



**MEETING NOTICE and AGENDA**  
**Multidisciplinary Advisory Committee**

The Mission Inn  
3649 Mission Inn Avenue,  
Riverside, California

**10:00 a.m. Tuesday, October 18, 2016**

1. Call to Order- Establishment of a Quorum
2. Introductions
3. Review and Approval of July 19, 2016 Meeting Minutes
4. Discussion and Consideration of “Extended Duty” for Registered Veterinary Technicians Regulations; Potential Recommendation to Full Board
5. Update on Survey of Public and Private Shelters and Discussion of Minimum Standards & Protocols for Shelter Medicine
6. Review and Discuss Veterinary Student Exemption [Duties and Supervision at University Hospitals]; Potential Recommendation to Full Board
7. Review and Consider Implementing Regulations Regarding the Compounding of Drugs Pursuant to the Enactment of Senate Bill 1193, Potential Recommendation to Full Board
8. Discuss Committee Recommendation Authorizing an RVT Under the Supervision of a Veterinarian to be the On-Site Practitioner for Rodeos
9. Discuss Definitions and Scope of Responsibility for “Induction” of Anesthesia vs. Sedation – Section 2034 of Title 16 of the California Code of Regulations; Possible Recommendation to Full Board
10. Public Comments on Items Not on the Agenda  
Note: The board may not discuss or take action on any matter raised during this public comment section, except to decide whether to place the matter on the agenda of a future meeting. (Government Code Sections 11125 and 11125.7(a)).
11. Agenda Items and Next Meeting Dates –
  - January 17, 2017
  - April 18, 2017
  - July 25, 2017
  - October 17, 2017
  - A. Multidisciplinary Advisory Committee Assignment Priorities
  - B. Agenda Items for Next Meeting – Minimum Standards for Small Animal Spay and Neuter Clinics
12. Adjournment

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

The Board plans to webcast items 1-13 at this meeting on its website at [www.vmb.ca.gov](http://www.vmb.ca.gov). Webcast availability cannot, however, be guaranteed due to limitations on resources or technical difficulties that may arise. If you wish to participate or to have a guaranteed opportunity to observe, please plan to attend at a physical location.

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

**MISSION**

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



**MEETING MINUTES**  
Multidisciplinary Advisory Committee  
1747 N. Market Blvd. – 1<sup>st</sup> Floor Hearing Room  
Sacramento, California

**10:00 a.m. Tuesday, July 19, 2016**

**1. Call to Order- Establishment of a Quorum**

Multidisciplinary Advisory Committee (MDC) Chair, Dr. Jon Klingborg called the meeting to order at 10:05 a.m. Veterinary Medical Board (Board) Executive Officer, Annemarie Del Mugnaio called roll; nine members of the MDC were present and thus a quorum was established.

**2. Introductions**

Members Present

Jon Klingborg, DVM, Chair  
Allan Drusys, DVM, Vice Chair  
William Grant, DVM  
David Johnson, RVT  
Jennifer Loredo, RVT, Board Liaison  
Kristi Pawlowski, RVT  
Jeff Pollard, DVM  
Richard Sullivan, DVM, Board Liaison  
Diana Woodward-Hagle, Public Member

Staff Present

Annemarie Del Mugnaio, Executive Officer  
Nina Galang, Administrative Program Coordinator  
Kurt Heppler, Legal Counsel  
Ethan Mathes, Administrative Program Manager  
Candace Raney, Enforcement Manager  
Caesar Victoria, DCA Webcast

Guests Present

Kathy Bowler, Public Member, Veterinary Medical Board  
Nancy Ehrlich, California Registered Veterinary Technician Association  
Valerie Fenstermaker, California Veterinary Medical Association  
Alex Henderson, Veterinary Allied Staff Education  
Shelly Jones, DCA Board & Bureau Relations  
Mark Nunez, DVM, Veterinary Medical Board  
John Pascoe, DVM, University of California, Davis  
Ken Pawlowski, California Veterinary Medical Association  
Cindy Savely, RVT, Sacramento Valley Veterinary Technician Association  
Dan Segna, California Veterinary Medical Association  
Leah Shufelt, RVT, CVMA  
Cheryl Waterhouse, DVM, Veterinary Medical Board

### **3. Review and Approval of April 19, 2016 Meeting Minutes**

The Board made a few minor spelling corrections.

- Dr. Allan Drusys moved and Dr. William Grant seconded the motion to approve the minutes as amended. The motion carried 9-0.

### **4. Update on the Complaint Process Audit Task Force Subcommittee**

Dr. Jeff Pollard updated the MDC regarding the audits performed by him and Dr. William Grant. Older cases were found to be less valuable than newer cases in terms of assessing expert review. The most interesting finding was that reviewing the case in a particular order may impact the expert witness's opinion and ultimately affect the outcome of the review. The Subcommittee suggested that the expert witness should read the medical records first, then the complaint and other related documentation.

Additionally, the Subcommittee found that the experts did not fully explain their reasoning and it may have been as a result of misunderstanding the expectations in the report writing process. Dr. Grant expressed that the information learned from this case audits need to be addressed with the expert witnesses and having Ms. Del Mugnaio and Ms. Raney present at the training would be critical.

Ms. Del Mugnaio, Candace Raney, and Ethan Mathes met with a legal firm that provides free legal service to California Veterinary Medical Association (CVMA) members. They discussed educating their members on how important it is to communicate with the Board on issues related to enforcement and continuing education.

Respondents are asked to respond to the Board's inquiry regarding an enforcement case, as required by regulations; otherwise the Board has no other choice but to proceed with enforcement action.

During Expert Witness Training, expert witnesses are reminded that if they are not an expert on a particular procedure a diagnosis, the case should be handed back to the Board. Expert witnesses are not obligated to weigh in on a case they are not expertly equipped to provide an opinion.

Ms. Del Mugnaio clarified that the motivation for the complaint is one aspect the Board staff considers when determining whether or not a case should be pursued, but it should not be a factor for the expert witnesses.

Ms. Del Mugnaio confirmed that no complaints against Registered Veterinary Technicians (RVT) have been reviewed by the Subcommittee, but if the Board decides to include RVT cases in the audit, it would be best to have an RVT Subcommittee member review the cases.

The MDC discussed the concern that the expert witnesses are not appropriately applying statutes and regulations. Ms. Del Mugnaio added the intent is for the expert witnesses to be extremely familiar with the Practice Act, not just the Disciplinary Guidelines.

Legal Counsel, Kurt Hepler, strongly urged against "helping the respondent," with their complaint submittal. While Board staff cannot provide legal counsel, Ms. Del Mugnaio added that staff have been working to provide as much guidance as possible regarding what information is necessary to adequately evaluate a case. The Board continues to work towards establishing a relationship with a veterinary profession and hopes to be an educational resource as well as the enforcement agency.



Valerie Fenstermaker noted that CVMA members have expressed that the initial letter sent by the Board does not state the nature of the complaint, therefore, they are reluctant to reply. Ms. Raney clarified that the initial contact letter includes a synopsis of the complaint with enough information to provide a response. The letter requests a statement and medical records from the respondent.

Ms. Fenstermaker expressed concern regarding only one expert witness review a case and asked the MDC to reconsider the model of an expert witness review panel. Dr. Grant noted that this issue was discussed at the previous MDC meeting and agreed that it would be beneficial to have more than one expert witness review the case. Dr. Grant clarified that the Board's current process is to have an in-house consultant review the case first, and then it is sent out to an expert witness, so there are at least two people currently reviewing the case.

## **5. Report from the Expert Witness Review Subcommittee**

Diana Woodward-Hagle noted that she attended a two-day Expert Witness training on May 4-5, 2016 at the Veterinary Medical Board. After the training, Ms. Diana Woodward-Hagle, Dr. Pollard, and Ms. Raney met to discuss the concerns expressed at the training and create the overview contained in the Board packet, which was intended to generate discussion at the next Expert Witness Training. When writing the Expert Witness Report, Ms. Woodward-Hagle felt that the expert witnesses must: emphasize facts, discuss standard of care, and understand the difference between negligence, incompetence, and unprofessional conduct.

Dr. Pollard added that for future Expert Witness trainings, it has been suggested that findings from closed case reviews should be presented at the training.

The MDC discussed the difference between "negligence," "incompetence," and "unprofessional conduct." Ms. Del Mugnaio added that "unprofessional conduct" is not just behavioral, but may also include deviation from standard of care [e.g. failure to establish a Veterinarian-Client-Patient Relationship (VCPR)].

## **6. Update on Minimum Standards for Alternate Premises**

David Johnson introduced the concept of changing "indirect supervision" to "general supervision" and changing "individual written order" to "standing general order."

Dr. Richard Sullivan suggested adding "diagnostic testing and treatment of medical conditions based upon clinical signs" as a general order and not specific orders for specific animals.

Ms. Del Mugnaio reminded the MDC that the intention of this update is not to consider formalized language for the Board, but instead to share it with the sheltering community to discuss at the October 2016 MDC meeting.

Mr. Johnson suggested looking into allowing an RVT to be the Managing Licensee as part of their extended duties.

Dr. Allan Drusys expressed that there are instances where an RVT should administer anesthesia over sedation for the betterment of the animal.

Jennifer Loreda noted that with regard to sedation, Animal Control Officers (ACO) may administer an undisclosed amount to dart the animal and a RVT administers a more accurate amount. Mr. Johnson added that RVTs can provide rescue services and administer sedation.

Mr. Heppler noted that the phrase in section 2035.5 (a)(1) “has direct knowledge of the animal population” may need to be modified for the purposes of providing clarity for the Office of Administrative Law (OAL).

Ms. Del Mugnaio added that the MDC should review section 2034 (i), Induce, at a future meeting. The language needs to define “induce” as the induction of “sedation,” which is separate and apart from “general anesthesia.”

Dr. Dan Segna, CVMA, noted that of the three CVMA Premises Task Force meetings held thus far, nearly half of the discussion was spent on the topic of shelter settings. As they related to shelters, the intent was to craft regulations that are non-prescriptive but served as guidelines.

Dr. Segna explained the reasoning behind the proposed regulations and suggested adding “diagnostic testing” language in section (a). Ms. Loreda added that diagnostic testing is not necessarily something that is done on intake.

Dr. Nunez asked the MDC if there has been any discussion on developing minimum standards for rescue groups. Dr. Drusys noted it will be discussed in Item #7.

Ms. Del Mugnaio clarified that the tasks performed in a shelter setting are still the practice of veterinary medicine and there is a misconception in the veterinary community that these tasks are exempt.

## **7. Update on Survey of Public and Private Shelters and Discussion of Minimum Standards & Protocols for Shelter Medicine**

Dr. Drusys noted that surveys were sent out, but there have been issues the collection of the data.

Dr. Klingborg added that the MDC can expect more data to be available by the MDC meeting in October 2016.

## **8. Review and Discuss Veterinary Student Exemption [Duties and Supervision at University Hospitals]; Potential Recommendation to Full Board**

Mr. Heppler reviewed the Veterinary Student Exemption memo and identified two statutory issues based on previous discussions that the MDC may consider:

- 1) Would it be beneficial to establish a link between the premises where the student performs animal health care tasks under supervision as part of their curriculum, and the expectations for the student, the supervisor, and perhaps the Board?
- 2) Should students with a specified amount of training be allowed to participate in surgery?

Mr. Heppler noted another concern regarding the provisions of CCR section 2027 allow a junior or senior student or a graduate of a recognized veterinary college to perform the duties of an RVT without a license and for an unspecified period of time.

Based on the understanding that the definition of “treatment” encompasses surgery, Dr. Grant expressed concern that BPC section 4826 (c) provides the authority to perform surgery at an off-campus site. The MDC agreed that the term “surgery” should be clearly stated if that is the intent.

Dr. John Pascoe, University of California, Davis (UCD), asked if the MDC would be open to a Task Force to develop language that meets the objective of ensuring that the educational institutions are graduating entry level veterinarians who are competent, where optimal patient care is provided in a

setting where students are actively engaged in learning, and where the consumer is protected. Dr. Pascoe volunteered to participate in the Task Force.

Dr. Pascoe clarified that the Council on Education's (COE) Standards for Education currently requires a minimum of four years to obtain a degree. From the UCD perspective, Dr. Pascoe noted that first and second year students have been getting more exposure to clinical experience. However, the MDC agreed that different educational institutions offer training on various areas of the required curriculum at different stages of the educational program.

Dr. Grant suggested using "students" instead of specifying a specific year in the student's veterinary education.

Dr. Klingborg identified three areas for the MDC to consider:

- 1) Should the MDC move forward with the language or form a Task Force?
- 2) Should the MDC decouple the language from exemptions and move it into a more appropriate section?
- 3) Should a veterinary graduate without a license be allowed to sit for the RVT license examination?

Dr. Sullivan suggested modifying BPC section 4830 (a)(5) to meet the MDC's objective.

Ms. Woodward-Hagle recommended considering limiting the statute to California students based on the challenges found with verification and enforcement of foreign graduates.

Nancy Ehrlich suggested allowing veterinary students to sit for the RVT license examination.

Dr. Sullivan agreed that the Task Force should consider this suggestion.

Dr. Drusys recommended including CCR section 2027 in the discussion, along with all of the documents that have been prepared under this item.

Ms. Del Mugnaio noted that it may be helpful to review the rulemaking record and research the intent of the changes that have occurred over time.

- Dr. Richard Sullivan moved and Dr. William Grant seconded the motion to convene a Task Force comprised of various educational institutions, members of the MDC and/or the Board, and Legal Counsel to study the BPC section 4830 (a)(5) and CCR section 2027 and present a recommendation to the full Board. The motion carried 9-0.

Dr. Sullivan requested to discuss premise permits for University clinics providing services to the public.

Ms. Del Mugnaio clarified that this issue is connected to the exemption in BPC section 4830 (a)(5). The change in SB 1193 removes the Universities and their facilities from the exemption to hold a premises permit, which is addressed under University licensure.

## **9. Discussion and Consideration of "Extended Duty" for Registered Veterinary Technicians Regulations; Potential Recommendation to Full Board**

The Extended Duties Subcommittee, Kristi Pawlowski and Mr. Johnson, reported that they found no specific extended duties that need to be addressed for RVTs at this time other than duties performed within the shelter community. The Subcommittee felt that the work they have done appears to be a duplication of work performed by the CVMA Premises Task Force and agreed that it would be best to continuously look at where RVTs stand on new and current issues brought up at the MDC.

Mr. Johnson added that the goal is to identify access to care issues, not to enhance the job duties or functions of RVTs.

Ms. Ehrlich expressed that she was surprised to hear that there are no extended duties identified that would benefit the consumer as she is able to come up with a whole list of examples.

Ms. Del Mugnaio clarified that is the Board's duty to define the duties that are already currently in practice. The Board may expand existing duties only if there is an access issue or if there is a demand that is not being met which creates a risk to consumers. Ms. Del Mugnaio added that the Board's consumer protection includes the client and the animal patient.

Leah Shufelt, CMVA, noted that she reached out to their members requesting ideas for RVT extended duties from a "need" and not a career advancement perspective, and did not receive much of a response from its RVT members.

Cindy Savely noted three potential RVT extended duties discussed at the most recent Sacramento Valley Veterinary Technician Association (SVVTA) Board meeting: 1) administering vaccinations (e.g. rabies), 2) providing parasite control, and 3) performing wound debridement in a shelter environment.

Dr. Klingborg will keep this item on the agenda for the next MDC meeting in October and hopes to hear from California Registered Veterinary Technician Association's (CaRVTA) Board or representative on this issue. At that time, Dr. Klingborg will decide if the item should continue to stay on the agenda.

Dr. Drusys suggested that the MDC, from a transparency perspective, should be as open as it can be to all stakeholders. Ms. Del Mugnaio clarified that an RVT standing report is on the Board's agenda, not the MDC. The MDC's issues are delegated from the Board.

#### **10. Review and Consider Implementing Regulations Regarding Veterinarian's and Registered Veterinary Technician's Authority to Compound Drugs Pursuant to the Adoption of Statutes in Senate Bill 1193.**

Ms. Del Mugnaio reviewed various background documents, including Code of Federal Regulations Title 21, Part 530.13, a summary of Federal Drug Administration (FDA) guidance document #230, and proposed Pharmacy Board regulations regarding compounding, for the Board's consideration prior to crafting Drug Compounding regulations.

The definition of "compounding" has been taken from the Board of Pharmacy regulations, CCR section 1735, and will need to be referenced and re-stated in the Board's regulations.

The Board asked two representatives from UCD questions regarding their experience with drug compounding in their practice.

Medical Oncologist, Dr. Jenna Burton, stressed the importance of appropriately dosing cancer patients and noted that she relies on compounding pharmacies to compound drugs for her animal patients.

Dr. Gary Magdesian, an Equine Internist who served on the American Veterinary Medical Association (AVMA) Task Force for compounding from bulk drugs, added that he also relies on compounding pharmacies to compound drugs except when mixing immediate-use drugs.

Dr. Burton and Dr. Magdesian both expressed concern regarding the quality of product received from the compounding pharmacies. Dr. Burton opined that the inaccuracy of drug potency may be due to the

nature of working with bulk product. Dr. Magdesian added that the drugs are not FDA-approved and are not as well regulated as they could be.

Dr. Burton noted that UCD published a study comparing the same drug, of the same potency, from five different compounding pharmacies. The potency results varied anywhere from 50 percent to 115 percent, with only one sample falling within plus or minus 10 percent of the labeled concentration.

Dr. Magdesian updated that the AVMA Task Force has completed its document and recommended legislative language for federal oversight of bulk compounding.

From the AVMA Task Force's point of view, Dr. Magdesian added that the need for compounding from bulk is critical, but can vary for each veterinary sector. Ms. Del Mugnaio noted that the Board will need input to define necessity for bulk compounding. The availability or lack thereof, of obtaining compounded drugs from a compounding pharmacy for veterinary practice may help better define necessity.

Dr. Magdesian noted that the AVMA Task Force has concern over the FDA Guidance #230 document with regard to access and whether existing facilities would be willing to produce veterinary drugs and register as an outsourcing facility.

Mr. Heppler clarified that the State of California does not recognize guidance documents and regulations must be adopted in order to be enforceable. He stated that the MDC and Board need to clearly define need in the regulation documents.

#### **11. Public Comments on Items Not on the Agenda**

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

#### **12. Agenda Items and Next Meeting Dates – October 18, 2016 (TBD)**

Ms. Del Mugnaio noted that the next MDC meeting will be in Southern California.

Next year's MDC meeting schedule is as follows:

- January 17, 2017
- April 18, 2017
- July 18, 2017
- October 17, 2017.

##### **A. Multidisciplinary Advisory Committee Assignment Priorities**

Dr. Klingborg reviewed the list of existing MDC assignment priorities:

1. Evaluate Structure and Audit Enforcement Case Outcomes
2. Develop Minimum Standards for Alternate Premises
3. Review Section 4830(a)(5) and Section 2027
4. Discuss Extended Duties for RVTs
5. Develop Drug Compounding Regulations
6. Rodeo Reporting and Requirements
7. Develop Minimum Standards for Spay and Neuter Clinics.

Dr. Grant requested Dr. Klingborg to address the issue of case management of mobile specialists such as surgeons or internists, doing procedures at hospitals as a priority assignment with the Board.

Dr. Klingborg will also ask the Board if the discussion on "sedation" vs. "anesthesia" can be added as a separate discussion item.

## B. Agenda Items for Next Meeting

Ms. Del Mugnaio clarified that standing items cannot be discussed without material. Meetings may include standing reports, but you cannot discuss the items without the items being placed on an agenda.

### **13. Adjournment**

The MDC adjourned at 3:23 p.m.

## RVT and Animal Shelter Subcommittee Research Report Outline

B&P 4840

- (a) Describes RVT **and** assistants are approved..."under the *supervision* of a veterinarian" ....Not otherwise defined. We feel a premise permit should be a prerequisite.
- (b) As discussed at the last MDC meeting and also in our directions from Dr. Klingborg, the term "written order" as used in the context of this article needs to be better defined to address how animal health care services are provided in a shelter setting. Legislative change would be required to better define it here so it is best to define it within the sections of CCR Article 4 - Practice, possibly in CCR 2034 or 2036 Animal Health Care Tasks Definitions.

B&P 4840.2

This article addresses unauthorized practices. (b) Specifically states that diagnosis and prognosis is prohibited. Diagnosis is further defined in B&P 4825.1 (a).

We need to somehow address the issue that exams and diagnostic tests are performed (i.e parvo etc) prior to an examination by a veterinarian or subsequent euthanasia. These tests are performed to protect the health and well-being of every other animal and the personnel within the shelter. The issue of appliances/splints needs discussion.

B&P 4840.5

This article defines and authorizes emergency aid with those specific tasks listed in CCR 2069 We may need to look at the phrase " may only be continued under the direction of a licensed veterinarian" to see if any clarification is needed for a shelter setting

B&P 4853

- (a) and (b) describe premises. Should include animal shelters (or limit to those who are animal control jurisdictions or who have contracts to provide animal sheltering services).
- Could RVTs hold an "animal shelter premise license"?

CCR 2032.1

This section defines the Veterinarian-Client -Patient Relationship (VCPR). At the end of (a) where is states "or the owner is unknown" do we need a special reference to impounded shelter animals which may be owned or whose owners are not forthcoming? Do we need to add a reference to animals seized under the provisions of PC 597?

CCR 2032.4

CCR 2036(b) in conflict with PC 597.1 (2) relative to administration of controlled substances/anesthesia by ACO and RVT? Is it not anesthesia as defined in CCR 2032.4?

## CCR 2035

This section defines the duties of the supervising veterinarian, In (c) it states that " the supervising veterinarian shall have examined the animal patient prior to the delegation of an animal health care task"

This is a major issue with regards to how animal health care tasks are performed in a shelter setting and needs to be reviewed and modified.

## CCR 2069

This is one of the original RVT task sections and it has worked well over the years. It has direct application in a shelter setting. It has not been updated in many years. With the current standards of practice for both shelter medicine and private practice, it would be appropriate to add an additional treatment type for "pain management"

In addition to the points that we have raised in the above articles and regulations, these other issues require consideration:

1. Sedation/anesthesia of animals in a shelter setting for the purpose of:
  - (a) Grooming severely matted hair coats
  - (b) Cleaning wounds
  - (c) Bandaging
  - (d) Splinting
  - (e) Removing foxtails from the eye
2. Sedation of animals in the field - (this is different than chemical capture by ACOs)
3. Vaccination upon entry into a shelter setting which is considered best practice in today's shelter environment
4. Diagnostic testing upon entry into a shelter setting or when herd health management practice would call for it.
5. Treatment of commonly recognized animal shelter disease symptoms (cough, upper-respiratory signs, diarrhea, endoparasites) prior to an examination by a veterinarian.
6. How long may an animal be treated under a written protocol before a veterinarian would be required to examine the animal? Redefine CCR 4840.5 to include shelter impounds?



## Public/Private Animal Shelters Survey

Early June 2016, Dr. Drusys of the MDC and Erica Hughes of the State Humane Association of California sent the following survey to public and private shelters and Humane Societies. Survey results will be reported at the MDC meeting.

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Please answer all that applies to your organization

1. Name of organization
2. Humane organization?
3. Non-profit 501(C)3 ?
4. Address
5. Open admission or limited admission
6. Does your organization hold any animal control contracts with the county or city?
7. How many ACOs work for you?
8. Do your ACOs carry controlled substances to tranquilize in the field?
9. Do your ACOs euthanize in the field?
10. Is your organization "No-Kill" by whatever definition?
11. Number of employees
12. Number of Veterinary Assistants
13. Do you employ full time Veterinarians, How many?
14. Do you employ RVTs, How many?
15. During the average shift what level of supervision is provided to the vet staff. Indirect by the DVM, direct by a DVM, no DVM supervision.
16. Approximate number of animal impounds
17. Approximate number of sheltered animals in inventory per day
18. Does your organization have a premise permit issued by the Vet Med Board?
19. Who holds the permit? A staff DVM or a contract DVM or a volunteer DVM?
20. Are you aware that a premise permit is free of charge to animal shelters?
21. If you do not have a staff DVM, does a DVM visit the shelter?, how often?
22. If an animal is impounded ill or injured is it treated on site or taken to a vet clinic/hospital?
23. If an animal becomes ill while at the shelter is it treated on site or taken to a vet clinic/hospital?
24. Does your organization operate a spay/neuter facility? At the shelter site or different location?
25. Does your organization conduct vaccination clinics? On site or offsite?
26. Does your organization offer any other veterinary services to the public? What kind?
27. Are the animals examined on impound and vaccinated? If so, by whom? ACO, ACT, VA, RVT, DVM
28. Are animals euthanized at your facility? By whom?



June 27, 2016

Annemarie Del Mugnaio, Executive Officer  
Veterinary Medical Board  
1747 N. Market Boulevard, Suite 230  
Sacramento, California 95834-2987

Dear Ms. Del Mugnaio:

At the request of the Veterinary Medical Board (VMB), the California Veterinary Medical Association (CVMA) formed a Premises Task Force to review premises permit laws and regulations as they relate to all species and practice types. As part of its charge to provide recommendations for a variety of practice types, the task force discussed the delegation of health care tasks to registered veterinary technicians in a shelter setting.

The CVMA invited veterinarians who work in shelters, shelter directors and a representative from State Humane Association of California to our last two task force meetings to discuss the unique issues associated with the delegation of tasks in a shelter setting. The issues identified were:

- The limited availability of veterinarians during shelter operating hours,
- The difficulty of establishing a Veterinarian-Client-Patient relationship for each animal,
- The need to perform certain procedures on animals upon intake at the shelter for the health and wellbeing of the individual animal and the shelter population as a whole,
- Protocols that would allow treatment for animals that are sick or injured when a veterinarian is not available to examine the animal.

As an outcome of these discussions, the task force developed a proposed regulation which would allow registered veterinary technicians to perform certain tasks on animals under indirect supervision following a veterinarian's written orders.

The CVMA Board of Governors approved the proposed regulation at its June, 2016, meeting and requests that this proposal be included in the agenda for the July meeting of the Multidisciplinary Advisory Committee.

We feel that this proposal addresses the primary issues that shelter personnel face when dealing with a large population of animals and the inability to have a veterinarian on site at all times. The regulation is intended to provide a guideline for what tasks a registered veterinary technician may perform under the direct written order of a veterinarian and to allow shelter veterinarians and staff the flexibility to provide care under specific circumstances.

The CVMA is pleased to submit the enclosed recommendation for consideration.

Sincerely,



Ken Pawlowski, DVM  
CVMA President

**The California Veterinary Medical Association Premises Task Force proposed regulation to the Veterinary Medical Board Multidisciplinary Advisory Committee**

**Section 2035.5 Duties of Supervising Veterinarian and Animal Health Care Tasks for Registered Veterinary Technicians in the Shelter Setting**

(a) Notwithstanding subsection (c) of 2035 and pursuant to 4840(b), limited medical care may be provided in a shelter setting by a registered veterinary technician for the specific purpose of controlling infectious and zoonotic disease, controlling acute pain, and preventing environmental contamination if all the following are met:

(1) The supervising veterinarian has direct knowledge of the animal population and examines the animal(s) at such time as good veterinary medical practice requires consistent with the particular delegated animal health care tasks.

(2) The supervising veterinarian establishes written orders for:

(A) Vaccination and prophylactic control of endo- and ecto-parasites on intake

(B) Treatment of medical conditions based on an animal's symptoms

(3) Treatment rendered under subsection (2) may only be continued under the direction of a licensed veterinarian

(b) Emergency animal care may be rendered by a registered veterinary technician pursuant to section 2069.

(c) An RVT shall not diagnose, perform surgery or prescribe pursuant to section 4840.2.

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

(e) Animals that have been adopted and returned to the shelter by the owner for treatment of a medical condition must be examined by a veterinarian prior to treatment or dispensing medication pursuant to 2032.1.

## **Current Law:**

### **4840. Authorized services by technicians and assistants**

(a) Registered veterinary technicians and veterinary assistants are approved to perform those animal health care services prescribed by law under the supervision of a veterinarian licensed or authorized to practice in this state.

(b) Registered veterinary technicians may perform animal health care services on those animals impounded by a state, county, city, or city and county agency pursuant to the direct order, written order, or telephonic order of a veterinarian licensed or authorized to practice in this state.

(c) Registered veterinary technicians may apply for registration from the federal Drug Enforcement Administration that authorizes the direct purchase of sodium pentobarbital for the performance of euthanasia as provided for in subdivision (d) of Section 4827 without the supervision or authorization of a licensed veterinarian.

### **4840.2 Unauthorized Practices**

- (a) Surgery
- (b) Diagnosis and prognosis of animal diseases
- (c) Prescribing of drugs, medicines and appliances

### **2035. Duties of Supervising Veterinarian.**

(a) The supervising veterinarian shall be responsible for determining the competency of the R.V.T. or unregistered assistant to perform allowable animal health care tasks.

(b) The supervising veterinarian of a R.V.T. or unregistered assistant shall make all decisions relating to the diagnosis, treatment, management and future disposition of the animal patient.

(c) The supervising veterinarian shall have examined the animal patient prior to the delegation of any animal health care task to either an R.V.T. or unregistered assistant. The examination of the animal patient shall be conducted at such time as good veterinary medical practice requires consistent with the particular delegated animal health care task.

### **2069. Emergency Animal Care.**

Emergency animal care rendered by registered veterinary technician. Under conditions of an emergency as defined in Section 4840.5, a registered veterinary technician may render the following lifesaving aid and treatment to an animal:

- (1) Application of tourniquets and/or pressure bandages to control hemorrhage.
- (2) Administration of pharmacological agents to prevent or control shock, including parenteral fluids, shall be performed after direct communication with a licensed veterinarian or veterinarian authorized to practice in this state. In the event that direct communication cannot be established, the registered veterinary technician may perform in accordance with written instructions established by the employing veterinarian. Such veterinarian shall be authorized to practice in this state.
- (3) Resuscitative oxygen procedures.
- (4) Establishing open airways including intubation appliances but excluding surgery.
- (5) External cardiac resuscitation.
- (6) Application of temporary splints or bandages to prevent further injury to bones or soft tissues.
- (7) Application of appropriate wound dressings and external supportive treatment in severe burn cases.
- (8) External supportive treatment in heat prostration cases.



# California Veterinary Medical Board

Multidisciplinary Advisory Committee

October 18<sup>th</sup>, 2016

# Summary of the Public Private Shelters Survey

Please answer all that applies to your organization

1. Name of organization
2. Humane organization?
3. Non-profit 501(C)3 ?
4. Address
5. Open admission or limited admission
6. Does your organization hold any animal control contracts with the county or city?
7. How many ACOs work for you?
8. Do your ACOs carry controlled substances to tranquilize in the field?
9. Do your ACOs euthanize in the field?
10. Is your organization "No-Kill" by whatever definition?
11. Number of employees
12. Number of Veterinary Assistants
13. Do you employ full time Veterinarians, How many?
14. Do you employ RVTs, How many?
15. During the average shift what level of supervision is provided to the vet staff. Indirect by the DVM, direct by a DVM, no DVM supervision.
16. Approximate number of animal impounds
17. Approximate number of sheltered animals in inventory per day
18. Does your organization have a premise permit issued by the Vet Med Board?
19. Who holds the permit? A staff DVM or a contract DVM or a volunteer DVM?
20. Are you aware that a premise permit is free of charge to animal shelters?
21. If you do not have a staff DVM, does a DVM visit the shelter?, how often?
22. If an animal is impounded ill or injured is it treated on site or taken to a vet clinic/hospital?
23. If an animal becomes ill while at the shelter is it treated on site or taken to a vet clinic/hospital?
24. Does your organization operate a spay/neuter facility? At the shelter site or different location?
25. Does your organization conduct vaccination clinics? On site or offsite?
26. Does your organization offer any other veterinary services to the public? What kind?
27. Are the animals examined on impound and vaccinated? If so, by whom? ACO, ACT, VA, RVT, DVM
28. Are animals euthanized at your facility? By whom?

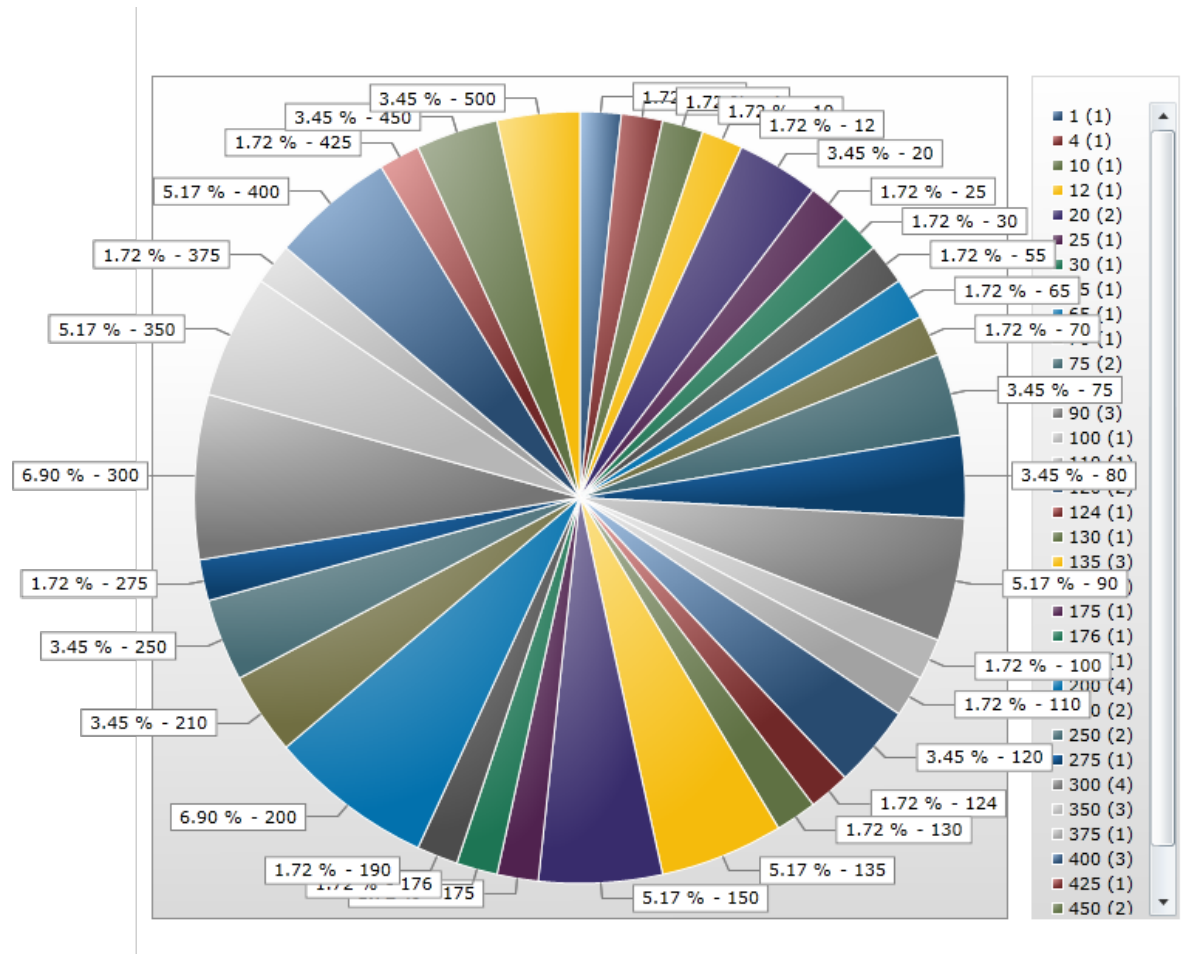


This superficial survey and summary was conducted over the last three months by the staff at the Riverside Department of Animal Services and the State Humane Association of California. It is based upon 64 respondents to RCDAS and 81 to SHAC. Special thanks to Erica Gaudet Hughes for SHAC's part in this endeavor.



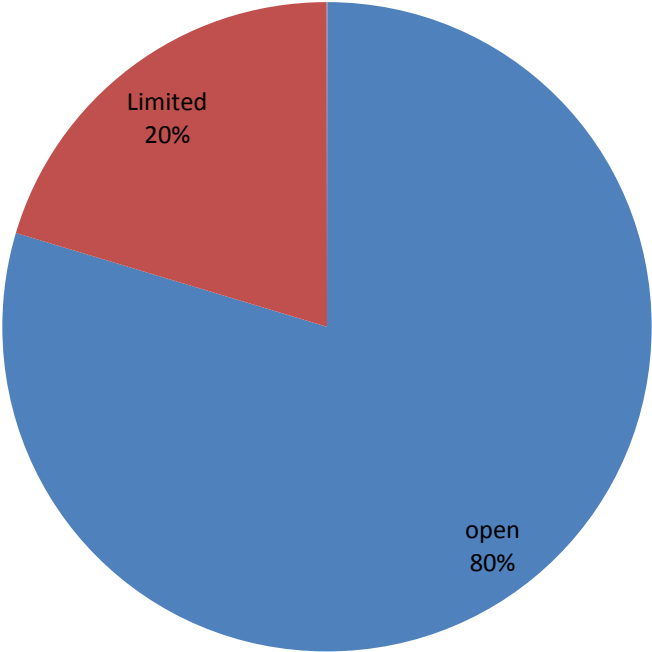


# Average Number of Sheltered Animals per Day

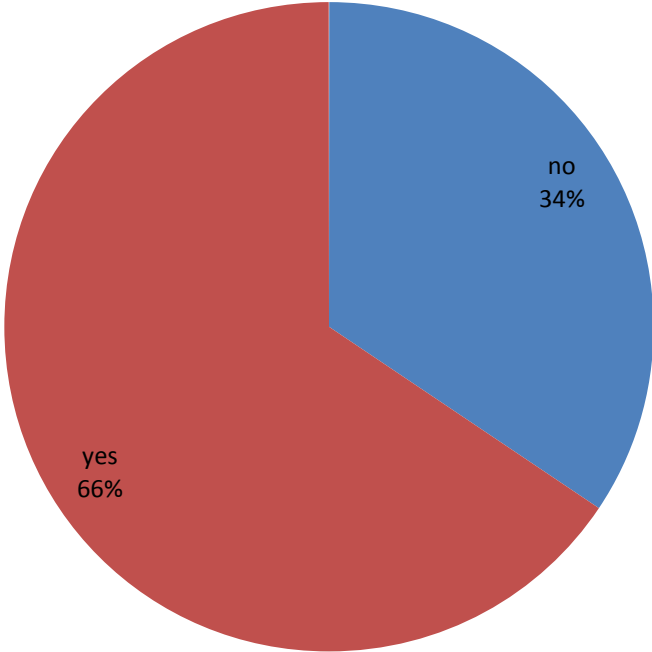


# Shelter Type

**Open Admission or Limited Admission**

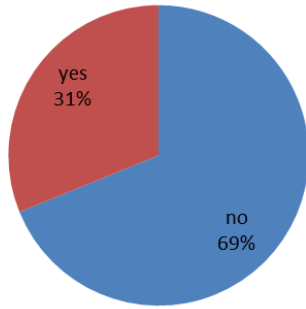


**Hold Contracts with a City or County**

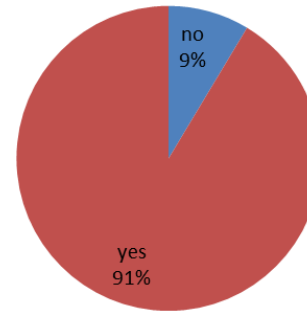


Exactly the same response in both surveys to both questions

### 501(c)3

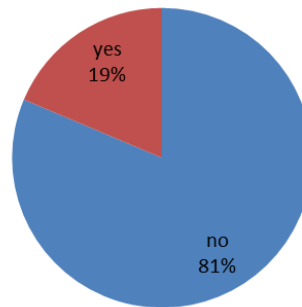


### Premise Permit?



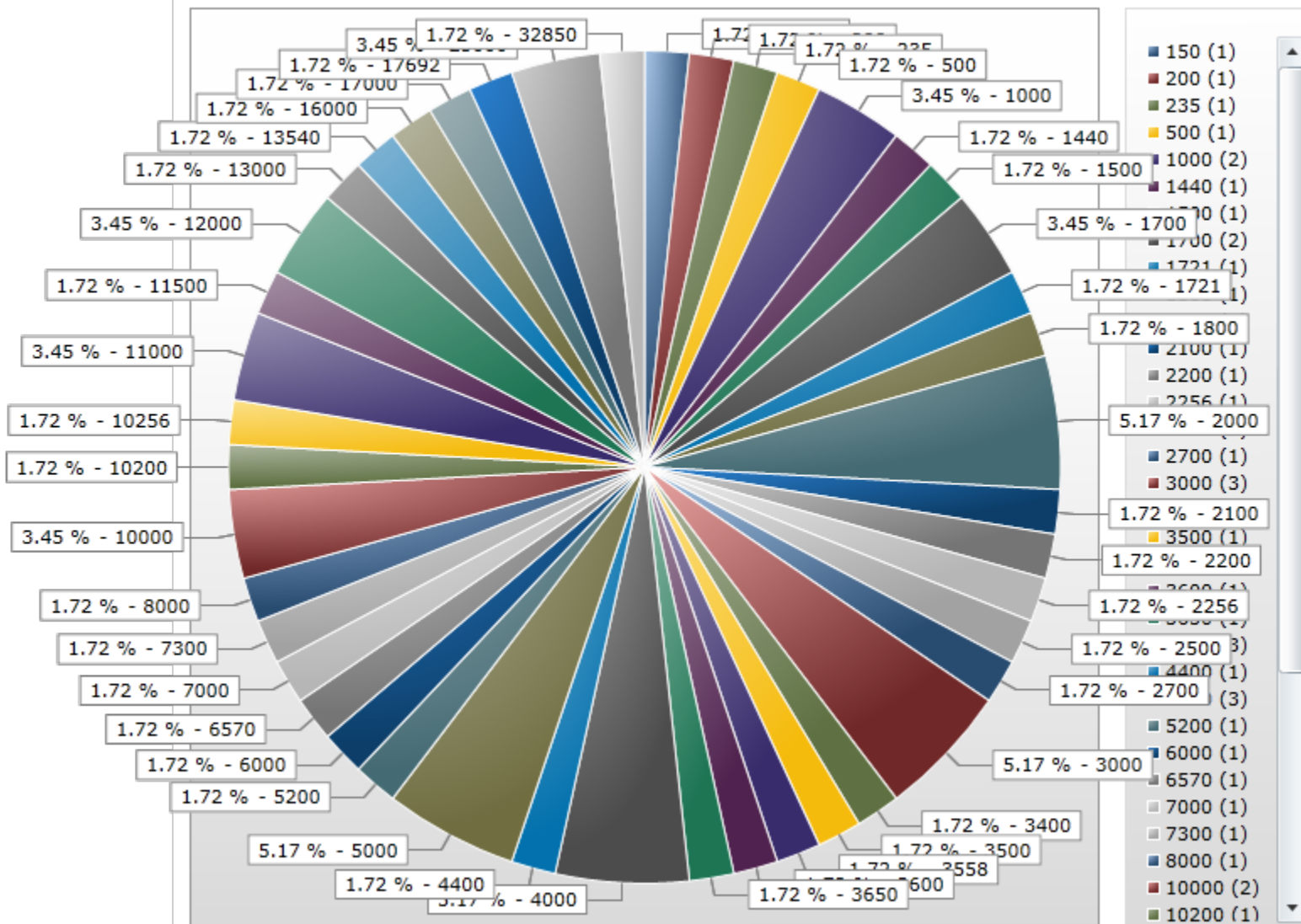
Exactly the same distribution in both surveys

### No Kill by any Definition



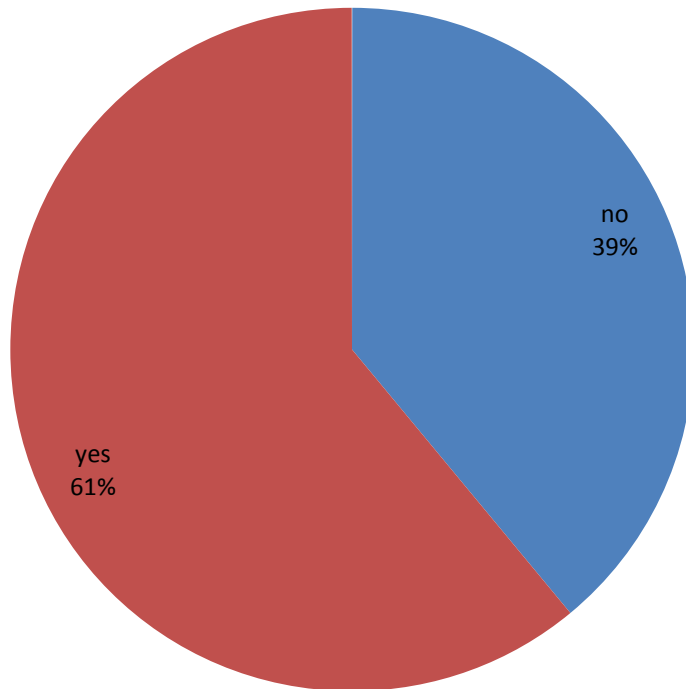


# Approximate Number of Yearly Impounds

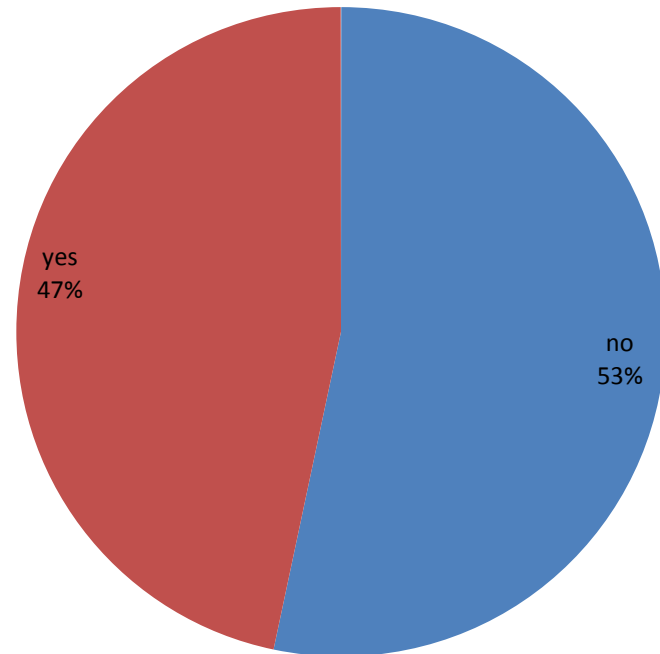


# Professional Staffing

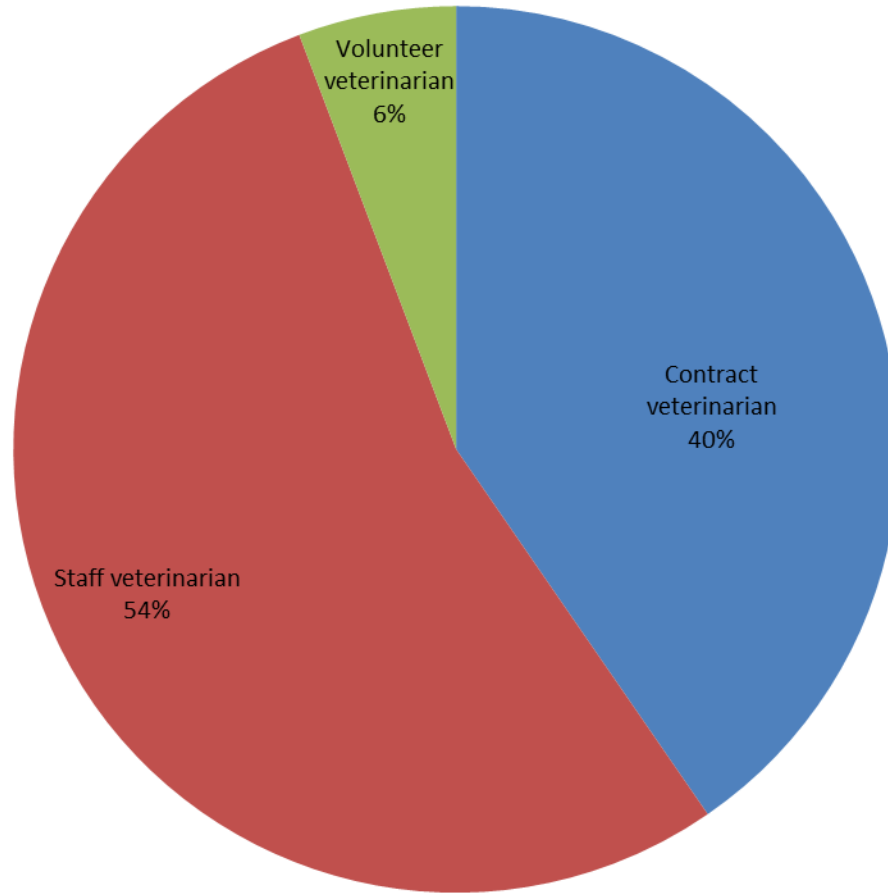
Do you employ RVT's



Do you employ full time Veterinarian(s)



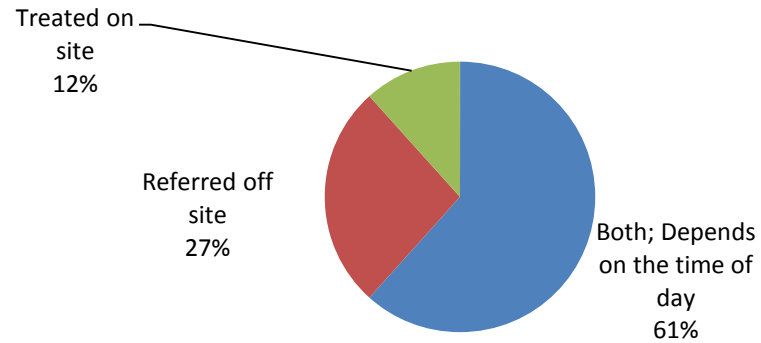
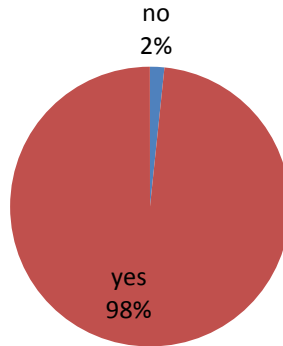
## Who Holds the Premise Permit



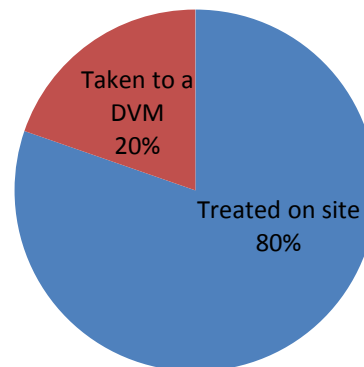


## If an animal is impounded sick or injured: treated on site or referred to a DVM

### Are animals examined on impound and vaccinated

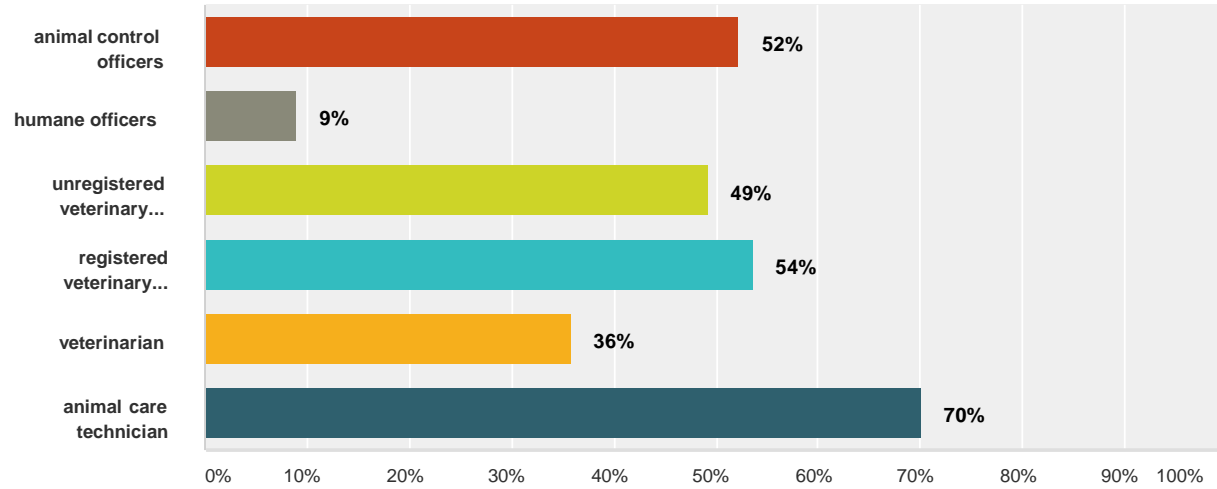


### If an animal becomes sick or injured: treated on site or referred to a DVM

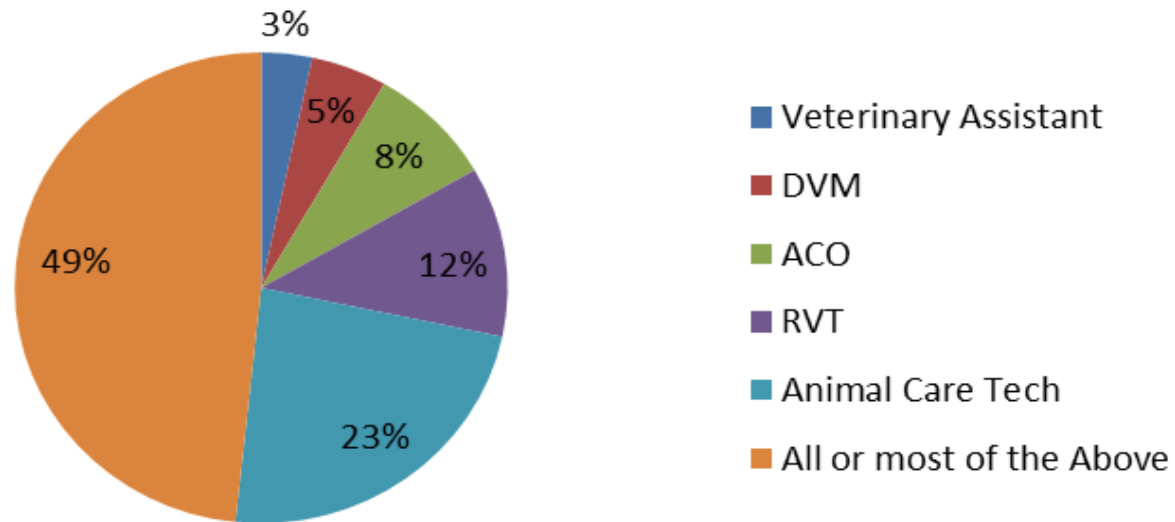


### Q18 If animals are examined on impound and vaccinated, who performs those procedures:

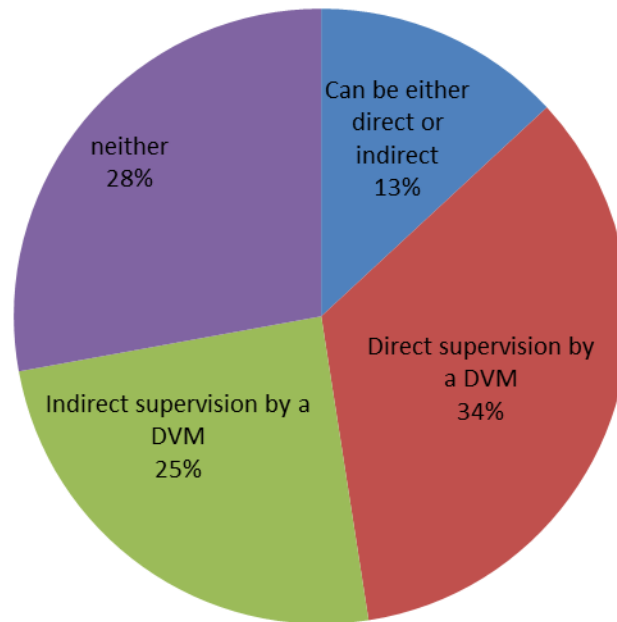
Answered: 67 Skipped: 14



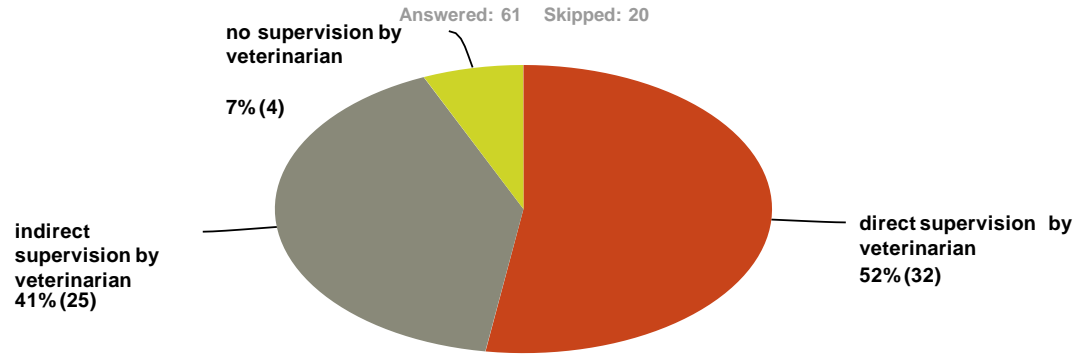
## Examination and Vaccination on impound by whom



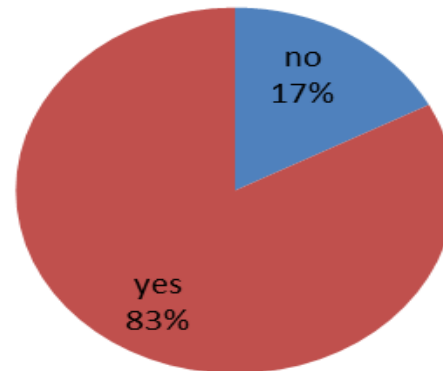
## On an Average Day What is the Level of Supervision?



**Q11 If you have veterinary staff, what level of supervision is provided to them during the average shift:**

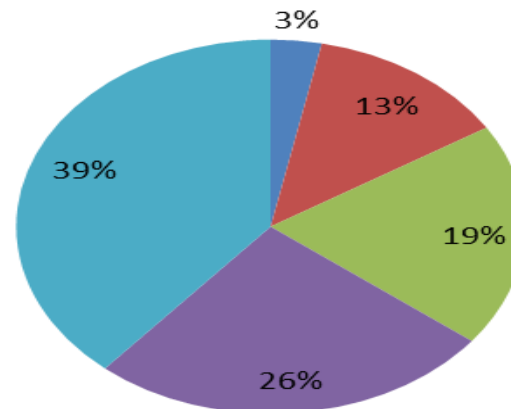


## If you do not have a staff DVM does one visit regularly



Respondants  
No = 5  
Yes = 24

## How often per month



once  
four times  
six times  
eight times  
twelve times

Q12: If you do not have a staff veterinarian, does a veterinarian visit the shelter?  
How often?

- Yes - Once per week
- YES - ONCE A WEEK
- Yes - 1.5 hrs twice a week
- Yes - varies from 2-4 times a week
- Yes - Less than once per month
- Yes - once a week only to give rabies vaccinations
- Yes - twice a week
- Yes - twice a week
- Yes - Weekly
- Yes - Daily
- YES - ONLY WHEN REQUESTED
- No - NA
- Yes - 3 to 4 times a week; always available by phone
- 2 contract vets - 2 daily M - F, 1 every Saturday
- Yes - 1 1/2 days a week or more
- Yes when needed - Occasionally
- Yes - 2-3 times per week
- Yes - weekly
- Yes - Twice per month
- Yes - 3-4 times/week
- no
- Yes - every Tuesday, for 2 hours every Thursday, and as needed for emergencies
- Yes - contract for two 7 hour days per week
- NA - Have contract vet once a week
- Yes - 1/week
- Yes - quarterly or more
- Yes - Every other week
- Yes - 5-6 days a week
- No - N/A
- Once a month (minimum)
- Once a week
- As needed - twice a year?
- Yes - Twice a week
- We have Veterinarians on duty 5 days per week
- Yes - Monthly
- Yes - 3 times per week
- No
- Yes
- Yes

Q13: Do you have access to a veterinarian at all times when the shelter is open? Please explain.

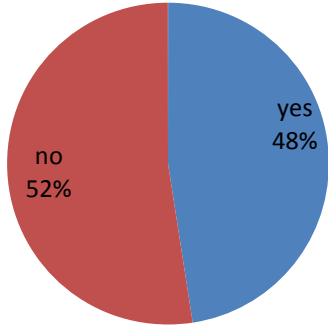
Q14: Do you have access to a veterinarian outside of shelter hours? Please explain.

Answer to both: Overwhelmingly YES

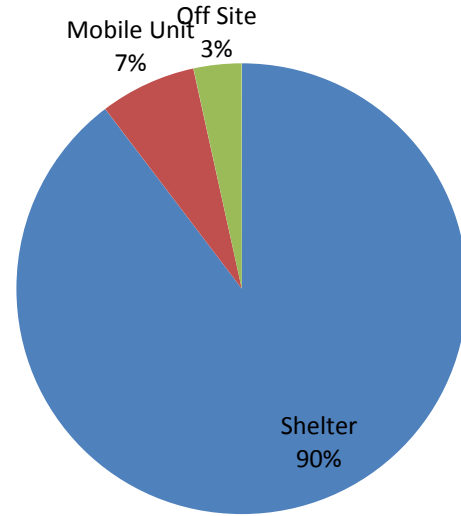




### Does Your Org Operate a Spay/Neuter Clinic

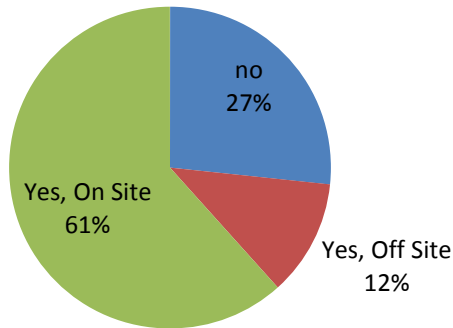


### Where is the Spay/Neuter clinic located

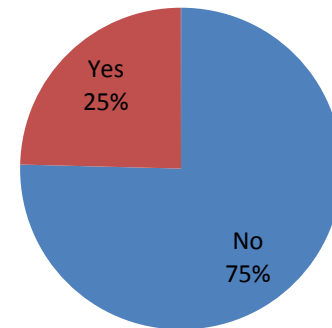


29 Respondents

### Does Your Org Conduct Vaccination Clinics

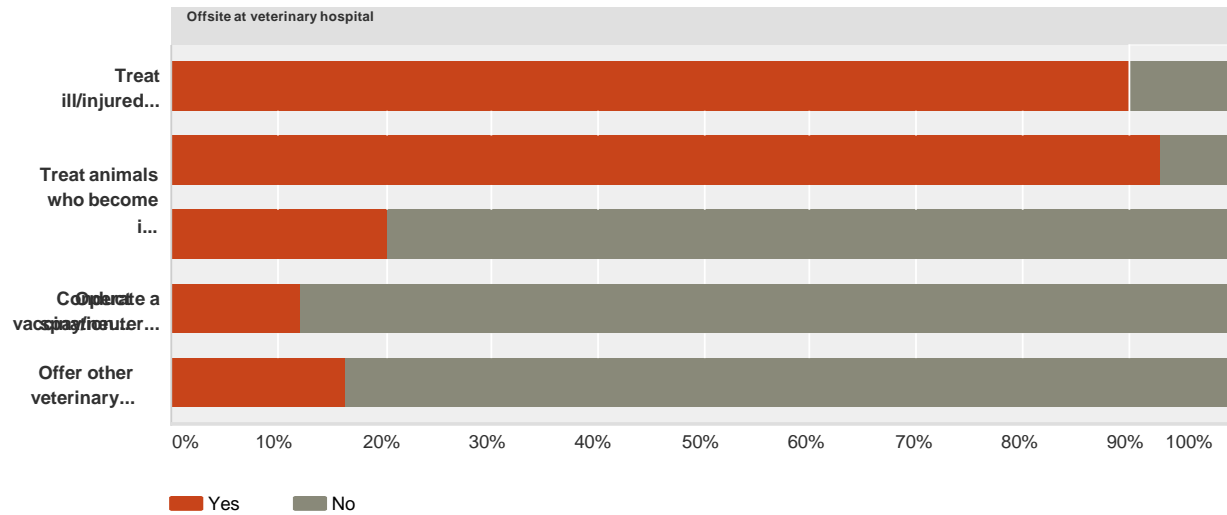
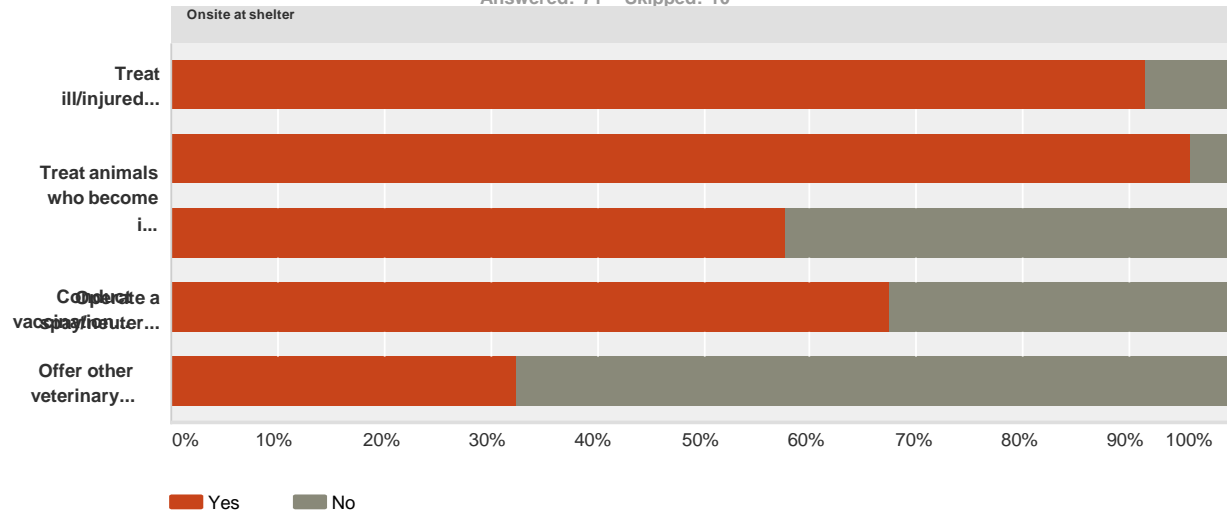


### Do You Offer Any Other Veterinary Services



### Q20 Does your organization/agency

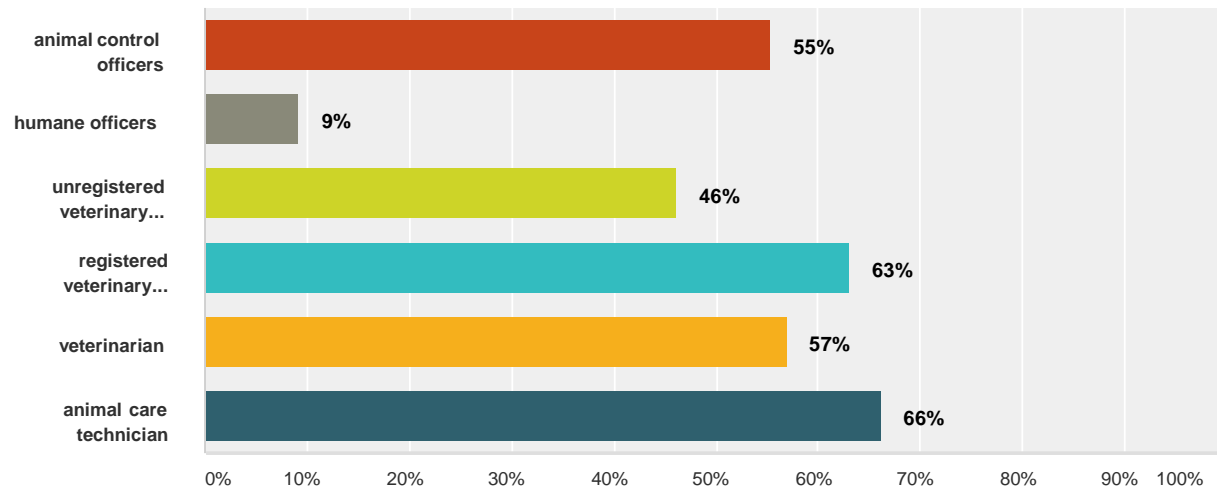
Answered: 71 Skipped: 10



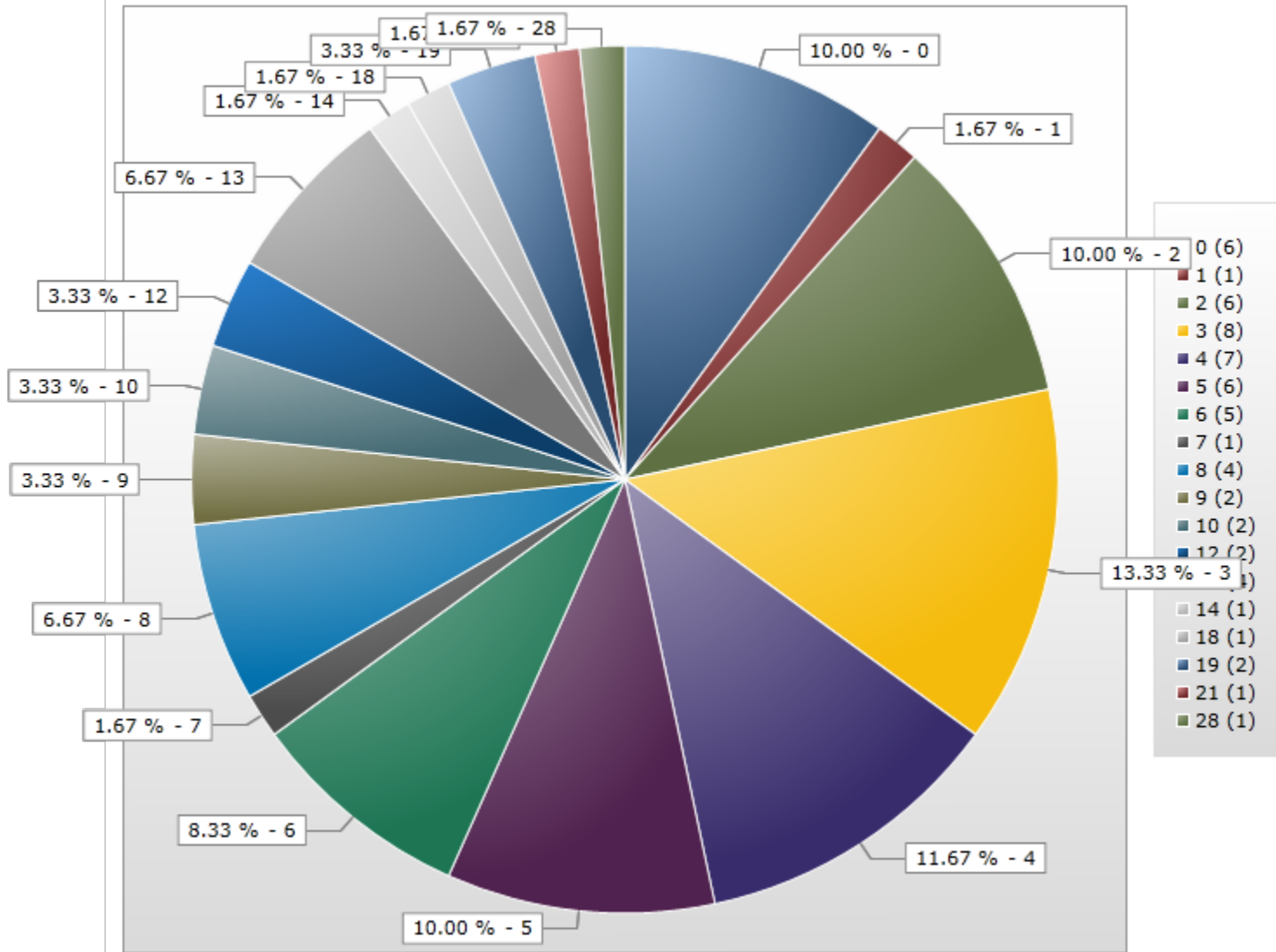
# Are Animals Euthanized at your Facility?

No	3	5.00%
Yes by the animal care technicians	7	11.67%
Yes by the DVM	5	8.33%
Yes by the vet staff (not a DVM)	10	16.67%
Yes by all or most of the above	35	58.33%

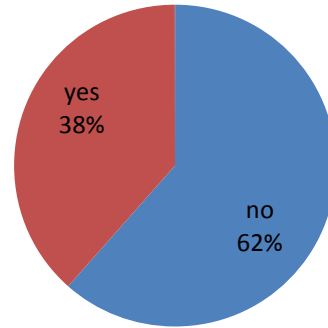
### Q19 If animals are euthanized at your shelter(s), who performs those procedures:



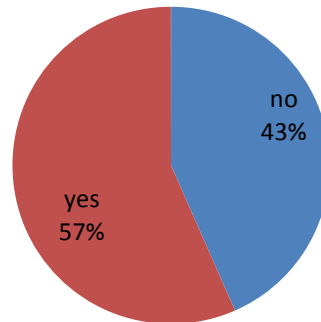
# How Many ACO's Are Employed



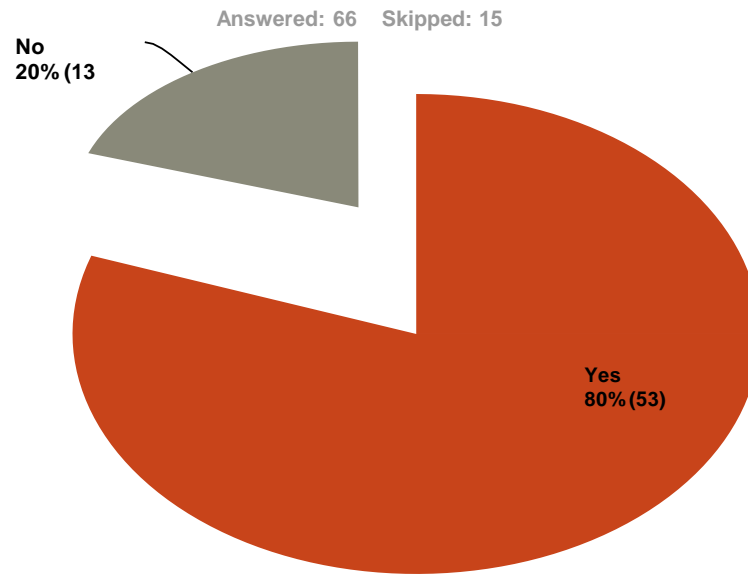
## Do ACO's Carry Controlled Substances in the Field



## Do ACO's Euthanize in the Field

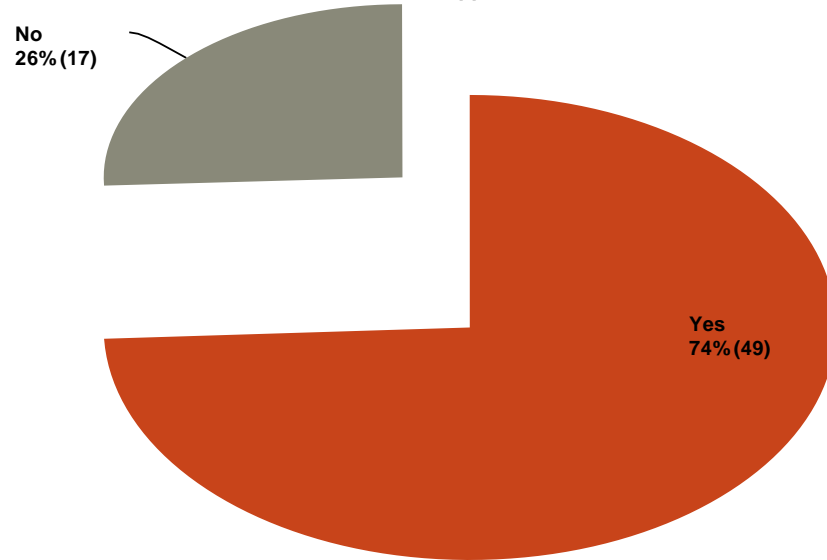


**Q9 Do you want your officers to be authorized to carry controlled substances to tranquilize in the field?**



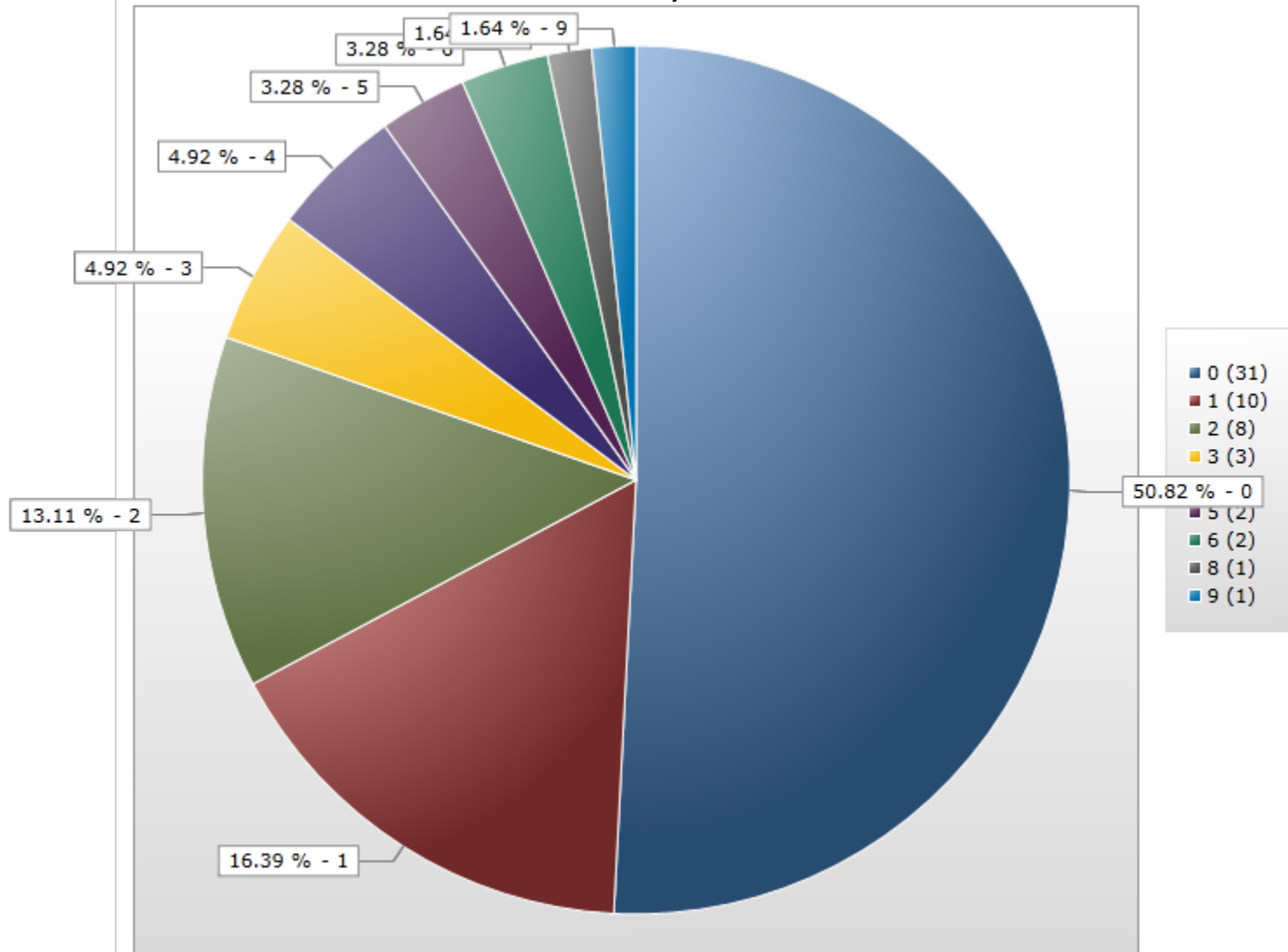
**Q10 Do you want your officers to be authorized to carry controlled substances to euthanize in the field?**

Answered: 66 Skipped: 15

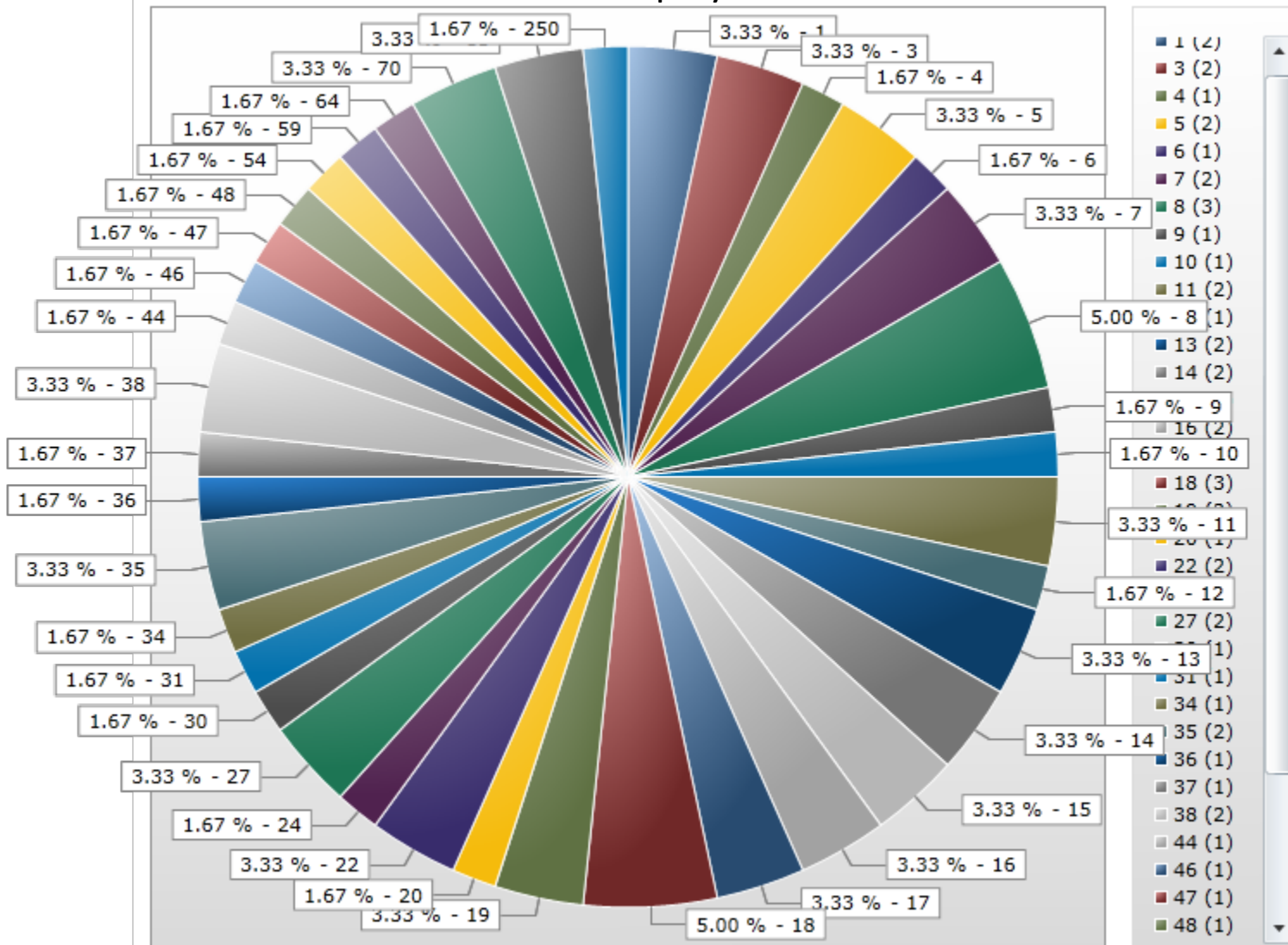




# Number of Veterinary Assistants



# Total Employees



Q21: Is there anything else you would like to share?

- We try very hard to provide good care for all the animals. Investigations, education and community outreach are priorities too.
- We do not have a public SN facility, however, we have a voucher system where the owner takes to a vet and we reimburse the costs to the vet.
  
- The option "under direct and indirect veterinary supervision" was not offered. This is more accurate, just like in veterinary hospitals.
- Our euthanasias are performed by CETs.
- Q20. On other veterinary services -- microchipping; and we pay a portion of s/n fees at local veterinary clinics as part of our quarterly spay/neuter assistance efforts.
- Is there a chance we can own and operate animal shelters with an organizational license or permit, rather than depend on one veterinarian to have his/her name on the license?
- I believe I completed this survey verbally a month or so ago with someone from San Diego HS.
- Thank you for doing the survey. Please share the results
- We don't have a spay/neuter facility for the public. Our contract vet does spay neuter adoptions and shelter medicine. We have a contract with V.I.P. to provide low cost vaccination clinics once a month. We offer a free wellness exam to adopters a several local clinics, the clinics provide a free exam only and the customer pays for any extras.
- We have our own Euthanasia By Injection certification program conducted by our Veterinarians to ensure ACOs and kennel staff are certified to perform euthanasia when needed.
- We treat all animals on-site during normal operating hours Monday-Friday and offsite outside of these hours.
- Concerned about the ability to offer vaccination clinics to the public when our vet has not examined the animal. Offering vaccinations is such an important public health and animal welfare service.
- It would be beneficial if rescue groups were also held to some kind of veterinary care standards.
- we would support legalization for unlicensed shelter employees to be able to administer vaccines, dewormers and other intake procedures
- Our animal attendants are the ones to do the vaccines, dewormings, basic treatments under indirect supervision. Just wanted to clarify.
- It is critical that unregistered assistants perform intakes and provide care to our animals on a daily basis
- While our shelter operates by contract for the City, the City is obligated to provide animal control services. With a

place. We would like to obtain more information about industry best practices standards as the lack of adequate staffing of animal control officers impacts our daily shelter work.

- Our County relies on the ability of its staff to perform euthanasia both onsite and in the field. All have received required training. ACOs also rely on the use of Telazol in the field based on the large number of stray/aggressive animals they come in contact with on a daily basis.
- We keep all controlled substances locked in a safe with limited access by staff. All substances must be signed for and each drop accounted for.
- Other services to the public in previous question is microchipping only.
- We provide space for spay/neuter clinics for the public at 5 shelters and contract with 4 spay/neuter vans to make spay/neuter more accessible for the public."
- We offer some other services to the homeless human population that have pets
- As a small shelter with limited staff and funding this new permit requirement will significantly impact how we are able to serve and care for the animals that come to our shelter for help. Our ability to handle critically injured/ill animals in a timely manner will be significantly impacted. This would result in our needing to use an off site veterinary hospital much more frequently thus increasing our costs and impacting our ability to provide other services due to a decrease in available funds.

# The End










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VMB/RVTC

## MEMORANDUM

DATE	July 1, 2016
TO	Members, MDAC
FROM	Kurt Heppler, Supervising Counsel Division of Legal Affairs Department of Consumer Affairs 
SUBJECT	Veterinary Students; Exemptions from Licensure

This memo addresses an inquiry that arose in the recent Multidisciplinary Advisory Committee (MDAC) regarding students enrolled in recognized veterinary schools and exemptions from licensure. As members may recall, this issue sprung from the Veterinary Medical Board's (Board) recent discussion of the "university exemption" provided for in subdivision (a)(4) of section 4830 of the Business and Professions Code (Code). This memo addresses subdivision (a)(5) of section 4830 of the Code, which provides:

"Students in the School of Veterinary Medicine of the University of California or the College of Veterinary Medicine of the Western University of Health Sciences who participate in diagnosis and treatment as part of their educational experience, including those in off-campus educational programs under the direct supervision of a licensed veterinarian in good standing, as defined in paragraph (1) of subdivision (b) of Section 4848, appointed by the University of California, Davis, or the Western University of Health Sciences."

The discussion at MDAC was focused on two concerns: 1) Was there additional definition needed as to the nexus among the "off-campus programs", the Board, and the essential elements of the education being provided and 2) Should an enrolled student, under the immediate supervision of a licensed veterinarian, be permitted to participate in animal surgery?

To be sure, these issues are policy matters best left to the MDAC members, Board members and ultimately the Legislature. In order to facilitate discussion, perhaps some examples of other healing arts would be helpful. Before those are presented, however, it is crucial to note that protection of the public is the highest priority of the Board and therefore MDAC. (See Bus. & Prof. Code, § 4800.1.) It is also critical to remember that this discussion involves exemptions from licensure.

In the arena of education for individuals seeking licensure from the Medical Board of California (MBC) as a physician and surgeon, the Legislature has spoken as to the nature of clinical medical training necessary. Specifically, section 2089.5 of the Code provides in pertinent part:

“ (e) If the institution, specified in subdivision (d), is formally affiliated with a medical school or a school of osteopathic medicine located outside the United States or Canada, it shall meet the following:

(1) The formal affiliation shall be documented by a written contract detailing the relationship between the medical school, or a school of osteopathic medicine, and hospital and the responsibilities of each.

(2) The school and hospital shall provide to the board a description of the clinical program. The description shall be in sufficient detail to enable the board to determine whether or not the program provides students an adequate medical education. The board shall approve the program if it determines that the program provides an adequate medical education. If the board does not approve the program, it shall provide its reasons for disapproval to the school and hospital in writing specifying its findings about each aspect of the program that it considers to be deficient and the changes required to obtain approval.

(3) The hospital, if located in the United States, shall be accredited by the Joint Commission on Accreditation of Hospitals, or the American Osteopathic Association’s Healthcare Facilities Accreditation Program, and if located in another country, shall be accredited in accordance with the law of that country.

(4) The clinical instruction shall be supervised by a full-time director of medical education, and the head of the department for each core clinical course shall hold a full-time faculty appointment of the medical school or school of osteopathic medicine and shall be board certified or eligible, or have an equivalent credential in that specialty area appropriate to the country in which the hospital is located.

(5) The clinical instruction shall be conducted pursuant to a written program of instruction provided by the school.

(6) The school shall supervise the implementation of the program on a regular basis, documenting the level and extent of its supervision.

(7) The hospital-based faculty shall evaluate each student on a regular basis and shall document the completion of each aspect of the program for each student.”

\* \* \*



From a policy perspective, it is unknown whether this level of regulatory oversight is necessary but MDAC may want to consider some essential elements such as supervision, participants' expectations, and evaluations.

MDAC's next discussion topic was the possible permitting of enrolled students to participate in surgery under the immediate supervision of a duly licensed veterinarian. For the purposes of the discussion, 'immediate supervision' was deemed to mean that the veterinarian was physically present in the same operating theatre as the student, was not providing services to another animal patient and had the capability to assist the student immediately. The policy issues that arise here are the level of competence of the student, whether that competence has to be demonstrated to the supervisor prior to engaging in surgery, and other matter that invoke consumer protection. Perhaps it may be necessary to only authorize students that have completed a specific amount or type of education to perform surgery or establish other safeguards.

Members may also want to consider decoupling the exemption from the educational requirements; in this manner, the issue is not so much as exemption from licensure as it a limited authorization to perform certain tasks or services under a specific set of circumstances. Additionally, members may also want to visit the issue of whether any revised educational requirements are best placed in section 4830's exemptions from licensure provisions.

MDAC also discussed the provisions of section 2027 of title 16 of the California Code of Regulations. Section 2027 provides:

"A junior or senior student or a graduate of a recognized veterinary college listed in Section 2022(a) who is performing any animal health care task in a veterinary premises registered by the Board may perform only the identical job tasks with the identical degree of supervision by the supervisor as specified for a R.V.T. pursuant to Section 2036."

MDAC was concerned that there was no time limit associated with the graduation date of the student, and by logical extension, an individual who graduated twenty years ago could essentially function as a Registered Veterinary Technician (RVT). Also, there was a concern that essentially treating section 2027's students and graduates as equivalent to an RVT may not fully embrace consumer protection as there is no Board fingerprint requirement, no application, and no examination. MDAC members may also want to focus on whether this regulation adequately addresses items such as educational leaves of absence or summer breaks. Accordingly, MDAC may want to suggest some revisions to section 2027.



## **ANIMAL HEALTH CARE TASKS VETERINARY STUDENTS MAY PERFORM AT OFF-CAMPUS LOCATIONS**

### **FACTS**

There are two AVMA-accredited veterinary schools in California: the University of California School of Veterinary Medicine at Davis (UCD) and Western University of Health Sciences at Pomona (Western).

Both UCD and Western have established off-campus veterinary clinical sites:

Since January 2006, the clinical facilities of the "University of California Veterinary Medical Center - San Diego" (UCVMC-SD) have been located at 10435 Sorrento Valley Road, Suite #101, San Diego 92121. UCD faculty members engage in "veterinary teaching", as well as participating in research and service programs. The clinic, which offers "...specialized clinical services to ... pet owners living in Southern California", is not registered with the Board.<sup>1</sup>

Since about 2005, Western has had an "affiliation agreement" with Banfield Pet Hospital at 611 East Second Street, Pomona 91766, presumably to offer clinical teaching opportunities for its veterinary students. In late 2014 or early 2015, Western took over the Banfield "primary care facility", renaming it WesternU Pet Health Center; the clinic offers the same veterinary services to the public as before.<sup>2</sup> On November 7, 2014, WesternU Pet Health Center became a Board-registered facility (HSP 7669).

### **QUESTIONS**

What animal health care tasks may a veterinary student perform off-campus under direct supervision of a veterinarian?

In what off-campus settings may a veterinary student perform animal health care tasks? Does the answer depend upon whether the student is in an off-campus veterinary-school educational experience or is working or volunteering independent of the student's veterinary school's programs?

### **ANSWERS**

Clearly, there is no authority for a student to perform surgery at an off-campus site.

Other than surgery, the answer may depend on whether the student is performing the tasks as part of their educational program or outside their educational program (whether as a volunteer or for compensation). And conflicts between the Veterinary Medicine Practice Act (VPA) (dealing with exemptions from the VPA's provisions) and regulations (which deal with tasks) complicate the analysis.

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<sup>1</sup> The center was established in 1988 as a joint venture between UCD and UC San Diego and, from 1988 to 2006, was located at the Helen Woodward Animal Center in Rancho Santa Fe, which is registered with the Board (HSP 2359, 5400, and 6987).

<sup>2</sup> "All the onsite veterinarians are...Western faculty...[and] the clinic is "part of clinical skills courses for first- and second-year [Western] students, is home to the two-week medicine rotation for third years, and is a general practice location for fourth-year students." Veterinary Practice News (2/20/2015)

## DISCUSSION

### "Animal Health Care Tasks"

#### (16 California Code of Regulations sections 2027, 2034, 2036, 2036.5)

##### Junior and Senior Veterinary Students

16 CCR section 2027<sup>3</sup> specifically deals with junior and senior veterinary students<sup>4</sup> enrolled in AVMA-accredited schools who are "...performing any animal health care task in a veterinary premises registered by the Board." These students "...may perform only the identical job tasks with the identical degree of supervision by the supervisor as specified for a R.V.T. pursuant to Section 2036."<sup>5</sup> (Emphasis added.)

Section 2027 applies to students at all off-campus "registered veterinary premises".<sup>6</sup> And because there is no limiting language, it applies to students performing animal health care tasks both as part of their educational program or outside an educational program.

We then look to 16 CCR section 2036<sup>7</sup>, as the animal health care tasks which junior and senior veterinary students are permitted off-campus is "identical" to those which an R.V.T. may perform. Section 2036 states the following:

*"(a) Unless specifically so provided by regulation, a R.V.T. shall not perform the following functions or any other activity which represents the practice of veterinary medicine or requires the knowledge, skill and training of a licensed veterinarian:*

*(1) Surgery;*

*(2) Diagnosis and prognosis of animal diseases;*

*(3) Prescription of drugs, medicines or appliances.*

*(b) An R.V.T. may perform the following procedures only under the direct supervision of a licensed veterinarian:*

*(1) Induce anesthesia;*

*(2) Apply casts and splints;*

*(3) Perform dental extractions;*

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<sup>3</sup> Captioned, "**Graduates and Students of Veterinary Colleges - Job Tasks**".

<sup>4</sup> And also "graduates of ...recognized veterinary college[s]...", although these individuals were not included in the question posed to the committee.

<sup>5</sup> That the word "identical" is used twice, and the word "only" also appears in a short paragraph emphasizes the intent to treat these students 'identically' to R.V.T.'s in the off-campus veterinary practice setting.

<sup>6</sup> Captioned, "**Registration of place of practice**", Bus. & Prof. Code section 4853(a) states that "[a]ll premises where veterinary medicine, veterinary dentistry, veterinary surgery, and the various branches thereof is being practiced shall be registered with the board...".

<sup>7</sup> Captioned, "**Animal Health Care Tasks for R.V.T.**".

(4) Suture cutaneous and subcutaneous tissues, gingiva and oral mucous membranes;

(5) Create a relief hole in the skin to facilitate placement of an intravascular catheter.

(c) An R.V.T. may perform the following procedures under indirect supervision of a licensed veterinarian:

(1) Administer controlled substances.

(d) Subject to the provisions of subsection(s) (a), (b) and (c) of this section, an R.V.T. may perform animal health care tasks under the direct or indirect supervision of a licensed veterinarian. The degree of supervision by a licensed veterinarian over a R.V.T. shall be consistent with standards of good veterinary medical practices."

#### Freshman and Sophomore Veterinary Students

The VPA is silent as to animal health care tasks which may be performed off-campus by freshman and sophomore veterinary students. This being so, they fall squarely within the definition of "unregistered assistants" [16 CCR section 2034(c)]<sup>8</sup>. Permissible tasks for unregistered assistants are stated in 16 CCR section 2036.5<sup>9</sup>, as follows:

"(a) Unregistered assistants shall be prohibited from performing any of the functions or activities specified in subsections (a) (b) and (c) of Section 2036 of these regulations, except that an unregistered assistant under the direct supervision of a licensed veterinarian or registered technician may administer a controlled substance.

(b) Subject to the provisions of subsection (a) of this section, unregistered assistants in an animal hospital setting<sup>10</sup> may perform auxiliary animal health care tasks<sup>11</sup> under the direct or indirect supervision of an R.V.T.. The degree of supervision by a licensed veterinarian over an unregistered assistant shall be higher than or equal to the degree of supervision required when an R.V.T. performs the same task and shall be consistent with standards of good veterinary medical practices."

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<sup>8</sup> Section 2034(c) defines "unregistered assistant" as "...any individual who is not an R.V.T. or a licensed veterinarian."

<sup>9</sup> Captioned, "**Animal Hospital Health Care Tasks for Unregistered Assistants**".

<sup>10</sup> Note that the "animal hospital" need not be registered with the board.

<sup>11</sup> "Auxiliary animal health care tasks" is not defined.

## Exemptions

### (Business & Professions Code sections 4828, 4830)

Basically, anyone who practices veterinary medicine<sup>12</sup> in the State of California must have a license issued by the Veterinary Medical Board and be subject to the VPA. (Bus. & Prof. Code sections 4825, 4828)

However, some individuals are exempt from the application of the VPA (Bus. & Prof. Code section 4830). Among the exemptions are veterinary students, as follows:

*"This chapter [Chapter 11, the Veterinary Medicine Practice Act, Bus. & Prof. Code sections 4800-4917] does not apply to:*

....

*(5) Students in the School of Veterinary Medicine of the University of California or the College of Veterinary Medicine of the Western University of Health Sciences who participate in diagnosis and treatment as part of their educational experience, including those in off-campus educational programs under the direct supervision of a licensed veterinarian in good standing, as defined in paragraph (1) of subdivision (b) of Section 4848, appointed by the University of California, Davis, or the Western University of Health Sciences."* [Bus. & Prof. Code section 4830(5)]

Note that section 4830(5) does not limit the off-campus student experience to a fixed facility or even to a veterinary facility; students are covered even if the facility is not registered with the Board. Nor does the section limit its application to a student's particular class year.

According to section 4830(5), students stay within the exemption from the VPA when, off campus, they perform only certain animal health care tasks<sup>13</sup>, under supervision. In particular, all of the following conditions of section 4830(5) must be met in off-campus sites:

- (1) The student is attending one of the two AVMA-rated California veterinary schools;
- (2) The student is "...participat[ing] in diagnosis and treatment...";
- (3) Performing the tasks must be "...part of [the student's] educational experience...".
- (4) When the "educational experience" is off campus, the student must be in an "...off campus educational program...".
- (5) The student must be "under the direct supervision of a licensed veterinarian in good standing...appointed by [one or the other] of the two California veterinary schools."<sup>14</sup>

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<sup>12</sup> "Practice of veterinary medicine" is defined in Bus. & Prof. Code section 4826.

<sup>13</sup> Actually, the practice of veterinary medicine is not limited to "tasks", but includes representing oneself as a veterinarian. [Bus. & Prof. Code section 4826(f)]

<sup>14</sup> The way the current subsection is written, only reciprocal licensees may supervise off-campus student experiences! (Bus. & Prof. Code Section 4848(b)(1). Note that the definition of "in good standing" is found in Section 4848 (b)(1)(A) and (B).

However---unlike R.V.T.'s, who are expressly prohibited from "diagnosis or prognosis of animal diseases" [16 CCR section 2036(a)(2)]---"[veterinary students ...who] participate in diagnosis and treatment as part of their educational experience, including those in off-campus educational programs...[are exempt from the application of Bus. & Prof. Code Chapter 11 (Veterinary Medicine)]...".

Thus, there is an ambiguity between the regulation setting forth permissible student tasks (which excludes "diagnosis"<sup>15</sup>) and the Code section exempting veterinary students from the application of the Veterinary Practice Act (VPA) while "...participat[ing] in diagnosis and treatment...".

Moreover, the exemption regulation simply contemplates that a veterinary student will be doing certain tasks ("participat[ing] in diagnosis and treatment...") so, when that occurs, the student is exempt from registration as an R.V.T. or licensure as a veterinarian. However, the regulation does not expressly give the student the right to engage in those tasks. (Perhaps the definition of "treatment" would be arguably broad enough to cover the permissible R.V.T. tasks and even more tasks---such as "diagnosis"---but that is engaging in a guessing game.<sup>16</sup>)

### **COMMENTS/RECOMMENDATIONS**

1. The off-campus clinical facilities of the two AVMA-accredited veterinary schools in California hold themselves out to the public as "clinics" and are sites for off-campus learning for veterinary students. But Western's clinic in Pomona is a registered premise with the Board, while UCVMC-SD's clinic in San Diego is not.

Even without more, this is an obvious anomaly.

But it also impacts the student experience: as noted above, 16 CCR section 2027 states that junior or senior veterinary students performing any animal health care task in a veterinary hospital registered by the Board may only perform those tasks permitted an R.V.T. .

As it appears that UCVMC-SD's veterinary facility meets the criteria of Bus. & Prof. Code section 4853, subsections (a) and (b), recommend that the Board direct staff to take action to register the clinic to ensure that it is subject to the same Board oversight as other California veterinary practices.

2. Recommend consistently defining the off-campus locations where students may be engaging in educational programs under the aegis of their veterinary schools as "off-campus educational program sites", language used in Bus. & Prof. Code Section 4854.5(a). This encompasses not only fixed facilities, but also ranges and barns---any location where teaching takes place.<sup>17</sup>

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<sup>15</sup> See Bus. & Prof. Code section 4825.1(a) for the definition of "diagnosis".

<sup>16</sup> Note that "...diagnosis and treatment of animals..." is also found in Bus. & Prof. Code section 4854.5(a), which requires "[e]very off-campus educational program site [to] display in a conspicuous place a consumer notification specifying that the veterinary facilities are also being used for diagnosis and treatment of animals by graduate students enrolled in a veterinary medicine program." However, this section adds to the analysis problem here, in that it only refers to "graduate students" while 16 CCR Section 2027 makes an explicit distinction between "junior or senior student[s]" and "graduate[s] of ...recognized veterinary college[s]..." .

<sup>17</sup> This language appears in Bus. & Prof. Code section 4854.5.

3. Separately deal with students performing tasks in off-campus settings which are part of their educational program versus students working or volunteering off-campus.

4. If the intent is to treat freshman and sophomore students in off-campus settings as "unregistered assistants", say so definitively.

5. The particular animal health care tasks, and the degree of supervision, which veterinary students may perform in off-campus educational settings is a matter of policy, to be determined by veterinarians. Here is a proposed framework:

"(a) Veterinary students enrolled in an AVMA-accredited veterinary school<sup>18</sup> may perform animal health care tasks in off-campus educational program sites as part of the clinical portion of their studies, as long as the following conditions are met:

(1) The students are under the direct supervision of a California licensed veterinarian in good standing; and

(2) If the site is a veterinary facility, it shall be registered with the Board and shall comply with Bus. & Prof. Code section 4854.5(a), or

(3) If the site is other than a veterinary facility, the supervising veterinarian shall, if practicable, orally inform the owner or custodian of the animal that graduate veterinary students may participate in the diagnosis and treatment of the animal.

(b) Students<sup>19</sup> may perform the following animal health care tasks in off-campus educational program sites as part of the clinical portion of their studies:

(1) \_\_\_\_\_

(2) \_\_\_\_\_

Etc.....

(c) As used herein, "direct supervision" shall mean \_\_\_\_\_

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"In good standing" shall be as set forth in Bus. & Prof. Code section 4848(b)(1)(A) and (B)."

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<sup>18</sup> Per 16 CCR Section 2022(a), there is no reason to specifically name UCD and Western veterinary schools. Moreover, students may be from AVMA-accredited schools outside California.

<sup>19</sup> If it's important to break out permissible tasks of junior and senior students versus freshmen and sophomores, simply say "Junior and senior students...." and, in a separate paragraph, "Freshmen and sophomore students....".





# COE Accreditation Policies and Procedures: Off-campus

March 2014

## 8. Off-campus and Distributive Sites

### 8.1. Off-campus Clinical Education Sites for Colleges with Teaching Hospitals

1. An off-campus site where a specific educational objective is offered.
2. The site is externally located from the main campus and is (usually) not administratively associated with the degree granting institution.
3. Professional staff providing education might not be employees of the degree granting institution but may be receiving remuneration as a contractor, fee-for-service provider, etc. for time/effort devoted to the educational program.
4. The off-campus site must be reviewed to ensure that the educational program is being delivered appropriately.
5. There must be a written description of the educational objectives expected to be achieved at the site and a mechanism for assessing the success of the educational process, i.e. proof that educational objectives are being met.
6. These guidelines do not apply to off-campus educational experiences that are attended sporadically by individual students to augment their on-campus education.

### 8.2. COE Guidelines for Implementation of a Distributive Veterinary Clinical Education Model

1. The clinical sites selected by a college to serve in a distributive clinical educational model should receive appropriate financial remuneration per student from the college in order to help ensure that students receive on-site supervised clinical instruction, with formal written contract of expectations.
2. The college must prepare and distribute appropriate materials for clinical site educators that detail objectives of the program, expectations of the site coordinators, clinical site educator training materials, instructions concerning the format the college wants used to evaluate student performance and provide feedback to students on progress/deficiencies associated with site experience.
3. Additionally the college must provide to the students, and clinical site educators alike, the expectations of the college for student safety and security while the student is on site.

4. Distributed clinical sites must be selected on the basis of specific criteria and identified for instruction in precise disciplines (defined by the college) such as, but not limited to: Food Animal/Equine/Small Animal Medicine; Food Animal/Equine/Small Animal Surgery or Food Animal or Equine or Small Animal Medicine and Surgery; Dermatology, Imaging (radiology, etc.), Neurology, Cardiology, Critical Care Emergency Medicine, etc.
5. For distributed clinical sites the college must take steps to ensure that the educational objectives and anticipated outcomes are thoroughly promulgated and understood by students and clinical site coordinators alike.
6. The college must designate to the COE what clinical sites are considered as primary instructional sites as defined by Standard 9 (c) and these will be considered by COE as core instructional sites. These sites must be in compliance with AVMA-COE Standards.
7. The college must document/assess that students and educators clearly understand how evaluation and grading practices will be conducted at each clinical site including clinical competencies.
8. Veterinarians must be licensed and technicians should be certified, licensed, or registered as appropriate to that jurisdiction.
9. The college must document that students are fully informed concerning their ability to report any and all safety, physical, and emotional concerns to the college.
10. The college must put in place a system to regularly monitor/supervise the instructional activities at each clinical site and report this system with any subsequent changes and outcomes to the COE.
11. Each clinical site educator must abide by a process devised by the college to provide a written evaluation of the performance of each student.
12. Students must provide the college with an evaluation of each site (after the respective rotation) including an evaluation of teaching at the site and the student's opportunity to perform hands-on procedures at the site. The college must summarize this information for the COE.
13. The COE may inspect clinical sites at any time students are present; these inspections, including travel and per diem costs, will be at the expense of the college.
14. The college must put in place a system to measure and document clinical competencies outcomes at clinical sites as specified by the COE (see Section 12.11.2) to assess clinical sites

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## Student Exemption Issue as Presented by MDC Chair Dr. Klingborg:

UCD has noted that there is confusion regarding students and the Practice Act.

Previously, UCD has been told that “including those in off-campus educational programs” only applied to institutionally approved training and not ‘voluntary’ experience (ie, extra-curricular). Further the section (2027) on DVM Students “functioning as an RVT” has been interpreted to mean that DVM students cannot perform surgery even under direct supervision, which is not what is happening.

Clearly, it is in the profession’s ultimate interests to facilitate learning opportunities in practice to better prepare graduates for entry level practice, we just need to have unambiguous language that governs that.

So to clarify – the 2 fundamental questions are:

- 1) What is permissible for a student to do when under direct supervision?
- 2) Does that cover any experience – curricular and extracurricular?

Under Practice Provisions **§4828 Licensure Requirement for Veterinarians Employed by Governmental Entities**. All veterinarians actually engaged and employed as veterinarians by the state, or a county, city, corporation, firm or individual are practicing veterinary medicine and shall secure a license issued by the board.

### **4830 (Current)**

4830(a)(5) Students in the School of Veterinary Medicine of the University of California or the College of Veterinary Medicine of the Western University of Health Sciences who participate in diagnosis and treatment as part of their educational experience, including those in *off-campus educational programs* under the direct supervision of a licensed veterinarian in good standing, as defined in paragraph (1) of subdivision (b) of Section 4848, appointed by the University of California, Davis, or the Western University of Health Sciences.

### **Proposed language for 4830**

4830(a)(5)(A) Students of an American Veterinary Medical Association Council on Education accredited veterinary medical program may participate, as part of their formal curriculum, in diagnosis and treatment with direct supervision or in surgery with immediate supervision. The student must have prior training in these activities as part of the formal curriculum and supervision must be by a California licensed veterinarian in good standing, as defined in paragraph (1) (A) and (B) of subdivision (b) of Section 4848.

4830 (a)(5)(B) Where Off-Campus or Distributive Sites provide the formal curriculum in place of on-campus education, a Memorandum of Understanding between the accredited veterinary medical program and the Off-Campus or Distributive Site must be in place that provides for: 1) a written description of the educational objectives expected to be achieved at the site, 2) an annual review conducted by the accredited veterinary medical program of the off-campus site to ensure that the educational program is being delivered in accordance with the Memorandum of Understanding ~~will be conducted by the program~~ to ensure that the formal curriculum and/or clinical training is appropriate, and 3) a mechanism for assessing training outcomes of the educational process.

**Comment [D1]:** Site visit? Nationally most colleges with off campus sites do visit the sites at least annually and for distributive models this has been the practice – I think it could be left to the college to determine the best method as long as it is done regularly

**Comment [D2]:** Do you want to add anything in here about the type or degree of supervision provided to the student? That addition would make it consistent with (a)

### **Proposed language for 4830 (a)(5)(b) as submitted by Dr. Terra of Western University**

4830 (a)(5)(B) Where Off-Campus or Distributive Sites provide the formal curriculum in place of on-campus education, a Memorandum of Understanding between the accredited veterinary medical program and the Off-Campus or Distributive Site must be in place that provides for: 1) a written description of the responsibilities of all parties signing the MOU educational objectives expected to be achieved at the site, 2) an annual review conducted by the accredited veterinary medical program of the off-campus site to ensure that the points outlined in the MOU are being accomplished educational program is being delivered in accordance with the Memorandum of Understanding will be conducted by the program to ensure that the formal curriculum and/or clinical training is appropriate, and 3) a mechanism for ensuring that the consumer is protected as the student is training at the site. assessing training outcomes of the educational process.

### **Proposed Changes to CCR 2027**

**Current 2027** A junior or senior student or a graduate of a recognized veterinary college listed in Section 2022(a) who is performing any animal health care task in a veterinary premises registered by the Board may perform only the identical job tasks with the identical degree of supervision by the supervisor as specified for a R.V.T. pursuant to Section 2036.

*Note: A DVM student becomes a junior or senior student upon completion of their course of study of their sophomore and junior years, i.e., they are a junior student during the summer between their sophomore and junior year. Freshman and sophomore students may practice as veterinary assistants. Junior and senior students may practice as registered veterinary technicians.*

**Proposed CCR 2027** A veterinary student listed in Section 2022(a) who is performing any animal health care task in a veterinary premises registered by the Board, provided they have received prior training in these activities as part of the formal curriculum, may perform only the identical job tasks with the identical degree of supervision by the supervisor as specified for a R.V.T. pursuant to Section 2036.

**Proposed CCR 2027.5** A graduate of a recognized veterinary college listed in Section 2022(a), for the period of one year from the date of graduation, may perform the identical job tasks with the identical degree of supervision as specified for a R.V.T. pursuant to Section 2036.

## Veterinary Compounding

### Draft Statutory Proposal

**August 2016**

**Jon Klingborg, DVM**

#### § 4825.1. Definitions – ADD

(e) Drug compounding may be performed by a licensed veterinarian. A Registered Veterinary Technician may compound when following a licensed veterinarian's written protocol or direct order.

~~(Notwithstanding this section, a licensed Pharmacist, Pharmacy Intern or Licensed Pharmacy Technician may compound within the scope of their practice.)~~

1. "Compounding" means any of the following activities occurring in a veterinary premise, by or under the supervision of a licensed veterinarian ~~or pharmacist~~, pursuant to a prescription:
  - (A) 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 drug preparation from chemicals or bulk drug substances
2. "Compounding" does not include reconstitution of a drug pursuant to a manufacturer's direction(s) nor does it include tablet splitting or crushing, capsule opening, or the addition of flavoring agent(s) to enhance palatability.

#### § 4826.3. Veterinary Compounding

(a) Notwithstanding section 4051, a licensed veterinarian may compound a drug or direct an RVT to compound a drug under indirect supervision following a written protocol or direct order, within the scope of professional practice, only under the following conditions:

- (1) Where there is no FDA-approved animal or human drug that can be used as labeled or in an appropriate extra-label manner to properly treat the disease, symptom, or condition for which the drug is being prescribed;
- (2) Where the compounded drug is not commercially available from a compounding pharmacy, outsourcing facility, or other compounding supplier, in a dosage form and concentration or in a timely basis to appropriately treat the disease, symptom, or condition for which the drug is being prescribed;
- (3) Where the need and prescription for the compounded medication has

~~arisen within an~~ been established by means of the veterinarian-client-patient relationship, ~~as a means~~ to treat a disease, symptom, or condition observed and diagnosed by the veterinarian in an animal, or animals within the same group, herd, or flock, that threatens the health of the animal(s) or will cause suffering or death ~~or if the drug cannot be procured on a timely basis to treat the disease, symptom or condition;~~

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

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

(6) All veterinarians engaged in compounding must follow the standards of USP <795> for non-sterile preparations and USP <797> for sterile preparations.

(b) Compounding from an approved human drug for use in food-producing animals is not permitted if an approved animal drug can be used for compounding.

(c) A veterinarian or an RVT under indirect supervision may compound a compounded veterinary drug ~~may be prepared~~ from bulk drug substances only when:

(1) The drug is prescribed by the veterinarian to treat an animal or animals as directed within the VCPR;

(2) The drug is not intended for use in animals intended for food or food production;

~~(3) If the drug contains a bulk drug substance that is a component of any marketed FDA-approved animal or human drug, there is a change between the compounded drug and the comparable marketed drug made for the animal(s) that produces a clinical difference for that an animal or animals within the same group, herd, or flock, as determined by the veterinarian prescribing the compounded drug for his or her patient, and subsequently noted in the medical record for the animal patient(s);~~

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

(5) All bulk drug substances used in compounding are manufactured by an

establishment registered under 21 U.S.C. § 360 and are accompanied by a valid certificate of analysis;

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

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

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

(d) Each compounded veterinary drug preparation shall meet the labeling requirements set forth in the Veterinary Practice Act CCR 2032.2(b).

(e) ~~A veterinarian or RVT shall provide information to Use of a compounded preparation should be accompanied by the same precautions followed when using an approved drug, which include counseling of~~ the client regarding potential adverse reactions, including therapeutic failure, and attention to the potential for unintended human or animal exposure to the drug, and shall disclose. ~~Further, clients should be informed~~ that the compounded preparation has not been evaluated by the FDA for potency, purity, stability, efficacy or safety, and client consent should be obtained.

(1) Veterinarians ~~should~~ shall report suspected adverse events including therapeutic failure and quality defects involving compounded preparations to ~~the compounding pharmacist~~, the State Board of Pharmacy and the FDA Center for Veterinary Medicine. ~~Instructions for reporting adverse events to FDA can be found at the FDA website. Pharmacists should instruct pet owners to contact both the prescribing veterinarian and pharmacist immediately if a compounded preparation is associated with an adverse event, including therapeutic failure, and quality defects.~~

(2) Veterinarians ~~should~~ shall comply with all aspects of the federal extralabel drug use regulations including record-keeping and labeling requirements ~~and urge compounding pharmacies to do the same.~~ The compounded preparation should be labeled that it is not FDA approved.

(3) It is not legal for veterinarians to compound preparations in large quantities and sell these compound preparations to third parties.

(f) Sterile compounding for exclusive use within the veterinary premise must be for Immediate Use only or shall meet the sterile compounding requirements for pharmacies and pharmacists as stated in USP 797 and by Article 7 of Title 16 of the California Code of Regulations (sections 1751 through 1751.8, inclusive.) .

(1) As defined in USP 797, 'Immediate Use' means that:

(A) The compounding process involves simple transfer of not more than three commercially manufactured packages of sterile nonhazardous products or diagnostic radiopharmaceutical products from the manufacturers' original containers and not more than two entries into any one container or package (e.g., bag, vial) of sterile infusion solution or administration container/device. (For example, anti-neoplastics shall not be prepared as immediate-use Compounded Sterile Preparations because they are hazardous drugs.)

(B) Unless required for the preparation, the compounding procedure is a continuous process not to exceed 1 hour.

(C) During preparation, aseptic technique is followed and, if not immediately administered, the finished Compounded Sterile Preparation is under continuous supervision by the preparer to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, mix-ups with other Compounded Sterile Preparation, and direct contact of outside surfaces.

(D) Administration begins not later than 1 hour following the start of the preparation of the Compounded Sterile Preparation.

(E) Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the Compounded Sterile 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 1-hour BUD and time.

(F) If administration has not begun within 1 hour following the start of preparing the Compounded Sterile Preparation, the Compounded Sterile Preparation shall be promptly, properly, and safely discarded.

(g) A veterinarian must ensure the safety and efficacy of a compounded drug, including but not limited to avoiding known drug incompatibilities and inappropriate combinations, and must use a pharmacist to perform drug compounding when the complexity of the compounding exceeds the veterinarian's knowledge, skill, facilities, or available equipment.



(1) It is the responsibility of the compounding veterinarian to ensure that the product is sterile, bioavailable, stable, efficacious and the appropriate safety standards have been met.

(h) Limitations on Promotion and Sale of Compounded Drugs.

(1) A veterinarian shall not prepare for sale any compounded drugs which employ fanciful names or trade names, colorings or other additives, or that in any way imply that the compounds have some unique effectiveness or composition.

(2) A veterinarian shall not advertise, promote, display, resell, or in any other way market prepared compounded drugs.

(i) The California State Board of Pharmacy and the California Veterinary Medical Board shall have authority ~~to ensure compliance with this section, and each shall have the right~~ to inspect any veterinary premises engaged in compounding to ensure compliance.

(1) The Veterinary Medical Board is specifically charged with enforcing the provisions of this Chapter.~~this section with regard to its licensees.~~

## Board of Pharmacy

### Order of Adoption

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

#### 1735. Compounding in Licensed Pharmacies.

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

- (1) Altering the dosage form or delivery system of a drug
- (2) Altering the strength of a drug
- (3) Combining components or active ingredients
- (4) Preparing a compounded drug product preparation from chemicals or bulk drug substances

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

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

~~(d)~~(c) The parameters and requirements stated by this Article 4.5 (Section 1735 et seq.) apply to all compounding practices. Additional parameters and requirements applicable solely to sterile ~~injectable~~ compounding are stated by Article 7 (Section 1751 et seq.).

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

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

**1735.1. Compounding Definitions.**

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

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

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

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

(e) “Cleanroom or clean area or buffer area” means a room or area with HEPA-filtered air that provides ISO Class 7 or better air quality where the primary engineering control (PEC) is physically located.

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

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

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

(g) "Compounding Aseptic Isolator (CAI)" means a form of isolator specifically designed for non-hazardous compounding of pharmaceutical ingredients or preparations while bathed with unidirectional HEPA-filtered air. It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes. Air exchange into the isolator from the surrounding environment should not occur unless the air has first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Air within the CAI shall not be recirculated nor turbulent.

(h) "Controlled cold temperature" means 2 degrees to 8 degrees C (35 degrees to 46 degrees F).

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

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

(k) "Copy or essentially a copy" of a commercially available drug product includes all preparations that are comparable in active ingredients to commercially available drug

products, except that it does not include any preparations in which there has been a change, made for an identified individual patient, which produces for that patient a clinically significant difference, as determined by a prescribing practitioner, between that compounded preparation and the comparable commercially available drug product.

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

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

(n) "Dosage unit" means a quantity sufficient for one administration to one patient.

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

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

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

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

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

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

ingredient(s).

(u) "Media-fill test" means a test used to measure the efficacy of compounding personnel in aseptic techniques whereby compounding procedures are mimicked using a growth-based media and then the resulting preparation is evaluated for sterility. The media-fill test must mimic the most complex compounding procedures performed by the pharmacy.

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

(w) "Parenteral" means a preparation of drugs administered in a manner other than through the digestive tract. It does not include topical, sublingual, rectal or buccal routes of administration.

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

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

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

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

(ab) "Primary Engineering Control (PEC)" means a device that provides an ISO Class 5 or better environment through the use of non-turbulent, unidirectional HEPA-filtered first air for

compounding sterile preparations. Examples of PEC devices include, but are not limited to, laminar airflow workbenches, biological safety cabinets, sterile compounding automated robots, compounding aseptic isolators, and compounding aseptic containment isolators.

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

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

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

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

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

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

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

preparation.

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

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

**1735.2. Compounding Limitations and Requirements; Self-Assessment.**

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

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

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

(1) ~~is~~ ordered by the prescriber or the prescriber’s agent 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 office administration or application to patients in the prescriber’s office, or for distribution of not more than a 72-hour supply to the prescriber’s patients, as estimated by the prescriber; and

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

(3) is sufficient for administration or application to patients solely in the prescriber's office, or



for furnishing of not more than a 120-hour supply for veterinary medical practices, solely to the prescriber's own veterinary patients seen as part of regular treatment in the prescriber's office, as fairly estimated by the prescriber and documented on the purchase order or other documentation submitted to the pharmacy prior to furnishing; and

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

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

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

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

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

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

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

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

(1) Active ingredients to be used.

(2) Equipment to be used.

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

(4) Inactive ingredients to be used.

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

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

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

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

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

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

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

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

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

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

- (B) the chemical stability of any one ingredient in the compounded drug preparation;
- (C) the chemical stability of the combination of all ingredients in the compounded drug preparation,
- (D) 180 days for non-aqueous formulations,
- (E) 14 days for water-containing oral formulations, and
- (F) 30 days for water-containing topical/dermal and mucosal liquid and semisolid formulations.

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

- (A) The shortest expiration date or beyond use date of any ingredient in the sterile compounded drug product preparation,
- (B) The chemical stability of any one ingredient in the sterile compounded drug preparation,
- (C) The chemical stability of the combination of all ingredients in the sterile compounded drug preparation, and
- (D) The beyond use date assigned for sterility in section 1751.8.

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

- (A) Method Suitability Test,
- (B) Container Closure Integrity Test, and
- (C) Stability Studies

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

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

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

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

~~(k)~~ (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, both active and inactive, that lack a supplier’s expiration date are subject to the following limitations:

(1) such ingredients cannot be used for any non-sterile compounded drug preparation more than three (3) years after the date of receipt by the pharmacy.

(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.

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

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

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

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

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

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

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

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

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

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

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

(i) Exempt from the requirements in this paragraph ~~(1735.3(a)(2)(F))~~ are sterile ~~products preparations~~ compounded ~~on a one-time basis in a single lot~~ for administration within seventy-two (72) hours to a patient in a health care facility licensed under section 1250 of the Health and Safety Code and stored in accordance with standards for “Redispensed CSPs” found in Chapter 797 of the United States Pharmacopeia – National Formulary (USP37-NF32) Through 2nd Supplement (35 37<sup>th</sup> 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)~~ (G) A pharmacy-assigned unique reference or lot number for the compounded drug ~~product preparation~~.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(5) The date compounded; and

(6) The lot number or pharmacy reference number.

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

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

~~A statement that the drug has been compounded by the pharmacy shall be included on the container or on the receipt provided to the patient.~~

(c) Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient shall also include, on the container label or on a receipt provided to the patient, a statement that the drug has been compounded by the pharmacy. Drug products-  
~~preparations compounded into unit dose containers that are too small or otherwise impractical for full compliance with subdivisions (a) and (b) shall be labeled with at least the name(s) of the active ingredient(s), concentration or strength, volume or weight of the preparation, pharmacy reference or lot number, and expiration date.~~

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

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

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

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

**1735.5. Compounding Policies and Procedures.**

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

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

(c) The policies and procedures ~~manual~~ shall include at least the following:

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



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

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

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

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

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

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

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

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

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

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

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

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

**1735.6. Compounding Facilities and Equipment.**

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

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

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

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

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

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

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

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

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

(f) Where compliance with the January 1, 2017 amendments to Article 4.5 or Article 7, requires physical construction or alteration to a facility or physical environment, the board or its designee may grant a waiver of such compliance for a period of time to permit such physical change(s). Application for any waiver shall be made by the licensee in writing, and the request shall identify the provision(s) requiring physical construction or alteration, and the timeline for any such change(s). The board or its designee may grant the waiver when, in its discretion, good cause is demonstrated for such waiver.

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

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

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

**1735.7. Training of Compounding Staff.**

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

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

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

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

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

**1735.8. Compounding Quality Assurance.**

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

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

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

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

(e) The quality assurance plan shall include a written procedure for responding to out-of-range

temperature variations within the pharmacy and within patient care areas of a hospital where furnished drug is returned for redispensing.

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

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

**Article 7. Sterile ~~Injectable~~ Compounding**

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

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

(b) Any pharmacy compounding sterile ~~injectable~~ drug ~~products~~ preparations shall have a ~~designated~~ compounding area designated for the preparation of sterile ~~injectable~~ drug products preparations that is in a restricted location where traffic has no impact on the performance of the PEC(s). The cleanroom, including the walls, ceilings, and floors, shall be constructed in accordance with Section 1250.4 of Title 24, Part 2, Chapter 12, of the California Code of Regulations. The pharmacy shall be ventilated in a manner in accordance with Section 505.5 of Title 24, Part 4, Chapter 5 of the California Code of Regulations. ~~which shall meet the following standards:~~ The environments within the pharmacy shall meet the following standards:

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

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

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

~~(4) Be~~ Each ISO environment shall be certified annually at least every six months by a qualified

technician ~~who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with standards adopted by the United States General Services Administration~~ in accordance with Section 1751.4. Certification records must be retained ~~for at least 3 years~~ in the pharmacy.

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

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

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

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

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127 and 4127.7, Business and Professions Code; and Section 18944, Health and Safety Code.

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

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

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

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

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

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

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

(4) Results of viable air and surface sampling.

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

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

(A) Controlled room temperature.

(B) Controlled cold temperature.

(C) Controlled freezer temperature.

(7) Certification(s) of the sterile compounding environment(s).

(8) Documents indicating daily documentation of air pressure differentials or air velocity measurements between all adjoining ISO rooms or areas, including those associated with compounding aseptic (containment) isolators, and air pressure differentials or air velocity

measurements between all rooms or spaces with an immediate entry or opening to ISO rooms or areas.

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

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

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

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

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

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



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

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

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

- (a) ~~The~~ Telephone number of the pharmacy., ~~except~~ The telephone number is not required on the label for sterile injectable drug products preparations dispensed administered for to inpatients of a within the hospital pharmacy.
- ~~(b) Name and concentration of ingredients contained in the sterile injectable drug product.~~
- ~~(c)~~ Instructions for storage, and handling, and administration.;
- ~~(d)~~ All cytotoxic hazardous agents shall bear a special label which states "Chemotherapy - Dispose of Properly" or "Cytotoxic Hazardous – Dispose of Properly."

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

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

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

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

- (1) Action levels for colony-forming units (CFUs) detected during viable surface sampling, glove

fingertip, and viable air sampling and actions to be taken when the levels are exceeded.

(2) Airflow considerations and pressure differential monitoring.

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

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

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

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

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

(8) Depyrogenation of glassware (if applicable)

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

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

(11) Hand hygiene and garbing.

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

(13) Methods by which the supervising pharmacist will fulfill his or her responsibility to ensure the quality of compounded drug preparations.

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

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

(16) Procedures for handling, compounding and disposal of hazardous agents. The written

policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.

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

(18) Proper use of equipment and supplies.

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

(20) Record keeping requirements.

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

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

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

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

~~(a) Any pharmacy engaged in compounding sterile injectable drug products shall maintain a written policy and procedures 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.~~

~~(2) Labeling of the sterile injectable product compounded drug preparations based on the intended route of administration and recommended rate of administration.~~

~~(3) Equipment and supplies.~~

~~(4) Training of staff in the preparation of sterile injectable products.~~

~~(5) Procedures for handling cytotoxic agents.~~

~~(6) Quality assurance program.~~

~~(7) 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.~~

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

(1) Use of master formula documents and compounding logs.

(2) Appropriate documentation.

(3) Appropriate sterility and potency testing.

~~(c) For non-sterile-to-sterile batch compounding, the pharmacy shall maintain written policies and procedures for compounding that includes, in addition to the elements required by section 1735.5, 1751.3(a), and 1751.7(e), written policies and procedures regarding the following: must be established for the use of master formulas and work sheets and for appropriate documentation.~~

~~(1) Process validation for chosen sterilization methods.~~

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

~~Pharmacies compounding sterile injectable products shall have written policies and procedures for the disposal of infectious materials and/or materials containing cytotoxic residues. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.~~

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

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

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

~~(A) Competency evaluation.~~

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

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

~~(D) Process validation.~~

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

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

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

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

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

#### **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 shall be done using a germicidal detergent and sterile water. The use of a sporicidal agent is required to be used at least monthly.

(1) All ISO Class 5 surfaces, work table surfaces, carts, counters, and the cleanroom floor shall be

cleaned at least daily. After each cleaning, disinfection using a suitable sterile agent shall occur on all ISO Class 5 surfaces, work table surfaces, carts, and counters.

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

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

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

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

(1) At the beginning of each shift;

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

(3) After each spill; and

(4) When surface contamination is known or suspected.

~~(d) 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.~~

(f) Pharmacies preparing sterile compounded preparations require the use of a PEC that provides ISO Class 5 air or better air quality. Certification and testing of primary and secondary engineering controls shall be performed no less than every six months and whenever the device or area designated for compounding is relocated, altered or a service to the facility is performed that would impact the device or area. Certification must be completed by a qualified technician who is familiar with certification methods and procedures in accordance with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-13, Revised May 20, 2015), which is hereby incorporated by reference. Certification records must be retained for at least 3 years. Unidirectional compounding aseptic isolators or compounding aseptic containment isolators may be used outside of an ISO Class 7 cleanroom if the isolator is certified to meet 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 that do not meet the requirements as outlined in this subdivision or are not located within an ISO Class 7 cleanroom may only be used to compound preparations that meet the criteria specified in accordance with subdivision (d) of Section 1751.8 of Title 16, Division 17, of the California Code of Regulations.

(g) Pharmacies preparing parenteral cytotoxic sterile hazardous agents shall do so in accordance with Section 505.125.1 of Title 24, Chapter 5, of the California Code of Regulations, requiring a ~~laminar air flow hood~~ negative pressure PEC. Additionally, each PEC used to compound hazardous agents shall be externally vented. The ~~hood~~ negative pressure PEC must be certified ~~annually~~ every six months by a qualified technician who is familiar with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-13, Revised May 20, 2015), which is hereby incorporated by reference. ~~the methods and procedures for certifying laminar air flow hoods and cleanroom requirements, in accordance with National Sanitation Foundation Standard 49 for Class II (Laminar Flow) Biohazard Cabinetry, as revised May, 1983 (available from the National Sanitation Foundation, 3475 Plymouth Road, P.O. Box 1468, Ann Arbor, Michigan 48106, phone number (313) 769-8010) or manufacturer's specifications. Certification records must be retained for at least 3 years.~~ Any drug preparation that is compounded in a PEC where hazardous drugs are prepared must be labeled as hazardous, regardless of whether the drug ingredients are considered hazardous.

(1) During the hazardous drug compounding that is performed in a compounding aseptic containment isolator, full hand hygiene and garbing must occur. Garbing shall include hair

cover, facemask, beard cover (if applicable), polypropylene or low shedding gown that closes in the back, shoe covers, and two pairs of sterile ASTM D6978-05 standard gloves.

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

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

(j) Viable surface sampling shall be done at least every six months for all sterile-to-sterile compounding and quarterly for all non-sterile-to-sterile compounding. Viable air sampling shall be done by volumetric air sampling procedures which test a sufficient volume of air (400 to 1,000 liters) at each location and shall be done at least once every six months. Viable surface and viable air sampling shall be performed by a qualified individual who is familiar with the methods and procedures for surface testing and air sampling. Viable air sampling is to be performed under dynamic conditions that simulate actual production. Viable 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 pursuant to its policies and procedures. Remediation shall include, at minimum, an immediate investigation of cleaning and compounding operations and facility management.

(k) The sterile compounding area in the pharmacy shall have a comfortable and well-lighted working environment, which includes a room temperature of 20-24 degrees Celsius (68-75 degrees Fahrenheit) or cooler to maintain comfortable conditions for compounding personnel when attired in the required compounding garb.



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

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

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

**1751.5. Sterile ~~Injectable~~ Compounding Attire.**

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

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

~~(1) Cleanroom garb~~ Personal protective equipment consisting of a ~~low non~~-shedding ~~coverall gown~~, head cover, face mask, facial hair covers (if applicable), and shoe covers must be worn inside the designated area at all times. For hazardous compounding double shoe covers are required.

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

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

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

~~sterile glove.~~

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

~~(5) Gloves made of low-shedding materials are required. Sterile gloves that have been tested for compatibility with disinfection with isopropyl alcohol are required. Hand cleansing with a persistently active alcohol-based product followed by the donning of sterile gloves may occur within the ante or cleanroom. Gloves are to be routinely disinfected with sterile 70 percent isopropyl alcohol before entering or re-entering the PEC and after contact with non-sterile objects. Gloves shall also be routinely inspected for holes, punctures, or tears and replaced immediately if such are detected.~~

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

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

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

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

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

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

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

supplies furnished by the pharmacy.

(b) The pharmacist-in-charge shall be responsible to ensure that all pharmacy personnel engaging in compounding sterile ~~injectable drug products~~ preparations shall have training and demonstrated competence in the safe handling and compounding of sterile ~~injectable drug products~~ preparations, including ~~cytotoxic~~ hazardous agents if the pharmacy compounds products with ~~cytotoxic~~ hazardous agents.

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

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

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

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

(A) Aseptic technique.

(B) Pharmaceutical calculations and terminology.

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

(D) Quality assurance procedures.

(E) Aseptic preparation procedures.

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

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

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

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

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

(2) Each person ~~assigned to the controlled area~~ engaged in sterile compounding must successfully complete practical skills training in aseptic technique and aseptic area practices.

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

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

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

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

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

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

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

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

~~(4)~~(3) Written justification of Documentation justifying the chosen expiration beyond use dates

for compounded sterile ~~injectable drug products~~ preparations.

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

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

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

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

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

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

~~Each individual involved in the preparation of sterile injectable products must first successfully~~

~~complete a validation process on technique before being allowed to prepare sterile injectable drug products. 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 same personnel, procedures, equipment, and materials must be involved. Completed medium-media samples must be incubated. If microbial growth is detected, then the sterile preparation process must be evaluated, corrective action taken and documented, and the validation process repeated. Personnel competency must be revalidated at least every twelve months whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile injectable drug products preparations is repaired or replaced, the facility is modified in a manner that affects airflow or traffic patterns, or whenever improper aseptic techniques are observed. Revalidation must be documented.~~

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

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

~~(e)~~ (e)(1) Batch-produced sterile drug preparations compounded from one or more non-sterile ingredients, except as provided in paragraph (2), shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens. Sterility testing shall be USP chapter 71 compliant and pyrogens testing shall confirm acceptable levels of pyrogens per USP chapter 85 limits,

before dispensing. This requirement of end product testing confirming sterility and acceptable levels of pyrogens prior to dispensing shall apply regardless of any sterility or pyrogen testing that may have been conducted on any ingredient or combination of ingredients that were previously non-sterile. Exempt from pyrogen testing are topical ophthalmic and inhalation preparations.

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

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

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

~~Batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.~~

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

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

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

**1751.8. Beyond Use Dating for Sterile Compounded Drug Preparations.**

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

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

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

(2) The compounding process involves transferring, measuring, and mixing manipulations using not more than three commercially manufactured packages of sterile preparations and not more than two entries into any one sterile container or package of sterile preparations or administration containers/devices to prepare the drug preparation; and

(3) Compounding manipulations are limited to aseptically opening ampules, penetrating disinfected stoppers on vials with sterile needles and syringes or spiked transfer devices, and transferring sterile liquids in sterile syringes to sterile administration devices, package



containers of other sterile preparations, and containers for storage dispensing.

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

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

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

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

(c) The beyond use date shall specify that storage and exposure periods cannot exceed 24 hours at controlled room temperature, 3 days at controlled cold temperature, and 45 days in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations using non-sterile ingredients, regardless of intervening sterilization of that ingredient and the following applies:

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

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

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

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

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

(e) Where any sterile compounded drug preparation was compounded either outside of an ISO class 5 PEC or under conditions that do not meet all of the requirements for any of subdivisions

(a) through (d), the sterile compounded drug preparation shall be labeled "for immediate use only" and administration shall begin no later than one hour following the start of the compounding process. Unless the "immediate use" preparation is immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the preparation shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the compounded sterile preparation, and the exact one-hour beyond use date and time. If administration has not begun within one hour following the start of the compounding process, the compounded sterile preparation shall be promptly, properly, entirely, and safely discarded. This provision does not preclude the use of a PEC to compound an "immediate use" preparation. A PEC used solely to compound 'immediate use' preparations need not be placed within an ISO Class 7 cleanroom, with an ante-area. Such "immediate use" preparations shall be compounded only in those limited situations where there is a need for immediate administration of a sterile preparation compounded outside of an ISO class 5 environment and where failure to administer could result in loss of life or intense suffering. Any such compounding shall be only in such quantity as is necessary to meet the immediate need and the circumstance causing the immediate need shall be documented in accordance with policies and procedures.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**Article 7.5 Furnishing for Home Administration**

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

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

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

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

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

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

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

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

- (1) furnished by a registered pharmacist;
- (2) sealed in such a manner that a tamper-proof seal must be broken to gain access to the drugs;
- (3) under the effective control of a registered nurse, pharmacist or delivery person at all times when not in the pharmacy;
- (4) labeled on the outside of the container with a list of the contents;
- (5) maintained at an appropriate temperature according to United States Pharmacopeia Standards (1995, 23rd Revision), and protected at all times from extreme temperatures that could damage the contents.

(b) The portable container may contain up to:

- (1) 1000mL of 0.9% sodium chloride intravenous infusion in containers of a size determined by the pharmacy;
- (2) 1000mL of 5% dextrose in water injection in containers of a size determined by the pharmacy;
- (3) two vials of urokinase 5000 units;
- (4) Each of the following items shall be in sealed, unused containers; the furnishing pharmacy

may select any or all of these dangerous drugs in up to five dosage units for inclusion in the sealed, portable container:

- (A) heparin sodium lock flush 100 units/mL;
- (B) heparin sodium lock flush 10 units/mL;
- (C) epinephrine HCl solution 1:1,000;
- (D) epinephrine HCl solution 1:10,000;
- (E) diphenhydramine HCl 50mg/mL;
- (F) methylprednisolone 125mg/2mL;
- (G) normal saline, preserved, up to 30 mL vials;
- (H) naloxone 1mg/mL 2 mL;
- (I) droperidol 5mg/2mL;
- (J) prochlorperazine 10mg/2mL;
- (K) promethazine 25mg/mL;
- (L) dextrose 25gms/50mL;
- (M) glucagon 1mg/mL;
- (N) insulin (human) 100 units/mL;
- (O) bumetamide 0.5mg/2mL;
- (P) furosemide 10mg/mL;
- (Q) EMLA Cream 5 gm tube;
- (R) Lidocaine 1 percent 30mL vials.

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

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

(1) implement and maintain policies and procedures for:

- (A) the storage, temperature stability and transportation of the portable container;
- (B) the furnishing of dangerous drugs from the portable container upon the written or oral authorization of a prescriber; and

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

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

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

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

(f) The pharmacy shall ensure that within seven days (168 hours) after the seal has been broken on the portable container, the home health agency's director of nursing service or a registered nurse employed by the home health agency or licensed hospice returns the container to the furnishing pharmacy. The furnishing pharmacy shall then perform an inventory of the drugs used from the container, and if the container will be reused, must restock and reseal the container before it is again furnished to the home health agency or licensed hospice.

(g) The furnishing pharmacy shall have written policies and procedures for the contents, packaging, inventory monitoring, labeling and storage instructions of the portable container.

(h) The furnishing pharmacy shall ensure that the home health agency or licensed hospice returns the portable containers to the furnishing pharmacy at least every 60 days for verification of product quality, quantity, integrity and expiration dates, or within seven days (168 hours) after the seal has been broken.

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

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

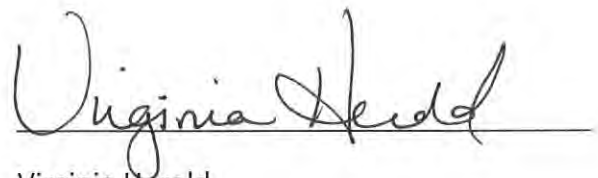
**To Amend § 1751.12 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

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

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

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

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

A handwritten signature in black ink that reads "Virginia Herold". The signature is written in a cursive style and is positioned above a horizontal line.

Virginia Herold  
Executive Officer  
California State Board of Pharmacy





**CODE OF FEDERAL REGULATIONS:**

**TITLE 21--FOOD AND DRUGS  
CHAPTER I--FOOD AND DRUG ADMINISTRATION  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
SUBCHAPTER E--ANIMAL DRUGS, FEEDS, AND RELATED PRODUCTS  
PART 530 EXTRALABEL DRUG USE IN ANIMALS**

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

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

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

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

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

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

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

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

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

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





## FDA Proposed Guidance Document

### *Compounding Animal Drugs from Bulk Drug Substances*

May 19, 2015

#### Overview

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

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

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

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

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

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

#### Deadlines:

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

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

#### Web Resources:

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

# Overview of FDA’s Proposed Guidance for Industry #230

## Bulk Ingredient Compounding In a State-Licensed Pharmacy

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

### Highlights

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

### No Office-Use Compounding Permitted

- Compounding with bulk ingredients must be patient-specific. Dispensing to the patient is permitted only after a valid

prescription has been received by the pharmacy.

### Compounding “Marketed” Drugs

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

### Documentation and Mandatory Statements

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

## Overview of FDA’s Proposed Guidance for Industry #230

### Bulk Ingredient Compounding By a Licensed Veterinarian

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

#### Highlights

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

### Bulk Ingredient Compounding By a 503B Outsourcing Facility

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

#### Highlights

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

## Overview of FDA’s Proposed Guidance for Industry #230

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intended for animal use.

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

### Positive List

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

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

### Labeling Requirements

- The labeling of animal drugs compounded using bulk ingredients by outsourcing facilities must include:
  - Active ingredients, inactive ingredients, dosage form, strength, flavoring (if any), directions for use, quantity/volume, lot/batch number, date of compounding, Beyond-Use-Date, name of veterinarian who ordered or

prescribed the drug, address and phone number of the outsourcing facility.

- A clear statement that says, “Not for resale.”
- A statement, “For use in [species, condition, and limitations].”
- The statement, “Compounded by [name of 503B outsourcing facility].”
- The statement, “Adverse events associated with this compounded drug should be reported to the FDA on Form FDA1932a.”
- If the drug is being dispensed based upon the receipt of patient specific prescription, the name of the animal, the animal owner/caretaker’s name, and the species must be included.

## Overview of FDA’s Proposed Guidance for Industry #230

### Specific Veterinary-Related Questions Posed in the Guidance Notice

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

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





November 16, 2015

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

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

Dear Dr. Bataller:

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

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

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

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

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

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

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

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


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

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

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

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

Respectfully,

A handwritten signature in black ink that reads "W. Ron DeHaven". The signature is fluid and cursive, with the first letters of each word being capitalized and prominent.

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



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

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

	Chemical grade	UNII	Description of the strength, quality, stability, and purity of the ingredient	Ingredient format	Recognition in Pharmacopeias	Presence of USP monograph?	Final compounded formulation dosage form(s)	Final compounded formulation strength(s)	Final compounded formulation route(s) of administration	Species and condition(s)	Bibliographies on safety and efficacy data	Why necessary (why approved drug is not suitable for patients)
Cisapride	Benzamide, 4-amino-5-chloro-N-[1-[3-(4-fluorophenoxy)propyl]-3-methoxy-4-piperidinyl]-2-methoxy-, cis- cis-4-Amino-5-chloro-N-[1-[3-(p-fluorophenoxy)propyl]-3-methoxy-4-piperidyl]-o-anisamide	UVL329170W	USP	Neat	Yes	Yes - Veterinary Clinical Drug Information Monograph (available on AAVPT.org)	Oral suspension, IV solution. See available data in Veterinary Clinical Drug Information Monograph	See available data in Veterinary Clinical Drug Information Monograph	oral capsule/tab and oral suspension, GI motility disorders	Feline	USP Clinical Drug Information Monograph, Plumb's Veterinary Handbook, 8th Ed, 2015, Can Vet Jv.36(2); 1995 Feb, Equine Veterinary Education Volume 3, Issue 3, pages 143-145, September 1991 Volume 3, Issue 3, pages 138-142, September 1991 Volume 21, Issue S7, pages 52-55, June 1989	no FDA product available
Dexamethasone	Pregna-1,4-diene-3,20-dione, 9-fluoro-11,17,21-trihydroxy-16-methyl-, (11,16)- 9-Fluoro-11,17,21-trihydroxy-16-methylpregna-1,4-diene-3,20-dione	755I7G3JQL	USP	Neat	yes	Yes - Veterinary Clinical Drug Information Monograph (available on AAVPT.org)	Powder	Packets of 10 mg	Oral	Equine	Detailed info on USP Clinical Drug Monograph. Willis-Goulet HS, Schmidt, BA, Nicklin CF, et al. Comparison of serum dexamethasone	Azium product off the market; dex injectable available but not useable
Dipyrrone	sodium;[(1,5-dimethyl-3-oxo-2-phenylpyrazol-4-yl)-methylamino]methanesulfonate	<a href="#">YSU62Z74QN</a>	USP	Neat	yes	No	Injectable solution	250-500 mg/dog	Subcutaneous	Canine	Shimada SG, Otterness IG, Stitt JT. A study of the mechanism of action of the mild analgesic dipyrrone. Agents Actions 1994; 41: 188-192. Jasiocka A, Maslanka T, Jaroszewski JJ. Pharmacological characteristics of metamizole. Polish J Vet Sci 2014; 17:207-214. Imagawa VH, Fantoni DT, Tatarunas AC, Mastrocinque S, Almeida TF, Ferreira F, Posso IP. The use of different doses of metamizole for post-operative analgesia in dogs. Vet Anaesth Analg. 2011 Jul;38(4):385-93.	Shar Pei Fever



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

	Chemical grade	UNII	Description of the strength, quality, stability, and purity of the ingredient	Ingredient format	Recognition in Pharmacopeias	Presence of USP monograph?	Final compounded formulation dosage form(s)	Final compounded formation strength(s)	Final compounded formulation route(s) of administration	Species and condition(s)	Bibliographies on safety and efficacy data	Why necessary (why approved drug is not suitable for patients)
Doxycycline	2-Naphthacene-carboxamide, 4-(dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,5,10,12,12a-pentahydroxy-6-methyl-1,11-dioxo-, [4S-(4,4a,5,5a,6,12a)]-, monohydrate; 4-(Dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,5,10,12,12a-pentahydroxy-6-methyl-1,11-dioxo-2-naphthacene-carboxamide monohydrate	N12000U130	USP	Neat	yes	Yes (Vet Compounding Monograph for oral Suspension)	Reformulated capsule, pill, solution	Equine: 10 mg/kg	Oral	Equine	Plumb's Veterinary Handbook, 8th Ed, 2015	inappropriate mg strength for equine use
Gabapentin	Cyclohexaneacetic acid, 1-(aminomethyl)-; 1-(Aminomethyl)cyclohexaneacetic acid	6CW7F3G59X	USP	Neat	yes	No	Oral suspension, capsules	100 mg/ml	Oral	Feline	Plumb's Veterinary Handbook, 8th Ed, 2015. Muller G. Compounded gabapentin suspension for lower back pain in an older cat: a case report. Int J Pharm Compd. 2010;14(3):215-7.	Smallest FDA product too high mg for most feline patients
Idoxuridine	Uridine, 2'-deoxy-5-iodo-; 2'-Deoxy-5-iodouridine	LGP81V5245	USP	Neat	yes	No	Ophthalmic ointment or solution	0.1%.	Ophthalmic	Feline	Maggs, DJ. Update on pathogenesis, diagnosis and treatment of feline herpesvirus type 1. Clin Techniques Small Anim Practice. 2005; 20:94-101.	Human product is only injectable; no ophthalmic product on market
Itraconazole	3H-1,2,4-Triazol-3-one, 4-[4-[4-[[2-(2,4-dichlorophenyl)-2-(1H-1,2,4-triazol-1-ylmethyl)-1,3-dioxolan-4-yl]methoxy]phenyl]-1-piperazinyl]phenyl]-2,4-dihydro-2-(1-methylpropyl)-; (±)-1-sec-Butyl-4-[p-[4-[p-[[[2R*,4S*]-2-(2,4-dichlorophenyl)-2-(1H-1,2,4-triazol-1-ylmethyl)-1,3-dioxolan-4-yl]methoxy]phenyl]-1-piperazinyl]phenyl]-D2-1,2,4-triazolin-5-one	304NUG5GF4	USP	Neat	yes	No	Ophthalmic ointment or solution	1%	Ophthalmic	Equine	Plumb's Veterinary Handbook, 8th Ed, 2015. Ball MA, Rebhun WC, Trepanier L. Corneal concentrations and preliminary toxicological evaluation of an itraconazole/dimethyl sulphoxide ophthalmic	No approved products; for ophthalmic indication is okay; would not reference any oral at all
Metronidazole benzoate	2-(2-Methyl-5-nitroimidazol-1-yl)ethyl benzoate	A355C835XC	USP	Neat	yes	Yes Metronidazole Benzoate Compounded Oral Suspension	oral suspension, tabs or capsules	80 mg/ml	oral	Canine, feline	Plumb's Veterinary Handbook, 8th Ed, 2015; Davidson, G. To benzoate or not to benzoate: Cats are the question. Int J Pharm Compounding 2001; 5: 89-90. Scorza AV, Lappin MR. Metronidazole for the treatment of feline giardiasis. J feline Med Surg 2004; 6: 157-160.	FDA tab (250) mg too high mg to split accurately for many cats that require 30-40 mg; benzoate liquid lacks bitter metallic taste of HCl salt

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

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

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

Wildlife and Zoo Animal Nominations

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

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Atipamezole	Atipamezole; 104054-27-5; Antisedan; MPV-1248; Atipamezol [Spanish]; Atipamezolum [Latin]; 5-(2-ethyl-1,3-dihydroinden-2-yl)-1H-imidazole	Atipamezole	03N9U5JAF6	ACS	neat	No	no information	Sterile Injectable	25 mg/ml	parenteral - IV, SC, IM	any and all exotic species (such as captive and free ranging mammals, birds, reptiles and elasmobranchs) for which alpha-2 agonist anesthesia is utilized; which is considered standard of care within the zoo and wildlife community for balance anesthetic efforts, reduced quantities of more potent anesthetics, and improved quality of anesthetic episodes	Throughout JZWM, Fowler, and West, repeated documentation of the use and efficacy of the alpha-2 agonist for which this product reverses the effects - older generation of reversals are not as effective or potentially as concentrated for delivery by projectile when supplementaiton is needed.	Variable concentration of this product maximizes the flexibility of its application throughout the exotic animal discipline. Injection volume necessary for effect is not possible by dart delivery or hand injection in many species.	approved formulation too dilute to use in large hoofstock	explained in other blocks	more concentrated solution is needed, so cannot use FDA-approved drug	None known	
Azaperone	Azaperone; Fluoperidol; Stresnil; Suicalm; 1649-18-9; Azaperon; 1-(4-fluorophenyl)-4-(4-pyridin-2-yl)piperazin-1-yl)butan-1-one	Azaperone	19BV78AK7W	USP	USP	neat	USP	Solution	30 and 50 mg/ml	parenteral - IV, SC, IM	Captive and free ranging mammals, birds and reptiles and elasmobranchs	throughout JZWM, Fowler, and West, repeated documentation of the use of this product for tranquilization especially in transport situations of hoofstock and charismatic megavertebrates and acclimation of anxious species. Previously held NADA.	variable concentration of this product maximizes the flexibility of its application throughout the exotic animal discipline	Not available	explained in other blocks	tranquilization	None known	

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Buprenorphine Buprenorphine; Buprenex; Temgesic; Subutex; Buprenorfina; Buprenorphinum;	Buprenorphine	<a href="#">40D3SCR4GZ</a>	USP	USP	neat	USP	Sterile Injectable	3 mg/ml and slow release	parenteral - IV, SC, IM - generally and IM for slow release; has been used orally	Captive and free ranging mammals and birds	exceptional analgesia and part of balanced anesthetic plans; thoroughout JZWM, West, Fowler, and AAZV proceedings, this product has been identified as useful and beneficial to multitudes of species. Article Citation: Christine M. Molter, Lorraine Barbosa, Shawn Johnson, Heather K. Knych, Sathya K. Chinnadurai, and Raymund F. Wack (2015) PHARMACOKINETICS OF A SINGLE SUBCUTANEOUS DOSE OF SUSTAINED RELEASE BUPRENORPHINE IN NORTHERN ELEPHANT SEALS (MIROUNGA ANGUSTIROSTRIS). Journal of Zoo and Wildlife Medicine: March 2015, Vol. 46, No. 1, pp. 52-61.	More concentrate d solution is critical to release dart and administrati on volume for a variety of patients. Injection volume necessary for effect is not possible by dart delivery or hand injection in many species.	see below	specific concentra tion formulatio n would be needed from bulk drug	pain manageme nt, improved animal welfare	analgesic; to alleviate potentially serious captive and free-ranging wild animal health and welfare, or public safety, problems or emergencies and in treatment situations, reduced handling needs by higher concentrations with smaller volumes.	None known



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Butorphanol	Butorphanol	QV897JC36D	USP	USP	neat	USP	Sterile Injectable	30 and 50 mg/ml	parenteral - IV, SC, IM	Captive and free ranging mammals and birds	exceptional analgesia and part of balanced anesthetic plans; throughout JZWM, West, Fowler, and AAZV proceedings, this product has been identified as useful and beneficial to multitudes of species. Michele Miller, Peter Buss, Jenny Joubert, Nomkhosi Mathebula, Marius Kruger, Laura Martin, Markus Hofmeyr, and Francisco Olea-Popelka (2013) USE OF BUTORPHANOL DURING IMMOBILIZATION OF FREE-RANGING WHITE RHINOCEROS (CERATOTHERIUM SIMUM). Journal of Zoo and Wildlife Medicine: March 2013, Vol. 44, No. 1, pp. 55-61.	More concentrated solution is critical to release dart and administration volume for a variety of patients. Injection volume necessary for effect is not possible by dart delivery or hand injection in many species.	see below	specific concentration formulation would be needed from bulk drug	Combined with potent alpha 2 for immobilization	sedation; to alleviate potentially serious captive and free-ranging wild animal health and welfare, or public safety, problems or emergencies; and in treatment situations, for analgesia, reduced handling needs by higher concentrations with smaller volumes, or less dart impact.	None known

Wildlife and Zoo Animal Nominations

Chemical name	Common name	UNII Code	Chemical grade	Description of the strength, quality, stability, and purity of the ingredient	Ingredient format(s)	Recognition in Pharmacopeias	Final compound formulation dosage form(s)	Final compound formulation strength(s)	Final compound formulation route(s) of administration	Species and condition(s)	Bibliographies on safety and efficacy data	Why necessary (why approved drug is not suitable for patients)	Literature review to determine whether FDA-approved animal or human drugs that could be prescribed as an extra-label use	Explanation supported by scientific data of why drug cannot be compounded from approved drug	Final compound formulation rational and history of past use	Why immediate treatment is needed	Safety concerns
Calcium edetate	Calcium EDTA	9G34HU7RVQ	USP	USP	neat	USP	Solution	As specified by clinician	parenteral - IV or IM	Zoo animals (raptors)-any zoo species with heavy metal poisoning - esp lead; but particularly - galliforms, raptors, penguins; additionally, wildlife rehabilitation raptors (esp concern California condors); water birds (such as loons); cranes.	Of note, publications are available in JZWM on lead intoxication in sea ducks as wildlife concern; galliforms in zoo setting (Bronx Zoo); penguins from personal experience and proceedings documentation AAZV; California condor medicine in Fowler ZAWAM and AAZV proceedings cite lead intoxication as one of primary medical concerns in free-ranging/released condors; cranes also listed in Fowler as species of major concern.	cost prohibitive human formulation that has true acquisition potential issues when emergency arises for this treatment as it is preferentially provided for humans; concentration of product can produce painful injection concerns	see below	necessary product that is currently used in formulation available but needed for more species specific flexibility in compounded form	emergency intoxications need rapid response; high profile endangered species release program	None known	
Carfentanil	Wildnil	LA9DTA2L8F	ACS	ACS	Carfentanil citrate 4.46 mg (equivalent to 3 mg Carfentanil), sodium chloride 8 mg, methyl paraben 1.8 mg, propyl paraben 0.2 mg in water for injection.	no information	Sterile Injectable	3 mg/ml	Intramuscular	Captive and free ranging mammals, birds and elasmobranchs	Common in current text books	not available	see below	not available	In published literature	anesthesia	None known

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Cisapride	(±)- <i>cis</i> -4-amino-5-chloro- <i>N</i> -(1-[3-(4-fluorophenoxy)propyl]-3-methoxy-piperidin-4-yl)-2-methoxybenzamide		UVL329170W	no information	no information	no information	no information	Suspension	Variable 1-10 mg/ml based on size of species	Oral	Zoo species: GI motility disorders	see below	Not currently commercially available	see below	No available FDA approved drug	Literature supports its effectiveness	Gastrointestinal motility disorders can result in death	None known
Clotrimazole	Clotrimazole; Lotrimin; Canesten; Mycelex; Empecid; Mycosporin. 1-[(2-chlorophenyl)-diphenylmethyl]imidazole DEXMEDETOMIDINE;	Clotrimazole	G07GZ97H65	USP	USP	neat; 10 mg/ml in propylene glycol	USP	Nebulization	10 mg/ml	Inhalant	Zoo animals	see below	Formulation for nebulization not commercially available	see below	Appropriate formulation not commercially available.	In published literature	Birds will die quickly from respiratory aspergillosis	None known
Dexmedetomidine	Dexmedetomidina; Dexmedetomidinum; MPV 1440; 113775-47-6; CHEMBL778; 5-[(1 <i>S</i> )-1-(2,3-dimethylphenyl)ethyl]-1 <i>H</i> -imidazole	Dexmedetomidine	67VB76HONO	USP	USP	Neat	USP	not available	not available	not available	Captive and free ranging mammals, birds, reptiles, fish and elasmobranchs	see below	not available	see below	not available	not available	not available	None known
Diazepam	Diazepam; Valium; Ansolisina; Diazemuls; Apaurin; Faustan; 7-chloro-1-methyl-5-phenyl-3 <i>H</i> -1,4-benzodiazepin-2-one	Diazepam	Q3JTX2Q7TU	USP	USP	neat	USP	not available	10 mg/ml	not available	Captive and free ranging mammals, birds, reptiles, fish and elasmobranchs	see below	see below	see below	not available	not available	tranquilization	None known
Enrofloxacin	Enrofloxacin; Baytril; 93106-60-6; Enrofloxacin; CFPQ; Bay-Vp-2674; 1-cyclopropyl-7-(4-ethylpiperazin-1-yl)-6-fluoro-4-oxoquinoline-3-carboxylic acid	Enrofloxacin	3DX3XEK1BN	USP	USP	neat	USP	Suspension	Variable; greater than 200 mg/ml	Oral	Zoo animals; treatment of bacterial infections. Once daily dosing is advantageous.	see below	Concentrated formulation facilitates delivery of feasible	see below	High concentration formulation not commercially	Routinely used by zoo clinicians	Delayed treatment of bacterial diseases can result in death.	None known
Etorphine	6,14-Ethenomorphinan-7-methanol, 4,5-epoxy-3-hydroxy-6-methoxy- $\delta$ ,17-dimethyl- $\alpha$ -propyl-, (5 <i>á</i> ,7 <i>á</i> -( <i>R</i> ))- hydrochloride.	M99	8CBE01N748	ACS	ACS	Etorphine Hcl, citric acid, propylene glycol and WFI		Sterile Injectable	10 mg/ml and 1 mg/ml	Intramuscular	Captive and free ranging mammals and reptiles	Common in current text books	not available	see below	not available	Common in published literature	anesthesia	None known
Famciclovir	Famciclovir; Famvir; 104227-87-4; Famciclovirum; BRL-42810; Oravir; [2-(acetyloxymethyl)-4-(2-aminopurin-9-yl)butyl] acetate	Famciclovir	QIC03ANI02	USP	USP	neat	USP	not available	not available	not available	Zoo animals	see below	not available	see below	not available	not available	not available	None known
Fentanyl	<i>N</i> -(1-(2-phenylethyl)-4-piperidinyl)- <i>N</i> -phenylpropanamide	Duragesic, Sublimase 50 mcg/ml	UF599785JZ	USP	USP	neat	Yes	Sterile Injectable	not available	not available	Captive and free ranging mammals	see below	not available	see below	not available	not available	not available	None known

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Fluphenazine	FLUPHENAZINE; Triflumethazine; Fluorophenazine; Fluorfenazine; Fluorphenazine; Squaline; 2-[4-[3-[2-(trifluoromethyl)phenothiazin-10-yl]propyl]piperazin-1-yl]ethanol	Fluphenazine	<a href="#">S79426A41Z</a>	USP	USP	neat	USP	not available	not available	not available	Zoo animals	see below	not available	see below	not available	not available	not available	None known
Guaifenesin	Glycerol guaiacolate; Guaiacol glyceryl ether; 93-14-1;	Guaifenesin	495W7451VQ	USP	USP	neat	USP	not available	not available	not available	Zoo animals	see below		see below	not available	not available	not available	None known
Haloperidol	Haloperidol; Haldol; Eukystol; Serenace; Aloperidin; Aloperidol; 4-[4-(4-chlorophenyl)-4-hydroxypiperidin-1-yl]-1-(4-fluorophenyl)butan-1-one	Haloperidol	<a href="#">J6292F8L3D</a>	USP	USP	neat	USP	Sterile Injectable	20 mg/ml	Intramuscular	Captive and free ranging mammals	see below	Injection volume necessary for effect is not possible by dart delivery or hand injection in many species.	see below	not available	not available	long term tranquilization	None known
Hyaluronidase	Hyaluronidase/; Apaziquone/; Cetuximab/; Desloratadine/; Prucalopride/; Rosuvastatin/; 6-(3,3-dimethyl-2-methylideneindol-1-yl)hexanoic acid;hydrobromide	Hyaluronidase	8KOG53Z5EM	USP	USP	neat	USP	not available	not available	not available	Zoo animals	see below	not available	see below	not available	not available	not available	None known
Isoxsuprine	Isoxsuprine; Vasodilian; Dilavase; Vasosurpine; 395-28-8; Isoxsuprine [INN:BAN]; 4-[1-hydroxy-2-(1-phenoxypropan-2-ylamino)propyl]phenol	Isoxsuprine	R15UI3245N	USP	USP	neat	USP	not available	not available	not available	Zoo animals	see below	not available	see below	not available	not available	not available	None known

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Itraconazole	Itraconazole; Sporanox; Oriconazole; Itraconazolium; Itraconazol; Itrizole (TN); 2-butan-2-yl-4-[4-[4-[[[(2R,4S)-2-(2,4-dichlorophenyl)-2-(1,2,4-triazol-1-ylmethyl)-1,3-dioxolan-4-yl]methoxy]phenyl]piperazin-1-yl]phenyl]-1,2,4-triazol-3-one	Itraconazole	304NUG5GF4	USP	USP	neat	USP	not available	40 mg capsules	not available	zoo birds, primarily penguins (aspergillosis)	see below	not available	see below	API is not bioavailable in penguins	not available	not available	None known
Ketamine	Ketamine; Ketaject; Ketalar; DI-Ketamine; Ketanest; CI 581 base; 2-(2-chlorophenyl)-2-(methylamino)cyclohexan-1-one	Ketamine	690G0D6V8H	USP	USP	neat	USP	not available	200 mg/ml	not available	Captive and free ranging mammals, birds, reptiles, fish and elasmobranchs	see below	not available	see below	not available	not available	anesthesia	None known
Large-volume parenteral fluids	not available	not available	not available	not available	not available	not available	not available	Sterile injectable	not available	not available	Zoo animals	see below	not available	not available	not available	not available	not available	None known
Leuprolide acetate	Leuprolide acetate; Leuprorelin acetate; Enantone; Abbott-43818; CHEBI:63597; TAP-144;acetic acid;(2S)-N-[[[(2S)-1-[[[(2S)-1-[[[(2S)-1-[[[(2R)-1-[[[(2S)-1-[[[(2S)-5-(diaminomethylideneamino)-1-[[[(2S)-2-(ethylcarbamoyl)pyrrolidin-1-yl]-1-oxopentan-2-yl]amino]-4-methyl-1-oxopentan-2-yl]amino]-4-methyl-1-oxopentan-2-yl]amino]-3-(4-hydroxyphenyl)-1-oxopropan-2-yl]amino]-3-hydroxy-1-oxopropan-2-yl]amino]-3-(1H-indol-3-yl)-1-oxopropan-2-yl]amino]-3-(1H-imidazol-5-yl)-1-oxopropan-2-yl]-5-oxopyrrolidine-2-carboxamide	Leuprolide acetate	37JNS02E7V	USP	USP	neat	USP	not available	not available	not available	Zoo animals	see below	not available	see below	human product might/might not be right	not available	not available	None known

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Medetomidine  -4-[1-(2,3-dimethylphenyl) ethyl]-1H-imidazole monohydrochloride.	Domitor 1 mg/ml	MR15E85MQM	ACS	ACS	neat	not available	Sterile Injectable	10, 20, and 40 mg/ml	Intramuscular	Captive and free ranging mammals, birds, reptiles, fish and elasmobranchs	see below	Injection volume necessary for effect is not possible by dart delivery or hand injection in many species.	see below	Too dilute	not available	sedation/anesthesia, animal welfare, public safety	None known
Melengestrol acetate  MELENGESTROL ACETATE; 2919-66-6; UNII-4W5HDS3936; CHEBI:34831; 17-Hydroxy-6-methyl-16-methylenepregna-4,6-diene-3,20-dione acetate; NSC-70968; [(8R,9S,10R,13S,14S,17R)-17-acetyl-6,10,13-trimethyl-16-methylidene-3-oxo-1,2,8,9,11,12,14,15-octahydrocyclopenta[a]phenanthren-17-yl] acetate	Melegestrol acetate	4W5HDS3936	ACS	ACS	neat	not available	Sterile implant or feed additive	Variable based on individual weight	SQ or in feed	Contraception for primates, carnivores, hoofstock species	see below	There is no approved formulation	see below	There is no approved formulation	Common contraceptive in use in the zoo community for 25+ years	Population management	None known
Meloxicam  Meloxicam; Mobic; 71125-38-7; Metacam; Movalis; Meloxicamum; 4-hydroxy-2-methyl-N-(5-methyl-1,3-thiazol-2-yl)-1,1-dioxo-1,2,3,4-tetrahydro-2H-benzothiazine-3-carboxamide	Meloxicam	VG2QF83CGL	USP	USP	neat	USP	not available	2 mg/ml	not available	Captive and free ranging mammals, birds, reptiles	see below	not available	see below	comes as 5 mg/ml solution	not available	analgesic	None known
Midazolam  Midazolam; Versed; Dormicum; Midazolamum; 59467-70-8; Midazolamum [INN-Latin]; 8-chloro-6-(2-fluorophenyl)-1-methyl-4H-imidazo[1,5-a][1,4]benzodiazepine	Midazolam	R60LQSM5BC	USP	USP	Neat	USP	not available	20 mg/ml	not available	Captive and free ranging mammals, birds, reptiles	see below	not available	see below	not available	not available	tranquilization	None known

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Nalbuphine	–)-17-(cyclobutylmethyl)- 4,5α-epoxymorphinan- 3,6α,14-triol hydrochloride	Nubain (human) 10 mg/ml	L2T84IQI2K	USP	USP	neat	USP	Sterile Injectable	50 mg/ml	Intramuscular	Captive and free ranging mammals	Published use combined with Med and Azaperone in Bears and Cervids	Injection volume necessary for effect is not possible by dart delivery or hand injection in many species.	see below	not available	not available	long term sedation, animal welfare and public safety	None known
Naloxone	Naloxone; L-Naloxone; Narcan; N-Allylnoroxymorphone; Naloxona; Naloxonum; (4R,4aS,7aR,12bS)-4a,9-dihydroxy-3-prop-2-enyl-2,4,5,6,7a,13-hexahydro-1H-4,12-methanobenzofuro[3,2-e]isoquinoline-7-one	Naloxone	36B82AMQ7N	USP	USP	neat	usp	not available	10 mg/ml	not available	Wildlife	see below	see below	see below		human reversal for narcotic exposure	None known	
Naltrexone	17-(cyclopropylmethyl)-4,5-epoxy-3,14 dihydroxy-morphinan-6-one hydrochloride.	Revia 50 mg tablet for human use	5S6W795CQM	USP	USP	neat	USP	Sterile Injectable	50 mg/ml	not available	Captive and free ranging mammals, birds and elasmobranchs	Previously a FDA approved product	Currently not commercially available	see below	Revia is an oral tablet	Previously an approved NADA	reversal of narcotics	None known
Ponazuril	Toltrazuril sulfone; Ponazuril; 69004-04-2; UNII-JPW84AS66U; NCGC00182044-01; 1-methyl-3-[3-methyl-4-[4-(trifluoromethylsulfonyl)phenoxy]phenyl]-1,3,5-triazinane-2,4,6-trione; 1-methyl-3-[3-methyl-4-[4-(trifluoromethylsulfonyl)phenoxy]phenyl]-1,3,5-triazinane-2,4,6-trione	Ponazuril	JPW84AS66U	ACS	ACS	neat	?	Solution or suspension	Variable based on species	not available	Zoo species susceptible to protozoal diseases such as Sarcocystis, Coccidiosis, Atxoplasmosis, Toxoplasmosis	see below	Paste formulation not ammendable for oral suspensions or for treatment of groups of birds in the water	see below	not available	not available	Protozoal diseases left untreated will result in death	None known

Wildlife and Zoo Animal Nominations

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



Wildlife and Zoo Animal Nominations

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

Wildlife and Zoo Animal Nominations

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

Wildlife and Zoo Animal Nominations

Chemical name	Common name	UNII Code	Chemical grade	Description of the strength, quality, stability, and purity of the ingredient	Ingredient format(s)	Recognition in Pharmacopeias	Final compounded formulation dosage form(s)	Final compounded formulation strength(s)	Final compounded formulation route(s) of administration	Species and condition(s)	Bibliographies on safety and efficacy data	Why necessary (why approved drug is not suitable for patients)	Literature review to determine whether FDA-approved animal or human drugs that could be prescribed as an extra-label use	Explanation supported by scientific data of why drug cannot be compounded from approved drug	Final compounded formulation clinical rational and history of past use	Why immediate treatment is needed	Safety concerns
Vitamin K1 (phytonadione)	Phytonadione	S5Z3U87QHF	USP	USP	neat	USP	injectable	not available	SC, IV, Oral	Large zoo animals	see below	Concentrated form for larger animals; used for coagulopathies, rodenticide toxicities, newborn hemorrhagic disease,	see below	approved formulation too dilute to use in large hoofstock		coagulopathies, rodenticide toxicities, newborn hemorrhagic disease	None known
Voriconazole	Voriconazole	JFU09187TR	USP	USP	Neat	USP	oral suspension	300 mg/ml	Oral	Zoo animals, exotic pets, aquaria, wildlife	see below	Concentrated formulations for treating fungal infections in a variety of species	see below	approved formulation too dilute to use in large hoofstock		antifungal	None known
Xylazine (concentrated)	Cervizine	<u>2KFG9TP5V8</u>	USP	USP	neat	USP	sterile injectable	300 and 450 mg/ml	IM, IV, SC	Captive and free ranging mammals, birds, reptiles	see below	Injection volume necessary for effect is not possible by dart delivery or hand injection in many species.	see below	approved formulation too dilute to use in large hoofstock		sedation	None known

Wildlife and Zoo Animal Nominations

Chemical name	Common name	UNII Code	Chemical grade	Description of the strength, quality, stability, and purity of the ingredient	Ingredient format(s)	Recognition in Pharmacopeias	Final compound formulation dosage form(s)	Final compound formulation strength(s)	Final compound formulation route(s) of administration	Species and condition(s)	Bibliographies on safety and efficacy data	Why necessary (why approved drug is not suitable for patients)	Literature review to determine whether FDA-approved animal or human drugs that could be prescribed as an extra-label use	Explanation supported by scientific data of why drug cannot be compounded from approved drug	Final compound formulation clinical rational and history of past use	Why immediate treatment is needed	Safety concerns
Yohimbine (concentrated)	Yohimban-16-carboxylic acid, 17-hydroxy-, methyl ester, hydrochloride	Antagonil	not available	no information	no information	no information	sterile injectable	10 mg/ml, 30 ml/ml	IM, IV, SC	Captive and free ranging mammals, birds, reptiles	see below	Concentrated form to antagonize concentrated xylazine hydrochloride	see below	approved formulation too dilute to use in large hoofstock		anesthetic antagonist	None known
References																	
West, G., Heard, D., & Caulkett, N. (Eds.). (2007). Zoo animal and wildlife immobilization and anesthesia. Blackwell Publishing.																	
West, G., Heard, D., & Caulkett, N. (Eds.). (2014). Zoo animal and wildlife immobilization and anesthesia, second edition. John Wiley & Sons, Inc.																	
Handbook of Wildlife Chemical Immobilization. Terry J. Kreeger and Jon M. Arnemo. T. Kreeger. Published by Author. 2012. 448 pp																	
Michele Miller, Peter Buss, Jenny Joubert, Nomkhosi Mathebula, Marius Kruger, Laura Martin, Markus Hofmeyr, and Francisco Olea-Popelka (2013) USE OF BUTORPHANOL DURING IMMOBILIZATION OF FREE-RANGING WHITE RHINOCEROS (CERATOTHERIUM SIMUM). Journal of Zoo and Wildlife Medicine: March 2013, Vol. 44, No. 1																	
Kurt K. Sladky, Lisa Krugner-Higby, Elizabeth Meek-Walker, Timothy D. Heath, Joanne Paul-Murphy. Serum concentrations and analgesic effects of liposome-encapsulated and standard butorphanol tartrate in parrots. American Journal of Veterinary Research May 2006, Vol. 67, No. 5, Pages 775-781.																	
Corrine S. Brown, Joanne Luebbert, Daniel Mulcahy, Jason Schamber, and Daniel H. Rosenberg. 2006. BLOOD LEAD LEVELS OF WILD STELLER'S EIDERS (POLYSTICTA STELLERI) AND BLACK SCOTERS (MELANITTA NIGRA) IN ALASKA USING A PORTABLE BLOOD LEAD ANALYZER. Journal of Zoo and Wildlife Medicine 37(3):361-365.																	
Christine M. Molter, Lorraine Barbosa, Shawn Johnson, Heather K. Knych, Sathya K. Chinnadurai, and Raymund F. Wack (2015) PHARMACOKINETICS OF A SINGLE SUBCUTANEOUS DOSE OF SUSTAINED RELEASE BUPRENORPHINE IN NORTHERN ELEPHANT SEALS (MIROUNGA ANGUSTIROSTRIS). Journal of Zoo and Wildlife Medicine: M																	
CISAPRIDE																	





November 16, 2015

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

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

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

Dear Sir/Madam:

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

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

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

## I. USP Position

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

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## II. USP's Standards-Setting Role

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

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

### 1. [Monographs for drug articles](#)

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

### 2. [Veterinary-specific compounded preparation monographs](#)

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

### 3. [General Chapters](#)

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

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

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

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

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

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

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

Sincerely,



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





## **SB 1193, Hill. Healing arts.**

**APPROVED:** September 22, 2016. Filed with Secretary of State September 22, 2016.

### **SEC. 46.**

Section 4826.5 is added to the Business and Professions Code, to read:

#### **4826.5.**

Notwithstanding any other law, a licensed veterinarian or a registered veterinary technician under the supervision of a licensed veterinarian may compound drugs for animal use pursuant to Section 530 of Title 21 of the Code of Federal Regulations and in accordance with regulations promulgated by the board. The regulations promulgated by the board shall, at a minimum, address the storage of drugs, the level and type of supervision required for compounding drugs by a registered veterinary technician, and the equipment necessary for the safe compounding of drugs. Any violation of the regulations adopted by the board pursuant to this section shall constitute grounds for an enforcement or disciplinary action.



## MEMORANDUM

<b>DATE</b>	September 20, 2016
<b>TO</b>	MDC
<b>FROM</b>	Annemarie Del Mugnaio, Executive Officer DCA/Veterinary Medical Board
<b>SUBJECT</b>	<b>RVTs Onsite at Rodeo Events</b>

### **Background:**

The issue of onsite veterinary care for animals at rodeo events was raised during the Board's 2015/16 Sunset Review process. Specifically, the Legislature recommended that a practitioner be onsite to provide veterinary treatment for animals at rodeo events. The recommendation from the Legislature is as follows:

*It should be required that the management of any professionally sanctioned or amateur rodeo that intends to perform in any city or county shall ensure that there is a licensed veterinarian present at all times during the performances of the rodeo or a RVT who is under the appropriate degree of supervision of the veterinarian for those animal health care tasks that may be performed by the RVT at a rodeo event. The on-call requirement for a veterinarian should be considered as insufficient to provide for appropriate oversight and the immediate treatment of injured animals at rodeo events.*

The Board responded by confirming that RVTs may provide emergency care and treatment at rodeos pursuant to Business and Professions Code (BPC) Section 4840.5, without a veterinarian present. Further, Section 2069 of the California Code of Regulations provides for the specific aid and treatment that an RVT may provide an animal under the conditions of an emergency which includes: application of tourniquets or pressure bandages to control bleeding, administration of pharmacological agents under direction of the veterinarian, application of temporary splints or bandages to prevent further injury to bones or soft tissue, external cardiac resuscitation, and intubation for opening airways, to name a few. The Board made it clear that an RVT may provide treatment at a rodeo event under current law and regulation to assist in emergency situations. However, the Board expressed its position that the presence of the RVT at a rodeo event should not be a substitute for the requirement that a veterinarian be on-call for any professionally sanctioned or amateur rodeo. Instead, if an RVT will be present at the event to provide emergency care and treatment, a veterinarian should be on-call to provide direction to the RVT until such time as the injured animal may be transported to a veterinary hospital as deemed necessary.

The Board indicated it would refer the matter to the MDC to recommend protocols under which an RVT may provide emergency care to animals at sanctioned rodeo events in the absence of a veterinarian.

**Issues:**

Does the owned-animal exception of BPC 4827 impact the ability of a veterinarian or RVT to treat injured animals at a rodeo?

- Penal Code Section 596.7 (d)(1) appears to require mandatory treatment in that the language states: “Any animal that is injured during the course of, or as a result of, any rodeo event **shall** receive immediate examination and appropriate treatment by a veterinarian licensed to practice in this this state within one hour of the determination of the injury requiring veterinary treatment. [Emphasis Added]

In consulting with the Professional Rodeo Cowboys Association (PRCA), staff was informed that there is no waiver of treatment form or any like form notifying entrants that should their animal be injured during the rodeo, the on-site veterinarian will provide treatment. The PRCA representative stated that individual committees may have their own forms, but a waiver of treatment form is not standard. The representative commented about the bylaws and rules that all rodeos follow, which includes a veterinarian on premises at all times. However, it was further stated that people involved with rodeos are well aware that they have a right to have their animal treated by their own veterinarian, and don’t need to seek treatment from the onsite assigned veterinarian.

Are there protocols that a non-veterinarian, in this case an RVT, may follow to provide on-site or transport emergency care to an injured animal until such time as the animal is treated by a veterinarian (PC 596.7 requires care within one hour)?

**Attachments:**

- Business and Professions Code Sections 4827, 4830.8 & 4840.5
- California Code of Regulations Title 16, Section 2069- Emergency Animal Care
- Penal Code Section 596.7
- 2016/2017 Rodeo Reporting Data
- Sample Renewal Form Notifying Licensees of the Rodeo Reporting Requirement

**Action:**

- Provide a recommendation to the VMB regarding appropriate protocols for RVTs to provide onsite care and treatment to injured animals at rodeo events.

**Business & Professions Code**  
**Division 2. Healing Arts**  
**Chapter 11. Veterinary Medicine**  
**Article 2. Practice Provisions**

**§ 4827. Excepted Practices**

Nothing in this chapter prohibits any person from:

(a) Practicing veterinary medicine as a bona fide owner of one's own animals. This exemption applies to the following:

(1) The owner's bona fide employees.

(2) Any person assisting the owner, provided that the practice is performed gratuitously.

(b) Lay testing of poultry by the whole blood agglutination test. For purposes of this section, poultry means flocks of avian species maintained for food production, including, but not limited to, chickens, turkeys, and exotic fowl.

(c) Making any determination as to the status of pregnancy, sterility, or infertility upon livestock, equine, or food animals at the time an animal is being inseminated, providing no charge is made for this determination.

(d) Administering sodium pentobarbital for euthanasia of sick, injured, homeless, or unwanted domestic pets or animals without the presence of a veterinarian when the person is an employee of an animal control shelter and its agencies or humane society and has received proper training in the administration of sodium pentobarbital for these purposes.

Added Stats 1937 ch 933. Amended Stats 1945 ch 278 1; Stats 1955 ch 1158 2; Stats 1978 ch 1146 1; Stats 1995 ch 60 13.5 (SB 42), effective July 6, 1995; Stats 1999 ch 83 5 (SB 966).

**§ 4830.8. Report of Animal Injury Requiring Veterinary Treatment at Rodeo Event;  
Contents of Report; Posting Form on Internet Web Site**

(a) An attending or on-call veterinarian at a rodeo event shall, pursuant to Section 596.7 of the Penal Code, report to the board any animal injury at the event requiring veterinary treatment within 48 hours of the conclusion of the rodeo.

(b) A veterinarian, other than a veterinarian identified in subdivision (a), shall report to the board within seven days of rendering treatment to an animal for an injury that the veterinarian knows occurred at a rodeo event.

(c) A report submitted pursuant to this section shall include the title, location, and date of the rodeo event, the name of the attending veterinarian at the event, the name of the reporting veterinarian, the type of animal, and a brief description of the injury suffered by the animal. The board shall post a form on its Internet Web site to be used by veterinarians for purposes of submitting this report.

(d) For purposes of this section, rodeo has the same meaning set forth in Section 596.7 of the Penal Code.

Added Stats 2010 ch 538 8, 9 (AB 1980), effective January 1, 2011.

#### **§ 4840.5. Emergency Aid**

Under conditions of an emergency, a registered veterinary technician may render such lifesaving aid and treatment as may be prescribed under regulations adopted by the board pursuant to Section 4836. Such emergency aid and treatment if rendered to an animal patient not in the presence of a licensed veterinarian may only be continued under the direction of a licensed veterinarian. Emergency for the purpose of this section, means that the animal has been placed in a life-threatening condition where immediate treatment is necessary to sustain life.

Added Stats 1974 ch 1223 1. Amended Stats 1995 ch 60 25 (SB 42), effective July 6, 1995.

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

**§ 2069. Emergency Animal Care**

Emergency animal care rendered by registered veterinary technician.

Under conditions of an emergency as defined in Section 4840.5, a registered veterinary technician may render the following life saving aid and treatment to an animal:

(1) Application of tourniquets and/or pressure bandages to control hemorrhage.

(2) Administration of pharmacological agents to prevent or control shock, including parenteral fluids, shall be performed after direct communication with a licensed veterinarian or veterinarian authorized to practice in this state. In the event that direct communication cannot be established, the registered veterinary technician may perform in accordance with written instructions established by the employing veterinarian. Such veterinarian shall be authorized to practice in this state.

(3) Resuscitative oxygen procedures.

(4) Establishing open airways including intubation appliances but excluding surgery.

(5) External cardiac resuscitation.

(6) Application of temporary splints or bandages to prevent further injury to bones or soft tissues.

(7) Application of appropriate wound dressings and external supportive treatment in severe burn cases.

(8) External supportive treatment in heat prostration cases.

**NOTE**

Authority cited: Sections [4808](#) and [4836](#), Business and Professions Code. Reference: Section [4840.5](#), Business and Professions Code.

**Penal Code**  
**Part 1. Of Crimes and Punishments**  
**Title 14. Malicious Mischief**

**§ 596.7. Rodeos; Veterinarians Present at Performances; Violation of Section**

(a)(1) For purposes of this section, “rodeo” means a performance featuring competition between persons that includes three or more of the following events: bareback bronc riding, saddle bronc riding, bull riding, calf roping, steer wrestling, or team roping.

(2) A rodeo performed on private property for which admission is charged, or that sells or accepts sponsorships, or is open to the public constitutes a performance for the purpose of this subdivision.

(b) The management of any professionally sanctioned or amateur rodeo that intends to perform in any city, county, or city and county shall ensure that there is a veterinarian licensed to practice in this state present at all times during the performances of the rodeo, or a veterinarian licensed to practice in the state who is on-call and able to arrive at the rodeo within one hour after a determination has been made that there is an injury which requires treatment to be provided by a veterinarian.

(c)(1) The attending or on-call veterinarian shall have complete access to the site of any event in the rodeo that uses animals.

(2) The attending or on-call veterinarian may, for good cause, declare any animal unfit for use in any rodeo event.

(d)(1) Any animal that is injured during the course of, or as a result of, any rodeo event shall receive immediate examination and appropriate treatment by the attending veterinarian or shall begin receiving examination and appropriate treatment by a veterinarian licensed to practice in this state within one hour of the determination of the injury requiring veterinary treatment.

(2) The attending or on-call veterinarian shall submit a brief written listing of any animal injury requiring veterinary treatment to the Veterinary Medical Board within 48 hours of the conclusion of the rodeo.



(3) The rodeo management shall ensure that there is a conveyance available at all times for the immediate and humane removal of any injured animal.

(e) The rodeo management shall ensure that no electric prod or similar device is used on any animal once the animal is in the holding chute, unless necessary to protect the participants and spectators of the rodeo.

(f) A violation of this section is an infraction and shall be punishable as follows:

(1) A fine of not less than five hundred dollars (\$500) and not more than two thousand dollars (\$2,000) for a first violation.

(2) A fine of not less than one thousand five hundred dollars (\$1,500) and not more than five thousand dollars (\$5,000) for a second or subsequent violation.

CREDIT(S)

(Added by Stats.2000, c. 992 (S.B.1462), § 1. Amended by Stats.2007, c. 714 (A.B.1614), § 1.)





**STATISTICS FOR  
 RODEO INJURY REPORTS  
 As of 8/29/2016**

7/1/2013 - 6/30/2014	3
7/1/2011 - 6/30/2012	4
7/1/2009 - 6/30/2010	2
7/1/2007 - 6/30/2008	6
7/1/2005 - 6/30/2006	0
7/1/2003 - 6/30/2004	7
<b>Total</b>	<b>58</b>

\*These numbers are the number of individual reports received. Some of these reports contain injury reports for multiple animals.



**Veterinary Medical Board**

1747 N. Market Boulevard, Suite 230, Sacramento, CA 95834

Telephone: 916-515-5220 Fax: 916-928-6849 | [www.vmb.ca.gov](http://www.vmb.ca.gov)



## DCA'S BREEZE SYSTEM UPDATE

### IMPORTANT INFORMATION REGARDING YOUR RENEWAL

Expected to **launch in early-2016**, the Department's new BreEZe online system will incorporate all of the functionality of the Board's existing licensing system but in a new online environment, including capability to renew online and pay by credit card.

For those licensees **renewing in December and January**, prior to BreEZe launch, the Board strongly encourages you to **renew by mail early** in order to avoid renewal application delays due to the transition from the Board's existing licensing system to the new BreEZe system.

### SOCIAL MEDIA FOR THE VETERINARY MEDICAL BOARD (VMB)

The VMB would like to hear from you! Check us out of Facebook and Twitter at the following:



<https://www.facebook.com/pages/California-Veterinary-Medical-Board/1452060421747924>

*(See the VMB Website for a link to Facebook)*



<https://twitter.com/vetmedboard>

### RODEO INJURY REPORTS

Section 4830.8 requires veterinarians, whether attending or on-call for a rodeo event, to report to the VMB any animal injury that occurred at the event where veterinary treatment was provided. Such reporting must occur within 48 hours of the conclusion of the rodeo.

If you are not serving as the attending veterinarian for a rodeo event but subsequently treat an animal injured at a rodeo, you must report the injury and the treatment to the VMB within 7 days of treating the injured animal.

Specific reporting requirements and forms are available on the VMB's website at [www.vmb.ca.gov](http://www.vmb.ca.gov) under the "Licensees" tab.

### DIVERSION PROGRAM

The VMB offers a confidential program for the rehabilitation of veterinary practitioners impaired due to chemical dependency. The purpose of the Diversion Program is to identify and rehabilitate licensed veterinary professionals who are dealing with drug and/or alcohol abuse by providing counseling, intervention services, assessment of treatment needs and referral to appropriate resources, and assistance in development of a recovery plan among other support services.

Persons wanting to obtain information, arrange an intervention, or apply to the Diversion Program may call MAXIMUS at 800.522.9198.

### SUBJECT MATTER EXPERTS NEEDED FOR EXAMINATION DEVELOPMENT PROGRAM

Help make your profession better — join other active and committed practitioners by becoming a part of the examination development process! The Veterinary Medical Board (Board) is

looking for current licensed Veterinarians and Registered Veterinary Technicians actively working in California to help write and review test questions (items) for the Veterinary Medical Board and the Registered Veterinary Technician (RVT) examinations.

The two-day workshops, conducted in Sacramento, are led by personnel from the Department of Consumer Affairs' Office of Professional Examination Services. Item writing workshops start with instruction in question and answer writing and progress to composing them in a clear, relevant manner. Item review workshops are separate events that concentrate on ensuring test questions are correct, comprehensive, applicable to the practice, and are written at the appropriate level of difficulty.

What's in it for you? You get to feel good about your role in contributing to your profession by ensuring the examinations are current and relevant, and you can engage in spirited discussions on hot topics. Your travel expenses will be paid, you will receive a stipend, meet interesting colleagues, and you can earn up to 16 hours of continuing education credit.

Feedback from past participants indicates the experience is satisfying. Not only do you have the opportunity to have an impact on the examination, but you also acquire new knowledge from meeting and exchanging views with other practitioners from throughout the State who represent a diverse group in terms of their specialties, their years licensed, and their practice settings.

Invite a colleague to join you! Veterinarians and Registered Veterinary Technicians, particularly newly licensed individuals, from all areas of expertise are needed — exotic, feline, emergency, small animal, food animal, equine, dentistry, surgeons, etc.

If you are interested, go to the Board's website at [www.vmb.ca.gov](http://www.vmb.ca.gov) and follow the link to the application under "What's New" or call Jacqueline French at (916) 515-5220.

## **EXPERT WITNESSES NEEDED**

The Veterinary Medical Board is continually enhancing its enforcement program and is seeking people interested in participating as expert witnesses. An expert witness reviews complaints from the public and submits a written report of their findings to the Board.

In order to serve as an expert witness, you must:

- Hold a current and valid license to practice veterinary medicine in California
- Have at least five years' work experience in clinical practice
- Have knowledge of State laws, rules and regulations, and standards regarding veterinary medicine

If you would like additional information, please email Joely Walker at [joely.walker@dca.ca.gov](mailto:joely.walker@dca.ca.gov) or call (916) 515-5230

## **JOIN THE BOARD'S INTERESTED PARTY EMAIL LIST!**

In an effort to reduce our consumption of natural resources and streamline our business process, the Veterinary Medical Board is going to an all-electronic Interested Parties List. Signup is easy!

1. Go to [www.vmb.ca.gov](http://www.vmb.ca.gov)
2. Select 'Join Our Email List' under 'Quick Hits'
3. Select 'Subscribe' and enter your Email Address and Security Word

By joining the interested party list, you will be notified by email of important Board news and information, law changes, Board and Committee meetings, Newsletters, and much more.

## **Induction of Anesthesia vs. Sedation**

MDC Chair Dr. Klingborg developed the following statement in consultation with Dr. Jan Ilkiw and other UC Davis Faculty:

*The difference between anesthesia and sedation is that anesthesia results in loss of consciousness.*

*When looking at safety with some of these potent alpha-2 drugs, which can produce a state close to anesthesia, a patient that is sedated should still be responsive to its environment i.e., movement in response to environmental stimuli such as loud noises etc.*

*It is suggested that RVTs and veterinary assistants should not take animals deeper than this without a veterinarian presence as the risk of harm to the patient increases.*

### **Relevant Title 16 California Code of Regulations**

#### **2034. Animal Health Care Tasks Definitions.**

For purposes of the rules and regulations applicable to animal health care tasks for registered veterinary technicians and unregistered assistants, contained in the article, the term:

- (a) "Veterinarian" means a California licensed veterinarian.
- (b) "R.V.T." means a registered veterinary technician certified by the Board.
- (c) "Unregistered assistant" means any individual who is not an R.V.T. or a licensed veterinarian.
- (d) "Supervisor" means a California licensed veterinarian or if a job task so provides an R.V.T.
- (e) "Direct Supervision" means: (1) the supervisor is physically present at the location where animal health care job tasks are to be performed and is quickly and easily available; and (2) the animal has been examined by a veterinarian at such time as good veterinary medical practice requires consistent with the particular delegated animal health care job task.
- (f) "Indirect Supervision" means: (1) that the supervisor is not physically present at the location where animal health care job tasks are to be performed, but has given either written or oral instructions ( "direct orders") for treatment of the animal patient; and (2) the animal has been examined by a veterinarian at such times as good veterinary medical practice requires, consistent with the particular delegated animal health care task and the animal is not anesthetized as defined in Section 2032.4.
- (g) "Animal Hospital Setting" means all veterinary premises which are required by Section 4853 of the Code to be registered with the Board.

(h) "Administer" means the direct application of a drug or device to the body of an animal by injection, inhalation, ingestion, or other means.

(i) "Induce" means the initial administration of a drug with the intended purpose of rendering an animal unconscious.

Authority cited: Sections 4808, 4826 and 4836, Business and Professions Code. Reference: Sections 4836 and 4853, Business and Professions Code.

### **2036. Animal Health Care Tasks for R.V.T.**

(a) Unless specifically so provided by regulation, a R.V.T. shall not perform the following functions or any other activity which represents the practice of veterinary medicine or requires the knowledge, skill and training of a licensed veterinarian:

- (1) Surgery;
- (2) Diagnosis and prognosis of animal diseases;
- (3) Prescription of drugs, medicines or appliances.

(b) An R.V.T. may perform the following procedures only under the direct supervision of a licensed veterinarian:

- (1) Induce anesthesia;
- (2) Apply casts and splints;
- (3) Perform dental extractions;
- (4) Suture cutaneous and subcutaneous tissues, gingiva and oral mucous membranes,
- (5) Create a relief hole in the skin to facilitate placement of an intravascular catheter

(c) An RVT may perform the following procedures under indirect supervision of a licensed veterinarian:

- (1) Administer controlled substances.

(d) Subject to the provisions of subsection(s) (a), (b) and (c) of this section, an R.V.T. may perform animal health care tasks under the direct or indirect supervision of a licensed veterinarian. The degree of supervision by a licensed veterinarian over a R.V.T. shall be consistent with standards of good veterinary medical practices.

Authority cited: Sections 4808, 4826 and 4836, Business and Professions Code. Reference: Sections 4836, 4840 and 4840.2, Business and Professions Code.



**2036.5. Animal Hospital Health Care Tasks for Unregistered Assistants.**

(a) Unregistered assistants shall be prohibited from performing any of the functions or activities specified in subsections (a) (b) and (c) of Section 2036 of these regulations, except that an unregistered assistant under the direct supervision of a licensed veterinarian or registered technician may administer a controlled substance.

(b) Subject to the provisions of subsection (a) of this section, unregistered assistants in an animal hospital setting may perform auxiliary animal health care tasks under the direct or indirect supervision of a licensed veterinarian or the direct supervision of an R.V.T. The degree of supervision by a licensed veterinarian over an unregistered assistant shall be higher than or equal to the degree of supervision required when an R.V.T. performs the same task and shall be consistent with standards of good veterinary medical practices.

Authority cited: Sections 4808 and 4836, Business and Professions Code. Reference: Sections 4836 and 4840, Business and Professions Code.



# Multidisciplinary Advisory Committee Assignments

October 2016

## EXISTING PRIORITIES – Currently being addressed by MDC

- 1) **Evaluate Structure and Audit Enforcement Case Outcomes**  
*Complaint Process/Audit Taskforce -  
~~a. Expert Witness Subcommittee~~*
- 2) **Develop minimum standards for alternate premises (large animal, equine mobile, public and private shelter medicine, ambulatory, etc.)**
  - a. **Shelter Medicine Subcommittee**
- 3) **Review Business and Professions Code Section 4830(5) regarding veterinary student exemption, duties and supervision at a California veterinary university. (*Off –site surgery programs- should they be limited to 3<sup>rd</sup>/4<sup>th</sup> year students?*)**
  - (a) CCR Section 2027 Alternate pathway for Junior/Senior Students to obtain the RVT License
- 4) **Pursue "extended duty" for Registered Veterinary Technicians.**
  - a. **RVT Subcommittee**
- 5) **Develop regulations to implement the authorization for Veterinarians and RVTs under direct supervision to compound drugs.**
- 6) **Develop standards for on-site veterinary care at Rodeos.**
- 7) **Sedation vs Anesthesia – Definitions/Scope of Responsibility**

## FUTURE PRIORITIES

- 8) **Develop Minimum Standards for Spay and Neuter Clinics**
- 9) **Minimum Standards for Mobile Specialists - Responsibility for Case Management**
- 10) **Drug Counseling/Risks and Side Effects**



### **2030.35. Small Animal Spay/Neuter Clinic.**

#### Minimum Standards for Small Animal Spay & Neuter Clinics

a) Veterinarians working in a small animal spay/neuter clinic shall establish a VCPR prior to performing surgery as defined in 2032.1.

b) For purposes of these regulations, a "small animal spay/neuter clinic" shall mean a facility established to function as a veterinary premises that concentrates in providing spay and neuter surgical services to common domestic household pets and is required by section 4853 of the code to be registered with the board.

(c) A small animal spay/neuter 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 spay/neuter 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.

(d) A small animal spay/neuter 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 spay/neuter 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) A small animal spay/neuter 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.

(e) A small animal spay/neuter clinic shall provide either after hours emergency services to its patients or, if no after hours emergency care is available, the small animal spay/neuter 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.

(f) 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.

(g) The small animal spay/neuter clinic shall maintain all medical records as set forth in 2032.3 for a minimum of three (3) years from the date of the last visit.

(h) 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.