Department of Consumer Affairs
Veterinary Medical Board

Multidisciplinary Advisory Committee Meeting

Monday, October 20, 2014
11:00 a.m. – 5:00 p.m.

Embassy Suites Anaheim
400 N. State College Blvd.
Orange, California

Committee Members

William A. Grant II, DVM Chair
Jennifer E. Boyle, RVT, Vice-Chair
Allan Drusys, B Vet Med
David F. Johnson, RVT
Jon A. Klingborg, DVM
Jeff Pollard, DVM
Diana Woodward Hagle, Public Member
Jennifer Loredo, RVT, Board Liaison
Richard Sullivan, DVM, Board Liaison

Executive Officer

Annemarie Del Mugnaio

1747 North Market Blvd., Suite 230 ■ Sacramento, CA 95834 ■ www.vmb.ca.gov
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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
Embassy Suites Anaheim
400 N. State College Boulevard
Orange, California

Monday, October 20, 2014 – 11:00 a.m. to 5:00 p.m.

I. Call to Order- Establishment of a Quorum

II. Introductions

III. Approval of April 23, 2014 Meeting Minutes

IV. Discuss Ongoing Issues
- A. RVT Alternate Route Regulations
  - i. Review of Alternate Route School Curriculum
  - ii. Review of Alternate Route Education and Application
  - iii. Proposed Alternate Route Regulations
- B. RVT Student Exemption Issues
- C. Review and Consider University License
- D. Proposed Amendments to New Minimum Standards
- E. Premise Permit Limitations
- F. Laws and Regulations Regarding Compounding Medications

VI. Comments from Public/Outside Agencies/Associations
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, 11125.7(a)).

VII. Agenda Items and Next Meeting Dates
- A. Agenda Items for Next Meeting- Review of MDC Priorities
- B. Multidisciplinary Advisory Committee Meetings – 2015 Schedule

VIII. Adjourn

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 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

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MEETING MINUTES - DRAFT
Multidisciplinary Advisory Committee
April 23, 2014

I. Call to Order- Establishment of a Quorum

Multidisciplinary Advisory Committee (MDC) Chair Dr. William Grant, II called the meeting to order at 9:00 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.

Members Present
William Grant, II, DVM, Chair
Jennifer Boyle, RVT, Vice-Chair
Oscar Chavez, B Vet Med
Allan Drusys, B Vet Med
David Johnson, RVT
Jon Klingborg, DVM
Kim Williams, RVT, Veterinary Medical Board Vice-President
Diana Woodward Hagle, Public Member
Richard Sullivan, DVM, Board Liaison

Staff Present
Annemarie Del Mugnaio, Executive Office, Veterinary Medical Board
Paul Sanchez, Assistant Executive Officer
Rebecca Bon, Legal Counsel
Diann Sokoloff, Deputy Attorney General Liaison
Ethan Mathes, Administrative Programs Coordinator
Sandra Monterrubio, Enforcement Program Coordinator
Karen Robison, Administrative Analyst
Beth Parvin, DVM
Julia Price, Administrative Staff
Lou Galiano, DCA Webcast Producer

Guests Present
Jeff Backus, California Registered Veterinary Technicians Association
Nancy Ehrlich, RVT, California Registered Veterinary Technicians Association
Val Fenstermaker, Executive Director, California Veterinary Medical Association
Ron Kelpe, DVM, California Veterinary Medical Association
Tom Kendall, DVM, Veterinary Medical Board President
Mark Nunez, DVM, Board Member
Kristi Pawlowski, RVT, California Veterinary Medical Association
Greg Prudin, Department of Consumer Affairs, Legislative Unit
Dan Segna, DVM, California Veterinary Medical Association
Cheryl Waterhouse, DVM, Board Member
Dayna Weidenkeller, California Veterinary Medical Association

II. Introductions

III. Approval of November 13, 2013 Meeting Minutes

- **Dr. Richard Sullivan motioned and Dr. Jon Klingborg seconded the motion to approve the November 13, 2013 meeting minutes. The motion carried 8-0**

IV. Executive Officer Report

A. Board Program Reports

Ms. Del Mugnaio gave an overview of the budget report and the additional staff allocated to the Board through budget change proposals in fiscal year 2014/15. She reported that many of our positions were granted based on the mandates in SB304. She updated the MDC on the enforcement programs and how the two vacancies will impact the unit.

Discuss Ongoing Issues

A. RVT Alternate Route Regulations

Ms. Del Mugnaio spoke about the alternate route program, why it was created, and the school versus ad hoc application pathways. She then went on to inform the MDC that although the ad hoc candidates had a higher pass rate on the exam; 30% of ad hoc applicants did not meet the eligibility requirement for registration.

Discussion ensued between the MDC and members of the audience about the demand for the ad hoc pathway, access to accredited programs, depth of candidate knowledge, and how the ad hoc pathway needs to evolve with the profession. It was noted that the RVT Alternate Route Program regulations have been drafted, but there is trouble moving forward from this point because "equivalency" has not been determined.

Dr. Klingborg mentioned work on bringing the Alternate Route program pathway to be equivalent to the AVMA/California accredited school pathway and then work on bringing the ad hoc pathway equivalent to the schools. Dr. Segna stated the education criteria is listed in CCR Section 2065 and should be the same regardless of the route. He suggested amending the law as a minimum eligibility standard and let the candidate determine how they achieve the end result.

The RVT Alternate Route regulations will be included on the next agenda to give staff time to compile detailed RVT statistics.

B. RVT Student Exemption Issues

The RVT Student exemption is tabled until the RVT Alternate Route Regulations are complete.

C. Update on Minimum Standards and the Impact of Implementation – *(Informational Only)*
   - Hospital Standards Checklist

Ms. Del Mugnaio informed the MDC that the minimum standards were included because the profession has some questions about interpretation and implementation of some of the amended sections. Dr. Grant will request the Board to refer the minimum standards back to the MDC to address the questions during his report to the Board.

D. Review and Consider Telemedicine

Dr. Klingborg explained what the sub-committee found as they gathered information on Telemedicine/Telehealth. The sub-committee included amendments to the VCPR language in sections 2032.1 and 2032.15 and new language defining veterinary telehealth.

- **Dr. Richard Sullivan motioned and Dr. Jon Klingborg seconded the motion to request the Board refer the language to staff and legal and report back to the MDC. The motion carried 9-0**

E. Review and Consider University License

The University subcommittee contacted the Deans from U.C. Davis and Western University to obtain input from them on provisions for a University License. Ms. Del Mugnaio noted a University License would create a new license type which will involve a statutory change, new applications, and fees. She clarified what the MDC would like the regulations to capture. Dr. Grant will request the Board to direct staff to write language in his report to the Board.

F. Review and Consider Electronic Record Keeping

Electronic record keeping has been tabled.

VI. Comments from Public/Outside Agencies/Associations

The shorter length of the MDC meeting was brought up and there was a request to lengthen the MDC meetings to all day.

VII. Agenda Items and Next Meeting Dates
A. Agenda Items for Next Meeting
B. Multidisciplinary Advisory Committee Meetings – Sacramento July 22, 2014

VIII. Adjourn

The MDC meeting adjourned at 2:00 p.m.

Veterinary Medical Board Action Plan Excerpts 2012 - 2014

Multidisciplinary Committee Proposed Assignments

July 2014

EXISTING PRIORITIES

4.6 Examine the feasibility of implementing an approval program for alternate routes for obtaining Registered Veterinary Technician licensure.

- Consider efficacy of ad hoc alternate route in conjunction with approved alternate route programs

4.7 Examine the current system of licensure exemptions for UC Davis and Western University and determine if legislative options are available to affect change.

- Review current license exemption for teachers.

Review Pharmacy Law related to drug compounding and the 72-hour dispensing requirement

Review minimum standards regulation implementation and interpretation issues including veterinary premises, small animal vaccination clinics, veterinary-client-patient relationships, and written prescriptions in absence of original prescribing veterinarian

Review Business and Professions Code Section 4830 regarding veterinary student exemption, duties and supervision at a California veterinary university

4.5 Pursue regulations to define Registered Veterinary Technician student exemptions.

FUTURE MDC ISSUES

2.3 Review 1st year licensure as a temporary license, working under the supervision of a currently licensed Veterinarian.

- Review feasibility of 1st year licensure with Multidisciplinary Committee.

3.5 Review the feasibility of requiring written estimates for fees and implementation of Euthanasia forms in conjunction with the Multidisciplinary Committee.

5.5 Add English language proficiency as a requirement for licensure.

- Discuss expanding current regulations to include non-English colleges with MDC.

5.7 Revisit the provisions for temporary licenses during disaster situations for out-of-state practitioners.

5.12 Discuss responsibility for electronic record keeping and confidentiality requirements for electronic records.

5.13 Pursue "extended duty" for Veterinary Technicians.

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MEMORANDUM

DATE	October 20, 2014
TO	Veterinary Medical Board
FROM	Annemarie Del Mugnaio, Executive Officer DCA/Veterinary Medical Board
SUBJECT	RVT Alternate Route Regulations

Background:

Registered veterinary technician (RVT) examination eligibility in CCR section 2068.5 is commonly referred to as the "Alternate Route" because it is an examination eligibility pathway (requiring a mix of education and experience) that is an alternative to completing a two-year curriculum at an AVMA accredited RVT program. The pathway was originally designed for individuals who were already working in the profession and for whom it was difficult or impossible to stop working in order to go to a full time two year program.

Education required under the Alternate Route pathway is commonly obtained through organized alternate route "programs" or through a collection of college and continuing education courses (ad hoc qualifying method). Alternate Route education is required in ten specific RVT task areas and six general science areas for a total of 300 hours of education.

Issues:

Based on multiple RVT Task Force discussions the Multidisciplinary Advisory Committee (MDC), at its April 2015 meeting, discussed the history of the alternate route, how applicant education qualifies them for the ad hoc alternate route pathway, and education offered in existing alternate route ad hoc "programs".

The MDC agreed 1) there needs to be educational equivalency between the traditional RVT eligibility pathway (AVMA accredited RVT program graduate) and the alternate route pathway, 2) ad hoc alternate "programs" may be a viable option for Board approval in order to strengthen the legitimacy of alternate route applicants, and 3) the ad hoc alternate route pathway needs additional exploration and refinement.

In order to better understand how RVT applicants are meeting educational requirements through the alternate route pathway, the MDC collected a sample of existing alternate route "program" curriculum and staff collected a sample of recent RVT applicant education data. This research is included.

Specific to the sample of recent RVT education data, the data shows that applicant education across the ten specific RVT task areas and six general science areas is varied. On average, education in general science makes up a larger portion of the total education hours obtained

(87%) whereas education in specific RVT task areas is uneven and a smaller portion of the total hours obtained (13%).

Action(s) Requested

Review sample alternate route program curriculum and applicant qualifying education and discuss:

- Educational equivalency between RVT eligibility pathway and the alternate route pathway
- Viability of Board approval of alternate route “programs”
- Continuance of the ad hoc alternate route pathway as equivalent

Attachment(s):

- Alternate Route Program curriculum
- Sample of RVT Alternate Route qualifying education for examination eligibility
- RVT Alternate Route supplemental application forms
- Proposed language as modified at the April 23, 2015 MDC Meeting

Sample of RVT Alternate Route Qualifying Education for Examination Eligibility

ATS ID#	19696	18435	16249	16514	15638	15735	19790	19824	19999	19384	19742	19825	19145	18039	19485	19188	16408	Avg. Hours per Category	Pct. of Total Req. Hours
Dental	5	3.5	2	1	11	4	11	8.5	3	1	3	1	2	15	2	6	3	4.8	1.6%
Anesthesia	12	6	1	20	9	1	8	83	2	16	1	1	1	12	2	6	3	10.8	3.6%
Surgery	7	2	1	1	1.5	2	3	71	1	2	5	1	2	18	2	15	2	8.0	2.7%
Suturing	1.5	3	2	1	0	2	1	5.5	2	1	5	1	1	2	1	1	1	1.8	0.6%
Casts/Splints	1	2	0	2	0	4	2	10	2	1	3	1	1	4	1	1	2	2.2	0.7%
Radiation	5	2	2	1	4	4	2	51	4	5	6	3	2	5	1	2	45	8.5	2.8%
Diseases	10	4	3	45	0	4	2	10	2	1	8	30	2	3	1	8	2	7.9	2.6%
Zoonotic	1	2	5	5	15	4	10	10	2	5	1	1	1	1	1	5	2	4.2	1.4%
Emergency	12	3	1	15	1	8.5	4	20	2	1	15	1	3	1	1	3	1	5.4	1.8%
IV Catheter	2	1.5	1	1	1	1	1	18	2	1	5	1	1	1	1	1	1	2.4	0.8%
Chemistry	120	160	15	1	60	160	90	0.5	1	75	60	120	40	60	270	270	1	88.4	29.5%
Math	150	80	45	30	15	120	40	0.5	45	75	60	40	105	45	90	80	45	62.7	20.9%
Biology	550	40	135	15	60	80	80	0.5	60	60	60	150	150	60	280	90	60	113.6	37.9%
Microbiology	50	60	60	0	2	40	30	0.5	1	1	1	40	3	60	40	40	1	25.3	8.4%
A&P	45	40	60	0	60	50	50	1	1	75	60	40	5	60	210	220	60	61.0	20.3%
Terminology	0	0	0	0	2	2	15	10	6	3	3	1	1	30	2	70	30	10.3	3.4%

417.3

Did not qualify	X	X		X	X	X	X	X	X							X	X
Failed Exam			X												X		
Passed/ Licensed										X	X						
Has Not Taken Exam												X	X	X			

INSTRUCTIONS FOR COMPLETING POSTSECONDARY ACADEMIC COURSE REQUIREMENTS CHECKLIST

Section 2068.5 of the California code of Regulations defines the parameters under which candidates can qualify for the Registered Veterinary Technician (RVT) Examination with a combination of postsecondary coursework and directed clinical experience. Applications submitted under the Alternate Route eligibility category, must include documentation of the courses taken, that include references to the specific courses listed in the requirements and they must supplement that documentation by completely filling in the 'Alternate Route Eligibility Category Postsecondary Academic Course Requirement Checklist' and including it with the application.

Candidates are required to submit a course outline/syllabus for each course that covers the specific requirements listed on the checklist and either final transcripts and/or a certificate of attendance. If general science courses are covered in an RVT course, the specific title of the area covered must be clearly stated in the course outline/syllabus or the transcripts. One course may be used for multiple subjects, however, the individual subjects within a course must be clearly segmented out and the hours for specific subjects can only be counted once. Vague descriptions in the course outline/syllabus are not acceptable. The specific terms listed in the checklist must be clearly stated in the course outline.

The education shall consist of a total of 20 semester units, 30 quarter units, or 300 hours of instructions. If you have a combination of the above the following calculation can be used to figure whether you have a total of 300 hours of postsecondary coursework:

- 1 semester unit = 15 lecture hours
- 1 quarter unit = 10 lecture hours

EXAMPLE:

(A) RVT Specific Subjects must be completed within the five (5) years immediately preceding the application date	**Date Courses Completed**	**Course Title or Course Number**	**CE Hours**	**Semester Units**	**Quarter Units**
Dental prophylaxis & extractions	Date	Dental Procedures	10		
Anesthetic instrumentation, induction and monitoring	Date	VETT 3		3	

(B) General Science Courses					
Chemistry	Date	Chemistry I		4	
Math	Date	Algebra II			2

	TOTALS	**10**	(7x15) **105**	(2x10) **20**
GRAND TOTAL OF RVT / GENERAL SCIENCE COURSES				**135**

ALTERNATE ROUTE ELIGIBILITY CATEGORY
POSTSECONDARY ACADEMIC COURSE REQUIREMENTS CHECKLIST

Category 5 of the RVT Exam Eligibility Requirements Category List outlines the requirements for qualifying with a combination of postsecondary coursework and practical experience. Please use this checklist to show your completed courses (RVT specific subjects must be completed within the 5 years immediately preceding the application date). In the appropriate spaces, you must list the date the course was completed, the course title/course number, the number of completed CE hours, semester or quarter units.

If you have a combination of college units and postsecondary education hours, the following calculations can be used to figure whether you have a total of 300 hours of postsecondary coursework: 1 semester unit = 15 lecture hours and 1 quarter unit = 10 lecture hours.

Dental prophylaxis & extractions					
Anesthetic instrumentation, induction and monitoring					
Surgical nursing, assisting and instrumentation					
Suturing techniques					
Application of casts & splints					
Radiology & radiation safety (may include diagnostic imaging)					
Diseases and animal nursing					
Zoonotic diseases					
Emergency veterinary care					
IV Catheter placement					

Chemistry					
Math					
Biology					
Microbiology					
Anatomy & Physiology					
Medical Terminology					

APPLICANT NAME_____ **DATE**_____

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REGISTERED VETERINARY TECHNICIAN
TASK LIST- PROOF OF EXPERIENCE

(Required for eligibility categories 4 and 5)

_____ (candidate name) has applied to take the Registered Veterinary Technician examination, under Section 4832, Business and Professions Code. In order for a candidate to be eligible to sit for the examination, verification of successful accomplishment of basic job related knowledge and skills is required.

For each category listed below, please check the appropriate box as it pertains to the candidate under your supervision.

1. COMMUNICATION WITH CLIENTS/MEDICAL RECORDS

The candidate is able to establish an effective line of communication with the client to obtain pertinent information concerning the patient. The candidate has the ability to instruct clients concerning the home care required in order to promote and maintain the health of the patient and safety of the client.

☐ Acquire patient history
☐ Provide client information regarding preventive measures and routine care including:
- A. Parasite control
- B. Vaccination protocols
- C. Administration of medication
- D. Care of the bandages and orthopedic devices
- E. Post-surgical care
- F. Dental Care

☐ Maintain patient records in accordance with minimum standards

2. PATIENT EXAMINATIONS

The candidate has knowledge of basic parameters of animal health and can recognize variations from normal.

☐ Determine and know normal values of TPR.
☐ Auscultate heart and lungs using a stethoscope

3. EMERGENCY PROCEDURES

The candidate can recognize emergency situations and has a basic understanding of emergency treatment protocols.

☐ Recognize emergencies
☐ Observe or assist in cardiopulmonary resuscitation
☐ Place intravenous catheter
☐ Apply temporary bandages
☐ Institute hemostasis

4. LABORATORY PROCEDURES

The candidate can collect and prepare specimens and samples for diagnostic evaluation, can perform basic diagnostic tests, and can maintain laboratory equipment.

☐ Collect, prepare and properly submit and label specimens for diagnostic evaluations including:
- A. hematology
- B. cytology
- C. urinalysis
- D. microbiology
- E. blood chemistry

☐ Perform the following tests:
- A. Complete blood count including:
  1. PCV
  2. Total protein
  3. Total white blood cell count
  4. Differential white blood cell count
  5. Red blood cell morphology
  6. Platelet estimate

LABORATORY PROCEDURES *(continued)*

B. Urinalysis including:
   7. Specific gravity
   8. Chemistries (dipstick)
   9. Evaluation of sediment
C. Fecal evaluation for endoparasites
D. Standard tests for heartworm (Dirofilaria)

Please note: If Urinalysis is not performed in the clinic, the veterinarian must still be able to verify that the candidate has demonstrated his/her ability to perform these tests.

5. DIAGNOSTIC IMAGING

The candidate can produce diagnostic radiographs and other electronic images with acceptable safety protocols, patient positioning, exposure techniques and specialized procedures.

☐ Produce diagnostic radiographs and other electronic images
☐ Understand and implement acceptable safety protocols

6. SURGICAL ASSISTING

The candidate can prepare and maintain the surgical environment in order to ensure an asepsis for both patient and personal safety. The candidate can assist in and has knowledge of specific job tasks related to surgical procedures.

☐ Implement knowledge of aseptic technique in preparation of instruments, patient and self (when acting as surgical assistant)
☐ Has assisted in and understands principles of application of splints and casts
☐ Has assisted in and has knowledge of techniques and patterns relevant to suturing of skin wounds

7. ANESTHESIA

The candidate can assist in monitoring anesthesia for the patient to facilitate pain free diagnostic, treatment and surgical procedures.

☐ Has assisted in and has knowledge of procedures and risks associated with general anesthesia
☐ Has assisted in monitoring a patient under general anesthetic
☐ Perform endotracheal intubation
☐ Understands principals of safety for both patient and personnel

8. ANIMAL NURSING

The candidate can perform basic nursing skills as required for the health and safety of the patient.

☐ Restrain patients
☐ Administer oral and parenteral medications
☐ Apply and maintain bandages
☐ Provides for basic physical and psychological needs of the patient

9. NUTRITION

The candidate has knowledge of basic nutritional requirements of the animal patient.

☐ Assist in counseling clients regarding animal nutrition
☐ Feed patients according to nutritional requirements

10. DENTISTRY

The candidate has knowledge of proper dental techniques in order to maintain the dental health of the patient and the safety of personnel.

☐ Gather data for the assessment of dental health
☐ Perform supragingival and subgingival scaling and polishing
☐ Has assisted in and has knowledge of techniques for dental extractions

11. ANIMAL BEHAVIOR

The candidate has knowledge of the normal behavior of the animal patients and can recognize abnormal behavior in order to provide for the safety and well-being of the patient and personnel and to foster the human-animal bond between client and patient.

☐ Has knowledge, skills and ability to recognize normal vs. abnormal behavior and respond appropriately

12. PHARMACY AND PHARMACOLOGY

The candidate can handle pharmacological and biological agents in such a way as to ensure the safety of the patient, client and personnel, and efficacy of the product.

- ☐ Prepare and dispense medication
- ☐ Calculate dosages
- ☐ Recognize drug classification
- ☐ Recognize adverse reactions
- ☐ Knowledge of regulations regarding the safe handling of biohazardous materials

On the chart below, you must state the beginning and ending dates of employment, total number of months you worked and indicate if experience was full time (40 hrs/wk) or part time. If part time, include number of hours per week (hrs/wk), and indicate the total hours worked (if a range of approximate number of hours is used, the lower number will be used to calculate work experience hours).

A separate *Task List* is required for the supervising veterinary of "each location" when there is more than one location where experience was obtained.

BEGINNING DATE OF EMPLOYMENT *FROM (month/day/year)*	**ENDING DATE OF EMPLOYMENT** *TO (month/day/year)*	**NO. OF MONTHS WORKED**	**FULL TIME** (40 hrs./week)	**PART TIME** (hrs./week)

SUPERVISING VETERINARIAN: _____

TITLE: _____ PHONE NUMBER: _____

CA. VET. LICENSE #: _____ OTHER STATE VET. LICENSE #: _____

ADDRESS: _____

I certify that the statements made above are true to the best of my knowledge and belief.

_____

SIGNATURE OF SUPERVISING VETERINARIAN *DATE*

Information provided will be used to determine eligibility for approval and/or registration. Authority which authorizes the maintenance of this information: Section 4841.5 and 4842 of the Business and Professions Code. Failure to provide the requested information will result in the application being rejected as incomplete. All information is mandatory.

Title 16. Professional and Vocational Regulations
Division 20. Veterinary Medical Board

RVT Alternate Route Programs – Proposed Concept Language
7/2014

§ 2065.6. School Approval Process.

The following procedures shall be applicable to an institution applying to the board for initial approval of its registered veterinary technician curriculum in accordance with sections 2065 and 2065.6.1 of these rules:

(a) The board shall conduct a qualitative review and assessment of the institution's registered veterinary technician curriculum through a comprehensive review process, performed by an inspection team impaneled by the board for that purpose.

(b) After reviewing the inspection team's evaluation report and recommendations, the board shall take one of the following actions:

(1) Grant provisional approval for a period not to exceed two years. An additional two-year provisional approval may be granted by the board for good cause.

(2) Disapprove the application.

(c) Full approval of an institution offering a registered veterinary technician curriculum in accordance with section 2065 and 2065.6.1 shall not be granted until the curriculum has been in operation under provisional approval for at least two years and the board has determined that the curriculum is in full compliance with the provisions of section 2065 and 2065.6.1.

2065.6.1. Criteria for Practical Experience and Education Equivalent Programs

Notwithstanding provisions in section 2065 of these rules, programs who offer education in compliance with the following criteria must be approved by the board and are deemed “the equivalent thereof as determined by the board” pursuant to Section 4841.5 of the code:

(a) Programs shall verify that students entering a program have completed 2,208 of the required 4,418 hours of directed clinical practice within the five (5) years immediately preceding entrance into the program.

(b) Education shall consist of a total of 20 semester units, 30 quarter units, or 300 hours of instruction.

(c) Animal health technology education shall consist of a minimum of 200 hours and minimum of 5 hours in each subject area of instruction in the following:

(1) Orientation to the vocation of veterinary technology,

(2) Ethics and jurisprudence in veterinary medicine,

(3) Anesthetic nursing and monitoring including anesthetic evaluation, induction, and maintenance. It shall also include care and use of anesthetic and monitoring equipment,

(4) Animal husbandry, including restraint, species and breed identification, sex determination and sanitation,

(5) Animal nutrition and feeding,

(6) Client communication,

(7) Dental care of companion and laboratory animals including prophylaxis and extractions,

(8) Diseases and nursing management of companion, food, and laboratory animals,

(9) Emergency and critical care nursing,

(10) Laboratory procedures to include clinical biochemistry, cytology, hematology, immunology, basic microbiology, parasitology, and urine analysis testing.

(11) Imaging to include radiography, basic endoscopy and ultrasound principles,

(12) Medical terminology,

(13) Medical office management,

(14) Basic necropsy techniques including specimen collection and handling,

(15) Pharmacology,

(16) Surgical nursing and assisting including instrumentation, suturing, bandaging and splinting.

(d) General education shall consist of a minimum of 100 hours and minimum of 5 hours in each subject area of instruction in the following:

(1) Chemistry,

(2) Mathematics,

(3) Biology and microbiology,

(4) Anatomy and physiology,

(5) Medical terminology.

(e) When seeking Board approval programs shall submit the following:

(1) Syllabi or course outlines for all courses;

(2) Sample of each form used in program:

(A) Registration forms

(B) Certificate of course completion

(C) Evaluation forms for students to evaluate program

(D) Record of attendance

(3) Names and qualifications of program director, instructors and other persons involved in education of students and verification of their qualifications.

(g) If the program seeking approval is part of a private postsecondary institution, the institution shall also be approved by the Bureau of Private Postsecondary Education.

(h) The institution shall have adequate resources for conducting the program and may include Internet resources.

(i) If there is a physical plant and equipment used for instruction in the academic teaching, it shall be adequate for the purposes intended.

(j)(1) The faculty shall include a California licensed veterinarian employed by the school or degree program as an advisor, administrator, or instructor. Instructors shall include, but need not be limited to~~,~~ a California registered veterinary technician. If there is any change in the faculty, the board must be immediately notified.

(2) Instructors shall be knowledgeable, current, skillful, and possess at least two years of experience in performing or teaching in the specialized area in which they are teaching. Each instructor shall have or currently be receiving training in current teaching methods. School or degree programs shall effectively evaluate the teaching ability of each instructor.

(3) An approved school or degree program shall have a director who meets the requirements of subdivision (j)(2) and who shall hold a current active California license as a veterinarian or registration as an RVT. The director shall have a minimum of three years' experience as a veterinarian or RVT. This shall include one year of experience in teaching, administration, or clinical supervision or a combination thereof within the last five years. The director shall have completed or be receiving course work in administration.

(4) In the absence of a director an approved program may appoint an interim director. The interim director shall meet the requirements of (j)(3), except that the interim director may have applied for, but not yet have received licensure or registration. An approved program shall not have an interim director for a period exceeding eighteen months.

(k) The number of students enrolled shall be at a ratio to the number of faculty and size of the facilities which is not detrimental to the quality of education. When animal patients are used as part of the curriculum the ratio shall be adequate to protect the health and safety of the animal patients and the students, taking into consideration the species of animal being treated.

(l) All students admitted shall possess a high school diploma or its equivalent.

(m) The program shall be part of an institution which is approved by the Department of Consumer Affairs, Bureau of Private Postsecondary Education, unless otherwise exempted from Education Code section 94800 et seq.

(n) Every school or degree program shall be in compliance with the laws regulating the practice of veterinary medicine and the regulations adopted pursuant thereto.

(o) The programs shall provide all prospective students, prior to enrollment, with literature which discloses the program's pass rate for first time candidates and the state average pass rate for first time candidates on the board's registered veterinary technician examination during the two-year period immediately preceding the student's proposed enrollment and a description of the requirements for registration as a registered veterinary technician.

(p) All programs shall provide each prospective veterinary technology student prior to enrollment written information regarding transferability of the units they receive in the courses that they take. Said information shall be posted at all times in a conspicuous location at the program facility so that there is ample opportunity for it to be read by the veterinary technology students.

Note: Authority cited: Section 4808, Business and Professions Code. Reference: Sections 4841.5 and 4843, Business and Professions Code.

2068.5. Practical Experience and Education As Equivalent Curriculum.

In lieu of a two year curriculum in animal health technology, completion of a combination of practical experience and education in compliance with the following criteria is deemed to be "the equivalent thereof as determined by the board" pursuant to Section 4841.5 of the code:

(a) ~~The e~~Education shall consist of a total of ~~15~~ 20 semester units, 30 quarter units, or 300 hours of instruction. The education shall be provided by a postsecondary academic institution or a qualified instructor as defined by Section 2068.5(~~e~~g). ~~The education shall be accumulated in the fundamentals and principles of all of the following subjects:~~

(b) Animal health technology education shall consist of a minimum of 200 hours and minimum of 5 hours in each subject area of instruction in the following:

(1) Dental prophylaxis and extraction,

(2) Anesthetic machine, anesthetic equipment, induction and monitoring,

(3) Surgical nursing and assisting, including instrumentation and suturing techniques,

(4) Emergency veterinary care including IV Catheter placement and application of casts and splints,

(5) Imaging to include radiography, basic endoscopy and ultrasound principles,

(6) Patient examination,

(7) Diseases and nursing of animals including zoonotic disease,

(8) Laboratory procedures to include clinical biochemistry, cytology, hematology, immunology, basic microbiology, parasitology, and urine analysis testing,

(9) Veterinary pharmacology,

(10) Veterinary law and ethics.

~~(1) Dental prophylaxis and extraction.~~

~~(2) Anesthetic, induction and monitoring.~~

~~(3) Surgical nursing and assisting, including instrumentation, suturing techniques, intravascular catheter placement and application of casts and splints.~~

~~(4) Radiography and radiation safety.~~

~~(5) Diseases and nursing of animals, including zoonotic diseases and emergency veterinary care.~~

(~~b~~c) ~~The~~ General education shall ~~include~~ consist of a minimum of 100 hours and minimum of 5 hours in each subject area of instruction in ~~chemistry, mathematics, biology, microbiology, anatomy and physiology, and medical terminology, or these subjects may be obtained as separate courses.~~in the following:

(1) Chemistry,

(2) Mathematics,

(3) Biology and microbiology,

(4) Anatomy and physiology,

(5) Medical terminology.

(~~c~~d) All educational requirements in subsection (~~a~~b) shall have been completed by the applicant within five (5) years prior to the date of the examination for registration as a registered veterinary technician.

(~~d~~e) Interactive distance-learning shall be accepted if the course meets all the criteria listed in this section and includes a certificate of attendance and completion.

(~~e~~f) The candidate shall provide the board with a syllabus or an outline for each course. The candidate shall provide documentation of attendance for each course in the form of one of the following:

(1) a certificate of attendance,

(2) an official transcript, or

(3) a letter on official stationery signed by the course instructor documenting that the candidate attended a particular course.

(~~f~~g)(1) In order for education to be approved for qualification under Section 2068.5, the instructor must meet at least two of the following minimum requirements:

(A) A license, registration, or certificate in an area related to the subject matter of the course. The license, registration, or certificate shall be current, valid, and free from restrictions due to disciplinary action by this board or any other health care regulatory agency;

(B) A master's or higher degree from an educational institution in an area related to the subject matter of the course;

(C) Training, certification, or experience in teaching the subject matter of the course; or

(D) At least two years' experience in an area related to the subject matter of the course.

(2) The instructor shall provide each participant with a course syllabus or detailed outline which includes a description of the material covered.

(~~g~~h) The directed clinical practice shall consist of at least 4,416 hours, completed in no less than 24 months, of directed clinical practice under the direct supervision of a California-licensed veterinarian who shall attest to the completion of that experience at the time the application is made to the board for the registered veterinary technician examination. This experience shall have been completed by the applicant within five (5) years prior to the date of the examination for registration as a registered veterinary technician.

(~~h~~i) The directed clinical practice required in subsection (g) shall have provided the applicant with knowledge, skills, and abilities in the areas of communication with clients, patient examinations, emergency procedures, laboratory procedures, diagnostic imaging, surgical assisting, anesthesia, animal nursing, nutrition, dentistry, animal behavior, and pharmacology. The supervising veterinarian(s) shall complete a check list attesting to proficiency in specific skill areas within the preceding categories.

Note: Authority cited: Section 4808, Business and Professions Code. Reference: Section 4841.5, Business and Professions Code.

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MEMORANDUM

DATE	October 20, 2014
TO	Multidisciplinary Advisory Committee
FROM	Annemarie Del Mugnaio, Executive Officer DCA/Veterinary Medical Board
SUBJECT	RVT Student Exemption

Background:

AB 1980 (Hayashi), Chapter 538, effective January 1, 2011, created a provision in law (BPC Section 4841.1) for RVT students in the clinical portion of their final year of study in a board-approved California veterinary technology program to perform the job tasks for registered veterinary technicians as a part of their educational experience including students both on and off campus acting under the supervision of a licensed veterinarian in good standing.

The bill also required the Board to adopt regulations defining the parameters of supervision required for the students who were to perform such tasks. The consensus of the former RVT Committee and its recommendation to the Board at its last meeting in June 2011 was that the level of supervision should be “immediate” supervision meaning the supervision was physically present and the supervision was one on one.

There was also discussion regarding students in structured two year programs versus alternate route candidates and the RVT Committee recommended that the Board include in the regulations the parameters under which all RVT students could have experience actually performing the RVT job tasks at some time toward the end of their clinical training.

The RVT Task Force discussed and proposed changes to student exemption regulations at their March and June 2013 meetings. Amendments to the proposed language were made based on the Task Force discussion at the June 2013 meeting.

Statutory References:

4841.1. (a) This article shall not apply to students in the clinical portion of their final year of study in a board-approved California veterinary technology program who perform the job tasks for registered veterinary technicians as part of their educational experience, including students both on and off campus acting under the supervision of a licensed veterinarian in good standing, as defined in paragraph (1) of subdivision (b) of Section 4848.

(b) The board shall adopt regulations defining the parameters of supervision required for the students described in subdivision (a).

4848 (b) For purposes of reciprocity, the board shall waive the examination requirements of subdivision (a), and issue a license to an applicant to practice veterinary medicine if the

applicant meets all of the following requirements and would not be denied issuance of a license by any other provision of this code:

(1) The applicant holds a current valid license in good standing in another state, Canadian province, or United States territory and, within three years immediately preceding filing an application for licensure in this state, has practiced clinical veterinary medicine for a minimum of two years and completed a minimum of 2,944 hours of clinical practice. Experience obtained while participating in an American Veterinary Medical Association (AVMA) accredited institution's internship, residency, or specialty board training program shall be valid for meeting the minimum experience requirement.

Issue:

Regulations may only be crafted and clearly discussed once there is a policy decision as to whether the term "students" or "program" as defined in BPC Section 4848.1 should include alternate route (ad hoc) applicants who are obtaining work experience through on-the-job training. Only then, can the Board move forward with defining regulations in terms of supervision of the RVT student and the criteria under which the RVT students qualifies to perform such tasks. Items for further consideration:

1. If the alternate route (ad hoc) applicant is deemed a student for the purposes of gaining the specified clinical experience (performing the RVT job tasks), how will the Board determine whether the applicant has met the criteria to qualify for the student exemption?
2. Should RVT students/applicants be granted a provisional or temporary license during their last year of clinical experience authorizing the students to perform the RVT job tasks?

Action Requested:

The MDC is requested to consider and make recommendations regarding:

1. Discuss whether the terminology in section 4841.1 regarding "Board Approved Programs" Should Include the Ad Hoc Alternate Route "student."
2. Discuss Whether Alternate Route Approved Programs Should Include an Externship to Allow for Performing RVT Job Tasks Prior to Graduation.

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MEMORANDUM

DATE	October 7, 2014
TO	Multidisciplinary Advisory Committee
FROM	Annemarie Del Mugnaio, Executive Officer DCA/Veterinary Medical Board
SUBJECT	**Review and Consider University License**

Background:
At the April 23, 2014 MDC meeting, the MDC requested legal review of proposed language that would create a "Limited License" for veterinarians employed by, and working in, a veterinary academic institution.

Legal counsel reviewed the pertinent statutes, BPC section 4830 (a)(4), and concluded that the existing exemption for veterinarians employed by the University of California would need to be amended to either:

1. Strike the language in BPC section 4830(a)(4) and create a "Limited License" in regulations, or
2. Qualify the language in BPC section 4830(a)(4) to state…*this chapter does not apply to veterinarians employed by the UC while engaged in…if and only if, that veterinarian obtains a limited license to practice as defined by the board.* Regulations defining the terms of the "Limited License" would then be adopted to implement the statute.

Dr. Klingborg and Dr. Grant have continued their discussions with both UC Davis and Western University and have compiled questions surrounding the purpose and intent of Limited License/Faculty License.

Attachments:
- Background information and questions compiled by Dr. Klingborg
- Draft statutory changes to BPC section 4830 and new language BPC section 4848.1

Action Requested:
This item is up for discussion and consideration by the MDC.

Faculty Licensure

Jon Klingborg, DVM

What is the need for this type of Licensure? (VMB Perspective)

"In states that have veterinary schools, there are either exemptions or some form of university licensure that accommodates the schools need for hiring of veterinarians from all over the world who sometimes come into a state for a limited period of time and do not remain and who do not practice outside the confines of the university.

The problem arises when the university veterinary hospital is providing services to the general public and the consumer does not have recourse through the licensing board when there is a problem. In its Strategic Plan, the Board discussed the possibility of changing the law to require a license for veterinarians providing services to the public at the veterinary clinic. The discussion revolved around a "university" license that would not require the standard exams or equivalency programs, but would be issued and could be disciplined if necessary."

Annemarie Del Mugnaio, EO
April 8, 2014

What is the need for the type of Faculty Licensure? (University perspective)

Some form of Faculty Licensure would allow a Resident/Intern to write prescriptions and sign health certificates— activities which they cannot currently perform. So, this would streamline health care delivery in these institutions.

Will Statutory change be necessary for this new form of Faculty Licensure?

Yes. There will need to be Statue written for:

1) a new type of License, and

2) to remove exceptions in 4830 that would undermine the need for this Faculty License.

Does this new License set a different scale in terms of penalties or standards of behavior?

"No." Once a license is earned, the Licensees are treated equally by the system, regardless of the route by which they achieved the license.

How does this Faculty Licensure help the VMB limit, control, or oversee the expansion of a University into the public sector?

It doesn't. That was never the intention of this License— (see EO Annemarie Del Mugnaio's charge to the MDC above.)

If it is the wish of the committee to limit the University Faculty from providing services to the general public, we believe that is going to be a complicated uphill battle, with pushback from the providers and the California consumers who benefit from those services, *and* it is beyond the scope of this proposal.

How do we tell the difference between when a University-employed veterinarian is "teaching" vs simply "providing veterinary services to the public?"

This gets tricky. One cannot say that the University License is only in effect when a student is present—In the case of food animal medicine, there are cohorts of students that will rotate through various on-farm programs throughout the year. However, there are not *always* students present when Faculty (including Residents/Interns) are providing these services, yet the animals still need to be examined on a regular basis (e.g. Dairy Cows are often checked every two weeks, but there may not be a student in the rotation every two weeks.)

In other words, it is not reasonable to expect a legitimate University program to shut its doors to the public simply because there isn't a student inside the building.

Do we have to disclose that they didn't have to take a test to get a license? Will we need a category called "Non-Test Veterinarian"?

No. We do not delineate between Licensee's based on the route by which they achieved their license (e.g. Reciprocity.)

Is a new subdivision in the Temporary License category the best answer?

Maybe, however Temporary Licenses are issued for one year. So, the language will require some modification.

- Residents who are involved in the ECFVG program have a two year road to licensure, so, as written, this would not work for them.
- Also, the intent of this language is to allow oversight of Faculty, not just Residents or Interns. Renewing on an annual basis may place an unnecessary burden on individuals who maintain constant employment with a University or are in a 2-4 year education program.

Will a consumer be satisfied with a Limited License?

Good question. Rephrased: If a consumer lodges a complaint, and the VMB pursues the complaint through the typical process for any Licensee, will the consumer be satisfied with the result of that investigative process? The answer is undoubtedly going to vary from case to case.

However, the Temporary License has worked well for Medical Doctors and consumers, so there's no reason to think the Veterinary experience would be any different.

4830. Exemptions

4830. (a) This chapter does not apply to:

(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 providing ~~in actual~~ consultation. ~~from other states~~.

(a) **Consultation** means when a Veterinarian provides advice or assistance in person, telephonically, electronically, or by any other method of communication to another Veterinarian who has the primary responsibility for the welfare of the animal.

~~(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)~~ (3) 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.

(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.

4. Any veterinarian who is licensed in another state or country, or any person whose expertise, in the opinion of the veterinarian licensed in this state, would benefit an animal, and who is consulting with a veterinarian licensed in this state provided such service is limited to such consultation;

5. Any person in this state other than a veterinarian whose expertise, in the opinion of a veterinarian licensed in another state or country, would benefit an animal, and who is consulting with such veterinarian provided such service is limited to such consultation;

4848.1 Faculty Licensure

(a) For purposes of Faculty Licensure, the board shall waive the examination requirements of 4848, and issue a license to an applicant to practice veterinary medicine if the applicant has either graduated from a veterinary college recognized by the board under Section 4846, or has earned or enrolled to earn a certificate issued by the Educational Commission for Foreign Veterinary Graduates (ECFVG) or the Program for the Assessment of Veterinary Education Equivalence (PAVE).

(1) The applicant's sole professional capacity is within a veterinary academic institution or with a government diagnostic laboratory recognized by the board.

A) A veterinarian holding a Faculty license is authorized to engage in the practice of veterinary medicine only to the extent necessary to fulfill the person's employment or educational obligations as an instructor, diagnostician, intern, resident, clinical fellow, or other post graduate training position

(b) The applicant:

(1) Is not currently under investigation nor has been charged with an offense for any act substantially related to the practice of veterinary medicine by any public agency, nor entered into any consent agreement or been subject to an administrative decision that contains conditions placed by an agency upon an applicant's professional conduct or practice, including any voluntary surrender of license, nor been the subject of an adverse judgment resulting from the practice of veterinary medicine that the board determines constitutes evidence of a pattern of incompetence or negligence.

(2) Has no physical or mental impairment related to drugs or alcohol, and has not been found mentally incompetent by a physician so that the applicant is unable to undertake the practice of veterinary medicine in a manner consistent with the safety of a patient or the public.

(c) The applicant passes an examination concerning the statutes and regulations of the California Veterinary Medicine Practice Act (the Veterinary Law Exam) administered by the board, pursuant to subparagraph (C) of paragraph (2) of subdivision (a).

(d) The applicant completes an approved educational curriculum on regionally specific and important diseases and conditions. The board, in consultation with the California Veterinary Medical Association(CVMA), shall approve educational curricula that cover appropriate regionally specific and important diseases and conditions that are common in California. The curricula shall focus on small and large animal diseases consistent with the current proportion of small and large animal veterinarians practicing in the state. The approved curriculum shall not exceed 30 hours of educational time. The approved curriculum may be offered by multiple providers so that it is widely accessible to candidates licensed under this subdivision.

(e) The board shall issue a temporary Faculty license valid for two year to an applicant to practice veterinary medicine under the supervision of another California-licensed veterinarian in good standing if the applicant satisfies all of the above requirements and upon completion of the curriculum described in paragraph (c) and (d), a temporary Faculty licensee shall submit an application accompanied by verification of completion of that curriculum and all applicable fees.

(f) The board, in its discretion, may extend the expiration date of a temporary Faculty license for no more than one year if requested by the applicant, in order to correlate with

the applicant's residency or internship duration. An application for an extension shall be submitted on a form provided by the board.

(g) A Faculty member that has received this temporary license and is employed beyond a two year period may apply for a renewal every two years, without needing to retake the curriculum mentioned in (c) and (d) above. An application for an extension shall be submitted on a form provided by the board.

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MEMORANDUM

DATE	October 4, 2014
TO	Multidisciplinary Advisory Committee
FROM	Annemarie Del Mugnaio, Executive Officer DCA/Veterinary Medical Board
SUBJECT	**Update on Minimum Standards**

Background:
The minimum standards of practice regulations took effect January 1, 2014.

The Board delegated the issue of clarifying the recent changes to the minimum standards to the MDC. Below are some of the issues raised for further consideration and possible regulatory action:

Issues:

CCR Section 2030.3 - Small Animal Vaccination Clinic

- Subdivision (b) defines the requirements when a veterinarian is only administering vaccinations or performing preventative procedures for parasite control. (l) Specifically states that a VCPR must be established including a *complete physical exam* and medical records.
    - Establishing a VCPR and the requirement for the complete physical examination and medical records are not listed as a requirement in subdivision (b).
    - Other than 2030.3(l), the need to establish a VCPR is not mentioned anywhere else in sections 2030 through 2030.3. Why is the VCPR specifically mentioned in 2030.3(l), but not included in (b)?
    - The VCPR is defined in another code section (2032.1) and is required whenever veterinary procedures are performed. However, subdivision (l) mentions a *complete physical exam* which is not defined anywhere in the regulations.
        - One option would be to eliminate the VCPR reference in 2030.3(l) and clarify "examination" in 2032.1(b)(2) such as – *"(2) The veterinarian has sufficient knowledge of the animal(s) to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s). This means that the veterinarian is personally acquainted with the care of the animal(s) by virtue of an examination <u>appropriate to the condition</u> of the animal <u>and the treatment being prescribed</u> or by medically appropriate and timely visits to the premises where the animals are kept and…"*

CCR Section 2032.1 – Veterinarian-Client-Patient Relationship

- (a) refers to "…a drug, medicine, appliance, or treatment of whatever nature…"
- (c) only references a drug.
    - Should this section be amended to include "medicine, appliance, or treatment of whatever nature"?

CCR Section 2032.15 - Veterinarian-Client-Patient Relationship in Absence of Client Communication (a)(3) – Allows the designated veterinarian to establish a VCPR by consulting with the original veterinarian without an examination of the animal.

- (b) – If the designated veterinarian decides to change the treatment, diagnosis or therapeutic plan from that established by the original veterinarian, they may do so without consulting the client.
- The combination of these 2 sections paves the way for telemedicine where the original veterinarian refers the patient to another veterinarian (designated veterinarian) who is at a remote location from the patient allowing the designated veterinarian to establish a VCPR and change the diagnosis and treatment without ever being physically present with the animal

[Recent Telemedicine Language adopted by the VMB addresses this issue]
2032.1 (e) No person may practice veterinary medicine in the State except within the context of a veterinarian-client-patient relationship. A veterinarian-client-patient relationship cannot be established solely by telephonic or electronic means.

CCR Section 2032.25 - Written Prescriptions in Absence of Originally Prescribing Veterinarian.

- Section (b) is somewhat unclear. It is difficult to determine the exact circumstances that allow a veterinarian to refill a prescription without establishing a VCPR.
    - Does this regulation allow a veterinarian to act as a pharmacist by filling prescriptions written by another veterinarian?
    - Does the veterinarian providing the refill of a prescription in the absence of the prescribing veterinarian need to work at the same facility and have access to the patient's medical records?

Attachments:

- Business and Professions Code Section 4853- Registration of Place of Practice/ California Code of Regulations Sections 2030-2037 – Minimum Standards

Action Requested:
Review the issues and provide a recommendation to the VMB regarding clarifying regulations.

Business and Professions Code Section 4853- Registration of Place of Practice
California Code of Regulations Sections 2030-2037 – Minimum Standards

2030. Minimum Standards - Fixed Veterinary Premises.
2030.05. Minimum Standards - Licensee Manager.
2030.1. Minimum Standards - Small Animal Fixed Premises.
2030.2. Small Animal Mobile Clinic.
2030.3. Small Animal Vaccination Clinic.
2032.05. Humane Treatment.
2032. Minimum Standards of Practice.
2032.1. Veterinarian-Client-Patient Relationship.
2032.15. Veterinarian-Client-Patient Relationship in Absence of Client Communication
2032.2. Written Prescriptions.
2032.25. Written Prescriptions in Absence of Originally Prescribing Veterinarian.
2032.3. Record Keeping; Records; Contents; Transfer.
2032.35. Altering Medical Records
2032.4 Anesthesia.
2037. Dental Operation, Defined

2030. Minimum Standards - Fixed Veterinary Premises.

All fixed premises where veterinary medicine and its various branches are being practiced, and all instruments, apparatus and apparel used in connection with those practices, shall be kept clean and sanitary at all times and shall conform to or possess the following minimum standards:

(a) Indoor lighting for halls, wards, reception areas, examining and surgical rooms shall be adequate for their intended purpose.

(b) A reception room and office, or a combination of the two.

(c) An examination room separate from other areas of the facility and of sufficient size to accommodate the doctor, assistant, patient and client.

(d) If animals are housed or retained for treatment, the following shall be provided:

(1) Compartments for animals which are maintained in a comfortable and sanitary manner.

(2) Effective separation of known or suspected contagious animals.

(3) If there are to be no personnel on the premises during any time an animal is left at the veterinary facility, prior notice of this fact shall be given to the client. For purposes of this paragraph, prior notice may be accomplished by posting a sign in a place and manner conspicuous to the clients at the entrance of the premises, stating that there may be times when there are no personnel on the premises.

(e) When a veterinary premises is closed, a sign shall be posted and visible outside the primary entrance with a telephone number and location where emergency care is available. An answering machine or service shall be used to notify the public when the veterinary premises will be re-opened and where after hours emergency care is available. If no after hours emergency care is available, full disclosure shall be provided to the public prior to rendering services.

(f) The veterinary premises shall meet the following standards:

(1) Fire precautions shall meet the requirements of local and state fire prevention codes.

(2) The facility, its temperature, and ventilation shall be maintained so as to assure the comfort of all patients.

(3) The disposal of waste material shall comply with all applicable state, federal, and local laws and regulations.

(4) The veterinary premises shall have the capacity to render diagnostic radiological services, either on the premises or through other commercial facilities. Radiological procedures shall be conducted in accordance with Health and Safety Code standards.

(5) Clinical pathology and histopathology diagnostic laboratory services shall be available within the veterinary premises or through outside services.
(6) All drugs and biologicals shall be maintained, administered, dispensed and prescribed in compliance with state and federal laws.
(7) Sanitary methods for the disposal of deceased animals shall be provided and maintained.
(8) Veterinary medical equipment used to perform aseptic procedures shall be sterilized and maintained in a sterile condition.
(9) Current veterinary reference materials shall be readily available on the premises.
(10) Anesthetic equipment in accordance with the procedures performed shall be maintained in proper working condition and available at all times.
(11) The veterinary premises shall have equipment to deliver oxygen in emergency situations.
(12) Appropriate drugs and equipment shall be readily available to treat an animal emergency.

(g) A veterinary premises which provides aseptic surgical services shall comply with the following:

(1) A room, separate and distinct from all other rooms shall be reserved for aseptic surgical procedures which require aseptic preparation. A veterinarian may perform emergency aseptic surgical procedures in another room when the room designated for aseptic surgery is occupied or temporarily unavailable.

(A) A veterinary premises which is currently registered with the board, but does not have a separate room reserved for aseptic surgical procedures, shall obtain compliance with this subdivision on or before January 1, 2014.

(B) The board may exempt a veterinary premises which is currently registered with the board, but does not have a separate aseptic surgery room, where it determines that it would be a hardship for the veterinary premises to comply with the provisions of this subdivision.

In determining whether a hardship exists, the board shall give due consideration to the following factors:

1. Zoning limitations.
2. Whether the premises constitutes a historical building.
3. Whether compliance with this requirement would compel the veterinary practice to relocate to a new location.

(2) Storage in the surgery room shall be limited to items and equipment normally related to aseptic surgery and surgical procedures. Equipment not normally related to surgery and surgical procedure includes, but is not limited to, equipment used for dental prophylaxis, autoclaves and non-surgical radiographic equipment.
(3) Open shelving is prohibited in the surgical room.
(4) The surgery room shall not contain a functional sink with an open drain.
(5) The doors into the surgery room must be able to be fully closed, fill the entire door space, be made of non-porous material and not provide access from outside the hospital. In cases where the size of the animal prevents entry to the hospital via a regularly-sized door, doors for outside access are permitted as long as such doors are able to be fully closed, fill the entire door space and be made of non-porous material.
(6) The surgery room shall be well-lighted, shall have equipment for viewing radiographs and shall have effective emergency lighting with a viable power source.
(7) The floors, table tops, and counter tops of the surgery room shall be of a non-porous material suitable for regular disinfecting, and cleaning, and shall be cleaned and disinfected regularly.
(8) Surgical instruments and equipment shall be:

(A) Adequate for the type of surgical procedures performed.
(B) Sterilized as required by the surgical procedure performed and instruments used.

(9) In any sterile procedure, a separate sterile pack shall be used for each animal.
(10) All instruments, packs and equipment that have been sterilized shall have an indicator that reacts to and verifies sterilization.

(11) The following attire shall be required for aseptic surgery:

(A) Each member of the surgical team shall put on an appropriate sanitary cap and sanitary mask which covers his or her hair and mouth, nose and any facial hair, except for eyebrows or eyelashes. All members of the surgical team who will be handling the instruments or touching the surgical site shall wear sterilized surgical gowns with long sleeves and sterilized gloves.

(B) Ancillary personnel in the surgery room shall wear clean clothing, footwear, sanitary cap and mask.

(h) When performing clean surgery, the instruments used to perform such surgery shall have been sterilized and the surgeon(s) and ancillary personnel shall wear clean clothing and footwear when appropriate.

For purposes of this section, “clean surgery” shall mean the performance of a surgical operation for the treatment of a condition and under circumstances which, consistent with the standards of good veterinary medicine, do not warrant the use of aseptic surgical procedures.

2030.05. Minimum Standards - Licensee Manager.

(a) A Licensee Manager is the California licensed veterinarian named as the Licensee Manager on a facility’s premises permit.

(b) The Licensee Manager is responsible for ensuring that the premises for which he/she is manager complies with the requirements in sections 4853, 4854, 4855 and 4856 of the Business and Professions Code, Division 2, Chapter 11, Article 3. The Licensee Manager is responsible for ensuring that the physical and operational components of a premises meet the minimum standards of practice as set forth in sections 2030 through 2032.5 of the California Code of Regulations, Title 16, Division 20, Article 4.

(c) The Licensee Manager is responsible for ensuring that no unlicensed activity is occurring within the premises or in any location where any function of veterinary medicine, veterinary surgery or veterinary dentistry is being conducted off the premises under the auspices of this premises license.

(d) The Licensee Manager shall maintain whatever physical presence is reasonable within the facility to ensure that the requirements in (a) - (c) are met.

(e) Each licensed veterinarian shall be responsible for their individual violations of the Veterinary Medicine Practice Act or any regulation adopted thereunder.

2030.1. Minimum Standards - Small Animal Fixed Premises.

For purposes of these rules and regulations, a “small animal fixed premises” shall mean a fixed veterinary premises which concentrates in providing veterinary services to common domestic household pets.

In addition to the requirements in section 2030, small animal fixed premises shall provide:

(a) Where animals are kept on the veterinary premises for 24 hours or more, the animals shall be provided with an opportunity for proper exercise. Compliance with this section may be achieved by the use of exercise runs or by providing the animal with the opportunity for outdoor walks. Where a premises has exercise runs, they shall be clean and sanitary and provide for effective separation of animals and their waste products.

(b) When the client has not given the veterinarian authorization to dispose of his or her deceased animal, the veterinarian shall be required to retain the carcass in a freezer for at least 14 days prior to disposal.

2030.2. Small Animal Mobile Clinic.

For purposes of these regulations, a “small animal mobile clinic” shall mean a trailer or mobile facility established to function as a veterinary premises which concentrates in providing veterinary services to common domestic household pets and is required by section 4853 of the code to be registered with the board.

(a) A small animal mobile clinic shall have:
(1) Hot and cold water.
(2) A 110-volt power source for diagnostic equipment.
(3) A collection tank for disposal of waste material.
(4) Lighting adequate for the procedures to be performed in the mobile clinic.
(5) Floors, table tops, and counter tops shall be of a non-porous material suitable for regular disinfecting, and cleaning, and shall be cleaned and disinfected regularly.
(6) Compartments to transport or hold animals, if applicable.
(b) A small animal mobile clinic shall also have:
(1) indoor lighting for halls, wards, reception areas, examining and surgical rooms, which shall be adequate for its intended purpose.
(2) an examination room separate from other areas of the facility, which shall be of sufficient size to accommodate the doctor, assistant, patient and client.
(3) fire precautions that meet the requirements of local and state fire prevention codes,
(4) temperature and ventilation controls adequate to assure the comfort of all patients.
(5) a small animal mobile clinic which provides aseptic surgical services shall also have a room separate and distinct from other rooms, which shall be reserved for aseptic surgical procedures. Storage in the surgery room shall be limited to items and equipment normally related to surgery and surgical procedures. A veterinarian may perform emergency aseptic surgical procedures in another room when the room designated for aseptic surgery is occupied or temporarily unavailable. A small animal mobile clinic which provides aseptic surgical services and that is currently registered with the board, but does not have a separate room reserved for aseptic surgical procedures, shall provide the board with the vehicle identification number of the mobile clinic and obtain compliance with this subdivision on or before January 1, 2006.
(A) A small animal mobile clinic that provides aseptic surgery shall also have an examination area separate from the surgery room that is large enough to conduct an examination.
(c) A small animal mobile clinic shall have the ability and equipment to provide immediate emergency care at a level commensurate with the specific veterinary medical services it is providing.
(d) A small animal mobile clinic shall provide either after hours emergency services to its patients or, if no after hours emergency care is available, full disclosure to the public prior to rendering services.
(e) When the client has not given the veterinarian authorization to dispose of his or her deceased animal, the veterinarian shall be required to retain the carcass in a freezer for at least 14 days prior to disposal.

2030.3. Small Animal Vaccination Clinic.

(a) The term “small animal vaccination clinic” shall mean a privately or publicly supported vaccination clinic where a veterinarian performs vaccinations and/or immunizations against disease on multiple animals, and where the veterinarian may also perform preventative procedures for parasitic control.
(b) A veterinarian must remain on site throughout the duration of a vaccination clinic and must maintain responsibility for all medical decisions made. The veterinarian is responsible for proper immunization and parasitic procedures and the completeness of recommendations made to the public by the paraprofessional staff that the veterinarian supervises or employs. The veterinarian is responsible for consultation and referral of clients when disease is detected or suspected.
(c) The disposal of waste material shall comply with all applicable state, federal, and local laws and regulations.
(d) All drugs and biologicals shall be stored, maintained, administered, dispensed and prescribed according to the manufacturer’s recommendations and in compliance with state and federal laws.
(e) Lighting shall be adequate for the procedures to be performed in the vaccination clinic.

(f) Floors, table tops, and counter tops shall be of a non-porous material suitable for regular disinfecting, and cleaning, and shall be cleaned and disinfected regularly.
(g) Equipment shall be of the type and quality to provide for the delivery of vaccines and parasiticides in the best interest of the patient and with safety to the public.
(h) Fresh, clean water shall be available for sanitizing and first aid. Disposable towels and soap shall be readily available.
(i) A vaccination clinic shall have the ability and equipment to provide immediate emergency care at a level commensurate with the specific veterinary medical services it is providing.
(j) The vaccination clinic shall provide a legible list of the name, address, and hours of operation of all facilities that provide or advertise emergency services and, when applicable, the location of other clinics provided by the same entity on that day, that are located within a 30-minute or 30-mile radius.
(k) The vaccination clinic shall maintain all vaccination records for a minimum of three (3) years from the date of the vaccination.
(l) If any diagnostic tests are performed or dangerous drugs are provided, administered, prescribed or dispensed, then a valid veterinary-client-patient relationship must be established, including a complete physical exam and Medical Records as set forth in section 2032.3.
(m) The veterinarian shall be identifiable to the public, including, but not limited to the posting of a copy of the veterinarian's license, as set forth in section 4850 of the Business and Professions Code.

2032. Minimum Standards of Practice.

The delivery of veterinary care shall be provided in a competent and humane manner. All aspects of veterinary medicine shall be performed in a manner consistent with current veterinary medical practice in this state.

2032.05. Humane Treatment.

When treating a patient, a veterinarian shall use appropriate and humane care to minimize pain and distress before, during and after performing any procedure(s).

2032.1. Veterinarian-Client-Patient Relationship.

(a) It is unprofessional conduct for a veterinarian to administer, prescribe, dispense or furnish a drug, medicine, appliance, or treatment of whatever nature for the prevention, cure, or relief of a wound, fracture or bodily injury or disease of an animal without having first established a veterinarian-client-patient relationship with the animal patient or patients and the client, except where the patient is a wild animal or the owner is unknown.
(b) A veterinarian-client-patient relationship shall be established by the following ~~occur~~:
(1) The client has authorized the veterinarian to assume responsibility for making medical judgments regarding the health of the animal, including the need for medical treatment,
(2) The veterinarian has sufficient knowledge of the animal(s) to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s). This means that the veterinarian is personally acquainted with the care of the animal(s) by virtue of an examination of the animal or by medically appropriate and timely visits to the premises where the animals are kept, and
(3) The veterinarian has assumed responsibility for making medical judgments regarding the health of the animal and has communicated with the client a course of treatment appropriate to the circumstance.
(c) A drug shall not be prescribed for a duration inconsistent with the medical condition of the animal(s) or type of drug prescribed. The veterinarian shall not prescribe a drug for a duration longer than one year from the date the veterinarian examined the animal(s) and prescribed the drug.

(d) As used herein, “drug” shall mean any controlled substance, as defined by Section 4021 of Business and Professions code, and any dangerous drug, as defined by Section 4022 of Business and Professions code.

2032.15. Veterinarian-Client-Patient Relationship in Absence of Client Communication

(a) A veterinary-client-patient relationship may continue to exist, in the absence of client communication, when:

(1) A veterinary-client-patient relationship was established with an original veterinarian, and another designated veterinarian serves in the absence of the original veterinarian, and;

(2) The designated veterinarian has assumed responsibility for making medical judgments regarding the health of the animal(s), and;

(3) The designated veterinarian has sufficient knowledge of the animal(s) to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s). This means that the veterinarian is personally acquainted with the care of the animal(s) by virtue of an examination of the animal(s) or by medically appropriate and timely visits to the premises where the animal(s) is kept, or has consulted with the veterinarian who established the veterinary-client-patient relationship, and;

(4) The designated veterinarian has continued the medical, treatment, diagnostic and/or therapeutic plan that was set forth and documented in the medical record by the original veterinarian.

(b) If the medical, treatment, diagnostic and/or therapeutic plan differs from that which was communicated to the client by the original veterinarian, then the designated veterinarian must attempt to communicate the necessary changes with the client in a timely manner.

2032.2. Written Prescriptions.

(a) A written order, by a veterinarian, for dangerous drugs, as defined by Section 4022 of Business and Professions Code, shall include the following information:

(1) The name, signature, address and telephone number of the prescribing veterinarian.

(2) The veterinarian's license number and his or her federal registry number if a controlled substance is prescribed.

(3) The name and address of the client.

(4) The species and name, number or other identifying information for the animal.

(5) The name, strength, and quantity of the drug(s).

(6) Directions for use, including, if applicable, withdrawal time.

(7) Date of issue.

(8) The number of refills.

(b) All drugs dispensed shall be labeled with the following information:

(1) Name, address and telephone number of the facility.

(2) Client's name.

(3) The species and name, number, or other identifying information for the animal.

(4) Date dispensed.

(5) Directions for use, including, if applicable, withdrawal time.

(6) The manufacturer’s trade name of the drug or the generic names, strength (if more than one dosage form exists), and quantity of drug, and the expiration date when established by the manufacturer.

(7) Name of prescribing veterinarian.

(c) Pursuant to section 4170(a)(6) and (7) of the Business and Professions Code, veterinarians must notify clients that they have a choice to obtain either the medication or a written prescription and that they shall not be charged for the written prescription.

2032.25. Written Prescriptions in Absence of Originally Prescribing Veterinarian.

(a) Prescribing, dispensing, or furnishing dangerous drugs as defined in Section 4022 of the

Business and Professions Code without an appropriate prior examination and a medical indication, constitutes unprofessional conduct.
(b) No licensee shall be found to have committed unprofessional conduct within the meaning of this section if, at the time the drugs were prescribed, dispensed, or furnished, any of the following applies:

(1) The licensee was a veterinarian serving in the absence of the treating veterinarian and the drugs were prescribed, dispensed, or furnished only as necessary to maintain the animal patient until the return of the originally treating veterinarian, but in any case no longer than 72 hours.

(2) The veterinarian transmitted the order for the drugs to another veterinarian or registered veterinary technician and both of the following conditions exist:

(A) The licensee had consulted with the veterinarian or registered veterinary technician who had reviewed the patient's records.

(B) The licensee was designated as the veterinarian to serve in the absence of the animal patient's veterinarian.

(3) The licensee was a veterinarian serving in the absence of the treating veterinarian, was in possession of and had reviewed the animal patient's records, and ordered the renewal of a medically indicated prescription for an amount not exceeding the original prescription in strength or amount or for more than one refill.

2032.3. Record Keeping; Records; Contents; Transfer.

(a) Every veterinarian performing any act requiring a license pursuant to the provisions of Chapter 11, Division 2, of the code, upon any animal or group of animals shall prepare a legible, written or computer generated record concerning the animal or animals which shall contain the following information:

(1) Name or initials of the person responsible for entries.

(2) Name, address and phone number of the client.

(3) Name or identity of the animal, herd or flock.

(4) Except for herds or flocks, age, sex, breed, species, and color of the animal.

(5) Dates (beginning and ending) of custody of the animal, if applicable.

(6) A history or pertinent information as it pertains to each animal, herd, or flock’s medical status.

(7) Data, including that obtained by instrumentation, from the physical examination.

(8) Treatment and intended treatment plan, including medications, dosages, route of administration, and frequency of use.

(9) Records for surgical procedures shall include a description of the procedure, the name of the surgeon, the type of sedative/anesthetic agents used, their route of administration, and their strength if available in more than one strength.

(10) Diagnosis or assessment prior to performing a treatment or procedure.

(11) If relevant, a prognosis of the animal’s condition.

(12) All medications and treatments prescribed and dispensed, including strength, dosage, route of administration, quantity, and frequency of use.

(13) Daily progress, if relevant, and disposition of the case.

(b) Records shall be maintained for a minimum of three (3) years after the animal’s last visit. A summary of an animal’s medical records shall be made available to the client within five (5) days or sooner, depending if the animal is in critical condition, upon his or her request. The summary shall include:

(1) Name and address of client and animal.

(2) Age, sex, breed, species, and color of the animal.

(3) A history or pertinent information as it pertains to each animal’s medical status.

(4) Data, including that obtained by instrumentation, from the physical examination.

(5) Treatment and intended treatment plan, including medications, their dosage and frequency of use.

(6) All medications and treatments prescribed and dispensed, including strength, dosage, route of administration, quantity, and frequency of use.

(7) Daily progress, if relevant, and disposition of the case.

(c)(1) Radiographs and digital images are the property of the veterinary facility that originally ordered them to be prepared. Radiographs or digital images shall be released to another veterinarian upon the request of another veterinarian who has the authorization of the client. Radiographs shall be returned to the veterinary facility which originally ordered them to be prepared within a reasonable time upon request. Radiographs originating at an emergency hospital shall become the property of the next attending veterinary facility upon receipt of said radiograph(s). Transfer of radiographs shall be documented in the medical record.

(2) Radiograph and digital images, except for intraoral radiographs, shall have a permanent identification legibly exposed in the radiograph or attached to the digital file, which shall include the following:

(A) The hospital or clinic name and/or the veterinarian's name,

(B) Client identification,

(C) Patient identification, and

(D) The date the radiograph was taken.

(3) Non-digital intraoral radiographs shall be inserted into sleeve containers and include information in subdivision (c)(2)(A) - (D). Digital images shall have identification criteria listed in subdivision (c)(2)(A) - (D) attached to the digital file.

(d) Laboratory data is the property of the veterinary facility which originally ordered it to be prepared, and a copy shall be released upon the request of the client.

(e) The client shall be provided with a legible copy of the medical record when the patient is released following emergency clinic service. The minimum information included in the medical record shall consist of the following:

(1) Physical examination findings

(2) Dosages and time of administration of medications

(3) Copies of diagnostic data or procedures

(4) All radiographs and digital images, for which the facility shall obtain a signed release when transferred

(5) Surgical summary

(6) Tentative diagnosis and prognosis, if known

(7) Any follow-up instructions.

2032.35. Altering Medical Records

Altering or modifying the medical record of any animal, with fraudulent intent, or creating any false medical record, with fraudulent intent, constitutes unprofessional conduct in accordance with Business and Professions Code section 4883(g).

2032.4. Anesthesia.

(a) General anesthesia is a condition caused by the administration of a drug or combination of drugs sufficient to produce a state of unconsciousness or dissociation and blocked response to a given pain or alarming stimulus.

(b) When administering general anesthesia, a veterinarian shall comply with the following standards:

(1) Within twelve (12) hours prior to the administration of a general anesthetic, the animal patient shall be given a physical examination by a licensed veterinarian appropriate for the procedure. The results of the physical examination shall be documented in the animal patient's medical records.

(2) An animal under general anesthesia shall be observed for a length of time appropriate for its safe recovery.

(3) Provide respiratory monitoring including, but not limited to, observation of the animal's chest movements, observation of the rebreathing bag~~,~~ or respirometer.

(4) Provide cardiac monitoring including, but not limited to, the use of a stethoscope, pulseoximeter or electrocardiographic monitor.
(5) When administering general anesthesia in a hospital setting, a veterinarian shall have resuscitation or rebreathing bags of appropriate volumes for the animal patient and an assortment of endotracheal tubes readily available.
(6) Records for procedures involving general anesthesia shall include a description of the procedure, the name of the surgeon, the type of sedative and/or anesthetic agents used, their route of administration, and their strength if available in more than one strength.

2032.5. Emergency Hospitals.

(a) Any veterinary premises that displays any sign, card, or device that indicates to the public that it is an emergency veterinary clinic or hospital shall comply with the following:
(1) Maintain a licensed veterinarian on the premises at all times during the posted hours of operation.
(2) Its advertisements shall clearly state:
(A) A licensed veterinarian is on the premises during the posted emergency hours.
(B) The hours the facility will provide emergency services.
(C) The address and telephone number of the premises.
(b) The phrase “veterinarian on call” shall mean that a veterinarian is not present at the hospital, but is able to respond within a reasonable time to requests for emergency veterinary services and has been designated by a daytime veterinary facility to do so after regular office hours. A veterinary premises which uses a veterinarian on call service shall not be considered to be or advertised as an emergency clinic or hospital.

2037. Dental Operation, Defined

(a) The term “dental operation” as used in Business and Professions Code section 4826 means:
(1) The application or use of any instrument, device, or scaler to any portion of the animals tooth, gum or any related tissue for the prevention, cure or relief of any wound, fracture, injury or disease of an animal’s tooth, gum or related tissue; and
(2) Preventive dental procedures including, but not limited to, the removal of calculus, soft deposits, plaque, stains or the smoothing, filing, scaling or polishing of tooth surfaces.
(b) Nothing in this regulation shall prohibit any person from utilizing cotton swabs, gauze, dental floss, dentifrice, or toothbrushes on an animal’s teeth.

STATE OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS

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

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MEMORANDUM

DATE	October 20, 2014
TO	Multidisciplinary Advisory Committee
FROM	Annemarie Del Mugnaio, Executive Officer DCA/Veterinary Medical Board
SUBJECT	Premise Permit - Registration

Background:

Section 4853, states, in part: *(a) All premises where veterinary medicine, veterinary dentistry, veterinary surgery, and the various branches thereof is being practiced shall be registered with the board…."* Subdivision (b) defines a "premise" as including a building, kennel, mobile unit or vehicle. The statute further states that *mobile units and vehicles shall be exempted from independent registration with the board when they are operated from a building or facility which is the licensee manager's principle place of business and the building is registered with the board, and the registration identifies and declares the use of the mobile unit or vehicle.*

Issues:

BPC 4853 (b) has been interpreted to allow a managing licensee with a fixed premise, the authority to provide care at alternate locations (e.g., pet stores, feed stores, etc.), such that the care provided at the alternate locations was considered part of a mobile practice. The concern is that these locations are fixed buildings that may or may not have adequate resources and sanitation provisions, and the Board has no knowledge of their existence. The law exempts "mobile units or vehicles" identified and declared to the Board as an extension of the fixed premise permit, but does not appear to extend to alternate/third party locations.

With the implementation of the new minimum standards, the Board is fielding questions from professional associations, attorneys, and licensees regarding the authority of a veterinarian to "use" the premise permit at locations other than the primary fixed animal hospital, clinic, etc. The issue was discussed at the April 23-24, 2014, MDC and VMB meetings and again at the July 23, 2014, VMB meeting where the Board delegated the matter to the MDC to discuss whether regulations should be adopted to further define minimum standards for alternate types of practice, that is, large animal and specialty services providing dental care, as opposed to defining the premise license as "mobile or ambulatory."

Legal Counsel's read of the statute is as follows:

> *Section 4853(b) allows only "mobile units and vehicles" to be exempt, and even then they must be identified and declared in the registration for the principal place of business. Other fixed structures (alternate/third party locations) would be buildings that should be independently registered with the Board pursuant to this section.*

While § 4809.5 states that the "inspection authority does not extend to premises that are not registered with the board" "that" use of the word 'premises' is unclear because "premises where veterinary medicine…is being practiced" is already defined as being a place that shall be registered with the board (§ 4853(a)). In other words, there would be no such place as a "premise" not registered with the Board.

Attachments:

- Business and Professions Code Sections 4853 & 4809.5
- California Code of Regulations Sections 2030-2037 – Minimum Standards

Action Requested:

Review current premise definitions and minimum standards to determine appropriate oversight of veterinary services provided at locations not currently addressed in statute or regulation.

BPC 4853

(a) All premises where veterinary medicine, veterinary dentistry, veterinary surgery, and the various branches thereof is being practiced shall be registered with the board. The certificate of registration shall be on a form prescribed in accordance with Section 164.

(b) "Premises" for the purpose of this chapter shall include a building, kennel, mobile unit, or vehicle. Mobile units and vehicles shall be exempted from independent registration with the board when they are operated from a building or facility which is the licensee manager's principal place of business and the building is registered with the board, and the registration identifies and declares the use of the mobile unit or vehicle.

(c) Every application for registration of veterinary premises shall set forth in the application the name of the responsible licensee manager who is to act for and on behalf of the licensed premises. Substitution of the responsible licensee manager may be accomplished by application to the board if the following conditions are met:

(1) The person substituted qualifies by presenting satisfactory evidence that he or she possesses a valid, unexpired, and unrevoked license as provided by this chapter and that the license is not currently under suspension.

(2) No circumvention of the law is contemplated by the substitution.

BPC 4809.5

The board may at any time inspect the premises in which veterinary medicine, veterinary dentistry, or veterinary surgery is being practiced. The board's inspection authority does not extend to premises that are not registered with the board. Nothing in this section shall be construed to affect the board's ability to investigate alleged unlicensed activity or to inspect a premises for which registration has lapsed or is delinquent.

(Amended by Stats. 2013, Ch. 515, Sec. 21. Effective January 1, 2014.)

CCR Sections 2030-2037

2030. Minimum Standards - Fixed Veterinary Premises.

All fixed premises where veterinary medicine and its various branches are being practiced, and all instruments, apparatus and apparel used in connection with those practices, shall be kept clean and sanitary at all times and shall conform to or possess the following minimum standards:
(a) Indoor lighting for halls, wards, reception areas, examining and surgical rooms shall be adequate for their intended purpose.
(b) A reception room and office, or a combination of the two.
(c) An examination room separate from other areas of the facility and of sufficient size to accommodate the doctor, assistant, patient and client.
(d) If animals are housed or retained for treatment, the following shall be provided:

(1) Compartments for animals which are maintained in a comfortable and sanitary manner.
(2) Effective separation of known or suspected contagious animals.
(3) If there are to be no personnel on the premises during any time an animal is left at the veterinary facility, prior notice of this fact shall be given to the client. For purposes of this paragraph, prior notice may be accomplished by posting a sign in a place and manner conspicuous to the clients at the entrance of the premises, stating that there may be times when there are no personnel on the premises.
(e) When a veterinary premises is closed, a sign shall be posted and visible outside the primary entrance with a telephone number and location where emergency care is available. An answering machine or service shall be used to notify the public when the veterinary premises will be re-opened and where after hours emergency care is available. If no after hours emergency care is available, full disclosure shall be provided to the public prior to rendering services.
(f) The veterinary premises shall meet the following standards:
(1) Fire precautions shall meet the requirements of local and state fire prevention codes.
(2) The facility, its temperature, and ventilation shall be maintained so as to assure the comfort of all patients.
(3) The disposal of waste material shall comply with all applicable state, federal, and local laws and regulations.
(4) The veterinary premises shall have the capacity to render diagnostic radiological services, either on the premises or through other commercial facilities. Radiological procedures shall be conducted in accordance with Health and Safety Code standards.
(5) Clinical pathology and histopathology diagnostic laboratory services shall be available within the veterinary premises or through outside services.
(6) All drugs and biologicals shall be maintained, administered, dispensed and prescribed in compliance with state and federal laws.
(7) Sanitary methods for the disposal of deceased animals shall be provided and maintained.
(8) Veterinary medical equipment used to perform aseptic procedures shall be sterilized and maintained in a sterile condition.
(9) Current veterinary reference materials shall be readily available on the premises.
(10) Anesthetic equipment in accordance with the procedures performed shall be maintained in proper working condition and available at all times.
(11) The veterinary premises shall have equipment to deliver oxygen in emergency situations.
(12) Appropriate drugs and equipment shall be readily available to treat an animal emergency.
(g) A veterinary premises which provides aseptic surgical services shall comply with the following:
(1) A room, separate and distinct from all other rooms shall be reserved for aseptic surgical procedures which require aseptic preparation. A veterinarian may perform emergency aseptic surgical procedures in another room when the room designated for aseptic surgery is occupied or temporarily unavailable.
(A) A veterinary premises which is currently registered with the board, but does not have a separate room reserved for aseptic surgical procedures, shall obtain compliance with this subdivision on or before January 1, 2014.
(B) The board may exempt a veterinary premises which is currently registered with the board, but does not have a separate aseptic surgery room, where it determines that it would be a hardship for the veterinary premises to comply with the provisions of this subdivision.
In determining whether a hardship exists, the board shall give due consideration to the following

factors:
1. Zoning limitations.
2. Whether the premises constitutes a historical building.
3. Whether compliance with this requirement would compel the veterinary practice to relocate to a new location.
(2) Storage in the surgery room shall be limited to items and equipment normally related to aseptic surgery and surgical procedures. Equipment not normally related to surgery and surgical procedure includes, but is not limited to, equipment used for dental prophylaxis, autoclaves and non-surgical radiographic equipment.
(3) Open shelving is prohibited in the surgical room.
(4) The surgery room shall not contain a functional sink with an open drain.
(5) The doors into the surgery room must be able to be fully closed, fill the entire door space, be made of non-porous material and not provide access from outside the hospital. In cases where the size of the animal prevents entry to the hospital via a regularly-sized door, doors for outside access are permitted as long as such doors are able to be fully closed, fill the entire door space and be made of non-porous material.
(6) The surgery room shall be well lighted, shall have equipment for viewing radiographs and shall have effective emergency lighting with a viable power source.
(7) The floors, table tops, and counter tops of the surgery room shall be of a non-porous material suitable for regular disinfecting, and cleaning, and shall be cleaned and disinfected regularly.
(8) Surgical instruments and equipment shall be:
(A) Adequate for the type of surgical procedures performed.
(B) Sterilized as required by the surgical procedure performed and instruments used.
(9) In any sterile procedure, a separate sterile pack shall be used for each animal.
(10) All instruments, packs and equipment that have been sterilized shall have an indicator that reacts to and verifies sterilization.
(11) The following attire shall be required for aseptic surgery:
(A) Each member of the surgical team shall put on an appropriate sanitary cap and sanitary mask which covers his or her hair and mouth, nose and any facial hair, except for eyebrows or eyelashes. All members of the surgical team who will be handling the instruments or touching the surgical site shall wear sterilized surgical gowns with long sleeves and sterilized gloves.
(B) Ancillary personnel in the surgery room shall wear clean clothing, footwear, sanitary cap and mask.
(h) When performing clean surgery, the instruments used to perform such surgery shall have been sterilized and the surgeon(s) and ancillary personnel shall wear clean clothing and footwear when appropriate.
For purposes of this section, “clean surgery” shall mean the performance of a surgical operation for the treatment of a condition and under circumstances which, consistent with the standards of good veterinary medicine, do not warrant the use of aseptic surgical procedures.

2030.05. Minimum Standards - Licensee Manager.

(a) A Licensee Manager is the California licensed veterinarian named as the Licensee Manager on a facility’s premises permit.
(b) The Licensee Manager is responsible for ensuring that the premises for which he/she is manager complies with the requirements in sections 4853, 4854, 4855 and 4856 of the Business

and Professions Code, Division 2, Chapter 11, Article 3. The Licensee Manager is responsible for ensuring that the physical and operational components of a premises meet the minimum standards of practice as set forth in sections 2030 through 2032.5 of the California Code of Regulations, Title 16, Division 20, Article 4.
(c) The Licensee Manager is responsible for ensuring that no unlicensed activity is occurring within the premises or in any location where any function of veterinary medicine, veterinary surgery or veterinary dentistry is being conducted off the premises under the auspices of this premises license.
(d) The Licensee Manager shall maintain whatever physical presence is reasonable within the facility to ensure that the requirements in (a) - (c) are met.
(e) Each licensed veterinarian shall be responsible for their individual violations of the Veterinary Medicine Practice Act or any regulation adopted thereunder.

2030.1. Minimum Standards - Small Animal Fixed Premises.

For purposes of these rules and regulations, a “small animal fixed premises” shall mean a fixed veterinary premises which concentrates in providing veterinary services to common domestic household pets.
In addition to the requirements in section 2030, small animal fixed premises shall provide:
(a) Where animals are kept on the veterinary premises for 24 hours or more, the animals shall be provided with an opportunity for proper exercise. Compliance with this section may be achieved by the use of exercise runs or by providing the animal with the opportunity for outdoor walks. Where a premises has exercise runs, they shall be clean and sanitary and provide for effective separation of animals and their waste products.
(b) When the client has not given the veterinarian authorization to dispose of his or her deceased animal, the veterinarian shall be required to retain the carcass in a freezer for at least 14 days prior to disposal.

2030.2. Small Animal Mobile Clinic.

For purposes of these regulations, a “small animal mobile clinic” shall mean a trailer or mobile facility established to function as a veterinary premises which concentrates in providing veterinary services to common domestic household pets and is required by section 4853 of the code to be registered with the board.
(a) A small animal mobile clinic shall have:
(1) Hot and cold water.
(2) A 110-volt power source for diagnostic equipment.
(3) A collection tank for disposal of waste material.
(4) Lighting adequate for the procedures to be performed in the mobile clinic.
(5) Floors, table tops, and counter tops shall be of a non-porous material suitable for regular disinfecting, and cleaning, and shall be cleaned and disinfected regularly.
(6) Compartments to transport or hold animals, if applicable.
(b) A small animal mobile clinic shall also have:
(1) indoor lighting for halls, wards, reception areas, examining and surgical rooms, which shall be adequate for its intended purpose.
(2) an examination room separate from other areas of the facility, which shall be of sufficient

size to accommodate the doctor, assistant, patient and client.
(3) fire precautions that meet the requirements of local and state fire prevention codes,
(4) temperature and ventilation controls adequate to assure the comfort of all patients.
(5) a small animal mobile clinic which provides aseptic surgical services shall also have a room separate and distinct from other rooms, which shall be reserved for aseptic surgical procedures. Storage in the surgery room shall be limited to items and equipment normally related to surgery and surgical procedures. A veterinarian may perform emergency aseptic surgical procedures in another room when the room designated for aseptic surgery is occupied or temporarily unavailable. A small animal mobile clinic which provides aseptic surgical services and that is currently registered with the board, but does not have a separate room reserved for aseptic surgical procedures, shall provide the board with the vehicle identification number of the mobile clinic and obtain compliance with this subdivision on or before January 1, 2006.
(A) A small animal mobile clinic that provides aseptic surgery shall also have an examination area separate from the surgery room that is large enough to conduct an examination.
(c) A small animal mobile clinic shall have the ability and equipment to provide immediate emergency care at a level commensurate with the specific veterinary medical services it is providing.
(d) A small animal mobile clinic shall provide either after hours emergency services to its patients or, if no after hours emergency care is available, full disclosure to the public prior to rendering services.
(e) When the client has not given the veterinarian authorization to dispose of his or her deceased animal, the veterinarian shall be required to retain the carcass in a freezer for at least 14 days prior to disposal.

2030.3. Small Animal Vaccination Clinic.

(a) The term “small animal vaccination clinic” shall mean a privately or publicly supported vaccination clinic where a veterinarian performs vaccinations and/or immunizations against disease on multiple animals, and where the veterinarian may also perform preventative procedures for parasitic control.
(b) A veterinarian must remain on site throughout the duration of a vaccination clinic and must maintain responsibility for all medical decisions made. The veterinarian is responsible for proper immunization and parasitic procedures and the completeness of recommendations made to the public by the paraprofessional staff that the veterinarian supervises or employs. The veterinarian is responsible for consultation and referral of clients when disease is detected or suspected.
(c) The disposal of waste material shall comply with all applicable state, federal, and local laws and regulations.
(d) All drugs and biologicals shall be stored, maintained, administered, dispensed and prescribed according to the manufacturer’s recommendations and in compliance with state and federal laws.
(e) Lighting shall be adequate for the procedures to be performed in the vaccination clinic.
(f) Floors, table tops, and counter tops shall be of a non-porous material suitable for regular disinfecting, and cleaning, and shall be cleaned and disinfected regularly.
(g) Equipment shall be of the type and quality to provide for the delivery of vaccines and parasiticides in the best interest of the patient and with safety to the public.
(h) Fresh, clean water shall be available for sanitizing and first aid. Disposable towels and soap shall be readily available.

(i) A vaccination clinic shall have the ability and equipment to provide immediate emergency care at a level commensurate with the specific veterinary medical services it is providing.
(j) The vaccination clinic shall provide a legible list of the name, address, and hours of operation of all facilities that provide or advertise emergency services and, when applicable, the location of other clinics provided by the same entity on that day, that are located within a 30-minute or 30-mile radius.
(k) The vaccination clinic shall maintain all vaccination records for a minimum of three (3) years from the date of the vaccination.
(l) If any diagnostic tests are performed or dangerous drugs are provided, administered, prescribed or dispensed, then a valid veterinary-client-patient relationship must be established, including a complete physical exam and Medical Records as set forth in section 2032.3.
(m) The veterinarian shall be identifiable to the public, including, but not limited to the posting of a copy of the veterinarian's license, as set forth in section 4850 of the Business and Professions Code.

2032. Minimum Standards of Practice.

The delivery of veterinary care shall be provided in a competent and humane manner. All aspects of veterinary medicine shall be performed in a manner consistent with current veterinary medical practice in this state.

2032.05. Humane Treatment.

When treating a patient, a veterinarian shall use appropriate and humane care to minimize pain and distress before, during and after performing any procedure(s).

2032.1. Veterinarian-Client-Patient Relationship.

(a) It is unprofessional conduct for a veterinarian to administer, prescribe, dispense or furnish a drug, medicine, appliance, or treatment of whatever nature for the prevention, cure, or relief of a wound, fracture or bodily injury or disease of an animal without having first established a veterinarian-client-patient relationship with the animal patient or patients and the client, except where the patient is a wild animal or the owner is unknown.
(b) A veterinarian-client-patient relationship shall be established by the following occur:
(1) The client has authorized the veterinarian to assume responsibility for making medical judgments regarding the health of the animal, including the need for medical treatment,
(2) The veterinarian has sufficient knowledge of the animal(s) to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s). This means that the veterinarian is personally acquainted with the care of the animal(s) by virtue of an examination of the animal or by medically appropriate and timely visits to the premises where the animals are kept, and
(3) The veterinarian has assumed responsibility for making medical judgments regarding the health of the animal and has communicated with the client a course of treatment appropriate to the circumstance.
(c) A drug shall not be prescribed for a duration inconsistent with the medical condition of the animal(s) or type of drug prescribed. The veterinarian shall not prescribe a drug for a duration longer than one year from the date the veterinarian examined the animal(s) and prescribed the

drug.
(d) As used herein, “drug” shall mean any controlled substance, as defined by Section 4021 of Business and Professions code, and any dangerous drug, as defined by Section 4022 of Business and Professions code.

2032.15. Veterinarian-Client-Patient Relationship in Absence of Client Communication.

(a) A veterinary-client-patient relationship may continue to exist, in the absence of client communication, when:
(1) A veterinary-client-patient relationship was established with an original veterinarian, and another designated veterinarian serves in the absence of the original veterinarian, and;
(2) The designated veterinarian has assumed responsibility for making medical judgments regarding the health of the animal(s), and;
(3) The designated veterinarian has sufficient knowledge of the animal(s) to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s). This means that the veterinarian is personally acquainted with the care of the animal(s) by virtue of an examination of the animal(s) or by medically appropriate and timely visits to the premises where the animal(s) is kept, or has consulted with the veterinarian who established the veterinary-client-patient relationship, and;
(4) The designated veterinarian has continued the medical, treatment, diagnostic and/or therapeutic plan that was set forth and documented in the medical record by the original veterinarian.
(b) If the medical, treatment, diagnostic and/or therapeutic plan differs from that which was communicated to the client by the original veterinarian, then the designated veterinarian must attempt to communicate the necessary changes with the client in a timely manner.

2032.2. Written Prescriptions.

(a) A written order, by a veterinarian, for dangerous drugs, as defined by Section 4022 of Business and Professions Code, shall include the following information:
(1) The name, signature, address and telephone number of the prescribing veterinarian.
(2) The veterinarian's license number and his or her federal registry number if a controlled substance is prescribed.
(3) The name and address of the client.
(4) The species and name, number or other identifying information for the animal.
(5) The name, strength, and quantity of the drug(s).
(6) Directions for use, including, if applicable, withdrawal time.
(7) Date of issue.
(8) The number of refills.
(b) All drugs dispensed shall be labeled with the following information:
(1) Name, address and telephone number of the facility.
(2) Client's name.
(3) The species and name, number, or other identifying information for the animal.
(4) Date dispensed.
(5) Directions for use, including, if applicable, withdrawal time.
(6) The manufacturer’s trade name of the drug or the generic names, strength (if more than one

dosage form exists), and quantity of drug, and the expiration date when established by the manufacturer.
(7) Name of prescribing veterinarian.
(c) Pursuant to section 4170(a)(6) and (7) of the Business and Professions Code, veterinarians must notify clients that they have a choice to obtain either the medication or a written prescription and that they shall not be charged for the written prescription.

2032.25. Written Prescriptions in Absence of Originally Prescribing Veterinarian.

(a) Prescribing, dispensing, or furnishing dangerous drugs as defined in Section 4022 of the Business and Professions Code without an appropriate prior examination and a medical indication, constitutes unprofessional conduct.
(b) No licensee shall be found to have committed unprofessional conduct within the meaning of this section if, at the time the drugs were prescribed, dispensed, or furnished, any of the following applies:
(1) The licensee was a veterinarian serving in the absence of the treating veterinarian and the drugs were prescribed, dispensed, or furnished only as necessary to maintain the animal patient until the return of the originally treating veterinarian, but in any case no longer than 72 hours.
(2) The veterinarian transmitted the order for the drugs to another veterinarian or registered veterinary technician and both of the following conditions exist:
(A) The licensee had consulted with the veterinarian or registered veterinary technician who had reviewed the patient's records.
(B) The licensee was designated as the veterinarian to serve in the absence of the animal patient's veterinarian.
(3) The licensee was a veterinarian serving in the absence of the treating veterinarian, was in possession of and had reviewed the animal patient's records, and ordered the renewal of a medically indicated prescription for an amount not exceeding the original prescription in strength or amount or for more than one refill.

2032.3. Record Keeping; Records; Contents; Transfer.

(a) Every veterinarian performing any act requiring a license pursuant to the provisions of Chapter 11, Division 2, of the code, upon any animal or group of animals shall prepare a legible, written or computer generated record concerning the animal or animals which shall contain the following information:
(1) Name or initials of the person responsible for entries.
(2) Name, address and phone number of the client.
(3) Name or identity of the animal, herd or flock.
(4) Except for herds or flocks, age, sex, breed, species, and color of the animal.
(5) Dates (beginning and ending) of custody of the animal, if applicable.
(6) A history or pertinent information as it pertains to each animal, herd, or flock’s medical status.
(7) Data, including that obtained by instrumentation, from the physical examination.
(8) Treatment and intended treatment plan, including medications, dosages, route of administration, and frequency of use.
(9) Records for surgical procedures shall include a description of the procedure, the name of the

surgeon, the type of sedative/anesthetic agents used, their route of administration, and their strength if available in more than one strength.
(10) Diagnosis or assessment prior to performing a treatment or procedure.
(11) If relevant, a prognosis of the animal's condition.
(12) All medications and treatments prescribed and dispensed, including strength, dosage, route of administration, quantity, and frequency of use.
(13) Daily progress, if relevant, and disposition of the case.
(b) Records shall be maintained for a minimum of three (3) years after the animal's last visit. A summary of an animal's medical records shall be made available to the client within five (5) days or sooner, depending if the animal is in critical condition, upon his or her request. The summary shall include:
(1) Name and address of client and animal.
(2) Age, sex, breed, species, and color of the animal.
(3) A history or pertinent information as it pertains to each animal's medical status.
(4) Data, including that obtained by instrumentation, from the physical examination.
(5) Treatment and intended treatment plan, including medications, their dosage and frequency of use.
(6) All medications and treatments prescribed and dispensed, including strength, dosage, route of administration, quantity, and frequency of use.
(7) Daily progress, if relevant, and disposition of the case.
(c)(1) Radiographs and digital images are the property of the veterinary facility that originally ordered them to be prepared. Radiographs or digital images shall be released to another veterinarian upon the request of another veterinarian who has the authorization of the client. Radiographs shall be returned to the veterinary facility which originally ordered them to be prepared within a reasonable time upon request. Radiographs originating at an emergency hospital shall become the property of the next attending veterinary facility upon receipt of said radiograph(s). Transfer of radiographs shall be documented in the medical record.
(2) Radiograph and digital images, except for intraoral radiographs, shall have a permanent identification legibly exposed in the radiograph or attached to the digital file, which shall include the following:
(A) The hospital or clinic name and/or the veterinarian's name,
(B) Client identification,
(C) Patient identification, and
(D) The date the radiograph was taken.
(3) Non-digital intraoral radiographs shall be inserted into sleeve containers and include information in subdivision (c)(2)(A) - (D). Digital images shall have identification criteria listed in subdivision (c)(2)(A) - (D) attached to the digital file.
(d) Laboratory data is the property of the veterinary facility which originally ordered it to be prepared, and a copy shall be released upon the request of the client.
(e) The client shall be provided with a legible copy of the medical record when the patient is released following emergency clinic service. The minimum information included in the medical record shall consist of the following:
(1) Physical examination findings
(2) Dosages and time of administration of medications
(3) Copies of diagnostic data or procedures
(4) All radiographs and digital images, for which the facility shall obtain a signed release when

transferred
(5) Surgical summary
(6) Tentative diagnosis and prognosis, if known
(7) Any follow up instructions.

2032.35. Altering Medical Records.

Altering or modifying the medical record of any animal, with fraudulent intent, or creating any false medical record, with fraudulent intent, constitutes unprofessional conduct in accordance with Business and Professions Code section 4883(g).

2032.4. Anesthesia.

(a) General anesthesia is a condition caused by the administration of a drug or combination of drugs sufficient to produce a state of unconsciousness or dissociation and blocked response to a given pain or alarming stimulus.
(b) When administering general anesthesia, a veterinarian shall comply with the following standards:
(1) Within twelve (12) hours prior to the administration of a general anesthetic, the animal patient shall be given a physical examination by a licensed veterinarian appropriate for the procedure. The results of the physical examination shall be documented in the animal patient's medical records.
(2) An animal under general anesthesia shall be observed for a length of time appropriate for its safe recovery.
(3) Provide respiratory monitoring including, but not limited to, observation of the animal's chest movements, observation of the rebreathing bag, or respirometer.
(4) Provide cardiac monitoring including, but not limited to, the use of a stethoscope, pulseoximeter or electrocardiographic monitor.
(5) When administering general anesthesia in a hospital setting, a veterinarian shall have resuscitation or rebreathing bags of appropriate volumes for the animal patient and an assortment of endotracheal tubes readily available.
(6) Records for procedures involving general anesthesia shall include a description of the procedure, the name of the surgeon, the type of sedative and/or anesthetic agents used, their route of administration, and their strength if available in more than one strength.

2032.5. Emergency Hospitals.

(a) Any veterinary premises that displays any sign, card, or device that indicates to the public that it is an emergency veterinary clinic or hospital shall comply with the following:
(1) Maintain a licensed veterinarian on the premises at all times during the posted hours of operation.
(2) Its advertisements shall clearly state:
(A) A licensed veterinarian is on the premises during the posted emergency hours.
(B) The hours the facility will provide emergency services.
(C) The address and telephone number of the premises.
(b) The phrase "veterinarian on call" shall mean that a veterinarian is not present at the hospital,

but is able to respond within a reasonable time to requests for emergency veterinary services and has been designated by a daytime veterinary facility to do so after regular office hours. A veterinary premises which uses a veterinarian on call service shall not be considered to be or advertised as an emergency clinic or hospital.

2037. Dental Operation, Defined.

(a) The term “dental operation” as used in Business and Professions Code section 4826 means:
(1) The application or use of any instrument, device, or scaler to any portion of the animals tooth, gum or any related tissue for the prevention, cure or relief of any wound, fracture, injury or disease of an animal’s tooth, gum or related tissue; and
(2) Preventive dental procedures including, but not limited to, the removal of calculus, soft deposits, plaque, stains or the smoothing, filing, scaling or polishing of tooth surfaces.
(b) Nothing in this regulation shall prohibit any person from utilizing cotton swabs, gauze, dental floss, dentifrice, or toothbrushes on an animal’s teeth.

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

VETERINARY PREMISE APPLICATION

1. APPLICATION TYPE/FEES

☐ $200.00 - Initial Fixed or Mobile Premise Registration Premise Open Date _____ ☐ No Fee - Initial City, County, or State Owned Premise Registration Premise Open Date _____ ☐ $25.00 - Premise Relocation/Change of Address Premise Open Date _____ ☐ $25.00 - Change of Premise Name or Managing Licensee Date of Change _____ ☐ No Fee - Change of Business Type or Ownership	***Office Use Only*** **Receipt Number:** **Date Cashiered:** **ATS ID:** **Amount Paid:** **Refund:** Please make check or money order payable to the "VMB" Mail application and fee to: Veterinary Medical Board 1747 N. Market Blvd. Suite 230 Sacramento, CA 95834

2. FACILITY INFORMATION

NAME OF BUSINESS		PREMISE NUMBER
TELEPHONE NUMBER	FAX NUMBER	
PHYSICAL ADDRESS		
CITY	STATE	ZIP
MAILING ADDRESS*		
CITY	STATE	ZIP

**List only if there is no mail delivery to the physical address. Only your Mailing Address will be public information.*

3. MANAGING LICENSEE INFORMATION

LAST	FIRST	MIDDLE
CALIFORNIA VETERINARY LICENSE NUMBER	LICENSE EXPIRATION DATE	
MAILING ADDRESS		
CITY	STATE	ZIP
U.S. SOCIAL SECURITY NUMBER:	TELEPHONE NUMBER:	
EMAIL ADDRESS:		

4. MANAGING LICENSEE DISCLOSURE

Are you currently registered as a managing licensee of another veterinary premise? If YES, please list Permit Number(s):	YES ☐ NO ☐
Will those premises remain open?	YES ☐ NO ☐
Will you remain as managing licensee?	YES ☐ NO ☐

5. MANAGING LICENSEE CONVICTION INFORMATION

Have you been convicted or pled nolo contendere to a felony or misdemeanor, other than a minor traffic violation, or had any disciplinary action taken against you by any licensing/regulatory agency in this or any other state? If Yes, please provide detailed written explanation.*	YES ☐ NO ☐

*You must include all misdemeanor and felony convictions, regardless of the age of the conviction, including those which have been set aside and/or dismissed under Penal Code Section 1000, 1203.4 or 1210.1. Traffic violations involving driving under the influence, injury to persons or providing false information must be reported. The definition of conviction includes convictions following a plea of nolo contendere (no contest) as well as pleas or verdicts of guilty.

6. PRACTICE INFORMATION - *check all that apply*

☐ Small ☐ Vaccination Clinic ☐ Emergency ☐ House Call

☐ Large ☐ Mixed ☐ Mobile/Ambulatory

7. NUMBER OF EMPLOYEES

____ CA Licensed Veterinarians ____ Non-CA Licensed Veterinarians ____ Clerical/Administrative

____ Registered Veterinary Technicians ____ Veterinary Assistants ____ Other _____

8. BUSINESS TYPE

☐ Sole Owner ☐ City/County/State Owned ☐ Other _____

☐ Corporation - *you must include articles of Incorporation for all initial registrations and ownership changes*

Corporation Name _____ Incorporation Date _____

Corporation Number _____ Incorporation State_____ FEIN _____

☐ Partnership - *you must include information for all partners.*

Name _____ % Interest _____Title _____ License Number _____

Name _____ % Interest _____Title _____ License Number _____

Name _____ % Interest _____Title _____ License Number _____

9. BUSINESS OWNER INFORMATION

LAST	FIRST	MIDDLE

CALIFORNIA VETERINARY/RVT LICENSE NUMBER	LICENSE EXPIRATION DATE

MAILING ADDRESS

CITY	STATE	ZIP

U.S. SOCIAL SECURITY NUMBER:	TELEPHONE NUMBER:

EMAIL ADDRESS:

10. BUSINESS OWNER DISCLOSURE

Are you currently and owner of any other veterinary premises registered with the Veterinary Medical Board? If YES, please list Premise Number(s):	YES ☐ NO ☐

11. DISCLOSURE SIGNATURE - *must be signed by managing licensee*

Managing licensees are required to comply with the minimum standards of practice. As a managing licensee, you are responsible for ensuring that the permit for which you are applying is in compliance with all applicable laws. In the event that the premise is in violation of any applicable laws, you will be held responsible and may have disciplinary action taken against you.

I certify that I understand that I am responsible for ensuring that this premises for which I am applying meets the minimum standards of practice and is in compliance will all applicable laws.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Signature _____ Date _____

INFORMATION COLLECTION, ACCESS AND DISCLOSURE

The information you provide on this application is maintained by the Executive Officer of the Veterinary Medical Board, Department of Consumer Affairs, 1747 N. Market Blvd., Suite 230, Sacramento, CA 95834, (916) 515-5220. The information is requested pursuant to Business and Professions Code sections 4853 and 4853.1 and California Code of Regulations, Title 16, Sections 2030, 2030.1, and 2030.2.

It is mandatory that you provide all information requested. Omission of any item of required information will result in the application being rejected as incomplete.

Disclosure of your Social Security number is mandatory. Section 30 of the Business and Professions Code and Public Law 94-455[42 USCA §405(c)(2)(C)] authorize collection of your Social Security number. Your Social Security number will be used exclusively for tax enforcement purposes, for purposes of compliance with any judgment or order for family support in accordance with Section 17520 of the Family Code, or for verification of licensure or examination status by a licensing or examination entity which uses a national examination and where licensure is reciprocal with the requesting state. If you fail to disclose your Social Security number, you will be reported to the Franchise Tax Board, which may assess a $100 penalty against you.

Your completed application becomes the property of the Board and will be used by authorized personnel to determine you eligibility for a license, registration or permit. Information on your application may be transferred to other governmental or law enforcement agencies. Pursuant to the California Public Records Act (Gov. Code §6250 et seq.) and the Information Practices Act (Div. Code §1798.61), the names and addresses of persons possessing a license or registration may be disclosed by the department unless otherwise specifically exempt from disclosure under the law. **Consequently, the personal name and address information entered on the attached form(s) may become public information subject to disclosure.**

You have the right to review the records maintained on you by the Board or department unless the records are exempt by section 1798.40 of the Civil Code. You may gain access to the information by contacting the Veterinary Medical Board at the above address.

The name and address you have included on this application is subject to public disclosure and may be disclosed upon request, however if the residential address is different than the practice address, that address may remain confidential.

Incomplete applications will be returned. Please ensure that all information is complete and accurate. Please make check/money order payable to the Veterinary Medical Board and mail completed application to: Veterinary Medical Board, 1747 N. Market Blvd., Suite 230, Sacramento, CA 95834.

Please visit the Board's website at www.vmb.ca.gov for further information on the Board.

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MEMORANDUM

DATE	October 20, 2014
TO	Multidisciplinary Advisory Committee
FROM	Annemarie Del Mugnaio, Executive Officer DCA/Veterinary Medical Board
SUBJECT	**Compounded Medications and Veterinary Practice**

Background:

For several years the VMB has fielded questions from the profession regarding the provisions governing compounding medications for use in day-to-day veterinary practices and for dispensing to clients. The provisions, Pharmacy Law (BPC Sections 4051, 4052, and 4127 & CCR Sections 1735-1735.8 and 1751, et seq attached) have very specific requirements for pharmacies that compound and dispense medications. CFR Title 21 Part 530.13 (attached) provides for limited exceptions to when a veterinarian may be permitted to compound a medication within their office to treat an animal patient provided the veterinarian has an established Veterinary-Client Patient Relationship.

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.

In addition, CCR Section 1735.2 allows for a prescriber (veterinarian) to maintain a “reasonable quantity” of a compounded medication to administer to their patients within their facility or to dispense to their patient/client for not more than a 72-hour supply. The 72 hours or 3-day rule, is to provide a continuity of care to the patient until such time that the medication may be filled by a compounding pharmacy.

Issues:

The following factors must be considered in providing appropriate oversight and education to veterinarians who may on occasion compound medications for use in their hospitals and/or dispense to their clients:

- Is preparing sterile injectables in multiple dosage containers compounding (e.g., anesthetic cocktails and diluted Acepromazine).
- What is a “reasonable quantity” of a compounded drug that may be stored at a veterinary premise?
- How long should the compounded drug be stored, and what happens to the drug’s potency, efficacy and sterility if kept for too long?
- Is the 72 hour supply sufficient and reasonable to provide a continuity of care to the patient? Should this time frame be extended?

Attachments:

- Business and Professions Code Sections 4051, 4052, 4127- Pharmacy Law
- California Code of Regulations Sections 1735-1735.8 & 1751 et seq – Regulations Regarding Compounding
- Code of Federal Regulations Title 21, Part 530.13
- Veterinary Medical Board Fact Sheet 2010 – Drug Compounding for Companion Veterinary Patients

BOARD OF PHARMACY

BUSINESS & PROFESSIONS CODE

4051. Conduct Limited to Pharmacist; Conduct Authorized by Pharmacist

(a) Except as otherwise provided in this chapter, it is unlawful for any person to manufacture, compound, furnish, sell, or dispense a dangerous drug or dangerous device, or to dispense or compound a prescription pursuant to Section 4040 of
a prescriber unless he or she is a pharmacist under this chapter.
(b) Notwithstanding any other law, a pharmacist may authorize the initiation of a prescription, pursuant to Section 4052.1, 4052.2, 4052.3, or 4052.6, and otherwise provide clinical advice, services, information, or patient consultation, as set forth in this chapter, if all of the following conditions are met:
(1) The clinical advice, services, information, or patient consultation is provided to a health care professional or to a patient.
(2) The pharmacist has access to prescription, patient profile, or other relevant medical information for purposes of patient and clinical consultation and advice.
(3) Access to the information described in paragraph (2) is secure from unauthorized access and use.

4052. Furnishing to Prescriber; Permitted Procedures by Pharmacist

(a) Notwithstanding any other law, a pharmacist may:
(1) Furnish a reasonable quantity of compounded drug product to a prescriber for office use by the prescriber.
(2) Transmit a valid prescription to another pharmacist.
(3) Administer drugs and biological products that have been ordered by a prescriber.
(4) Perform procedures or functions in a licensed health care facility as authorized by Section 4052.1.
(5) Perform procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan,
or a physician, as authorized by Section 4052.2.
(6) Perform procedures or functions as authorized by Section 4052.6.
(7) Manufacture, measure, fit to the patient, or sell and repair dangerous devices, or furnish instructions to the patient or the patient’s representative concerning the use of those devices.
(8) Provide consultation, training, and education to patients about drug therapy, disease management, and disease prevention.
(9) Provide professional information, including clinical or pharmacological information, advice, or consultation to other health care professionals, and participate in multidisciplinary review of patient progress, including appropriate access to medical records.
(10) Furnish the medications described in subparagraph (A) in accordance with subparagraph (B):
(A)(1) Emergency contraception drug therapy and self-administered hormonal contraceptives, as authorized by Section 4052.3.
(2) Nicotine replacement products, as authorized by Section 4052.9.

(3) Prescription medications not requiring a diagnosis that are recommended by the federal Centers for Disease Control and Prevention for individuals traveling outside of the United States.
(B) The pharmacist shall notify the patient's primary care provider of any drugs or devices furnished to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider. If the patient does not have a primary care provider, the pharmacist shall
provide the patient with a written record of the drugs or devices furnished and advi
se the patient to consult a physician of the patient's choice.
(11) Administer immunizations pursuant to a protocol with a prescriber.
(12) Order and interpret tests for the purpose of monitoring and managing the efficacy and toxicity of drug therapies. A pharmacist who orders and interprets tests pursuant to this paragraph shall ensure that the ordering of those tests is done in coordination with the patient's primary care provider or diagnosing prescriber, as appropriate, including promptly transmitting written notification to the patient's diagnosing prescriber or entering the appropriate information in a patient record system shared with the prescriber, when available and as permitted by that prescriber.
(b) A pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy pursuant to this section shall personally register with the federal Drug Enforcement Administration.
(c) This section does not affect the applicable requirements of law relating to either of the following:
(1) Maintaining the confidentiality of medical records.
(2)The licensing of a health care facility.

Article 7.5 Compounded Sterile Drug Products

4127. Board Shall Adopt Regulations Establishing Standards (Effective January 1, 2014, and Inoperative on July 1, 2014)

(a) The board shall adopt regulations establishing standards for compounding injectable sterile drug products in a pharmacy.
(b) The board shall adopt emergency regulations in accordance with the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code) to establish policies, guidelines, and procedures to initially implement the provisions of this article that become operative on July 1, 2014. The initial adoption, amendment, or repeal of a regulation authorized by this section is deemed to address an emergency for purposes of Sections 11346.1 and 11346.6 of the Government Code, and the board is hereby exempted for that purpose from the requirements of subdivision (b) of Section 11346.1 of the Government Code. After the initial adoption, amendment, or repeal of an emergency regulation pursuant to this section, the board may request approval from the Office of Administrative Law to readopt the regulation as an emergency regulation pursuant to Section 11346.1 of the Government Code.
(c) This section shall become inoperative on July 1, 2014, and, as of January 1, 2015, is repealed, unless a later enacted statute, that becomes operative on or before January 1, 2015, deletes or extends the dates on which it becomes inoperative and is repealed.

4127. License to Compound Sterile Drug Products Required (Operative on July 1, 2014)
(a) A pharmacy that compounds sterile drug products for injection, administration into the eye, or inhalation shall possess a sterile compounding pharmacy license as provided in this article.
(b) The board shall adopt regulations in accordance with the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code)
to establish policies, guidelines, and procedures to implement this article.
(c) The board shall review any formal revision to General Chapter 797 of the United States Pharmacopeia and The National Formulary (USP–NF), relating to the compounding of sterile preparations, not later than 90 days after the revision becomes official, to determine whether amendments are necessary for the regulations adopted by the board pursuant to subdivision (b).
(d) This section shall become operative on July 1, 2014.

4127.1. License to Compound Injectable Sterile Drug Products Required (Effective January 1, 2014, and Inoperative on July 1, 2014)
(a) A pharmacy shall not compound injectable sterile drug products in this state unless the pharmacy has obtained a license from the board pursuant to this section. The license shall be renewed annually and is not transferable.
(b) A license to compound injectable sterile drug products may only be issued for a location that is licensed as a pharmacy. Furthermore, the license to compound injectable sterile drug products may only be issued to the owner of the pharmacy license at that location. A license to compound injectable sterile drug products may not be issued until the location is inspected by the board and found in compliance with this article and regulations adopted by the board.
(c) A license to compound injectable sterile drug products may not be renewed until the location has been inspected by the board and found to be in compliance with this article and regulations adopted by the board.

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.

Title 16. Board of Pharmacy

Proposed Language

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~~ preparation that is commercially available in the marketplace.

(d) 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" (also called ante-room) means an ISO Class 8 or better area 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 and maintains air flows from clean to dirty areas.

(b) "Batch" means compounding of two or more finished drug preparation units produced during the same continuous cycle of compounding and shall include any multiple dose vials prepared for administration to more than one patient.

(c) "Beyond use date" means the date or date and time after which a compounded drug preparation shall not be stored or transported, or administration begun.

(d) "Buffer area" means an area providing at least an ISO Class 7 or better air quality where the primary engineering control is physically located.

(e) "Bulk drug" means any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug, but the term does not include intermediates used in the synthesis of such substances.

(f) "Cleanroom" (which may also be referred to as a buffer area) means a physically separate room with walls and doors providing at least an ISO Class 7 or better air quality where the primary engineering control is physically located. This room maintains segregation from the adjacent ante-area (ante-room) by means of specific pressure differentials. For rooms providing a physical separation through the use of walls, doors, and pass-throughs, a minimum differential positive pressure of 0.02- to 0.05-inch water column is required. For buffer areas not physically separated from the ante-areas, 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 shall not be used for high-risk compounding.

(g) "Controlled cold temperature" means 2.2 degrees to 7.7 degrees C (36 degrees to 46 degrees F).

(h) "Controlled freezer temperature" means -25 degrees to -10 degrees C (-13 degrees to 14 degrees F).

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

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

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

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

~~(b)~~ (m) "Integrity" means ~~retention of potency~~ that all aspects of quality including sterility, packaging, chemical stability and potency, handling, and transport and storage are maintained throughout the drug preparation process, and until the ~~expiration~~ beyond use date ~~noted~~ provided on the label.

(n) "Media-fill test" means a test that mimics compounding procedures using a growth-based media to demonstrate that aseptic techniques of compounding personnel or processes routinely employed do not result in microbial contamination. Media fill tests are conducted on the most challenging and routine compounding procedures performed.

(o) "Parenteral" means a sterile preparation of drugs for injection or implantation through one or more layers of skin.

(p) “Personal protective equipment” means clothing or devices that protect the employee from exposure to drug products and minimize the contamination of compounded preparations. These include shoe covers, head and facial hair covers, face masks, gowns, and gloves.

~~(c)~~ (q) “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.

(r) “Preparation” means a drug or nutrient compounded in a licensed pharmacy; the preparation may or may not contain sterile products.

(s) '"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.

(t) “Primary Engineering Control (PEC)” means a device that provides an ISO Class 5 environment or better through the use of unidirectional HEPA filtered first air.

(u) “Process validation” means demonstrating that when a process is operated 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.

(v) “Product” means a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.

~~(d)~~ (w) “Quality” means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, and absence of active and inactive ingredients other than those noted on the label.

(x)“Segregated compounding area” means a designated space where a device that provides unidirectional airflow of ISO Class 5 air quality, including compounding aseptic isolators, is located within either a demarcated area (at least three foot perimeter) or room. Such area shall contain and shall be void of activities and materials that are extraneous to sterile compounding. The segregated 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, and shall not

have a sink located within at least three feet of the ISO Class 5 PEC. This sterile compounding area will be restricted to preparing sterile-to-sterile compounded preparations.

(y) "Smoke test" means an analysis of the airflow in the ISO Class 5 PEC using a smoke generating device.

~~(c)~~ (z) "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~~ 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) is ordered and paid for by the prescriber, 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 office and signed for by the prescriber; 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 solely to the prescriber's own patients seen as part of regular treatment in the prescriber's office, as estimated by the prescriber and documented on the purchase order or other documentation submitted to the pharmacy; and

(4) is reasonable considering the intended use of the compounded medication and the nature of the prescriber's practice; and

~~(3)~~ (5) for any individual prescriber and for all prescribers 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 a 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 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. The pharmacy shall retain a copy of the documentation of the shortage in the pharmacy records for three years.

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

(1) Active ingredients to be used.

(2) Equipment to be used.

(3) ~~Expiration dating requirements.~~ The rationale or reference source for determining the maximum allowable beyond use date for this preparation.

(4) Inactive ingredients to be used.

(5) ~~Process and/or procedure~~ Specific 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.

(~~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 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 beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used, stored, transported, or administration begun. This "beyond use date" of the compounded drug ~~product~~ preparation shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug ~~product~~ preparation, unless a longer date is supported by stability studies of finished drugs or compounded drug ~~products~~ preparations using the same components and packaging. 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.

(l) Packages of ingredients 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 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.

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.

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

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

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

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

(6) 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. Exempt from the requirements in this paragraph are sterile ~~products~~ preparations compounded on a one-time basis for administration within seventy-two (72) hours to an inpatient 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) A pharmacy-assigned reference or lot number for the compounded drug ~~product~~ preparation.

(8) The ~~expiration~~ beyond use date of the final compounded drug ~~product~~ preparation.

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

(10) Storage for the drug preparation.

(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 pharmaceutical ingredients shall be obtained from a FDA registered supplier. 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 for chemicals, and bulk drug substances~~, drug products, and components~~ used in compounding. ~~Certificate s of purity or analysis are not required for drug products that are~~

~~approved by the Food and Drug Administration.~~ Certificates of purity or analysis are to be matched to the product 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. 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) In addition to the labeling information required under Business and Professions Code section 4076, the label of a compounded drug ~~product~~ preparation shall contain the generic name(s) of the principal active ingredient(s).

(b) 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.

(c) 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, pharmacy reference or lot number, and ~~expiration~~ beyond use date.

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 and procedure 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. The pharmacy shall follow its policies and procedures. Failure to follow these policies and procedures shall constitute grounds for disciplinary action.

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

(c) The policy and procedure manual shall include the following:

(1) Procedures for notifying staff assigned to compounding duties of any changes in processes or to the policy and procedure manual.

(2) Evidence that staff have been educated and trained on all policies and procedures.

(~~2~~ 3) ~~Documentation of a~~ A written plan for recall of a dispensed compounded drug ~~product~~ preparation where subsequent verification demonstrates the potential for adverse effects with continued use ~~of a compounded drug product~~. All affected doses can be accounted for as part of the recall.

(~~3~~ 4) The 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.

(5) The 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~~ 6) Documentation of the methodology appropriate to compounded drug preparations used to ~~test~~ validate integrity, potency, quality, and labeled strength of compounded drug ~~products~~ preparations.

(~~5~~ 7) Documentation of the methodology used to determine appropriate ~~expiration~~ beyond use dates for compounded drug ~~products~~ preparations.

(8) Dates of annual reviews of the policy and procedure manual by the pharmacist-in-charge, signed and dated by the pharmacist-in-charge.

(9) Dates of any revisions to the policy and procedure manual approved by the pharmacist-in-charge, signed and dated by the pharmacist-in-charge.

(10) Policies and procedures for storage of compounded sterile drug preparations in the pharmacy and daily documentation of all room, refrigerator, and freezer temperatures.

(11) 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.

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 compounded drug ~~products~~ preparations. Where applicable, this shall include records of certification(s) of facilities or equipment.

(b) Any equipment used to compound drug ~~products~~ preparations shall be stored, used, and maintained 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, per manufacturer's specifications, to ensure accuracy. Documentation of each such calibration shall be recorded in writing and these records of calibration shall be maintained and retained in the pharmacy.

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) 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.
(b) The pharmacy shall develop and maintain an on-going 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 integrity, potency, quality, and labeled strength 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 with the compounding record and master formula.
(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 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, including for preparations furnished to patient care areas.

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, including the 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. The pharmacy shall be ventilated in a manner in accordance with Section 505.12 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 of Title 16, Division 17, of the California Code of Regulations. Certification records must be retained for at least 3 years.

~~(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 of Title 24, Part 2, of the California Code of Regulations. Sinks and drains shall not be present in an ISO Class 7 or better buffer area, nor within three feet of an ISO Class 5 PEC or better located in segregated compounding areas. A sink may be located in an ante-area.

~~(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.

(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, 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)~~, for sterile compounded drug ~~products~~ preparation ~~compounded from one or more non-sterile ingredients~~, the following records must be made and kept by the pharmacy:

(1) The training and competency evaluation of employees in sterile ~~product~~ preparation procedures.

(2) Results of hand hygiene and garbing assessment 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 testing.

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

~~(2)~~ (5) Daily documentation of room, ~~R~~ refrigerator, and freezer temperatures appropriate for 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) Certification(s) of the sterile compounding environment.

(7) Daily documentation of air pressure differentials or air velocity between adjoining all ISO rooms or areas and measurement between all ISO rooms or areas, including those associated with compounding aseptic (containment) isolators.

~~(4)~~ (8) Other facility quality control logs specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment).

~~(5)~~ (9) Logs or other documentation of ~~i~~inspections for expired or recalled pharmaceutical products or raw ingredients.

~~(6)~~ (10) Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation 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 of the compounded drug preparation, lot number, amount, and date on which the preparation was provided to a 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 section 1735.4, a pharmacy which compounds sterile ~~injectable~~ drug ~~products~~ preparations shall include the following information on the labels for those ~~products~~ preparations:

(a) Telephone number of the pharmacy, except for sterile ~~injectable~~ drug ~~products~~ preparations dispensed ~~for~~ to inpatients ~~of~~ by a hospital pharmacy.

(b) Name and concentration~~s~~ of ingredients contained in the sterile ~~injectable~~ drug ~~product~~ preparation.

(c) Instructions for storage and handling.

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

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 ~~injectable~~ drug ~~products~~ preparations shall maintain a written policy and procedure manual for compounding that includes, 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~~ drug ~~product~~ 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 all aspects of the preparation of sterile ~~injectable~~ drug ~~products~~ preparations including didactic training and knowledge/competency assessments that include at minimum: hand hygiene and garbing; cleaning and disinfection of controlled compounding areas and proper aseptic technique.

(5) Hand hygiene and garbing.

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

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

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

(9) Media fill testing procedure.

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

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

~~(5)~~ (12) Procedures for handling, compounding and disposal of ~~cytotoxic~~ hazardous agents.

~~(6)~~ (13) Quality assurance program.

~~(7)~~ (14) Record keeping requirements.

(b) 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) 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. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.

(d) Pharmacies compounding sterile ~~injectable~~ drug ~~products~~ preparations ~~from one or more non-sterile ingredients~~ must have written policies and procedures that comply with the following:

(1) All written policies and procedures shall be immediately available to all personnel involved in these activities and board inspectors.

(2) All personnel involved must read the policies and procedures before compounding sterile ~~injectable~~ drug ~~products~~ preparations, and any additions, revisions, and deletions to the written policies and procedures must be communicated to all personnel involved in sterile compounding.

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

(A) Orientation, training, and ~~C~~competency evaluation of compounding personnel.

(B) Storage and handling of products and supplies.

(C) Storage and delivery of final products.

(D) Media fill testing and ~~P~~process validation.

(E) ~~Personnel access and movement of materials into and near the controlled area~~ Conduct of personnel in controlled areas and aseptic technique overview.

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

(G) ~~Regular~~ Daily and monthly cleaning and disinfection schedule for the controlled areas and any equipment in the controlled area ~~and the alternation of disinfectants~~ as specified in California Code of Regulations section 1751.4. ~~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.~~ Non-viable particle testing.

(I) ~~For sterile batch compounding, written policies and procedures must be established for the use of master formulas and work sheets and for appropriate documentation.~~ Viable air sampling.

(J) ~~Sterilization.~~ Surface sampling.

(K) ~~End-product evaluation and testing.~~ Airflow considerations and pressure differential monitoring.

(L) Temperature and humidity monitoring in compounding and controlled storage areas.

(M) Facility management including certification and prevention maintenance of controlled environments and related equipment.

(N) Gloved fingertip sampling.

(O) Compounded sterile product stability and assignment of beyond use dating.

(P) Use of automated compounding devices (if applicable).

(Q) Hazardous drug compounding (if applicable).

(i) Hazardous drug employee training and safety program.

(ii) Hazardous drug handling, storage, labeling and transport.

(iii) Hazardous drug compounding techniques.

(iv) Hazardous drug spill, deactivation and waste management.

(R) Preparing sterile solutions from nonsterile components (if applicable).

(S) Hand hygiene and garbing.

(4) 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 subparagraph.

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

(B) For sterile batch compounding:,

(i) use of master formulas and compounding work sheets;

(ii) appropriate documentation; and

(iii) appropriate sterility and bacterial endotoxin testing.

(C) For non-sterile to sterile compounding:

(i) Sterilization methods

(ii) End-product evaluation and testing.

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

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:

(1) at the beginning of each shift;

(2) before and after each batch;

(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 (e.g., sterile isopropyl alcohol) daily. Walls, ceilings, storage shelving, tables and stools shall be cleaned with a germicidal detergent and water and disinfected with a suitable agent (e.g., sterile isopropyl alcohol) 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. 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-003-2006-11, Revised January 31, 2012). Certification records must be retained for at least 3 years. Compounding aseptic isolators or compounding aseptic containment isolators may be used outside of an ISO Class 7 buffer area if the isolator meets 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 and are not located within an ISO Class 7 buffer

area 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 505.12.1 of Title 24, Chapter 5, of the California Code of Regulations, requiring a ~~laminar air flow hood~~ negative pressure PEC. The ~~hood~~ negative pressure PEC must be certified ~~annually~~ every six months by a qualified technician who is familiar with ~~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.~~ CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-11, Revised January 31, 2012). ~~Certification records must be retained for at least 3 years.~~ Any drug preparation that is compounded in a hazardous drug PEC where hazardous drugs are prepared must be labeled as hazardous, regardless of whether the drug ingredients are considered hazardous.

During the hazardous drug compounding that is performed in a compounding aseptic containment isolator, full hand hygiene and garbing must occur, complete with hair cover, facemask, beard cover (if applicable), polyprophylen or low shedding gown that closes in the back, shoe covers, and two layers of gloves that have been tested to meet ASTM 6978-05 with the outermost glove that contacts the sterile drug preparation.

(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) Viable surface sampling shall be done at least monthly for low and medium risk-level compounding and weekly for high-risk compounding. Volumetric air sampling by impaction shall be done at least once every six months for low and medium risk-level compounding and weekly for high-risk compounding. Viable surface and volumetric 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. Surface 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. Remediation shall include an immediate investigation of cleaning and compounding operations and facility management.

(j) The pharmacy shall have a comfortable and well-lighted working environment, which includes a room temperature of 20 degrees Celsius (68 degrees Fahrenheit) or cooler to maintain comfortable conditions for compounding personnel when attired in the required compounding garb. Humidity levels should be consistent ASHRAE Standard 55 (30-65% RH).

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 are not 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 ~~H~~hand, finger, ~~and~~ or wrist jewelry ~~must be eliminated~~. 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. 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 rashes, sunburn, weeping sores, conjunctivitis, active respiratory infections, or those wearing cosmetics shall be excluded from the 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).

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 ~~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 of volume transferred during the selected manipulations.

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

(G) General conduct in the controlled area.

(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. 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) 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 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 promoted

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, 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~~ are 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 compounding personnel must successfully complete an initial competency evaluation. In addition, immediately following the initial hand hygiene and garbing procedure, all compounding personnel must successfully complete a gloved fingertip 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) Batch-produced sterile ~~injectable~~ drug ~~products~~ preparations compounded from one or more non-sterile ingredients ~~shall be subject to documented end product testing for sterility~~ that are exposed longer than 12 hours at 2 to 8 degrees C and longer than 6 hours at warmer than 8 degrees C before they are sterilized shall meet the sterility test in accordance with methodologies and processes found in Chapter 71 of the United States Pharmacopeia – National Formulary (USP37-NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014), and testing for pyrogens in accordance with the methods of Chapters 85 and 151 of the United States Pharmacopeia – National Formulary (USP37-NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014), hereby incorporated by reference, and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens 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.

In a circumstance where a batch-produced sterile drug preparation compounded from one or more non-sterile ingredients is necessary for immediate dispensing where failure to dispense could result in loss of life or intense suffering, the drug preparation may be dispensed before receipt of test results so long as the pharmacy complies with a written procedure included in the pharmacy's policies and procedures that includes:

(1) Prior to dispensing:

(A) Notifying the prescriber of the inability to conduct testing;

(B) Suggesting an available alternative product to the prescriber; and

(C) Securing the prescriber's written consent to dispense.

(2) And subsequent to dispensing:

(A) Daily observation of the incubating test specimens; and

(B) Immediate recall of the dispensed compounded sterile preparation's when there is any evidence of microbial or pyrogen growth in the test specimens.

Any such dispensing 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.

~~(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 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 conforms to the following limitations, except that the beyond use date shall not exceed any expiration date or beyond use date provided by the manufacturer for any component in the preparation.

(a) Where the sterile compounded drug preparation was compounded solely with aseptic manipulations

(1) entirely within an ISO Class 5 PEC located in an ISO Class 7 buffer area with an ante-area, 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, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile preparations, and containers for storage dispensing

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 extended beyond use date, the beyond use date shall specify that storage and exposure periods cannot exceed the following: 48 hours at controlled room temperature; 14 days at controlled cold temperature; and 45 days at controlled freezer temperature.

(b) Where the sterile compounded drug preparation was compounded solely with aseptic manipulations

(1) entirely within an ISO Class 5 PEC located in an ISO Class 7 buffer area with an ante-area, 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

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 extended beyond use date, the beyond use date shall specify that storage and exposure periods cannot exceed the following: 30 hours at controlled room temperature; 9 days at controlled cold temperature; and 45 days at controlled freezer temperature.

(c) Where the sterile compounded drug preparation was compounded solely with aseptic manipulations entirely within an ISO Class 5 PEC located in an ISO Class 7 buffer area with an ante-area, using non-sterile ingredients, 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, 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 extended beyond use date, the beyond use date shall specify that storage and exposure periods cannot exceed the following: 24 hours at controlled room temperature; 3 days at controlled cold temperature; and 45 days at controlled freezer temperature.

For the purposes of this paragraph, “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.

(d) Where the sterile compounded drug preparation was compounded solely with aseptic manipulations

(1) entirely within an ISO Class 5 PEC that is located in a segregated 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

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 extended beyond use date, the beyond use date shall specify that storage and exposure periods cannot exceed 12 hours in a laminar air flow workbench or biological safety cabinet.

(e) Where the sterile compounded drug preparation was compounded

(1) using or containing hazardous drugs or components; and

(2) in facilities that prepare a low volume of hazardous drugs, where low volume is defined as five or less per a week, the use of two tiers of containment (e.g., closed system transfer device within a biological safety cabinet or compounding aseptic containment isolator that is located in a non-negative pressure room)

the beyond use date shall specify that storage and exposure periods cannot exceed 12 hours.

(f) 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.

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.

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 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.

(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 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 condition.

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 1:1000;

(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 policy 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.

(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.

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.

Drug Compounding for Companion Veterinary Patients

Introduction

A compounded drug is any manipulation of a drug beyond the instructions on the drug's label. Veterinarians are allowed to use a compounded drug when there is not currently available a labeled veterinary or human drug that is appropriate for treatment of the particular needs of a specific animal patient. To meet this need, veterinarians and pharmacists are permitted to alter or mix drugs for treatment of an animal, or to prepare an alternate and / or diluted dosage form within the confines of legitimate practice and parameters set by law.

Parameters

Legitimate practice is defined as a pharmacist licensed in the state of California and dispensing in response to a valid prescription, and / or a veterinarian licensed in the state of California and prescribing or dispensing in response to a valid veterinary – client – patient relationship (VCPR).

There must also be a legitimate need for the drug when non-treatment would result in either suffering or death, and there is no marketed FDA approved animal or human drug, when used as labeled or in an extra-label fashion in its available dosage form and concentration, that will appropriately treat the patient.

Compounding is limited to preparation of drug products that do not meet the definition of a new animal drug, and the product must be made from FDA-approved drugs. The amount compounded must be commensurate with the need of the patient. Large batches of a drug already available may not be produced, as this is 'pirating' and illegal.

Summary

Veterinarians are allowed to compound drugs to administer to or dispense for their own patients' use following establishment of a VCPR. This means the veterinarian cannot compound more drug than is needed for the single, identified patient. Veterinarians are also allowed to order a compounded drug from a pharmacy and can keep a supply of the pharmacy-compounded drug in his / her facility for use on patients in the facility, or to provide *not more than 72 hours (3 days)* worth of the drug to go home. This 72-hour supply is allowed so the veterinarian can call in a prescription to a compounding pharmacist for that particular patient. The pharmacist then provides the prescription directly to the client; the veterinarian cannot act as the go-between. The veterinarian must comply with all aspects of the federal extra-label drug use regulations including record-keeping and labeling requirements.

Frequently Asked Questions

1.) **Q.** Is it legal for a veterinarian to compound drugs?

A. Yes, with restrictions. Veterinarians are allowed to compound drugs to administer or dispense to their own patients following the establishment of a VCPR, and when the following parameters are met:

- 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.

Refer to:

CCR 2032.1 – Veterinary-Client-Patient Relationship
CFR Title 21, Section 530.13(b)(2),(3),(4) and (5) – Extralabel use from compounding of approved new animal and approved human drugs

2.) **Q.** Is it legal for a pharmacy to dispense to a veterinarian a small supply of a dangerous drug, whether compounded or not, for 'office use' rather than for an identified patient?

A. Yes. A veterinarian may request a prescription from a pharmacy for a drug that is to be used in the office, i.e. administered to an animal patient in the office for a diagnosed condition, once the VCPR has been established. Refer to:

CCR 2032.1 – Veterinary-Client-Patient Relationship
B&P 4119.5(b) – Transfer or Repackaging Dangerous Drugs by Pharmacy

3.) **Q.** Is it legal for a veterinarian to dispense compounded drugs, obtained from a pharmacy for office use, to a patient?

A. Yes, with restrictions. The veterinarian can keep a supply of the frequently-used, pharmacy-compounded drug in his / her facility for administration to patients in the facility following the establishment of a VCPR, or to dispense to the patient a quantity of drug that will last *not more than 72 hours (3 days)*. This 72-hour supply is allowed so the veterinarian can call in a prescription to a compounding pharmacist for that particular patient. The pharmacist must then provide the prescription directly to the client; the veterinarian cannot act as the 'go-between'(i.e. as a wholesaler). Refer to:

CCR 1716.1 – Compounding Unapproved Drugs for Prescriber Office Use
B&P Section 4052(a)(1) – Furnishing to Prescriber
CFR[1] Title 21, Section 530.13(b)(2),(3),(4) and (5) – Extralabel use from compounding of approved new animal and approved human drugs

4.) **Q.** Is mixing anesthetic and / or other injectable drugs considered compounding?

A. Yes. Refer to:

CFR Title 21, Section 530.13(b)(2),(3),(4) and (5) – Extralabel use from compounding of approved new animal and approved human drugs

5.) **Q.** Is it legal for a veterinarian to prepare a large quantity of compounded anesthetic drug

[1] CFR refers to Code of Federal Regulations.

mixture for use on more than one patients, either the same day or on a future day?

A. No. Veterinarians are allowed to compound drugs only in a quantity commensurate with the need for a single, specified patient following the establishment of a VCPR. Refer to:

CCR 2032.1 – Veterinary-Client-Patient Relationship
CFR Title 21, Section 530.13(b)(2),(3),(4) and (5) – Extralabel use from compounding of approved new animal and approved human drugs

Laws

Code of Federal Regulations

CFR Title 21, Section 530.13(b)(2),(3),(4) and (5) – Extralabel use from compounding of approved new animal and approved human drugs

This can be found online at:

www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=530&showFR=1

California Pharmacy Codes and Regulations

CCR 1716.1 – Compounding Unapproved Drugs for Prescriber Office Use
B&P 4024 – Dispense
B&P 4026 – Furnish
B&P 4040 – Prescription
B&P 4044 – Repackager
B&P 4052(a)(1) – Furnishing to Prescriber
B&P 4076(a) – Prescription Container – Requirements for Labeling
B&P 4059(a) – Furnishing Dangerous Drugs Prohibited Without Prescription
B&P 4059.5(d) – Who May Order Dangerous Drugs
B&P 4119.5(b) – Transfer or Repackaging Dangerous Drugs by Pharmacy
B&P 4160 – Wholesaler: License Required
B&P 4169(a)(1) – Prohibited Acts
B&P 4169(a)(4) – Prohibited Acts
B&P 4170 – Conditions for Dispensing Drugs
B&P 4342 – Actions by Board to Prevent Sales of Preparations or Drugs Lacking Quality or Strength

These can be found in the "Lawbook for Pharmacy" located online at:

www.pharmacy.ca.gov/laws_regs/lawbook.pdf

California Veterinary Medicine Regulations

CCR 2032.1 – Veterinary-Client-Patient Relationship

To find this code section online, start at the California VMB website:

www.vmb.ca.gov/

click on the 'Laws/Regs' tab
click on 'California Code of Regulations'
click on 'Title 16. Professional and Vocational Regulations'
click on 'Division 20. Veterinary Medical Board'
click on 'Article 4. Practice'
click on '2032.1. Veterinary-Client-Patient Relationship'

Additional Resources

1. California Veterinary Medical Board

2005 Evergreen St. Suite 2250
Sacramento, CA 95815-2621
916-263-2610
www.vmb.ca.gov/

2. "California Veterinary Medicine Practice Act"

To order the Practice Act, type California Veterinary Medicine Practice Act in the search box at the top of the page at the following website:

www.lexisnexis.com/store/us/

3. American Veterinary Medical Association (AVMA)

http://www.avma.org/issues/drugs/compounding/default.asp

The column along the left-hand side of this page has a series of links explaining various aspects of veterinary compounding including FAQs, pharmacology basics, rules, AVMA policies, etc.

4. Food and Drug Administration (FDA)

This Compliance Policy Guidance document provides guidance on compounding drugs by veterinarians and pharmacists for use in animals.

http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm117042.htm

Click on "CPG Sec 608.400 Compounding of Drugs for Use in Animals"