STATE OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS

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

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

MEETING NOTICE and AGENDA
MULTIDISCIPLINARY ADVISORY COMMITTEE

January 17, 2017
1747 N. Market Blvd. – 1st Floor Hearing room
Sacramento, California

10:00 a.m. Tuesday, January 17, 2017

1. Call to Order- Establishment of a Quorum
2. Introductions
3. Review and Approval of October 18, 2016 Meeting Minutes
4. Update from the Complaint Process Audit Subcommittee
5. Discussion and Consideration of "Extended Duty" for Registered Veterinary Technicians Regulations; Potential Recommendation to Full Board
6. Discussion and Consideration of Proposed Amendments to RVT Job Tasks, Emergency Animal Care – Sedation and Pain Management – Section 2069 of Title 16 of the California Code of Regulations; Potential Recommendation to Full Board
7. Discussion and Consideration of Alternate Route for DVM Graduates to Practice as RVTs – Proposed Section 2027.5 of Title 16 of the California Code of Regulations; Potential Recommendation to Full Board
8. Discussion and Consideration of Recommendations from State Humane Association of California and California Veterinary Medical Association Regarding Public and Private Shelters and Minimum Standards & Protocols for Shelter Medicine; Potential Recommendation to Full Board
9. Review and Consider Proposed Regulations Regarding the Compounding of Drugs Pursuant to the Enactment of Senate Bill 1193 (2016), Potential Recommendation to Full Board
10. Discussion and Consideration of Proposed Amendments Regarding Drug Information to be Provided to Clients – Section 2032.1 of Title 16 of the California Code of Regulations; Possible Recommendation to Full Board
11. Discuss Definitions and Scope of Responsibility for "Induction" of Anesthesia vs. Sedation – Section 2034 of Title 16 of the California Code of Regulations; Potential Recommendation to Board
12. Discuss Minimum Standards for Spay/Neuter Clinics
13. 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)).

14. Future Agenda Items and Next Meeting Dates –
    - April 18, 2017 (Oakland)
    - July 25, 2017 (Sacramento/Southern California)
    - October 17, 2017 (Fresno)

    A. Multidisciplinary Advisory Committee Assignment Priorities
    B. Agenda Items for Next Meeting – Minimum Standards for Small Animal Spay and Neuter Clinics

15. Adjournment

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

The Board plans to webcast items 1-15 at this meeting on its website at www.vmb.ca.gov. Webcast availability cannot, however, be guaranteed due to limitations on resources or technical difficulties that may arise. If you wish to participate or to have a guaranteed opportunity to observe, please plan to attend at a physical location.

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

MISSION

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

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MEETING MINUTES
Multidisciplinary Advisory Committee

The Mission Inn
3649 Mission Inn Avenue,
Riverside, California

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

1. Call to Order- Establishment of a Quorum

Multidisciplinary Advisory Committee (MDC) Chair, Dr. Jon Klingborg called the meeting to order at 10:02 a.m. Veterinary Medical Board (Board) Executive Officer, Annemarie Del Mugnaio called roll; nine members of the MDC were present and thus a quorum was established.

2. Introductions

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

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

Guests Present
Shayda Ahkami, DVM, Palm Springs Animal Shelter
Manuel Balcazar, RVT, San Diego County
Madeline Bernstein, SPCA Los Angeles
Kathy Bowler, Public Member, Veterinary Medical Board
Isha Buis, Northwest Society for the Prevention of Cruelty to Animals (SPCA)
Brian Cronin, San Bernardino County
Daniel DeSousa, San Diego County
Nancy Ehrlich, RVT, California Registered Veterinary Technician Association
Carla Faulkner, Ventura County Animal Services

Valerie Fenstermaker, California Veterinary Medical Association
Cassie Hamilton, San Diego County
Jennifer Hawkins, Orange County Animal Care
Alex Henderson, Veterinary Allied Staff Education
Susy Horowitz, Pasadena Humane Society
Erica Hughes, State Humane Association of California
Shelly Jones, DCA Board & Bureau Relations
Cynthia Kinney, DVM, Inland Valley Humane Society and SPCA
Marcia Mayeda, Los Angeles County Department of Animal Care and Control
Mark Nunez, DVM, Veterinary Medical Board
John Pascoe, DVM, University of California, Davis
Ken Pawlowski, California Veterinary Medical Association
Elizabeth Ocampo, Pasadena Humane Society and SPCA
Cindy Savely, RVT, Sacramento Valley Veterinary Technician Association
Dan Segna, California Veterinary Medical Association
Leah Shufelt, RVT, California Veterinary Medical Association
Healther Skogerson, Ventura County Animal Services
Maria Solacito, Los Angeles County Department of Animal Care and Control
Ron Terra, DVM, Western University of Health Sciences
Cheryl Waterhouse, DVM, Veterinary Medical Board
Gina Schwin-Whiteside, Director of Animal Services, Town of Apple Valley

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

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

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

David Johnson reported that the "Extended Duty" Subcommittee continued to reach out to various organizations requesting input and that the California Registered Veterinary Technicians Association (CaRVTA) submitted a formal document on the expanded functions for Registered Veterinary Technicians (RVTs) a week prior to the October 18, 2016 Board meeting.

Ms. Del Mugnaio noted that the Board and members of the public did not receive an advanced copy of CaRVTA's formal document. Legal Counsel, Kurt Heppler, suggested discussing CaRVTA's document at the next meeting when Board members have been given more time to look at it.

Dr. Klingborg requested a more complete document from CaRVTA to clarify issues of access to care and for additional services from RVTs.

Nancy Ehrlich briefly explained CaRVTA's formal document which identified job tasks that veterinary assistants are currently allowed to perform, which should be restricted to RVTs.

Ms. Del Mugnaio noted that it is not part of in the Board's delegation to the MDC to discuss the restriction of duties. The task was to discuss potential extended duties which respond to a need and increase access to care.

Leah Schufelt added that the RVT Committee at the California Veterinary Medical Association (CVMA) met recently and no areas of need or access, that would benefit from the expansion of RVT duties, were identified.

Jennifer Loredo noted that based on comments from the public there is a access to care issue within the shelter environment, but nothing in terms of regular practice.

Mr. Heppler clarified the action agreed upon by the Board for Dr. Klingborg to bring this issue to the Board and request continued authorization to address this issue, with the understanding that it would be added to the agenda for the next MDC meeting.

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

Dr. Allan Drusys presented the slideshow on the survey responses received from over 60 public and private animal shelters and 81 responses from a similar survey that Erica Hughes from the State Humane Association of California (SHAC) provided to its members regarding the environment within animal shelters. Each survey contained nearly identical questions; however, Ms. Hughes noted that SHAC's survey questions were posed in a way that aimed to learn what those in the animal shelter environment would be interested in addressing within the field, rather than what is currently being practiced.

Ms. Del Mugnaio clarified that euthanasia in the field is lawful pursuant to Business and Professions Code (BPC) section 597.1; however, regulations for the training to implement that law are in still in process.

Mr. Johnson expressed that historically, the regulations written for RVTs to practice were primarily focused around the functioning within a private veterinary hospital setting, and consideration had not been given to minimum standards within animal shelters. Veterinary professionals should agree on a basic level of care that must be provided within both public and private shelters.

Ms. Del Mugnaio noted that there are certain animal health care tasks that need to be performed upon intake by non-veterinarians. The MDC must examine if those tasks are considered the practice of veterinary medicine, and if so, what level of supervision is needed to perform those tasks in animal shelters.

The MDC discussed the differences between "veterinary assistants" and "animal care technicians." Based on experience, Ms. Loredo described "veterinary assistants" as someone who assists the RVTs, and assists in performing medical tasks. "Animal care technicians" typically cleans the kennels; however, "veterinary assistants" is the lawful term in accordance with statute.

Madeline Bernstein shared that some shelters have no access to a veterinarian and staff tends to help out where they are needed, furthering the point that roles may become confusing within the shelter environment. Dr. Drusys shared that the description of a veterinary assistant or an animal care technician may differ from shelter to shelter.

Ms. Hughes shared a list of items that SHAC's animal shelter committee felt needed to be prioritized:

1. Allow veterinary assistants to perform routine health tasks on impound and intake such as a basic physical exam, administer vaccines, administer prophylactic medicine for parasites, and basic testing and screening (particularly on cats)

2. Administer a rabies vaccine without establishing a Veterinary-Client-Patient Relationship (VCPR) on owned animals when they are redeemed
3. Allow access to non-controlled, pre-euthanasia sedatives
4. Amend California Code of Regulations (CCR) section 2039 to allow shelter staff to euthanize wild life
5. Resolve confusion regarding applicability of the Veterinary Assistant Controlled Substances Permit (VACSP)

Regarding Item #1, the MDC discussed the lack of veterinarians and RVTs in rural areas and how the results of the survey may not be representative of the animal shelters in rural areas.

Mr. Johnson added that the duties listed in Item #1 are exempt based on past Board policy, not by law, and opined that within the area of shelter medicine, there should be more leniency.

Dr. Richard Sullivan opined that if there are facilities operating with no oversight, perhaps those facilities should not be operating. There is an assumption that some care is better than no care; however, the animals might not be getting the proper care.

Regarding Item #2, Dr. Sullivan noted that rabies vaccinations are outside of the Board's control as they are controlled entirely by the California Department of Public Health (CDPH). Ms. Hughes noted that based on her research, there are at least three other states which have provisions that allow lay people to administer vaccines. It will have to be researched further to see if training is needed.

Regarding Item #3, Ms. Hughes opined that if shelter staff are performing euthanasia, they should be given the tools to do so humanely. It can be difficult to access euthanasia drugs because a veterinarian may be needed to order it.

Dr. Drusys expressed concerns regarding drug compounding being advocated. He also noted a discussion before the MDC regarding the difference between anesthetizing and sedation. Dr. Drusys opined that the issues are so intertwined that they cannot be dealt with individually without affecting the other.

Dr. Eric Anderson noted that in 90 percent of cases, three primary non-controlled drugs that are often used in a shelter setting are Xylazine/Ketamine premix, Telazol, and Diazepam.

Regarding Item #4, Ms. Hughes added that she understands the amendment would intersect with other laws that affect wild life, therefore, would require further research.

Additionally, Ms. Hughes added that the way CCR section 2039 is written makes it impossible for new instructors in California to be certified in euthanasia training without at least three years of experience teaching, since training requires a certification. Only instructors from outside of California have been able to qualify.

Regarding Item #5, Ms. Del Mugnaio noted that the VACSP issues will be placed on the Board's agenda to discuss further. The intent of the legislation is to control diversion issues, and the regulations must be written to achieve this goal. After the program rolled out, many of the gaps were revealed and as a result, the Board will need to further examine the definition of "animal hospital setting" as it is written today.

Ms. Hughes also discussed various other definitions within Business and Professions Code section 4840(b) that are unclear.

Dr. Jennifer Hawkins shared that is has been challenging trying to adopt out an animal with prescriptions. Adoptions must occur when a veterinarian can prescribe the medication, and when a veterinarian is not present, RVTs are unable to prescribe.

Isha Buis suggested the creation of a separate section in law, specific to shelter medicine. Ms. Woodward-Hagle agreed with the suggestion and noted that it was also suggested that animal shelters hold an organizational license, rather than depend on one veterinarian to have their name on the license.

Dr. Cynthia Kinney expressed support for the VACSP, for kennel technicians to immediately triage animals upon intake, and veterinarian oversight of the administration of the rabies vaccine.

Ms. Kinney clarified that with regard to BPC section 4840 (b), she would like RVTs to follow written protocols and veterinary assistants to either follow written protocol, or receive written or verbal instructions to document within the medical record.

Dr. Dan Segna explained that the document prepared by CVMA aims to address the unique needs within shelter settings. CVMA's proposal includes the creation of a new section in the Practice Act specific to shelters. The proposed language is written for RVTs, but CVMA would be open to amending it to include veterinary assistants.

Ms. Bernstein asked the MDC Shelter Medicine Subcommittee and the CVMA Premises Task Force to clarify what is considered "veterinary medicine" and if it triggers the need to have a premises permit.

Mr. Heppler, summarized the discussion that going forward, Dr. Klingborg will report back to the Board that the MDC held a robust discussion on the results of the survey, identified the top 7 issues for consideration (including carving out shelter medicine as its out section within the Practice Act), and the MDC Shelter Medicine Subcommittee and CVMA Premises Task Force will continue discussions on future meetings to come.

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

<u>BPC sections 4830(a)(5)(A) and 4830(a)(5)(B)</u>
Dr. William Grant identified the biggest change to the proposed language is to not only apply the exemption to students of University of California, Davis (UCD) and Western University of Health Sciences (WesternU) but to all American Veterinary Medical Association (AVMA) accredited schools.

Dr. John Pascoe of UCD identified an issue of consumer protection within the Practice Act that does not address students from schools other than UCD and WesternU that are involved in veterinary activities and practice in California.

Ms. Del Mugnaio noted that the university should be responsible for those students participating in externships in California until they graduate. Dr. Pascoe clarified that students are covered under the university's general liability policy if they are in any program that is approved by the institution, including compensation for the loss of an animal.

Dr. Sullivan expressed support for the establishment and enforcement of a Memorandum of Understanding (MOU) as a way of linking the student back to the school and the program.

Dr. Klingborg noted the difference between the two versions of the proposed language in BPC section 4830(a)(5)(B) regards the off-campus sites and the MOU.

Ms. Del Mugnaio clarified that it is under the purview of the Board to globally regulate the prequalifications to licensure, which includes approval of an accrediting body.

Diana Woodward-Hagle noted that the statute does not state that the institution is responsible for drafting the expectations of the supervising licensed veterinarian.

Mr. Heppler explained that the first version of the proposed language allows out-of-state students to perform certain tasks. The second version does not include a formal description of what should be learned.

On behalf of WesternU, Dr. Ron Terra expressed support for an MOU and opposition towards an educational content mandate within the Practice Act.

Dr. Terra clarified that club activities are not part of formal curriculum, but the student would still be covered under the university's insurance and AVMA as long as a faculty member was involved. It is incumbent on the externship site to have an agreement with the university.

Dr. Segna opined that the first version seems to look at enforcing quality of the learning experience. The second version is about ensuring consumer protection. Dr. Segna and Mr. Johnson expressed support for the second version.

- Dr. Richard Sullivan moved and Dr. Allan Drusys seconded the motion to recommend to the Board approve version #1 of BPC section (a)(5)(A) as written and revise BPC section (a)(5)(B) by deleting "in place of on-campus education." The motion carried 5-4. Dr. William Grant, David Johnson, Kristi Pawlowski, and Diana Woodward-Hagle opposed the motion.

<u>CCR section 2027</u>

Dr. Klingborg reviewed the summary of the discussion from the last MDC meeting. CCR section 2027 allows veterinary graduates to function as RVTs indefinitely without passing the veterinary licensing examination. Proposed language of CCR section 2027.5 deals with the veterinary students and omits the year in which they are in their curriculum (e.g. junior or senior) and instead, requires that they must have had training in the activity they will be engaging in, may only function up to the level of an RVT, and supervision must be provided as it would be for an RVT.

Ms. Woodward-Hagle proposed adding "of a recognized veterinary college" after "veterinary student."

The MDC discussed that the liability of the veterinary student or graduate is with the supervising veterinarian.

Ms. Ehrlich suggested adding "a student may not obtain or administer unless they hold a VACSP" at the end of CCR section 2027. The MDC noted that the requirement to hold a VACSP is already in law.

Instead of re-writing parts of the section, the MDC discussed a more simple change of removing "or a graduate" from the current language because specifying junior or senior students instead would promote consumer protection by requiring that individuals have at least two years of experience.

- Dr. Richard Sullivan moved and Dr. William Grant seconded the motion to eliminate "or a graduate" from the current language in CCR section 2027. The motion carried 8-1. Dr. Drusys opposed the motion.

CCR section 2027.5

Dr. Sullivan opined that one year is too long to have a veterinary graduate function as an RVT without a license. There would be no enforcement avenue and activity would have to be pursued through unlicensed activity. Dr. Sullivan expressed support for providing an avenue for veterinary graduates to sit for the RVT exam.

The MDC discussed that the veterinary graduate is able to take the licensing examination twice in one year. Dr. Sullivan noted that a licensee is not always present to provide supervision, such as in an animal shelter setting.

Members of the MDC expressed opinions which varied from support for one year of RVT practice to support for an avenue to sit for the RVT examination.

Ms. Ehrlich expressed support for creating an avenue for veterinary graduates to sit for the RVT exams.

Ms. Buis suggested offering a provisional license where the licensee would be required to be fingerprinted.

- Allan Drusys moved and Dr. Jon Klingborg seconded the motion to table the discussion regarding BPC section 2027.5 and recommend to the Board that the MDC continue study on the matter. The motion carried 8-1. Dr. Sullivan opposed the motion.

7. Review and Consider Implementing Regulations Regarding the Compounding of Drugs Pursuant to the Enactment of Senate Bill 1193, Potential Recommendation to Full Board

The MDC was unable to discuss this item during the allotted amount of time; therefore, it will be placed on the agenda for discussion at the next MDC meeting.

8. Discuss Committee Recommendation Authorizing an RVT Under the Supervision of a Veterinarian to be the On-Site Practitioner for Rodeos

The Board discussed two issues:

1) Does the owned-animal exception of BPC section 4827 impact the ability of a veterinarian or RVT to treat injured animals at a rodeo?
2) Are there protocols that a non-veterinarian, in this case an RVT, may follow to provide on-site or transport emergency care to an injured animal until such time as the animal is treated by a veterinarian (Penal Code section 596.7 requires care within one hour)?

Ms. Del Mugnaio noted that Penal Code section 596.7 states that it is the rodeo manager of a professional sanctioned or amateur rodeo to ensure veterinary care is available to be provided. The

Board does not have authority over the rodeo, therefore, is unable to enforce that the owners have their animals treated.

The Professional Rodeo Cowboys Association (PRCA) confirmed that is not standard protocol to have a release that the owner signs requiring their animal to be treated at the event.

Ms. Del Mugnaio noted that rodeo injuries reported to the Board has been low, but has been increasing due to the Board's outreach and communication to the rodeo population.

Ms. Loredo suggested that "pain and sedation" should be added to the list of protocols for an RVT. Mr. Johnson agreed and added that there are non-controlled drugs that are useful to calming an animal. He also noted that some animals are so injured that they must be euthanized immediately.

Mr. Johnson expressed that there is an advantage to having an RVT present at a rodeo since they know the law. The RVT may intervene and contact animal control and if necessary, the owner can by cited and the animal can be seized.

Dr. Sullivan expressed that the Board's oversight of rodeos may deter some veterinarians from being present at the rodeos and suggested that oversight should be transitioned to animal control. The Board would still maintain oversight of the reporting aspect.

Ms. Del Mugnaio suggested that the MDC recommend to the Board that animal control officers need to become more involved to resolve enforcement issue, as owners may refuse to have their animals treated at the rodeo.

- Dr. Richard Sullivan moved and Jennifer Loredo seconded the motion to recommend the Board's a response to the Legislature is to reinforce that RVT tasks under emergency care provisions are appropriate on-site at rodeos, with a veterinarian on-call, and encourage working with animal control officers to enforce a requirement for owners to have their animals treated when they have been injured at rodeos. The motion carried 9-0.

9. Discuss Definitions and Scope of Responsibility for "Induction" of Anesthesia vs. Sedation – Section 2034 of Title 16 of the California Code of Regulations; Possible Recommendation to Full Board

The MDC was unable to discuss this item during the allotted amount of time; therefore, it will be placed on the agenda for discussion at the next MDC meeting.

10. Public Comments on Items Not on the Agenda

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

11. Agenda Items and Next Meeting Dates –

- January 17, 2017 – Sacramento
- April 18, 2017 – Oakland (TBD)
- July 25, 2017 – Sacramento/Southern California (TBD)
- October 17, 2017 – Sacramento/Southern California (TBD)

Ms. Del Mugnaio noted that the location of the July 2017 and October 2017 MDC meetings may be switched depending on the availability of hotels.

A. Multidisciplinary Advisory Committee Assignment Priorities

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

- Structure and Audit Enforcement Case Outcomes
- Minimum Standards for Alternate Premises
- CCR section 2027(a)(5) – Alternate Route for DVM Graduates to Practice as RVTs
- Extended Duties for RVTs
- RVT Job Tasks, Emergency Language – Sedation and Pain Management
- Drug Compounding Regulations
- CCR section 2034 - Definitions and Scope of Responsibility for "Induction" of Anesthesia vs. Sedation

Future priorities include:

- Minimum Standards for Spay and Neuter Clinics
- Minimum Standards for Mobile Specialists – Responsibility for Case Management

B. Agenda Items for Next Meeting – Minimum Standards for Small Animal Spay and Neuter Clinics

Dr. Klingborg noted that drug counseling risks and side effects will be placed on the agenda for the next meeting.

12. Adjournment

The MDC adjourned at 4:53 p.m.

Enforcement Report
January 17, 2017
Drs. Grant & Pollard

Since the last Multidisciplinary Committee (MDC) meeting, Drs. Grant & Pollard attended the Expert Witness (EW) Roundtable on Nov 3, 2016 in San Diego.

The Agenda included:
1. Veterinary Practice Act (VPA) – Executive Officer Annemarie Del Mugnaio
   a) Standard of Care
   b) Statute -> Regulation -> Code
      i. if there is a regulation, there will be a statute; not vice versa
      ii. at bottom of pages, NOTE includes AUTHORITY & HISTORY

2. Expert's Role in Complaint Process – Enforcement Manager Candace Raney
   a) flowchart (attached) "Complaint Received By Board", aka VMB
   b) correlation between medical treatment and outcome?
   c) evaluation of respondent's diagnostic algorithm
   d) process of review, order in which EW reads case

3. Audit Review Taskforce Report – Drs. Grant & Pollard
   a) January 14, 2016 memo to MDC
   b) June 1, 2016 summary of taskforce findings

4. Expert Witness Guidelines Subcommittee – Diane Woodward Hagle & Dr. Pollard
   a) overview of report writing components
      i. summary of facts
      ii. standard of care
      iii. negligence, incompetence, unprofessional conduct, statutory & regulatory standards
   b) Expert Witness Manual revised May 2, 2016

5. Report Writing Process – VMB consultants, Drs. Beth Parvin & Lisa Franz-Weiss
   a) report template, expert review worksheet
   b) **open table discussion**; "what if?", "what to do in [this] situation?", "what part of the VPA applies?", i.e., appropriate use of statutory & regulatory references

6. Testimony at Hearing – Supervising Deputy Attorney General, Diann Sokoloff
   a) knowledge, experience, & training = EW. Threshold question: 'am I the right expert?'

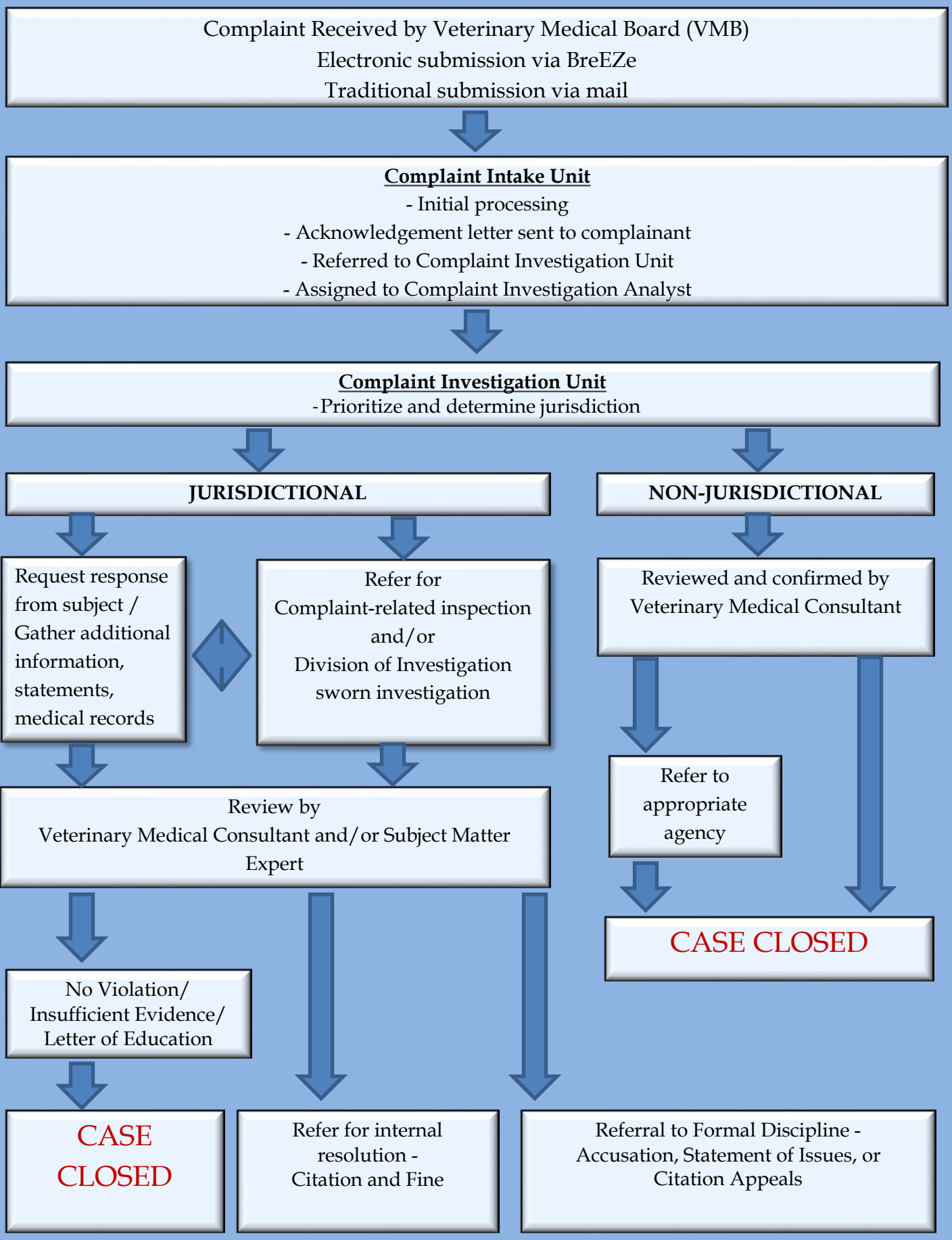
**

Topics of discussion:
-Challenges of EW; writing report, establishing violation per VPA, ethical issues
-Biases
-Reason to be EW
-MDC unknown, unrecognized
-Morphing of the EW Guidelines Subcommittee, Audit Review Taskforce, & the EW Roundtable.
-Multiple EW

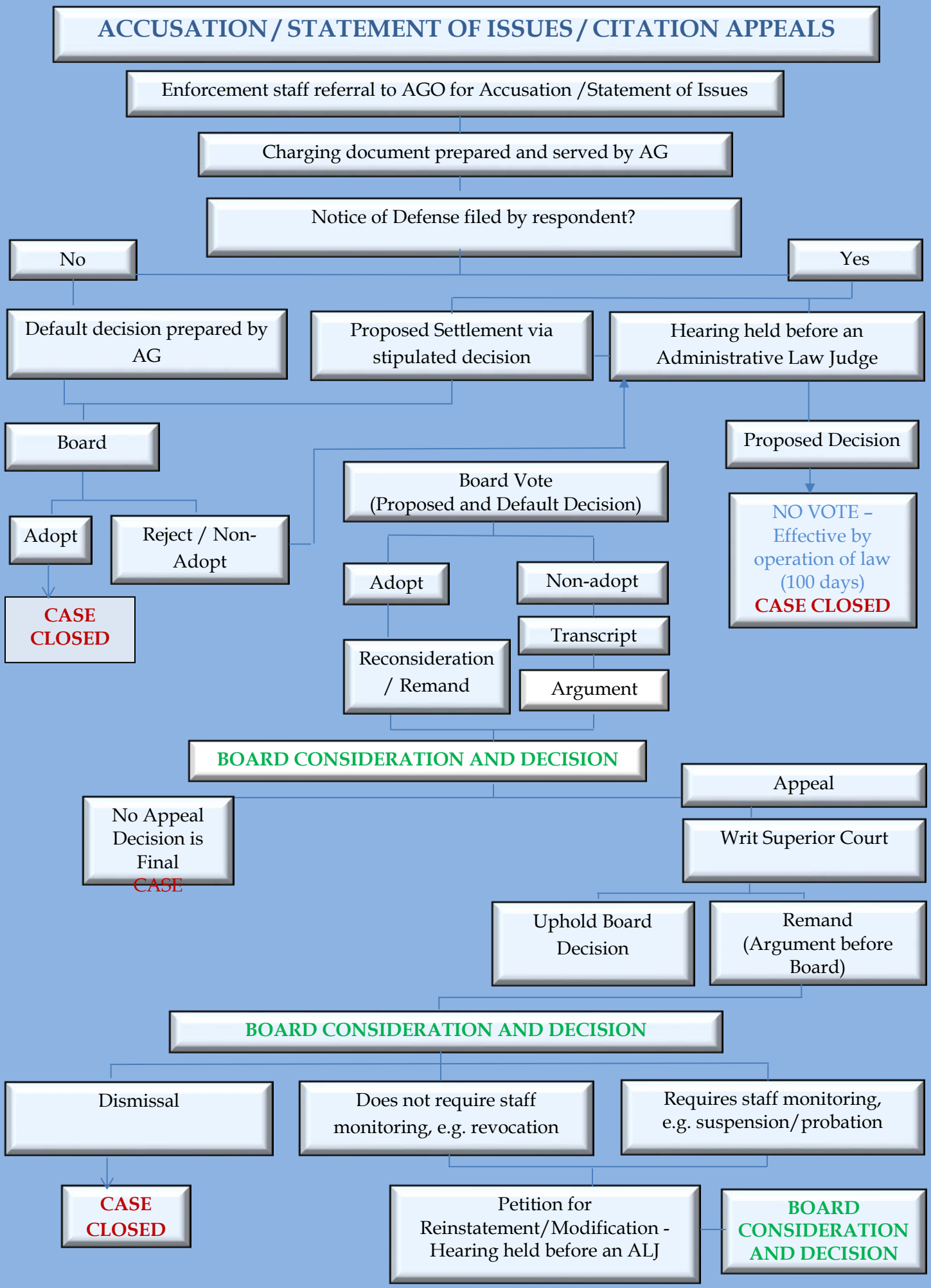
Respectfully submitted,

William A. Grant II, DVM
D. Jeff Pollard, DVM

COMPLAINT INVESTIGATION FLOWCHART



ACCUSATION / STATEMENT OF ISSUES / CITATION APPEALS



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

As you recall, our previous discussion centered around "Extended Duties for RVTs." At that time, the "Extended Duties" Sub-Committee reported that there might be a place for extended duties within the Shelter setting but not in terms of regular practice.

CaRVTA submitted a document intended to identify job tasks that veterinary assistants are currently allowed to perform, but that CaRVTA suggests should be restricted to RVTs within the regular practice setting.

Ms. Del Mugnaio noted that the Board and members of the public did not receive an advanced copy of CaRVTA's formal document. Legal Counsel, Kurt Heppler, suggested discussing CaRVTA's document at the next meeting when Board members have been given more time to look at it.

Dr. Klingborg requested a more complete document from CaRVTA to clarify issues of access to care and for additional services from RVTs.

Ms. Del Mugnaio noted that the current "Extended Duties" task was to discuss potential extended duties which respond to a need and increase access to care.

Subsequently, the VMB authorized the MDC to consider the following line items from the original CaRVTA document:

CARVTA proposed list of "exclusions for veterinary assistants in private facilities."

1. Central line placement (jugular or femoral PICCs)
2. Invasive procedures including inserting nasogastric tubes, inserting urinary catheters, or tracheal placement/suctioning
3. CSF/spinal tabs
4. Chest tube placement
5. Intraosseous catheter placement
6. Centesis including (cysto, abdominal, thoraco)
7. Advanced nerve blocking techniques

Discussion:

How should the MDC proceed with the current list of proposed exclusions for veterinary assistants?

Suggestions for Extended Functions for RVTs

a. No California licensed, practicing veterinarian shall assign unregistered personnel to perform veterinary nursing functions in lieu of a registered veterinary technicians; and may not allow unlicensed personnel to perform functions under the direct clinical supervision of a registered veterinary technician or veterinarian that require a substantial amount of scientific knowledge and technical skills, including, but not limited to, any of the following:
(1) Administration of anesthetic agents during induction, monitoring and recovery from anesthesia
(2) Central line placement (jugular or femoral PICCs)
(3) Invasive procedures including inserting nasogastric tubes, inserting urinary catheters, or tracheal placement/suctioning.
(4) Assessment of patient condition.
(5) CSF/Spinal taps
(6) Rabies specimen processing
(7) Chest tube placement
(8) Intraosseous catheter placement
(9) Centesis including (Cysto, abdominal, thoraco)
(10) Advanced nerve blocking techniques

b. Justification

(1) Anesthetic induction is currently covered in 2036 b (1); however, only RVT's and DVM's are guaranteed to have the required training in anesthesia, surgical nursing, anatomy and physiology, and pharmacology, to provide the safest monitoring and recovery from anesthesia. Possible consequences of inexperienced or under educated assistants monitoring or recovering animals from anesthesia include: failure to recognize apnea, failure to recognize cardiac arrest, failure to maintain a patent airway, premature removal of the endotracheal tube causing apnea and respiratory arrest, incorrect removal of the endotracheal tube causing tracheal bruising and/or tears, failure to recognize abnormal cardiac rhythms, failure to recognize abnormal ecg waves, blood oxygen saturation, or end tidal CO2; all causing patient distress, prolonged recovery, or death.

(2)Only RVT's and DVM's are guaranteed to have the requisite training in anatomy and physiology, sterile technique, and patient monitoring to safely place a Peripherally Inserted

Central Catheter (PICC). These catheters are meant to stay in the patient for an extended period of time. Complications arising from lay staff improperly placing these catheters include: blood infection, catheter site infection, jugular vein laceration, cardiac puncture, and tissue sloughing from fluids and medications administered outside of the vein.

(3) Only RVT's and DVM's are guaranteed to have the requisite training in anatomy and physiology, sterile technique, and patient monitoring to safely place nasogastric tubes, insert urinary catheters, or tracheal placement/suctioning. Complications arising from lay staff improperly performing these tasks include: According to 2036.5 (a), Lay staff are not allowed to perform sutures making the securing of a nasogastric tube via suture against code; improperly placed tubes can cause aspiration pneumonia; improperly placed urinary catheters can cause urethra tears, bladder puncture, and/or iatrogenic infections; improper tracheal suctioning can cause aspiration pneumonia, tracheal bruising/tearing, apnea, and/or patient death.

(4) Only RVT's and DVM's are guaranteed to have the requisite training in anatomy and physiology, physical examination techniques, and patient monitoring to properly assess a patient in their care. Complications of allowing lay staff to asses patients include: unrecognized symptoms, abnormal exam results not brought to the attention of the DVM, emergent symptoms ignored resulting in prolonged patient recovery, or patient death.

(5) Only RVT's and DVM's are guaranteed to have the requisite training in anatomy and physiology, sterile technique, and patient monitoring to safely perform cerebral spinal fluid collection and epidural catheter placement. Complications of allowing lay staff to perform these tasks include: lacerated spinal cord, iatrogenic infections, permanent neurological damage, and patient death.

(6) Only RVT's and DVM's are guaranteed to have the requisite training in anatomy and physiology, zoonotic disease, and personal protective safety equipment/practices to safely collect and process tissue for suspected rabid animals. Consequences of allowing lay staff to perform rabies testing include: zoonotic infection, staff contracting rabies, incorrect sample processed giving false test results, causing a bite victim to not receive life saving treatment.

(7) Only RVT's and DVM's are guaranteed to have the requisite training in anatomy and physiology, sterile technique, and patient monitoring to safely perform chest tube placement. Complications of allowing lay staff to perform these tasks include: lacerated lung lobe, iatrogenic infections, cardiac laceration, vena cava or aorta laceration, intrathoracic bleeding, patient death.

(8) Only RVT's and DVM's are guaranteed to have the requisite training in anatomy and physiology, sterile technique, and patient monitoring to safely perform intraosseous catheter placement. Complications of allowing lay staff to perform these tasks include: iatrogenic infection, unnecessary pain, prolonged patient recovery, and bone fracture.

(9) Only RVT's and DVM's are guaranteed to have the requisite training in anatomy and physiology, sterile technique, and patient monitoring to safely perform centisis. Complications of allowing lay staff to perform these tasks include: lacerated lung lobe, iatrogenic infections, cardiac laceration, vena cava or aorta laceration, intrathoracic bleeding, patient death. Cystocentesis: Risks include bladder, caudal vena cava puncture, abdominal aorta puncture, and contamination of either urine sample or a patient's abdomen.
-Abdominocentesis: Risks include internal organ laceration and subsequent hemoabdomen, iatrogenic pneumoperitoneum, iatrogenic septic peritonitis.
-Thoracocentesis: Risks include lung laceration, pneumothorax, and distress to the patient.

(10) Only RVT's and DVM's are guaranteed to have the requisite training in anatomy and physiology, sterile technique, and patient monitoring to safely perform advanced nerve blocking techniques (need to list them). Complications of allowing lay staff to perform these tasks include: lacerated spinal cord, iatrogenic infections, permanent neurological damage, and patient death.

2069. Emergency Animal Care.
Emergency animal care rendered by registered veterinary technician.

Under conditions of an emergency as defined in Section 4840.5, a registered veterinary technician may render the following life saving aid and treatment to an animal:

(1) Application of tourniquets and/or pressure bandages to control hemorrhage.
(2) Administration of pharmacological agents to prevent or control shock, including parenteral fluids, shall be performed after direct communication with a licensed veterinarian or veterinarian authorized to practice in this state. In the event that direct communication cannot be established, the registered veterinary technician may perform in accordance with written instructions established by the employing veterinarian. Such veterinarian shall be authorized to practice in this state.
(3) Resuscitative oxygen procedures.
(4) Establishing open airways including intubation appliances but excluding surgery.
(5) External cardiac resuscitation.
(6) Application of temporary splints or bandages to prevent further injury to bones or soft tissues.
(7) Application of appropriate wound dressings and external supportive treatment in severe burn cases.
(8) External supportive treatment in heat prostration cases.
(9) Administration of a drug or drugs to manage the pain or to sedate an animal for examination or to prevent further injury. Such a task shall only be performed after direct communication with a veterinarian licensed or otherwise authorized to practice in this state In the event that direct communication cannot be established, the registered veterinary technician may administer the drug or drugs in accordance with written instructions as established by his or her employing veterinarian, or, in the case of a sanctioned rodeo or other sporting event, the veterinarian charged with the responsibility to provide treatment to the animals at the rodeo or event.

Authority cited: Sections 4808 and 4836, Business and Professions Code.
Reference: Section 4840.5, Business and Professions Code.

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

STATE OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS

Veterinary Medical Board
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MEMORANDUM

DATE	January 4, 2017
TO	Multidisciplinary Advisory Committee
FROM	Annemarie Del Mugnaio, Executive Officer Veterinary Medical Board
SUBJECT	DVM Graduate – RVT License

Background:

The MDC has discussed the issue of DVM student exemptions for the better part of three years. The initial focus of the discussion was the exemption language in Business and Professions Code Section 4830, and California Code of Regulations Section 2027. At its last meeting of October 18, 2016, the MDC recommended to the Board and the Board subsequently adopted the following language:

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

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

CCR Section 2027

*A junior or senior student ~~or a graduate~~ of a recognized veterinary college listed in Section 2022(a) who is performing any animal health care task in a veterinary premises, [**not within the university] that is** 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.*

The language of Section 4830 will require a statutory change and the Board will need to seek a vehicle (bill) to carry the provisions. Similarly, the changes to CCR Section 2027 and any new provisions (2027.5) will need to be submitted through the rulemaking process.

Issue:
The outstanding issue remaining before the MDC, is that of allowing a DVM graduate to function as an RVT for an indefinite period of time. Prior to the changes adopted by the VMB as noted above, Section 2027 included "graduates." The VMB requested that the MDC discuss viable avenues for a DVM graduate to sit for both the state and national veterinary technician examinations and thus qualify for a license as an RVT. The VMB also requested Legal Counsel examine the impact of limiting the amount of time a DVM graduate may function as an RVT before taking the examinations as the impact may be considerable for prior DVM graduates.

Mr. Heppler provided a memo to the MDC of July 1, 2016 to address some of the fundamental policy considerations surrounding CCR 2027 and now a proposed 2027.5.

> "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. Accordingly, MDAC may way want to suggest some revisions to sections 2027."

Chair Klingborg formed a subcommittee of himself and Jennifer Loredo to formulate language for consideration by the MDC. The subcommittee worked with Ms. Del Mugnaio and Mr. Mathes on the following policy considerations and draft language.

Policy considerations:

1. Should the DVM graduate be issued a provisional or temporary RVT license while waiting to take and pass the RVT examinations?

2. What is the retroactive impact or prospective impact for individuals who graduated before the adoption of a regulation?

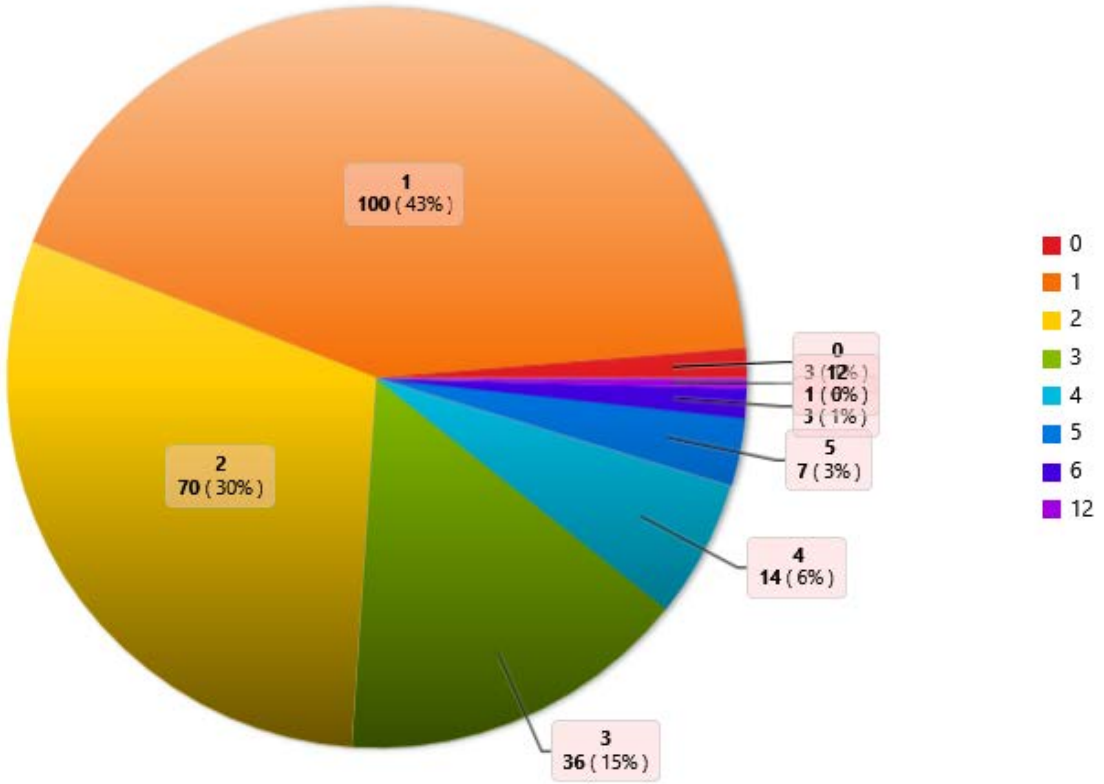
Action(s) Requested
Review and discuss the proposed language and consider the policy questions noted above.

2027.5 DVM Graduate Eligibility for RVT Licensure
Any person who receives a Doctorate of Veterinary Medicine degree from a recognized veterinary college listed in Section 2022(a), or a person who is within eight (8) months of his or her anticipated graduation from a recognized veterinary college, shall be eligible for a period of one year to apply for the national veterinary technician examination and the California veterinary technician examination as provided for in section 2010.

Vaccination Clinic Questionnaire

MDC January 17th, 2017

How Many Pets Do You Currently Own



When Was This Pet Last Taken to a Veterinarian

0 = Never

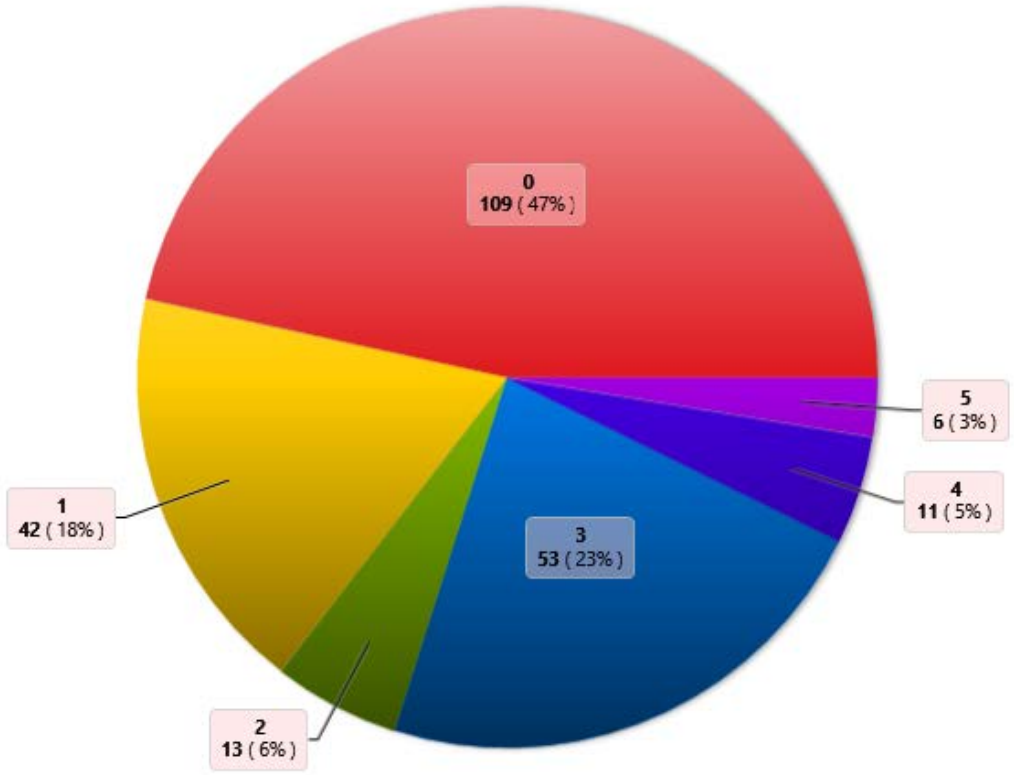
1 = Within the last 6 months

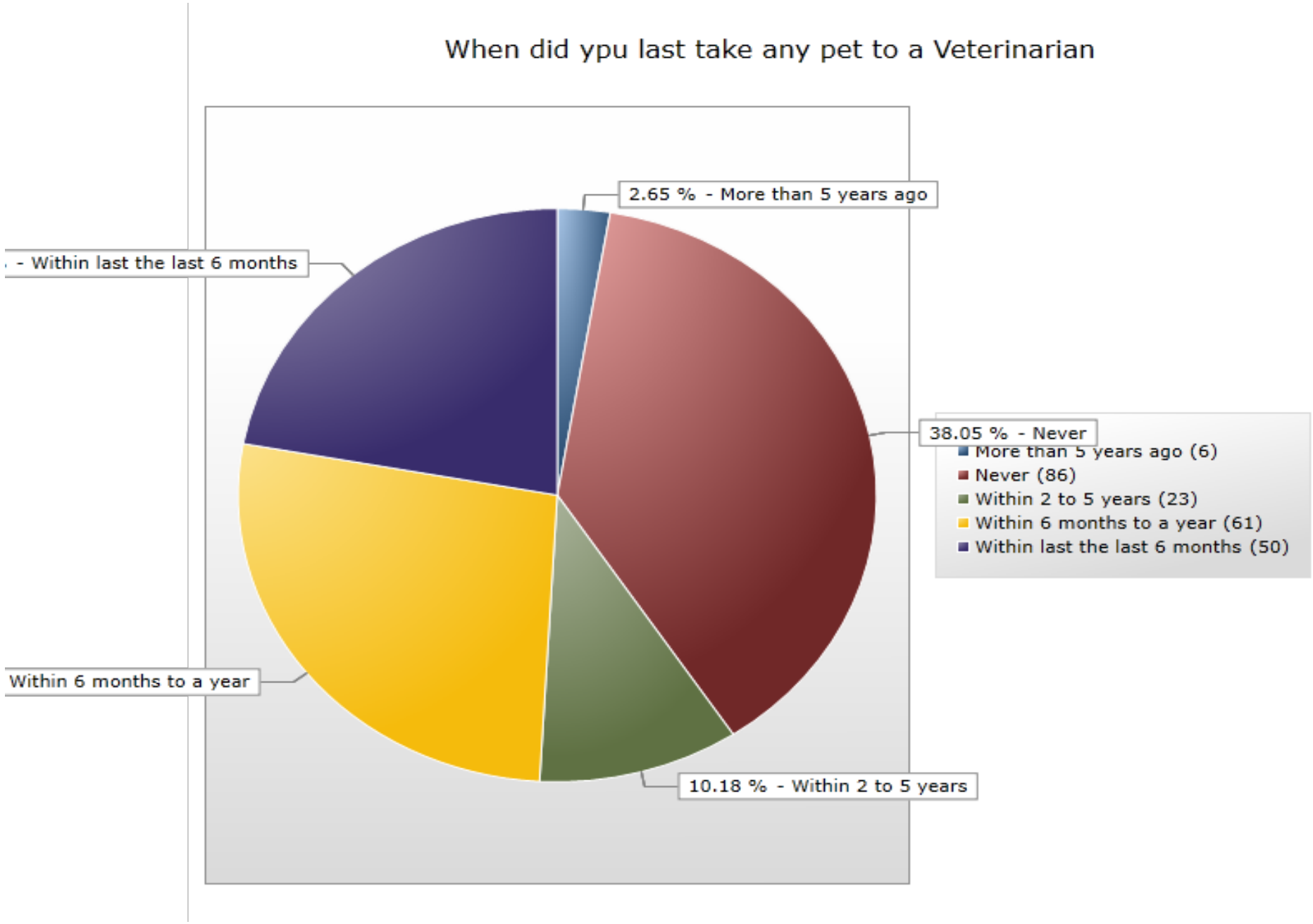
2 = 6 months to a year ago

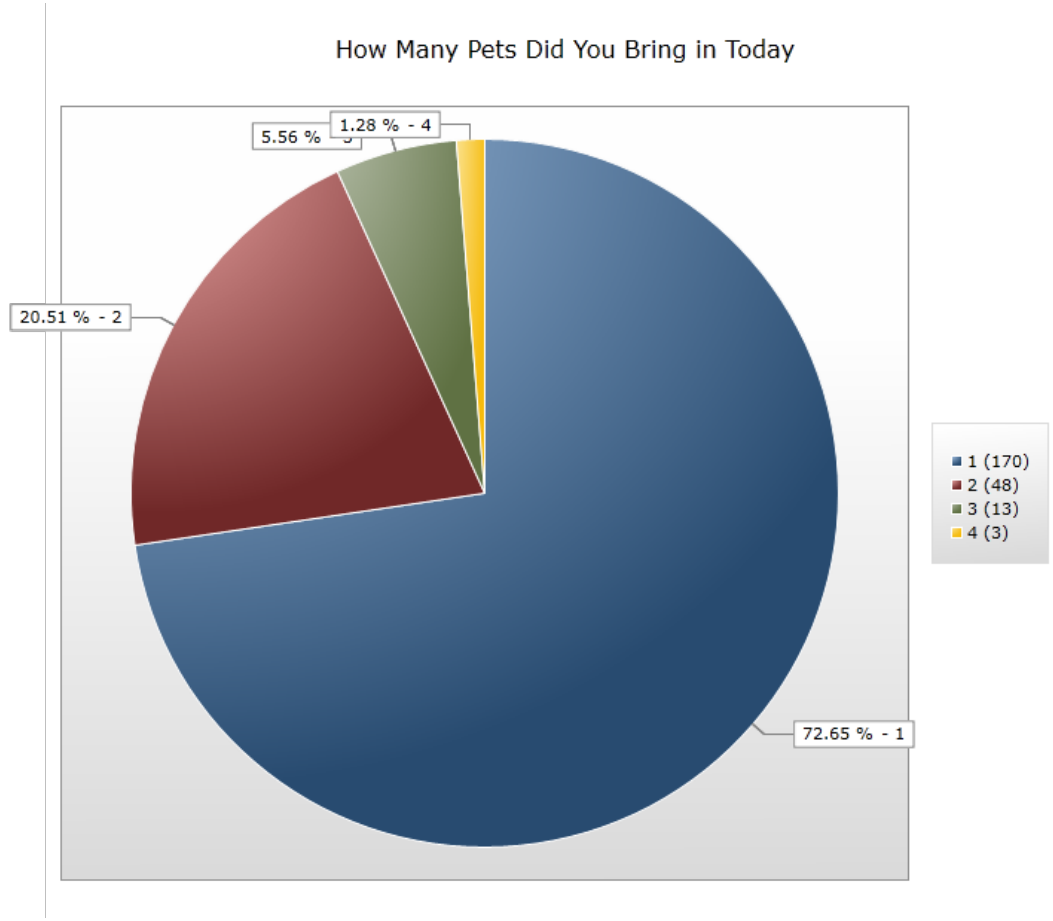
3 = 1 to 2 years ago

4 = 3 to 4 years ago

5 = 5 or more years ago




When did ypu last take any pet to a Veterinarian
2.65 % - More than 5 years ago
- Within last the last 6 months
38.05 % - Never
Within 6 months to a year
10.18 % - Within 2 to 5 years
More than 5 years ago (6)
Never (86)
Within 2 to 5 years (23)
Within 6 months to a year (61)
Within last the last 6 months (50)

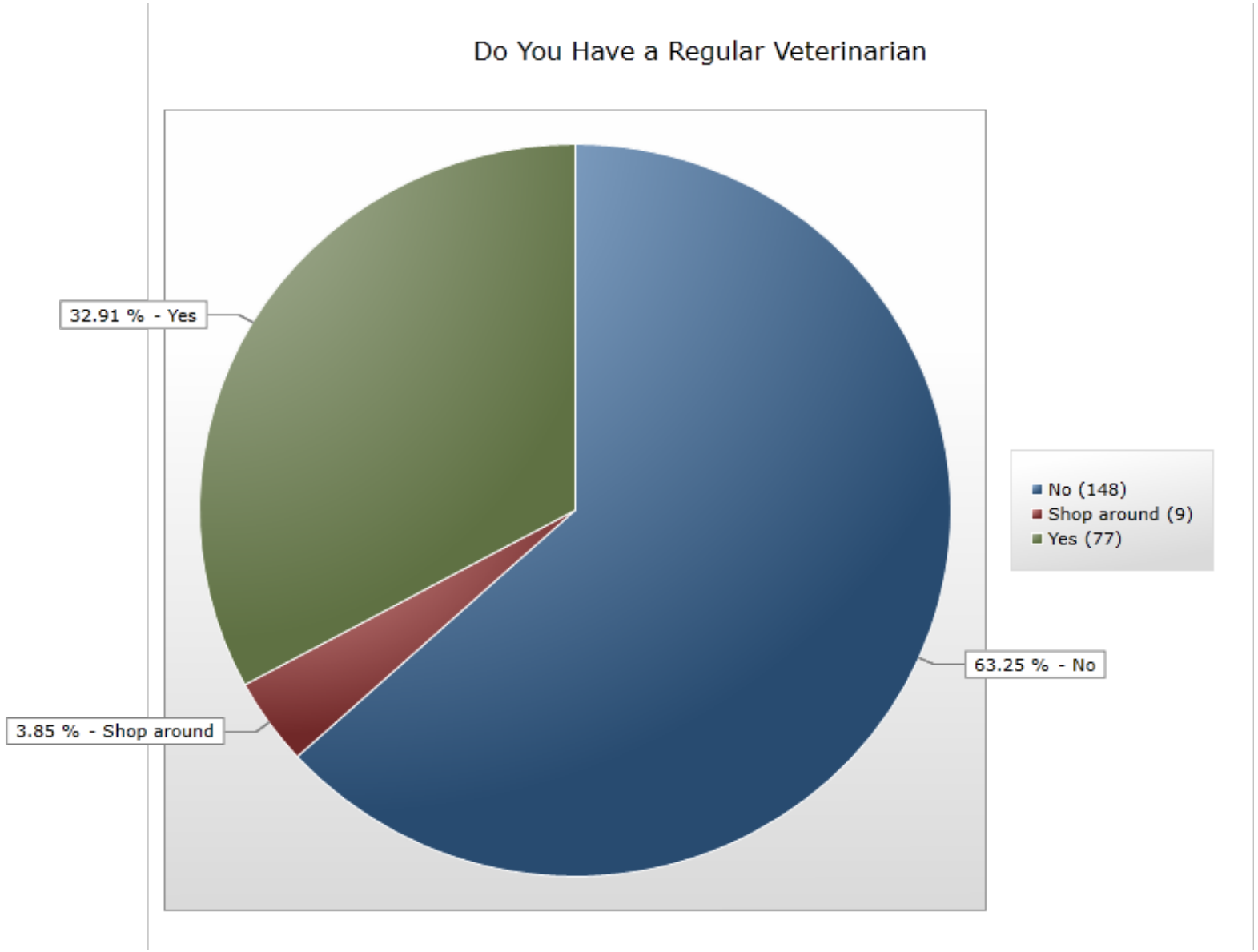

How Many Pets Did You Bring in Today
1.28 % - 4
5.56 %
20.51 % - 2
72.65 % - 1
1 (170)
2 (48)
3 (13)
4 (3)

AVMA pet owning assumptions and estimates

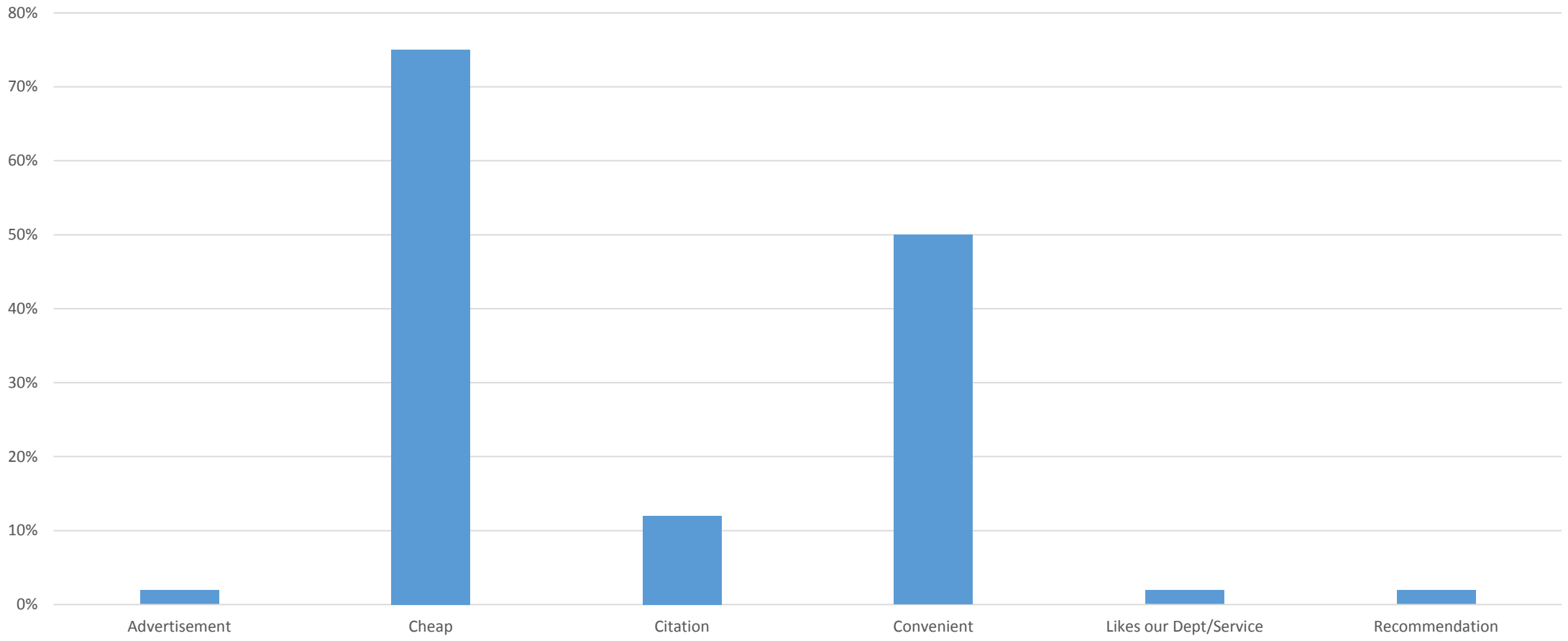
	Dogs	Cats	Birds	Horses
Percent of households owning	36.5%	30.4%	3.1%	1.5%
Number of households owning	43,346,000	36,117,000	3,671,000	1,780,000
Average number owned per household	1.6	2.1	2.3	2.7
Total number in United States	69,926,000	74,059,000	8,300,000	4,856,000
Veterinary visits per household per year (mean)	2.6	1.6	0.3	1.9
Veterinary expenditure per household per year (mean)	$378	$191	$33	$373
Veterinary expenditure per animal (mean)	$227	$90	$14	$133

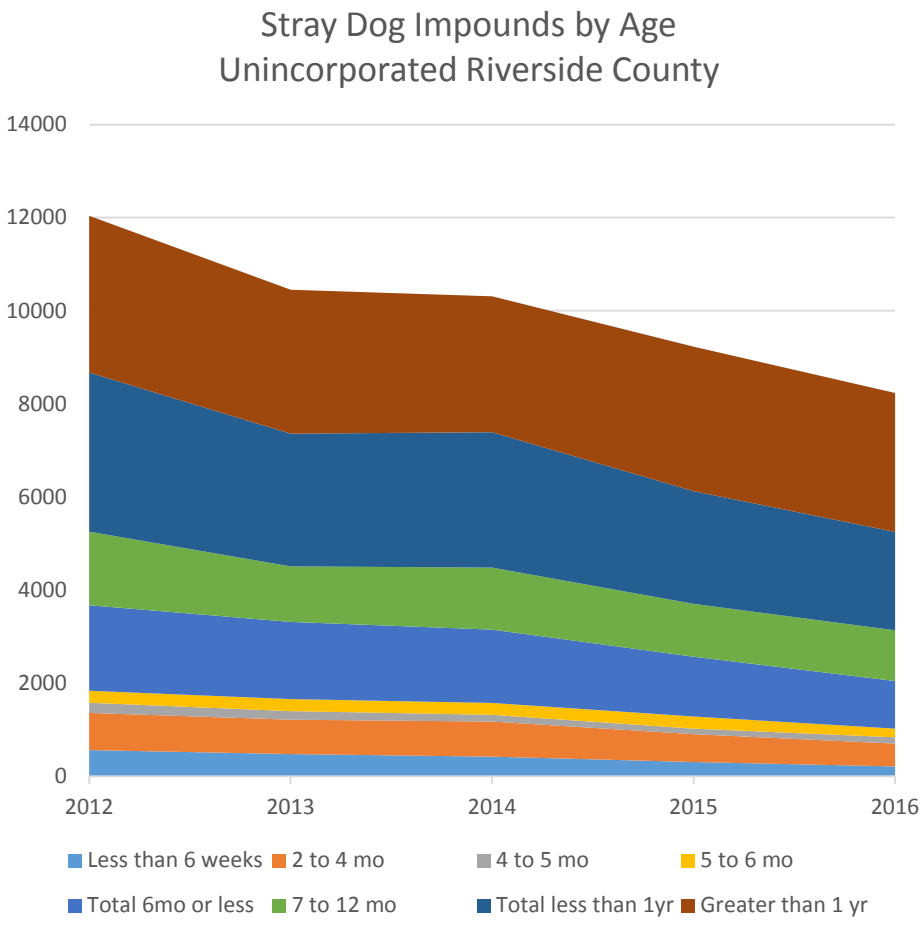
Riverside data indicated:

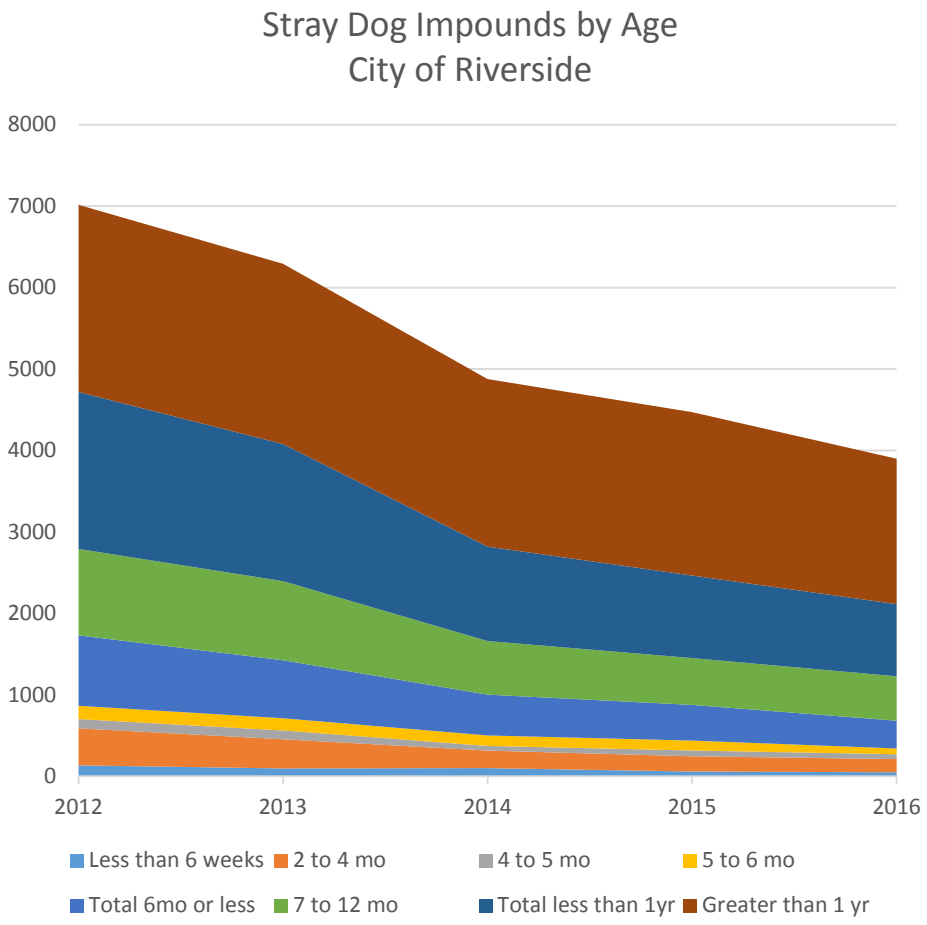
- The average number of pets in the home = 2
- The median number of pets in the home = 2
- The average age of the pets presented to the clinic = 2.8 years
- The median age of the pets presented to the clinic = 2.0
- A little more than one third (34%) of the pets presented aged one year or less did not have a DVM and that percent rose to almost 50% of the pets aged 2 and under.


Do You Have a Regular Veterinarian
32.91 % - Yes
3.85 % - Shop around
63.25 % - No
No (148)
Shop around (9)
Yes (77)

Why Did You Attend This Clinic




Stray Dog Impounds by Age
Unincorporated Riverside County
14000
12000
10000
8000
6000
4000
2000
0
2012
2013
2014
2015
2016
Less than 6 weeks
2 to 4 mo
4 to 5 mo
5 to 6 mo
Total 6mo or less
7 to 12 mo
Total less than 1yr
Greater than 1 yr


Stray Dog Impounds by Age
City of Riverside
8000
7000
6000
5000
4000
3000
2000
1000
0
2012
2013
2014
2015
2016
Less than 6 weeks
2 to 4 mo
4 to 5 mo
5 to 6 mo
Total 6mo or less
7 to 12 mo
Total less than 1yr
Greater than 1 yr

Veterinary Compounding – Draft Proposal
Subcommittee Member Richard Sullivan
January 2017

Statute:

BPC 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.

Proposed Regulations:

2033. Compounding in a Veterinary Practice. [Pharm 1735.2]
(a) "Compounding" means any of the following activities occurring in a licensed veterinary premises by a veterinarian that has established the VCPR for the patient(s) or a RVT under the indirect orders of that veterinarian.
(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 preparation from chemicals or bulk 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.

2033.1 Compounding Limitations and Requirements. [Pharm 1735.2]
(a) No drug should be compounded prior to its need by a patient.
(b) A veterinarian should prepare a written master formula record that includes:
(1) Active ingredients
(2) Equipment used
(3) The BUD of the preparation or expiration date
(4) Inactive ingredients used
(5) Specific compounding steps used to prepare the drug.
(6) Instructions for storage, handling, and administration of preparation.
(c) Where the veterinarian does not routinely compound a particular preparation, the formula record for that preparation may be kept in the medical record of the patient.
(d) The veterinarian performing or supervising compounding is the person that is responsible for the preparation including:
(1) The training and oversight of the RVT that is compounding the preparation
(2) Labeling information as to storage, handling, and administration of the preparation
(3) BUD or expiration date on the label which shall be the shortest expiration date of any of its ingredients and shall not exceed 180 days.

2033.2 Recordkeeping for Compounded Drug Preparations: [Pharm 1735.3]
(a) The record of the compounded preparation shall be kept in the patient file and shall include:
(1) The name or initials of the veterinarian who established the VCPR that established the need for the compounded preparation.
(2) The veterinarian's name or initials that made or oversaw the RVT (name or initials) that made the preparation.
(3) Its BUD or expiration date
(4) The directions for its administration.

2033.3 Labeling of Compounded Drug Preparations. [Pharm 1735.4]
(a) All labeling of any compounded drug preparation shall comply with Section 2032.2(b) of the VPA.

2033.4 Compounding Policies and Procedures. [Pharm 1735.5]
(a) A veterinary premises that engages in compounding drug preparations must only do simple compounding procedures as defined in "<795> Pharmaceutical Compounding – Nonsterile Preparations, Revision Bulletin, Official January 1, 2014.", Unless that compounding is in accordance with 1751: Sterile Compounding in Veterinary Premises.
(b) The veterinary premises that engage in compounding drug preparations must develop a policy and procedure manual. The manual will describe the process of how each compounded preparation is made and the training of RVT(s) that may have that responsibility. Those preparations that are rare may be documented in the medical records as stated in 1735.2(c).

2033.5 Compounding Facilities and Equipment. [Pharm 1735.6]
(a) The location and the equipment where simple compounded preparations are made shall be kept clean and well maintained.
(b) No hazardous drug compounding will be done at a veterinary premises without the proper equipment, protective gear, and trained personal.

2033.5 Training of Compounding Staff. [Pharm 1735.7]
(a) The Policy and Procedure manual will document the training of the RVT staff who are qualified to compound simple drug preparations. Only those staff members that the licensee manager feels are competent to compound simple drug preparations will be allowed to do so.

2033.6 Sterile Compounding in Veterinary Premises. [Pharm 1751]
(a) Sterile compounding shall be for immediate use except in the following conditions:
(1) A dilution of the ingredients is essential for the safe administration of the preparation.
(2) There are no other human or animal drugs that satisfy the need of this preparation.
(3) There is a historical documentation of the need, safety, and efficacy of this preparation.
(4) Only FDA approved sterile drugs can be used as the ingredients.
(5) BUD of 30 days unless an ingredient has a shorter BUD.
(6) No hazardous drugs may be used.

2033.7 Inspection Authority.
The California State Board of Pharmacy and the California Veterinary Medical Board shall have authority to inspect any veterinary premises engaged in compounding to ensure compliance.

The Veterinary Medical Board is charged with enforcing the provisions of this Chapter.

〈795 PHARMACEUTICAL COMPOUNDING—NONSTERILE PREPARATIONS

INTRODUCTION

The purpose of this chapter is to provide compounders with guidance on applying good compounding practices for the preparation of nonsterile compounded formulations for dispensing and/or administration to humans or animals. Compounding is an integral part of pharmacy practice and is essential to the provision of healthcare. This chapter and applicable monographs on formulation help define good compounding practices. Furthermore, this chapter provides general information to enhance the compounder's ability in the compounding facility to extemporaneously compound preparations that are of acceptable strength, quality, and purity. Pharmacists, other healthcare professionals, and others engaged in the compounding of drug preparations should comply with applicable state and federal compounding laws, regulations, and guidelines.

DEFINITIONS

ACTIVE PHARMACEUTICAL INGREDIENT (API)—Any substance or mixture of substances intended to be used in the compounding of a drug preparation, thereby becoming the active ingredient in that preparation and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans and animals or affecting the structure and function of the body.

ADDED SUBSTANCES—Ingredients that are necessary to compound a preparation but are not intended or expected to cause a pharmacologic response if administered alone in the amount or concentration contained in a single dose of the compounded preparation. The term is used synonymously with the terms *inactive ingredients, excipients,* and *pharmaceutical ingredients.*

BEYOND-USE DATE (BUD)—The date after which a compounded preparation should not to be used; determined from the date the preparation is compounded.

COMPONENT—Any ingredient used in the compounding of a drug preparation, including any active ingredient or added substance that is used in its preparation.

COMPOUNDER—A professional authorized by the appropriate jurisdiction to perform compounding pursuant to a prescription or medication order by a licensed prescriber.

COMPOUNDING—The preparation, mixing, assembling, altering, packaging, and labeling of a drug, drug-delivery device, or device in accordance with a licensed practitioner's prescription, medication order, or initiative based on the practitioner/patient/pharmacist/compounder relationship in the course of professional practice. Compounding includes the following:

- Preparation of drug dosage forms for both human and animal patients
- Preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns
- Reconstitution or manipulation of commercial products that may require the addition of one or more ingredients
- Preparation of drugs or devices for the purposes of, or as an incident to, research (clinical or academic), teaching, or chemical analysis
- Preparation of drugs and devices for prescriber's office use where permitted by federal and state law

HAZARDOUS DRUG—Any drug identified by at least one of the following six criteria:

- Carcinogenicity
- Teratogenicity or developmental toxicity
- Reproductive toxicity in humans
- Organ toxicity at low doses in humans or animals
- Genotoxicity
- New drugs that mimic existing hazardous drugs in structure or toxicity [for examples see current National Institute for Occupational Safety and Health (NIOSH) publications]

MANUFACTURING—The production, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction of the drug from substances of natural origin or by means of chemical or biological synthesis. Manufacturing may also include any packaging or repackaging of the substance(s) or labeling or relabeling of containers for resale by pharmacies, practitioners, or other persons.

PREPARATION—For the purposes of this chapter, a compounded drug dosage form or dietary supplement or a device to which a compounder has introduced a drug. This term will be used to describe compounded formulations; the term *product* will be used to describe manufactured pharmaceutical dosage forms. (For the definitions of *official substance* and *official products*, see *General Notices and Requirements*.)

STABILITY—The extent to which a preparation retains, within specified limits and throughout its period of storage and use, the same properties and characteristics that it possessed at the time of compounding (see *Stability Considerations in Dispensing Practice* 〈1191, the table *Criteria for Acceptable Levels of Stability*).

VEHICLE—A component for internal or external use that is used as a carrier or diluent in which liquids, semisolids, or solids are dissolved or suspended. Examples include, but are not limited to, water, syrups, elixirs, oleaginous liquids, solid and semisolid carriers, and proprietary products.

CATEGORIES OF COMPOUNDING

In the three general categories of nonsterile compounding described in this section, different levels of experience, training, and physical facilities are associated with each category.

Criteria used to determine overall classification include:

- degree of difficulty or complexity of the compounding process
- stability information and warnings
- packaging and storage requirements
- dosage forms
- complexity of calculations
- local versus systemic biological disposition
- level of risk to the compounder
- potential for risk of harm to the patient

See *Pharmaceutical Compounding—Sterile Preparations* 〈797 for risk levels associated with sterile preparations. Specialty areas such as radiopharmaceuticals require special training and are beyond the scope of this chapter. Compounders shall acquire and maintain knowledge and skills in all areas (e.g., dosage form, patient population, and medical specialty) for which they compound.

Description of Categories

Simple—Making a preparation that has a *United States Pharmacopeia* (*USP*) compounding monograph or that appears in a peer-reviewed journal article that contains specific quantities of all components, compounding procedure and equipment, and stability data for that formulation with appropriate BUDs; or reconstituting or manipulating commercial products that may require the addition of one or more ingredients as directed by the manufacturer. Examples include *Captopril Oral Solution*, *Indomethacin Topical Gel*, and *Potassium Bromide Oral Solution, Veterinary*.

Moderate—Making a preparation that requires special calculations or procedures (such as calibration of dosage unit mold cavities) to determine quantities of components per preparation or per individualized dosage units; or making a preparation for which stability data for that specific formulation are not available. Examples include *Morphine Sulfate Suppositories*, diphenhydramine hydrochloride troches, and mixing two or more manufactured cream products when the stability of the mixture is not known.

Complex—Making a preparation that requires special training, environment, facilities, equipment, and procedures to ensure appropriate therapeutic outcomes. Examples of possible complex preparation types include transdermal dosage forms, modified-release preparations, and some inserts and suppositories for systemic effects.

RESPONSIBILITIES OF THE COMPOUNDER

The compounder is responsible for compounding preparations of acceptable strength, quality, and purity and in accordance with the prescription or medication order. The compounder is also responsible for dispensing the finished preparation, with appropriate packaging and labeling, and in compliance with the requirements established by the applicable state agencies, state boards of pharmacy, federal law, and other regulatory agencies where appropriate. Individuals who are engaged in drug or dietary supplement compounding shall be proficient in compounding and should continually expand their compounding knowledge by participating in seminars and/or studying appropriate literature. They shall be knowledgeable about the contents of this chapter and should be familiar with *Pharmaceutical Compounding—Sterile Preparations* ⟨797, *Pharmaceutical Dosage Forms* ⟨1151, *Pharmaceutical Calculations in Prescription Compounding* ⟨1160, *Quality Assurance in Pharmaceutical Compounding* ⟨1163, *Prescription Balances and Volumetric Apparatus* ⟨1176, *Stability Considerations in Dispensing Practice* ⟨1191, *Written Prescription Drug Information—Guidelines* ⟨1265, and all applicable compounding laws, guidelines, and standards.

To ensure the quality of compounded preparations, compounders shall adhere to the following general principles (additional information on these general principles is provided in the sections that follow).

General Principles of Compounding

1. Personnel are appropriately trained and are capable of performing and qualified to perform their assigned duties. Such training should be documented.
2. Compounding ingredients of the appropriate identity, purity, and quality are purchased from reliable sources and are properly stored according to manufacturer specifications or *USP* standards.
3. Bulk component containers are labeled with appropriate Occupational Safety and Health Administration (OSHA) hazard communication labels (see OSHA.gov), and Material Safety Data Sheets (MSDSs) are available to compounding personnel for all drugs and chemicals used in compounding.
4. All equipment used in compounding is clean, properly maintained, and used appropriately.
5. The compounding environment is suitable for its intended purpose; and procedures are implemented to prevent cross-contamination, especially when compounding with drugs (e.g., hazardous drugs and known allergens like penicillin) that require special precautions.
6. Only authorized personnel are allowed in the immediate vicinity of the drug compounding operations.
7. There is assurance that processes are always carried out as intended or specified and are reproducible.
8. Compounding conditions and procedures are adequate for preventing errors.
9. All aspects of compounding are appropriately documented.
10. Adequate procedures and records exist for investigating and correcting failures or problems in compounding, testing, or the preparation itself.

COMPOUNDING PROCESS

The compounder is responsible for ensuring that each individual incidence of compounding meets the criteria given in this section (additional information on these criteria is provided in the sections that follow).

Criteria When Compounding Each Drug Preparation

1. The dose, safety, and intended use of the preparation or device has been evaluated for suitability in terms of:
   - the chemical and physical properties of the components
   - dosage form
   - therapeutic appropriateness and route of administration, including local and systemic biological disposition
   - legal limitations, if any
2. A Master Formulation Record should be created before compounding a preparation for the first time. This record shall be followed each time that preparation is made. In addition, a Compounding Record should be completed each time a preparation is compounded.
3. Ingredients used in the formulation have their expected identity, quality, and purity. If the formulation is for humans, ingredients are not on a list of federally recognized drugs or specific drug products that have been withdrawn or removed from the market for safety or efficacy reasons (see www.FDA.gov). If the formulation is for food-producing animals, ingredients are not on a list of components prohibited for use in food-producing animals. Certificates of Analysis, when applicable, and MSDSs have been consulted for all ingredients used.
4. Compounding is done in an appropriately clean and sanitized area dedicated to this activity (see the section *Compounding Facilities*).
5. Only one preparation is compounded at one time in a specific workspace.
6. Appropriate compounding equipment has been selected and inspected for cleanliness and correct functioning and is properly used.

7. A reliable BUD is established to ensure that the finished preparation has its accepted potency, purity, quality, and characteristics, at least until the labeled BUD.
8. Personnel engaged in compounding maintain good hand hygiene and wear clean clothing appropriate to the type of compounding performed (e.g., hair bonnets, coats, gowns, gloves, facemasks, shoes, aprons, or other items) as needed for protection of personnel from chemical exposures and for prevention of drug contamination.
9. The preparation is made in accordance with this chapter, other official standards referenced in this chapter, and relevant scientific data and information.
10. Critical processes (including but not limited to weighing, measuring, and mixing) are verified by the compounder to ensure that procedures, when used, will consistently result in the expected qualities in the finished preparation.
11. The final preparation is assessed using factors such as weight, adequacy of mixing, clarity, odor, color, consistency, pH, and analytical testing as appropriate; and this information is recorded on the Compounding Record (see chapter 〈1163).
12. The preparation is packaged as recommended in the *Packaging and Drug Preparation Containers* section of this chapter.
13. The preparation container is labeled according to all applicable state and federal laws. The labeling shall include the BUD and storage and handling information. The labeling should indicate that "this is a compounded preparation."
14. The Master Formulation Record and the Compounding Record have been reviewed by the compounder to ensure that errors have not occurred in the compounding process and that the preparation is suitable for use.
15. The preparation is delivered to the patient or caregiver with the appropriate consultation.

COMPOUNDING FACILITIES

Compounding facilities shall have an adequate space that is specifically designated for compounding of prescriptions. This space shall provide for the orderly placement of equipment and materials to prevent mixups among ingredients, containers, labels, in-process materials, and finished preparations and is designed, arranged, and used to prevent adventitious cross-contamination. Areas used for sterile preparations shall be separated and distinct from the nonsterile compounding area (see *Pharmaceutical Compounding—Sterile Preparations* 〈*797, Environmental Quality and Control*).

Potable water shall be supplied for hand and equipment washing. This water meets the standards prescribed in the Environmental Protection Agency's National Primary Drinking Water Regulations (40 CFR Part 141). *Purified Water* (see *Purified Water* monograph) shall be used for compounding nonsterile drug preparations when formulations indicate the inclusion of water. *Purified Water* should be used for rinsing equipment and utensils. In those cases when a water is used to prepare a sterile preparation, follow the appropriate monographs and general chapters (see *Water for Pharmaceutical Purposes* 〈1231).

The plumbing system shall be free of defects that could contribute to contamination of any compounded preparation. Adequate hand and equipment washing facilities shall be easily accessible to the compounding areas. Such facilities shall include, but are not limited to, hot and cold water, soap or detergent, and an air-drier or single-use towels. The areas used for compounding shall be maintained in clean, orderly, and sanitary conditions and shall be maintained in a good state of repair. Waste shall be held and disposed of in a sanitary and timely manner and in accordance with local, state, and federal guidelines.

The entire compounding and storage area should be well lighted. Heating, ventilation, and air conditioning systems shall be controlled to avoid decomposition and contamination of chemicals (see the *General Notices and Requirements*, *Preservation, Packaging, Storage, and Labeling*, *Storage Temperature and Humidity*; and the manufacturers' labeled storage conditions). Appropriate temperature and humidity monitoring should be maintained as required for certain components and compounded dosage forms. All components, equipment, and containers shall be stored off the floor and in a manner to prevent contamination and permit inspection and cleaning of the compounding and storage area.

Hazardous drugs shall be stored, prepared, and handled by appropriately trained personnel under conditions that protect the healthcare workers and other personnel. The following are references for the safe handling of antineoplastic and hazardous drugs in healthcare settings:

- OSHA Technical Manual—Section VI: Chapter 2, *Controlling Occupational Exposure to Hazardous Drugs*
- NIOSH Alert: *Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health Care Settings* (DHHS (NIOSH) Publication No. 2004-165) and updates.

Disposal of all hazardous drug wastes shall comply with all applicable federal and state regulations. All personnel who perform routine custodial waste removal and cleaning activities in storage and preparation areas for hazardous drugs shall be trained in appropriate procedures to protect themselves and prevent contamination.

COMPOUNDING EQUIPMENT

The equipment and utensils used for compounding of a drug preparation shall be of appropriate design and capacity. The equipment shall be of suitable composition that the surfaces that contact components are neither reactive, additive, nor sorptive and therefore will not affect or alter the purity of the compounded preparations. The types and sizes of equipment depend on the dosage forms and the quantities compounded (see chapter 〈1176 and equipment manufacturers' instruction manuals).

Equipment shall be stored to protect it from contamination and shall be located to facilitate its use, maintenance, and cleaning. Automated, mechanical, electronic, and other types of equipment used in compounding or testing of compounded preparations shall be routinely inspected, calibrated as necessary, and checked to ensure proper performance. Immediately before compounding operations, the equipment shall be inspected by the compounder to determine its suitability for use. After use, the equipment shall be appropriately cleaned.

Extra care should be used when cleaning equipment used in compounding preparations that require special precaution (e.g., antibiotics and cytotoxic and other hazardous materials). When possible, special equipment should be dedicated for such use, or when the same equipment is being used for all drug products, appropriate procedures shall be in place to allow meticulous cleaning of equipment before use with other drugs. If possible, disposable equipment should be used to reduce chances of bioburden and cross-contamination.

COMPONENT SELECTION, HANDLING, AND STORAGE

The following guidelines shall be followed when selecting, handling, and storing components for compounded preparations.

1. A *United States Pharmacopeia* (*USP*), *National Formulary* (*NF*), or *Food Chemicals Codex* (*FCC*) substance is the recommended source of ingredients for compounding all preparations.
2. Compounders shall first attempt to use components manufactured in an FDA-registered facility. When components cannot be obtained from an FDA-registered facility, compounders shall use their professional judgment in selecting an acceptable and reliable source and shall establish purity and safety by reasonable means, which should include Certificate of Analysis, manufacturer reputation, and reliability of source.
3. Official compounded preparations are prepared from ingredients that meet requirements of the compendial monograph for those individual ingredients for which monographs are provided. These preparations may be labeled *USP* or *NF* as appropriate.
4. When components of compendial quality are not obtainable, components of high quality such as those that are chemically pure, analytical reagent grade, or American Chemical Society–certified may be used. However, these components should be used cautiously because the standards for analytical reagents or American Chemical Society–grade materials do not consider whether any impurity present raises human or animal safety concerns.
5. For components in containers that have an expiration date from the manufacturer or distributor, the material may be used in compounding before that expiration date (a) when the material is stored in its original container under conditions to avoid decomposition of the chemicals (see chapter ⟨1191 and *Packaging and Storage Requirements* ⟨659, unless other conditions are noted on the label), (b) when there is minimal exposure of the remaining material each time material is withdrawn from the container, and (c) when any withdrawals from the container are performed by those trained in the proper handling of the material. If the component has been transferred to a different container, that container shall be identified with the component name, original supplier, lot or control number, transfer date, and expiration date and shall provide integrity that is equivalent to or better than that of the original container.
6. For components that do not have expiration dates assigned by the manufacturer or supplier, the compounder shall label the container with the date of receipt and assign a conservative expiration date, not to exceed three years after receipt, to the component (see the *General Notices and Requirements*, *Preservation, Packaging, Storage, and Labeling*, *Labeling*, *Expiration Date and Beyond-Use Date*) based on the nature of the component and its degradation mechanism, the container in which it is packaged, and the storage conditions.
7. If a manufactured drug product is used as the source of active ingredient, the drug product shall be manufactured in an FDA-registered facility, and the manufacturer's product container shall be labeled with a batch control number and expiration date. When compounding with manufactured drug products, the compounder shall consider all ingredients, including excipients, present in the drug product relative to the intended use of the compounded preparation and the effect of manipulating the drug product on the therapeutic appropriateness and stability of the components.
8. If the preparation is intended for use as a dietary or nutritional supplement, then the compounder must adhere to this chapter and must also comply with any federal and state requirements. Generally, dietary supplements are prepared from ingredients that meet *USP, FCC*, or *NF* standards. Where such standards do not exist, substances may be used in dietary supplements if they have been shown to have acceptable food-grade quality using other suitable procedures.
9. When a component is derived from ruminant animals (e.g., bovine, caprine, ovine), the supplier shall provide written assurance that the component is in compliance with all federal laws governing processing, use, and importation requirements for these materials.
10. When compounding for humans, the compounder should consult the list of components that have been withdrawn or removed from the market for safety or efficacy reasons by FDA (see www.FDA.gov). When compounding for food-producing animals, the compounder should consult the list of components prohibited for use in food-producing animals.
11. All components used in the compounding of preparations must be stored as directed by the manufacturer, or according to *USP, NF,* or *FCC* monograph requirements, in a clean area, and under appropriate temperature and humidity conditions (controlled room temperature, refrigerator, or freezer). All components shall be stored off the floor, handled and stored to prevent contamination, and rotated so that the oldest stock is used first. All containers shall be properly labeled.

Change to read:

STABILITY CRITERIA AND BEYOND-USE DATING

The BUD is the date after which a compounded preparation shall not be used and is determined from the date when the preparation is compounded. Because compounded preparations are intended for administration immediately or following short-term storage, their BUDs are assigned on the basis of criteria different from those applied to assigning expiration dates to manufactured drug products.

BUDs should be assigned conservatively. When assigning a BUD, compounders shall consult and apply drug-specific and general stability documentation and literature when available and should consider:

- the nature of the drug and its degradation mechanism
- the dosage form and its components
- the potential for microbial proliferation in the preparation
- the container in which it is packaged
- the expected storage conditions
- the intended duration of therapy (see the *General Notices and Requirements*, *Preservation, Packaging, Storage, and Labeling*, *Labeling*, *Expiration Date and Beyond-Use Date*).

When a manufactured product is used as the source of the API for a nonsterile compounded preparation, the product expiration date cannot be used solely to assign a BUD for the compounded preparation. Instead, the compounder shall refer to the manufacturer for stability information and

to the literature for applicable information on stability, compatibility, and degradation of ingredients; shall consider stability factors in chapter ⟨1191; and shall use his or her compounding education and experience. All stability data shall be carefully interpreted in relation to the actual compounded formulation.

At all steps in the compounding, dispensing, and storage process, the compounder shall observe the compounded drug preparation for signs of instability. For more specific details of some of the common physical signs of deterioration (see chapter ⟨1191, *Observing Products for Evidence of Instability*). However, excessive chemical degradation and other drug concentration loss due to reactions may be invisible more often than visible.

General Guidelines for Assigning Beyond-Use Dates

In the absence of stability information that is applicable to a specific drug and preparation, the following table presents maximum BUDs recommended for nonsterile compounded drug preparations that are packaged in tight, light-resistant containers and stored at controlled room temperature, unless otherwise indicated (see the *General Notices and Requirements*, *Preservation, Packaging, Storage, and Labeling*). Drugs or chemicals known to be labile to decomposition will require shorter BUDs.

BUD by Type of Formulation[a]
For Nonaqueous Formulations—The BUD is not later than the time remaining until the earliest expiration date of any API or 6 months, whichever is earlier.
For Water-Containing Oral Formulations—The BUD is not later than 14 days when stored at controlled cold temperatures.
For Water-Containing Topical/Dermal and Mucosal Liquid and Semisolid Formulations—The BUD is not later than 30 days.

[a] These maximum BUDs are recommended for nonsterile compounded drug preparations in the absence of stability information that is applicable to a specific drug or preparation. The BUD shall not be later than the expiration date on the container of any component.

Susceptible preparations should contain suitable antimicrobial agents to protect against bacteria, yeast, and mold contamination inadvertently introduced during or after the compounding process. When antimicrobial preservatives are contraindicated in such compounded preparations, storage of the preparation at controlled cold temperature is necessary; to ensure proper storage and handling of such compounded preparations by the patient or caregiver, appropriate patient instruction and consultation is essential. Antimicrobial preservatives should not be used as a substitute for good compounding practices.

For information on assigning BUDs when repackaging drug products for dispensing or administration, see the *General Notices and Requirements*, *Preservation, Packaging, Storage, and Labeling*, *Labeling*, *Expiration Date and Beyond-Use Date*, and *Packaging and Repackaging—Single-Unit Containers* ⟨1136.

Assurance of sterility in a compounded sterile preparation is mandatory. Compounding and packaging of sterile drugs (including ophthalmic preparations) requires strict adherence to guidelines presented in chapter ⟨797 and in the manufacturers' labeling instructions.

PACKAGING AND DRUG PREPARATION CONTAINERS

The compounder shall ensure that the containers and container closures used in packaging compounded preparations meet *USP* requirements (see *Packaging and Storage Requirements* ⟨659; *Containers—Glass* ⟨660 *Containers—Plastics* ⟨661; *Containers—Performance Testing* ⟨671 chap-ter ⟨1136); and when available, compounding monographs. Compounders are not expected to perform the tests described in these chapters but should be knowledgeable about the standards described in them. Container suppliers shall supply, upon request, verification of *USP* container compliance. Containers and container closures intended for the compounding of sterile preparations must be handled as described in chapter ⟨797.

The containers and closures shall be made of suitable clean material in order not to alter the quality, strength, or purity of the compounded drug preparation. The container used depends on the physical and chemical properties of the compounded preparation. Container–drug interaction should be considered for substances that have sorptive or leaching properties.

The containers and closures shall be stored off the floor, handled and stored to prevent contamination, and rotated so that the oldest stock is used first. The containers and container closures shall be stored in such a way as to permit inspection and cleaning of the storage area.

COMPOUNDING DOCUMENTATION

Documentation, written or electronic, enables a compounder, whenever necessary, to systematically trace, evaluate, and replicate the steps included throughout the preparation process of a compounded preparation. All compounders who dispense prescriptions must comply with the record-keeping requirements of their state boards of pharmacy. When the compounder compounds a preparation according to the manufacturer's labeling instructions, then further documentation is not required. All other compounded preparations require further documentation as described in this section.

These records should be retained for the same period of time that is required for any prescription under state law. The record may be a copy of the prescription in written or machine-readable form and should include a Master Formulation Record and a Compounding Record.

Master Formulation Record

This record shall include:

- official or assigned name, strength, and dosage form of the preparation
- calculations needed to determine and verify quantities of components and doses of active pharmaceutical ingredients
- description of all ingredients and their quantities
- compatibility and stability information, including references when available
- equipment needed to prepare the preparation, when appropriate
- mixing instructions that should include:
  1. order of mixing
  2. mixing temperatures or other environmental controls
  3. duration of mixing
  4. other factors pertinent to the replication of the preparation as compounded
- sample labeling information, which shall contain, in addition to legally required information:

1. generic name and quantity or concentration of each active ingredient
2. assigned BUD
3. storage conditions
4. prescription or control number, whichever is applicable

- container used in dispensing
- packaging and storage requirements
- description of final preparation
- quality control procedures and expected results

Compounding Record

The Compounding Record shall contain:

- official or assigned name, strength, and dosage of the preparation
- Master Formulation Record reference for the preparation
- names and quantities of all components
- sources, lot numbers, and expiration dates of components
- total quantity compounded
- name of the person who prepared the preparation, name of the person who performed the quality control procedures, and name of the compounder who approved the preparation
- date of preparation
- assigned control or prescription number
- assigned BUD
- duplicate label as described in the Master Formulation Record
- description of final preparation
- results of quality control procedures (e.g., weight range of filled capsules, pH of aqueous liquids)
- documentation of any quality control issues and any adverse reactions or preparation problems reported by the patient or caregiver

Standard Operating Procedures

All significant procedures performed in the compounding area should be covered by written standard operating procedures (SOPs). Procedures should be developed for the facility, equipment, personnel, preparation, packaging, and storage of compounded preparations to ensure accountability, accuracy, quality, safety, and uniformity in compounding. Implementing SOPs establishes procedural consistency and also provides a reference for orientation and training of personnel.

Material Safety Data Sheets File

MSDSs shall be readily accessible to all employees working with drug substances or bulk chemicals located on the compounding facility premises. Employees should be instructed on how to retrieve and interpret needed information.

QUALITY CONTROL

The safety, quality, and performance of compounded preparations depend on correct ingredients and calculations, accurate and precise measurements, appropriate formulation conditions and procedures, and prudent pharmaceutical judgment. As a final check, the compounder shall review each procedure in the compounding process. To ensure accuracy and completeness, the compounder shall observe the finished preparation to ensure that it appears as expected and shall investigate any discrepancies and take appropriate corrective action before the prescription is dispensed to the patient.

Compounding Controls

1. The Master Formulation Record, the Compounding Record, and associated written procedures shall be followed in execution of the compounding process. Any deviation in procedures shall be documented.
2. The compounder shall check and recheck each procedure at each stage of the process. If possible, a trained second person should verify each critical step in the compounding process.
3. The compounder shall have established written procedures that describe the tests or examinations conducted on the compounded preparation (e.g., the degree of weight variation among capsules) to ensure their uniformity and integrity.
4. Appropriate control procedures shall be established to monitor the output and to verify the performance of compounding processes and equipment that may be responsible for causing variability in the final compounded preparations.
5. For further guidance on recommended quality control procedures, see chapter ⟨1163.

PATIENT COUNSELING

At the time of dispensing the prescription, the patient or the patient's agent shall be counseled about proper use, storage, handling, and disposal of the compounded preparation. The patient or the patient's agent shall also be instructed to report any adverse event and to observe and report to the compounder any changes in the physical characteristics of the compounded preparation (see *Stability Considerations in Dispensing* ⟨1191*, Responsibility of Pharmacists*). The compounder shall investigate and document any reported problem with a compounded preparation and shall take corrective action.

TRAINING

All personnel involved in the compounding, evaluation, packaging, and dispensing of compounded preparations shall be properly trained for the type of compounding conducted. It is the responsibility of the compounder to ensure that a training program has been implemented and that it is ongoing. Compounding personnel should be evaluated at least annually. Steps in the training procedure include the following:

- All employees involved in pharmaceutical compounding shall read and become familiar with this chapter. They should also be familiar with the contents of the *USP Pharmacists' Pharmacopeia* and other relevant publications, including how to read and interpret MSDSs.
- All employees shall read and become familiar with each of the procedures related to compounding, including those involving the facility, equipment, personnel, actual compounding, evaluation, packaging, storage, and dispensing.
- All personnel who compound hazardous drugs shall be fully trained in the storage, handling, and disposal of these drugs. This training shall occur before preparing or handling hazardous drugs. For information on training for personnel who compound hazardous drugs, see the references in *Compounding Facilities* earlier in this chapter.
- All training activities shall be documented. The compounder shall meet with employees to review their

work and answer any questions the employees may have concerning compounding procedures.
- The compounder shall demonstrate the procedures for the employee and shall observe and guide the employee throughout the training process. The employee will then repeat the procedure without any assistance from, but under the direct supervision of, the compounder.
- When the employee has demonstrated to the compounder a verbal and functional knowledge of the procedure, then and only then will the employee be permitted to perform the procedure without direct supervision. However, the compounder should be physically present and shall approve all ingredients and their quantities and the final preparation.
- When the compounder is satisfied with the employee's knowledge and proficiency, the compounder will sign the documentation records to show that the employee was appropriately trained.
- The compounder shall continually monitor the work of the employee and ensure that the employee's calculations and work are accurate and adequately performed.
- The compounder is solely responsible for the finished preparation.

COMPOUNDING FOR ANIMAL PATIENTS

A compounder's responsibility for providing patients with high-quality compounded preparations extends beyond the human species. All portions of this chapter apply to compounded preparations formulated for animal patients. Intended use of any animal patient (e.g., companion, performance, food) shall be determined before compounding for that patient.

Because humans can consume animal patients as food, care must be taken to prevent drug residues from entering the human food chain when compounded preparations are used in animal patients. For this reason, all compounders preparing formulations for animals shall possess a functional knowledge of drug regulation and disposition in animal patients. Veterinarians are required by law to provide food-producing animal caregivers with an accurate length of time to withhold treated animal tissues (e.g., meat, milk, eggs) from the human food supply. This length of time is referred to as a withdrawal time (WDT) and must also, by law, be included on the dispensing label of every prescription prepared for a food-producing species.

Drug use in any performance animal is strictly regulated by federal and state governments, in addition to the governing bodies of each of the specific disciplines. Penalties for violation of these rules may be severe for all contributing to the violation, including the veterinarian, pharmacist, and caregiver.

The pharmacist shall be knowledgeable about the individual species' limitations in physiology and metabolic capacity that can result in toxicity when certain drugs or excipients are used in compounded preparations. For this reason, compounders making preparations for animals should use, when possible, formulations specifically developed for animal patients. If such formulations are not available, the compounder shall conduct a literature review to determine whether a specific component of the formula is toxic to the target species. Extrapolating compounding formulations intended for use in humans may not be appropriate for animal species and may contribute to negative outcomes.

Veterinarians and pharmacists making preparations for animal patients should be familiar with all state and federal regulations regarding drug use in animals, including but not limited to the Food, Drug, and Cosmetic Act; the Animal Drug Amendment; the Animal Medicinal Drug Use Clarification Act; and FDA's Compliance Policy Guideline for Compounding of Drugs for Use in Animal Patients.

Board of Pharmacy

Order of Adoption (CLEAN)

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 preparation from chemicals or bulk drug substances

(b) "Compounding" does not include reconstitution of a drug pursuant to a manufacturer's direction(s), 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) The parameters and requirements stated by Article 4.5 (Section 1735 et seq.) apply to all compounding practices. Additional parameters and requirements applicable solely to sterile 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 beyond use date 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, 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 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 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 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 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" 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 preparation that:

(1) Is ordered by the prescriber or the prescriber's agent using a purchase order or other documentation received by the pharmacy prior to furnishing that lists the number of patients seen or to be seen in the prescriber's office for whom the drug is needed or anticipated, and the quantity for each patient that is sufficient for office administration; 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

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

(5) With regard to any individual prescriber to whom the pharmacy furnishes, and with regard to all prescribers to whom the pharmacy furnishes, 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 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.

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

(1) Active ingredients to be used.

(2) Equipment to be used.

(3) 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) 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.

(f) Where a pharmacy does not routinely compound a particular drug preparation, the master

formula record for that preparation may be recorded on the prescription document itself.

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

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

(i) Every compounded drug preparation shall be given 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.

(1) For non-sterile compounded drug preparation(s), 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 compounded drug 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

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

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

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

(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 compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of each odd-numbered year, within 30 days of the start date of a new pharmacist-in-charge or change of location, and within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

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

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

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

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

1735.3. Recordkeeping for Compounded Drug Preparations.

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

(1) The master formula 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 preparation was compounded.

(C) The identity of any pharmacy personnel engaged in compounding the drug preparation.

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

(E) The quantity of each ingredient used in compounding the drug preparation.

(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 preparations compounded 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 (37th Revision, Effective December 1, 2014), hereby incorporated by reference.

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

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

(I) The final quantity or amount of drug 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 chemicals, bulk drug substances, and drug products used to compound drug preparations shall be obtained, whenever possible, from FDA-registered suppliers. The pharmacy shall acquire and retain certificates of purity or analysis, either written in English or translated into English, for chemicals, bulk drug substances, and drug products 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 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 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.

(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.

(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.

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

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

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

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

(2) A written plan for recall of a dispensed compounded drug preparation where subsequent information demonstrates the potential for adverse effects with continued use. 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) 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.

(5) Documentation of the methodology used to validate integrity, potency, quality, and labeled

strength of compounded drug preparations. The methodology must be appropriate to compounded drug preparations.

(6) Documentation of the methodology and rationale or reference source used to determine appropriate beyond use dates for compounded drug 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 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 preparations shall be stored, used, maintained,

and cleaned in accordance with manufacturers' specifications.

(c) Any equipment that weighs, measures, or transfers ingredients used to compound drug 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 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.

(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 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 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. All qualitative and quantitative analysis reports for compounded drug preparations shall be retained by the pharmacy and maintained along with the compounding log 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 preparation is ever discovered to be 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 Compounding

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

(a) Any pharmacy engaged in compounding sterile drug 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 compounding.
(b) Any pharmacy compounding sterile drug preparations shall have a compounding area designated for the preparation of sterile drug 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. The environments within the pharmacy shall meet the following standards:
(1) Each ISO environment shall be certified at least every six months by a qualified technician in accordance with Section 1751.4. Certification records must be retained in the pharmacy.
(2) Items related to the compounding of sterile drug preparations within the compounding area shall be stored in such a way as to maintain the integrity of an aseptic environment.
(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).
(4) There shall be a refrigerator and, 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.

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

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

1751.1. Sterile Compounding Recordkeeping Requirements.

(a) In addition to the records required by section 1735.3, any pharmacy engaged in any

compounding of sterile drug preparations shall maintain the following records, which must be readily retrievable, within the pharmacy:

(1) Documents evidencing training and competency evaluations of employees in sterile 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, 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 records specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment).

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

(11) Preparation records including the master formula document, the preparation compounding log, 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 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 that compounds sterile drug preparations shall include the following information on the labels for each such preparation:

(a) The telephone number of the pharmacy. The telephone number is not required on the label for sterile drug preparations administered to inpatients within the hospital.

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

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

(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) Policies and procedures shall be immediately available to all personnel involved in compounding activities and to board inspectors.

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

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

1751.4. Facility and Equipment Standards for Sterile Compounding.

(a) No sterile drug 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 drug preparations.

(b) During the compounding of sterile drug preparations, access to the areas designated for compounding must be limited to those individuals who are properly attired.

(c) All equipment used in the areas designated 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.

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

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

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

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

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

(g) Pharmacies preparing sterile hazardous agents shall do so in accordance with Section 505.5.1 of Title 24, Chapter 5, of the California Code of Regulations, requiring a negative pressure PEC. Additionally, each PEC used to compound hazardous agents shall be externally vented. The negative pressure PEC must be certified every six months by a qualified technician who is familiar with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-13, Revised May 20, 2015), which is hereby incorporated by reference. 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 Compounding Attire.

(a) When compounding sterile drug preparations the following standards must be met:

(1) Personal protective equipment consisting of a non-shedding 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) Personal protective equipment must be donned and removed 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.

(4) Compounding personnel shall not wear any wrist, hand, finger, or other visible jewelry, piercing, headphones, earbuds, or personal electronic device.

(5) 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.

(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 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 drug preparations and related supplies furnished by the pharmacy.

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

(e) Pharmacies that compound sterile drug 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 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 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 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 Compounding Quality Assurance and Process Validation.

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

(1) Procedures for cleaning and sanitization of the sterile preparation area.

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

(3) Documentation justifying the chosen beyond use dates for compounded sterile drug 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.

(c) All sterile compounding personnel must successfully complete an initial competency evaluation. In addition, immediately following the initial hand hygiene and garbing procedure,

each individual who may be required to do so in practice must successfully complete a gloved fingertip (all fingers on both hands) sampling procedure (zero colony forming units for both hands) at least three times before initially being allowed to compound sterile drug preparations.

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

(e)(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.

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:

1751.10. Sterile Compounding Reference Materials.

In any pharmacy engaged in compounding sterile drug preparations, there shall be current and appropriate reference materials regarding the compounding of sterile drug 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:

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:

1753. Furnishing to Home Health Agencies and Licensed Hospices.

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

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

(1) furnished by a registered pharmacist;

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

(3) under the effective control of a registered nurse, pharmacist or delivery person at all times when not in the pharmacy;

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

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

(b) The portable container may contain up to:

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

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

(3) two vials of urokinase 5000 units;

(4) Each of the following items shall be in sealed, unused containers; the furnishing pharmacy

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

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

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

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

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

(E) diphenhydramine HCl 50mg/mL;

(F) methylprednisolone 125mg/2mL;

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

(H) naloxone 1mg/mL 2 mL;

(I) droperidol 5mg/2mL;

(J) prochlorperazine 10mg/2mL;

(K) promethazine 25mg/mL;

(L) dextrose 25gms/50mL;

(M) glucagon 1mg/mL;

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

(O) bumetamide 0.5mg/2mL;

(P) furosemide 10mg/mL;

(Q) EMLA Cream 5 gm tube;

(R) Lidocaine 1 percent 30mL vials.

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

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

(1) implement and maintain policies and procedures for:

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

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

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

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

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

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

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

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

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

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

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

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

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 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 -1753.

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

Virginia Herold
Executive Officer
California State Board of Pharmacy

CODE OF FEDERAL REGULATIONS:

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

PART 530 EXTRALABEL DRUG USE IN ANIMALS

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

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

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

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

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

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

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

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

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

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

Support

Contact Information

Frequently Asked Questions

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<797> Pharmaceutical Compounding—Sterile Preparations

Frequently Asked Questions: <797> Pharmaceutical Compounding—Sterile Preparations

Adapted from USP's FAQ on Compounding.

1. **When was General Chapter <797> was last revised?**
   General Chapter <797> was first published in 2004. The chapter was last revised in USP31–NF26 2nd Supplement, which became official on June 1, 2008.

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2. **Is USP considering revisions to General Chapter <797>?**
   Yes, the Compounding Expert Committee began the revision process for General Chapter <797> in July 2010 and completed their work in 2015. The proposed revision was published for public comment in Pharmacopeial Forum 41(6) Nov—Dec 2015 and at www.usp.org/usp-nf/notices/general-chapter-797-proposed-revision. Public comments on the proposed chapter were due on January 31, 2016. The Compounding Expert Committee is currently reviewing all of the public comments received.

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3. **How can I obtain a copy of General Chapter <797>?**
   You can download a copy of the proposed revisions to <797> at www.usp.org/usp-nf/notices/general-chapter-797-proposed-revision.

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4. **When will the final revision to General Chapter <797> be published?**
   The earliest that General Chapter <797> may be published is on November 1, 2016 in USP 40-NF35 with the earliest official date of May 1, 2017. However, please note that this is highly dependent on the public comments that are submitted on the chapter. Based on the nature and significance of the public comments received, the Committee will determine whether the chapter will be revised, republished in the Pharmacopeial Forum, or forwarded to ballot. More information about USP's development process can be found here and the publication and comment schedule can be found here.

5. **How can I obtain a copy of the currently official General Chapter <797>?**
   You may purchase a copy of the currently official chapter through several publications. You may purchase the chapter through a subscription to the USP Compounding Compendium or USP-NF.

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2032.1. Veterinarian-Client-Patient Relationship.

(a) It is unprofessional conduct for a veterinarian to administer, prescribe, dispense or furnish a drug, medicine, appliance, or treatment of whatever nature for the prevention, cure, or relief of a wound, fracture or bodily injury or disease of an animal without having first established a veterinarian-client-patient relationship with the animal patient or patients and the client, except where the patient is a wild animal or the owner is unknown.

(b) A veterinarian-client-patient relationship shall be established by the following:

(1) The client has authorized the veterinarian to assume responsibility for making medical judgments regarding the health of the animal, including the need for medical treatment,

(2) The veterinarian has sufficient knowledge of the animal(s) to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s). This means that the veterinarian is personally acquainted with the care of the animal(s) by virtue of an examination of the animal or by medically appropriate and timely visits to the premises where the animals are kept, and

(3) The veterinarian has assumed responsibility for making medical judgments regarding the health of the animal and has communicated with the client a course of treatment appropriate to the circumstance.

(c) A drug shall not be prescribed for a duration inconsistent with the medical condition of the animal(s) or type of drug prescribed. The veterinarian shall not prescribe a drug for a duration longer than one year from the date the veterinarian examined the animal(s) and prescribed the drug. A veterinarian or RVT shall provide information to the client regarding potential adverse reactions to the prescribed drug.

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

INITIATIVE MEASURE TO BE SUBMITTED DIRECTLY TO THE VOTERS

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The Attorney General of California has prepared the following circulating title and summary of the chief purpose and points of the proposed measure:

(Here set forth the unique numeric identifier provided by the Attorney General and circulating title and summary prepared by the Attorney General. Both the Attorney General's unique numeric identifier and the circulating title and summary must also be printed across the top of each page of the petition whereon signatures are to appear.)

TO THE HONORABLE SECRETARY OF STATE OF CALIFORNIA

Type: Roman Boldface not smaller than 12-point

We, the undersigned, registered, qualified voters of California, residents of Marin County, hereby propose amendments to the Business and Professions Code, and petition the Secretary of State to submit the same to the voters of California for their adoption or rejection at the next succeeding general election or at any special statewide election held prior to that general election or as otherwise provided by law. The proposed statutory amendments read as follows:

SECTION 1. This act may be known as Lizzie's Law.

SEC. 2. Article 7 (commencing with Section 4920) is added to Chapter 11 of Division 2 of the Business and Professions Code, to read:

Article 7. Pharmacy

4920. (a) (1) In addition to complying with the labeling requirements described in Section 4076, in nonemergency situations and outpatient settings, each time a veterinarian prescribes, administers, dispenses, or furnishes a drug or medicine, the veterinarian shall offer to provide the client with counseling and pharmaceutical literature prepared by the pharmaceutical laboratory or a brief handout prepared by the veterinarian. The handout shall be based on accredited professional sources and publications and shall be in the most simple and nonacademic language.

(2) The veterinarian or authorized representative shall provide the counseling to the best of his or her ability, knowledge, and availability of information, but neither the veterinarian nor the authorized representative shall be liable for the veracity and completeness of the information provided in the literature or handout if it is information obtained through a pharmaceutical laboratory or is based on accredited professional sources and publications. For this purpose, the veterinarian or authorized representative shall provide the client with a printed disclaimer explaining the lack of liability for the information in the literature or handout if it is obtained under those circumstances and the client shall sign the disclaimer.

(3) Unless there is a life-threatening warning or a critical update about the drug or medicine, a client may decline to receive the counseling, literature, or handout.

(4) The counseling, literature, and handout shall include all of the following information:

(A) The name of the drug or medicine, what it does, and why it is necessary.

(B) How and when to give the drug or medicine to the pet or service animal and for how long.

(C) What to do if a dose is missed.

(D) Possible risks and side effects, and what the client should do if they occur.

(E) An explanation of whether the drug or medicine is standard, long acting, or extended release and the possible additional risks for a long-acting or extended release drug or medicine in case of adverse effects.

(F) Whether the new drug or medicine and the prescribed dosage are appropriate for the pet or service animal's age, weight, and kidney and liver function.

(G) Whether the new drug or medicine will work safely with other drugs, medicines, or supplements.

(H) Foods or activities that should be avoided while giving the drug or medicine.

(5) (A) For injections, the counseling shall be provided before the injection is administered to the pet or service animal.

(B) If a long-acting or extended release drug or medicine is to be administered, the client shall also be counseled before the injection about the difference between standard and long-acting or extended release drugs or medicines. This counseling may include, but is not limited to, explaining adverse reactions due to prolonged systemic drug or medicine clearance of long-acting drugs or medicines in such a way that the

client understands that once the animal is injected there is no way to retrieve the drug or medicine.

(6) The literature or handout shall be provided in readable-sized font.

(b) At the discretion of the veterinarian, the counseling, literature, or handout may be provided by a registered veterinary technician or veterinary assistant who is employed by and working under the supervision of the veterinarian.

(c) (1) The literature or handout may be provided electronically or in any other format using available technology as long as it allows the client to confirm the material was received.

(2) The literature or handout shall be available to clients in English and may also be provided in Spanish and in any other language appropriate for the veterinary practice.

(3) The literature or handout shall also be provided to clients with special needs or disabilities in an easily accessible format, such as, but not limited to, a large-sized font.

(4) The counseling may be provided to the client through a telephone consultation by the veterinarian or his or her authorized representative who has access to the pet or service animal's record.

(d) (1) In every veterinary practice, there shall be prominently posted in a place conspicuous to, and readable by, clients a poster in English, Spanish, and in any other appropriate languages for the veterinary practice notifying clients about all of the information described in subdivision (a). The heading of the poster shall read "NOTICE TO CONSUMERS". As an alternative to the poster format, the poster information may also be displayed using a video screen or any other format using available technology.

(2) The poster shall also inform clients about the following consumer rights:

(A) The right to be offered drug or medicine counseling by the veterinarian or his or her authorized representative.

(B) The right to know basic pharmaceutical and drug and medicine interaction information.

(C) The right to receive drug and medicine information in readable-sized font.

(D) The right to have a choice to obtain either the medication or a written prescription and to not be charged for the written prescription as described in Section 2032.2 of Title 16 of the California Code of Regulations.

(3) If the safety or health of any pet or service animal is at risk, consistent with Section 4800.1, the board may adopt a regulation requiring additional information to be included on the poster.

Definitions of Sedation, GA

(Approved by ASA October 13, 1999)

Minimal Sedation (Anxiolysis)

- A drug-induced state during which patients respond normally to verbal commands.
- Cognitive function and coordination may be impaired.
- Ventilatory and cardiovascular functions are unaffected.

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Moderate Sedation/ Analgesia ("Conscious Sedation")

- A drug-induced depression of consciousness during which
  - patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation
  - reflex withdrawal from a painful stimulus is NOT considered a purposeful response
- No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate.
- Cardiovascular function is usually maintained.

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Deep Sedation/ Analgesia

- A drug-induced depression of consciousness during which patients cannot be easily aroused, but
  - respond purposefully following repeated or painful stimulation.
  - reflex withdrawal from a painful stimulus is NOT considered a purposeful response
- The ability to independently maintain ventilatory function may be impaired.
  - Patients may require assistance in maintaining a patent airway.
  - Spontaneous ventilation may be inadequate.
- Cardiovascular function is usually maintained.

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General Anesthesia

- A drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation.
- The ability to independently maintain ventilatory function is often impaired.

    - Patients often require assistance in maintaining a patent airway.
    - Positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function.
- Cardiovascular function may be impaired.

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The Continuum of Sedation -- Anesthesia

- Because sedation is a continuum, it is not always possible to predict how an individual patient will respond.
- Practitioners intending to produce a given level of sedation should be able to rescue patients whose level of sedation becomes deeper than initially intended.
    - Individuals administering Moderate Sedation/Analgesia ("Conscious Sedation") should be able to rescue patients who enter a state of Deep Sedation/Analgesia
    - Those administering Deep Sedation/Analgesia should be able to rescue patients who enter a state of general anesthesia.

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Monitored Anesthesia Care (MAC)

- Does not describe the continuum of depth of sedation.
- Rather, it describes "a specific anesthesia service in which an anesthesiologist has been requested to participate in the care of a patient undergoing a diagnostic or therapeutic procedure."

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American Society of Anesthesiologists®

CONTINUUM OF DEPTH OF SEDATION: DEFINITION OF GENERAL ANESTHESIA AND LEVELS OF SEDATION/ANALGESIA*

Committee of Origin: Quality Management and Departmental Administration

(Approved by the ASA House of Delegates on October 13, 1999, and last amended on October 15, 2014)

	Minimal Sedation Anxiolysis	*Moderate Sedation/ Analgesia ("Conscious Sedation")*	*Deep Sedation/ Analgesia*	*General Anesthesia*
Responsiveness	Normal response to verbal stimulation	Purposeful** response to verbal or tactile stimulation	Purposeful** response following repeated or painful stimulation	Unarousable even with painful stimulus
Airway	Unaffected	No intervention required	Intervention may be required	Intervention often required
Spontaneous Ventilation	Unaffected	Adequate	May be inadequate	Frequently inadequate
Cardiovascular Function	Unaffected	Usually maintained	Usually maintained	May be impaired

Minimal Sedation (Anxiolysis) is a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway reflexes, and ventilatory and cardiovascular functions are unaffected.

Moderate Sedation/Analgesia ("Conscious Sedation") is a drug-induced depression of consciousness during which patients respond purposefully** to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

* Monitored Anesthesia Care ("MAC") does not describe the continuum of depth of sedation, rather it describes "a specific anesthesia service in which an anesthesiologist has been requested to participate in the care of a patient undergoing a diagnostic or therapeutic procedure."

** Reflex withdrawal from a painful stimulus is NOT considered a purposeful response.

Deep Sedation/Analgesia is a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully** following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

General Anesthesia is a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. Hence, practitioners intending to produce a given level of sedation should be able to rescue*** patients whose level of sedation becomes deeper than initially intended. Individuals administering Moderate Sedation/Analgesia ("Conscious Sedation") should be able to rescue*** patients who enter a state of Deep Sedation/Analgesia, while those administering Deep Sedation/Analgesia should be able to rescue*** patients who enter a state of General Anesthesia.

** Reflex withdrawal from a painful stimulus is NOT considered a purposeful response.

*** Rescue of a patient from a deeper level of sedation than intended is an intervention by a practitioner proficient in airway management and advanced life support. The qualified practitioner corrects adverse physiologic consequences of the deeper-than-intended level of sedation (such as hypoventilation, hypoxia and hypotension) and returns the patient to the originally intended level of sedation. It is not appropriate to continue the procedure at an unintended level of sedation.

Dexmedetomidine & Atipamezole

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Dexmedetomidine is an α_2-agonist that produces varying degrees of sedation, muscle relaxation, and analgesia. The duration of sedation is approximately 1 to 3 hours when administered at the recommended IM or IV doses (1-10 µg/kg), with IM administration providing longer periods of sedation. These effects are reversed by the α_2-antagonist atipamezole (0.1-0.3 mg/kg IM), which is available in a 5 mg/mL formulation (Antisedan; zoetisus.com).

Dexmedetomidine

Indications

Dexmedetomidine is approved for use in dogs and cats to facilitate physical examination, minor clinical procedures, and as a preanesthetic medication. Dexmedetomidine is also used to provide sedation during emergence delirium from general anesthesia. Constant rate infusions of dexmedetomidine (0.5-3.0 µg/kg/h IV) can also provide prolonged sedation for anxious or disorderly inpatients.[1]

Contraindications & Drug Interactions

Dexmedetomidine should, in general, be reserved for young, healthy patients. Dexmedetomidine has significant negative cardiovascular effects (see **Advantages & Disadvantages**, next page) and is contraindicated in any patient suffering from or having a predilection for cardiovascular disease. There is argument, however, that dexmedetomidine may be beneficial in cats with hypertrophic cardiomyopathy (HCM) showing dynamic left ventricular outflow tract (LVOT) obstruction, where the increase in systemic vascular resistance and decrease in heart rate produced by α_2-agonists may actually eliminate the LVOT obstruction.[2] Dexmedetomidine is also contraindicated in patients suffering from respiratory disorders, liver disease, kidney disease, shock, severe debilitation, or stress caused by extreme heat, cold, or fatigue.[3] The medication can produce vomiting in dogs and cats following IM administration, so it is also contraindicated when vomiting could be significantly detrimental to the patient (eg, increased intraocular pressure, increased intracranial pressure, increased intragastric pressure). Because α_2-agonists reduce uterine blood flow and may affect intrauterine pressure, dexmedetomidine is not recommended for use in pregnant animals.

Because of its sedative and analgesic properties, dexmedetomidine can potentiate the effects of other sedatives, induction agents, inhalant anesthetics, and opioids. Administered alone, α_2-agonists produce minimal respiratory effects in healthy dogs and cats, characterized by a decrease or no change in respiratory rate and minimal change in

1 **Oxygen supplementation via face mask to a dog following dexmedetomidine sedation. Hemoglobin saturation, read from the pulse oximeter placed on the lip, is 100% and heart rate is 75 beats per minute.**

HCM = hypertrophic cardiomyopathy, LVOT = left ventricular outflow tract

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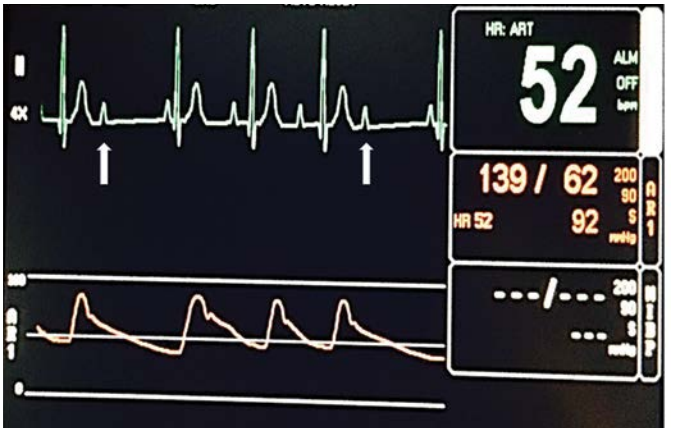
blood gas tension.[4] Nonetheless, significant hypoventilation resulting in hypoxia can occur when α_2-agonists are administered with other drugs (eg, opioids, ketamine, propofol), so oxygen supplementation is recommended when dexmedetomidine is administered with other drugs (**Figure 1**, previous page).[5] Supplemental oxygen may prevent hypoxemia but will not prevent respiratory acidosis. Premedication with dexmedetomidine can reduce the amount of anesthetic induction drug required by approximately 30% to 60% and the inhalant anesthetic requirements by approximately 35% to 90%, depending on dose.[3,5] With this in mind, anesthetic induction and maintenance drugs should always be titrated to effect, and patients should be closely monitored throughout the procedure.

Administration of dexmedetomidine results in increased systemic vascular resistance, bradycardia, and a marked decrease in cardiac output.[6] The initial decrease in heart rate is a reflex bradycardia caused by the increase in systemic vascular resistance. The use of anticholinergics before or after administration of dexmedetomidine is controversial. Treatment with anticholinergics before administration of dexmedetomidine prevents bradycardia; however, cardiac output can still be decreased by over 50%, despite normalization of heart rate.[6] Administering an anticholinergic after dexmedetomidine administration increases the risk of dysrhythmias; thus, routine use of anticholinergics concurrently or after treatment with dexmedetomidine is not recommended.[3] If a patient has profound bradycardia (ie, heart rate <40 beats per minute for dogs, <100 beats per minute for cats) following administration of dexmedetomidine, an electrocardiogram should be evaluated to assess rhythm and, if ventricular escape beats are present, atipamezole should be administered.

Advantages & Disadvantages

Dexmedetomidine produces profound sedation and muscle relaxation that facilitates examination, IV catheter placement, diagnostic procedures, and minor surgical procedures (eg, laceration repair, small tissue biopsy). Analgesia provided by α_2-agonists has been shown to be synergistic with opioids.[7] In addition, premedication with α_2-agonists attenuates the stress response elicited by surgery.[8,9] The 0.5 mg/mL formulation of dexmedetomidine also allows for smaller volumes to be injected IM, which may be easier to administer to fractious or less cooperative patients.

Dexmedetomidine has a relatively short duration of action, with sedation lasting from 1-3 hours in dogs and cats at the recommended doses, making it ideal for short procedures or when a patient needs to be discharged on the same day as the procedure. Another advantage of dexmedetomidine is that in the event of complications or excessive sedation, its effects can be reversed by atipamezole administration.



2 **Second-degree AV block in a dog following dexmedetomidine administration. There are multiple P waves on the electrocardiogram that do not have associated QRS complexes (arrows). Heart rate is 52 beats per minute.**

The major disadvantage of dexmedetomidine is its cardiovascular effects, limiting its use to young, healthy patients (American Society of Anesthesiologists [ASA] classification status I and II). Even small doses of α_2-agonists (approximately 1 µg/kg) can decrease cardiac output by approximately 50%.[10] The administration of α_2-agonists commonly results in a biphasic blood pressure response; initially the patient is bradycardic with elevated blood pressure, but with time the systemic vascular resistance may decrease, resulting in hypotension with continued bradycardia.[11] In addition to bradycardia, a variety of dysrhythmias may be observed, including second-degree atrioventricular (AV) block, third-degree AV block, supraventricular or ventricular tachycardia, supraventricular or ventricular precontractions, and ventricular or junctional escape beats (**Figure 2**).

Cost

Although the cost of dexmedetomidine may be more than for other sedatives (eg, acepromazine), the reduced amount of induction and maintenance drugs required for anesthesia is likely to offset any additional cost incurred by dexmedetomidine use.

AV = atrioventricular

Atipamezole

Indications

Atipamezole reverses the sedative, analgesic, and cardiovascular effects of dexmedetomidine. Atipamezole is approved for IM administration in dogs; it has also been used successfully off-label in cats.[12] Atipamezole is typically administered after completion of a minor procedure performed under dexmedetomidine sedation. When dexmedetomidine has been used for premedication, atipamezole can be administered during anesthesia to treat excessive bradycardia and dysrhythmias, or it can be administered after anesthesia if recovery is prolonged. Atipamezole is also indicated during cardiopulmonary resuscitation when the patient has received dexmedetomidine; in this circumstance, it can be administered IV (0.1 mg/kg).[13]

Contraindications & Drug Interactions

IV administration of atipamezole is usually contraindicated, except for emergency situations. Atipamezole administered IV may result in rapid relaxation of vascular tone, which coupled with bradycardia could result in cardiovascular collapse.[11] Atipamezole is also formulated with the preservative methylparaben, which can cause histamine release leading to hypotension. It has been recommended that atipamezole and anticholinergics not be used concurrently, as both can cause significant increases in heart rate.[14]

Advantages & Disadvantages

The major advantage of atipamezole is that it can rapidly reverse the sedative and cardiovascular effects of dexmedetomidine, and cardiac output is returned to baseline levels following administration.[6] Atipamezole is highly selective for the α_2-receptor and does not have some of the adverse effects associated with less selective α_2-antagonists (eg, tolazoline, yohimbine). Atipamezole also has a wide safety margin when administered IM.[11]

The major advantage of atipamezole is that it can rapidly reverse the sedative and cardiovascular effects of dexmedetomidine, and cardiac output is returned to baseline levels following administration.[6]

Atipamezole is approved only for IM use, as IV administration of α_2-antagonists can result in hypotension, tachycardia, or even cardiovascular collapse. Another disadvantage is that all analgesia and sedation provided by dexmedetomidine will be reversed by atipamezole. Appropriate analgesia (ie, opioids) should be provided for painful procedures; this will help reduce the dose of dexmedetomidine and provide additional pain control if atipamazole is administered.

In addition, there is the potential for resedation from the initial dose of α_2-agonist approximately 30 to 60 minutes after atipamezole because of its short duration of action.

Cost

Any additional cost associated with atipamezole can be easily justified by its ability to reverse the negative cardiovascular effects of dexmedetomidine. Atipamezole can minimize the time that patients experience significant cardiovascular depression.

Conclusion

Dexmedetomidine and atipamezole are useful in many veterinary situations involving healthy dogs and cats requiring sedation, muscle relaxation, and analgesia. However, selection should be on an individual patient basis as dexmedetomidine is associated with significant negative cardiovascular effects. ■ cb

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Injectable Anesthetics

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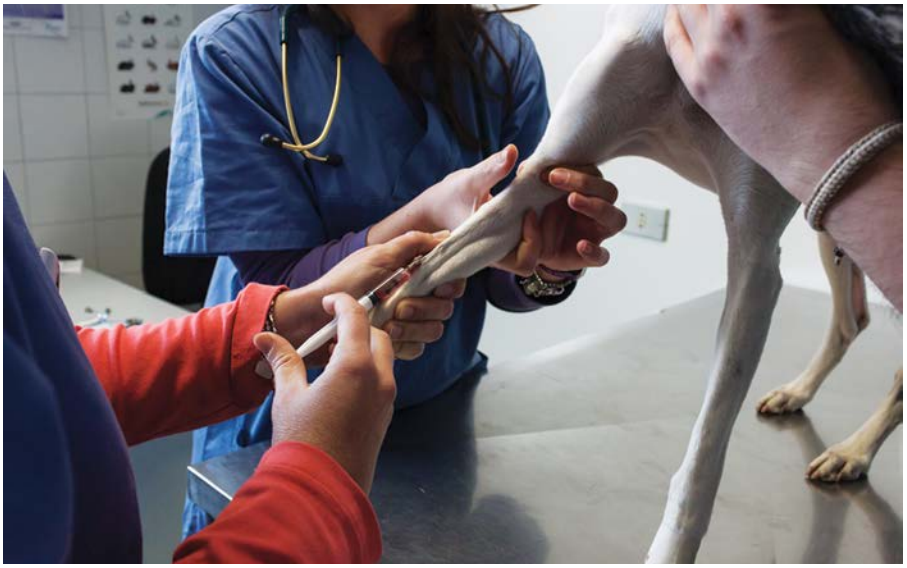
Injectable anesthetics are useful in situations where inhalational techniques are not readily available. They are also a suitable alternative when anesthesia must be provided outside of a hospital setting or for quick procedures, such as clinical examinations, diagnostic imaging, and minor surgical procedures.



Indications

Injectable anesthetic agents are mostly employed in situations where rapid induction of anesthesia is indicated, and some agents are also suitable for maintenance of anesthesia. Important factors for the indication of these agents include onset of action, duration of anesthetic effect, routes of administration, and cardiorespiratory responses.[1]

Products with rapid onset of action and brief duration of effects (propofol, thiopental, alfaxalone) are mainly employed as induction agents.[1]

The author mainly uses products with rapid onset of action and brief duration of effect (eg, propofol, thiopental, or alfaxalone) for anesthetic induction. These agents are administered IV because of tissue irritation (thiopental) or poor bioavailability (propofol) when administered via other routes.

Alfaxalone can be administered IM to induce a light plane of anesthesia in sedated cats, but the large volume of the injection and the potential for a poor recovery are limiting factors for use by this route.[2]

Although these agents produce loss of consciousness and reasonable muscle relaxation, they do not provide analgesia. They should be injected slowly to effect because they can easily induce states of hypotension, respiratory depression, and post-induction apnea.

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Agents with rapid metabolism and no cumulative effects, such as propofol and alfaxalone, are also suitable for maintenance of anesthesia via repeated boluses or through constant/variable rate infusions, depending on the case.[3–6] Long or repeated infusions of propofol can accumulate in cats, because they cannot rapidly metabolize the drug.[1,6] Thiopental is not suitable for anesthetic maintenance because it has cumulative effects and is metabolized slowly.

Orotracheal intubation should be performed to protect the patient's airway, as these agents will suppress protective reflexes; intubation will also help in management of apneic events. Oxygen supplementation is also recommended to prevent hypoxemia. These agents are rarely employed in settings with few technical capabilities, aside from providing anesthesia for very brief procedures (between 5–15 minutes).

Dissociative anesthetics (eg, ketamine, tiletamine) have a relatively rapid onset of action, a longer duration of effect (20–45 minutes), and are suitable for IV and IM administration.[7,8,9] Dissociative anesthetics are preferred for shelter anesthesia protocols.

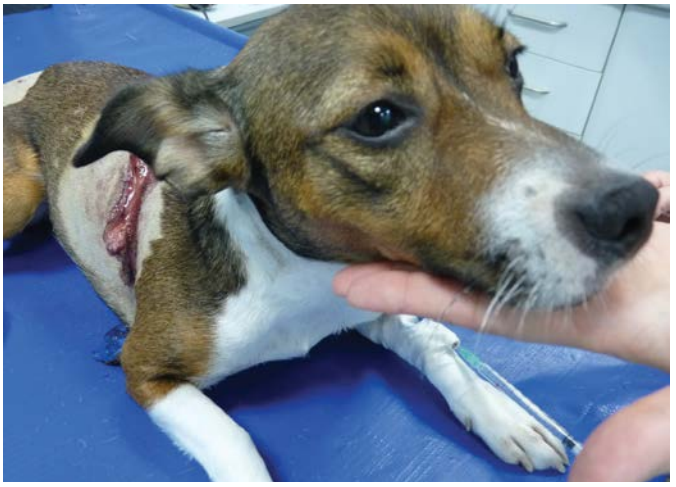
This type of anesthesia is characterized by catalepsy, amnesia, profound somatic analgesia, muscle rigidity (spontaneous movements and tremors are possible), the presence of active reflexes (ie, palpebral reflexes, gagging, swallowing), and salivation.

These agents cause minimal respiratory depression (irregular and apneustic breathing patterns may be observed) and moderate cardiovascular stimulation in healthy patients.[1,7,8] Because of potential adverse effects, dissociative anesthetics should not be used alone. Ketamine is routinely employed in combination with sedatives (eg, benzodiazepines or α–2 agonists) and analgesics to improve muscle relaxation, surgical analgesia (antinociception), and quality of recovery.

1 **A lubricating ointment has been administered to protect the cornea in a 1-year-old male cat anesthetized with IM dexmedetomidine (30 µg/kg), buprenorphine (0.02 mg/kg), and ketamine (7.5 mg/kg).**

2 **The same cat intubated. A nebulization of lidocaine 2% has been sprayed onto the larynx to facilitate intubation.**

Dissociative anesthetics (ketamine and tiletamine) have a relatively rapid onset of action, a longer duration of effects, and are suitable for IV and IM administration.



3 **Two-year-old male dog admitted for suturing of lacerations. The patient was sedated with IM dexmedetomidine (7 µg/kg)and methadone (0.2 mg/kg). After 10 minutes, ketamine (7.5 mg/kg) was administered IV, providing 20 minutes of surgical anesthesia.**

4 **External disturbances, such as intense light and noises, should be reduced during recovery from dissociative anesthesia.**

Injectable Anesthesia: The Good & the Bad

Pros

- Less equipment compared with inhaled anesthesia
- No human exposure to waste gases
- Decreased cost

Cons

- Increased risk for overdose
- Rapid manipulation of anesthetic plane not possible
- For many of these agents, reversal is not possible once administered, even if severe complications occur
- Safety measures can easily be neglected

Tiletamine is closely related to ketamine but is more potent with a longer duration of effect.[1,7] It is marketed in combination with zolazepam, a benzodiazepine, to reduce muscle rigidity. Because of its higher potency, small injection volumes of tiletamine-zolazepam are effective for achieving a rapid effect in fractious patients, even when administered IM.[8]

The quality of anesthesia with tiletamine-zolazepam can also be improved and its dose reduced by the inclusion of α-2 agonists and analgesics within the protocol. The persistence of cranial reflexes with dissociative agents does not guarantee adequate protection of the patient's airway. Therefore, tracheal intubation and oxygen supplementation are also recommended.

If the eyes remain open and centered in their orbit and the ocular reflexes are active, judgment of the adequacy of the anesthetic plane may be difficult under dissociative anesthesia. This eye position may also increase the risk of corneal drying and ulceration. The use of an eye lubricant is recommended in anesthetized patients to prevent corneal injuries.

Complete recovery from dissociative anesthesia is typically prolonged. Spontaneous movements, tonic-clonic spasms, and excitation are observed in cats and dogs if adjunctive drugs are not administered or if they are given at inadequate doses.[7,9] These undesirable effects can be accentuated by an inadequate use of α–2 antagonists (atipamezole) to enhance the speed of recovery.

In the author's experience, reversal drugs can be safely administered 45–50 minutes after the administration of the dissociative agent. Premature reversal may result in a rough recovery, particularly in dogs.[8] In these cases, the use of diazepam or midazolam at normal doses (0.2–0.4 mg/kg IM or IV) is useful to alleviate the excitatory effects of dissociative agents. During recovery, external disturbances such as intense light and loud noises, should be avoided.

Drug Interactions & Contraindications

Anesthesia is a complex state where unconsciousness, lack of perception or memory, and antinociception and proper muscle relaxation (the so-called "triad of general anesthesia") must be ensured. "Balanced" anesthesia can only be achieved by the use of several drugs.[1] Therefore, it is essential to provide the patient with a suitable preanesthetic medication (or adjuvant drug combination) that includes the use of sedatives and analgesics. It is particularly important to consider the use of analgesics, tailoring potency to the aggressiveness of the intended procedure.

continues

Table 1. Sedatives & Opioids for Pre-anesthetic Medication

Drug	*Dog*	*Cat*	*Comments*
Acepromazine	0.01–0.05 mg/kg IM	0.05–0.1 mg/kg IM	Mild sedative effect Onset of action: 20–40 min Prolonged effect: 4–8 hr Enhanced sedation with opioids Vasodilation
Medetomidine	5–15 µg/kg IM	5–50 µg/kg IM	Potent sedative effect Onset of action: 10–15 min Duration of action: 40–140 min Reduced doses in combination with opioids Vomiting may occur Bradycardia, initial hypertension Can be antagonized with atipamezole to speed recovery (approximately same volume of medetomidine administered in dogs and half that volume in cats) Dexmedetomidine has similar effects with half the dose; can also be antagonized, but this is usually unnecessary
Xylazine	0.2–1.0 mg/kg IM	0.2–2.0 mg/kg IM	Potent sedative effect Onset of action: 5–15 min Duration of action: 60 min Reduced doses in combination with opioids Vomiting, bradycardia, and hypertension followed by prolonged hypotension Can be antagonized with low doses of atipamezole (xylazine is not a highly selective α-2 agonist)
Buprenorphine	0.01–0.02 mg/kg IM Half the dose IV	0.01–0.02 mg/kg IM Half the dose IV	Enhances sedation Slow onset of action: 20–40 min Prolonged effects 6–8 hr Good in postoperative phase to treat moderate pain Moderate analgesia (potent in cats) Unlikely to cause vomiting
Butorphanol	0.1–0.5 mg/kg IM Half the dose IV	0.2–0.5 mg/kg IM Half the dose IV	Enhances sedation Suitable analgesia (1–2 hr) for minor to moderate procedures (eg, castration) Unlikely to cause vomiting or panting
Hydromorphone	0.05–0.2 mg/kg IM	0.05–0.1 mg/kg IM	Similar to oxymorphone
Morphine	0.1–0.5 mg/kg IM	0.1–0.2 mg/kg IM	Enhances sedation Onset of action: 10–20 min Effect: 2–6 hrs Potent analgesic Salivation, vomiting, defecation Bradycardia, dose-dependent respiratory depression Unlikely to cause panting
Methadone	0.1–0.3 mg/kg IM	0.1–0.3 mg/kg IM	Enhance sedation Rapid onset of action: 5–10 min Effect: 2–6 hrs Potent analgesia Bradycardia, dose-dependent respiratory depression, panting effect Unlikely to cause vomiting
Oxymorphone	0.05–0.2 mg/kg IM	0.05–0.1 mg/kg IM	Similar to morphine Less likely to cause vomiting, panting effect

Table 2. Injectable General Anesthetics

Drug	*Induction dose*	*Maintenance*	*Comments*
Alfaxalone	Dogs: 2–3 mg/kg Cats: 5 mg/kg Lower doses may be required after sedation	Additional boluses as required (30%–50% of the initial dose) CRI studies conducted, but need to be better evaluated for clinical use	Inject slowly (over 1 min) to avoid respiratory depression Rapid effect (1–2 min) Rapid metabolism Minimally cumulative Minimal cardiovascular depression
Propofol	Dogs & cats: 5–8 mg/kg in nonpremedicated patients Reduced doses after premedication	Additional boluses as required (30%–50% of the initial dose) CRI: 0.5–1.0 mg/kg reduced over time	Rapid effect (1–2 min) Recovery after 5–15 min Rapid metabolism Cardiovascular and respiratory depression Minimally cumulative (except in cats)
Thiopental	Dogs & cats: 5–10 mg/kg after acepromazine-opioid premedication Half the dose after α-2/opioid premedication	Not recommended	Rapid effect (30–60 sec) Recovery after 5–15 min Cardiovascular and respiratory depression Irritant if given extravascularly Cumulative effects

Table 3. Dissociative Anesthetics

Drug	*Anesthetic dose*		*Comments*
Ketamine	Dogs: 2.5–10 mg/kg IM Cats: 5–10 mg/kg IM Use lower doses after α-2/opioid premedication Suitable doses for combination with 0.1–0.3 mg/kg of diazepam (IV) or midazolam (IM or IV) for noninvasive procedures; otherwise, analgesics should be added to this combination; half the doses for IV use	Additional boluses can be given as required to prolong anesthesia (30%–40% of the initial dose)	Effect in 5–10 min Duration 20–30 min Use in combination with sedatives (α-2 agonists) and opioids Excitement during recovery
Tiletamine-zolazepam	Dogs: 7–13 mg/kg IM Cats: 9–12 mg/kg IM Use lower doses after α-2/opioid premedication Reduce dose by 50%–60% for IV use	One or two additional boluses can be given to prolong anesthesia (25%–30% of the initial dose)	Effect in 5–10 min Duration: 40–45 min Better results in combination with sedatives (α-2 agonists) and opioids Excitement during recovery

continues

Good control of intraoperative nociception will produce a more stable plane of surgical anesthesia. Dissociative anesthetics are able to provide intense but brief analgesia, mainly for somatic-type pain. Ketamine (and possibly other dissociative drugs) has an antihyperalgesic effect through the inhibitory action on *N*-methyl D-aspartate (NMDA) receptors. At subanesthetic doses, it can be effective for treatment of patients with chronic pain and central sensitization, and to reduce hyperalgesia following tissue trauma.[1,6,7,10]

The inclusion of an NSAID in the anesthetic protocol is also recommended when opioids are not available or in combination with opioids for major procedures (eg, orthopedic surgery, major soft tissue procedures).[10] The availability of veterinary licensed products with a cyclooxygenase-2 (COX-2) selective profile has improved the safety profile of these drugs. However, adverse effects may be induced if these drugs are used in anesthetized patients with hypovolemia, hypotension, or renal, gastrointestinal, or coagulation disorders.

Close monitoring of blood pressure and adequate intraoperative cardiovascular support (fluid therapy) should be performed when NSAIDs are administered preoperatively. The inclusion of locoregional analgesia techniques can be extremely useful to achieve balanced anesthesia and to control perioperative pain more efficiently.[10]

In the author's experience, the administration of the preanesthetic medication before anesthesia will decrease the necessary doses of anesthetic agents and will enhance the quality of the anesthesia and recovery. In healthy cats, for example, a suitable protocol may involve sedation with a combination of medetomidine (40 µg/kg) and butorphanol (0.3 mg/kg) IM. Once sedation is established, anesthesia may be induced with ketamine 2.5–5.0 mg/kg IV or 5.0–7.5 mg/kg IM. The final dose of ketamine can be adjusted based on depth of sedation and duration of the scheduled procedure.

In fractious animals, simultaneous administration of sedative, analgesic, and dissociative agent could be a preferred technique to ensure quicker effect.

Every anesthetic event has risks, even in young, healthy patients. Injectable techniques should be employed with caution. The patient should be fasted to reduce the incidence of vomiting or regurgitation, particularly when tracheal intubation cannot be performed.

Routine examinations and laboratory studies should be performed to determine the health status of the patient, as anesthesia may not be well tolerated in all patients. Body weight should also be accurately measured to avoid the risk of overdose. Every effort should be made to ensure that tracheal intubation, supplemental oxygen, and a form of respiratory support are readily available if necessary.

Pulse rate and rhythm, respiratory rate and breathing pattern, mucous membrane color, muscle tone, and eye position should be monitored at regular intervals, even if electronic monitoring devices are available. Hypothermia should be prevented, as it slows the metabolism of injectable agents and may cause unwanted consequences.

Cost

Injectable agents are not necessarily less expensive than inhalational agents, but the equipment required to administer the agents decreases the overall cost. Economic restrictions should not justify denying the patients rational anesthetic (and analgesic) protocols that can help ensure the basic safety principles required for an uneventful recovery from anesthesia. ■ cb

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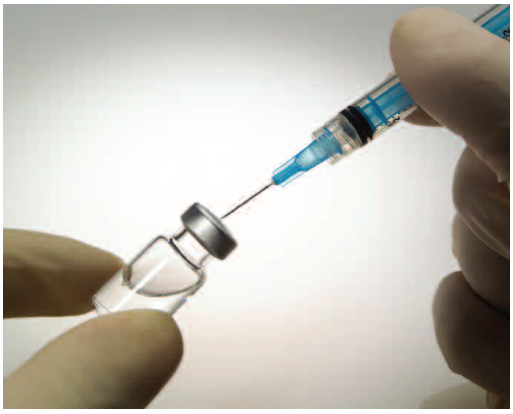

Sedation & Analgesia for Canine Emergencies

Profile

Definition

- Procedural sedation and analgesia (PSA) techniques include a broad spectrum of protocols from anxiolysis and pain relief to deep sedation for patients undergoing diagnostic or therapeutic procedures.
- In many emergency situations, general anesthesia may be preferable to PSA because it allows complete control of the airway and the ability to assist ventilation and/or provide 100% oxygen. The following guidelines are based on the assumption that the veterinarian has appropriately selected sedation rather than general anesthesia.
- One challenge when discussing guidelines for PSA is covering the wide mix of patient situations, operator skills, procedures, and conditions under which a particular patient is treated. As such, these guidelines may require modification for individual case scenarios.
- Despite the commonality of PSA, no controlled veterinary trials are available. Therefore, recommendations provided in this article are based on the author's personal experiences and on consensus opinions from academic and private practice specialists.

PSA = procedural sedation & analgesia

Objective

The goal is to provide maximum patient comfort in the absence of general anesthesia and with minimal complications when performing painful or stressful procedures. Scenarios include:

- Necessary sedation to assess a patient or to complete a diagnostic or therapeutic procedure
- Necessary analgesia to relieve pain or anxiety caused by the underlying pathology or the required procedure or treatment.

Examination/Assessment

The needs of the patient and the concomitant procedure must be considered simultaneously when designing the protocol, selecting the procedural and monitoring equipment, and transitioning to postsedation care.

- First, establish the **degree of urgency**. Determine if the situation is life-threatening (in which case, general anesthesia may be faster and safer) or if the patient is stable but requires rapid treatment.
- Then, determine the **degree of presedation** preparation (hydration, electrolyte and metabolic status) necessary to stabilize the patient prior to the procedure. While it is always prudent to "fast" a patient when time permits, the fasting guideline is based upon consensus opinion rather than case-based evidence.[1] Often action must be taken immediately, regardless of the patient's fasting status. The risk of aspiration or regurgitation can be minimized by controlling the depth of sedation and by protecting the airway (head elevated and/or short-term intubation).
- Estimate **degree of sedation** necessary to perform the required procedure. This will be a main parameter in selection of the drugs and their dosages.
- Assess **severity of pain** caused by the underlying pathology or anticipated during and after the proposed procedure. Several articles provide detailed methods of quantifying pain in dogs.[2-4]

Medications

Applications

- Being familiar with the specifics of a particular drug, its potential side effects, and the degree of sedation and analgesia at different doses is an important factor in preventing complications. Unfamiliar drugs should not be used in critical situations.
- The route of administration (IV or IM) is case-dependent. IV administration is more potent, provides a more rapid onset, and has a shorter duration of effect. Therefore, it is generally the favored route of administration in acute care scenarios.
- Logically, a lower dose will provide lighter sedation of shorter duration. However, in

continues

severely debilitated patients, even a low dose may result in oversedation or even induction of general anesthesia. It is important to administer the dose slowly and progressively until the desired effect is achieved.

- The recommendations for PSA in the dog (listed below) are based on the author's personal experiences. They are neither exhaustive nor without controversy. See **Table 1** for suggested doses.

Hydromorphone + Diazepam *or* Fentanyl + Diazepam

- **Indications**: Provides analgesia and sedation; effect is similar to the combination of oxymorphone and diazepam with reported acceptable cardiovascular parameters in moderately hypovolemic dogs (30 mL/kg blood loss).[5]
- **Contraindications**: Fentanyl + diazepam should not be used in healthy dogs as excitation may occur. Due to mild respiratory depression and possible hypercapnia, avoid heavy sedation in dogs with head trauma since an increase in intracranial pressure may occur. Alternatively, these drugs can be used in a patient with head trauma but the patient should be intubated and ventilated to maintain normocapnia.
- **Monitoring**: Monitor for respiratory depression (pulse oximeter, respiratory rate, mucous membrane color, depth and quality of chest excursions) and treat as necessary (ie, intubation and ventilation, oxygen supplementation); also monitor for bradycardia and treat as necessary (ie, anticholinergic).
- **Duration**: Relatively short acting (5–20 min), depending upon dose and underlying condition of dog. Fentanyl combinations are of shorter duration (5–15 min) than hydromorphone combinations (10–20 min).
- Since dogs receiving any opioid/benzodiazepine combination are highly sensitive to noise, place cotton in ears or keep room quiet.

Fentanyl/Ketamine/Midazolam Combination

- **Indications**: Provides analgesia and sedation; primarily for debilitated dogs or those with mild to severe degree of shock. Dose likely to be inadequate for normal, healthy dogs and administering higher dose to healthy dogs may result in profound respiratory depression, necessitating intubation and possible ventilation.
- **Contraindications**: Ketamine combinations should be avoided in head trauma patients or those with corneal lacerations due to potential for an elevation in intracranial or intraocular pressure.
- **Dosages & Duration**:
  - *Single injection*: 1 mL each of ketamine (100 mg/mL) and midazolam (5 mg/mL) plus 2 to 3 mL of fentanyl (50 µg/mL), mixed in the same syringe and administered to effect (0.05–0.1 mL/kg IV). The higher dose results in about 2 hours of deep sedation. Reversal of midazolam using flumazenil (0.05–0.1 mg/kg slow IV) generally results in rapid recovery.
  - *CRI for procedures lasting longer than 2 hours*: Ketamine (0.5–1.5 mg/kg/H), midazolam (1–3 mg/kg/H), and fentanyl (10–20 µg/kg/H)
  - Drugs should be combined immediately prior to use (in any order) as stability has not been established.
- **Monitoring**: Monitor for respiratory depression and treat as necessary (ie, intubation and ventilation, oxygen supplementation). Due to inclusion of ketamine, bradycardia is not as likely to occur as with the hydromorphone or fentanyl + diazepam combination.

CRI = constant rate infusion; PSA = procedural sedation and analgesia

Table 1. Suggested Dosages

Medication Combination	Dose
Acepromazine + Buprenorphine	0.02–0.05 mg/kg IV 0.01 mg/kg IV
Acepromazine + Butorphanol	0.02–0.05 mg/kg IV 0.2 mg/kg IV
Acepromazine + Diazepam	0.02–0.05 mg/kg IV 0.1–0.2 mg/kg IV
Acepromazine + Hydromorphone	0.02–0.05 mg/kg IV 0.05–0.2 mg/kg IV
Acepromazine + Midazolam	0.02–0.05 mg/kg IV 0.05–0.1 mg/kg IV
Buprenorphrine + Diazepam	0.01–0.05 mg/kg IV 0.1–0.2 mg/kg IV
Butorphanol + Diazepam	0.2 mg/kg IV 0.1–0.2 mg/kg IV
Fentanyl + Diazepam	5–20 µg/kg IV 0.1–0.2 mg/kg IV
Fentanyl/ketamine/midazolam	0.05–0.1 mL of solution/kg IV (see text for preparation instructions)
Hydromorphone + Diazepam	0.05–0.2 mg/kg IV 0.1–0.2 mg/kg IV
Ketamine + Diazepam	3–10 mg/kg IV 0.1–0.2 mg/kg IV
Ketamine + Midazolam	3–10 mg/kg IV 0.05–0.1 mg/kg IV
Propofol	2–6 mg/kg IV
Propofol + Ketamine	1–4 mg/kg IV 0.5–2 mg/kg IV

Ketamine + Diazepam *or* Ketamine + Midazolam

- **Indications**: Provides analgesia and sedation; acceptable for both healthy and critically ill dogs when administered to effect.
- **Contraindications**: Ketamine combinations should be avoided in patients with head or corneal lacerations due to potential for an elevation in intracranial or intraocular pressure. These combinations should be avoided in dogs that are already very tachycardic (since dysrhythmias may occur) or in dogs with hypertrophic cardiomyopathy (where elevations in heart rate may reduce cardiac output).

- **Monitoring**: This combination is less likely to require airway interventions than an opioid combination.
- **Duration**: Sedation lasts 10 to 15 minutes.

Acepromazine + Opioid *or* Acepromazine + Benzodiazepine

- **Indications**: Acepromazine/benzodiazepine combinations provide only sedation; acepromazine/opioid combinations provide analgesia and sedation. Most useful for a healthy to mildly sick patient requiring PSA.
- **Contraindications**: Acepromazine combinations should be avoided in dogs in shock.
- **Monitoring**: Acepromazine combinations may cause hypotension due to associated vasodilation; therefore, volume replacement and monitoring of blood pressure are especially important.
- **Duration**: When acepromazine is used with an opioid, the result is a deeper and longer lasting sedation when compared to a combination of acepromazine and a benzodiazepine. This is most pronounced with acepromazine and hydromorphone.

Propofol

- **Indications**: Sedation only, no analgesia provided; most useful for a relatively healthy patient.
- **Contraindications**: Should not be used in hypovolemic dogs due to its detrimental cardiovascular effects (vasodilation, reduced cardiac output) or in hypoxemic dogs (ie, pneumothorax) because profound cyanosis may occur inconsistently (other drugs are adequate without having the potential to cause cyanosis). Oxygen supplementation (ie, oxygen mask) should be provided to all dogs receiving propofol PSA and, if dose results in oversedation, intubation may be required.
- **Dosages & Duration**: For procedures longer than a few minutes, a single dose may not provide sedation for entire procedure. Repeat doses, slowly to effect, may be necessary or CRI (6–15 mg/kg/H, starting at the low dose and adjusting to effect) can be used. Care must be taken to titrate this drug or general anesthesia, requiring intubation, may result.

Propofol + Ketamine

While this drug combination is not in most veterinary anesthesia textbooks, preliminary reports in human literature indicate it is a safe and effective protocol for induction or maintenance of anesthesia (the latter when administered via a CRI). It seems likely that this drug combination, while needing more investigation, may be quite useful for canine PSA as well.

Nerve Blocks

In many situations, a nerve block may be used to provide additional analgesia and reduce the dose, and therefore side effects, of PSA. Specific information on techniques for nerve blocks is outside the scope of this article but excellent reviews on peripheral and regional nerve blocks are found in most veterinary anesthesia textbooks (see also Peripheral Nerve Block Techniques in the March 2004 issue of *Clinician's Brief,* available at www.cliniciansbrief.com).

Dexmedetomidine & Pure μ-Receptor Agonists

The use of low-dose dexmedetomidine in combination with a pure μ-receptor agonist (ie, hydromorphone) is a controversial topic among anesthesiologists. This protocol is beyond the scope of this article and will be covered in a future issue of *Clinician's Brief*.

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When to Use—Common Examples

Drug/Drug Combination	Examples
Hydromorphone *or* fentanyl + Diazepam	Wound care (inspection, debriding, cleansing), bandaging
Fentanyl/ketamine/midazolam	Broad range of dose-dependent applications ranging from debriding superficial burns to chest tube placement to closed reduction of limb fracture and cast application
Ketamine + Diazepam *or* midazolam	Foreign body removal (thorn in footpad, quills in oral cavity or on muzzle), radiographs for gastrointestinal foreign body in elderly dog, lance & lavage of superficial abscess, insertion of nasal tube for oxygen supplementation
Acepromazine/opioid *or* Acepromazine/benzodiazepine	Examination or radiographs of rambunctious, healthy dog needing orthopedic exam (ie, acute lameness)
Propofol	Nonpainful, minor procedure such as removal of minor foreign body (stick in roof of mouth, thorn in footpad), bandage change in stable patient

CRI = constant rate infusion; PSA = procedural sedation and analgesia

Follow-Up

Monitoring

- Depth of sedation:
  - Preservation of laryngeal reflex is essential or intervention to protect the airway is required.
  - Depth determined by muscle relaxation, jaw tone, palpebral reflex, eye positioning.
  - It is NOT necessary to prevent mild responses to the procedure unless strict immobility is required for patient safety or procedural success. Frequently, the depth of sedation necessary to achieve nonresponsiveness is also likely to result in adverse side effects (ie, loss of laryngeal reflex, hypoventilation, regurgitation, hypotension).
- Respiratory function:
  - Pulse oximetry
  - Respiratory rate and quality
  - Capnography for intubated patients
- Hemodynamic measures:
  - Indirect blood pressure monitoring
  - ECG for heart rate, rhythm, and signs of myocardial ischemia (hypoxemia)
- Post-PSA:
  - If patient is being admitted, monitor as per the standard hospital postanesthesia protocol.
  - If PSA is for outpatient procedure, assess patient for adequate recovery prior to hospital discharge.
  - Based on specifics of the case, a postprocedural analgesic plan should be established.

Complications

- The most common complications from PSA are hypoxia and vomiting. A cuffed endotracheal tube, laryngoscope blade with light, and method of manual ventilation should be available when PSA is used.
- Oversedation may occur, increasing the risk of cardiopulmonary complications and aspiration. It is essential that serial qualitative assessment of depth of sedation be made to decide whether or not to intubate, provide oxygen supplementation, or give the antidote to reversible drugs.
- **Table 2** lists some specific side effects of different individual drugs.

See Aids & Resources, back page, for references, contacts, and appendices.

Articles archived on www.cliniciansbrief.com

Table 2. Side Effects of Individual Drugs

Drug	Side Effects	Notes
Propofol	Respiratory depression, hypoxia, cyanosis;[6] causes vasodilation and reduced cardiac output	• All dogs should receive oxygen supplementation by oxygen mask; if dose results in anesthesia, patient should be intubated. • Since cerebral perfusion pressure may be decreased in dogs with head trauma, propofol should not be used in affected patients.
Ketamine	• Poor recovery, hallucination, hypersalivation, tachycardia • Potential for elevation in intracranial or intraocular pressure (avoid use in patients with head trauma or corneal laceration) • Direct depressant effects (negative inotropic effects) may be observed when administered to critically ill patients who have no additional catecholamine stores (more likely to be observed when used at higher doses; ie, induction or maintenance of anesthesia).	• Should not be used in cases where elevations in heart rate or blood pressure may be contraindicated • While hypersalivation can be offset with an anticholinergic, the author does not recommend its use because heart rate is further increased. • To minimize other side effects, ketamine should always be given in combination with another drug. • Less respiratory depression but more vomiting are present with ketamine/benzodiazepine combinations compared to ketamine/fentanyl combinations.[7]
Opioid	Respiratory depression (hypoxia and hypercapnia), bradycardia	• The need for respiratory support and airway intervention is dose-dependent and likely to be more common when fentanyl combinations are used instead of another opioid. • Heart rate should be monitored during the procedure or treatment and also during recovery. • Bradycardia can be treated prophylactically with a standard anticholinergic in dogs with normal heart rates but should not be administered to dogs with preexisting tachycardia or if elevations in heart rate are contraindicated.

ECG = electrocardiography; PSA = procedural sedation and analgesia

Table 1. Sedatives & Opioids for Pre-anesthetic Medication

Drug	*Dog*	*Cat*	*Comments*
Acepromazine	0.01–0.05 mg/kg IM	0.05–0.1 mg/kg IM	Mild sedative effect Onset of action: 20–40 min Prolonged effect: 4–8 hr Enhanced sedation with opioids Vasodilation
Medetomidine	5–15 µg/kg IM	5–50 µg/kg IM	Potent sedative effect Onset of action: 10–15 min Duration of action: 40–140 min Reduced doses in combination with opioids Vomiting may occur Bradycardia, initial hypertension Can be antagonized with atipamezole to speed recovery (approximately same volume of medetomidine administered in dogs and half that volume in cats) Dexmedetomidine has similar effects with half the dose; can also be antagonized, but this is usually unnecessary
Xylazine	0.2–1.0 mg/kg IM	0.2–2.0 mg/kg IM	Potent sedative effect Onset of action: 5–15 min Duration of action: 60 min Reduced doses in combination with opioids Vomiting, bradycardia, and hypertension followed by prolonged hypotension Can be antagonized with low doses of atipamezole (xylazine is not a highly selective α-2 agonist)
Buprenorphine	0.01–0.02 mg/kg IM Half the dose IV	0.01–0.02 mg/kg IM Half the dose IV	Enhances sedation Slow onset of action: 20–40 min Prolonged effects 6–8 hr Good in postoperative phase to treat moderate pain Moderate analgesia (potent in cats) Unlikely to cause vomiting
Butorphanol	0.1–0.5 mg/kg IM Half the dose IV	0.2–0.5 mg/kg IM Half the dose IV	Enhances sedation Suitable analgesia (1–2 hr) for minor to moderate procedures (eg, castration) Unlikely to cause vomiting or panting
Hydromorphone	0.05–0.2 mg/kg IM	0.05–0.1 mg/kg IM	Similar to oxymorphone
Morphine	0.1–0.5 mg/kg IM	0.1–0.2 mg/kg IM	Enhances sedation Onset of action: 10–20 min Effect: 2–6 hrs Potent analgesic Salivation, vomiting, defecation Bradycardia, dose-dependent respiratory depression Unlikely to cause panting
Methadone	0.1–0.3 mg/kg IM	0.1–0.3 mg/kg IM	Enhance sedation Rapid onset of action: 5–10 min Effect: 2–6 hrs Potent analgesia Bradycardia, dose-dependent respiratory depression, panting effect Unlikely to cause vomiting
Oxymorphone	0.05–0.2 mg/kg IM	0.05–0.1 mg/kg IM	Similar to morphine Less likely to cause vomiting, panting effect

Table 2. Injectable General Anesthetics

Drug	*Induction dose*	*Maintenance*	*Comments*
Alfaxalone	Dogs: 2–3 mg/kg Cats: 5 mg/kg Lower doses may be required after sedation	Additional boluses as required (30%–50% of the initial dose) CRI studies conducted, but need to be better evaluated for clinical use	Inject slowly (over 1 min) to avoid respiratory depression Rapid effect (1–2 min) Rapid metabolism Minimally cumulative Minimal cardiovascular depression
Propofol	Dogs & cats: 5–8 mg/kg in nonpremedicated patients Reduced doses after premedication	Additional boluses as required (30%–50% of the initial dose) CRI: 0.5–1.0 mg/kg reduced over time	Rapid effect (1–2 min) Recovery after 5–15 min Rapid metabolism Cardiovascular and respiratory depression Minimally cumulative (except in cats)
Thiopental	Dogs & cats: 5–10 mg/kg after acepromazine-opioid premedication Half the dose after α-2/opioid premedication	Not recommended	Rapid effect (30–60 sec) Recovery after 5–15 min Cardiovascular and respiratory depression Irritant if given extravascularly Cumulative effects

Table 3. Dissociative Anesthetics

Drug	*Anesthetic dose*		*Comments*
Ketamine	Dogs: 2.5–10 mg/kg IM Cats: 5–10 mg/kg IM Use lower doses after α-2/opioid premedication Suitable doses for combination with 0.1–0.3 mg/kg of diazepam (IV) or midazolam (IM or IV) for noninvasive procedures; otherwise, analgesics should be added to this combination; half the doses for IV use	Additional boluses can be given as required to prolong anesthesia (30%–40% of the initial dose)	Effect in 5–10 min Duration 20–30 min Use in combination with sedatives (α-2 agonists) and opioids Excitement during recovery
Tiletamine-zolazepam	Dogs: 7–13 mg/kg IM Cats: 9–12 mg/kg IM Use lower doses after α-2/opioid premedication Reduce dose by 50%–60% for IV use	One or two additional boluses can be given to prolong anesthesia (25%–30% of the initial dose)	Effect in 5–10 min Duration: 40–45 min Better results in combination with sedatives (α-2 agonists) and opioids Excitement during recovery

continues

1 Introduction to Anesthesia

OUTLINE

LEARNING OBJECTIVES

When you have completed this chapter, you will be able to:

- List two North American professional organizations that offer specialization in anesthesia and analgesia to credentialed individuals, and summarize the aims of each.
- Define anesthesia, and differentiate topical, local, regional, general, and surgical anesthesia.
- Differentiate sedation, tranquilization, hypnosis, and narcosis.
- Explain the concept of balanced anesthesia and the advantages of this approach.
- List common indications for anesthesia.
- Describe fundamental challenges and risks associated with anesthesia.
- List the qualities and abilities of a successful veterinary anesthetist.

KEY TERMS

The Academy of Veterinary Technicians in Anesthesia and Analgesia (AVTAA)
American College of Veterinary Anesthesia and Analgesia (ACVAA)
Analgesia
Anesthesia
Balanced anesthesia
Epidural anesthesia
General anesthesia
Hypnosis
Local anesthesia
Narcosis
Noxious
Regional anesthesia
Sedation
Surgical anesthesia
Therapeutic index
Topical anesthesia
Tranquilization

BOX 1-2 The Mission of the Academy of Veterinary Technicians in Anesthesia and Analgesia (AVTAA)

- The Academy of Veterinary Technicians in Anesthesia and Analgesia (AVTAA) exists to promote interest in the discipline of veterinary anesthesia.
- The Academy provides a process by which a veterinary technician may become certified as a Veterinary Technician Specialist (Anesthesia/Analgesia).
- The Academy provides the opportunity for members to enhance their knowledge and skills in the field of veterinary anesthesia.
- The Veterinary Technician who becomes certified as a VTS (Anesthesia/Analgesia) demonstrates superior knowledge in the care and management of anesthesia cases.
- Certification as a VTS (Anesthesia/Analgesia) promotes patient safety, consumer protection, professionalism and excellence in anesthesia care.
- The Veterinary Anesthesia arena is constantly evolving, thus, the attainment of competence is a continual activity.

BOX 1-3 ACVAA Mission Statement

The American College of Veterinary Anesthesia and Analgesia (ACVAA) is an American Veterinary Medical Association recognized, not-for-profit veterinary medical organization founded in 1975 to serve society by:

- defining and promoting the highest standards of clinical practice of veterinary anesthesia and analgesia
- defining criteria for designating veterinarians with advanced training as specialists in the clinical practice of veterinary anesthesiology
- issuing certificates to those meeting these criteria
- maintaining a list of such veterinarians, and
- advancing scientific research and education in veterinary anesthesiology and analgesia.

TERMINOLOGY OF ANESTHESIA

In addition to its historical importance, Dr. Morton's demonstration in 1846 is of special interest to students of anesthesia because it attracted the attention of the prominent physician Oliver Wendell Holmes Sr., who, in a letter to Dr. Morton dated November 21, 1846, suggested adoption of the word *anesthesia* to describe the state of insensibility to pain produced by diethyl ether. Then he powerfully expressed the importance of this discovery by accurately predicting that the terms *anesthesia* and *anesthetic* would "be repeated by the tongues of every civilized race of mankind."

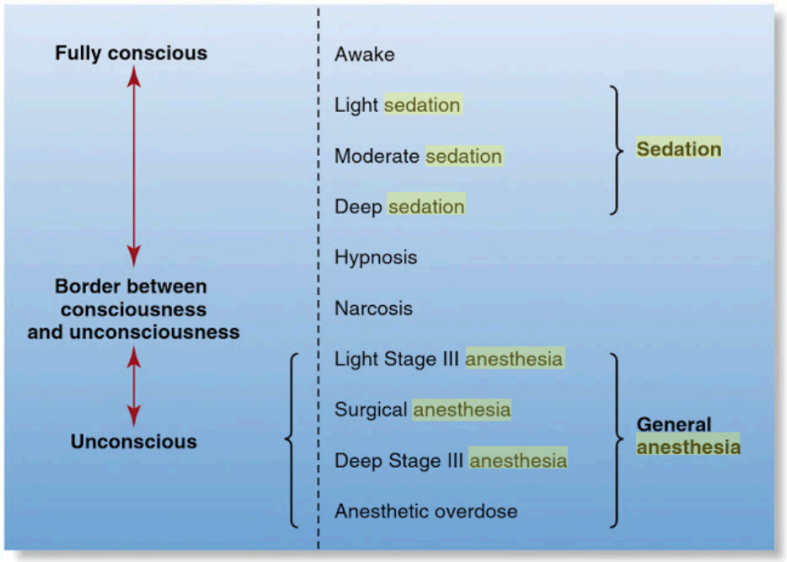
The term **anesthesia** (derived from the Greek word *anaisthesia* which means "without feeling" or "insensibility") may be defined as "a loss of sensation." By providing a loss of sensation, or more specifically the loss of sensitivity to pain, the development and use of anesthetics solved one of the primary problems associated with the practice of medicine. Now, anesthesia is used daily in most veterinary practices to provide sedation, tranquilization, immobility, muscle relaxation, unconsciousness, and pain control for a diverse range of indications including surgery, dentistry, grooming, diagnostic imaging, wound care, and capture and transport of wild animals, just to name a few. The literal definition of the term *anesthesia* accurately describes one of its fundamental effects, however, when viewed from the perspective of current practice, the word falls far short of capturing the many facets of this complex discipline.

TECHNICIAN NOTE Anesthesia is used daily in most veterinary practices to provide sedation, tranquilization, immobility, muscle relaxation, unconsciousness, and pain control for a diverse range of indications.

Most people associate the word *anesthesia* with general anesthesia, which is only one extreme in a continuum of levels of central nervous system (CNS) depression that can be induced by administration of anesthetic agents (Figure 1-1). **General anesthesia** may be defined as a reversible state of unconsciousness, immobility, muscle relaxation, and loss of sensation throughout the entire body produced by administration of one or more anesthetic agents. While under general anesthesia, a patient cannot be aroused even with painful stimulation. For this reason, general anesthesia is commonly used to prepare patients for surgery or other acutely painful procedures. **Surgical anesthesia** is a specific stage of general anesthesia in which there is a sufficient degree of **analgesia** (a loss of sensitivity to pain) and muscle relaxation to allow surgery to be performed without patient pain or movement.

Other states within the continuum of CNS depression include *sedation* and *tranquilization*. **Sedation** refers to drug-induced CNS depression and drowsiness that vary in intensity from light to deep. A sedated patient generally is minimally aware or unaware of its surroundings but can be aroused by **noxious** stimulation. Sedation is often used to prepare patients for diagnostic imaging, grooming, wound treatment, and other minor procedures. **Tranquilization** is a drug-induced state of calm in which the patient is reluctant to move and is aware of but unconcerned about its surroundings. Although the terms *tranquilization* and *sedation* are not exactly the same in meaning, they are often used interchangeably.

The terms *hypnosis* and *narcosis* are also used to describe anesthetic-induced states. **Hypnosis** is a drug-induced sleeplike state that impairs the ability of the patient to respond appropriately to stimuli. This meaning of this term is somewhat imprecise, as it is used to describe various degrees of CNS depression. In this text, hypnosis will be used to mean a sleeplike state from which the patient can be aroused with sufficient stimulation. The term **narcosis** refers to a drug-induced sleep from which the patient is not easily aroused and that is most often associated with the administration of narcotics.



Notes:
- *In addition to CNS depression, most anesthetics cause a variety of other effects such as analgesia and muscle relaxation.*
- *Although most anesthetics cause CNS depression as noted above, some agents such as dissociatives may also stimulate the CNS (see Chapter 3 for a discussion of these agents).*
- *Transient excitement may also occur during some stages of anesthesia (see Chapter 6 for a discussion of the stages and planes of general anesthesia).*

FIGURE 1-1 The continuum of levels of central nervous system depression induced by anesthetic agents.

The effect of anesthetic agents may be selectively directed to affect specific areas or regions of the body. Smaller areas can be targeted by use of local or topical anesthesia. **Local anesthesia** refers to loss of sensation in a small area of the body produced by administration of a local anesthetic agent in proximity to the area of interest. Infiltration of local anesthetic into the tissues surrounding a small tumor to facilitate removal is an example of local anesthesia. **Topical anesthesia** is the loss of sensation of a localized area produced by administration of a local anesthetic directly to a body surface or to a surgical or traumatic wound. Use of ophthalmic local anesthetic drops in the eye before an ophthalmic examination and application of local anesthetic to an open declaw incision for the purpose of pain control are examples of topical anesthesia.

Larger areas can be targeted by use of **regional anesthesia,** which refers to a loss of sensation in a limited area of the body produced by administration of a local anesthetic or other agent in proximity to sensory nerves. Regional anesthesia can be produced with a variety of techniques including nerve blocks and epidural anesthesia. For example, a brachial plexus block can be used to anesthetize the forelimb distal to and including the elbow; a maxillary nerve block can be used to anesthetize the upper dental arcade; and **epidural anesthesia** can be used to provide pain control of the hindquarters and pelvic region.

When anesthetics are administered, it is common practice to administer multiple drugs concurrently in smaller quantities than would be required if each were given alone. This technique, termed **balanced anesthesia,** maximizes the benefits of each drug, minimizes adverse effects, and gives the anesthetist the ability to produce anesthesia with the degree of CNS depression, muscle relaxation, analgesia, and immobilization appropriate for the patient and the procedure. Premedication with acepromazine, anesthetic induction with a combination of ketamine and diazepam, maintenance with isoflurane, and administration of a morphine and lidocaine infusion for analgesia is one example of balanced anesthesia.

> **TECHNICIAN NOTE** Balanced anesthesia maximizes benefits, minimizes adverse effects, and gives the anesthetist the ability to produce anesthesia with the degree of CNS depression, muscle relaxation, analgesia, and immobilization appropriate for the patient and the procedure.

THE VETERINARY TECHNICIAN'S ROLE IN THE PRACTICE OF ANESTHESIA

Preparation, operation, and maintenance of anesthetic equipment, administration of anesthetic agents, endotracheal intubation, and patient monitoring are considered part of the credentialed veterinary technician's scope of practice and are a required part of any accredited veterinary technology program's curriculum. Competency in each of these areas of responsibility requires an advanced knowledge and skill level

that can be achieved only with a substantial commitment of time and effort on the part of the student. Before embarking on a study of anesthesia, the student must be aware of the following fundamental challenges and inherent risks he or she will face when acting as anesthetist.

- Most anesthetic agents have a very narrow **therapeutic index,** so the consequences of a calculation or administration error may be serious. Therefore care and attention to detail are critical when dosages are calculated and rates of administration are adjusted.
- Most anesthetic agents cause significant changes in cardiovascular and pulmonary function (e.g., decreased cardiac output, respiratory rate, tidal volume, and blood pressure), which can be dangerous or lethal if not carefully assessed and managed. These changes often occur quickly and without much warning. Consequently, vital signs and indicators of anesthetic depth must be closely monitored.
- The anesthetist must accurately interpret a wide spectrum of visual, tactile, and auditory information from the patient, anesthetic equipment, and monitoring devices. To do this successfully, he or she must be able to assess rapidly multiple pieces of information and distinguish those that require action from those that do not.
- The anesthetist must have a comprehensive understanding of the significance of physical parameters (e.g., heart rate, respiratory rate, and reflex responses) and machine-generated data (e.g., blood pressure and oxygen saturation readings). The anesthetist must also be able to use his or her knowledge to make rapid and decisive judgments regarding patient management and to carry out corrective actions quickly and effectively.
- The potential for patient harm during administration of anesthetics is relatively high when compared with many other procedures. When serious anesthetic accidents occur, they are often devastating not only for the patient, but also for the client and the anesthetist. In addition, after an accident, clients may choose to pursue legal action or file a complaint with the state veterinary medical board if they feel negligence was involved. These factors underscore the importance of maintaining a high standard to maximize the likelihood of a favorable outcome. This high standard includes not only sound practices but also maintenance of detailed and accurate medical records, which are the cornerstone of a solid legal defense should a complaint arise. (See Chapter 6 for more information about anesthetic records.)

In view of each of these risks and challenges, the anesthetist must approach any anesthetic procedure with a genuine willingness to take personal responsibility for the well-being of the patient. Acceptance of this responsibility by the anesthetist is dependent on development of competence and confidence. Ultimately, competence and confidence are acquired only with much study, practice, persistence, an attitude of caring, and a dedication to excellence. Only then can the accomplished anesthetist use his or her skills and knowledge to protect and improve the life of each and every patient in a way that is infinitely gratifying and unique to this complex and challenging discipline.

TECHNICIAN NOTE The anesthetist must approach each and every anesthetic procedure with a genuine willingness to take personal responsibility for the well-being of the patient.

KEY POINTS

1. General anesthesia is a reversible state of unconsciousness, immobility, muscle relaxation, and generalized loss of sensation, produced by administration of anesthetic agents. It is only one extreme in a continuum of levels of CNS depression produced by anesthetic agents, which also include sedation, hypnosis, and narcosis.
2. Many techniques including sedation, tranquilization, and topical, local, regional, and general anesthesia are used to produce specific effects appropriate to each patient.
3. Balanced anesthesia (the administration of multiple drugs to the same patient during one anesthetic event) is commonplace in the practice of anesthesia and produces many benefits not possible with administration of a single anesthetic.
4. Anesthesia involves a number of unique risks and dangers, of which the anesthetist must be conscious and aware.
5. The successful practice of anesthesia requires a high level of knowledge, competency, commitment, and acceptance of responsibility on the part of the anesthetist.

REVIEW QUESTIONS

1. A drug-induced state of calm in which the patient is reluctant to move and is aware of but unconcerned about its surroundings.
   a. Sedation
   b. Hypnosis
   c. Narcosis
   d. Tranquilization
2. The term *regional anesthesia* refers to:
   a. Loss of sensation in a limited area of the body produced by administration of a local anesthetic or other agent in proximity to sensory nerves
   b. Loss of sensation in a small area of the body produced by administration of a local anesthetic agent in proximity to the area of interest
   c. Loss of sensation of a localized area produced by administration of a local anesthetic directly to a body surface or to a surgical or traumatic wound
   d. A drug-induced sleeplike state that impairs the ability of the patient to respond appropriately to stimuli
3. A sleeplike state from which the patient can be aroused with sufficient stimulation.
   a. Narcosis
   b. Sedation
   c. Hypnosis
   d. Tranquilization

2030.35. Small Animal Spay/Neuter Clinic.
Minimum Standards for Small Animal Spay & Neuter Clinics

a) Veterinarians working in a small animal spay/neuter clinic shall establish a VCPR prior to performing surgery as defined in 2032.1.
b) For purposes of these regulations, a "small animal spay/neuter clinic" shall mean a facility established to function as a veterinary premises that concentrates in providing spay and neuter surgical services to common domestic household pets and is required by section 4853 of the code to be registered with the board.
(c) A small animal spay/neuter clinic shall have:
(1) Hot and cold water.
(2) A 110-volt power source for diagnostic equipment.
(3) A collection tank for disposal of waste material.
(4) Lighting adequate for the procedures to be performed in the spay/neuter clinic.
(5) Floors, table tops, and counter tops shall be of a non-porous material suitable for regular disinfecting, and cleaning, and shall be cleaned and disinfected regularly.
(6) Compartments to transport or hold animals, if applicable.
(d) A small animal spay/neuter clinc shall also have:
(1) indoor lighting for halls, wards, reception areas, examining and surgical rooms, which shall be adequate for its intended purpose.
(2) an examination room separate from other areas of the facility, which shall be of sufficient size to accommodate the doctor, assistant, patient and client.
(3) fire precautions that meet the requirements of local and state fire prevention codes,
(4) temperature and ventilation controls adequate to assure the comfort of all patients.
(5) a small animal spay/neuter clinic which provides aseptic surgical services shall also have a room separate and distinct from other rooms, which shall be reserved for aseptic surgical procedures. Storage in the surgery room shall be limited to items and equipment normally related to surgery and surgical procedures. A veterinarian may perform emergency aseptic surgical procedures in another room when the room designated for aseptic surgery is occupied or temporarily unavailable.
(A) A small animal spay/neuter clinic shall have the ability and equipment to provide immediate emergency care at a level commensurate with the specific veterinary medical services it is providing.
(e) A small animal spay/neuter clinic shall provide either after hours emergency services to its patients or, if no after hours emergency care is available, the small animal spay/neuter clinic shall provide a legible list of the name, address, and hours of operation of all facilities that provide or advertise emergency services and, when applicable, the location of other clinics provided by the same entity on that day, that are located within a 30-minute or 30-mile radius.
(f) When the client has not given the veterinarian authorization to dispose of his or her deceased animal, the veterinarian shall be required to retain the carcass in

a freezer for at least 14 days prior to disposal.

(g) The small animal spay/neuter clinic shall maintain all medical records as set forth in 2032.3 for a minimum of three (3) years from the date of the last visit.

(h) The veterinarian shall be identifiable to the public, including, but not limited to the posting of a copy of the veterinarian’s license, as set forth in section 4850 of the Business and Professions Code.

Multidisciplinary Advisory Committee Assignments

January 2017

EXISTING PRIORITIES – Currently being addressed by MDC

1) **Evaluate Structure and Audit Enforcement Case Outcomes**
   Complaint Process/Audit Taskforce -

2) **Develop minimum standards for alternate premises (large animal, equine mobile, public and private shelter medicine, ambulatory, etc.)**
   a. **Shelter Medicine Subcommittee**

3) **Review CCR Section 2027 Alternate pathway for Junior/Senior Students to obtain the RVT License**

4) **Pursue "extended duty" for Registered Veterinary Technicians.**
   a. **RVT Subcommittee**

5) **Define RVT Job Tasks, Emergency Language – Sedation and Pain Management**

6) **Develop regulations to implement the authorization for Veterinarians and RVTs under direct supervision to compound drugs.**

7) **Sedation vs Anesthesia – Definitions/Scope of Responsibility**

8) **Drug Counseling/Risks and Side Effects**

FUTURE PRIORITIES

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

10) **Minimum Standards for Mobile Specialists - Responsibility for Case Management**