STATE OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS

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

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

AGENDA

Multidisciplinary Advisory Committee
1747 N. Market Blvd. – 1st Floor Hearing Room
Sacramento, California

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

1. Call to Order- Establishment of a Quorum
2. Introductions
3. Review and Approval of April 19, 2016 Meeting Minutes
4. Update on the Complaint Process Audit Task Force Subcommittee
5. Report from the Expert Witness Review Subcommittee
6. Update on Minimum Standards for Alternate Premises
7. Update on Survey of Public and Private Shelters and Discussion of Minimum Standards & Protocols for Shelter Medicine
8. Review and Discuss Veterinary Student Exemption [Duties and Supervision at University Hospitals]; Potential Recommendation to Full Board
9. Discussion and Consideration of "Extended Duty" for Registered Veterinary Technicians Regulations; Potential Recommendation to Full 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.
11. 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)).
12. Agenda Items and Next Meeting Dates – October 18, 2016 (TBD)
    A. Multidisciplinary Advisory Committee Assignment Priorities
    B. Agenda Items for Next Meeting
13. Adjournment

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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.

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MEETING MINUTES

Multidisciplinary Advisory Committee
1625 N. Market Blvd. – 1st Floor Hearing Room
Sacramento, California

9:00 a.m. Tuesday, April 19, 2016

1. Call to Order- Establishment of a Quorum

Multidisciplinary Advisory Committee (MDC) Chair, Dr. Jon Klingborg called the meeting to order at 9:08 a.m. Veterinary Medical Board Executive Officer, Annemarie Del Mugnaio called roll; eight members of the MDC were present and thus a quorum was established. Jennifer Loredo was absent.

2. Introductions

Members Present
Jon Klingborg, DVM
Allan Drusys, DVM
William Grant, DVM
Diana Woodward Hagle, Public Member
David Johnson, RVT
Kristi Pawlowski, Public Member
Jeff Pollard, DVM
Richard Sullivan, DVM, Board Liaison

Staff Present
Elizabeth Coronel, Enforcement Analyst
Annemarie Del Mugnaio, Executive Officer
Nina Galang, Administrative Program Coordinator
Kurt Heppler, Legal Counsel
Candace Raney, Enforcement Manager
Bryce Penny, DCA Webcast
Diann Sokoloff, Supervising Deputy Attorney General

Guest Present
Kathy Bowler, Veterinary Medical Board
Jonathan Burke, Department of Consumer Affairs
Nancy Ehrlich, RVT, California Registered Veterinary Technician Association
Valerie Fenstermaker, California Veterinary Medical Association
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 Medical Association
Dan Segna, DVM, California Veterinary Medical Association
Leah Shufelt, RVT, California Veterinary Medical Association
Cheryl Waterhouse, DVM, Veterinary Medical Board

3. Review and Approval of January 19, 2016 Meeting Minutes

The MDC made minor changes to Page 2, 5, and 6 of the proposed meeting minutes.

- Dr. Allan Drusys motioned and Dr. William Grant seconded the motion to approve the amended January 19, 2016 meeting minutes. The motion carried 8-0.

4. Update on the Complaint Process Audit Task Force – Report from the Expert Witness Review Subcommittee

Dr. William Grant updated the MDC regarding the audits performed by him and Dr. Pollard. Dr. Grant indicated that a meeting will be scheduled with Enforcement Manager, Candace Raney, and Ms. Del Mugnaio to review the next steps and for further case audits. Reviews will occur twice a year based on ebbs and flows of the volume of cases. This is an area that has proved to be beneficial for consistency in assessing expert review and application of standard of care.

Dr. Pollard updated the Subcommittee on work that he and Diana Woodward Hagle have been doing related to reviewing Expert Witness Guidelines and training. Expert Witness training is scheduled for May 4-5, 2016 in Sacramento, CA.

Adding more than two members to the Subcommittee would require discussions to be held in an open meeting; therefore, the MDC will keep the Subcommittee to two members.

Kristi Pawlowski inquired whether MDC and Board members may attend the Expert Witness training. Ms. Del Mugnaio confirmed that it is permissible, as long as there are no more than four members of the Board or MDC attending to avoid establishing a quorum.

Diana Woodward-Hagle suggested that the staff should provide a thorough overview of the complaint process and the Subcommittee should focus on the expert review part of the process.

Ms. Del Mugnaio suggested that the Subcommittee examine the quality and consistency in which the experts are applying the Practice Act. The MDC could consider creating a Subcommittee or panel to interview those who are interested in becoming an expert witness. The review may include developing questions for interviews and looking at expert witness writing samples. Expert witnesses need to understand Disciplinary Guidelines.

Enforcement Manager, Candace Raney, noted that the Board currently has 13 experts, with one application pending, and the Board is continuously recruiting. Ms. Del Mugnaio suggested that the Board does not currently interview the potential experts, but it may be a step that is added in the future.

Dr. Drusys suggested adding a communication skills assessment to the review process, in order to assess if the expert witness is able to communicate clearly to those not familiar with veterinary terminology.

Ms. Del Mugnaio shared that there may be challenges in finding quality experts and expressed that the Board would rather hire a smaller number of quality experts, rather than expand the pool to those less qualified.

Supervising Deputy Attorney General, Diann Sokoloff, added that the rough draft of the Complaint Review Worksheet is incorrect. It should be “and” instead of “or” when it refers to “incompetent” and “negligent.”

5. Update on Minimum Standards for Alternate Premises

Dr. Klingborg noted that the California Veterinary Medical Association (CVMA) Alternate Premises Task Force is ongoing. Dr. Klingborg and Dr. Sullivan are serving on the Task Force as Board liaisons and Ms. Del Mugnaio will be attending as well.

Ms. Hagle expressed challenges in navigating through the Practice Act via the index. Dr. Klingborg noted that the index is a product of the publishers and it is not within our power to change. Dr. Klinborg stated the Board will vote on the final language regarding alternate premises minimum standards.

6. Update on Report for Shelter Medicine Minimum Standards & Protocols

Dr. Drusys noted that he attended a joint meeting of the State Humane Association of California (SHAC) and California Animal Control Directors' Association (CACDA) at the Animal Care Conference. Dr. Drusys added that there was a misunderstanding that the work done by the Task Force was a product of the Board, and not a collective effort. Dr. Drusys suggested that we invite other stakeholders to engage in the discussion, as not to alienate other stakeholder groups from participating.

At the joint meeting of SHAC and CACDA at the Animal Care Conference, Mr. Johnson found that there is great concern in the community that the public was not included in the process to provide input. The public felt that decisions had already been made based on the CVMA Task Force, and as a result, efforts will be made to better involve stakeholders in the discussion.

Ms. Del Mugnaio noted that one major concern that was discussed at the Animal Care Conference was how the ownership of the animal changes within the shelter environment. The second major concern is determining what should be exempt from the Practice Act within the shelter environment, e.g. vaccinations and parasite control, and what level of supervision is appropriate for the animal shelter staff.

Mr. Johnson identified, in his opinion, three different types of "animal shelters": 1) municipal shelters (government entities termed "animal control agency" or "animal shelter"), 2) humane societies (ownership is relinquished by owner to humane society), and 3) a hybrid model in which humane societies inherit city or county contracts for animal control (non-governmental agency with animal control responsibilities, by contract). Not all shelter types are the same and a decision must be made whether or not it should fall under the purview of the Board and if so, which type of "animal shelters" should require a premises permit.

Dr. Grant added that there are private veterinary hospitals that are taking on sheltering responsibilities, which is another example of a different animal shelter type.

Dr. Drusys suggested doing more research with SHAC and CACDA regarding what types of premises are out there and which ones have premises permits. The findings will then be brought before the MDC and Board for further discussion and to determine if the Practice Act applies. Dr. Drusys also added inviting CACDA and SHAC to the next MDC meeting to participate in the discussion.

Business and Professions Code (BPC) section 4840 is related to BPC section 4840.2 in terms of "written order." Mr. Johnson shared his concern that "direct order," "written order," and "telephone order" can be interpreted as three distinct types of orders. Additionally, Dr. Klingborg noted that BPC section 2034(f) refers to "direct orders" as "written or oral instructions." The MDC agreed that the various terms used create confusion.

The MDC discussed reaching out to various organizations to collect on the various types of animal shelters that exist and how they operate, and also engage in a discussion with SHAC and CACDA regarding the findings. Following that, Dr. Drusys suggested holding an open forum meeting with all stakeholders including SHAC and CACDA at the October MDC Meeting.

The MDC discussed using the number of impound shelters, number of employees, and whether or not they have a veterinarian and/or Registered Veterinary Technician (RVT) on staff as the basis for the statistical analysis. Additionally, the animal shelter guidelines on the Board's website could be used as part of the Subcommittee's discussion. In-person testimony, telephonic testimony and/or presentation slides could be helpful for the October MDC meeting.

Mr. Johnson suggested beginning the research by determining how many premise permits the Board has on file.

- Dr. Richard Sullivan motioned and Dr. William Grant seconded the motion to direct the Subcommittee to gather and analyze all relevant statistics and data with the assistance of staff, and prepare for an open forum with interested parties at the October MDC meeting. The motion carried 8-0.

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

Dr. Klingborg explained that there has been some confusion regarding which type of students, schools, and off campus educational programs are covered under the Veterinary Student Exemption, BPC section 4830(a)(5).

Ms. Woodward-Hagle noted that her findings have changed since they were last presented at the October 2015 Board meeting. It appears that students are receiving clinical instruction at off-campus locations. The issue is that the off-campus, clinical program exemptions are intertwined with the statutory and regulatory definitions of animal healthcare tasks within the Veterinary Practice Act. Additionally, animal healthcare tasks are spelled out for third and fourth year veterinary students, but not first and second year students.

Ms. Woodward-Hagle recommended the following changes:

1) Direct the off-campus San Diego clinic used to instruct UCD students to be a registered premises
2) Define off-campus locations where clinical instruction takes place as "off-campus educational program sites"
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 first and second year students in off-campus settings as "veterinary assistants," say so definitively.
5) Consider the proposed framework regarding particular animal health care tasks, and the degree of supervision which veterinary students may perform at off-campus educational settings, to be determined by veterinarians.

Dr. Klingborg identified differences in the California Code of Regulations (CCR) section 2027, compared with BPC section 4830(a)(5). The student described in CCR section 2027 is a junior or senior veterinary student, authorized to perform animal healthcare tasks, not necessarily as part of their educational program. The student described in BPC section 4830(a)(5) can perform surgery, whether on-campus or off-campus, as part of an educational program.

Ms. Woodward-Hagle expressed support for creating a separate statute(s) dealing with students in the clinical experience.

Dr. Klingborg clarified that BPC 4830(a)(5) addresses AVMA accredited schools instead of only UCD or Western University.

Dr. Sullivan expressed two issues: 1) the need to expand the regulations is unclear and 2) the Board would need to have a contract established with the out-of-state school to be considered an approved program. Dr. Sullivan added that the first priority should be UCD and Western University of Health Sciences students and expressed no issue with surgery, as long as it is attached to an approved part of the veterinary education program, especially where liability is concerned.

Dr. Grant agreed that "diagnosis and treatment" encompasses "surgery."

Dr. Pascoe, Executive Associate Dean at UCD, noted that the interpretation of BPC section 4830(a)(5) has been an ongoing problem and the issue comes down to surgery. UCD proposed two major changes: 1) not restrict the regulations to UCD and Western University of Health Sciences and 2) any student from an AVMA accredited school in a California practice must have completed foundational training before doing spay or neuter type surgery.

Dr. Pascoe added that, from a specialty college perspective, "direct supervision" is understood to mean that the veterinarian must be in the operating room. Dr. Pascoe also added that the San Diego site is considered a part of UCD and is not considered as "off-campus" by UCD, even though it is physically located in a different area.

Ms. Woodward-Hagle expressed that it was not clear that one section addresses tasks and the other addresses exemptions. Rather than creating a comprehensive task list, Dr. Pascoe suggested framing the language to be like BPC section 4830(a)(5) and should be crafted as all-encompassing "umbrella" language over all educational activity since UCD and Western University have different educational approaches.

Dr. Pascoe clarified his understanding that in order to be promoted to fourth year, a student doing an externship would have to have completed all pre-clinical training. The only way that the student would be covered under the University's general liability insurance would be for a formal contractual agreement to exist between the university and the premises. Dr. Sullivan clarified his understanding that if a contract is in place, the student would fall under the exemption of BPC section 4830(a)(5).

Ms. Del Mugnaio expressed that there may be some discomfort if the language opens it up to all AVMA accredited programs. If students are coming from out-of-state from universities where externships are not part of the curriculum, it may not be covered under the University's general liability insurance and would have no authority to practice unless they are under some provision of the code. Opening up the language in BPC section 4830(a)(5) to include all AVMA accredited programs would provide an exemption beyond UCD and Western University students. There is no assurance that those students operating in California under an externship are under the curriculum of their (out-of-state) University.

Dr. Pascoe expressed support with opening up BPC section 4830(a)(5) to AVMA accredited schools as long as the student coming from out-of-state is under direct supervision while performing surgery.

Dr. Grant noted that BPC section 4830(a)(5) is differentiated from CCR section 2027 in that it includes the language "as part of their educational experience." Ms. Del Mugnaio clarified that if it is part of their

curriculum and it is performed under direct supervision as part of their AVMA accredited University program, it will fall under the proposed exemption.

Dr. Drusys identified AVMA accreditation as an issue in question and added that foreign graduates would have no legal opportunities to perform the same duties.

Mr. Heppler interpreted BPC section 4830(a)(5) as a blanket exemption and CCR section 2027 is an authorization of what you can do. It is up to the Board to make sure that there is clarity through regulations.

Dr. Sullivan expressed concern regarding not having control over out-of-state schools, only the clinician or the practice. He expressed support only if there is a concrete benefit to adding AVMA accredited schools to the language.

Dr. Klingborg confirmed that the intent of CCR section 2027 was to expand the language so that it limits junior and senior students to only perform RVT tasks if they are not in an educational program, but rather working a part time job.

Dr. Pascoe clarified that clubs are not considered part of the veterinary program and from a liability perspective, are considered independent of the school. Students are prohibited from doing more than what is part of the educational program. Dr. Klingborg inquired whether students are qualified as students while they are on break. Dr. Pascoe confirmed that a student is a student from the time of admission until graduation.

Dr. Klingborg identified four main points of the discussion:

1) Should AVMA accredited schools be added?
2) Should surgery be added?
3) Should the phrase "provided the student has satisfactorily completed training and the activities as part of the formal curriculum of the veterinary program" be added?
4) Should the phrase "provided such off campus training is an approved part of the veterinary student's educational program" be added?

Dr. Sullivan expressed support for adding "surgery," but not under the current definition of "direct supervision." The MDC agreed to add "immediate supervision" as the fifth point of discussion.

Dr. Klingborg requested feedback from the MDC on each of the five points identified.

The MDC agreed that all AVMA accredited schools should be added.

Dr. Klingborg decided to skip the "surgery" and "immediate supervision" points since they are related.

Ms. Del Mugnaio clarified that you cannot hold a veterinarian responsible for completing the training because they are not the program, they are only responsible for providing supervision.

Mr. Heppler clarified that BPC section 4830 is not about "sites," it is about the program.

Dr. Klingborg referenced that the proposed RVT student exemption language used for their final year of study as follows: "individuals who have, in the opinion of program instructors, have knowledge and familiarity with RVT animal health care tasks and have completed a sufficient portion of the classroom and clinical instruction set forth in subsections..."

Mr. Johnson recommended mimicking the language in CCR section 2035, Duties of Supervising Veterinarians over RVTs, to develop language of the duties of supervising veterinarians over students.

Supervising Deputy Attorney General, Diann Sokoloff, warned against using the word "sufficient" because it is subjective and cannot be measured. Dr. Klingborg suggested striking language.

The MDC discussed whether the responsibility should fall on the University or the person engaged in direct supervision.

Dr. Klingborg suggested striking the word "completed" with regard to the proposed RVT language.

Dr. Dan Segna noted that past conversations regarding this topic limited the language to only third and fourth year students, instead of specifying UCD, Western University and AVMA accredited schools.

Dr. Mark Nunez spoke in favor of keeping the language regarding completing the training as a matter of consistency with the RVT student exemption regulatory language.

Mr. Johnson noted that "treatment" is used in RVT job task descriptions and therefore, is not necessarily interpreted as "surgery." Dr. Klingborg agrees with adding "surgery."

Dr. Grant recommended removing "satisfactorily completed" and keeping the following proposed RVT language: "participate in diagnosis, treatment, and surgery as part of their educational experience provided the student has training in these activities as part of the formal curriculum of the veterinary program." Ms. Pawlowski suggested placing "diagnosis and treatment" under direct supervision and "surgery" under immediate supervision.

The MDC also agreed to keep the last part of the sentence: "provided such off-campus training is an approved part of the veterinary student's curriculum."

Under CCR section 2027, graduates are considered unlicensed until they pass their Board exams and can be cited for unlicensed activity. Ms. Ehrlich suggested amending the language to allow third year veterinary students to be eligible to sit for the RVT exam.

Mr. Heppler expressed that CCR section 2027 stands as an exemption for the student, not the graduate. Ms. Del Mugnaio noted that statute authority would need to be amended in order to add a graduate exemption as referenced in CCR section 2027. The MDC suggested removing "graduate" from CCR section 2027.

Dr. Klingborg noted that it is not on the agenda to open up a new pathway for taking the RVT exam and it is best to capture it and discuss it at a future meeting.

Ms. Del Mugnaio reviewed the proposed additions to BPC section 4830(a)(5): AVMA accreditation, direct supervision of treatment and diagnosis, immediate supervision of surgery, "provided the student has training in the activities" (includes all educational programs, not just off-campus program), supervision by a licensed veterinarian in good standing.

- Dr. William Grant motioned and David Johnson seconded the motion to direct staff to craft language in Business and Professions Code section 4830(a)(5) based on discussion and bring back before MDC. The motion passed 8-0.

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

Mr. Johnson provided background information on "Extended Duty" for RVTs and clarified that the issue is aimed to address is access to services, not advancing a person or profession within the practice of veterinary medicine. Support was received throughout the community regarding the issue; however, only general concepts were presented.

BPC section 2069 clearly defines some RVT activities, but should be revisited since it has not been updated in several years. Mr. Johnson suggested the castration of male cats, administration of rabies vaccination, issues within the dentistry field, home care services, and tasks within the animal shelter environment as examples of potential "Extended Duty" RVT tasks.

The MDC discussed reaching out to shelters on the issues, identifying who the stakeholders are, inviting various groups to the public MDC meetings and attending outside meetings.

The MDC agreed that consumer protection must be addressed when considering the regulations.

Ms. Pawlowski expressed concerns for the animal's health since RVT's have not been trained in surgery. Mr. Johnson clarified that these functions would be performed in shelter environments where the animals are not owner-owned and documented training would be required.

Dr. Klingborg added that he will reconstitute the Task Force since the other member has been unavailable and asked Mr. Johnson to continue serving on the Task Force.

Nancy Ehrlich stated that the California Registered Veterinary Technician Association (CaRVTA) has not taken an official position on the matter, but would be happy to provide an official position. CaRVTA can discuss the matter at their annual meeting will be held on July 23, 2016 at UCD.

9. Update from Sunset Review Hearing

Ms. Del Mugnaio noted that the Sunset Review background paper is the Senate Committee on Business, Professions and Economic Development and Assembly Committee on Business and Professions Joint Legislative (Committee's) response to the Board's Supplemental Sunset Review Report. On March 14, 2016, Dr. Nunez, Mr. Johnson, and Ms. Del Mugnaio attended a hearing to testify on behalf of the Board on the issues contained in the background paper. On April 20, 2016, the Board will review the Board's written response to the Committee's recommendations.

Ms. Del Mugnaio, Dr. Sullivan, and Valerie Fenstermaker (CVMA), attended a hearing on Senate Bill (SB) 1195. The Bill was found to be unpopular amongst the boards at the Department of Consumer Affairs because it contains the North Carolina provisions on Anti-Trust, which is a highly controversial topic at the moment. The Board will continue to watch the SB 1195.

Ms. Del Mugnaio reviewed the issues and Committee's recommendations contained within the background paper.

The MDC felt that Issue #2, regarding RVT issues persisting and not being addressed, was misrepresented by CaRVTA. Past MDC and Board meeting minutes show that RVT issues have been discussed and there has been a great track record of addressing these issues.

In order to demonstrate that RVT issues are a priority and provide a level of certainty that the issues are not being forgotten, the MDC expressed support for including a standing RVT agenda item for future meetings.

Dr. Grant used the accreditation of RVT Schools as an example of an RVT topic that the MDC has spent a great deal of time discussing. Dr. Grant shared that he spoke with the American Veterinary Medical Association (AVMA) regarding what the AVMA Council on Education (COE) requires from RVT schools seeking accreditation and the standards are much more stringent than what is required in California.

The MDC agreed that there is misinformation being presented by CaRVTA regarding the handling of RVT issues and work needs to be done on improving the perception.

The Committee's recommendation for Issue #4, regarding University Licensure, is that university-employed veterinarians should be licensed. Testimony was given from UCD and the Committees agreed to carry the statutory change.

Regarding Issue #5, Delinquent Registration Status, there is currently no provision to cancel a premises permit. As a result, the Committee has agreed to carry statutory language to authorize the cancellation of a premises permit after five years if it is not renewed.

Issue #6, Compounding of Drugs, is now in SB 1195. Ms. Del Mugnaio added that the bill will change and her understanding is that amendments will be made to the current statutory structure to become broader and provide a grant of authority for veterinarians and RVTs under supervision, to compound drugs. The Board and the California Board of Pharmacy will craft regulations to address limitations for veterinarians in compounding drugs.

A Task Force is being created to address Issue #7, Animal Rehabilitation. The Board President will provide an update on the progress at the Board meeting on April 20, 2016.

There is nothing in SB 1195 that speaks to Issue #8, Animal Injuries at Rodeo Events. At the Board meeting on April 20, 2016, the Board will discuss whether or not to accept the Committee's recommendation. Mr. Johnson added that he will look into this as a potential "Extended Duty" for RVTs.

Issue #9, Use of Antimicrobial Drugs, involves SB 27 and SB 361; however, SB 1195 contains a change (originally contained within SB 361) regarding the one hour of continuing education on the judicious use of antimicrobial drugs. Beginning January 1, 2018, veterinarians will be required to take coursework and the Board will begin auditing the completion of the coursework in 2022. The Board has begun working with California Department of Food and Agriculture (CDFA) on establishing stewardship guidelines and best practices. It will likely be a two year adhoc Task Force with the Board of Pharmacy, CDFA and stakeholders in the livestock industry.

Dr. Grant shared that there is a segment on the accredited veterinary course on the judicious use of antimicrobials through the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) that could be utilized. Ms. Del Mugnaio noted that CDFA is aware.

Issue #10, Increased Inspection of Veterinary Premises, will create a budgetary impact as the Board will need to hire more inspectors in order to meet the goal of inspecting 20 percent of all hospitals on an annual basis. The Committee's have asked for more information regarding the Board's current resources and the Committees will then assist the Board in getting the additional resources through the budget process.

With the regards to Issue #11, Formal Discipline, the Committee requested more information on the Board's efforts to reduce the timeframe for taking formal disciplinary action against a licensee. The

Board has found that the most advantageous practice has been to set internal benchmarks to hold ourselves to, which helps stay on top of the progress of the case.

The Committee's recommendation for Issue #12, Continuation of the Veterinary Medical Board, was to extend the Board for another four years, which is the maximum length that the Committees may extend a 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)).

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

11. Agenda Items and Next Meeting Dates – July 19, 2016 (TBD); October 18, 2016 (TBD)

Ms. Del Mugnaio noted that either the July or October 2016 meeting will be held in Southern California.

A. Multidisciplinary Advisory Committee Assignment Priorities

Dr. Klinborg noted that the Animal Dentistry item was removed from the priorities list at the January 19, 2016 MDC meeting, therefore, it is not a future priority.

Dr. Grant suggested bringing forward spay and neuter clinic standards (mobile, fixed premise, etc.) to the Board at the next meeting as a potential MDC assignment priority.

B. Agenda Items for Next Meeting

Ms. Del Mugnaio reviewed the agenda items for the next meeting:

- Expert Witness Training
- Shelter Medicine
- Minimum Standards for Alternate Premises
- Veterinary Student Exemption
- Extended Duties for RVTs
- When DVM Students and Graduates may sit for the exam
- Spay and Neuter Clinic Standards.

12. Adjournment

The MDC adjourned at 3:04 p.m.

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MEETING AGENDA

MDC Complaint Process Audit Task Force
Veterinary Medical Board Conference Room
1747 N. Market Blvd., Suite 236
Sacramento, CA 95834

9:00 a.m., Wednesday, June 1, 2016

Taskforce Members: Dr. William Grant, II
Dr. Jeff D. Pollard

Board Staff: Annemarie Del Mugnaio, Executive Officer
Candace Raney, Enforcement Program Manager

Purpose: To review enforcement cases and identify areas of opportunity for process improvement of complaint handling with a focus on examining expert witness reports (opinions) and ultimate case outcomes.

Audit Findings: The taskforce met and conducted a review of 3 cases jointly. Upon completing the audits, Dr. Grant and Dr. Pollard met with Annemarie and Candace to share insight regarding the quality and consistency in the expert witness reports and opinions, as well as general comments regarding the process:

- *Cases reviewed prior to 2013 seemed to be more inconsistent in terms of the expert's conclusion regarding standard of care and also knowledge and application of the Veterinary Medicine Practice Act.*

- *A number of experts do not follow the standard template which makes following the sequence of events more difficult.*

- *Experts receive so much information pertaining to a case, but much of the information is anecdotal (comments) and letters by Board staff requesting further information relative to the complaint, but such information may not substantiated facts or statements supported by facts. Weeding through the material may make it more difficult for the expert to base their opinion on the documented facts as opposed to comments or conjecture.*

- *Experts need to examine whether the deviation from the standard of care resulted in a poor outcome (patient harm), or was there no correlation between the substandard care and the outcome. This is vital to the formulated opinion.*

- *There needs to be consistency AND validity with the EW evaluations at all levels, including evaluation of the medical/surgical aspects and referencing to the appropriate statute(s). This is particularly important with regard to the PROCESS that the respondent*

worked through. If the Respondent approached the case through a logical algorithm with appropriate Diagnostics and Rule Outs but had a negative outcome, then the respondent was within the standard of care. This was not evidenced in the case reviews.

- *Motivation for complaint? Should this be considered by the EW? (Expert Witness) e.g.; one of the cases reviewed resulted in no harm to the patient yet complainant argued that the correct diagnosis wasn't arrived at as expediently as desired.*

- *The order in which an expert reads case material may have an impact on their opinion and one should be cognizant of the potential for subconscious bias.*
  For example, the typical linear review may look like this: complaint ➔ investigation/inspection ➔ expert witness report ➔ hearing decision or settlement agreement (if after reviewing multiple cases with prior discipline). What if the expert read the expert witness report before the complaint? Would this change the expert's initial perspective of the case?

- *Unfortunately, it is clear that the EW's are aware of the case outcome prior to evaluating the respondent's diagnostic algorithm. [Correlation from Dr. Grant : To digress for a moment, when I was sitting on the VMB Anghoff Exam Committee we used to have the test key available while we were taking the exam. When we began taking the examination without the key available, as the candidates do, the exam became much more difficult and subsequently the pass point changed. The point is evidenced with reference to the EW's outcome influence in determining the standard of care.*

- *One of the cases reviewed involved a DDx (differential diagnosis) that was too narrow; i.e., the list of possible diagnoses did not include that which was ultimately confirmed. Yet, many times, medical records are written so verbosely and include a universe of DDx considerations so vast as to be unrealistic. (e.g., could the mosquito I just shooed off my arm have been carrying malaria? Sure, in the world of all possibilities; but in San Diego, most probably not.*

  Thus it falls to the EW to REALISTICALLY evaluate the case and the evidence in as pragmatic and unbiased a way as possible.

- *Another thought, related to the EW in only a peripheral way: in the majority of cases reviewed, the respondent provided a completely ineffectual response letter or worse, no response letter, to the initial complaint. This may suggest: a) they misunderstand the enforcement analyst's request; b) don't take it seriously, c) follow ill-informed legal counsel, d) other.*

- *It seems a number of issues have been identified in the review of old cases, most of which have been addressed in current and future EW training modules. Perhaps the next step for MDC Audit Review Taskforce is to establish a goal for review of more current resolved cases. For example, an annual/biannual review of cases selected by any of: VMB, enforcement staff, or DAG office, with the goal of continuing a certain level of quality control.*

VETERINARY MEDICAL BOARD

EXPERT WITNESS OVERVIEW

Summary of Facts Presented:

First, write a summary of the facts taken from the records provided to you by the Board. Arranging the facts in chronological order is the best approach---be sure to include dates and, if relevant, times.

A complaint will, in most cases, be part of the records. Include only the factual recitations of the complainant, not the complainant's opinion or allegations of wrongdoing.

Sometimes there will be factual discrepancies in the records. Do note these discrepancies in your summary, but understand that you may or may not be able to resolve the discrepancies.

Spend a good deal of time writing this factual summary. It is important to you, since it is the "four corners" of the facts on which you will base your expert opinion of the veterinarian's conduct.

Remember that your expert opinion will be based on records reciting observations seen or heard by someone other than yourself. Most often, these persons will be the complainant (a consumer or an employee) or the Board hospital inspector who has visited the premise in question, has observed the practice, and has inspected records. These persons are "percipient witnesses", for obvious reasons. In contrast, you are an "expert witness", and you are basing your expert opinion on the information ("facts") you are given by the "percipient" witnesses.

It is possible that the "facts" in the records presented to you may turn out to be incomplete, misleading or just not true. However, you must assume the facts are true for the purpose of writing your expert witness report.

Evaluation and Findings:

Your task as an expert witness is to evaluate a veterinarian's standard of care in regard to the care of an animal. "Standard of care" is also sometimes called "standard of practice" and is the competent and humane practice of veterinary medicine currently practiced in the State of California.[1]

The expert is expected to use his or her experience to realistically evaluate the veterinarian's conduct (or non-conduct) in light of the resources; equipment; training; knowledge; medical history, condition, age and breed of the patient; relationship and communication with the client;

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[1] See Title 16 California Code of Regulations section 2032.

and all other attendant circumstances that the veterinarian was faced with which gave rise to the complaint. It is not a "gold standard".[2]

Experts should be aware of Title 16 CCR Sections 2032 (**Minimum Standards of Practice)** and 2032.05 (**Humane Treatment**):

> Section 2032 states, "The delivery of veterinary care shall be provided in a competent and humane manner. All aspects of veterinary medicine shall be performed in a manner consistent with current veterinary medical practice in this state." This clarifies not only that veterinary medicine must be practiced to "current" standards, but also that standard of practice care means in the State of California and not in a specific local town or county.
>
> Section 2032.05 states, "When treating a patient, a veterinarian shall use appropriate and humane care to minimize pain and distress before, during and after performing any procedure(s)." This defines "humane" practice.

If---after reading all the documents provided by the VMB Enforcement staff---the expert finds that the veterinarian has departed from the appropriate standard of care in some, many or all aspects of the care of an animal, these departures must be explained by the expert in the expert witness report. The report will set forth the expert's opinion of the appropriate standard of care and how the veterinarian's conduct (or non-conduct) departed from the appropriate standard of care. And the report will explain why adhering to the standard of care is important in the circumstances.

Departures from standards of care fall into categories. In regard to the categories of negligence and incompetence (both violations of the Practice Act[3]), it is the expert's task to explain why a veterinarian's departure from an appropriate standard of care was negligent or incompetent. Any such departure must, of course, have a nexus between the conduct (or non-conduct) of the veterinarian and the practice of veterinary medicine.

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[2] "Standard of care 'is a matter peculiarly within the knowledge of experts; it…can only be proved by their testimony.' This is because '[t]he standard of care in a … malpractice case requires the [veterinarian] exercise in diagnosis and treatment that reasonable degree of skill, knowledge and care ordinarily possessed and exercised by members of the [veterinary] medical profession under similar circumstances." *Quigley* v. *McClellan* (____) 214 Cal.App. 4th 1276, 1283. Similarly, the appropriate standard of care is "the level of skill, knowledge, and care in diagnosis and treatment that other reasonably careful veterinarians would use in the same or similar circumstances". California Civil Jury Instructions, _____.

[3] Bus. & Prof. Code section 4883(i) states that "[t]he board may deny, revoke, or suspend a license or registration or assess a fine as provided in Section 4875 for any of the following:…(i)Fraud, deception, negligence, or incompetence in the practice of veterinary medicine".

1. Negligence [Business & Professions Code section 4883(i)].

To prove negligence, the Board must show that the veterinarian failed to meet the appropriate standard of care. Injury or death of the animal resulting from the veterinarian's conduct (or non-conduct) does not necessarily mean that the veterinarian was negligent in the care of the animal; conversely, survival of an animal does not mean that the standard of care has been met.

As professionals, veterinarians have discretion in practicing veterinary medicine. Picture the scope of discretion as a circle; inside the circle may be different ways of caring for an animal, all within an appropriate standard of care, even though the expert might have done things differently. However, if the expert is of the opinion that the veterinarian's conduct (or non-conduct) falls outside the circle, that exceeds permissible discretion and the expert will find negligence on the part of the veterinarian, i.e., the veterinarian has departed from the appropriate standard of care. The discretionary circle a useful tool for the expert in analyzing a veterinarian's conduct because the standard of care is dynamic---"…it evolves due to court rulings, advances in [scientific] research, continuing education, and the progression of the practice of [veterinary] medicine".[4]

2. Incompetence [Business & Professions Code section 4883(i)]

A person who is incompetent is incapable of discharging professional veterinary medical obligations because of lack of ability or knowledge.

Incompetence means that the veterinarian does not know how to do something, while negligence means that the veterinarian knows what to do, but fails to do it as the average reasonable veterinarian would in the same or similar circumstances. Sometimes it is difficult to tell the difference between negligence and incompetence, especially from just a written record, but both are violations of Bus. & Prof. Code section 4883(i).

3. Unprofessional Conduct [Business and Professions Code section 4883(g)]

This is a valuable section for the expert, since there may be facts in the Investigative Report which are actionable, but do not fit neatly into the negligence or incompetence categories. Unprofessional conduct is variously defined as immoral, dishonest or dishonorable conduct, "…or such conduct which is unbecoming member of profession in good standing".[5]

[4] Dental Board meeting notes, 2014.

[5] Black's Law Dictionary (1951 ed.)

4. Statutory and Regulatory Standards

The Veterinary Medicine Practice Act (Bus. & Prof. Code sections 4800 et seq) is composed of statutes. Statutes are enacted by the state legislature. Regulations implementing the Act (Title 16 California Code of Regulations sections 2000 et seq) are the product of agency (~~DCA~~ *VMB*) action and "flesh out" the Act's provisions with more specific guidance.

In addition, there are statutes and regulations (both federal and state) other than those in the Veterinary Practice Act and Title16 CCR which regulate the practice of veterinary medicine. For example, some statutes and regulations in the state Pharmacy Law apply to the practice of veterinary medicine.

Many of these statutes and regulations have clearly spelled out standards (especially in regard to dangerous drugs and controlled substances) which require no expert interpretation. However, the expert should be familiar with regulations pertaining to written prescriptions [16 CCR section 2032.2], record keeping [16 CCR section 2032.3] and administration of anesthesia [16 CCR section 2032.4]. This list is not exclusive.

CVMA CALIFORNIA VETERINARY MEDICAL ASSOCIATION

1400 River Park Drive, Suite 100
Sacramento, CA 95815-4505
916-649-0599
fax 916-646-9156
staff@cvma.net
www.cvma.net

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.

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.

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?

STATE OF CALIFORNIA
dca
DEPARTMENT OF CONSUMER AFFAIRS

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

LEGAL AFFAIRS DIVISION
1625 N. Market Blvd., Suite S 309, Sacramento, CA 95834
P (916) 574-8220 F (916) 574-8623 | www.dca.ca.gov

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.

Multidisciplinary Advisory Committee
California Veterinary Medical Board
Meeting: January 19th, 2016

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

FACTS

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

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

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

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

QUESTIONS

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

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

ANSWERS

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

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

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

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

DISCUSSION

"Animal Health Care Tasks"

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

Junior and Senior Veterinary Students

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

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

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

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

(1) Surgery;

(2) Diagnosis and prognosis of animal diseases;

(3) Prescription of drugs, medicines or appliances.

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

(1) Induce anesthesia;

(2) Apply casts and splints;

(3) Perform dental extractions;

---

[3] Captioned, **"Graduates and Students of Veterinary Colleges - Job Tasks"**.

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

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

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

[7] Captioned, **"Animal Health Care Tasks for R.V.T."**.

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

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

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

(1) Administer controlled substances.

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

Freshman and Sophomore Veterinary Students

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

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

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

[8] Section 2034(c) defines "unregistered assistant" as "…any individual who is not an R.V.T. or a licensed veterinarian."
[9] Captioned, **"Animal Hospital Health Care Tasks for Unregistered Assistants"**.
[10] Note that the "animal hospital" need not be registered with the board.
[11] "Auxiliary animal health care tasks" is not defined.

Exemptions

(Business & Professions Code sections 4828, 4830)

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

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

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

….

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

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

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

(1) The student is attending one of the two AVMA-rated California veterinary schools;

(2) The student is "…participat[ing] in diagnosis and treatment…";

(3) Performing the tasks must be "…part of [the student's] educational experience…".

(4) When the "educational experience" is off campus, the student must be in an "…off campus educational program…".

(5) The student must be "under the direct supervision of a licensed veterinarian in good standing…appointed by [one or the other of the two California veterinary schools]."[14]

---

[12] "Practice of veterinary medicine" is defined in Bus. & Prof. Code section 4826.

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

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

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

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

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

COMMENTS/RECOMMENDATIONS

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

Even without more, this is an obvious anomaly.

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

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

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

[15] See Bus. & Prof. Code section 4825.1(a) for the definition of "diagnosis".

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

[17] This language appears in Bus. & Prof. Code section 4854.5.

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

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

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

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

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

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

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

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

(1) _____

(2) _____

Etc…..

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

_____.

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

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

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

COE Accreditation Policies and Procedures: Off-campus

March 2014

8. Off-campus and Distributive Sites

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

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

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

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

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

STATE OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS

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

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

MEMORANDUM

DATE	July 5, 2016
TO	MDC
FROM	Annemarie Del Mugnaio, Executive Officer DCA/Veterinary Medical Board
SUBJECT	**Compounded Medications and Veterinary Practice**

Background:

Senate Bill 1193, Hill includes a provision that authorizes a veterinarian and an RVT under direct supervision, to 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 which shall at a minimum address the storage of drugs, the level and type of supervision required for RVTs, and the necessary equipment for safe compounding.

In early 2016, the MDC and the Board reviewed text as crafted by Deputy Attorney General (DAG) Joshua Room which was intended to serve as a statutory grant of authority for veterinarians to compound drugs. After further consideration and input from stakeholders, a decision was made to scale back the statutory text to a broad grant of authority and instead use the regulatory scheme to make specific the requirements for compounding drugs within a veterinary practice, including both FDA-approved drugs, and compounding from bulk drug substances.

At the April 20, 2016 VMB meeting, the Board delegated to the MDC, the charge of developing regulatory text to further implement the statutory provision in SB 1193. As such, Dr. Klingborg revisited the work started by DAG Room and began incorporating edits to address issues raised by the professional community for the purpose of generating discussion before the MDC.

The following are pertinent federal and state provisions that must be considered in developing regulations (attached):

- Code of Federal Regulations Title 21, Part 530.13
- Summary of FDA Guidance #230 – AVMA
- Pharmacy Board Proposed Regulations- California Code of Regulations Title 16, Sections 1735-1735.8 & 1751 et seq. – Regulations Regarding Compounding

Additional Attachments:

- Excerpts from SB 1193 (Hill)
- Draft working document of regulatory text
- Letter from UC Davis faculty
- Comments from CVMA

Action:

- Develop proposed regulations to implement the statutory authority of SB 1193 as it relates to drug compounding for veterinarians and RVTs and recommend action to the VMB.

CODE OF FEDERAL REGULATIONS:

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

PART 530 EXTRALABEL DRUG USE IN ANIMALS

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

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

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

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

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

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

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

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

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

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

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

Overview

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

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

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

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

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

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

Deadlines:

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

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

Web Resources:

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

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

Overview of FDA's Proposed Guidance for Industry #230

Bulk Ingredient Compounding In a State-Licensed Pharmacy

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

Highlights

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

No Office-Use Compounding Permitted

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

Compounding "Marketed" Drugs

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

Documentation and Mandatory Statements

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

Overview of FDA's Proposed Guidance for Industry #230

Bulk Ingredient Compounding By a Licensed Veterinarian

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

Highlights

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

Bulk Ingredient Compounding By a 503B Outsourcing Facility

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

Highlights

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

intended for animal use.

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

Positive List

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

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

Labeling Requirements

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

Overview of FDA's Proposed Guidance for Industry #230

Specific Veterinary-Related Questions Posed in the Guidance Notice

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

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

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) ~~i~~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 compendia~~l~~ and other applicable requirements to maintain their integrity, potency, quality, and labeled strength.

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

(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.

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

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

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

(l) Packages of ingredients, 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, Sections 1735, 1735.1, 1735.8, and 1751.1-1751.8 of Title 16, Division 17, of the California Code of Regulations.

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

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

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

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

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

(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~~ 37th Revision, Effective ~~May~~ December 1, ~~2012~~ 2014), hereby incorporated by reference~~, to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code~~.

~~(7)~~(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 ~~record~~ 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 and under California Code of Regulations section 1707.5, the label of a compounded drug product preparation shall contain the generic or brand name(s) of the principal all active ingredient(s).~~

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

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

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

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

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

(1) Procedures for notifying staff assigned to compounding duties of any changes in ~~processes or to the~~ policyies 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 ~~collated~~ 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~~, /or~~ where appropriate, a freezer, of sufficient capacity to meet the storage requirements for all material requiring refrigeration or freezing, and a backup plan to ensure continuity of available compounded drug preparations in the event of a power outage.

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

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127 ~~and 4127.7~~, Business and Professions Code; Sections

1735, 1735.1-1735.8., and 1751.1-1751.8. of Title 16, Division 17, of the California Code of Regulations; and Section 18944, Health and Safety Code.

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

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

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

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

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

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

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

(4) Results of viable 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 ~~l~~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 label~~s~~ for each such ~~those products~~ preparation:

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

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

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

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

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

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

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

(a) Any pharmacy engaged in compounding sterile drug preparations shall maintain 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:

(1) Process validation for chosen sterilization methods.

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

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

~~(d)(2)~~(e) All personnel involved must read the policies and procedures before compounding sterile ~~injectable products~~ drug preparations.~~, and any~~ All 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.

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

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

(a) No sterile ~~injectable~~ drug ~~product~~ preparation shall be compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile ~~injectable~~ drug ~~products~~ preparations.

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

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

(d) Cleaning 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). 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.~~12~~5.1 of Title 24, Chapter 5, of the California Code of Regulations, requiring a ~~laminar air flow hood~~ negative pressure PEC. Additionally, each PEC used to compound hazardous agents shall be externally vented. The ~~hood~~ negative pressure PEC must be certified ~~annually~~ every six months by a qualified technician who is familiar with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-13, Revised May 20, 2015). ~~the methods and procedures for certifying laminar air flow hoods and cleanroom requirements, in accordance with National Sanitation Foundation Standard 49 for Class II (Laminar Flow) Biohazard Cabinetry, as revised May, 1983 (available from the National Sanitation Foundation, 3475 Plymouth Road, P.O. Box 1468, Ann Arbor, Michigan 48106, phone number (313) 769-8010) or manufacturer's specifications. Certification records must be retained for at least 3 years.~~ Any drug preparation that is compounded in a PEC where hazardous drugs are prepared must be labeled as hazardous, regardless of whether the drug ingredients are considered hazardous.

(1) During the hazardous drug compounding that is performed in a compounding aseptic containment isolator, full hand hygiene and garbing must occur. 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 ~~Q~~quality ~~A~~assurance ~~P~~program shall include at least the following:

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

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

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

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

(b)(1) The pharmacy and each individual involved in the compounding of sterile drug

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

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

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

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

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

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

~~Each individual involved in the preparation of sterile injectable drug products preparations must first successfully demonstrate competency by successfully performing aseptic media-fill tests complete a validation process on technique before being allowed to prepare sterile~~

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

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

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

~~(c)~~ (e)(1) Batch-produced sterile 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 policy~~y~~ies 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.

Legislation

A. SB 1193 (HILL) – VETERINARY MEDICAL BOARD: EXECUTIVE OFFICER

AMENDED: 6/21/16 **STATUS:** Re-referred to Assembly Committee on Appropriations

BOARD POSITION: Support

SUMMARY:

This bill would remove these provisions.

(2) The Veterinary Medicine Practice Act provides for the licensure and registration of veterinarians and registered veterinary technicians and the regulation of the practice of veterinary medicine by the Veterinary Medical Board, which is within the Department of Consumer Affairs, and authorizes the board to appoint an executive officer, as specified.

Existing law repeals the provisions establishing the board and authorizing the board to appoint an executive officer as of January 1, 2017.

This bill would extend the operation of the board and the authorization of the board to appoint an executive officer until January 1, 2021. The bill would authorize a veterinarian or registered veterinary technician who is under the direct supervision of a licensed veterinarian to compound a drug for animal use pursuant to federal law and regulations promulgated by the board and would require those regulations to, 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 safe compounding of drugs.

The Veterinary Medicine Practice Act exempts certain persons from the requirements of the act, including a veterinarian employed by the University of California or the Western University of Health Sciences while engaged in the performance of specified duties. That act requires all premises where veterinary medicine, dentistry, and surgery is being practiced to register with the board.

The bill would instead require veterinarians engaged in the practice of veterinary medicine employed by the University of California or by the Western University of Health Sciences and engaged in the performance of specified duties to be licensed as a veterinarian in the state or be issued a university license, as specified. The bill would authorize an individual to apply for and be issued a university license if he or she meets certain requirements, including paying an application and license fee. The bill would require a university license, among other things, to automatically cease to be valid upon termination or cessation of employment by the University of California or the Western University of Health Sciences. The bill would also prohibit a premise registration that is not renewed within 5 years after its expiration from being renewed, restored, reissued, or reinstated; however, the bill would authorize a new premise registration to be issued to an applicant if no fact, circumstance, or condition exists that would justify the

revocation or suspension of the registration if the registration was issued and if specified fees are paid.

The Veterinary Medicine Practice Act requires all fees collected on behalf of the board to be deposited into the Veterinary Medical Board Contingent Fund, which continuously appropriates fees deposited into the fund.

This bill would provide that the Veterinary Medical Board Contingent Fund is available for expenditure only upon an appropriation by the Legislature.

(3) The Pharmacy Law makes a violation of any of its provisions punishable as an infraction if no other penalty is provided. The Veterinary Medicine Practice Act makes a violation of any of its provisions punishable as a misdemeanor.

By placing new requirements on a pharmacy, this bill would expand an existing crime and would, therefore, impose a state-mandated local program. The bill would also expand the definition of an existing crime and, therefore, result in a state-mandated local program by requiring additional persons to be licensed under the act that were previously exempt.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

BILL TEXT:

The people of the State of California do enact as follows:

SEC. 26.
Section 4800 of the Business and Professions Code is amended to read:

4800.
(a) There is in the Department of Consumer Affairs a Veterinary Medical Board in which the administration of this chapter is vested. The board consists of the following members:

(1) Four licensed veterinarians.

(2) One registered veterinary technician.

(3) Three public members.

(b) This section shall remain in effect only until January 1, 2018, and as of that date is repealed.

(c) Notwithstanding any other law, the repeal of this section renders the board subject to review by the appropriate policy committees of the Legislature. However, the review of the board shall be limited to those issues identified by the appropriate policy committees of the Legislature and

shall not involve the preparation or submission of a sunset review document or evaluative questionnaire.

SEC. 27.
Section 4804.5 of the Business and Professions Code is amended to read:

4804.5.
The board may appoint a person exempt from civil service who shall be designated as an executive officer and who shall exercise the powers and perform the duties delegated by the board and vested in him or her by this chapter.

This section shall remain in effect only until January 1, 2021, and as of that date is repealed.

SEC. 28.
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.

SEC. 29.
Section 4830 of the Business and Professions Code is amended to read:

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

(1) Veterinarians while serving in any armed branch of the military service of the United States or the United States Department of Agriculture while actually engaged and employed in their official capacity.

(2) Regularly licensed veterinarians in actual consultation from other states.

(3) Regularly licensed veterinarians actually called from other states to attend cases in this state, but who do not open an office or appoint a place to do business within this state.

(4) 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.

(5) A veterinarian who is employed by the Meat and Poultry Inspection Branch of the California Department of Food and Agriculture while actually engaged and employed in his or her official

capacity. A person exempt under this paragraph shall not otherwise engage in the practice of veterinary medicine unless he or she is issued a license by the board.

(6) Unlicensed personnel employed by the Department of Food and Agriculture or the United States Department of Agriculture when in the course of their duties they are directed by a veterinarian supervisor to conduct an examination, obtain biological specimens, apply biological tests, or administer medications or biological products as part of government disease or condition monitoring, investigation, control, or eradication activities.

(b) (1) For purposes of paragraph (3) of subdivision (a), a regularly licensed veterinarian in good standing who is called from another state by a law enforcement agency or animal control agency, as defined in Section 31606 of the Food and Agricultural Code, to attend to cases that are a part of an investigation of an alleged violation of federal or state animal fighting or animal cruelty laws within a single geographic location shall be exempt from the licensing requirements of this chapter if the law enforcement agency or animal control agency determines that it is necessary to call the veterinarian in order for the agency or officer to conduct the investigation in a timely, efficient, and effective manner. In determining whether it is necessary to call a veterinarian from another state, consideration shall be given to the availability of veterinarians in this state to attend to these cases. An agency, department, or officer that calls a veterinarian pursuant to this subdivision shall notify the board of the investigation.

(2) Notwithstanding any other provision of this chapter, a regularly licensed veterinarian in good standing who is called from another state to attend to cases that are a part of an investigation described in paragraph (1) may provide veterinary medical care for animals that are affected by the investigation with a temporary shelter facility, and the temporary shelter facility shall be exempt from the registration requirement of Section 4853 if all of the following conditions are met:

(A) The temporary shelter facility is established only for the purpose of the investigation.

(B) The temporary shelter facility provides veterinary medical care, shelter, food, and water only to animals that are affected by the investigation.

(C) The temporary shelter facility complies with Section 4854.

(D) The temporary shelter facility exists for not more than 60 days, unless the law enforcement agency or animal control agency determines that a longer period of time is necessary to complete the investigation.

(E) Within 30 calendar days upon completion of the provision of veterinary health care services at a temporary shelter facility established pursuant to this section, the veterinarian called from another state by a law enforcement agency or animal control agency to attend to a case shall file a report with the board. The report shall contain the date, place, type, and general description of the care provided, along with a listing of the veterinary health care practitioners who participated in providing that care.

(c) For purposes of paragraph (3) of subdivision (a), the board may inspect temporary facilities established pursuant to this section.

SEC. 30.
Section 4846.5 of the Business and Professions Code is amended to read:

4846.5.
(a) Except as provided in this section, the board shall issue renewal licenses only to those applicants that have completed a minimum of 36 hours of continuing education in the preceding two years.

(b) (1) Notwithstanding any other law, continuing education hours shall be earned by attending courses relevant to veterinary medicine and sponsored or cosponsored by any of the following:

(A) American Veterinary Medical Association (AVMA) accredited veterinary medical colleges.

(B) Accredited colleges or universities offering programs relevant to veterinary medicine.

(C) The American Veterinary Medical Association.

(D) American Veterinary Medical Association recognized specialty or affiliated allied groups.

(E) American Veterinary Medical Association's affiliated state veterinary medical associations.

(F) Nonprofit annual conferences established in conjunction with state veterinary medical associations.

(G) Educational organizations affiliated with the American Veterinary Medical Association or its state affiliated veterinary medical associations.

(H) Local veterinary medical associations affiliated with the California Veterinary Medical Association.

(I) Federal, state, or local government agencies.

(J) Providers accredited by the Accreditation Council for Continuing Medical Education (ACCME) or approved by the American Medical Association (AMA), providers recognized by the American Dental Association Continuing Education Recognition Program (ADA CERP), and AMA or ADA affiliated state, local, and specialty organizations.

(2) Continuing education credits shall be granted to those veterinarians taking self-study courses, which may include, but are not limited to, reading journals, viewing video recordings, or listening to audio recordings. The taking of these courses shall be limited to no more than six hours biennially.

(3) The board may approve other continuing veterinary medical education providers not specified in paragraph (1).

(A) The board has the authority to recognize national continuing education approval bodies for the purpose of approving continuing education providers not specified in paragraph (1).

(B) Applicants seeking continuing education provider approval shall have the option of applying to the board or to a board-recognized national approval body.

(4) For good cause, the board may adopt an order specifying, on a prospective basis, that a provider of continuing veterinary medical education authorized pursuant to paragraph (1) or (3) is no longer an acceptable provider.

(5) Continuing education hours earned by attending courses sponsored or cosponsored by those entities listed in paragraph (1) between January 1, 2000, and January 1, 2001, shall be credited toward a veterinarian's continuing education requirement under this section.

(c) Every person renewing his or her license issued pursuant to Section 4846.4, or any person applying for relicensure or for reinstatement of his or her license to active status, shall submit proof of compliance with this section to the board certifying that he or she is in compliance with this section. Any false statement submitted pursuant to this section shall be a violation subject to Section 4831.

(d) This section shall not apply to a veterinarian's first license renewal. This section shall apply only to second and subsequent license renewals granted on or after January 1, 2002.

(e) The board shall have the right to audit the records of all applicants to verify the completion of the continuing education requirement. Applicants shall maintain records of completion of required continuing education coursework for a period of four years and shall make these records available to the board for auditing purposes upon request. If the board, during this audit, questions whether any course reported by the veterinarian satisfies the continuing education requirement, the veterinarian shall provide information to the board concerning the content of the course; the name of its sponsor and cosponsor, if any; and specify the specific curricula that was of benefit to the veterinarian.

(f) A veterinarian desiring an inactive license or to restore an inactive license under Section 701 shall submit an application on a form provided by the board. In order to restore an inactive license to active status, the veterinarian shall have completed a minimum of 36 hours of continuing education within the last two years preceding application. The inactive license status of a veterinarian shall not deprive the board of its authority to institute or continue a disciplinary action against a licensee.

(g) Knowing misrepresentation of compliance with this article by a veterinarian constitutes unprofessional conduct and grounds for disciplinary action or for the issuance of a citation and the imposition of a civil penalty pursuant to Section 4883.

(h) The board, in its discretion, may exempt from the continuing education requirement any veterinarian who for reasons of health, military service, or undue hardship cannot meet those requirements. Applications for waivers shall be submitted on a form provided by the board.

(i) The administration of this section may be funded through professional license and continuing education provider fees. The fees related to the administration of this section shall not exceed the costs of administering the corresponding provisions of this section.

(j) For those continuing education providers not listed in paragraph (1) of subdivision (b), the board or its recognized national approval agent shall establish criteria by which a provider of continuing education shall be approved. The board shall initially review and approve these criteria and may review the criteria as needed. The board or its recognized agent shall monitor,

maintain, and manage related records and data. The board may impose an application fee, not to exceed two hundred dollars ($200) biennially, for continuing education providers not listed in paragraph (1) of subdivision (b).

(k) (1) Beginning January 1, 2018, a licensed veterinarian who renews his or her license shall complete a minimum of one credit hour of continuing education on the judicious use of medically important antimicrobial drugs every four years as part of his or her continuing education requirements.

(2) For purposes of this subdivision, "medically important antimicrobial drug" means an antimicrobial drug listed in Appendix A of the federal Food and Drug Administration's Guidance for Industry #152, including critically important, highly important, and important antimicrobial drugs, as that appendix may be amended.

SEC. 31.
Section 4848.1 is added to the Business and Professions Code, to read:

4848.1.
(a) A veterinarian engaged in the practice of veterinary medicine, as defined in Section 4826, employed by the University of California and engaged in the performance of duties in connection with the School of Veterinary Medicine or employed by the Western University of Health Sciences and engaged in the performance of duties in connection with the College of Veterinary Medicine shall be issued a university license pursuant to this section or hold a license to practice veterinary medicine in this state.

(b) An individual may apply for and be issued a university license if all of the following are satisfied:

(1) He or she is currently employed by the University of California or Western University of Health Sciences, as defined in subdivision (a).

(2) He or she passes an examination concerning the statutes and regulations of the Veterinary Medicine Practice Act, administered by the board, pursuant to subparagraph (C) of paragraph (2) of subdivision (a) of Section 4848.

(3) He or she successfully completes the approved educational curriculum described in paragraph (5) of subdivision (b) of Section 4848 on regionally specific and important diseases and conditions.

(4) He or she completes and submits the application specified by the board and pays the application fee, pursuant to subdivision (g) of Section 4905, and the initial license fee, pursuant to subdivision (h) of Section 4905.

(c) A university license:

(1) Shall be numbered as described in Section 4847.

(2) Shall automatically cease to be valid upon termination or cessation of employment by the University of California or by the Western University of Health Sciences.

(3) Shall be subject to the license renewal provisions in Section 4846.4 and the payment of the renewal fee pursuant to subdivision (i) of Section 4905.

(4) Shall be subject to denial, revocation, or suspension pursuant to Sections 480, 4875, and 4883.

(5) Authorizes the holder to practice veterinary medicine only at the educational institution described in subdivision (a) and any locations formally affiliated with those institutions.

(d) An individual who holds a university license is exempt from satisfying the license renewal requirements of Section 4846.5.

SEC. 32.
Section 4853.7 is added to the Business and Professions Code, to read:

4853.7.
A premise registration that is not renewed within five years after its expiration may not be renewed and shall not be restored, reissued, or reinstated thereafter. However, an application for a new premise registration may be submitted and obtained if both of the following conditions are met:

(a) No fact, circumstance, or condition exists that, if the premise registration was issued, would justify its revocation or suspension.

(b) All of the fees that would be required for the initial premise registration are paid at the time of application.

SEC. 33.
Section 4904 of the Business and Professions Code is amended to read:

4904.
All fees collected on behalf of the board and all receipts of every kind and nature shall be reported each month for the month preceding to the State Controller and at the same time the entire amount shall be paid into the State Treasury and shall be credited to the Veterinary Medical Board Contingent Fund. This contingent fund shall be available, upon appropriation by the Legislature, for the use of the Veterinary Medical Board.

SEC. 34.
Section 4905 of the Business and Professions Code is amended to read:

4905.
The following fees shall be collected by the board and shall be credited to the Veterinary Medical Board Contingent Fund:

(a) The fee for filing an application for examination shall be set by the board in an amount it determines is reasonably necessary to provide sufficient funds to carry out the purpose of this chapter, not to exceed three hundred fifty dollars ($350).

(b) The fee for the California state board examination shall be set by the board in an amount it determines is reasonably necessary to provide sufficient funds to carry out the purpose of this chapter, not to exceed three hundred fifty dollars ($350).

(c) The fee for the Veterinary Medicine Practice Act examination shall be set by the board in an amount it determines reasonably necessary to provide sufficient funds to carry out the purpose of this chapter, not to exceed one hundred dollars ($100).

(d) The initial license fee shall be set by the board not to exceed five hundred dollars ($500) except that, if the license is issued less than one year before the date on which it will expire, then the fee shall be set by the board not to exceed two hundred fifty dollars ($250). The board may, by appropriate regulation, provide for the waiver or refund of the initial license fee where the license is issued less than 45 days before the date on which it will expire.

(e) The renewal fee shall be set by the board for each biennial renewal period in an amount it determines is reasonably necessary to provide sufficient funds to carry out the purpose of this chapter, not to exceed five hundred dollars ($500).

(f) The temporary license fee shall be set by the board in an amount it determines is reasonably necessary to provide sufficient funds to carry out the purpose of this chapter, not to exceed two hundred fifty dollars ($250).

(g) The fee for filing an application for a university license shall be one hundred twenty-five dollars ($125), which may be revised by the board in regulation but shall not exceed three hundred fifty dollars ($350).

(h) The initial license fee for a university license shall be two hundred ninety dollars ($290), which may be revised by the board in regulation but shall not exceed five hundred dollars ($500).

(i) The biennial renewal fee for a university license shall be two hundred ninety dollars ($290), which may be revised by the board in regulation but shall not exceed five hundred dollars ($500).

(j) The delinquency fee shall be set by the board, not to exceed fifty dollars ($50).

(k) The fee for issuance of a duplicate license is twenty-five dollars ($25).

(l) Any charge made for duplication or other services shall be set at the cost of rendering the service, except as specified in subdivision (k).

(m) The fee for failure to report a change in the mailing address is twenty-five dollars ($25).

(n) The initial and annual renewal fees for registration of veterinary premises shall be set by the board in an amount not to exceed four hundred dollars ($400) annually.

(o) If the money transferred from the Veterinary Medical Board Contingent Fund to the General Fund pursuant to the Budget Act of 1991 is redeposited into the Veterinary Medical Board Contingent Fund, the fees assessed by the board shall be reduced correspondingly. However, the reduction shall not be so great as to cause the Veterinary Medical Board Contingent Fund to have

a reserve of less than three months of annual authorized board expenditures. The fees set by the board shall not result in a Veterinary Medical Board Contingent Fund reserve of more than 10 months of annual authorized board expenditures.

Veterinary Compounding

Draft Statutory Proposal

SDAG Joshua A. Room – November 18, 2015

§ 4825.1. Definitions – ADD

(e) Within a veterinary premise, drug "~~C~~compounding~~," for the purposes of veterinary medicine~~ is allowable. Compounding may be performed by a licensed veterinarian or by a licensed pharmacist, or by a pharmacy technician, intern pharmacist or Registered Veterinary Technician when a written protocol or direct order is followed.~~, shall have the same meaning as that given in California Code of Regulations, title 16, section 1735, except that every reference therein to "pharmacy" and "pharmacist" shall be replaced by "veterinary premises" and "veterinarian," and except that only a licensed veterinarian or a licensed RVT (following the written protocol of a licensed veterinarian) may perform compounding, and may not delegate to or supervise any part of the performance of compounding by any other person~~ Only the Veterinarian or Licensed Pharmacist may delegate the performance of compounding to a Pharmacy Technician, Intern Pharmacist, or RVT.

1. (a) "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:

   (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 drug preparation from chemicals or bulk drug substances

2. (b) "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 veterinarian, pharmacist, pharmacy technician, intern pharmacist or RVT with a current ~~and active~~ license may compound a drug for the prevention, cure, or relief of a wound, fracture, bodily injury, or disease of an animal, in a veterinary premise~~premises currently and actively registered with the board~~, only under the following conditions:

(1) Where there is no FDA-approved animal or human drug that can be used as labeled or in an appropriate 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 established veterinarian-client-patient relationship, as a means to treat ~~a specific occurrence of~~ a disease, symptom, or condition observed and diagnosed by the veterinarian in ~~a specific animal~~an animal or animals within the same group, herd, or flock ~~which~~ that threatens the health of the animal(s) or will cause suffering or death ~~if~~ or if ~~left untreated~~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.

(b) A compounded veterinary drug may be prepared from an FDA-approved animal or human drug when there is no approved animal or human drug that, when used as labeled or in an appropriate extralabel manner will, in the available dosage ~~A compounded veterinary drug may be prepared from an FDA-approved animal or human drug for extralabel use only when there is no approved animal or human drug that, when used as labeled or in an appropriate extralabel manner will, in the available dosage~~ form and concentration, properly treat the disease, symptom, or condition. Compounding from an approved human drug for use in food-producing animals is not permitted if an approved animal drug can be used for compounding.

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

(1) The drug is ~~compounded and dispensed~~prescribed by the veterinarian to treat an ~~individually identified~~an animal ~~patient~~ or animals ~~under his or her care~~as directed within the VCPR;

(2) The drug is not intended for use ~~in food-producing animals~~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 ~~an individually identified animal patien~~ the animal(s)~~t~~ that produces a clinical difference for that an animal or animals within the same group, herd, or flock~~individually identified animal patient~~, 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 ~~veterinarian~~ 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 ~~patient~~, and the name of the owner or caretaker of the patient.

(d) Each compounded veterinary drug preparation shall meet the labeling requirements ~~of section 4076, and of California Code of Regulations, title 16, sections 1707.5 and 1735.4, except that every reference therein to "pharmacy" and "pharmacist" shall be replaced by "veterinary premises" and "veterinarian," and any reference to "patient" shall be understood to refer to the animal patient. In addition, each label on a compounded veterinary drug preparation shall include withdrawal/holding times, if needed, and the disease, symptom, or condition for which the drug is being prescribed. Any compounded veterinary drug preparation that is intended to be sterile, including for injection, administration into the eye, or inhalation, shall in addition meet the labeling requirements of California Code of Regulations, title 16, section 1751.2, except that every reference therein to "pharmacy" and "pharmacist" shall be replaced by "veterinary premises" and "veterinarian," and any reference to "patient" shall be understood to refer to the animal patient.~~ set forth in the Veterinary Practice Act (CCR 2032.2(b)

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

~~(1) Section 1735.1;~~

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

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

~~(4) Section 1735.4;~~

~~(5) Section 1735.5;~~

~~(6) Section 1735.6;~~

~~(7) Section 1735.7; and~~

~~(8) Section 1735.8.~~

(f) Any veterinarian, pharmacist, pharmacy technician, pharmacy intern, registered veterinary technician and veterinary premises engaged in sterile compounding of products intended for resale or distribution to other prescribers shall meet the sterile compounding requirements for pharmacies and pharmacists stated by Article 7 of Title 16 of the California Code of Regulations (sections 1751 through 1751.8, inclusive.)

Sterile compounding for exclusive use within the veterinary premise where the compounding occurred does not need to comply with USP 797. It is the responsibility of the compounding veterinarian or pharmacist to ensure that the product is sterile, bioavailable, stable, efficacious and the appropriate safety standards have been met.

Comment [JK1]:

~~), except that every reference therein to "pharmacy" and "pharmacist" shall be replaced by "veterinary premises" and "veterinarian," and any reference to "patient" shall be understood to refer to the animal patient. Section 1751.8 (e) allows a veterinarian or RVT to compound a "sterile IV product" outside of an ISO class 5 PEC or under conditions that do not meet all of the requirements for sterile compounding if the preparation is labeled "for immediate use only," and is used within one hour by the individual that has compounded the preparation.~~

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

(h) Language regarding Outsourcing Pharmacies and who can own them—issues UCD brought up about conflict of interest problems.

2/1/2016

Dear Dr. Klingborg,

We greatly appreciate your keeping us up to date concerning the drafted language on Compounded Medications and Veterinary Practice presented by the Multi-Disciplinary Committee. I have reviewed the drafted language and shared this with my Veterinary Pharmacy Associates. We all agree that FDA guidance policies and state regulations concerning compounding of drugs for use in animals needs clarification. This not only includes compounding by veterinarians for their own patients but also compounding by ancillary staff (Licensed Veterinary Technicians, Licensed Pharmacy Technicians, Licensed Pharmacists) for administration or dispensation to the veterinarian's own patients or for resale. Additionally, we understand that in order to enforce compounding guidance policies set forth by the FDA that California needs to codify regulations in statute.

Our primary fear is the economic impact that this will have on veterinarians in the state of California and their ability to practice veterinary medicine within the very restrictive regulations as written in the draft. After a brief review of the Draft Statutory Proposal the following comments have been raised under each subsection:

1) **4825.1 Definitions:** The statement "Licensed veterinarian and licensed veterinary technicians may perform veterinary compounding and may not delegate to or supervise any part of the performance of compounding by any other person" may be too restrictive. It implies that a licensed pharmacy technician, intern pharmacist or a licensed pharmacist cannot compound medications for animal use. Many large veterinary clinics (VCA's) are now hiring licensed pharmacy technicians to perform this function. Licensed pharmacists and pharmacy interns should also be able to legally compound for animals. Both have training in compounding as part of their didactic course work versus veterinarians and veterinary technicians that lack any training. We suggest that you include ancillary staff (licensed pharmacy techs, pharmacy interns and licensed pharmacists). In addition, although we agree with the requirement for licensure, the state of California (including the University) maintains exemptions for their veterinarians for licensure. We suggest that you include "licensed (or exempt) veterinarians" in the verbiage.

2) **4826.3 Veterinary Compounding (a):** This statement, similar to above may be too restrictive. It should include veterinarians (licensed or exempt) or ancillary staff (licensed veterinary technicians, licensed pharmacy technicians or licensed pharmacists). In addition, the statement that compounding must be performed "in a licensed premise currently and actively registered with the board" would exclude the University as well as many other facilities that are commonly visited by veterinarians that require compounded medications (zoos, raptor centers, marine mammal centers, wildlife agencies, shelters, rescue groups, ambulatory equine/food-animal trucks, etc.). We suggest that the word license be removed and replace by veterinary premises.

3) **4826.3 (a-2):** This states that a veterinarian must first outsource any compounded medications to a compounding pharmacy, outsourcing facility or other compounding supplier if the product is not commercially available. This presents a number of issues including: 1) Emergency compounded products needed acutely in the field would have a significant delay due to

processing the medication order, particularly in a rural area, which may be detrimental to the animal 2) Because there are no laws against a veterinarian owning their own compounding facility this may present opportunity for conflict of interest and fraudulent prescribing habits as was noted in human medicine prior to laws regulating physician financial investment in pharmacies and 3) Current Licensed Outsourcing Facilities are not a consideration by veterinarians due to a variety of reasons including; a) cost b) inability to legally compound much needed drugs for animals that have been withdrawn from the human market (cisapride, asparginase, chloramphenicol, etc.) c) inability to register as an outsourcing facility unless also engaged in the compounding of sterile human drugs or if activities being conducted are specific to animal patients and 4) The statement does not specify if these are licensed facilities in the state of California or if "compounding suppliers" from outside the state would have to be licensed in the state of California prior to importing into the State.

We suggest that a time frame be included ("must first outsource any compounded medications to a licensed compounding pharmacy or other compounding supplier if the product is not commercially available or cannot be procured on a timely basis to treat the animal's acute condition"). We further suggest that if this is included into law, that restrictions be placed on veterinary prescriber ownership of an "Outsourcing facility or other compounding supplier" to eliminate the potential for conflict of interest (similar to that required in Pharmacy Law (Section 4111)).

4) **4826.3 Veterinary Compounding (a-3):** We agree with a valid veterinary-client-patient relationship, but the statement "for a specific animal" may be too restrictive. Veterinarians must be able to compound drugs for litters, herds, flocks, pods, schools of fish or other groups of species which should be addressed in the wording. We suggest that the wording state "for a specific animal or grouping of animals in the same herd, flock, etc.").

5) **4826.3 Veterinary Compounding (b):** Because compounded drugs are not FDA labeled, it may not be appropriate to refer to their "off-label or extra-labeled" use here. So we suggest that the wording be "a compounded veterinary drug may be prepared from an FDA-approved animal or human drug when there is no approved animal or human drug that, when used as labeled or in an appropriate extralabel manner will, in the available dosage form, etc.).

6) **4826.3 Veterinary Compounding (c-1) Bulk drugs:** The statement "only when the drug is compounded and dispensed by the veterinarian under his or her care" implies that ancillary staff (licensed veterinary technicians, licensed pharmacy technicians or licensed pharmacists) cannot compound bulk medications for animal use. In place of "compounded and dispensed" we suggest a better choice of wording would be "prescribed". In addition, as stated above (a-3) "individually identified animals" may be too restrictive. Bulk drugs are often given to flocks of birds in water or into fish aquariums where individuals cannot always be identified. We suggest that the wording be expanded to include "for a specific animal or grouping of animals in the same flock, school, litter, etc.").

7) **4826.3 Veterinary Compounding (c-2) Bulk drugs:** Because food-producing animals are not well defined (ornamental fish, rabbits, etc.), we suggest changing the wording here to "animals intended for food or food production".

8) **4826.3 Veterinary Compounding (c-3) Bulk drugs:** Again, "individually identified animal patient" may be too restrictive. We suggest that the wording be expanded to include "for a specific animal or grouping of animals in the same flock, school, litter, etc."). We further suggest that the "Clinical difference" be required to be recorded in the medical record.

9) **4826.3 Veterinary Compounding (c-6) Bulk drugs**: The statement that "the drug cannot be sold or transferred by the veterinarian compounding the drug", does not eliminate ancillary staff from this function. We suggest this should also include ancillary staff that has compounded the bulk product.

10) **4826.3 Veterinary Compounding (c-8) Bulk drugs**: Again, in place of "animal's name" we suggest "the name of the animal patient or group of animals"

11) **4826.3 Veterinary Compounding (f)**: Veterinarians work out of their homes, ambulatory trucks, strip malls, zoos, wildlife parks, marine mammal centers, shelters, non-profit homeless shelters, spay/neuter vans, etc. Veterinarians working out of ambulatory trucks, vans, etc. do not have the option of installing a sterile hood or a sterile room. It is not physically possible for them to operate a veterinary practice within the proposed USP 797 restrictions. Only a minority of practices (VCA's or Banfield's) would be able to comply with USP 797 requirements for sterile products from an ISO Class 5 PEC environment. Minimum costs to accomplish this would be on the order of $200-300,000 /clinic. The cost, space, ongoing management, training, quality assurance, equipment and batch testing is cost and time prohibitive for the average veterinarian. In addition, the average animal owner would most likely have to euthanize their pet rather than pay for expensive out sourced sterile products.

    While many sterile products used by veterinarians may meet the requirement here "for immediate use only" or "use within one hour" many others fall outside this time limitation and would require processing in a sterile hood that meets 797 requirements. For small or exotic animals, diluted injectable expensive antibiotics/anti-coagulants drawn up or re-packaged into syringes (considered sterile compounding) and frozen for weeks to months is not uncommon. Chronic CRI's for pain control, antibiotics, etc. are used daily for up to 24 hours. Diluted insulin, heparin flush, chronic use of single dose vials of darbepoetin/epogen/DDAVP placed into multidose vials, foal TPN's, acute use antifungal or antibacterial ophthalmology products for equine melting corneal ulcers, uterine and nasal antibiotic or antifungal lavages, diluted acepromazine injectable solutions, etc. are all considered common practice in veterinary medicine and would all fall outside the "immediate use" (1 hour) exemption.

    We suggest that there be separate rules for "Sterile Compounding". If the product is for transferring or resale, all applicable USP 797 laws should apply. If the sterile compounded

product is to be compounded for and used on the prescribing veterinarians own patient(s) then an exemption should be applied. At minimum, a 72 hour exemption for sterile products compounded in-house and being dispensed to the prescribers own patient would allow for treatment of animal patients until further product could be outsourced to a Sterile Compounding facility.

The mixing and administration of hazardous sterile chemicals, including chemotherapy is a further topic of discussion and needs to be addressed in veterinary medicine on many levels. It is not uncommon for veterinary practices to admix very dangerous chemotherapeutic agents on counter tops or in barns without any protective gear (PPE) or chemical hoods. A few of the larger small animal clinics own small hoods that would not qualify to meet USP 797 standards. OSHA oversight of veterinary clinics has been ill defined and rarely enforced. These topics need further addressing aside from compounding issues.

In conclusion, much needed veterinary medications are often not commercially available and must be compounded for animals. Due to the species differences in size, veterinarians must have the ability to easily and readily compound oral, topical and sterile medications for their patients. The cost of medications is not covered by insurance companies and owners can often not afford to treat their animals if the cost of medications is too high. Unlike human medicine, if the cost is absorbent, owners have the option of euthanasia. Although we appreciate the need for clarification over veterinary compounding, we also see that too many restrictions may have severe consequences on the animals we treat and a devastating economic impact on veterinarians.

Concerns on SB 1195 - Compounding Issues

California Veterinary Medical Association (CVMA) – 4/12/16

Current pharmacy regulations that are related to compounding are written specifically for use by pharmacists and in pharmacies. The veterinary profession needs compounding regulations that are applicable to veterinary practice. Unlike pharmacists, veterinarians have a veterinarian-client-patient relationship and do not fill prescriptions from other prescribers. They administer medications to their animal patients and dispense medications to clients for animal patient use. A veterinarian has an intimate knowledge of the patient whereas a pharmacist is preparing a prescription on a prescriber's order. Veterinarians are not in the business of compounding and only do so as needed.

Veterinarians need to compound on a regular basis. This includes administering medications in a clinical setting such as with IV fluids and pre-anesthetics. It also includes dispensing, such as making a flavored liquid out of a pill or combining two medications.

The CVMA supports giving veterinarians the authority to compound drugs however we have concerns about sections of the proposed language.

Comments on proposed Sections 9 and 10 of SB 1195:

Section 4825.1(e) – Definition of compounding

- Replacing "pharmacy" and "pharmacist" with "veterinarian" and "veterinary premises" is problematic in statute and in many of the regulations in Section 1735 of Title 16 of the CCR. This statute needs to indicate that new regulations will be written specifically for veterinarians and veterinary premises.

Section 4826.3(d) – Regarding labeling requirements

- Section 4076 would be confusing for veterinarians. Dispensed medication labeling requirements for veterinarians already exist in CCR 16, 2032.2(b) and differ from those required in human medicine.
- Section 1707.5 talks about translations for (human) patients with limited or no English speaking proficiency which would not apply to animal patients. AB 1073 by Assemblyman Ting (2015) exempted veterinarians from having to translate prescription labels, as veterinary labeling is quite unique. Pointing to this regulation that now excludes veterinarians in statute would be confusing.
- Section 1707.5(1) requires label directions that are geared toward human use – take 2 in the morning, take three at bedtime, if you have pain, etc. These would not be directions given by a veterinarian.
- This language would be a problem with existing veterinary software systems that generate dispensing labels which are in compliance with existing regulation Section 2032.2(b).
- Same concerns as in the definition of compounding in section 4825.1(e).

Section 4826.3(e) –

- Same concerns as in the definition of compounding in Section 4825.1(e)

Section 4826.3(e)1-8

There are many areas throughout these regulations (1735.1 – 1735.8) that would not be reasonable for the type of compounding done by veterinarians. A couple of examples:

- Veterinarians often compound to dilute medications based on the weight, species and physiology of the animal patient. A master formula would not be necessary, as required in 1735.2(d), because compounding is only being used to alter the strength of the drug and on a case-by-case basis.
- Maintaining records, as required in Section 1735.3 would not be reasonable for veterinarians because the compounding is being done for a specific patient.

Comments on Proposed Section 11 and 12

Section 11 deems that Section 4826.5 would be added to the Business and Professions Code and that "failure to comply with the provisions of this article shall be deemed unprofessional conduct and constitute grounds for discipline". This sounds like unprofessional conduct could be applied to all of Article 2 rather than the compounding provisions.

The same applies to Section 12 which states that Section 4826.7 would be added that the board may adopt regulations to implement the provisions of all of Article 2 rather than to implement the compounding provisions.

Both of these sections should only apply to sections related to compounding.

Examples of Veterinary Compounding

The following are some examples of why specific regulations are needed for veterinarians and veterinary premises:

- Veterinarians often use a combination of ketamine, valium, and acepromazine for an IV anesthetic or as an inducing anesthetic. They mix 1 ml of acepromazine with 10 mls of ketamine and then draw up what is needed of that mixture with an equal amount of Valium. When given to a cat or small dog (less than 10 lbs.) they will use .3 ml. of the ketamine/acepromazine mixture which is less than .03 ml of acepromazine. To comply with existing pharmacy regulations, a veterinarian would have to draw these drugs up separately leaving little room for error; whereas when a veterinarian includes 1 ml in 10 mls of ketamine, that dilution is exact and safe. If acepromazine is not used in the patient, they wake up very agitated. Oftentimes cats will be hypersensitive to stimuli and lunge against the side of the cage. This combination has been used safely in the veterinary profession for over 30 yrs. As a side note, it is also cost

prohibitive to add 1 ml of acepromazine to 10 ml of ketamine; use .35 ml of the solution and then dispose of the bottle because it is not being used again within an hour. This would likely increase costs to the client.

- Veterinarians need to compound potassium bromide for seizures in dogs. They primarily use phenobarbital for seizures; however, in some cases it doesn't give the needed results and in other cases they may not be able to use phenobarbital because of an existing liver disease. Dr. Wayne Berry, former professor of neurology at UC Davis who now practices in Irvine, developed directions to obtain and use a bulk form of potassium bromide. Veterinarians will weigh 50 grams of potassium bromide and mix it with 200 ml. of distilled water to give 250 mg./ml. concentration of the medication. They then calculate the amount of this solution to give to the patient at a loading dose of 350 mg./kg. divided and given every 6 hrs. the first day and then 10 mg./kg. given twice daily as a maintenance dosage. This is soaked on a piece of bread and given to the patient with their food. With this formula, they can treat a 5 lb. Chihuahua or a 120 lb. Rottweiler effectively and safely. After two to three weeks of treatment, they obtain a blood sample to determine if there is a good therapeutic blood level of the medication. Potassium bromide is the example quoted in the USP <795> report as an example of "Simple Compounding - Potassium Bromide Oral Solution, Veterinary."

- Resistant ear infection is another issue. Veterinarians obtain culture samples of the external ear canal and find out what medication or combination of medications will be effective in treating this condition. Veterinary dermatologists provide examples for veterinarians of combinations of injectable antibiotics and antifungal (for yeast infections) medication to mix in saline for a topical ear canal treatment. These cases are complicated by the fact that the anatomy of the dog and cat ear is very different then the human ear canal.

- Horses in parts of northern California are subject to a tick-borne intracellular bacterial infection called Anaplasma (“Tick Bite Fever.”) The infection causes high fever, rapid onset anemia, limb swelling and diarrhea. It can be fatal if not treated with intravenous oxytetracycline immediately. Because oxytetracycline can cause heart arrhythmia if administered without dilution, veterinarians will commonly dilute the curative dose into 1 liter of IV fluids (sterile to sterile compounding) and then administer it immediately to horses in the field. The dose of oxytetracycline is specific to the patient since too much can cause kidney damage. Therefore, having the ability to dilute the correct dose in the field to administer immediately provides a life-saving treatment in an emergency situation.

Multidisciplinary Advisory Committee Assignments

July 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 3rd/4th 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.**

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.**

FUTURE PRIORITIES

7) **Develop Minimum Standards for Spay and Neuter Clinics**