the veterinarian simply must be physically present at the location ("direct supervision" as defined in

section 2034) or present in the same room where the AR is being performed. This will cause a lot of confusion in interpretation.
No. of Commenters: 1.

Comment 29: Section 2038.5(b)(2)(C) should not be part of (b)(2) because it is not part of the "protocol" referred to in section (b)(2). Renumber as 2038.5(c).
No. of Commenters: 1.

Comment 30: Move 2038.5(b)(2)(D) under (b)(2) and renumber as 2038.5 (b)(2)(C).
No. of Commenters: 1.

Comment 31: Section 2038.5(b)(2)(E) should not be part of (b)(2) because it is not part of the "protocol" referred to in section (b)(2). Renumber as 2038.5(d).
No. of Commenters: 1.

Comment 32: Renumber 2038.5(c) as 2038.5(e).
No. of Commenters: 1.

Comment 33: Need further definition of the "supervisory relationship" and how it can be "terminated" in section 2038.5(c).
No. of Commenters: 1.

Comment 34: Is the intent that the supervising veterinarian is one specific person? If a veterinarian in a practice establishes the VCPR and has the supervisory relationship with the PT or RVT, does that specific veterinarian have to be physically present every time? Or can the PT or RVT perform AR in the presence of another veterinarian at that practice? Does the second veterinarian have to also establish the VCPR?
No. of Commenters: 1.

Comment 35: There is another state regulation that refers to animal "rehabilitation" in the California Code of Regulations, CCR Title 14 Section 679 – Wildlife Rehabilitation. Although the intent of Section 2038.5 seems to be intended for domestic animals, clarification is needed in order to prevent a conflict within state regulations. Please consider adding a statement in Section 2038.5 such as this: "Section 2038.5(d). This section does not apply to persons permitted by the State Department of Fish and Wildlife to rehabilitate orphaned, sick or injured wildlife as defined in CCR Title 14 Section 679, for the purpose of restoring animals to the wild."
No. of Commenters: 1.

Comment 36: Requests that the following changes be made to the regulations:
--Amend section 2038.5(a) to exclude swim therapy conducted in swimming pools by RVTs.
--Delete section 2038.5(b)(2)(B).
No. of Commenters: 23.

Comment 37: Requests that "swim therapy" be carved out of "hydrotherapy."
No. of Commenters: 2.

Comment 38: Amend section 2038.5(b)(2)(B) to protect swim therapy in pools as long as regular and consistent communication is occurring between the swim therapist and prescribing vet.
No. of Commenters: 1.

Comment 39: Add "(except as performed under Section 2038, Musculoskeletal Manipulation)" after "manual therapy" in the regulation.
No. of Commenters: 329, including Monterey Bay Area Veterinary Medical Association petition.

Comment 40: Please remove "manual therapy" from the proposed new definition on animal rehabilitation.
No. of Commenters: 291.

Comment 41: Please change the language of the regulation to either remove "manual therapy" from the definition of animal rehabilitation, or add licensed chiropractors to the list of people who are allowed to perform animal rehabilitation.
No. of Commenters: 14.

Comment 42: Please delete the language "the supervising veterinarian shall be physically present wherever the AR is being performed."
No. of Commenters: 1.

Comment 43: Please modify the language of the regulation to include chiropractors with specialty training in animal chiropractic as practitioners allowed to provide animal rehab services.
No. of Commenters: 5.

Comment 44: Please remove "instruction" from the definition of AR. The current wording would mean nearly everything presented in massage and bodywork schools would fall under the definition of AR. These topics and subject modalities are not included in veterinary curricula and very little in physical therapy schools; particularly none in California currently. California would forfeit the expertise of non-veterinarian instructors who have years, even decades of experience in the subject matter.
No. of Commenters: 6307 (Equinology petition).

Comment 45: The proposed language might better serve the Board's best intentions by allowing "indirect supervision by an attending veterinarian, unless direct supervision is deemed necessary or appropriate by said veterinarian."
No. of Commenters: 6307 (Equinology petition).

Comment 46: "Manual therapy" is not clearly defined in the proposed language, and can be referenced to have a diverse variety of definitions in numerous resources. As long as the practitioner does not diagnose, prescribe, practice MSM (unless qualified), then the touch therapies should be excluded, without a case by case interpretation.
No. of Commenters: 6307 (Equinology petition).

Comment 47: Please remove "active, passive, and resistive exercise for (the) prevention…". Proper training and conditioning is required for all animal disciplines and sports. This is

purposely done not only to enhance performance, but also to prepare the body so as to hopefully avoid injury. The proposed wording directly limits trainers, especially those specializing in fitness training. Additionally, during sessions, most professional animal bodyworkers will address a muscle or group of muscles and offer active range of motion exercises or suggest training parameters for a healthy sound animal.
No. of Commenters: 6307 (Equinology petition).

Comment 48: Please include an express exception for "relaxation, recreational or wellness massage". As written, the proposed regulation does not except such useful activities, which cannot be considered the practice of veterinary medicine.
No. of Commenters: 1.

Comment 49: Please delete "massage" from the proposed definition of animal rehabilitation.
No. of Commenters: 2.

Comment 50: Commenter proposes that the VMB follow the same California safe harbor exemption law for unlicensed practice on humans (Exhibit 1).

Comment 50.1: The regulations do not define "rehabilitation" or "exercise".
No. of Commenters: 1.

Comment 51: Commenter would like the language requiring the supervising veterinarian to be physically present wherever the AR is being performed to be changed to "a supervising veterinarian prescribing [AR] should provide a working diagnosis of the medical condition, provide consumers with a direct referral to a professional licensed to perform [AR] services, and maintain direct communication with the [AR] professional performing the [AR] regarding treatment plan and progress.

A California licensed physical therapist (PT), registered veterinary technician (RVT), or other certified and licensed animal massage or animal wellness professional, working under the indirect supervision of a veterinarian, may also perform [AR] treatments within the scope of their certification."
No. of Commenters: 1.

Comment 52: Commenter suggests that the Board adopt the approach taken by states such as Colorado, which allows the practice of animal massage without a license if the person performing the animal massage:

(A) " Does not prescribe drugs, perform surgery, or diagnose medical conditions; and
(B) Has earned a degree or certificate in animal massage from a school approved by [appropriate state agency], an out of state school offering an animal massage program with an accreditation recognized by the United States Department of Education, or a school that is exempt under [applicable statute]."
Colo. Rev. Stat. Section 12-35.5-110(1)(f)
No. of Commenters: 1.

C. Indirect Supervision:

Comment 53: Wants a medical model parallel to that of humans in which access would be given to PTs without the need for direct supervision by a veterinarian. Claims that this has been very successful in other states such as Colorado (Exhibit 2) and Nevada (Exhibit 3).
No. of Commenters: 6.

Comment 54: As a nationally recognized organization, the Animal Rehabilitation Special Interest Group (ARSIG) of the orthopedic section of the American Physical Therapy Association, commenters oppose the language that seeks to mandate direct supervision requirements on physical therapists who treat animals, particularly since physical therapists have been treating animals in this state for more than 10 years.
No. of Commenters: ARSIG.

Comment 55: True provision of consumer protection would involve devising proper competency standards that practitioners should be required to meet in order to practice under indirect supervision. Allow AR practitioners to practice under indirect supervision as long as competency standards have been met.
No. of Commenters: 7 + ARSIG.

Comment 56: Verbal or written rehab consent and/or plan from a licensed veterinarian should be sufficient for non-veterinary rehab providers to perform their services. The non-vet rehab practitioner should be required to maintain contact with the prescribing/referring veterinarian on at least a monthly basis.
No. of Commenters: 2.

Comment 57: Chiropractic care should only need a referral and chiropractors should be able to work autonomously as they do on humans. The usefulness of veterinarians is they can provide X-rays for the chiropractor to read. The relationship should be one of consultation and mutual respect between professionals, not of supervision.
No. of Commenters: 5.

Comment 58: Commenter, a DVM licensed in this state, wants to allow licensed physical therapists to provide rehabilitation on animals under indirect supervision. Physical therapists with additional training and education in animal rehabilitation should be accepted providers of rehabilitation and physical therapy services for animals without requiring direct supervision. This has been the trend in other states, and this trend has proven to be successful, reasonable and safe.
No. of Commenters: 2, both DVMs.

Comment 59: Direct supervision is not always practical because most animal hospitals have limited room; adding space for AR and AR equipment is not always a practical option for most vets.
No. of Commenters: 1 DVM.
Comment 60: Direct supervision is not always practical because most small animals become tense and fearful when they enter veterinary premises. This prevents accurate assessment of muscle tone and effective response to therapy. In the calm atmosphere of the animal's home, the animal's

physical/mental status can be more accurately assessed, and the AR itself will prove more efficacious.
No. of Commenters: 1 DVM.

Comment 61: Direct supervision is not always practical because ambulatory vets, especially equine vets, do not have the time to stay in a barn or home during every AR session.
No. of Commenters: 1 DVM.

Comment 62: Indirect supervision would enable AR to be significantly more cost effective because more AR could be administered in the field. The animals' owners would not have to lose work bringing an animal to the hospital for AR, nor would they have to pay to transport the animal.
No. of Commenters: 2.

Comment 63: Indirect supervision, like we have with medical doctors and physical therapists for humans, would promote the integrity of the care being offered while ensuring affordable treatment for animal patients.
No. of Commenters: 3 + ARSIG.

Comment 64: Direct supervision required for AR sessions with a veterinarian is not necessary. If a veterinarian has prescribed AR for a client, then there is no reason for them to be there for the session. It should be "indirect supervision," or left to the veterinarian's professional discretion.
No. of Commenters: 6037 (Equinology petition) + 1.

Comment 65: Requiring direct supervision for all activities described in the new wording would render a tremendous scope of services cost prohibitive for owners and therefore the animals would be denied these services. This is especially true for horses.
No. of Commenters: 6307 (Equinology petition) + 1.

Comment 66: Please reconsider the need for direct supervision of PT's trained and certified in specific areas of AR. Requiring direct supervision of PT's would limit access to services that could benefit the animal and client. Doctors of Physical Therapy are highly educated professionals who are capable of providing services without direct supervision. Assuring that PTs have appropriate qualifications and providing adequate systems for communication between PTs and DVMs should allow for safe and effective provision of services.
No. of Commenters: 1 + ARSIG.

Comment 67: Restricting all AR services to provision under direct supervision prevents the ability to offer mobile services to animal patients who are homebound due to their size or disabilities and who are unable to be brought in to a veterinary clinic for treatment.
No. of Commenters: 1.

Comment 68: Restricting services to veterinary practice only or requiring direct supervision by a veterinarian for therapies such as massage or acupressure is ill-advised and only serves to hurt the consumer, the veterinary community, practitioners of complementary therapies, the California economy, and most significantly, the animals themselves.
No. of Commenters: 1.

Comment 68.1: Direct supervision would cause problems in the equine world. Having to transport an injured horse could make the injury worse.
No. of Commenters: 1.

Comment 68.2: Veterinarians will not be available for urgent issues if they must supervise AR.
No. of Commenters: 1.

D. Massage/Bodywork:

Comment 69: Since when did vets and RVTs know how to do massage? There is no training in massage among vets, RVTs and PTs except for PTs, and that training is cursory and doesn't come close to what a well-trained animal massage therapist knows.
No. of Commenters: 1.

Comment 70: Therapeutic massage needs to be clarified; it must be clear that massage not done for therapeutic purposes but for comfort is legal.
No. of Commenters: 1.

Comment 71: Commenter wants to be able to do "wellness" massage sessions on dogs and horses, similar to those provided to humans in the human massage industry.
No. of Commenters: 7.

Comment 72: Direct supervision for massage therapy sessions will effectively eliminate these services, because most sessions are done at barns and the owner cannot afford to have a veterinarian present. In addition, there would be scheduling difficulties. In some cases, the nearest vet is 2 hours driving distance. The regulation will effectively eliminate the ability of horse owners to have their horses receive massage/bodywork that can be beneficial for their health and well-being.
No. of Commenters: 7.

Comment 73: The regulation will effectively eliminate the ability for horse owners to have their horses receive massage/bodywork that can be beneficial for their health and well-being.
No. of Commenters: 6.

Comment 74: Graduates of the Equinology INC and Caninology program are trained not to work on an animal until cleared by the attending veterinarian, if the animal is currently under veterinary care. If a graduate is called to work on an animal that they feel needs to be seen by a vet first, they are trained to walk away from that session and advise the owner to contact their veterinarian. Graduates of this program are members of the Equine Body Workers Association which requires them to carry liability insurance and attend 16 hours of annual continuing education. They are serious about providing service within the current practice act.
No. of Commenters: 1.

Comment 75: If the Board decides that massage is a component of AR and only allowed to be presented by those specified in the regulations, commenter and the graduates of her school are effectively shut down. Commenter has provided training in animal massage for 21 years.
No. of Commenters: 1.

Comment 76: There is no distinction as to what constitutes "therapeutic massage" vs. "massage". The definitions of these terms from various sources overlap, and include many of the words found in the definition of AR.
No. of Commenters: 6307 (Equinology petition).

Comment 77: Regular "massage" sessions can restore movement through strokes and techniques, induce relaxation, increase circulation, and promote general health. Does that really make it the practice of AR?
No. of Commenters: 6307 (Equinology petition).

Comment 78: Few veterinary facilities have the space and atmosphere conducive to a non-distracting and relaxing massage. Veterinary facilities visited by commenter were filled with noise, activity and distractions. Massage requires a quiet, dark, and undisturbed room or area.
No. of Commenters: 2.

Comment 79: Adding veterinary control and oversight would add to the cost of massage, reduce the number of good massage therapists, and promote an undercover economy. Please keep pet massage as it is/remove "massage" from the definition of animal rehabilitation.
No. of Commenters: 4.

Comment 80: Commenter objects to and disagrees with including animal massage as a part of animal rehabilitation. Massage is a stand-alone wellness and care activity that consumers should be allowed to access as they see fit, as they are allowed to do for themselves.
No. of Commenters: 1,757 (Shelah Barr petitions).

Comment 81: Commenter objects to and disagrees with the idea that massage is a medical procedure that needs to be prescribed and overseen by a medical professional. Animal massage is no different than human massage and should not be treated or regulated any differently. Commenter does not have to receive a prescription in order to receive a massage, and requiring her to get a prescription from a vet for her pet is unnecessary and unfair.
No. of Commenters: 1,758 (Shelah Barr petitions).

Comment 82: By the Board's own reasoning, unqualified persons should not be performing massage. The proposed language makes no stipulation that the veterinarian, veterinary technician, or physical therapist be trained in the art of massage. Therefore, the veterinarian, veterinary technician, or physical therapist should not be performing massage.
No. of Commenters: 1,756 (Shelah Barr petitions).

Comment 83: Commenter objects to and disagrees with having to bring her pet to a veterinary clinic for a massage because it will cause undue stress upon the animal.
No. of Commenters: 1,756 (Shelah Barr petitions).

Comment 84: Commenter objects to and disagrees with having to bring her pet to a veterinary clinic for a massage because this will make it exclusionary for people with disabilities, financial or time restrictions.
No. of Commenters: 1,756 (Shelah Barr petitions).

Comment 85: Commenter objects to and disagrees with having to bring her pet to a veterinary clinic for a massage because it creates a monopoly and is an unfair trade and an unfair competition practice which are federally illegal. Commenter objects to and disagrees with the Board knowingly and purposely forcing small local businesses to close, with the intention of funneling the business to veterinarians.
No. of Commenters: 1,757 (Shelah Barr petitions) + 2.

Comment 86: Commenter requests that the Board redefine "Animal Rehabilitation" by referring to massage only in the context of physical therapy that has been prescribed by a veterinarian. She also requests that the Board remove all language that requires massage to be prescribed by a veterinarian, and that restricts a person trained in animal massage who has received a certification in that field and carries liability insurance from practicing freely, without sanction or penalty from the Board.
No. of Commenters: 1,758 (Shelah Barr petitions).

Comment 87: There is no human equivalent to what this new definition will require. The human equivalent would mean that if one wanted a relaxing therapeutic massage one could only get one by a physical therapist or physical therapist aid with an MD on site. This will cause the massage industry to dry up.
No. of Commenters: 7.

Comment 88: Why can we use alternative or complementary modalities without direct doctor supervision for ourselves but not for our animals?
No. of Commenters: 10.

Comment 89: How does the proposed wording change protect the public and their pets, and from what? Where are the statistics to show harm done by those providing wellness sessions? What form/type of damage can be done through massage that would necessitate a veterinarian on site?
No. of Commenters: 5.

Comment 90: Commenter has and will continue to use the services of a certified equine massage therapist and recommend her, as she has done a lot of good for his horses. There has not been a single horse owner that commenter is aware of who has had a single negative experience from the massage therapist he uses.
No. of Commenters: 3.

Comment 91: There are few horse owners who can afford the cost of a bodyworker when they also have to pay for a vet to be present.
No. of Commenters: 7.

Comment 92: There are few, if any, veterinarians who will want to, or are capable of, performing equine massage or bodywork.
No. of Commenters: 6.

Comment 93: Animal owners are perfectly capable of determining who to use for bodywork/massage; they don't need the VMB's protection. Animal owners should have a right to choose a bodyworker for their animals without the need for a veterinarian to be involved.
No. of Commenters: 20.
Comment 94: As a bodyworker, commenter does not diagnose or treat illness or lameness. Her role does not sidestep the veterinary treatment her clients' animals might need.
No. of Commenters: 3.

Comment 95: Requiring certification through an approved program such as Equissage or Equinology makes much more sense than requiring owners to pay double fees, and vets to virtually waste their time observing equine bodyworkers.
No. of Commenters: 2.

Comment 96: Many massage therapists have been working on animals for a long time. It would be difficult for these practitioners to go back to school or work under a vet. Some certification should be required, but not a whole new degree.
No. of Commenters: 1.

Comment 97: There are already national boards that certify animal massage and acupressure.
No. of Commenters: 2.

Comment 98: Sweeping certified animal massage workers into the scope of practicing veterinary medicine is a revision from the Board's previous stance, which did not seek to restrict the practice of massage or bodywork for animals under veterinary care.
No. of Commenters: 1.

Comment 99: Commenter's dogs were provided with relief by a certified small animal massage practitioner.
No. of Commenters: 2.

Comment 100: Commenters utilized the services of a certified animal massage therapists who came to their homes to work on their dogs, and the dogs benefitted from relaxing and relieving their muscle pain without the stress of being transported to the vet.
No. of Commenters: 2.

Comment 101: Commenter believes that animal massage therapists need training in animal massage, but doesn't believe that they need direct supervision any more than a human need's an MD's direct supervision.
No. of Commenters: 1.

Comment 102: Please take into account that many animals currently benefit from massage therapy. Requiring this to be performed in the presence of or by a veterinarian will be

unnecessarily limited to certified practitioners, and will result in animals not getting this beneficial treatment.
No. of Commenters: 13.

Comment 103: Massage is considered a normal part of the grooming process. Responsible practitioners do not prescribe, adjust, manipulate or diagnose, therefore massage is classified as animal husbandry. The VMB does not regulate animal husbandry, so it cannot legally be listed as the practice of veterinary medicine.
No. of Commenters: 2.

Comment 104: Commenters submit that this severe restriction fails to address or rectify any real safety issue or other legitimate concern. Associated Bodywork & Massage Professionals (ABMP) requires that their animal massage practitioner members must have completed at least 100 hours of education in the field of animal massage. According to commenters' records, not one professional negligence insurance claim has been submitted against any of commenters' animal massage practitioner members in the past 15 years. The practice of animal massage by trained, professional therapists is simply not a safety risk to animals, and the evidence does not indicate any need for the professional restriction of animal massage as proposed in 16 CCR 2038.5.
No. of Commenters: ABMP + 1.

Comment 104.1: The National Board of Certification for Animal Acupressure and Massage (NBCAAM) certifies practitioners who are trained professionals and who have undergone a rigorous testing process. While NBCAAM practitioners are encouraged to communicate with veterinarians and other licensed animal health care professionals, NBCAAM maintains that neither veterinarian referrals nor veterinarian supervision are required for the non-invasive practices of acupressure or massage except where state regulations dictate.
No. of Commenters: NBCAAM.

Comment 104.2: NBCAAM certified practitioners do not provide medical diagnosis, prescribe medications, perform surgical procedures, or provide chiropractic manipulations. Animal acupressure and massage do not replace veterinary physical therapy. Practitioners do not provide veterinary technician services.
No. of Commenters: NBCAAM.

E. Water Therapy:

Comment 105: Commenter opposes the animal rehabilitation regulations Section 2038.5., because it will remove/deny the ability of many animals to receive water therapy.
No. of Commenters: 9.

Comment 106: If the regulation passes, then will veterinarians serve as "lifeguards" directly overseeing the therapy in a swimming pool?
No. of Commenters: 5.

Comment 107: The proposed regulation would eliminate swim therapy provided by an RVT in a swimming pool. Commenters object because their dogs have benefitted from the therapy and the

cost was affordable. Commenters believe that the proposed regulation would deny disabled and recovering pets and their owners the ability to get truly beneficial therapy at a reasonable cost.
No. of Commenters: 30.

Comment 108: Want to amend section 2038.5(a) to exclude swim therapy conducted in swimming pools by RVTs and to delete section 2038.5(b)(2)(B).
No. of Commenters: 14.

Comment 109: If the proposed regulation passes, will vets go to the expense of putting in a natural environment swimming pool? In the current drought environment, the expense of installing and maintaining a new swimming pool will not only be cost prohibitive, but impractical. Veterinarians are not motivated to incur the cost, liability, and devoted time it takes for a truly rehabilitative experience a swimming pool provides. They will not have the space or the willingness to spend the money. Commenter has never found a veterinarian in her region that has a pool on site.
No. of Commenters: 25.

Comment 110: The additional cost of having a licensed veterinarian physically present at every swim therapy session will make such sessions cost-prohibitive.
No. of Commenters: 2.

Comment 111: Swim therapy is very different from other water therapy such as underwater treadmills. Swim therapy can accomplish things that an underwater treadmill can't.
No. of Commenters: 9.

Comment 112: The RVT with which commenter is familiar truly cares for pets receiving water therapy; the dogs and the owners receive attentive, personal care and tremendous benefit. This RVT is trained, stays current with therapy methods and ongoing training, and provides a caring rehabilitative service at an affordable cost.
No. of Commenters: 6.

Comment 113: The regulation will destroy a very valuable service to our dogs (i.e., swim therapy) that cannot be replaced by veterinarians, certainly not at an approachable cost that such regular therapy requires for optimum results.
No. of Commenters: 4.

F. <u>Chiropractic</u>:

Comment 114: Will the new proposal affect animal chiropractic?
No. of Commenters: 1.

Comment 115: Does the Board intend to leave 2038 intact, and only add regulation to PTs and RVTs in 2038.5?
Commenters: James Israelsen, DVM, Legislative Chair of AVCA, Michael Welker, President of AVCA.

Comment 116: Chiropractors must already practice under the direct supervision of a licensed veterinarian. Under the proposed wording, animals may no longer be able to receive this care. There are already laws mandating that chiropractors work by referral only and under supervision of a veterinarian – which already dramatically increased the cost of care.
No. of Commenters: 7.

Comment 117: Commenters' dogs' quality of life and wellbeing greatly improved from the care they received through a licensed chiropractor.
No. of Commenters: 40.

Comment 118: This proposal would negatively impact thousands of horses, dogs, etc. who currently receive chiropractic adjustments to maintain a healthy, balanced body.
No. of Commenters: 2.

Comment 119: Manual therapy as performed by properly trained and certified animal chiropractors is critical to the health and wellbeing of commenter's horses. The knowledge that properly trained and certified animal chiropractors possess is vast and paramount in keeping commenter's herd performing at an elite level.
No. of Commenters: 5.

Comment 120: Eliminating properly trained and certified animal chiropractors from caring for pets or performance animals is cruel and wrong/would cause many animals to suffer.
No. of Commenters: 2.

Comment 121: Please do not take away animal chiropractors. It would be a huge mistake eliminating properly trained and certified animal chiropractors from caring for our pets.
No. of Commenters: 43.

Comment 122: Vets who have referred clients to several veterinary chiropractors say that they do not have training in veterinary chiropractic care and don't have time to pursue another degree. They would not be nearly as skilled as the professionals they have been working with. Eliminating their services from the community would be arbitrary and hurtful to the patients that need their services.
No. of Commenters: 6.

Comment 123: AVCA (American Veterinary Chiropractic Association) certificants have been practicing under Code section 2038 since 1998, and it has been an effective method of preventing unlicensed or untrained individuals from performing chiropractic adjustments on animals in the State of California. Surely a certification for animal chiropractors from the American Veterinary Chiropractic Association should be sufficient to allow these caregivers license to apply their skill and healing touch.
No. of Commenters: 16.

Comment 124: If properly trained chiropractors are not allowed to legally treat animals with veterinary supervision, the public will still demand this treatment and be forced to seek the care of an ill-trained (or untrained) illegal practitioner. This will put the pets' wellbeing in jeopardy.

No. of Commenters: 485 (including Monterey Bay Area Veterinary Medical Association petition).

Comment 125: Professional human athletes get regular body work, so active sports dogs should have the same ability to get body work. Sports dogs should also be able to get chiropractic treatment.
No. of Commenters: 6.

Comment 126: By limiting chiropractic care to properly trained vets only, the demand will greatly overwhelm the qualified vets, leaving the option of chiropractic care unavailable to many. Veterinarians are much too busy/do not have the time or inclination to learn manual therapy. It would be like asking an orthopedist to learn physical therapy.
No. of Commenters: 10.

Comment 127: What would happen if only MDs could give chiropractic care to humans?
No. of Commenters: 1.

Comment 128: Veterinarians, physical therapists and registered veterinary technicians are not generally trained in chiropractic. Permitting untrained individuals to practice chiropractic is dangerous and illogical, and forbidding chiropractors to practice unless they are vets, PTs or RVTs is unnecessary and unrealistic. Commenter would much prefer her chiropractor, certified by the American Veterinary Chiropractic Association, treat her dog than a veterinarian, RVT or PT who doesn't have specialty chiropractic training. Commenter would not allow a veterinarian to do any type of manual manipulation on her pet.
No. of Commenters: 27.

Comment 129: There is already a shortage of animal chiropractors. Typical wait times in the Bay Area are already over one month. The AVCA website lists 41 certified doctors in California. Only 13 of these are DVMs. The proposed change would make it even more difficult to find the quality animal chiropractic care their animals need.
No. of Commenters: 1.

Comment 130: The proposed regulation will do nothing but further drive up the costs of care for pet owners while eliminating the livelihood of qualified, licensed and supervised animal chiropractors.
No. of Commenters: 7.

Comment 131: The VMB is seeking to deprive commenter of his right to continue a legally established (chiropractic) business. This is a violation of commenter's civil rights under Article IV and the 14th Amendment of the Constitution.
No. of Commenters: 1.

Comment 132: A properly trained and certified animal chiropractor offers invaluable service to animals in pain without the use of drugs or surgery.
No. of Commenters: 7.

Comment 133: If animal trained chiropractors are prevented from working, many vets will not have qualified doctors to refer to.
No. of Commenters: 2.

Comment 134: When seeking care for her dog, the local vets were unable to help commenter except to heavily prescribe pain medications. This did not resolve the underlying issue. A chiropractor was able to help.
No. of Commenters: 4.

Comment 135: To mandate that chiropractic must be directly overseen by a vet is irresponsible and short sighted. Certified animal chiropractors would be put out of business and these are precisely the people who have the expertise and specialization to be effective for this common form of pet rehab. Leave chiropractic to certified chiropractors.
No of Commenters: 3.

Comment 136: Commenter thinks it is wrong that [animal chiropractic] is even an issue, because the AVCA has grown and established this business and now that it is a thriving successful industry, the veterinarians want a piece of it.
No. of Commenters 1.

Comment 137: Commenter thinks it is wrong that the [veterinary] industry would put their personal agendas and their need for a piece of the pie in front of the care of the animals they are to protect.
No. of Commenters: 2.

Comment 138: Years ago, anyone could set up a table and sign at a [dog] agility competition and say they were doing animal chiropractic. It is a huge step forward in providing quality care for our canine athletes that animal chiropractors are now certified and work under the supervision of a veterinarian.
No. of Commenters: 4.

Comment 139: Commenter's vet does not peform chiropractic care, so she recommended the best [an animal chiropractor] for her dog.
No. of Commenters: 1.

Comment 140: If a human can see a chiropractor/ alternative modalities without an MD's supervision, commenters believes they should be allowed to seek the same treatment for their animals without a DVM's supervision.
No. of Commenters: 3.

Comment 141: A certain chiropractor helped commenter's dog such that they were able to avoid an expensive, unnecessary surgery that could have had a bad outcome.
No. of Commenters: 2.

Comment 142: Commenters wish to express support for certified health practitioners who are not veterinarians, including chiropractors, physical therapists, acupuncturists, and dental aligners, that perform work on their animals.
No. of Commenters: 2.

Comment 143: There are no veterinarians trained in animal chiropractic in commenter's area.
No. of Commenters: 1.

Comment 144: There is no reason to exclude chiropractors from the list of professionals who can perform AR under this proposal. There are multiple reputable post-graduate training programs available to chiropractors who go on to work with animals under the supervision of DVMs. These chiropractors receive a specialized education on the exact workings of the nervous system, the biomechanics of the animals they will be adjusting, and the specificity needed for each adjustment.
No. of Commenters: 4.

Comment 145: Do not remove manual therapy from the definition of animal rehabilitiation. Chiropractic from well-trained professionals is very valuable.
No. of Commenters: 1.

Comment 146: The AVCA feels that PTs and RVTs do not have appropriate training to practice animal chiropractic, and the Board should utilize the pre-existing national certification program of the AVCA as the gold standard in animal chiropractic training. Doing so will assure the continued safety of the public and animals in need of chiropractic adjustment.
Commenters: James Israelsen, DVM, Legislative Chair of AVCA, Michael Welker, President of AVCA, September 1, 2015.

Comment 147: By including "manual therapy" in the language of the rule, the VMB will make it impossible for commenter to obtain the degree of care that she has heretofore been getting. This stands the concept of "consumer and animal protection" on its head.
No. of Commenters: 1.

Comment 148: Commenter's veterinarian recommends animal chiropractic precisely because it is a specialty and because he is not trained to provide it. Why does the vet board not trust the wisdom of its own members who recommend chiropractic and who trust the professionalism of the chiropractors with whom they partner?
No. of Commenters: 1.

Comment 149: Why should commenter as a consumer have to pay for a veterinarian call as well as a chiropractor call when her animal needs to be seen? Why should a vet have to stand around while her animal is adjusted when he/she could be seeing other patients?
No. of Commenters: 2.

Comment 150: There would be a huge hole in the care of commenter's patients without chiropractic care, acupuncture, and physical therapy that is already being performed well.
No. of Commenters: 2.

Comment 151: The vets commenter knows do not want to do chiropractic and have no problem with commenter seeking chiropractic care for her pets.
No. of Commenters: 1.

G. Acupuncture:

Comment 152: No mention of acupuncture or electro-acupuncture in the definition of AR. Commenter is concerned that if they call it AR, vets cannot use licensed acupuncturists.
No. of Commenters: 1.

Comment 153: Please work to allow alternative treatments referred by vets, such as chiropractic, massage therapy, and acupuncture, but practiced by qualified, less expensive practitioners.
No. of Commenters: 4.

Comment 154: Please add veterinary chiropractors and acupuncturists to the list of who may perform animal rehabilitation.
No. of Commenters: 3.

H. General Opposition:

Comment 155: The regulations would allow any veterinarian or RVT to practice AR, even if they are not qualified to do so.
No. of Commenters: 16.

Comment 156: The regulations would drive up rehab prices/costs.
No. of Commenters: 4,238 (including CAAPT petition) + 26.

Comment 157: The regulations would limit public access to uniquely qualified professionals.
No. of Commenters: 8.

Comment 158: The regulations would not yield any increase in safety for pets or owners. The proposed regulation will do nothing to stop those who are already operating outside the law.
No. of Commenters: 4,238 (including CAAPT petition) +5.

Comment 159: Restricting consumer access to physical rehabilitation and wellness-type activities delivered only by a veterinarian or in a veterinarian's clinic will take away the consumer's right to choose who they want to treat their animals. Don't take away consumers' right to choose.
No. of Commenters: 4,235 (including CAAPT petition) and 6,307 (Equinology petition) + 21.

Comment 160: By including a broad definition of "Animal Rehabilitation" and a narrow list of people who can perform such rehabilitation, this amendment is excluding people licensed in other professions who are valuable in the rehabilitation process. In particular, excluding licensed massage therapists, licensed chiropractors, acupuncturists, and reiki masters from the list of allowed professionals would prohibit vets from using the valuable services offered by these practitioners.
No. of Commenters: 12.

Comment 161: The regulations put veterinarians in danger of prosecution for aiding and abetting unlicensed activity when in fact the veterinarian may be using a licensed professional with knowledge and skills superior to their own or that of a PT or RVT.
No. of Commenters: 1.

Comment 162: Where is the proof that the public or animals are being harmed by unlicensed or unauthorized practitioners? This is a completely false statement and the Board needs to prove that the public and animals are being harmed. Commenter wants scientific proof, clinical studies, court cases where animals were harmed.
No. of Commenters: 8.

Comment 163: The Board's main mission is to promote and protect its member doctors and to consolidate control of all animal medical care under its influence. Increased demand for PTs, RVTs and vets is the true goal of this regulation, not the protection of animals or the public.
No. of Commenters: 6.

Comment 164: There will be lawsuits that will cost the Board a lot of money when they, for instance, go after a massage therapist for violating the regulations.
No. of Commenters: 3.

Comment 165: The public will not be willing to pay for a supervising vet and a PT to be with an animal at the same time.
No. of Commenters: 4.

Comment 166: The Board is overreaching its authority. If an animal's owner wants to get instruction in animal massage or any other health care modality then that is their right. Animals are property and the owner can do as they wish as long as they don't break the law by abusing an animal. Clients often know their animals better than their own bodies.
No. of Commenters: 4.

Comment 167: Please do not penalize veterinarians who wish to utilize or refer a paraprofessional who is not listed under the proposed AR definition, especially when the paraprofessional has obtained an appropriate and acceptable standard of specialized training.
No. of Commenters: 6,307 (Equinology petition).

Comment 168: AR training is not necessarily included in the curricula of veterinary, RVT and PT programs. Belonging to one of these licensed professions does not necessarily qualify one to administer AR, as defined in the proposed language, without obtaining additional specialized education. The Board would need to put guidelines in place for veterinarians, RVTs and PTs requiring additional education for AR services.
No. of Commenters: 6,307 (Equinology petition) + 3.

Comment 169: "Evaluation" is not the practice of AR. Any ethical professional bodyworker, trainer, or farrier understands the need to evaluate the body and movement of an animal. The temperature, tone, and texture of the muscles must be evaluated by the bodyworker, to make sure

there are no contraindications before proceeding. If the animal is not moving properly, it needs to be referred to the veterinarian first before initiating a session. Should this critical practice of horse care really be the exclusive domain of veterinarians who are already stretched thin in their efforts to treat horses truly in need of their care?
No. of Commenters: 6,307 (Equinology petition).

Comment 170: A physical therapist's unique skill set is different than a veterinarian's and certainly more advanced than a veterinary technician's. Having access to a physical therapist's skills is important to the commenters and crucial to them for the care of their animals.
No. of Commenters: 4,235 (CAAPT petition) + 1.

Comment 171: Currently, it is very often impossible to get a veterinarian to commenter's location for a serious issue. There has been no consideration shown in these regulations to workloads, locations, time and travel.
No. of Commenters: 2.

Comment 172: If the proposed regulation was enacted, commenter believes that commenter's animals would be less well cared for than they are now.
No. of Commenters: 3.

Comment 173: Commenter wonders why it is okay to use alternative or complementary modalities without direct doctor supervision for ourselves, but not our animals?
No. of Commenters: 6.

Comment 174: This proposed regulation monopolizes all areas of animal care – looking after the board's interest instead of the public's interest. This is a regulation to benefit the vet industry only – not pet owners or animals. This is not appropriate or adequate to meet consumer needs.
No. of Commenters: 6,307 (Equinology petition) + 7.

Comment 175: Commenter has the right to seek help for their animal using one of the alternative treatments that most veterinarians neither offer nor understand. Noninvasive treatment has never been restricted to medical professionals, even for people.
No. of Commenters: 13.

Comment 176: Requiring that all animal treatment be done by or through veterinarians will be hugely expensive to the animal owning public.
No. of Commenters: 21.

Comment 177: This regulation will put many alternative care businesses out of business and deprive some excellent animal massage/bodyworkers/chiropractors/hydrotherapists from earning a living/eliminate jobs. Qualified professionals will lose their main source of income under the proposed regulations.
No. of Commenters: 21.

Comment 178: This regulation will cause the flight of entrepreneurial AR practitioners and business owners from California, which will harm both animals and their owners.

No. of Commenters: 1.

Comment 179: Vets are good at many things, but they often miss soft tissue damage. Body workers can help.
No. of Commenters: 3.

Comment 180: There is no reason to deprive pet owners of what are normally lower cost treatment modalities.
No. of Commenters: 5.

Comment 181: Do not pass a regulation that is geared at the percentage of individuals who are not qualified and, because of such, all those with skill and integrity will be paying the price for their mistakes.
No. of Commenters: 1.

Comment 182: There are many appropriately trained animal massage, acupressure, and cranial-sacral (to name a few) practitioners who have every right to provide treatment and therapy to animals. Rarely can these practitioners injure an animal and they do not diagnose nor prescribe. They are not doing anything invasive.
No. of Commenters: 5.

Comment 183: The proposed regulation would restrict a veterinary practice from sending out an appropriately trained and certified RVT to perform follow-up ECSW (extracorporeal shock wave therapy) or LLLT (low level laser therapy) treatments unless they were constantly accompanied by a veterinarian. This is not necessary.
No. of Commenters: 1.

Comment 184: Commenter, a DVM, does not feel qualified to supervise the activities of alternate modalities, including physical therapy, chiropractic care, swim therapy, and therapeutic massage, but she trusts their competence and knowledge of when to refer back to commenter or a general practitioner or a specialist.
No. of Commenters: 1.

Comment 185: By constraining the veterinarian's time, the vet necessarily will have to charge more for AR, thus limiting its access to animals with wealthier owners.
No. of Commenters: 4.

Comment 186: The proposed regulations remind commenter of the ban on non-vet teeth cleaning for dogs, which commenter feels is ridiculous.
No. of Commenters: 1.

Comment 187: From a business model, the proposed regulations make no sense for a veterinary practice. Commenter does not know of one veterinarian who is content with passively overseeing AR, while his/her own clinical cases are waiting.
No. of Commenters: 3.

Comment 188: Rather than narrow the scope of practice, it would be a far more viable and positive solution to work towards a new directive, whereby paraprofessional AR activity by qualified and insured practitioners is regulated under the realm of veterinary practice.
No. of Commenters: 2.

Comment 189: There would be absolutely no reason for a veterinarian to be present at a reiki energy healing session. There is no manipulation involved in reiki, just the laying on of hands and sometimes just hovering over the body.
No. of Commenters: 4.

Comment 190: The regulation potentially impacts the activities of pet owners and their own pets, as well as those of others involved in animal care businesses (e.g., pet sitters and dog walkers), and people who work with their friends' animals. Pet owners and others are impacted through the use of the terms "active, passive, and resistive exercise". Simply walking a dog could be considered to be active exercise for the prevention of bodily injury. There is no specific recognition for pet owners provided in Business & Professions Code Section 4827(a).
No. of Commenters: 1.

Comment 191: It is possible that pet owners will take it upon themselves to try and provide the needed services to their animals, without undergoing the necessary training to act properly and avoid injury to their animals. Without the necessary training, it is highly likely that these people will injure animals and/or themselves, adding to the pain and suffering of both humans and animals.
No. of Commenters: 1.

Comment 192: Commenter believes the notice of the regulatory hearing scheduled for September 10, 2015, is defective and that the public hearing must be rescheduled.
No. of Commenters: 1.

Comment 193: Commenter believes that the California Veterinary Medical Association [sic] has no legal authority or standing to shut down providers of animal physical rehabilitation.
No. of Commenters: 1.

Comment 194: The proposed regulation would deny consumers the rights they currently have, place millions of jobs in peril, and endanger the animals who currently depend on non-veterinary wellness modalities.
No. of Commenters: 16.

Comment 195: Commenter suggests creating language that restricts medical diagnosis, surgery, use of needles and dispensing of controlled substances by anyone other than a veterinarian, and allow all other practitioners to have their clients sign a waiver before treatment. This would be reasonable and would not restrict the consumer's right to choose. It would also not endanger the California economy.
No. of Commenters: 15.

Comment 196: Right now, commenter can have her child, if commenter chooses, treated by a wellness modality. But, under the proposed regulation, she will not have the same right to choose to treat her animal?
No. of Commenters: 2.

Comment 197: The proposed regulations could have a negative impact on the creation of new businesses, new and old jobs, and a negative fiscal impact on present businesses.
No. of Commenters: 7.

Comment 198: Decreased availability and increased costs as a result of these regulations would very likely prevent consumers from pursuing AR for their animals, thus limiting comprehensive veterinary medical care.
No. of Commenters: 7.

Comment 199: Commenter strongly urges the Board to instead consider regulations such as those found in the Colorado practice act revisions of 2007. These regulations spell out the educational requirements for physical therapists to practice in collaboration with veterinarians to provide rehabilitation services to veterinary patients. To date there have been no complaints registered regarding the practice of PTs working under these regulations, and the veterinary rehabilitation industry is flourishing there.
No. of Commenters: 2.

Comment 200: There are very few veterinary schools in California as well as in the United States which already creates a shortage of veterinarians leading to access issues and a gap in care.
No. of Commenters: 2.

Comment 201: Please stop any additional legislation that would limit animal care and access. Allow the free market and excellent service dictate the need for animal rehabilitation and not the special interest lobby of the state veterinarians.
No. of Commenters: 1.

Comment 202: No one at commenter's veterinarians' practice is able to perform the functions of animal chiropractor, massage therapist, farrier, etc. Nor is anyone who could perform these functions employed in their practice.
No. of Commenters: 2.

Comment 203: Commenter expresses general opposition to the proposed regulation.
No. of Commenters: 3.

Comment 204: The language in the Notice that says "the Board is not aware of any cost impact that any other representative private person or business would necessarily incur in reasonable compliance with the proposed action" is false. There are hundreds, if not thousands, of individuals providing excellent wellness care and other sought-after therapies. For these individuals, Section 2038.5 will make their only source of income unlawful. The cost of seeking additional advanced degrees is prohibitive for them.
No. of Commenters: 2.

Comment 205: What happens if an emergency arises and the vet has to leave in the middle of treatment? Does the PT or RVT have to cease treatment as well? How is that to the animal's benefit?
No. of Commenters: 1.

Comment 206: Commenter's animals have benefitted tremendously from alternative modality professionals.
No. of Commenters: 3.

Comment 207: Commenter feels that licensed, certified and insured alternative modality practitioners should be allowed to provide autonomous services for animals.
No. of Commenters: 4.

Comment 208: The proposed animal rehabilitation regulation defines "Animal Rehabilitation" so over-broadly that the entire regulation becomes ludicrous. Under the proposed regulation, ordinary things such as massage, exercise, and swimming in warm water are being construed as requiring a veterinary degree. That is as nonsensical as requiring a physician to supervise back rubs.
No. of Commenters: 1.

Comment 209: The American Association of Rehabilitation Veterinarians (AARV) proposes that Section 2038.5 not be approved as written. The AARV Board recommends that the VMB consider implementing language that urges veterinarians to obtain rehabilitation certification and choose appropriately trained and certified PTs and RVTs for their animal rehabilitation team. The AARV supports animal rehabilitation teams composed of a referring veterinarian, certified rehabilitation veterinarian, physical therapist certified in veterinary rehabilitation, and credentialed veterinary technicians certified in veterinary rehabilitation. The AARV Model Standards for Veterinary Physical Rehabilitation Practice outline the composition of a veterinary medical team, recommended educational standards, and continuing education requirements, as well as the role each person plays within the team.
No. of Commenters: AARV Board of Directors.

Comment 210: There is no medically grounded rationale by which veterinarians must be involved in therapeutic massage or manual therapy. Requiring a DVM to supervise treatments in which he or she is untrained and unneeded, while the supervised party is licensed and certified, is arrogant overreaching.
No. of Commenters: 1.

Comment 211: Commenter's experience with alternative providers is that they were equally or more capable than veterinarians of giving exceptional treatment because of their focus in a specialty area.
No. of Commenters: 2.

Comment 212: Commenter runs an animal rescue organization, which is a great consumer of alternative medical treatments for animals. There would be a great economic impact on this

organization if services like swim therapy, acupuncture, and massage were only available with direct supervision of a veterinarian.
No. of Commenters: 1.

Comment 213: The education level of the AR practitioner should dictate the level of supervision that is needed.
No. of Commenters: 1.

Comment 214: Commenter sees "alternative" methods of AR as "complimentary" to veterinary medicine.
No. of Commenters: 4.

Comment 215: The regulation as written is too broad. The language could conceivably cover energy therapy, horse shoeing and hoof care, among others. Please stick to regulating the practice of veterinary medicine.
No. of Commenters: 2.

Comment 216: There is no exemption in the regulations for owners to work on their animals, or horse trainers.
No. of Commenters: 1.

Comment 217: There are professionals specially trained in canine fitness. "Active, passive" therapy and "prevention" captures too much. Vets, RVTs, and PTs are not trained in canine fitness. Commenter wants to adapt the human model.
No. of Commenters: 1.

Comment 218: "Hydrotherapy" is very vague. The underwater treadmill should be excluded, as it is exercise equipment.
No. of Commenters: 1.

Comment 219: RVTs have been practicing AR for a long time under indirect supervision, with no complaints.
No. of Commenters: 1.

Comment 220: Where are the provisions for animals that are in a shelter?
No. of Commenters: 1.

Comment 221: If the regulation language is adopted as is, a veterinarian will have to make house calls to house-bound animals for every therapy on the list.
No. of Commenters: 1.

Comment 222: Implying that veterinarians are trained and competent in chiropractic and other complimentary methods may constitute consumer fraud.
No. of Commenters: 1.

Comment 223: Invalidating or blatantly dismissing the education, expertise, and collaborative efforts of qualified (AR) practitioners with veterinarians is highly objectionable. Just as in the human medical field, veterinary practice and complementary health care are no longer mutually exclusive.
No. of Commenters: 1.

F. The parties to any proceeding pursuant to this rule shall be the Board and the petitioner. Any other person may seek leave of the Board to intervene in such a proceeding, and leave to intervene will be granted at the sole discretion of the Board. A petition to intervene shall set forth the same matters as are required by Section D of this Rule. Any reference to a "petitioner" in this rule also refers to any person who has been granted leave to intervene by the Board.

G. Any declaratory order or other order disposing of a petition pursuant to this rule shall constitute agency action subject to judicial review pursuant to the Colorado Administrative Procedures Act at § 24-4-106, C.R.S.

210. Requirements for Physical Therapists to Perform Physical Therapy on Animals

The purpose of this rule is to implement the requirements of § 12-41-103.6(2)(b)(II), C.R.S., regarding the authority of Physical Therapists to treat animals.

A. A Physical Therapist must have the knowledge, skill, ability and documented competency to perform an act that is within the scope of practice for Physical Therapists.

B. The Director shall maintain a data base of all Physical Therapists that are qualified pursuant to this rule to practice physical therapy on animals in this state.

C. All Physical Therapists that choose to practice physical therapy on animals shall provide the Board with such therapist's name, current address, education and qualifications to perform physical therapy on animals for inclusion in the data base referenced in part B of this rule. Information in the data base shall be open to public inspection at all times. Forms for Physical Therapists to provide such information shall be provided by the Board.

D. A Physical Therapist that desires to perform physical therapy on animals must comply with the following educational requirements:

1. Minimum of 80 contact hours over and above entry-level human physical therapy program course work for non-human animals, to include:

a. FOUNDATION/CLINICAL SCIENCES

i. Gross and applied non-human animal anatomy/physiology

ii. Wound healing and response of tissues to disuse and remobilization in the non-human animal

iii. Animal behavior

iv. Animal restraint

v. Zoonotic and infectious diseases

b. EXAMINATION/EVALUATION/PROGNOSIS/PT DIAGNOSIS

i. Medical and surgical management of orthopedic, neurological, critically injured, geriatric, arthritic and obese non-human animals

ii. Gait and other movement analyses

c. INTERVENTION/PLAN OF CARE/OUTCOME

i. Therapeutic exercise applied to non-human animals

ii. Therapeutic modalities

iii. Outcome assessment and documentation

d. CLINICAL EXPERIENCE

i. Documented successful completion of a minimum of 120 hours under the supervision of a licensed physical therapist listed in the data base maintained by DORA to perform physical therapy of animals or a licensed veterinarian.

E. Prior to performing physical therapy on an animal, the Physical Therapist shall obtain veterinary medical clearance of the animal by a Colorado-licensed Veterinarian and must document such clearance in the animal patient's record.

F. Veterinary medical clearance means:

1. The Veterinarian has previously examined the animal patient and has provided a differential diagnosis if appropriate.

2. The Veterinarian has cleared the animal for physical therapy.

G. It is expected that the Physical Therapist and the Veterinarian will continue professional collaboration as necessary for the well-being of the animal patient.

H. Once veterinary medical clearance has been received, the Physical Therapist is responsible for developing the plan of care for the animal patient's physical therapy.

I. The animal patient's record must include the verbal or written veterinary medical clearance. If verbal clearance is received, the Physical Therapist must document the verbal clearance in the animal patient's record, including the name of the veterinarian, date and time clearance was received.

J. Complaints against Physical Therapists alleging a violation related to animal physical therapy will be forwarded to the Colorado State Board of Veterinary Medicine for its review and advisory recommendation to the State Physical Therapy Board. The State Physical Therapy Board retains the final authority by statute for decisions related to discipline of any physical therapist.

211. Requirements for Physical Therapists to Perform Dry Needling

A. Dry needling (also known as Trigger Point Dry Needling) is a physical intervention that uses a filiform needle to stimulate trigger points, diagnose and treat neuromuscular pain and functional movement deficits; is based upon Western medical concepts; requires an examination and diagnosis, and treats specific anatomic entities selected according to physical signs. Dry needling does not include the stimulation of auricular or distal points.

B. Dry needling as defined pursuant to this rule is within the scope of practice of physical therapy.

[Rev. 1/2/2015 3:32:23 PM]

This chapter of NAC has changes which have been adopted but have not been codified; you can see those changes by viewing the following regulation(s) on the Nevada Register of Administrative Regulations: R063-13

[NAC-638 Revised Date: 11-13]

CHAPTER 638 - VETERINARIANS

GENERAL PROVISIONS

NAC 638.001 Definitions. (NRS 638.070) As used in this chapter, unless the context otherwise requires, the words and terms defined in NAC 638.005 to 638.0185, inclusive, have the meanings ascribed to them in those sections.

(Added to NAC by Bd. of Veterinary Med. Exam'rs, eff. 3-19-86; A 7-7-94; R069-01, 10-12-2001; R041-02, 8-7-2003; R074-06, 6-28-2006)

NAC 638.005 "Board" defined. (NRS 638.070) "Board" means the Nevada State Board of Veterinary Medical Examiners.

(Added to NAC by Bd. of Veterinary Med. Exam'rs, eff. 3-19-86)

NAC 638.006 "Direct supervision" defined. (NRS 638.070) "Direct supervision" means that the supervising veterinarian or licensed veterinary technician is on the premises with or in the same area as the animal and the person treating the animal and is quickly and easily available.

(Added to NAC by Bd. of Veterinary Med. Exam'rs, eff. 3-19-86; A by R074-06, 6-28-2006)

NAC 638.007 "Emergency" defined. (NRS 638.070) "Emergency" means an animal has a condition which threatens its life and immediate treatment is necessary to sustain life.

(Added to NAC by Bd. of Veterinary Med. Exam'rs, eff. 3-19-86)

NAC 638.009 "Immediate supervision" defined. (NRS 638.070) "Immediate supervision" means the supervising veterinarian or licensed veterinary technician is in the immediate area and within visual and audible range of the animal and the person treating the animal.

(Added to NAC by Bd. of Veterinary Med. Exam'rs, eff. 3-19-86; A 7-7-94; 11-26-96; R069-01, 10-12-2001; R074-06, 6-28-2006)

NAC 638.011 "Indirect supervision" defined. (NRS 638.070) "Indirect supervision" means the supervising veterinarian is not on the premises with the animal and the person treating the animal, but has given written or oral instructions for treatment of the animal.

(Added to NAC by Bd. of Veterinary Med. Exam'rs, eff. 3-19-86; A 7-7-94; R074-06, 6-28-2006)

NAC 638.0115 "Licensed veterinarian" defined. (NRS 638.070) "Licensed veterinarian" has the meaning ascribed to it in NRS 638.007.

(Added to NAC by Bd. of Veterinary Med. Exam'rs by R074-06, eff. 6-28-2006)

(Added to NAC by Bd. of Veterinary Med. Exam'rs by R220-97, eff. 8-5-98; A by R069-01, 10-12-2001)

NAC 638.715 Requirements for performance of aseptic surgery. (NRS 638.070)
1. A veterinary facility which provides aseptic surgical services must reserve a room, separate and distinct from all other rooms, for aseptic surgical procedures.
2. When performing aseptic surgery:
(a) Each member of a surgical team shall wear the appropriate sanitary cap and sanitary mask;
(b) Any instrument used to perform aseptic surgery must be sterilized; and
(c) Each member of the surgical team who will be handling an instrument or touching the surgical site shall wear a sterilized surgical gown and sterilized gloves.
3. As used in this section, "aseptic surgery" means surgery performed under sterilized conditions to prevent the introduction of infectious microorganisms.
(Added to NAC by Bd. of Veterinary Med. Exam'rs by R075-06, eff. 11-13-2006)

NAC 638.720 Requirements for performance of clean surgery. (NRS 638.070)
1. When performing clean surgery:
(a) Any instrument used to perform clean surgery must be sterilized; and
(b) Each member of the surgical team who will be handling an instrument or touching the surgical site shall wear clean attire and gloves.
2. As used in this section, "clean surgery" means a surgical procedure which does not warrant the use of aseptic surgical procedures and which is conducted in a manner that is consistent with the prevailing standards of acceptable veterinary medical practice.
(Added to NAC by Bd. of Veterinary Med. Exam'rs by R075-06, eff. 11-13-2006)

NAC 638.725 Disposal of hypodermic devices. (NRS 638.070) Any person who is authorized to use hypodermic devices pursuant to the provisions of this chapter shall dispose of each hypodermic device he or she uses by placing the device directly into a rigid, labeled, leak-proof, puncture-resistant container. Needles must not be purposely bent or broken by hand or recapped.
(Added to NAC by Bd. of Veterinary Med. Exam'rs, eff. 7-7-94)—(Substituted in revision for NAC 638.0627)

ANIMAL PHYSICAL THERAPY

NAC 638.750 "Animal physical therapy" defined. (NRS 638.070) As used in NAC 638.750 to 638.790, inclusive, "animal physical therapy" means the rehabilitation of injuries in a nonhuman animal through the use of the following techniques, but does not include animal chiropractic:
1. Stretching;
2. Massage therapy;
3. Rehabilitative exercise;
4. Hydrotherapy;
5. Application of heat or cold; and
6. Stimulation by the use of:
(a) Low-level lasers;
(b) Electrical sources;
(c) Magnetic fields; or
(d) Noninvasive therapeutic ultrasound.
(Added to NAC by Bd. of Veterinary Med. Exam'rs by R009-04, eff. 4-26-2004; A by R091-06, 11-13-2006)

NAC 638.760 Requirements to practice; application for certificate of registration; fee. (NRS 638.070)
1. A person shall not practice animal physical therapy in this State unless he or she is:
(a) A veterinarian;
(b) A licensed veterinary technician who complies with the provisions of NAC 638.053; or
(c) A physical therapist who has obtained a certificate of registration pursuant to this section and complies with the provisions of NAC 638.780.

2. A physical therapist who desires to secure a certificate of registration to practice animal physical therapy in this State must make written application to the Board.

3. The application must be on a form provided by the Board, include any information required by the Board and be accompanied by satisfactory proof that the applicant:

(a) Is of good moral character;

(b) Has been an active licensed physical therapist in this State for at least 1 year;

(c) Is in good standing with the State Board of Physical Therapy Examiners;

(d) Has successfully completed at least 100 hours of instruction or course work, or a combination of both, in the area of animal physical therapy, which must include, without limitation, assessment and planning of treatment, behavior, biomechanics, common orthopedic and neurological conditions, comparative anatomy, neurology, and therapeutic modalities and exercises; and

(e) Has completed at least 125 hours of supervised clinical experience in animal physical therapy with a licensed veterinarian.

4. The application must be signed by the applicant and notarized.

5. Except as otherwise provided in NAC 638.790, upon receipt of the application and information required by subsection 3 and payment of the fee required pursuant to NAC 638.035, the Board will issue to the physical therapist a certificate of registration.

(Added to NAC by Bd. of Veterinary Med. Exam'rs by R009-04, eff. 4-26-2004; A by R075-06, 11-13-2006; R072-09, 4-20-2010)

NAC 638.770 Expiration and renewal of certificate; fee. (NRS 638.070)

1. Each certificate of registration issued pursuant to NAC 638.760 or renewed pursuant to this section expires on January 1 of each year.

2. Each application for renewal of a certificate of registration must be:

(a) Submitted in the form established by the Board;

(b) Signed by the physical therapist;

(c) Accompanied by proof that the physical therapist completed, during the 12-month period immediately preceding the beginning of the new registration year, at least 5 hours of continuing education in animal physical therapy approved by the Board; and

(d) Accompanied by proof that his or her license as a physical therapist in this State is active and that he or she is in good standing with the State Board of Physical Therapy Examiners.

3. A physical therapist who fails to renew his or her certificate of registration before it expires forfeits the certificate of registration.

4. Except as otherwise provided in NAC 638.790, upon receipt of the application for renewal and the information required by subsection 2 and payment of the renewal fee required pursuant to NAC 638.035, the Board will renew the certificate of registration of the physical therapist.

(Added to NAC by Bd. of Veterinary Med. Exam'rs by R009-04, eff. 4-26-2004; A by R072-09, 4-20-2010)

NAC 638.780 Standards of practice for physical therapist holding certificate; maintenance of records. (NRS 638.070)

1. A physical therapist who has been issued a certificate of registration pursuant to NAC 638.760 may practice animal physical therapy only:

(a) Under the direction of a veterinarian licensed in this State who has established a valid veterinarian-client-patient relationship concerning the animal receiving the animal physical therapy before the animal physical therapy is performed; and

(b) If the physical therapist assumes individual liability for the quality of the animal physical therapy performed.

2. The veterinarian under whose direction the physical therapist performs the animal physical therapy:

(a) Is not required to supervise the physical therapist during the animal physical therapy.

(b) Is not liable for the acts or omissions of the physical therapist who performs the animal physical therapy.

3. Each physical therapist who has been issued a certificate of registration shall:

(a) Maintain in this State for at least 4 years a separate written medical record of each animal receiving animal physical therapy from the physical therapist.

(b) Within 48 hours after the initial visit with the animal, mail or transmit by facsimile machine a complete copy of the medical record to the veterinarian under whose direction the physical therapist performs the animal physical therapy.

(c) Within 48 hours after each subsequent visit with the animal, mail or transmit by facsimile machine a progress report to the veterinarian under whose direction the physical therapist performs the animal physical therapy.

4. The veterinarian shall include the copy of the medical record received pursuant to subsection 3 in the medical record required pursuant to NAC 638.0475. The written medical record must include, without limitation:

(a) The name, address and telephone number of the owner of the animal;

(b) The name or identifying number, or both, of the animal;

(c) The age, sex and breed of the animal;

(d) The dates of care, custody or treatment of the animal;

(e) The results of a basic rehabilitation examination related to physical therapy;

(f) The diagnosis and treatment plan related to physical therapy recommended by the physical therapist for the animal; and

(g) The progress and disposition of the case.

(Added to NAC by Bd. of Veterinary Med. Exam'rs by R009-04, eff. 4-26-2004)

NAC 638.790 Disciplinary action. (NRS 638.070)

1. A violation of a provision of chapter 638 or 640 of NRS or a regulation adopted by the State Board of Physical Therapy Examiners or the Nevada State Board of Veterinary Medical Examiners is a ground for disciplinary action.

2. If the Nevada State Board of Veterinary Medical Examiners determines that an applicant for a certificate of registration pursuant to NAC 638.760 or a physical therapist who has been issued a certificate of registration pursuant to NAC 638.760 has committed any act which is a ground for disciplinary action, the Board may:

(a) Refuse to issue a certificate of registration;

(b) Refuse to renew a certificate of registration;

(c) Revoke a certificate of registration;

(d) Suspend a certificate of registration for a definite period or until further order of the Board;

(e) Impose a fine in an amount not to exceed $10,000 for each act that constitutes a ground for disciplinary action;

(f) Place a physical therapist who has been issued a certificate of registration on probation subject to any reasonable conditions imposed by the Board, including, without limitation, requiring courses in continuing education or a periodic or continuous review of his or her animal physical therapy practice;

(g) Administer a public reprimand;

(h) Require the physical therapist who has been issued a certificate of registration to take a competency examination or a mental or physical examination; and

(i) Require the physical therapist who has been issued a certificate of registration to pay all costs, including, without limitation, attorney's fees, incurred by the Board in taking disciplinary action against him or her.

(Added to NAC by Bd. of Veterinary Med. Exam'rs by R009-04, eff. 4-26-2004)

ANIMAL CHIROPRACTIC

NAC 638.800 "Animal chiropractic" defined. (NRS 638.070) As used in NAC 638.800 to 638.840, inclusive, "animal chiropractic" means the examination and treatment of a nonhuman animal through the manipulation and adjustment of specific joints and cranial sutures of the animal.

(Added to NAC by Bd. of Veterinary Med. Exam'rs by R115-99, eff. 12-7-99; A by R110-02, 11-6-2002)

NAC 638.810 Requirements to practice; application for registration certificate; fee. (NRS 638.070)

1. A person shall not practice animal chiropractic in this State unless he or she is:

(a) A veterinarian; or

(b) A chiropractor who has obtained a registration certificate pursuant to this section and complies with the provisions of NAC 638.830.

2. A chiropractor who desires to secure a registration certificate to practice animal chiropractic in this State must make written application to the Board.

3. The application must be on a form provided by the Board, include any information required by the Board and be accompanied by satisfactory proof that the applicant:

(a) Is of good moral character;

(b) Has been an active licensed chiropractor in this State for at least 1 year;

(c) Is in good standing with the Chiropractic Physicians' Board of Nevada; and

(d) Is certified by the American Veterinary Chiropractic Association.

4. The application must be signed by the applicant and notarized.

5. Except as otherwise provided in NAC 638.840, upon receipt of the application and information required by subsection 3 and payment of the fee required pursuant to NAC 638.035, the Board will issue to the chiropractor a certificate of registration.

(Added to NAC by Bd. of Veterinary Med. Exam'rs by R115-99, eff. 12-7-99; A by R110-02, 11-6-2002; R072-09, 4-20-2010)

NAC 638.820 Expiration and renewal of certificate; fee. (NRS 638.070)

1. Each certificate of registration issued pursuant to NAC 638.810 or renewed pursuant to this section expires on January 1 of each year.

2. Each application for renewal of a certificate of registration must be:

(a) Submitted in the form established by the Board;

(b) Signed by the chiropractor;

(c) Accompanied by proof that the chiropractor completed, during the 12-month period immediately preceding the beginning of the new registration year, at least 15 hours of continuing education in animal chiropractic approved by the Board; and

(d) Accompanied by proof that his or her license as a chiropractor in this State is active and that he or she is in good standing with the Chiropractic Physicians' Board of Nevada.

3. A chiropractor who fails to renew his or her certificate of registration before it expires forfeits his or her certificate of registration.

4. Except as otherwise provided in NAC 638.840, upon receipt of the application for renewal and information required by subsection 2 and payment of the fee required pursuant to NAC 638.035, the Board will renew the certificate of registration of the chiropractor.

(Added to NAC by Bd. of Veterinary Med. Exam'rs by R115-99, eff. 12-7-99; A by R059-01, 10-12-2001; R110-02, 11-6-2002; R091-06, 11-13-2006; R072-09, 4-20-2010)

NAC 638.830 Standards of practice for chiropractor holding certificate; maintenance of records. (NRS 638.070)

1. A chiropractor who has been issued a certificate of registration pursuant to NAC 638.810 may practice animal chiropractic only:

(a) Under the direction of a veterinarian licensed in this State who has established a valid veterinarian-client-patient relationship concerning the animal receiving the animal chiropractic before the animal chiropractic is performed; and

(b) If the chiropractor assumes individual liability for the quality of the animal chiropractic performed.

2. The veterinarian under whose direction the chiropractor performs the animal chiropractic:

(a) Is not required to supervise the chiropractor during the animal chiropractic.

(b) Is not liable for the acts or omissions of the chiropractor who performs animal chiropractic.

3. Each chiropractor who has been issued a certificate of registration shall:

(a) Maintain in this State for at least 4 years a separate written medical record of each animal receiving animal chiropractic.

(b) Within 48 hours after the initial visit with the animal, mail or transmit by facsimile machine a complete copy of the medical record to the veterinarian under whose direction the chiropractor performs the animal chiropractic.

(c) Within 48 hours after each subsequent visit with the animal, mail or transmit by facsimile machine a progress report to the veterinarian under whose direction the chiropractor performs the animal chiropractic.

4. The veterinarian shall include the copy of the medical record received pursuant to subsection 3 in the medical record required pursuant to NAC 638.0475. The written medical record must include, without limitation:

(a) The name, address and telephone number of the owner of the animal;
(b) The name or identifying number, or both, of the animal;
(c) The age, sex and breed of the animal;
(d) The dates of care, custody or treatment of the animal;
(e) The results of a basic physical examination related to musculoskeletal manipulation;
(f) The diagnosis and treatment plan related to musculoskeletal manipulation recommended by the chiropractor for the animal; and
(g) The progress and disposition of the case.

(Added to NAC by Bd. of Veterinary Med. Exam'rs by R115-99, eff. 12-7-99; A by R059-01, 10-12-2001; R110-02, 11-6-2002)

NAC 638.840 Disciplinary action. (NRS 638.070)

1. A violation of a provision of chapter 634 or 638 of NRS or a regulation adopted by the Chiropractic Physicians' Board of Nevada or the Nevada State Board of Veterinary Medical Examiners is a ground for disciplinary action.

2. If the Nevada State Board of Veterinary Medical Examiners determines that an applicant for a certificate of registration pursuant to NAC 638.810 or a person who has been issued a certificate of registration pursuant to NAC 638.810 has committed any act which is a ground for disciplinary action, the Board may:

(a) Refuse to issue a certificate of registration;
(b) Refuse to renew a certificate of registration;
(c) Revoke a certificate of registration;
(d) Suspend a certificate of registration for a definite period or until further order of the Board;
(e) Impose a fine in an amount not to exceed $10,000 for each act that constitutes a ground for disciplinary action;
(f) Place a person who has been issued a certificate of registration on probation subject to any reasonable conditions imposed by the Board, including, without limitation, requiring courses in continuing education or a periodic or continuous review of his or her animal chiropractic practice;
(g) Administer a public reprimand;
(h) Require the person who has been issued a certificate of registration to take a competency examination or a mental or physical examination; and
(i) Require the person who has been issued a certificate of registration to pay all costs, including, without limitation, attorney's fees, incurred by the Board in taking disciplinary action against him or her.

(Added to NAC by Bd. of Veterinary Med. Exam'rs by R115-99, eff. 12-7-99; A by R059-01, 10-12-2001; R110-02, 11-6-2002)

MISCELLANEOUS PROVISIONS

NAC 638.850 Inspection of veterinary facilities and vaccination clinics: Authorization and procedure. (NRS 638.070, 638.077, 638.132)

1. An inspector approved by the Board may conduct inspections of veterinary facilities and vaccination clinics.

2. Each inspector shall evaluate a veterinary facility or vaccination clinic for compliance with the practice of veterinary medicine pursuant to the provisions of this chapter and chapter 638 of NRS.

3. Each inspector shall:

(a) During an inspection, use a form for inspection approved by the Board. The form must include:
(1) A description of the nature of any violation;
(2) The specifications for any changes required to be made to correct the violation; and
(3) The time allowed to correct the violation.

UT
VMB
Practice Act

West's Utah Code Annotated
Title 58. Occupations and Professions
Chapter 28. Veterinary Practice Act (Refs & Annos)
Part 3. Licensing

U.C.A. 1953 § 58-28-307

§ 58-28-307. Exemptions from chapter

Currentness

In addition to the exemptions from licensure in Section 58-1-307 this chapter does not apply to:

(1) any person who practices veterinary medicine, surgery, or dentistry upon any animal owned by him, and the employee of that person when the practice is upon an animal owned by his employer, and incidental to his employment, except:

(a) this exemption does not apply to any person, or his employee, when the ownership of an animal was acquired for the purpose of circumventing this chapter; and

(b) this exemption does not apply to the administration, dispensing, or prescribing of a prescription drug, or nonprescription drug intended for off label use, unless the administration, dispensing, or prescribing of the drug is obtained through an existing veterinarian-patient relationship;

(2) any person who as a student at a veterinary college approved by the board engages in the practice of veterinary medicine, surgery, and dentistry as part of his academic training and under the direct supervision and control of a licensed veterinarian, if that practice is during the last two years of the college course of instruction and does not exceed an 18-month duration;

(3) a veterinarian who is an officer or employee of the government of the United States, or the state, or its political subdivisions, and technicians under his supervision, while engaged in the practice of veterinary medicine, surgery, or dentistry for that government;

(4) any person while engaged in the vaccination of poultry, pullorum testing, typhoid testing of poultry, and related poultry disease control activity;

(5) any person who is engaged in bona fide and legitimate medical, dental, pharmaceutical, or other scientific research, if that practice of veterinary medicine, surgery, or dentistry is directly related to, and a necessary part of, that research;

(6) veterinarians licensed under the laws of another state rendering professional services in association with licensed veterinarians of this state for a period not to exceed 90 days;

(7) registered pharmacists of this state engaged in the sale of veterinary supplies, instruments, and medicines, if the sale is at his regular place of business;

(8) any person in this state engaged in the sale of veterinary supplies, instruments, and medicines, except prescription drugs which must be sold in compliance with state and federal regulations, if the supplies, instruments, and medicines are sold in original packages bearing adequate identification and directions for application and administration and the sale is made in the regular course of, and at the regular place of business;

(9) any person rendering emergency first aid to animals in those areas where a licensed veterinarian is not available, and if suspicious reportable diseases are reported immediately to the state veterinarian;

(10) any person performing or teaching nonsurgical bovine artificial insemination;

(11) any person affiliated with an institution of higher education who teaches nonsurgical bovine embryo transfer or any technician trained by or approved by an institution of higher education who performs nonsurgical bovine embryo transfer, but only if any prescription drug used in the procedure is prescribed and administered under the direction of a veterinarian licensed to practice in Utah;

(12)(a) upon written referral by a licensed veterinarian, the practice of animal chiropractic by a chiropractic physician licensed under Chapter 73, Chiropractic Physician Practice Act, who has completed an animal chiropractic course approved by the American Veterinary Chiropractic Association or the division;

(b) upon written referral by a licensed veterinarian, the practice of animal physical **therapy** by a physical therapist licensed under Chapter 24b, Physical **Therapy** Practice Act, who has completed at least 100 hours of animal physical **therapy** training, including quadruped anatomy and hands-on training, approved by the division;

(c) upon written referral by a licensed veterinarian, the practice of animal massage **therapy** by a massage therapist licensed under Chapter 47b, Massage **Therapy** Practice Act, who has completed at least 60 hours of animal massage **therapy** training, including quadruped anatomy and hands-on training, approved by the division; and

(d) upon written referral by a licensed veterinarian, the practice of acupuncture by an acupuncturist licensed under Chapter

72, Acupuncture Licensing Act, who has completed a course of study on animal acupuncture approved by the division;

(13) unlicensed assistive personnel performing duties appropriately delegated to the unlicensed assistive personnel in accordance with Section 58-28-502;

(14) an animal shelter employee who is:

(a)(i) acting under the indirect supervision of a licensed veterinarian; and

(ii) performing animal euthanasia in the course and scope of employment; and

(b) acting under the indirect supervision of a veterinarian who is under contract with the animal shelter, administering a rabies vaccine to a shelter animal in accordance with the Compendium of Animal Rabies Prevention and Control; and

(15) an individual providing appropriate training for animals; however, this exception does not include diagnosing any medical condition, or prescribing or dispensing any prescription drugs or therapeutics.

Credits

Laws 2006, c. 109, § 11, eff. May 1, 2006; Laws 2009, c. 220, § 21, eff. July 1, 2009; Laws 2013, c. 278, § 36, eff. May 14, 2013; Laws 2014, c. 191, § 2, eff. May 13, 2014.

Editors' Notes

CROSS REFERENCES

Animal physical **therapy**, see § 58-24b-405.
Practice of massage **therapy**, definitions, see § 58-47b-102.

U.C.A. 1953 § 58-28-307, UT ST § 58-28-307
Current through 2015 First Special Session

End of Document

West's Utah Code Annotated
Title 58. Occupations and Professions
Chapter 28. Veterinary Practice Act (Refs & Annos)
Part 1. General Provisions

U.C.A. 1953 § 58-28-102

§ 58-28-102. Definitions

Currentness

In addition to the definitions in Section 58-1-102, as used in this chapter:

(1) "Abandonment" means to forsake entirely or to refuse to provide care and support for an animal placed in the custody of a licensed veterinarian.

(2) "Administer" means:

(a) the direct application by a person of a prescription drug or device by injection, inhalation, ingestion, or by any other means, to the body of an animal that is a patient or is a research subject; or

(b) a veterinarian providing to the owner or caretaker of an animal a prescription drug for application by injection, inhalation, ingestion, or any other means to the body of the animal by the owner or caretaker in accordance with the veterinarian's written directions.

(3) "Animal" means any animal other than a human.

(4) "AVMA" means American Veterinary Medical Association.

(5) "Board" means the Veterinary Board established in Section 58-28-201.

(6) "Client" means the patient's owner, the owner's agent, or other person responsible for the patient.

(7) "Direct supervision" means a veterinarian licensed under this chapter is present and available for face-to-face contact with the patient and person being supervised, at the time the patient is receiving veterinary care.

(8) "Extra-label use" means actual use or intended use of a drug in an animal in a manner that is not in accordance with approved labeling.

(9) "Immediate supervision" means the veterinarian licensed under this chapter is present with the individual being supervised, while the individual is performing the delegated tasks.

(10) "Indirect supervision" means a veterinarian licensed under this chapter:

(a) has given either written or verbal instructions for veterinary care of a patient to the person being supervised; and

(b) is available to the person being supervised by telephone or other electronic means of communication during the period of time in which the veterinary care is given to the patient.

(11) "Practice of veterinary medicine, surgery, and dentistry" means to:

(a) diagnose, prognose, or treat any disease, defect, deformity, wound, injury, or physical condition of any animal;

(b) administer, prescribe or dispense any drug, medicine, treatment, method, or practice, perform any operation or manipulation, apply any apparatus or appliance for the cure, relief, or correction of any animal disease, deformity, defect, wound, or injury, or otherwise practice any veterinary medicine, dentistry, or surgery on any animal;

(c) represent by verbal or written claim, sign, word, title, letterhead, card, or any other manner that one is a licensed veterinarian or qualified to practice veterinary medicine, surgery, or dentistry;

(d) hold oneself out as able to practice veterinary medicine, surgery, or dentistry;

(e) solicit, sell, or furnish any parenterally administered animal disease cures, preventions, or treatments, with or without the necessary instruments for the administration of them, or any and all worm and other internal parasitic remedies, upon any agreement, express or implied, to administer these cures, preventions, treatments, or remedies; or

(f) assume or use the title or designation, "veterinary," "veterinarian," "animal doctor," "animal surgeon," or any other title, designation, words, letters, abbreviations, sign, card, or device tending to indicate that such person is qualified to practice veterinary medicine, surgery, or dentistry.

(12) "Unlawful conduct" is defined in Sections 58-1-501 and 58-28-501.

(13) "Unlicensed assistive personnel":

(a) means any unlicensed person, regardless of title, to whom tasks are delegated by a veterinarian licensed under this chapter as permitted by administrative rule and in accordance with the standards of the profession; and

(b) includes:

(i) a veterinary assistant, if working under immediate supervision;

(ii) a veterinary technician who:

(A) has graduated from a program of veterinary technology accredited by the AVMA that is at least a two-year program; and

(B) who is working under direct supervision; and

(iii) a veterinary technologist who:

(A) has graduated from a four-year program of veterinary technology accredited by the AVMA; and

(B) is working under indirect supervision.

(14) "Unprofessional conduct" is as defined in Sections 58-1-501 and 58-28-502 and may be further defined by rule.

(15) "Veterinarian-client-patient relationship" means:

(a) a veterinarian licensed under this chapter has assumed responsibility for making clinical judgements regarding the health of an animal and the need for medical treatment of an animal, and the client has agreed to follow the veterinarian's instructions;

(b) the veterinarian has sufficient knowledge of the animal to initiate at least a general or preliminary diagnosis of the medical condition of the animal, including knowledge of the keeping and care of the animal as a result of recent personal examination of the animal or by medically appropriate visits to the premises where the animal is housed; and

(c) the veterinarian has arranged for emergency coverage for follow-up evaluation in the event of adverse reaction or the failure of the treatment regimen.

Credits

Laws 2006, c. 109, § 3, eff. May 1, 2006; Laws 2010, c. 189, § 1, eff. May 11, 2010.

U.C.A. 1953 § 58-28-102, UT ST § 58-28-102
Current through 2015 First Special Session

End of Document

UT PT practice Act

West's Utah Code Annotated
Title 58. Occupations and Professions
Chapter 24B. Physical Therapy Practice Act (Refs & Annos)
Part 1. General Provisions

U.C.A. 1953 § 58-24b-102

§ 58-24b-102. Definitions

Currentness

As used in this chapter:

(1) "**Animal** physical therapy" means practicing physical therapy or physiotherapy on an **animal**.

(2) "Board" means the Utah Physical Therapy Licensing Board, created in Section 58-24b-201.

(3) "Consultation by telecommunication" means the provision of expert or professional advice by a physical therapist who is licensed outside of Utah to a licensed physical therapist or a health care provider by telecommunication or electronic communication.

(4) "General supervision" means supervision and oversight of a person by a licensed physical therapist when the licensed physical therapist is immediately available in person, by telephone, or by electronic communication to assist the person.

(5) "Licensed physical therapist" means a person licensed under this chapter to engage in the practice of physical therapy.

(6) "Licensed physical therapist assistant" means a person licensed under this chapter to engage in the practice of physical therapy, subject to the provisions of Subsection 58-24b-401(2)(a).

(7) "Licensing examination" means a nationally recognized physical therapy examination that is approved by the division, in consultation with the board.

(8) "On-site supervision" means supervision and oversight of a person by a licensed physical therapist or a licensed physical therapist assistant when the licensed physical therapist or licensed physical therapist assistant is:

(a) continuously present at the facility where the person is providing services;

(b) immediately available to assist the person; and

(c) regularly involved in the services being provided by the person.

(9) "Physical impairment" means:

(a) a mechanical impairment;

(b) a physiological impairment;

(c) a developmental impairment;

(d) a functional limitation;

(e) a disability;

(f) a mobility impairment; or

(g) a bodily malfunction.

(10)(a) "Physical therapy" or "physiotherapy" means:

(i) examining, evaluating, and testing an individual who has a physical impairment or injury;

(ii) identifying or labeling a physical impairment or injury;

(iii) formulating a therapeutic intervention plan for the treatment of a physical impairment, injury, or pain;

(iv) assessing the ongoing effects of therapeutic intervention for the treatment of a physical impairment or injury;

(v) treating or alleviating a physical impairment by designing, modifying, or implementing a therapeutic intervention;

(vi) reducing the risk of an injury or physical impairment;

(vii) providing instruction on the use of physical measures, activities, or devices for preventative and therapeutic purposes;

(viii) promoting and maintaining health and fitness;

(ix) the administration of a prescription drug pursuant to Section 58-24b-403;

(x) subject to Subsection 58-28-307(12)(b), engaging in the functions described in Subsections (10)(a)(i) through (ix) in relation to an **animal**, in accordance with the requirements of Section 58-24b-405; and

(xi) engaging in administration, consultation, education, and research relating to the practices described in this Subsection (10)(a).

(b) "Physical therapy" or "physiotherapy" does not include:

(i) diagnosing disease;

(ii) performing surgery;

(iii) performing acupuncture;

(iv) taking x-rays; or

(v) prescribing or dispensing a drug, as defined in Section 58-37-2.

(11) "Physical therapy aide" means a person who:

(a) is trained, on-the-job, by a licensed physical therapist; and

(b) provides routine assistance to a licensed physical therapist or licensed physical therapist assistant, while the licensed physical therapist or licensed physical therapist assistant practices physical therapy, within the scope of the licensed physical therapist's or licensed physical therapist assistant's license.

(12) "Recognized accreditation agency" means an accreditation agency that:

(a) grants accreditation, nationally, in the United States of America; and

(b) is approved by the division, in consultation with the board.

(13)(a) "Testing" means a standard method or technique used to gather data regarding a patient that is generally and nationally accepted by physical therapists for the practice of physical therapy.

(b) "Testing" includes measurement or evaluation of:

(i) muscle strength, force, endurance, or tone;

(ii) cardiovascular fitness;

(iii) physical work capacity;

(iv) joint motion, mobility, or stability;

(v) reflexes or autonomic reactions;

(vi) movement skill or accuracy;

(vii) sensation;

(viii) perception;

(ix) peripheral nerve integrity;

(x) locomotor skills, stability, and endurance;

(xi) the fit, function, and comfort of prosthetic, orthotic, or other assistive devices;

(xii) posture;

(xiii) body mechanics;

(xiv) limb length, circumference, and volume;

(xv) thoracic excursion and breathing patterns;

(xvi) activities of daily living related to physical movement and mobility;

(xvii) functioning in the physical environment at home or work, as it relates to physical movement and mobility; and

(xviii) neural muscular responses.

(14)(a) "Trigger point dry needling" means the stimulation of a trigger point using a dry needle to treat neuromuscular pain and functional movement deficits.

(b) "Trigger point dry needling" does not include the stimulation of auricular or distal points.

(15) "Therapeutic intervention" includes:

(a) therapeutic exercise, with or without the use of a device;

(b) functional training in self-care, as it relates to physical movement and mobility;

(c) community or work integration, as it relates to physical movement and mobility;

(d) manual therapy, including:

(i) soft tissue mobilization;

(ii) therapeutic massage; or

(iii) joint mobilization, as defined by the division, by rule;

(e) prescribing, applying, or fabricating an assistive, adaptive, orthotic, prosthetic, protective, or supportive device;

(f) airway clearance techniques, including postural drainage;

(g) integumentary protection and repair techniques;

(h) wound debridement, cleansing, and dressing;

(i) the application of a physical agent, including:

(i) light;

(ii) heat;

(iii) cold;

(iv) water;

(v) air;

(vi) sound;

(vii) compression;

(viii) electricity; and

(ix) electromagnetic radiation;

(j) mechanical or electrotherapeutic modalities;

(k) positioning;

(*l*) instructing or training a patient in locomotion or other functional activities, with or without an assistive device;

(m) manual or mechanical traction;

(n) correction of posture, body mechanics, or gait; and

(o) trigger point dry needling, under the conditions described in Section 58-24b-505.

Credits

Laws 2009, c. 220, § 5, eff. July 1, 2009; Laws 2012, c. 117, § 1, eff. May 8, 2012; Laws 2014, c. 354, § 1, eff. May 13, 2014.

U.C.A. 1953 § 58-24b-102, UT ST § 58-24b-102
Current through 2015 First Special Session

End of Document

West's Utah Code Annotated
Title 58. Occupations and Professions
Chapter 24B. Physical Therapy Practice Act (Refs & Annos)
Part 4. Practice of Physical Therapy

U.C.A. 1953 § 58-24b-405

§ 58-24b-405. Animal physical therapy

Currentness

(1) Subject to Subsection 58-28-307 (12)(b), a licensed physical therapist may practice **animal** physical therapy if the licensed physical therapist completes at least 100 hours of **animal** physical therapy training and education, which shall include:

(a) 50 hours of on-the-job training under the supervision of a licensed veterinarian;

(b) completion of a quadruped anatomy course; and

(c) continuing education for the required hours remaining.

(2) Subject to Subsection 58-28-307(12)(b), a licensed physical therapist assistant may practice **animal** physical therapy, within the scope of the licensed physical therapist assistant's practice, if the licensed physical therapist assistant:

(a) is under the on-site supervision or general supervision of a physical therapist who has complied with the requirements of Subsection (1); and

(b) completes at least 100 hours of **animal** physical therapy training and education, which shall include:

(i) 50 hours of on-the-job training under the supervision of a licensed veterinarian;

(ii) completion of a quadruped anatomy course; and

(iii) continuing education for the required hours remaining.

Credits

Laws 2009, c. 220, § 16, eff. July 1, 2009.

U.C.A. 1953 § 58-24b-405, UT ST § 58-24b-405
Current through 2015 First Special Session

End of Document

West's Utah Code Annotated
Title 58. Occupations and Professions
Chapter 24B. Physical Therapy Practice Act (Refs & Annos)
Part 3. Licensing

U.C.A. 1953 § 58-24b-304

§ 58-24b-304. Exemptions from licensure

Currentness

(1) In addition to the exemptions from licensure described in Section 58-1-307, as modified by Subsection 58-24b-302(5), a person may engage in acts that constitute the practice of physical therapy without a license issued under this chapter if:

(a) the person is licensed under another law of the state to engage in acts that constitute the practice of physical therapy if that person does not:

(i) claim to be a physical therapist;

(ii) claim to be a provider of any type of physical therapy that is outside of the scope of practice of the license that is issued to the person; or

(iii) engage in any acts that constitute the practice of physical therapy that are outside of the scope of practice of the license that is issued to the person;

(b) the person practices physical therapy, under federal law, in:

(i) the United States armed services;

(ii) the United States Public Health Service; or

(iii) the Veteran's Administration;

(c) the person is:

(i) licensed as a physical therapist in:

(A) a state, district, or territory of the United States, other than Utah; or

(B) a country other than the United States; and

(ii)(A) teaching, demonstrating, or providing physical therapy in connection with an educational seminar, if the person engages in this conduct in Utah no more than 60 days per calendar year;

(B) practicing physical therapy directly related to the person's employment with, or contract with, an established athletic team, athletic organization, or performing arts company that plays, practices, competes, or performs in Utah no more than 60 days per calendar year; or

(C) providing consultation by telecommunication to a physical therapist;

(d) the person:

(i)(A) is licensed as a physical therapist assistant under federal law; and

(B) practices within the scope of practice authorized by federal law for a physical therapist assistant; or

(ii)(A) is licensed as a physical therapist assistant in:

(I) a state, district, or territory of the United States, other than Utah; or

(II) a country other than the United States; and

(B)(I) practices within the scope of practice authorized for a physical therapist assistant by the jurisdiction described in Subsection (1)(d)(ii)(A); and

(II) within the limitations for the practice of physical therapy described in Subsection (1)(c)(ii); or

(e) the person:

(i) is a physician, licensed under Title 58, Chapter 67, Utah Medical Practice Act;

(ii) is a physician, licensed under Title 58, Chapter 68, Utah Osteopathic Medical Practice Act; or

(iii) is a chiropractic physician, licensed under Title 58, Chapter 73, Chiropractic Physician Practice Act.

(2) A person who is exempted from licensure under Subsection (1)(b) may practice **animal** physical therapy without a license under this section if the person:

(a) is authorized to practice **animal** physical therapy under federal law; and

(b) practices **animal** physical therapy within the scope of practice authorized by federal law.

(3) A person who is exempted from licensure under Subsection (1)(c) may practice **animal** physical therapy without a license under this section if the person:

(a) is authorized to practice **animal** physical therapy in:

(i) a state, district, or territory of the United States, other than Utah; or

(ii) a country other than the United States; and

(b) practices **animal** physical therapy:

(i) within the scope of practice for the jurisdiction described in Subsection (3)(a) where the person is authorized to practice **animal** physical therapy; and

(ii) within the limitations for the practice of physical therapy described in Subsection (1)(c)(ii).

Credits

Laws 2009, c. 220, § 10, eff. July 1, 2009.

U.C.A. 1953 § 58-24b-304, UT ST § 58-24b-304
Current through 2015 First Special Session

End of Document

West's Utah Code Annotated
Title 58. Occupations and Professions
Chapter 24B. Physical Therapy Practice Act (Refs & Annos)
Part 5. Unlawful and Unprofessional Conduct

U.C.A. 1953 § 58-24b-501

§ 58-24b-501. Unlawful conduct

Currentness

In addition to the conduct described in Subsection 58-1-501(1), "unlawful conduct" includes:

(1) practicing physical therapy, unless the person:

(a) is licensed under this chapter to practice physical therapy and practices within the scope of that license; or

(b) is exempt from licensure under Section 58-24b-304;

(2) practicing **animal** physical therapy, unless the person is:

(a) authorized to practice **animal** physical therapy under Section 58-24b-405; or

(b) authorized to practice **animal** physical therapy under Subsection 58-24b-304(1)(a), (2), or (3);

(3) representing oneself as, or using the title of, a physical therapist, unless the person is:

(a) a licensed physical therapist; or

(b)(i) licensed as a physical therapist in a jurisdiction other than Utah;

(ii) does not represent oneself as being a physical therapist licensed in Utah; and

(iii) exempt from licensure under Section 58-24b-304;

(4) representing oneself as, or using the title of, a physical therapist assistant, unless the person:

(a) is a licensed physical therapist assistant; or

(b)(i) is licensed as a physical therapist assistant in a jurisdiction other than Utah;

(ii) does not represent oneself as being a physical therapist assistant licensed in Utah; and

(iii) is exempt from licensure under Section 58-24b-304; and

(5) conduct designated as "unlawful conduct" by the division, by rule.

Credits

Laws 2009, c. 220, § 17, eff. July 1, 2009.

U.C.A. 1953 § 58-24b-501, UT ST § 58-24b-501
Current through 2015 First Special Session

End of Document

2013

STATE OF NEBRASKA

STATUTES RELATING TO VETERINARY MEDICINE AND SURGERY PRACTICE ACT

Department of Health & Human Services
DHHS
NEBRASKA

Department of Health and Human Services
Division of Public Health
Licensure Unit

301 Centennial Mall South, Third Floor
PO Box 94986
Lincoln, NE 68509-4986

INDEX

VETERINARY MEDICINE AND SURGERY PRACTICE ACT

VETERINARY MEDICINE AND SURGERY PRACTICE ACT

38-3301. Act, how cited. Sections 38-3301 to 38-3335 shall be known and may be cited as the Veterinary Medicine and Surgery Practice Act.

Source: Laws 1967, c. 439, § 1, p. 1353; Laws 1988, LB 1100, § 54; Laws 2000, LB 833, § 3; R.S.1943, (2003), § 71-1,153; Laws 2007, LB463, § 1083; Laws 2009, LB463, § 2; Laws 2011, LB687, § 2. Effective Date: May 19, 2011.

38-3302 Definitions, where found. For purposes of the Veterinary Medicine and Surgery Practice Act and elsewhere in the Uniform Credentialing Act, unless the context otherwise requires, the definitions found in sections 38-3303 to 38-3318 apply.

Source: Laws 2007, LB463, § 1084; Laws 2009, LB463, § 3. Effective Date: August 30, 2009.

38-3303. Accredited school of veterinary medicine, defined. Accredited school of veterinary medicine means:

(1) One approved by the board;

(2) A veterinary college or division of a university or college that offers the degree of Doctor of Veterinary Medicine or its equivalent; and

(3) One that conforms to the standards required for accreditation by the American Veterinary Medical Association.

Source: Laws 2007, LB463, § 1085. Operative date December 1, 2008.

38-3304. Animal, defined. Animal means any animal other than man and includes birds, fish, and reptiles, wild or domestic, living or dead, except domestic poultry.

Source: Laws 2007, LB463, § 1086. Operative date December 1, 2008.

38-3305. Approved veterinary technician program, defined. Approved veterinary technician program means:

(1) One approved by the board;

(2) A school or college that offers the degree of Veterinary Technician, a degree in veterinary technology, or the equivalent; and

(3) One that conforms to the standards required for accreditation by the American Veterinary Medical Association.

Source: Laws 2007, LB463, § 1087. Operative date December 1, 2008.

38-3306. Board, defined. Board means the Board of Veterinary Medicine and Surgery.

Source: Laws 2007, LB463, § 1088. Operative date December 1, 2008.

38-3307. Direct supervision, defined. Direct supervision means that the supervisor is on the premises and is available to the veterinary technician or unlicensed assistant who is treating the animal and the animal has been examined by a veterinarian at such times as acceptable veterinary practice requires consistent with the particular delegated animal health care task.

Source: Laws 2007, LB463, § 1089. Operative date December 1, 2008.

38-3307.01 Health care therapy, defined. Health care therapy means health care activities that require the exercise of judgment for which licensure is required under the Uniform Credentialing Act.

Source: Laws 2009, LB463, § 4. Effective Date: August 30, 2009.

38-3308. Immediate supervision, defined. Immediate supervision means that the supervisor is on the premises and is in direct eyesight and hearing range of the animal and the veterinary technician or unlicensed assistant who is treating the animal and the animal has been examined by a veterinarian at such times as acceptable veterinary practice requires consistent with the particular delegated animal health care task.

Source: Laws 2007, LB463, § 1090. Operative date December 1, 2008.

38-3309. Indirect supervision, defined. Indirect supervision means that the supervisor is not on the premises but is easily accessible and has given written or oral instructions for treatment of the animal and the animal has been examined by a veterinarian at such times as acceptable veterinary practice requires consistent with the particular delegated animal health care task.

Source: Laws 2007, LB463, § 1091. Operative date December 1, 2008.

38-3309.01 Licensed animal therapist, defined. Licensed animal therapist means an individual who (1) has and maintains an undisciplined license under the Uniform Credentialing Act for a health care profession other than veterinary medicine and surgery, (2) has met the standards for additional training regarding the performance of that health care profession on animals as required by rules and regulations adopted and promulgated by the department upon the recommendation of the board, and (3) is licensed as an animal therapist by the department.

Source: Laws 2009, LB463, § 5. Effective Date: August 30, 2009.

38-3310. Licensed veterinarian, defined. Licensed veterinarian means a person who is validly and currently licensed to practice veterinary medicine and surgery in this state.

Source: Laws 2007, LB463, § 1092. Operative date December 1, 2008.

38-3311. Licensed veterinary technician, defined. Licensed veterinary technician means an individual who is validly and currently licensed as a veterinary technician in this state.

Source: Laws 2007, LB463, § 1093. Operative date December 1, 2008.

38-3312. Practice of veterinary medicine and surgery, defined. Practice of veterinary medicine and surgery means:

(1) To diagnose, treat, correct, change, relieve, or prevent animal disease, deformity, defect, injury, or other physical or mental conditions, including the prescription or administration of any drug, medicine, biologic, apparatus, application, anesthetic, or other therapeutic or diagnostic substance or technique, and the use of any manual or mechanical procedure for testing for pregnancy or fertility or for correcting sterility or infertility. The acts described in this subdivision shall not be done without a valid veterinarian-client-patient relationship;

(2) To render advice or recommendation with regard to any act described in subdivision (1) of this section;

(3) To represent, directly or indirectly, publicly or privately, an ability and willingness to do any act described in subdivision (1) of this section; and

(4) To use any title, words, abbreviation, or letters in a manner or under circumstances which induce the belief that the person using them is qualified to do any act described in subdivision (1) of this section.

Source: Laws 2007, LB463, § 1094. Operative date December 1, 2008.

38-3313. Supervision, defined. Supervisor means a licensed veterinarian or licensed veterinary technician as required by statute or rule or regulation for the particular delegated task being performed by a veterinary technician or unlicensed assistant.

Source: Laws 2007, LB463, § 1095. Operative date December 1, 2008.

38-3314 Unlicensed assistant, defined. Unlicensed assistant means an individual who is not a licensed veterinarian, a licensed veterinary technician, or a licensed animal therapist and who is working in veterinary medicine.

Source: Laws 2007, LB463, § 1096; Laws 2009, LB463, § 6. Effective Date: August 30, 2009.

38-3315. Veterinarian, defined. Veterinarian means a person who has received a degree of Doctor of Veterinary Medicine from an accredited school of veterinary medicine or its equivalent.

Source: Laws 2007, LB463, § 1097. Operative date December 1, 2008.

38-3316. Veterinarian-client-patient relationship, defined. Veterinarian-client-patient relationship means that:

(1) The veterinarian has assumed the responsibility for making clinical judgments regarding the health of the animal and the need for medical treatment, and the client has agreed to follow the veterinarian's instructions;

(2) The veterinarian has sufficient knowledge of the animal to initiate at least a general or preliminary diagnosis of the medical condition of the animal. This means that the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal by virtue of an examination of the animal or by medically appropriate and timely visits to the premises where the animal is kept; and

(3) The veterinarian is readily available or has arranged for emergency coverage and for followup evaluation in the event of adverse reactions or the failure of the treatment regimen.

Source: Laws 2007, LB463, § 1098. Operative date December 1, 2008.

38-3317. Veterinary medicine and surgery, defined. Veterinary medicine and surgery includes veterinary surgery, obstetrics, dentistry, and all other branches or specialties of veterinary medicine.

Source: Laws 2007, LB463, § 1099. Operative date December 1, 2008.

38-3318. Veterinary technician, defined. Veterinary technician means an individual who has received a degree in veterinary technology from an approved veterinary technician program or its equivalent.

Source: Laws 2007, LB463, § 1100. Operative date December 1, 2008.

38-3319. Board; membership; qualifications. The board shall consist of five members, including three licensed veterinarians, one licensed veterinary technician, and one public member.

Source: Laws 2007, LB463, § 1101. Operative date December 1, 2008.

38-3320. Board; purpose. The purpose of the board is to: (1) Provide for the health, safety, and welfare of the citizens; (2) insure that veterinarians and veterinary technicians serving the public meet minimum standards of proficiency and competency; (3) insure that schools of veterinary medicine and surgery and veterinary technician programs meet the educational needs of the students and qualify students to serve the public in a safe and efficient manner; and (4) control the field of veterinary medicine and surgery in the interest of consumer protection.

Source: Laws 1979, LB 96, § 1; Laws 1999, LB 828, § 127; Laws 2000, LB 833, § 2; R.S.1943, (2003) § 71-1,152.01; Laws 2007, LB463, § 1102. Operative date December 1, 2008.

38-3321. Veterinarian; veterinary technician; animal therapist; license; required; exceptions. No person may practice veterinary medicine and surgery in the state who is not a licensed veterinarian, no person may perform delegated animal health care tasks in the state who is not a licensed veterinary technician or an unlicensed assistant performing such tasks within the limits established under subdivision (2) of section 38-3326, and no person may perform health care therapy on animals in the state who is not a licensed animal therapist. The Veterinary Medicine and Surgery Practice Act shall not be construed to prohibit:

(1) An employee of the federal, state, or local government from performing his or her official duties;

(2) A person who is a student in a veterinary school from performing duties or actions assigned by his or her instructors or from working under the direct supervision of a licensed veterinarian;

(3) A person who is a student in an approved veterinary technician program from performing duties or actions assigned by his or her instructors or from working under the direct supervision of a licensed veterinarian or a licensed veterinary technician;

(4) Any merchant or manufacturer from selling feed or feeds whether medicated or nonmedicated;

(5) A veterinarian regularly licensed in another state from consulting with a licensed veterinarian in this state;

(6) Any merchant or manufacturer from selling from his or her established place of business medicines, appliances, or other products used in the prevention or treatment of animal diseases or any merchant or manufacturer's representative from conducting educational meetings to explain the use of his or her products or from investigating and advising on problems developing from the use of his or her products;

(7) An owner of livestock or a bona fide farm or ranch employee from performing any act of vaccination, surgery, pregnancy testing, retrievable transplantation of embryos on bovine, including recovering, freezing, and transferring embryos on bovine, or the administration of drugs in the treatment of domestic animals under his or her custody or ownership nor the exchange of services between persons or bona fide employees who are principally farm or ranch operators or employees in the performance of these acts;

(8) A member of the faculty of a veterinary school or veterinary science department from performing his or her regular functions, or a person lecturing or giving instructions or demonstrations at a veterinary school or veterinary science department or in connection with a continuing competency activity;

(9) Any person from selling or applying any pesticide, insecticide, or herbicide;

(10) Any person from engaging in bona fide scientific research which reasonably requires experimentation involving animals;

(11) Any person from treating or in any manner caring for domestic chickens, turkeys, or waterfowl, which are specifically exempted from the Veterinary Medicine and Surgery Practice Act;

(12) Any person from performing dehorning or castrating livestock, not to include equidae.

For purposes of the Veterinary Medicine and Surgery Practice Act, castration shall be limited to the removal or destruction of male testes;

(13) Any person who holds a valid credential in the State of Nebraska in a health care profession or occupation regulated under the Uniform Credentialing Act from consulting with a licensed veterinarian or performing collaborative animal health care tasks on an animal under the care of such veterinarian if all such tasks are performed under the immediate supervision of such veterinarian; or

(14) A person from performing a retrievable transplantation of embryos on bovine, including recovering, freezing, and transferring embryos on bovine, if the procedure is being performed by a person who (a) holds a doctorate degree in animal science with an emphasis in reproductive physiology from an accredited college or university and (b) has and can show proof of valid professional liability insurance.

(2) An applicant for a license to practice as a licensed veterinary technician based on a license in another state or territory of the United States, the District of Columbia, or a Canadian province shall meet the standards set by the board pursuant to section 38-126 and shall have been actively engaged in the practice of such profession at least one of the three years immediately preceding the application under a license in another state or territory of the United States, the District of Columbia, or a Canadian province.

Source: Laws 2007, LB463, § 1109. Operative date December 1, 2008.

38-3328. Fees. The department shall establish and collect fees for credentialing under the Veterinary Medicine and Surgery Practice Act as provided in sections 38-151 to 38-157.

Source: Laws 2007, LB463, § 1110. Operative date December 1, 2008.

38-3329. Advertising; offer of services; limitation. (1) Only a licensed veterinarian may advertise or offer his or her services in a manner calculated to lead others to believe that he or she is a licensed veterinarian.

(2) Only a licensed veterinary technician may advertise or offer his or her services in a manner calculated to lead others to believe that he or she is a licensed veterinary technician.

Source: Laws 2007, LB463, § 1111. Operative date December 1, 2008.

38-3330. Disclosure of information; restrictions. (1) Unless required by any state or local law for contagious or infectious disease reporting or other public health and safety purpose, no veterinarian licensed under the Veterinary Medicine and Surgery Practice Act shall be required to disclose any information concerning the veterinarian's care of an animal except under a written authorization or other waiver by the veterinarian's client or pursuant to a court order or a subpoena. A veterinarian who releases information under a written authorization or other waiver by the client or pursuant to a court order or a subpoena is not liable to the client or any other person.

(2) The privilege provided by this section is waived to the extent that the veterinarian's client or the owner of the animal places the veterinarian's care and treatment of the animal or the nature and extent of injuries to the animal at issue in any civil or criminal proceeding.

(3) The privilege provided by this section is waived to the extent and for purposes of notifying any owner or manager of cattle that have a significant risk for exposure to bovine trichomoniasis. A veterinarian who releases information about the risk for exposure to bovine trichomoniasis is not liable to the client or any other person.

(4) For purposes of this section, veterinarian includes the employees or agents of the licensed veterinarian while acting for or on behalf of such veterinarian.

Source: Laws 2000, LB 833, § 5; R.S.1943, (2003), § 71-1,164; Laws 2007, LB463, § 1112; Laws 2013, LB423, § 3. Effective Date: September 6, 2013.

38-3331 Civil penalty; recovery; lien. (1) In addition to the remedies authorized in section 38-140 or 38-1,124, a person who engages in the practice of veterinary medicine and surgery without being licensed or otherwise authorized to do so under the Veterinary Medicine and Surgery Practice Act shall be subject to a civil penalty of not less than one thousand dollars nor more than five thousand dollars for the first offense and not less than five thousand dollars nor more than ten thousand dollars for the second or subsequent offense. If a violation continues after notification, this constitutes a separate offense.

(2) The civil penalties shall be assessed in a civil action brought for such purpose by the Attorney General in the district court of the county in which the violation occurred.

(3) Any civil penalty assessed and unpaid under this section shall constitute a debt to the State of Nebraska which may be collected in the manner of a lien foreclosure or sued for and recovered in any proper form of action in the name of the State of Nebraska in the district court of the county in which the violator resides or owns property. The department may also collect in such action attorney's fees and costs incurred in the collection of the civil penalty. The department shall, within thirty days after receipt, transmit any collected civil penalty to the State Treasurer to be disposed of in accordance with Article VII, section 5, of the Constitution of Nebraska.

Source: Laws 2009, LB463, § 8. Effective Date: August 30, 2009

38-3332 Animal therapist; license; application; qualifications. Each applicant for a license as an animal therapist in this state shall present to the department:

(1) Proof that the applicant holds and maintains an undisciplined license under the Uniform Credentialing Act for a health care profession other than veterinary medicine and surgery;

(2) Proof that the applicant has met the standards for additional training regarding the performance of that health care profession on animals as required by rules and regulations adopted and promulgated by the department upon the recommendation of the board; and

(3) Such other information and proof as the department, with the recommendation of the board, may require

by rule and regulation.

Source: Laws 2009, LB463, § 9. Effective Date: August 30, 2009

38-3333 Animal therapist; health care therapy; conditions; letter of referral; liability. (1) A licensed animal therapist may perform health care therapy on an animal only if:

(a) The health care therapy is consistent with the licensed animal therapist's training required for the license referred to under subdivision (1) of section 38-3332;

(b) The owner of the animal presents to the licensed animal therapist a prior letter of referral for health care therapy that includes a veterinary medical diagnosis and evaluation completed by a licensed veterinarian who has a veterinarian-client-patient relationship with the owner and the animal and has made the diagnosis and evaluation within ninety days immediately preceding the date of the initiation of the health care therapy; and

(c) The licensed animal therapist provides health care therapy reports at least monthly to the referring veterinarian, except that a report is not required for any month in which health care therapy was not provided.

(2) A licensed veterinarian who prepares a letter of referral for health care therapy by a licensed animal therapist shall not be liable for damages caused to the animal as a result of the health care therapy performed by the licensed animal therapist.

Source: Laws 2009, LB463, § 10. Effective Date: August 30, 2009

38-3334 Animal therapist; additional disciplinary grounds. In addition to the grounds for disciplinary action found in sections 38-178 and 38-179, a license to practice as a licensed animal therapist may be denied, refused renewal, limited, revoked, or suspended or have other disciplinary measures taken against it in accordance with section 38-196 when the applicant or licensee is subjected to disciplinary measures with regard to his or her license referred to under subdivision (1) of section 38-3332.

Source: Laws 2009, LB463, § 11. Effective Date: August 30, 2009

38-3335. Veterinarian locum tenens; issuance; requirements; term. When circumstances indicate a need for the issuance of a veterinarian locum tenens in the State of Nebraska, the department, with the recommendation of the board, may issue a veterinarian locum tenens to an individual who holds an active license to practice veterinary medicine and surgery in another state if the requirements regarding education and examination for licensure in that state are equal to or exceed the requirements regarding education and examination for licensure in Nebraska. A veterinarian locum tenens may be issued for a period not to exceed ninety days in any twelve-month period.

Source: Laws 2011, LB687, § 3. Effective Date: May 19, 2011.

71-1,152. Repealed. Laws 1967, c. 439, §18.
71-1,152.01. Transferred to section 38-3320.
71-1,153. Transferred to section 38-3301.
71-1,154. Repealed. Laws 2007, LB 463, § 1319.
71-1,155. Transferred to section 38-3321.
71-1,156. Repealed. Laws 1987, LB 473, §63.
71-1,157. Transferred to section 38-3323.
71-1,158. Transferred to section 38-3322.
71-1,159. Repealed. Laws 1987, LB 473, §63.
71-1,160. Repealed. Laws 2007, LB 463, § 1319.
71-1,161. Repealed. Laws 2005, LB 301, s. 78.
71-1,162. Repealed. Laws 2007, LB 463, § 1319.
71-1,163. Transferred to section 38-3324.
71-1,164. Transferred to section 38-3330.
71-1,165 and 71-1,166. Transferred to section 38-3325 and 38-3326.
71-1,167. Repealed. Laws 1988, LB 1100, §185.
71-1,168 to 71-1,176. Repealed. Laws 2000, LB 833, § 12.
71-1,177. Repealed. Laws 1988, LB 1100, §185.
71-1,178. Repealed. Laws 2000, LB 833, § 12.
71-1,179. Repealed. Laws 1988, LB 1100, §185.
71-1,180 and 71-1,181. Repealed. Laws 2000, LB 833, § 12.
71-1,182. Repealed. Laws 1988, LB 1100, §185.
71-1,183 to 71-1,185. Repealed. Laws 2000, LB 833, § 12.

Maryland Board of Veterinary Medical Examiners
Agriculture Article §2-301, et seq.

§ 2-301

(a) In this subtitle the following words have the meanings indicated.

(b) "Board" means the State Board of Veterinary Medical Examiners.

(b-1) "Convicted" includes:

(1) A finding of guilt by a court or a jury; and

(2) The acceptance by a court of a defendant's plea of guilty, nolo contendere, or Alford plea.

(c) "Direct supervision" means that a veterinarian licensed and registered in the State is in the immediate vicinity where veterinary medicine is being performed and is actively engaged in the supervision of the practice of veterinary medicine.

(d) "License" means a license to practice veterinary medicine in the State.

(e) "Member" means a member of the State Board of Veterinary Medical Examiners.

(f) "Practice of veterinary medicine" includes, but is not limited to, the practice by any person who:

(1) Diagnoses, advises, prescribes, or administers a drug, medicine, biological product, appliance, application, or treatment of any nature, for the prevention, cure, or relief of a wound, fracture, bodily injury, or disease of an animal;

(2) Performs a surgical operation, including cosmetic surgery, upon any animal;

(3) Performs dentistry on any animal;

(4) Performs any manual procedure upon an animal for the diagnosis or treatment of sterility or infertility of the animal;

(5) Represents himself as engaged in the practice of veterinary medicine;

(6) Offers, undertakes, or holds himself out as being able to diagnose, treat, operate, vaccinate, or prescribe for any animal disease, pain, injury, deformity, or physical condition; or

(7) Uses any words, letters, or titles in connection or under circumstances as to induce the belief that the person using them is engaged in the practice of veterinary medicine. This use is prima facie evidence of the intention to represent himself as engaged in the practice of veterinary medicine.

(g) The term "practice of veterinary medicine" does not include or apply to:

(1) Any person practicing veterinary medicine in the performance of civil or military official duties in the service of the United States or of the State;

(2) Experimentation and scientific research of biological chemists or technicians engaged in the study and development of methods and techniques, directly or indirectly related or applicable to the problems of the practice of veterinary medicine;

(3) A person who advises with respect to or performs acts which the Board, by rule or regulation, has prescribed as accepted management practices in connection with livestock production;

(4) A physician licensed to practice medicine in the State or to his assistant while engaged in educational research;

(5) A person administering to the ills and injuries of his own animals if they otherwise comply with all laws, rules and regulations relative to the use of medicines and biologics;

(6) A farrier or a person actively engaged in the art or profession of horseshoeing as long as his actions are limited to the art of horseshoeing or trimming and maintaining horse hooves;

(7) Any nurse, attendant, technician, intern, or other employee of a licensed and registered veterinarian when administering medication or rendering auxiliary or supporting assistance under the responsible direct supervision of a licensed and registered veterinarian;

(8) A person who floats (files) equine teeth or removes caps;

(9) A person who scales or cleans animal teeth;

(10) A registered veterinary technician when performing a procedure under the responsible direct supervision of a veterinary practitioner as provided by regulations adopted by the Board;

(11) A person practicing acupuncture in accordance with the principles of oriental medical theories if the person:

(i) Is licensed under Title 1A of the Health Occupations Article;

(ii) Is certified as an animal acupuncturist by the Board of Acupuncture;

(iii) Practices only acupuncture, acupressure, and moxibustion;

(iv) Cooperates and consults with a veterinary practitioner by:

1. Beginning acupuncture treatment on an animal only if the animal has been seen by a veterinary practitioner within the previous 14 days;

2. Adhering to the terms and conditions of treatment decided by the veterinary practitioner, including the degree of communication and collaboration between the veterinary practitioner and the person practicing acupuncture;

3. Reporting to the veterinary practitioner at the end of treatment or at monthly intervals, at the discretion of the veterinary practitioner; and

4. Not working on an animal for which the person has not been appropriately trained, in accordance with regulations adopted by the Board of Acupuncture; and

(v) Has successfully completed a specialty training program in animal acupuncture that:

1. Is approved by the Board of Acupuncture;

2. Is offered by a school holding nationally recognized accreditation;

3. Consists of at least 135 hours; and

4. Enables the person to:

A. Design effective treatments of animals based on traditional acupuncture theories and principles, including appropriate knowledge of functional animal anatomy and physiology;

B. Handle and restrain animals to the extent appropriate in the practice of acupuncture;

C. Demonstrate sufficient knowledge of animal diseases and zoonoses that would require the immediate attention of a veterinary practitioner; and

D. Communicate effectively with a veterinary practitioner; or

(12) A veterinarian licensed in another jurisdiction while consulting with a veterinary practitioner in this State; or

(13) A student of veterinary medicine practicing veterinary medicine who has successfully completed 3 years of veterinary education at an institution approved by the Board and who works under the responsible direct supervision, as defined by the Board, of a veterinary practitioner.

(h) "Veterinarian" means any person who is a graduate of a college of veterinary medicine.

(i) "Veterinary practitioner" means a licensed and registered veterinarian engaged in the practice of veterinary medicine.

(j) "Veterinary technician" means a person who is registered with the Board as a veterinary technician.

§ 2-302

(a) There is a State Board of Veterinary Medical Examiners in the Department.

(b) The Board has seven members, five of whom:

(1) Are licensed and registered veterinarians of the State;

(2) Are residents of the State;

(3) Have engaged in active practice for five years at some time;

(4) Are in good standing; and

(5) Are appointed and qualified.

2015 Minnesota Statutes

Authenticate

156.075 REQUIREMENT FOR EQUINE TEETH FLOATERS.

Subdivision 1. **Definitions.** For purposes of this section the following terms have the meanings given them.

(a) "Equine teeth floating" means:

(1) removal of enamel points from teeth with handheld, nonmotorized, non-air-powered files or rasps;

(2) reestablishing normal molar table angles and freeing up lateral excursion and other normal movements of the mandible;

(3) shaping the lingual aspect of the lower arcades and the buccal aspect of the upper arcades to a rounded smooth surface; and

(4) removing points from the buccal aspect of the upper arcade and the lingual aspect of the lower arcade.

(b) "Indirect supervision" means a veterinarian must be available by telephone or other form of immediate communication. The veterinarian must be currently licensed under this chapter.

Subd. 2. **Equine teeth floating services.** (a) A person may perform equine teeth floating services after submitting to the board the following:

(1) proof of current certification from the International Association of Equine Dentistry or other professional equine dentistry association as determined by the board; and

(2) a written statement signed by a supervising veterinarian experienced in large animal medicine that the applicant will be under direct or indirect supervision of the veterinarian when floating equine teeth.

(b) The board must waive the requirement in paragraph (a), clause (1), and allow a person to perform equine teeth floating services if the person provides satisfactory evidence of being actively engaged in equine teeth floating for at least ten of the past 15 years and has generated at least $5,000 annually in personal income from this activity.

History: *1Sp2005 c 1 art 1 s 80*

2015 Minnesota Statutes

Authenticate

156.12 PRACTICE OF VETERINARY MEDICINE.

Subdivision 1. **Practice.** The practice of veterinary medicine, as used in this chapter, shall mean the diagnosis, treatment, correction, relief, or prevention of animal disease, deformity, defect, injury, or other physical or mental conditions; the performance of obstetrical procedures for animals, including determination of pregnancy and correction of sterility or infertility; and the rendering of advice or recommendations with regard to any of the above. The practice of veterinary medicine shall include but not be limited to the prescription or administration of any drug, medicine, biologic, apparatus, application, anesthetic, or other therapeutic or diagnostic substance or technique. The practice shall not be construed to include the dehorning of cattle and goats or the castration of cattle, swine, goats, and sheep, or the docking of sheep.

Subd. 2. **Authorized activities.** No provision of this chapter shall be construed to prohibit:

(a) a person from rendering necessary gratuitous assistance in the treatment of any animal when the assistance does not amount to prescribing, testing for, or diagnosing, operating, or vaccinating and when the attendance of a licensed veterinarian cannot be procured;

(b) a person who is a regular student in an accredited or approved college of veterinary medicine from performing duties or actions assigned by instructors or preceptors or working under the direct supervision of a licensed veterinarian;

(c) a veterinarian regularly licensed in another jurisdiction from consulting with a licensed veterinarian in this state;

(d) the owner of an animal and the owner's regular employee from caring for and administering to the animal belonging to the owner, except where the ownership of the animal was transferred for purposes of circumventing this chapter;

(e) veterinarians who are in compliance with subdivision 6 and who are employed by the University of Minnesota from performing their duties with the College of Veterinary Medicine, College of Agriculture, Agricultural Experiment Station, Agricultural Extension Service, Medical School, School of Public Health, or other unit within the university; or a person from lecturing or giving instructions or demonstrations at the university or in connection with a continuing education course or seminar to veterinarians or pathologists at the University of Minnesota Veterinary Diagnostic Laboratory;

(f) any person from selling or applying any pesticide, insecticide or herbicide;

(g) any person from engaging in bona fide scientific research or investigations which reasonably requires experimentation involving animals;

(h) any employee of a licensed veterinarian from performing duties other than diagnosis, prescription or surgical correction under the direction and supervision of the veterinarian, who shall be responsible for the performance of the employee;

(i) a graduate of a foreign college of veterinary medicine from working under the direct personal instruction, control, or supervision of a veterinarian faculty member of the College of Veterinary Medicine, University of Minnesota in order to complete the requirements necessary to obtain an ECFVG or PAVE certificate;

(j) a licensed chiropractor registered under section 148.01, subdivision 1a, from practicing animal chiropractic.

Subd. 3. **Requirement to be engaged in practice.** Any person who sells or offers to apply, any prescription drug, biologic preparation, including sera, vaccines, bacterins,

tuberculin, mallein, johnin, or any other agent for the treatment, vaccination, or testing of any animal belonging to another, shall be engaged in the practice of veterinary medicine.

Subd. 4. **Titles.** It is unlawful for a person who has not received a professional degree from an accredited or approved college of veterinary medicine, or ECFVG or PAVE certification, to use any of the following titles or designations: Veterinary, veterinarian, animal doctor, animal surgeon, animal dentist, animal chiropractor, animal acupuncturist, or any other title, designation, word, letter, abbreviation, sign, card, or device tending to indicate that the person is qualified to practice veterinary medicine.

Subd. 5. [Repealed, 1996 c 415 s 33]

Subd. 6. **Faculty licensure.** (a) Veterinary Medical Center clinicians at the College of Veterinary Medicine, University of Minnesota, who are engaged in the practice of veterinary medicine as defined in subdivision 1 and who treat animals owned by clients of the Veterinary Medical Center must possess the same license required by other veterinary practitioners in the state of Minnesota except for persons covered by paragraphs (b) and (c).

(b) A specialty practitioner in a hard-to-fill faculty position who has been employed at the College of Veterinary Medicine, University of Minnesota, for five years or more prior to 2003 or is specialty board certified by the American Veterinary Medical Association or the European Board of Veterinary Specialization may be granted a specialty faculty Veterinary Medical Center clinician license which will allow the licensee to practice veterinary medicine in the state of Minnesota in the specialty area of the licensee's training and only within the scope of employment at the Veterinary Medical Center.

(c) A specialty practitioner in a hard-to-fill faculty position at the College of Veterinary Medicine, University of Minnesota, who has graduated from a board-approved foreign veterinary school may be granted a temporary faculty Veterinary Medical Center clinician license. The temporary faculty Veterinary Medical Center clinician license expires in two years and allows the licensee to practice veterinary medicine as defined in subdivision 1 and treat animals owned by clients of the Veterinary Medical Center. The temporary faculty Veterinary Medical Center clinician license allows the licensee to practice veterinary medicine in the state of Minnesota in the specialty area of the licensee's training and only within the scope of employment at the Veterinary Medical Center while under the direct supervision of a veterinarian currently licensed and actively practicing veterinary medicine in Minnesota, as defined in section 156.04. The direct supervising veterinarian must not have any current or past conditions, restrictions, or probationary status imposed on the veterinarian's license by the board within the past five years. The holder of a temporary faculty Veterinary Medical Center clinician license who is enrolled in a PhD program may apply for up to two additional consecutive two-year extensions of an expiring temporary faculty Veterinary Medical Center clinician license. Any other holder of a temporary faculty Veterinary Medical Center clinician license may apply for one two-year extension of the expiring temporary faculty Veterinary Medical Center clinician license. Temporary faculty Veterinary Medical Center clinician licenses that are allowed to expire may not be renewed. The board shall grant an extension to a licensee who demonstrates suitable progress toward completing the requirements of their academic program, specialty board certification, or full licensure in Minnesota by a graduate of a foreign veterinary college.

(d) Temporary and specialty faculty Veterinary Medical Center clinician licensees must abide by all the laws governing the practice of veterinary medicine in the state of Minnesota and are subject to the same disciplinary action as any other veterinarian licensed in the state of Minnesota.

(e) The fee for a license issued under this subdivision is the same as for a regular license to practice veterinary medicine in Minnesota. License payment deadlines, late payment fees, and other license requirements are also the same as for regular licenses.

History: *(5851-12) 1937 c 119 s 12; 1965 c 204 s 11; 1976 c 285 s 11; 1984 c 427 s 1; 1985 c 228 s 4; 1986 c 444; 1996 c 415 s 18-20; 1999 c 231 s 162,163; 2004 c 254 s 25,26; 2008 c 297 art 1 s 38-40*

JAVMAnews
COMPANION ANIMALS
October 01, 2009

Pet rehab becoming mainstream practice

Physical therapy for animals increasingly seen as viable treatment option

By R. Scott Nolen
Posted Sept. 15, 2009

Over the past 10 years, pet rehabilitation has emerged from a boutique service to what is fast becoming a mainstream treatment option within veterinary medicine.

With animal rehabilitation services becoming increasingly commonplace, more and more clients are recognizing that physical therapy is not just for people but can also mean pain relief, increased mobility, and an improved quality of life for pets as well.

Courtesy of Veterinary Orthopedic and Sports Medicine Group

Hydrotherapy can help reduce joint pain and swelling and increase circulation.

Horse owners have long understood the value of rehabilitation in restoring an injured animal to health as have sporting dog enthusiasts. It's only recently, however, as pet owners in general have come to expect their companions will have access to the same medical options they themselves have, that the interest in physical therapy for pets has exploded.

The expectation really isn't all that surprising, according to Dr. Hilary M. Clayton. "A lot of people, after injury or surgery, get physical therapy, so it's natural to expect that might be available for pets," explained Dr. Clayton, the McPhail Dressage Chair in Equine Sports Medicine at Michigan State University College of Veterinary Medicine.

Dr. Clayton is part of an organizing committee that's been working with the American Board of Veterinary Specialties over the past few years to make sports medicine and physical therapy an AVMA-recognized veterinary specialty. Sports medicine is becoming a huge field in veterinary medicine, Dr. Clayton said, and a specialty college would advance the science and practice of veterinary rehab considerably.

A decision on the proposed specialty board—the American College of Veterinary Sports Medicine and Rehabilitation—is expected from the ABVS by the end of the year, according to Dr. Clayton.

While many veterinary colleges have rehabilitation clinics and several have expanded their curriculums to include rehab or are planning to, most current animal rehabbers have completed one of the nation's two most recognized programs.

Nearly a decade ago, Dr. Darryl L. Millis and a physical therapist friend started a certification program in canine rehabilitation, which is now offered at the University of Tennessee College of Veterinary Medicine.

"When we started the Certificate Program in Canine Rehabilitation, I had initially expected it to be more of a niche service," Dr. Millis, a professor of orthopedic surgery at the UT veterinary college, said. "But 10 years later, I'm surprised that interest has remained so strong."

Approximately 350 people have earned their certification from the UT program so far, Dr. Millis said, and more than 1,500 people have taken some of the courses. Only veterinarians, veterinary technicians, physical therapists, and PT assistants can take courses. Subject matter ranges from canine anatomy and how to design and implement a rehabilitation program to pain management and the use of lasers to improve joint mobility. The program has become so successful that it's taught in Europe and will soon be introduced in Japan.

Dr. Debra A. Canapp attended the nation's other top rehabilitation certification program—the Canine Rehabilitation Institute in Wellington, Fla.—where she earned the designation of "certified canine rehabilitation therapist" in 2006. Dr. Canapp, who had previously worked in emergency medicine and private practice, saw rehabilitation as an emerging field in veterinary medicine, and she wanted to be one of its forerunners.

A year prior to her certification, Dr. Canapp and her husband, Sherman, a board-certified veterinary surgeon also certified in canine rehabilitation, opened the Veterinary Orthopedic and Sports Medicine Group, now in Annapolis Junction, Md. The practice is dedicated to veterinary orthopedic surgery and rehabilitation and employs a large staff of veterinary professionals, even a veterinary sports trainer to help dogs quickly return to their sport.

Dr. Canapp and her husband believe rehabilitation is a logical part of orthopedic medicine. "We've always thought that dogs should receive the same care as humans, and that's the human model: You are seen by an orthopedic surgeon and then you go to physical therapy," she said.

And it's not just dogs getting the attention at the clinic. Despite the focus on dogs, Dr. Canapp has also treated cats—"If you work in the cat time frame, you've got about 20 minutes to chase them around the room with a cold laser," she joked—and a duck and a rabbit.

Business has been "very, very good," at least until recently when the recession started cutting into the number of surgery patients the clinic typically sees, according to Dr. Canapp. The physical therapy portion of the practice has been untouched, however, and the appointment schedule is booked for a month and a half.

"Our rehab practice has actually boomed," Dr. Canapp said. "People are looking at the big-ticket item of surgery and trying to hold off on that, so they're opting for the less expensive rehab."

One reason veterinarians are offering rehabilitation is that it's another way of protecting the human-animal bond. And the results can be immensely rewarding for everyone involved. Dr. Julia E. Tomlinson, owner of the Twin Cities Animal Rehabilitation Clinic in Burnsville, Minn., and a graduate of the UT rehab program, said many clients come to her thinking there's nothing more that can be done for a severely disabled or pain-wracked pet. A colleague has even called her clinic "the last hope veterinary hospital."

"I've been an emergency vet, I've been a surgeon, I've been an equine vet, and I've been a researcher, and rehab is singularly the most rewarding thing I've ever done. Just to watch an elderly dog play again ... people are so delighted they can go on a little walk with their dog again."

—DR. JULIA E. TOMLINSON, OWNER, TWIN CITIES ANIMAL REHABILITATION CLINIC

"I've been an emergency vet, I've been a surgeon, I've been an equine vet, and I've been a researcher, and rehab is singularly the most rewarding thing I've ever done," Dr. Tomlinson said. "Just to watch an elderly dog play again ... people are so delighted they can go on a little walk with their dog again."

Several pet insurance companies cover rehab when it's recommended by a veterinarian, Dr. Tomlinson noted.

In addition to her clinical work, Dr. Tomlinson is president of the American Association of Rehabilitation Veterinarians, which she started in 2008 with about 50 members. Today, the roster has grown to 130 and includes several veterinary students. The AARV, she said, is striving to be the voice for veterinarians in rehab.

"We feel like (pet rehabilitation) is not something fully accepted in the veterinary community, but it's getting there," Dr. Tomlinson said. The AARV talks to veterinary boards on the association's policies and the ways in which rehab should be practiced as a form of veterinary medicine. The association is also surveying its members regarding the rehab services they provide.

The ongoing debate within the physical therapy community is over who is qualified to practice pet rehabilitation. In Nevada and Colorado, for instance, the veterinary practice acts were amended to allow physical therapists access to animals when working with a referring veterinarian.

Dr. Tomlinson says the AARV's position on the matter is animal rehabilitation is part of the practice of veterinary medicine and a veterinarian should be directly involved in an animal's rehab program. In addition, while the association supports working with nonveterinary professionals in the rehabilitation process, it opposes allowing them direct access to animal patients.

"Veterinary involvement in rehab brings more to the table than does the nonveterinarian working alone. We're very happy to work with these professionals; we just think a veterinarian should be involved," she said.

Part of the examination process for the UT Certificate Program in Canine Rehabilitation requires students to explain how providing pet rehabilitation complies with their respective veterinary and physical therapist state practice acts, according to Dr. Millis, who worries about attempts to expand practice acts to nonveterinarians.

"We want to be sure that there's no misunderstanding on our students' part," Dr. Millis explained.

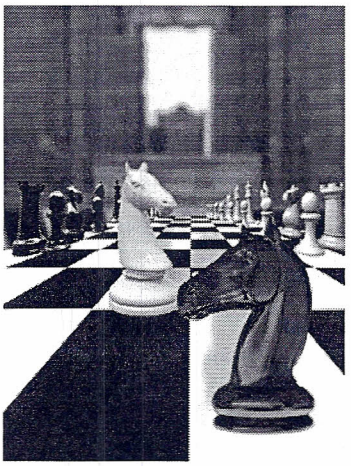
JAVMAnews

October 15, 2008

Scope-of-practice laws draw attacks

Laypersons challenge veterinary state boards in court

By Malinda Osborne
Posted Oct. 1, 2008



Veterinarians, like other licensed medical providers, have increasingly voiced concern over laypersons providing care without proper experience, training, or skills. The anxiety centers on quality of care, making sure there's appropriate supervision in place. Nonveterinarians argue they are being hindered or excluded from their right to earn a living practicing their trade.

In a few instances, the conflict has played out in court, all led by one law firm, the Institute for Justice, which challenges a wide variety of government regulations. The Arlington, Va.-based firm has filed four lawsuits against three state veterinary medical boards in the past three years.

The Institute for Justice is defending lay horse teeth floaters and a lay horse massager from what it calls "elitist veterinary cartels" in Minnesota, Texas, and Maryland.

According to court documents, the civil liberties law firm is fighting against the state laws for their clients' "constitutional right to economic liberty." Institute for Justice attorneys claim these veterinary state boards have an established public policy of unreasonable occupational licensing restrictions.

Members of veterinary state boards say they have the authority to regulate the profession and should do so, particularly as new technology and practices must be evaluated to determine whether they fall under the scope of veterinary practice.

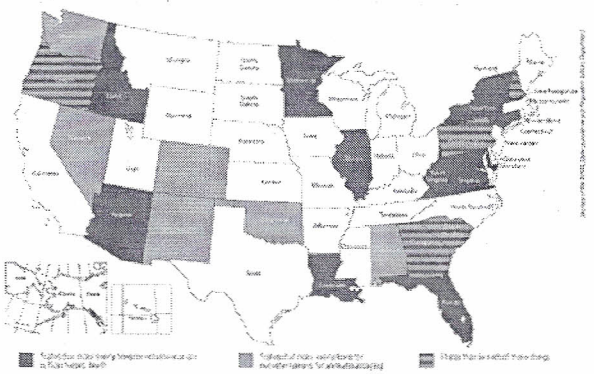
Two of the four cases, which were still pending at press time, involve the Texas State Board of Veterinary Medical Examiners. The state agency is being sued by about a dozen nonveterinarian horse teeth floaters.

In early 2007, the board changed the Texas Veterinary Licensing Act to prohibit laypersons from floating teeth. Subsequently, the board sent cease-and-desist letters to affected nonveterinarians. The first lawsuit challenges the new policy, claiming the plaintiffs have been denied their constitutional rights to earn a living filing horses' teeth. The other lawsuit, filed almost a year later in April, goes after the legality of the board's actions.

The Texas board has been granted a temporary injunction while it seeks to work out any pertinent issues through its administrative process, said Clark Neily, senior attorney for the Institute for Justice, who represents the plaintiffs. At this point, laypersons may still float teeth.

Elbert Hutchins, executive director of the Texas VMA, says Texas state law and board policy are clear about what falls under the practice of veterinary medicine.

"The state board has all the rule making it needs to protect the profession and should do so," Hutchins said.



(Click image to view larger version)

Hutchins maintains there are adequate laws and rules that define certain procedures in horses' mouths as constituting the practice of veterinary medicine.

"For many years, laypeople have been allowed to use a hand rasp to dress down horses' teeth so long as everything is done above the gumline," he said. "With the advent of power tools, they are noisy and most horses will not allow them in their mouth without sedation. Typically, drugs for sedation are prescription drugs, which are limited to trained professionals."

Hutchins says the veterinary profession is in a new age when it comes to floating teeth and other dental procedures. That, in turn, requires states to adapt their policies.

Maryland did just that in 2007 when the state adopted a rule enabling the State Board of Acupuncture to certify people performing acupuncture on animals under veterinary oversight. Animal massage therapy, however, remains under the scope of veterinary practice.

Mercedes Clemens, a lay horse massager and licensed human massage therapist, argued the law did not apply to her practice, and with representation from the Institute for Justice, filed suit against the Maryland State Board of Veterinary Medical Examiners and the Maryland Board of Chiropractic Examiners in June.

People who are pursuing various veterinary-related jobs are a common complaint, said Maryland State Board of Veterinary Medical Examiners president, Dr. Chris Runde, but "the big issue is how they promote themselves to the public."

Dr. Runde explained, "If the equine massage individual is massaging horses to make them relax or calm them down, then they have no problem promoting themselves like that. It's promoting in such a way that it reflects perhaps to diagnose and treat an ailment. That's when they step over the line."

Institute for Justice Staff Attorney Paul Sherman wants the legislature to overturn the existing Maryland Veterinary Practice Act to allow nonveterinarians to practice therapeutic massage on animals. According to his complaint, it is not reasonable for the state to make those who massage only animals to complete the same schooling as licensed veterinarians and therefore, the Maryland Veterinary Practice Act should be ruled unconstitutional.

The Maryland VMA, in a statement released Sept. 10, refuted that idea, stating: "If therapeutic animal massage were to be excluded from the Maryland Veterinary Practice Act, the State of Maryland would then be powerless to discipline an individual who causes harm to an animal as a result of practicing such therapies."

For ancillary services laypersons can perform, such as acupuncture, these "exist only where there are adequate safeguards to protect animal health and welfare," according to the MVMA statement.

Sherman argues his client "filed this civil rights lawsuit to vindicate her right to earn an honest living free from government regulations that serve no legitimate public purpose."

Many fields—not just veterinary medicine—have increased their requirements that persons be licensed to perform certain technical procedures, Sherman said.

"In Mercedes' case, regulating the animal massage industry has nothing to do with safety and everything to do with financial gain" by veterinarians, Sherman said, because they view her as potential competition.

AVMA's stance on scope of practice

Adrian Hochstadt, assistant director for state legislative and regulatory affairs in the AVMA Communications Division, said he sees three or four "skirmishes" a year at the state level about scope of practice issues.

"What's been pushing this issue is non-veterinarians who want to work independently," Hochstadt said. They say 'We have training' or 'We've been doing this for 20 years, the veterinarians are trying to protect their pocketbook.'

"Generally state VMAs, in negotiating these laws, insist on some sort of veterinary input, referral, or supervision and that's what (legislators) usually end up doing. There's at least a veterinary examination of an animal or diagnosis first. It seems to be a good compromise."

The AVMA Model Practice Act states that dentistry on animals is part of the practice of veterinary medicine and should be performed by veterinarians in accordance with their state veterinary practice act.

The Act also states alternative therapy, such as massage therapy, is the administration of a treatment or method to an animal designed to impact that animal's health, and as such, qualifies as the practice of veterinary medicine without any type of training or licensure.

For more information on the AVMA Model Practice Act or state legislative resources, visit www.avma.org and click on the "Advocacy" link.

Dr. John King, executive director of the Minnesota Board of Veterinary Medicine, said the positions that associations and veterinarians take on a legislative topic may be based at times on turf, but the board of veterinary medicine cannot take—and does not take—that position.

"It's all about the protection of the public and the animals they own—period," Dr. King said.

This was proved, he says, by the lawsuit the Institute for Justice lost this past June against the Minnesota Board of Veterinary Medicine.

Legislators passed an amendment to the Minnesota Veterinary Practice Act in 2005 allowing nonveterinarians to float teeth. The law says only licensed veterinarians, laypersons with more than 10 years' experience, and laypersons certified by the International Association of Equine Dentistry are allowed to perform the procedure.

Chris Johnson, a third-generation lay teeth floater, filed suit against the Minnesota board in August 2006 because he did not want to meet the new criteria by getting properly certified.

Clark Neily, who also represents Johnson, calls the requirement of teeth floaters to be licensed "absurd."

"You don't want to be singled out and have livelihoods taken away while others who work with animals on procedures that are more invasive are not subjected to these disabilities," Neily said, citing examples such as farrier work or dehorning.

"Our clients believe they should have a right to earn a living providing a service they are good at, and ultimately the decision to work on someone's horse is between the horse owner and practitioner."

The court disagreed and dismissed Johnson's case with prejudice.

According to court documents: "The state may legitimately exercise its police power to protect public health, safety, or welfare through the regulation of occupations that require specialized training or skill and the public will benefit from assurance of initial or continuing occupational ability ... Veterinarians are the natural group to provide education and training with respect to the overall health and anatomy of animals."

"Basically the ruling says there is reasonable cause for requiring trained individuals to float horses' teeth," Dr. King said. "It doesn't have to be just veterinarians in Minnesota. There are avenues for other people to do it, provided they prove some sort of competency."

Dr. King points to consumer demand for less expensive animal care with more options as a driving force behind laypersons pushing to take up more of the market.

"Where it falls down is, although animals are property, they are also living beings. ... Animals can be harmed by incompetent care," Dr. King said.

Additionally, the only recourse an animal owner has against a layperson creating harm to an animal is litigation. There, only a finite amount of money may be collected, and the nonregulated layperson may be not prevented from working elsewhere, even if found guilty.

"If an individual is regulated and there are complaints to the regulating authority, they can be prevented from doing it further," Dr. King said.

Dale Atkinson, legal counsel for the American Association of Veterinary State Boards, has been representing associations of regulatory boards for 20 years.

He says state veterinary boards exist to carry out the practice act and should work with the legislature to ensure the act sufficiently empowers the board to protect the public.

Ideally, Atkinson said, "they take their vet hat off when looking at things from a regulatory perspective," so that legislative interpretation occurs to protect the health of the public, regardless of internal influence or outside pressure.

"To the extent it allows or disallows people in the practice, so be it," Atkinson said.

Correction: The map should not have included Delaware as a state that makes exemptions for nonveterinarians to float horses' teeth.

Model Standards for Veterinary Physical Rehabilitation Practice

Updated February 2014; originally published February 7, 2011.

Introduction

This document is intended to serve as a model set of guiding principles for the ideal practice of veterinary physical rehabilitative medicine. This model has been developed by the board of directors of the American Association of Rehabilitation Veterinarians in collaboration with the American Physical Therapy Association Animal Rehabilitation Special Interest Group.
Veterinary rehabilitation and physical medicine is defined as the treatment of physical injury or illness in an animal to decrease pain and restore function. A physical rehabilitation veterinarian treats muscle, tendon, ligament, nerve, bone, and joint injuries and uses physical medicine to restore maximal function and relieve pain, akin to the Physiatrist in human medicine.
The motivation for publication of these model standards is in line with the mission statement of the American Association of Rehabilitation Veterinarians.

Ideal standards of practice for animal rehabilitation facilities

- Patient care in the rehabilitation facility should be under the authority, supervision or approval of a licensed veterinarian certified in rehabilitation therapy.
- Initial examination and diagnosis should be determined by a licensed veterinarian with rehabilitation certification.
- The rehabilitation treatment plan should be formulated and the case managed by a licensed veterinarian with rehabilitation certification, or a combination of this veterinarian in consultation with an appropriately licensed physical therapist certified in animal rehabilitation.
- No technician/assistant (certified or otherwise) shall manage a rehabilitation patient.
- There shall be a formal policy in place to monitor and evaluate patient response to care.
- The practice shall use individualized rehabilitation and therapy plans including fitness plans.

- For patients with concurrent conditions: Clients shall be advised early in the course of care of the opportunity to request a second opinion or referral to a specialist for treatment of these conditions.
- The rehabilitation practice shall regularly update the patient's primary care veterinarian as well as any other veterinarian involved with the patient's current care.
- A summary of the initial rehabilitation evaluation findings should be sent to the referring veterinarian at the earliest opportunity, preferably within 24 hours of the evaluation.
- The patient shall be discharged back to the care of the primary veterinarian once therapy is complete.
- When referring a patient for additional workup, appropriate referral communication (such as letter, email, phone conversation) shall occur and should be properly documented in the patient's record.
- Evaluation for pain shall be part of every patient visit.
- Practice team members shall be trained to recognize pain and work in collaboration with the veterinarian to provide appropriate pain management including physical and pharmaceutical modalities.
- Since medical and emergent issues may arise during treatment, and pain management monitoring needs to be addressed by a veterinarian, having the rehabilitation veterinarian on site is ideal. A plan must be in place to address emergent care medical issues and pain management in the absence of direct (on site) veterinary supervision.
- Practice team members should be trained to identify causes of pain, levels of pain, medications and physical methods used to control pain.
- Pain scores should be documented in the medical record at each visit.
- Pain Management techniques should be used when the presence of pain in a patient is uncertain.
- Clients should be adequately educated to recognize pain in their pet.
- Clients should be adequately educated about the possible effects of any dispensed analgesic, including adverse events.
- Tentative diagnoses and medical plans, or their subsequent revisions shall be communicated to clients at the earliest reasonable opportunity.
- A rehabilitation veterinarian should have current knowledge of veterinary-approved diets, nutraceuticals and supplements as well as knowledge and skills in weight loss and weight-management programs.

- Nutritional assessment and counseling should be part of routine care.
- Recommended continuing education requirements:
    - Each veterinarian should have a minimum of 15 hours continuing education every 2 years specifically in veterinary rehabilitation topics.
    - Each veterinarian should have a minimum of 20 hours per year of documented continuing education in the field of veterinary medicine.
    - Each veterinary technician should have a minimum of 10 hours of documented continuing education in the field of veterinary rehabilitation every 2 years.
    - Each veterinary technician should have a minimum of 10 hours of documented continuing education in the field of veterinary technology every two years.
    - Each physical therapist should have a minimum of 15 hours of documented continuing education in the field of veterinary rehabilitation every 2 years.
    - Each physical therapist should complete continuing education in their own field as recommended by their governing state board.

Links to the Ohio and Louisiana Veterinary Practice Acts:

Ohio Laws and Rules: (link is below)

http://codes.ohio.gov/orc/4741.01

4741.01 Veterinary Defn.:

L) "Allied medical support" means a licensed dentist, physician, chiropractor, or physical therapist who is in good standing as determined under Chapter 4715., 4731., 4734., or 4755. of the Revised Code, as applicable.

4741.19 *[Effective Until 9/29/2015]* Practice without license - student interns.

(F) Allied medical support may assist a licensed veterinarian to the extent to which the law that governs the individual providing the support permits, if all of the following apply:
(1) A valid veterinary-client-patient-relationship exists.
(2) The individual acts under direct veterinary supervision.
(3) The allied medical support individual receives informed, written, client consent.
(4) The veterinarian maintains responsibility for the patient and keeps the patient's medical records. The board may inspect the facilities of an allied medical support individual in connection with an investigation based on a complaint received in accordance with section 4741.26 of the Revised Code involving that individual.

Louisiana Veterinary Practice Act: (link below)

http://www.lsbvm.org/docs/Practice%20Act%20thru%20%20Nov%202014.pdf

§712. Alternative Therapy and Collaborative Treatment
A. Alternative therapy and/or collaborative treatment may be performed by a layperson (a person not licensed, registered, or certified by the board) only with an order or prescription from a Louisiana licensed, supervising veterinarian who has first established the veterinarian-client patient

relationship, and can be performed only under such supervising veterinarian's direct supervision and with the written informed consent of the owner of the animal (client) or his duly authorized agent. The layperson must possess a license, registration, or certification issued by another Louisiana regulatory authority, or he must possess verification of an educational level acceptable by the board, in the subject matter of the alternative therapy and/or collaborative treatment at issue.

B. Direct supervision as used in this Section means the supervising veterinarian must be on the premises where the alternative therapy and/or collaborative treatment are being performed and is directly responsible for the on-going evaluation and/or diagnosis. A lay person (a person not licensed, registered, or certified by the board) cannot perform surgery, on-going evaluation and/or diagnosis, prognosis, or prescribe treatment, medicines, or appliances as set forth in §702.A.2.

C. The supervising veterinarian will be held accountable for the proper diagnosis and treatment of the animal, including the work delegated to the layperson, as well as compliance with proper documentation in the patient's medical record as set forth in §701, including the written informed consent for the alternative therapy and/or collaborative treatment obtained from the client or his duly authorized agent. The supervising veterinarian will also be held accountable for the maintenance of the confidential relationship with the client and patient.

D. Alternative therapy as used in this Section includes, but is not limited to, ultrasonography, magnetic field therapy, holistic medicine, homeopathy, animal chiropractic treatment, animal acupuncture, animal physical therapy, animal massage therapy, and laser therapy.

E. Collaborative treatment as used in this Section includes, but is not limited to, ophthalmology, cardiology, neurology, radiology, and oncology.

F. Written informed consent as used in this Section means the supervising veterinarian has informed the client or his duly authorized agent, in a manner that would be understood by a reasonable person, of the diagnostic and treatment options, risk assessment, and prognosis, and the client or his duly authorized agent has consented in writing to the recommended alternative therapy and/or collaborative treatment.

Nevada regulations

NAC 638.053 Licensed veterinary technician: Prohibited tasks; tasks requiring immediate, direct or indirect supervision. (NRS 638.070, 638.124)

3. A licensed veterinary technician may perform the following tasks under the immediate or direct supervision of a supervising veterinarian:

(a) Induction of anesthesia.

(b) Endotracheal intubation.

(c) Blood administration.

(d) Internal anal gland expression.

(e) Application of casts and splints.

(f) Tasks listed in subsection 4, if the animal is anesthetized.

(g) External noninvasive ultrasonography and ultrasonography for the purpose described in paragraph (h).

(h) Cystocentesis to obtain a urine specimen, performed with or without the aid of ultrasonography.

(i) Dental prophylaxis.

(j) Physical therapy.

MDC Agenda Item #6 – Review and Consider Recommendations from the Complaint Process Audit Task Force Report

HAND CARRY

(Complaint Review Audit Subcommittee meets January 6, 2016)

RVT and Animal Shelter Subcommittee Research Report Outline

B&P 4840

(a) Describes RVT **and** assistants are approved…"under the *supervision* of a veterinarian"….Not otherwise defined. We feel a premise permit should be a prerequisite.
(b) As discussed at the last MDC meeting and also in our directions from Dr. Klingborg, the term "written order" as used in the context of this article needs to be better defined to address how animal health care services are provided in a shelter setting. Legislative change would be required to better define it here so it is best to define it within the sections of CCR Article 4 - Practice, possibly in CCR 2034 or 2036 Animal Health Care Tasks Definitions.

B&P 4840.2

This article addresses unauthorized practices. (b) Specifically states that diagnosis and prognosis is prohibited. Diagnosis is further defined in B&P 4825.1 (a).

We need to somehow address the issue that exams and diagnostic tests are performed (i.e parvo etc) prior to an examination by a veterinarian or subsequent euthanasia. These tests are performed to protect the health and well-being of every other animal and the personnel within the shelter.
The issue of appliances/splints needs discussion.

B&P 4840.5

This article defines and authorizes emergency aid with those specific tasks listed in CCR 2069 We may need to look at the phrase " may only be continued under the direction of a licensed veterinarian" to see if any clarification is needed for a shelter setting

B&P 4853

(a) and (b) describe premises. Should include animal shelters (or limit to those who are animal control jurisdictions or who have contracts to provide animal sheltering services).
Could RVTs hold an "animal shelter premise license"?

CCR 2032.1

This section defines the Veterinarian-Client -Patient Relationship (VCPR). At the end of (a) where is states "or the owner is unknown" do we need a special reference to impounded shelter animals which may be owned or whose owners are not forthcoming? Do we need to add a reference to animals seized under the provisions of PC 597?

CCR 2032.4

CCR 2036(b) in conflict with PC 597.1 (2) relative to administration of controlled substances/anesthesia by ACO and RVT? Is it not anesthesia as defined in CCR 2032.4?

CCR 2035

This section defines the duties of the supervising veterinarian, In (c) it states that " the supervising veterinarian shall have examined the animal patient prior to the delegation of an animal health care task"

This is a major issue with regards to how animal health care tasks are performed in a shelter setting and needs to be reviewed and modified.

CCR 2069

This is one of the original RVT task sections and it has worked well over the years. It has direct application in a shelter setting. It has not been updated in many years. With the current standards of practice for both shelter medicine and private practice, it would be appropriate to add an additional treatment type for "pain management"

In addition to the points that we have raised in the above articles and regulations, these other issues require consideration:

1. Sedation/anesthesia of animals in a shelter setting for the purpose of:
   (a) Grooming severely matted hair coats
   (b) Cleaning wounds
   (c) Bandaging
   (d) Splinting
   (e) Removing foxtails from the eye

2. Sedation of animals in the field - (this is different than chemical capture by ACOs)

3. Vaccination upon entry into a shelter setting which is considered best practice in today's shelter environment

4. Diagnostic testing upon entry into a shelter setting or when herd health management practice would call for it.

5. Treatment of commonly recognized animal shelter disease symptoms (cough, upper-respiratory signs, diarrhea, endoparasites) prior to an examination by a veterinarian.

6. How long may an animal be treated under a written protocol before a veterinarian would be required to examine the animal? Redefine CCR 4840.5 to include shelter impounds?

Multidisciplinary Committee Proposed Assignments

January 2016

EXISTING PRIORITIES – Currently being addressed by MDC

1) ***Animal Rehabilitation assigning task force – 5 specific content areas***

2) **Develop Language to Grant Authority for Veterinarians to Compound Drugs within FDA Guidelines**

   Met with Board of Pharmacy on Nov 12, 2015
   Language before MDC Jan 2016

3) **Evaluate Structure and Audit Enforcement Case Outcomes**
   Complaint Process/Audit Taskforce
   Subcommittee is performing in-house case audits - Report to the MDC Jan 2016.

4) **Develop minimum standards for alternate premises (large animal, equine mobile, public and private shelter medicine, ambulatory, etc.)**
   a) *CVMA Task Force held September 30, 2015*
   b) *Subcommittee on Shelter Medicine – Report to the MDC Jan 2016*
      a. *RVT protocols*
      b. *Minimum Standards*

5) **Review Business and Professions Code Section 4830(5) regarding veterinary student exemption, duties and supervision at a California veterinary university. *(Off –site surgery programs- should they be limited to 3rd/4th year students?)***

   Subcommittee drafting language – Before the MDC Jan 2016

FUTURE MDC PRIORITIES

6) **Pursue "extended duty" for Registered Veterinary Technicians.**

7) **Review standard of care for animal dentistry**

8) **Review 1st year licensure as a temporary license, working under the supervision of a currently licensed Veterinarian.**

BUSINESS, CONSUMER SERVICES, AND HOUSING AGENCY • GOVERNOR EDMUND G. BROWN JR.

STATE OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS

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

MEMORANDUM

DATE	January 1, 2016
TO	Multidisciplinary Advisory Committee
FROM	Jon Klingborg, DVM, Chair MDC/Veterinary Medical Board
SUBJECT	DVM Student Exemption

Background:

Business and Professions Code Sections 4828 & 4830, and California Code of Regulations Section 2027 provide for the authority of licensing based on specified settings. BPC 4830 (a)(5), exempts students in a school of veterinary medicine from licensure provided the student's participation in diagnosis and treatment is part of their educational experience within the university. Section 2037 further defines that type of services a student or a graduate may perform in a registered veterinary premises without first obtaining a license.

Statutory Reference:

BPC 4828

All veterinarians actually engaged and employed as veterinarians by the state, or a county, city, corporation, firm or individual are practicing veterinary medicine and shall secure a license issued by the board.

BPC 4830

(1) Veterinarians while serving in any armed branch of the military service of the United States or the United States Department of Agriculture while actually engaged and employed in their official capacity.
(2) Regularly licensed veterinarians in actual consultation from other states.
(3) Regularly licensed veterinarians actually called from other states to attend cases in this state, but who do not open an office or appoint a place to do business within this state.
(4) Veterinarians employed by the University of California while engaged in the performance of duties in connection with the College of Agriculture, the Agricultural Experiment Station, the School of Veterinary Medicine, or the agricultural extension work of the university or employed by the Western University of Health Sciences while engaged in the performance of duties in connection with the College of Veterinary Medicine or the agricultural extension work of the university.
(5) Students in the School of Veterinary Medicine of the University of California or the College of Veterinary Medicine of the Western University of Health Sciences who participate in diagnosis and treatment as part of their educational experience, including those in off-campus educational programs under the direct supervision of a licensed veterinarian in good standing, as defined in paragraph (1) of subdivision (b) of Section 4848, appointed by the University of California, Davis, or the Western University of Health Sciences.
(6) A veterinarian who is employed by the Meat and Poultry Inspection Branch of the California Department of Food and Agriculture while actually engaged and employed in his or her official

capacity. A person exempt under this paragraph shall not otherwise engage in the practice of veterinary medicine unless he or she is issued a license by the board.
(7) Unlicensed personnel employed by the Department of Food and Agriculture or the United States Department of Agriculture when in the course of their duties they are directed by a veterinarian supervisor to conduct an examination, obtain biological specimens, apply biological tests, or administer medications or biological products as part of government disease or condition monitoring, investigation, control, or eradication activities.
(b) This section shall become operative on January 1, 2011.

CCR Section 2027
A junior or senior student or a graduate of a recognized veterinary college listed in Section 2022(a) who is performing any animal health care task in a veterinary premises registered by the Board may perform only the identical job tasks with the identical degree of supervision by the supervisor as specified for a R.V.T. pursuant to Section 2036.

Issue:
UCD has noted that there is confusion regarding student exemptions and the Veterinary Practice Act. UCD was has been previously informed by the Board that "including those in off-campus educational programs" only applied to institutionally approved training and not 'voluntary' experience (ie, extra-curricular). Further CCR Section 2027 pertains to students in their junior or senior year of the program or as a graduate of a recognized veterinary college, "functioning as an RVT" has been interpreted to mean that DVM students cannot perform surgery even under direct supervision.

Clearly, it is desirable to facilitate learning opportunities in practice to better prepare graduates for entry level practice, we just need to have unambiguous language that governs that.

The two fundamental questions are:
1) What is permissible for a student under direct supervision of a veterinarian?
2) What settings are covered under the student exemptions– curricular and extracurricular?

Action(s) Requested
Review and discuss proposed changes to the existing language regarding the student exemption as provided below:

Proposed language for 4830
(5) Students in the School of Veterinary Medicine of the University of California or the College of Veterinary Medicine of the Western University of Health Sciences who participate in diagnosis and treatment as part of their educational experience, including those in off-campus educational programs, **provided the student has satisfactorily completed training in these activities as part of the formal curriculum of their veterinary program,** under the direct supervision of a licensed veterinarian in good standing, as defined in paragraph(1) of subdivision (b) of Section 4848, appointed by the University of California, Davis, or the Western University of Health Sciences.

Attachment(s):
- Veterinary Student Tasks Document
- COE Accreditation Policies and Procedures: Off-campus - March 2014

Multidisciplinary Advisory Committee
California Veterinary Medical Board
Meeting: January 19th, 2016

ANIMAL HEALTH CARE TASKS VETERINARY STUDENTS MAY PERFORM AT OFF-CAMPUS LOCATIONS

FACTS

There are two AVMA-accredited veterinary schools in California: the University of California School of Veterinary Medicine at Davis (UCD) and Western University of Health Sciences at Pomona (Western).

Both UCD and Western have established off-campus veterinary clinical sites:

Since January 2006, the clinical facilities of the "University of California Veterinary Medical Center - San Diego" (UCVMC-SD) have been located at 10435 Sorrento Valley Road, Suite #101, San Diego 92121. UCD faculty members engage in "veterinary teaching", as well as participating in research and service programs. The clinic, which offers "…specialized clinical services to … pet owners living in Southern California", is not registered with the Board.[1]

Since about 2005, Western has had an "affiliation agreement" with Banfield Pet Hospital at 611 East Second Street, Pomona 91766, presumably to offer clinical teaching opportunities for its veterinary students. In late 2014 or early 2015, Western took over the Banfield "primary care facility", renaming it WesternU Pet Health Center; the clinic offers the same veterinary services to the public as before.[2] On November 7, 2014, WesternU Pet Health Center became a Board-registered facility (HSP 7669).

QUESTIONS

What animal health care tasks may a veterinary student perform off-campus under direct supervision of a veterinarian?

In what off-campus settings may a veterinary student perform animal health care tasks? Does the answer depend upon whether the student is in an off-campus veterinary-school educational experience or is working or volunteering independent of the student's veterinary school's programs?

ANSWERS

Clearly, there is no authority for a student to perform surgery at an off-campus site.

Other than surgery, the answer may depend on whether the student is performing the tasks as part of their educational program or outside their educational program (whether as a volunteer or for compensation). And conflicts between the Veterinary Medicine Practice Act (VPA) (dealing with exemptions from the VPA's provisions) and regulations (which deal with tasks) complicate the analysis.

---

[1] The center was established in 1988 as a joint venture between UCD and UC San Diego and, from 1988 to 2006, was located at the Helen Woodward Animal Center in Rancho Santa Fe, which is registered with the Board (HSP 2359, 5400, and 6987).

[2] "All the onsite veterinarians are…Western faculty…[and] the clinic is "part of clinical skills courses for first- and second-year [Western] students, is home to the two-week medicine rotation for third years, and is a general practice location for fourth-year students." Veterinary Practice News (2/20/2015)

DISCUSSION

"Animal Health Care Tasks"

(16 California Code of Regulations sections 2027, 2034, 2036, 2036.5)

Junior and Senior Veterinary Students

16 CCR section 2027[3] specifically deals with junior and senior veterinary students[4] enrolled in AVMA-accredited schools who are "…performing any animal health care task in a veterinary premises registered by the Board." These students "…may perform only the identical job tasks with the identical degree of supervision by the supervisor as specified for a R.V.T. pursuant to Section 2036."[5] (Emphasis added.)

Section 2027 applies to students at all off-campus "registered veterinary premises".[6] And because there is no limiting language, it applies to students performing animal health care tasks both as part of their educational program or outside an educational program.

We then look to 16 CCR section 2036[7] , as the animal health care tasks which junior and senior veterinary students are permitted off-campus is "identical" to those which an R.V.T. may perform. Section 2036 states the following:

"(a) Unless specifically so provided by regulation, a R.V.T. shall not perform the following functions or any other activity which represents the practice of veterinary medicine or requires the knowledge, skill and training of a licensed veterinarian:

(1) Surgery;

(2) Diagnosis and prognosis of animal diseases;

(3) Prescription of drugs, medicines or appliances.

(b) An R.V.T. may perform the following procedures only under the direct supervision of a licensed veterinarian:

(1) Induce anesthesia;

(2) Apply casts and splints;

(3) Perform dental extractions;

---

[3] Captioned, **"Graduates and Students of Veterinary Colleges - Job Tasks"**.

[4] And also "graduates of …recognized veterinary college[s]...", although these individuals were not included in the question posed to the committee.

[5] That the word "identical" is used twice, and the word "only" also appears in a short paragraph emphasizes the intent to treat these students 'identically' to R.V.T.'s in the off-campus veterinary practice setting.

[6] Captioned, **"Registration of place of practice"**, Bus. & Prof. Code section 4853(a) states that "[a]ll premises where veterinary medicine, veterinary dentistry, veterinary surgery, and the various branches thereof is being practiced shall be registered with the board…".

[7] Captioned, **"Animal Health Care Tasks for R.V.T."**.

(4) Suture cutaneous and subcutaneous tissues, gingiva and oral mucous membranes;

(5) Create a relief hole in the skin to facilitate placement of an intravascular catheter.

(c) An R.V.T. may perform the following procedures under indirect supervision of a licensed veterinarian:

(1) Administer controlled substances.

(d) Subject to the provisions of subsection(s) (a), (b) and (c) of this section, an R.V.T. may perform animal health care tasks under the direct or indirect supervision of a licensed veterinarian. The degree of supervision by a licensed veterinarian over a R.V.T. shall be consistent with standards of good veterinary medical practices."

Freshman and Sophomore Veterinary Students

The VPA is silent as to animal health care tasks which may be performed off-campus by freshman and sophomore veterinary students. This being so, they fall squarely within the definition of "unregistered assistants" [16 CCR section 2034(c)][8]. Permissible tasks for unregistered assistants are stated in 16 CCR section 2036.5[9], as follows:

"(a) Unregistered assistants shall be prohibited from performing any of the functions or activities specified in subsections (a) (b) and (c) of Section 2036 of these regulations, except that an unregistered assistant under the direct supervision of a licensed veterinarian or registered technician may administer a controlled substance.

(b) Subject to the provisions of subsection (a) of this section, unregistered assistants in an animal hospital setting[10] may perform auxiliary animal health care tasks[11] under the direct or indirect supervision of an R.V.T.. The degree of supervision by a licensed veterinarian over an unregistered assistant shall be higher than or equal to the degree of supervision required when an R.V.T. performs the same task and shall be consistent with standards of good veterinary medical practices."

[8] Section 2034(c) defines "unregistered assistant" as "…any individual who is not an R.V.T. or a licensed veterinarian."
[9] Captioned, **"Animal Hospital Health Care Tasks for Unregistered Assistants"**.
[10] Note that the "animal hospital" need not be registered with the board.
[11] "Auxiliary animal health care tasks" is not defined.

Exemptions

(Business & Professions Code sections 4828, 4830)

Basically, anyone who practices veterinary medicine[12] in the State of California must have a license issued by the Veterinary Medical Board and be subject to the VPA. (Bus. & Prof. Code sections 4825, 4828)

However, some individuals are exempt from the application of the VPA (Bus. & Prof. Code section 4830). Among the exemptions are veterinary students, as follows:

"This chapter [Chapter 11, the Veterinary Medicine Practice Act, Bus. & Prof. Code sections 4800-4917] does not apply to:

….

(5) Students in the School of Veterinary Medicine of the University of California or the College of Veterinary Medicine of the Western University of Health Sciences who participate in diagnosis and treatment as part of their educational experience, including those in off-campus educational programs under the direct supervision of a licensed veterinarian in good standing, as defined in paragraph (1) of subdivision (b) of Section 4848, appointed by the University of California, Davis, or the Western University of Health Sciences." [Bus. & Prof. Code section 4830(5)]

Note that section 4830(5) does not limit the off-campus student experience to a fixed facility or even to a veterinary facility; students are covered even if the facility is not registered with the Board. Nor does the section limit its application to a student's particular class year.

According to section 4830(5), students stay within the exemption from the VPA when, off campus, they perform only certain animal health care tasks[13], under supervision. In particular, all of the following conditions of section 4830(5) must be met in off-campus sites:

(1) The student is attending one of the two AVMA-rated California veterinary schools;

(2) The student is "…participat[ing] in diagnosis and treatment…";

(3) Performing the tasks must be "…part of [the student's] educational experience…".

(4) When the "educational experience" is off campus, the student must be in an "…off campus educational program…".

(5) The student must be "under the direct supervision of a licensed veterinarian in good standing…appointed by [one or the other of the two California veterinary schools]."[14]

---

[12] "Practice of veterinary medicine" is defined in Bus. & Prof. Code section 4826.

[13] Actually, the practice of veterinary medicine is not limited to "tasks", but includes representing oneself as a veterinarian. [Bus. & Prof. Code section 4826(f)]

[14] The way the current subsection is written, only reciprocal licensees may supervise off-campus student experiences! (Bus. & Prof. Code Section 4848(b)(1). Note that the definition of "in good standing" is found in Section 4848 (b)(1)(A) and (B).

However---unlike R.V.T.'s, who are expressly prohibited from "diagnosis or prognosis of animal diseases" [16 CCR section 2036(a)(2)]---"[veterinary students …who] participate in diagnosis and treatment as part of their educational experience, including those in off-campus educational programs…[are exempt from the application of Bus. & Prof. Code Chapter 11 (Veterinary Medicine]...".

Thus, there is an ambiguity between the regulation setting forth permissible student tasks (which excludes "diagnosis"[15]) and the Code section exempting veterinary students from the application of the Veterinary Practice Act (VPA) while "…participat[ing] in diagnosis and treatment…".

Moreover, the exemption regulation simply contemplates that a veterinary student will be doing certain tasks ("participat[ing] in diagnosis and treatment…") so, when that occurs, the student is exempt from registration as an R.V.T. or licensure as a veterinarian. However, the regulation does not expressly give the student the right to engage in those tasks. (Perhaps the definition of "treatment" would be arguably broad enough to cover the permissible R.V.T. tasks and even more tasks---such as "diagnosis"---but that is engaging in a guessing game.[16])

COMMENTS/RECOMMENDATIONS

1. The off-campus clinical facilities of the two AVMA-accredited veterinary schools in California hold themselves out to the public as "clinics" and are sites for off-campus learning for veterinary students. But Western's clinic in Pomona is a registered premise with the Board, while UCVMC-SD's clinic in San Diego is not.

Even without more, this is an obvious anomaly.

But it also impacts the student experience: as noted above, 16 CCR section 2027 states that junior or senior veterinary students performing any animal health care task in a veterinary hospital registered by the Board may only perform those tasks permitted an R.V.T. .

As it appears that UCVMC-SD's veterinary facility meets the criteria of Bus. & Prof. Code section 4853, subsections (a) and (b), recommend that the Board direct staff to take action to register the clinic to ensure that it is subject to the same Board oversight as other California veterinary practices.

2. Recommend consistently defining the off-campus locations where students may be engaging in educational programs under the aegis of their veterinary schools as "off-campus educational program sites", language used in Bus. & Prof. Code Section 4854.5(a). This encompasses not only fixed facilities, but also ranges and barns---any location where teaching takes place.[17]

[15] See Bus. & Prof. Code section 4825.1(a) for the definition of "diagnosis".

[16] Note that "…diagnosis and treatment of animals…" is also found in Bus. & Prof. Code section 4854.5(a), which requires "[e]very off-campus educational program site [to] display in a conspicuous place a consumer notification specifying that the veterinary facilities are also being used for diagnosis and treatment of animals by graduate students enrolled in a veterinary medicine program." However, this section adds to the analysis problem here, in that it only refers to "graduate students" while 16 CCR Section 2027 makes an explicit distinction between "junior or senior student[s]" and "graduate[s] of …recognized veterinary college[s]…".

[17] This language appears in Bus. & Prof. Code section 4854.5.

3. Separately deal with students performing tasks in off-campus settings which are part of their educational program versus students working or volunteering off-campus.

4. If the intent is to treat freshman and sophomore students in off-campus settings as "unregistered assistants", say so definitively.

5. The particular animal health care tasks, and the degree of supervision, which veterinary students may perform in off-campus educational settings is a matter of policy, to be determined by veterinarians. Here is a proposed framework:

"(a) Veterinary students enrolled in an AVMA-accredited veterinary school[18] may perform animal health care tasks in off-campus educational program sites as part of the clinical portion of their studies, as long as the following conditions are met:

(1) The students are under the direct supervision of a California licensed veterinarian in good standing; and

(2) If the site is a veterinary facility, it shall be registered with the Board and shall comply with Bus. & Prof. Code section 4854.5(a), or

(3) If the site is other than a veterinary facility, the supervising veterinarian shall, if practicable, orally inform the owner or custodian of the animal that graduate veterinary students may participate in the diagnosis and treatment of the animal.

(b) Students[19] may perform the following animal health care tasks in off-campus educational program sites as part of the clinical portion of their studies:

(1) _____

(2) _____

Etc…..

(c) As used herein, "direct supervision" shall mean _____

_____.

"In good standing" shall be as set forth in Bus. & Prof. Code section 4848(b)(1)(A) and (B)."

[18] Per 16 CCR Section 2022(a), there is no reason to specifically name UCD and Western veterinary schools. Moreover, students may be from AVMA-accredited schools outside California.

[19] If it's important to break out permissible tasks of junior and senior students versus freshmen and sophomores, simply say "Junior and senior students…." and, in a separate paragraph, "Freshmen and sophomore students….".

COE Accreditation Policies and Procedures: Off-campus

March 2014

8. Off-campus and Distributive Sites

8.1. Off-campus Clinical Education Sites for Colleges with Teaching Hospitals

1. An off-campus site where a specific educational objective is offered.
2. The site is externally located from the main campus and is (usually) not administratively associated with the degree granting institution.
3. Professional staff providing education might not be employees of the degree granting institution but may be receiving remuneration as a contractor, fee-for-service provider, etc. for time/effort devoted to the educational program.
4. The off-campus site must be reviewed to ensure that the educational program is being delivered appropriately.
5. There must be a written description of the educational objectives expected to be achieved at the site and a mechanism for assessing the success of the educational process, i.e. proof that educational objectives are being met.
6. These guidelines do not apply to off-campus educational experiences that are attended sporadically by individual students to augment their on-campus education.

8.2. COE Guidelines for Implementation of a Distributive Veterinary Clinical Education Model

1. The clinical sites selected by a college to serve in a distributive clinical educational model should receive appropriate financial remuneration per student from the college in order to help ensure that students receive on-site supervised clinical instruction, with formal written contract of expectations.
2. The college must prepare and distribute appropriate materials for clinical site educators that detail objectives of the program, expectations of the site coordinators, clinical site educator training materials, instructions concerning the format the college wants used to evaluate student performance and provide feedback to students on progress/deficiencies associated with site experience.
3. Additionally the college must provide to the students, and clinical site educators alike, the expectations of the college for student safety and security while the student is on site.

4. Distributed clinical sites must be selected on the basis of specific criteria and identified for instruction in precise disciplines (defined by the college) such as, but not limited to: Food Animal/Equine/Small Animal Medicine; Food Animal/Equine/Small Animal Surgery or Food Animal or Equine or Small Animal Medicine and Surgery; Dermatology, Imaging (radiology, etc.), Neurology, Cardiology, Critical Care Emergency Medicine, etc.
5. For distributed clinical sites the college must take steps to ensure that the educational objectives and anticipated outcomes are thoroughly promulgated and understood by students and clinical site coordinators alike.
6. The college must designate to the COE what clinical sites are considered as primary instructional sites as defined by Standard 9 (c) and these will be considered by COE as core instructional sites. These sites must be in compliance with AVMA-COE Standards.
7. The college must document/assess that students and educators clearly understand how evaluation and grading practices will be conducted at each clinical site including clinical competencies.
8. Veterinarians must be licensed and technicians should be certified, licensed, or registered as appropriate to that jurisdiction.
9. The college must document that students are fully informed concerning their ability to report any and all safety, physical, and emotional concerns to the college.
10. The college must put in place a system to regularly monitor/supervise the instructional activities at each clinical site and report this system with any subsequent changes and outcomes to the COE.
11. Each clinical site educator must abide by a process devised by the college to provide a written evaluation of the performance of each student.
12. Students must provide the college with an evaluation of each site (after the respective rotation) including an evaluation of teaching at the site and the student's opportunity to perform hands-on procedures at the site. The college must summarize this information for the COE.
13. The COE may inspect clinical sites at any time students are present; these inspections, including travel and per diem costs, will be at the expense of the college.
14. The college must put in place a system to measure and document clinical competencies outcomes at clinical sites as specified by the COE (*see* Section 12.11.2) to assess clinical sites