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DEPARTMENT OF CONSUMER AFFAIRS • VETERINARY MEDICAL BOARD
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MEMORANDUM

Date	December 29, 2023
To	Multidisciplinary Advisory Committee (MDC)
From	Drug Compounding Subcommittee (Subcommittee) Richard Sullivan, DVM, MDC Chair Marie Ussery, RVT, MDC Vice Chair
Subject	**Agenda Item 5. Update, Discussion, and Potential Recommendation on Previously Approved Text to Amend CCR, Title 16, Sections 2036.5, 2090, 2091, 2092, 2093, and 2094 Regarding Drug Compounding**

Background

On January 25, 2023, the Board voted to initiate a rulemaking to adopt proposed amendments to allow Veterinary Assistant Controlled Substance Permit (VACSP) holders in a registered veterinary premises setting to be able to perform certain drug compounding functions under the supervision of a licensed veterinarian. In addition, the approved language added a definition for "immediate use" to clarify the timeframe for when a sterile compounded drug preparation was to be used, clarified the locations where office stock may be used, and established the veterinarian's supervisory duties over a registered veterinary technician (R.V.T.) and VACSP holder when drug compounding.

The proposed amendments also clarified the requirements to maintain a master formula document for each compounded drug preparation, the documentation requirements for animal patient specific compounded drug preparations, and the documentation requirements for immediate use compounded drug preparations. The Board also adopted amendments to change instances of "animal hospital" to the standardized term "registered veterinary premises."

During that meeting, it was noted that a legislative proposal was necessary to amend Business and Profession Code (BPC) section 4826.5 to allow VACSP holders to compound. If the legislative proposal was not successful, it was understood the regulatory language would return to the Board to remove VACSP holders from the proposed regulatory language.

During the Board's October 2023 meeting, Board staff noted the legislative proposal was not successful and proposed striking all instances of VACSP holders from the regulatory proposal. In addition, the Board's Regulations Counsel raised multiple concerns throughout the proposal. After further discussion about the concerns, the Board requested the regulatory proposal be sent back to the Subcommittee to review the concerns and proposed changes and bring recommendations back to the MDC and the Board at the January meeting.

Subcommittee's Review and Recommendations
As requested, the Subcommittee reviewed the concerns and recommended changes (identified in ~~double strikethrough~~ and double underline) and makes the following recommendations:

Section 2090(f) definition for "Office Stock":
Regulations Counsel raised a clarity concern with "use" and recommended it be revised to more clearly define the "use" proposed for office stock consistent with Federal Food and Drug Administration (FDA) guidance in this area and other state compounding laws and regulations. To address this concern, Regulations Counsel recommended the following changes:

> (~~e~~f) "Office stock" means a compounded drug prepared without a patient-specific prescription that may be ~~used~~ either (A) administered to an animal patient within the registered veterinary premises where the drug preparation was compounded or administered to an animal patient in mobile units and vehicles operated ~~from the registered~~ by a veterinary premises that is exempted from independent registration in accordance with section 4853 of the code, or (B) dispensed only to a client, client's representative, or other veterinarian at the same veterinary premises.

Subcommittee Recommendation:
To be more concise and address the concern with "use," and maintain consistency with the statutory use of the term "authorized agent of the client," the Subcommittee recommends the following revisions:

> (~~e~~f) "Office stock" means a compounded drug prepared without a patient-specific prescription that may be ~~used~~administered to an animal patient within the registered veterinary premises where the drug preparation was compounded~~,~~ or administered in mobile units and vehicles operated from the registered veterinary premises in accordance with section 4~~3~~853 of the code, or dispensed only to a client, client's ~~representative~~authorized agent, or other veterinarian at the same veterinary premises.

Section 2092(a)(1) written policies and procedures manual's recordkeeping requirements:
Regulations Counsel raised a concern that Section 2092(a)(1) was not updated to reflect the revisions and new documentation/record keeping requirements, including renumbering the current (e) to (f). As such, it was recommended to add those subsections, as follows.

> (a) A veterinary premises that engages in compounding drug preparations shall develop and maintain a written policies and procedures manual, which shall include:
>
> > (1) A list of each of the requirements of subsections (b), (d), ~~and~~ (e), and (f) and sections 2093 and 2094.

Subcommittee Recommendation:
The Subcommittee recommends accepting this proposed revision.

Section 2092(d) and (e) regarding revisions to animal patient medical record requirements and newly proposed text for intravenous (IV) compounded drug preparations:
Regulations Counsel raised a concern that "the currently proposed subsection does not clearly state whether this documentation needs to be included or excluded from the master formulary or non-routine compounding formula records in subsections (b) and (d) or whether a separate compounding record must be maintained as part of the patient's medical record." During the Board discussion, Regulations Counsel further stated the concern relates to using the term "notwithstanding," because it causes confusion. As such, the following changes were recommended:

> (e) ~~Notwithstanding subsections (b) and (d), f~~For intravenous (IV) compounded drug preparations for immediate use on an animal patient that contain a sterile solution that is not otherwise compounded at the veterinary premises ("IV drug preparation"), neither a master formula document as provided in subsection (b) nor a formula record as provided in subsection (d) needs to be maintained for each IV compounded drug preparation. However, for each IV drug preparation, the name and quantity of the sterile solution and the name, strength, and quantity of the ingredient(s) added to the sterile solution shall be recorded in the animal patient's medical record.

Subcommittee Recommendation:
The Subcommittee is concerned the additions make the subsection less concise and harder to understand. In addition, the Subcommittee notes that the Board has discussed this language, at length, with multiple licensees and stakeholders, and none raised a clarity concern with "notwithstanding." As such, the Subcommittee recommends maintaining the language from the previously approved proposal.

However, during the October 2023 Board discussion, it was noted that subsection (d) was not updated to reflect previously renumbered sections, and a recommendation was made to update the reference of paragraphs (2) through (7) to paragraphs (1) through (6).

In addition, the Subcommittee notes that the proposed addition of subsection (e) does not account for subcutaneous (SQ) compounded drug preparations. The Subcommittee also believes including "that is not otherwise compounded at the veterinary premises" is unnecessary, since all IV and SQ compounded drug preparations for immediate use will always be compounded at the veterinary premises.

As such, the Subcommittee recommends the following changes to Section 2092, subsections (d) and (e):

> (d) If the compounded drug preparation is not routinely compounded and a master formula document is not otherwise maintained pursuant to subsection (b), a formula record for the compounded drug preparation ~~may~~ shall be kept in the medical record

of the animal patient and shall include all information required in paragraphs (~~2~~1) through (~~7~~6) of subsection (b).

(e) Notwithstanding subsections (b) and (d), for intravenous (IV) or subcutaneous (SQ) compounded drug preparations for immediate use on an animal patient that contain a sterile solution ~~that is not otherwise compounded at the veterinary premises~~, the name and quantity of the sterile solution and the name, strength, and quantity of the ingredient(s) added to the sterile solution shall be recorded in the animal patient's medical record.

Section 2094(a) regarding office stock labeling requirements:
Regulations Counsel recommends striking the phrase "pursuant to paragraph (7) of subsection (b) of section 2092" from section 2094, subsection (a) as the phrase is redundant:

(~~b~~a) All ~~other compounded drug preparations~~ office stock shall be labeled with the following information:

(1) Name assigned to the compounded drug preparation ~~pursuant to paragraph (7) of subsection (b) of section 2092~~.

Subcommittee Recommendation:
The Subcommittee recommends accepting this proposed revision. If left as is, the language would essentially be saying "Name assigned to the compounded drug preparation pursuant to *the name assigned to the compounded drug preparation*."

Additional Subcommittee Recommendations:
Based on further discussion during the October 2023 Board meeting and review, the Subcommittee makes the following additional recommendations:

Add Section 2093(c) to clarify expiration of IV and SQ preparations:
It is currently unclear when IV and SQ preparations that do not meet the definition of "immediate use" expire. As such, the Subcommittee recommends adding new subsection (c) to section 2093 as follows:

(c) For a compounded intravenous (IV) or subcutaneous (SQ) drug preparation that does not satisfy the definition of "immediate use," the preparation shall expire 24 hours after the preparation is initially compounded.

Amend Section 2094 to add IV and SQ labeling requirements:
During the October 2023 meeting, a concern was raised that there are no labeling requirements for IV/SQ compounded drug preparations being administered within a veterinary premises. This is a safety concern, as no one other than the preparer knows what is in the hanging bag of IV/SQ fluids or when it was prepared. As such, the Subcommittee recommends the following amendments to section 2094 (note: existing subsection (a) is proposed to be moved to subsection (c)):

(~~b~~a) All ~~other compounded drug preparations~~ office stock shall be labeled with the following information:

(1) Name assigned to the compounded drug preparation ~~pursuant to paragraph (7) of subsection (b) of section 2092~~.

(~~1~~2) Name, strength, and quantity of each active ingredient.

(~~2~~3) Expiration date.

~~(3) Lot number or control number assigned by the preparer.~~

(4) Name or initials of the preparer.

(5) Date of drug preparation.

(b) All intravenous (IV) and subcutaneous (SQ) compounded drug preparations for an animal patient that contain a sterile solution shall be labeled with the following information:

(1) Name, strength, and quantity of the ingredient(s) added to the sterile solution.

(2) Date and time of the initial preparation.

(3) Name or initials of the preparer.

(~~a~~c) In addition to the label specifications specified above, ~~A~~all labeling of any dispensed compounded drug preparation shall comply with subsection (b) of section 2032.2.

(~~c~~d) If the label or packaging of a component or ingredient in the compounded drug preparation indicates refrigeration is required, the label of the compounded drug preparation shall state refrigeration is required.

Action Requested

If the MDC agrees with the Subcommittee's recommendations, please entertain a motion to:

Recommend the Board proceed as follows: Rescind the Board's prior January 25, 2023 motion approving proposed amendments to Sections 2036.5, 2090, 2091, 2092, and 2094 and approve the proposed regulatory text for Sections 2036.5, 2090, 2091, 2092, 2093 and 2094 as set forth in Attachment 2.

Direct staff to submit the text to the Director of the Department of Consumer Affairs and the Business, Consumer Services, and Housing Agency for review and if no adverse comments are received, authorize the Executive Officer to take all steps necessary to initiate the rulemaking process, make any non-substantive changes to the text and the package, and set the matter for a hearing if requested.

If after the 45-day public comment period, no adverse comments are received, and no public hearing is requested, authorize the Executive Officer to take all steps necessary to complete the rulemaking, and adopt the proposed regulations as described in the text notice for 16 CCR sections 2036.5, 2090, 2091, 2092, 2093, and 2094.

Attachments

1. Proposed Regulatory Language to Amend CCR, Title 16, Sections 2036.5, 2090, 2091, 2092, 2093, and 2094 (Veterinary Drug Compounding) – *Identifying New Changes*
2. Proposed Regulatory Language to Amend CCR, Title 16, Sections 2036.5, 2090, 2091, 2092, 2093, and 2094 (Veterinary Drug Compounding) - *Clean Version for OAL Submission*

DEPARTMENT OF CONSUMER AFFAIRS
TITLE 16. PROFESSIONAL AND VOCATIONAL REGULATIONS
DIVISION 20. VETERINARY MEDICAL BOARD

PROPOSED REGULATORY LANGUAGE

Veterinary Drug Compounding

Previously adopted proposed amendments to the regulatory language are shown in single underline for added text and ~~single strikethrough~~ for deleted text.

Changes to the previously adopted proposed amendments to the regulatory language are shown in double underline for added text and ~~double strikethrough~~ for deleted text.

Amend section 2036.5 of article 4 and sections 2090, 2091, 2092, 2093, and 2094 of article 11 of division 20 of title 16 of the California Code of Regulations as follows:

ARTICLE 4. PRACTICE

§ 2036.5. Animal ~~Hospital~~ Health Care Tasks for Permit Holders and Veterinary Assistants.

(a) Permit holders and veterinary assistants shall be prohibited from performing any of the functions or activities specified in subsections (a), (b), and (c) of ~~S~~section 2036 of these regulations, except that a permit holder under the direct or indirect supervision of a licensed veterinarian may administer a controlled substance ~~or perform drug compounding as specified in subsections (c) or (d)~~.

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

~~(c) Permit Holders Permit Holders in a registered veterinary premises may perform drug compounding from bulk drug substances under the direct supervision of a licensed veterinarian.~~

~~(d) Permit holders in a registered veterinary premises may perform drug compounding from non-bulk drug substances under the direct or indirect supervision of a licensed veterinarian or the direct supervision of an R.V.T.~~

Note: Authority cited: Sections 4808 and 4836, Business and Professions Code. Reference: Sections ~~4826.5,~~ 4836~~,~~ and 4840, Business and Professions Code.

ARTICLE 11. COMPOUNDING IN A VETERINARY PREMISES

§ 2090. Definitions.

(a) "Compounding" means any of the following activities performed in a registered veterinary premises by a licensed veterinarian, ~~that~~who has established the veterinarian-client-patient relationship for the animal patient(s), or an R.V.T. ~~or a permit holder registered veterinary technician~~ under the direct or indirect supervision 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.

(b) "Compounding" also means preparing a compounded drug preparation from bulk substances by a licensed veterinarian, who has established a veterinarian-client-patient relationship for the animal patient or prepares the compounded drug preparation for office stock, or by an R.V.T. ~~or permit holder registered veterinary technician~~ under the direct supervision of that veterinarian.

(c) "Compounding" does not include:

(1) Reconstitution of a drug pursuant to a manufacturer's direction(s) for oral, rectal, topical, or injectable administration.

(2) The sole act of tablet splitting or crushing~~,~~ or capsule opening.

(3) Addition of flavoring agent(s) to enhance palatability.

(d) "Expiration date" means the date, or date and time, determined from the date the preparation is compounded, 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.

(e) "Immediate use" means administration of a sterile compounded drug preparation to an animal patient beginning within four hours from the time the drug preparation was compounded.

(~~e~~f) "Office stock" means a compounded drug prepared without a patient-specific prescription that may be ~~used~~administered to an animal patient within the registered veterinary premises where the drug preparation was compounded~~,~~ or administered in mobile units and vehicles operated from the registered veterinary premises in accordance with section 4~~3~~853 of the code, or dispensed only to a client, client's ~~representative~~authorized agent, or other veterinarian at the same veterinary premises.

Note: Authority cited: Sections 4808 and 4826.5, Business and Professions Code. Reference: Section 4826.5, Business and Professions Code.

§ 2091. Veterinary Drug Compounding.

(a) A veterinarian shall ensure the safety and efficacy of a compounded drug preparation, through reliance on drug compounding standards in the profession and in accordance with section 2032.

(b) A veterinarian shall not perform or supervise the performance by an R.V.T. ~~or permit holder~~ of either sterile or non-sterile drug compounding when the complexity of the drug compounding exceeds the veterinarian's knowledge, skill, facilities, or available equipment.

(c) A veterinarian shall not perform or supervise the performance by an R.V.T. ~~or permit holder~~ of either sterile or non-sterile drug compounding unless there are no other human or animal drugs approved by the United States Food and Drug Administration (FDA) and available that satisfy the need for this preparation.

(d) Sterile drug 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 is historical documentation of the need, safety, and efficacy of the preparation.

(e) Only sterile drugs approved by the FDA shall be used as the ingredients in a sterile compounded drug preparation.

(f) For non-sterile compounded drug preparations, active pharmaceutical ingredients (APIs) shall be purchased from an FDA-registered facility, and all records of such purchases shall be maintained for three (3) years to prove the origin of the APIs.

Note: Authority cited: Sections 4808 and 4826.5, Business and Professions Code. Reference: Section 4826.5, Business and Professions Code.

§ 2092. Policies and Procedures.

(a) A veterinary premises that engages in compounding drug preparations shall develop and maintain a written policies and procedures manual, which shall include:

(1) A list of each of the requirements of subsections (b), (d), ~~and~~ (e), and (f) and sections 2093 and 2094.

(2) Policies and procedures for the training of an R.V.T. ~~or permit holder registered veterinary technician~~ who may perform compounded drug preparations.

(3) Policies and procedures for a quality assurance program established pursuant to section 2095.

(b) ~~For each compounded drug preparation~~Except as provided under subsections (d) and (e), a master formula document shall be maintained for each compounded drug preparation and include all of the following:

(1) Name, strength, and quantity of each a~~A~~ctive ingredients to be used.

(2) Equipment to be used.

(3) Calculation of e~~E~~xpiration date of the compounded drug preparation.

(4) Name, strength, and quantity of each i~~I~~nactive ingredients to be used.

(5) Specific compounding steps to be used to prepare the compounded drug preparation.

(6) Instructions for storage, handling, and administration of the compounded drug preparation.

(7) Name assigned to the compounded drug preparation.

(c) The master formula document may be included in the policies and procedures manual maintained pursuant to subsection (a).

(d) If the compounded drug preparation is not routinely compounded and a master formula document is not otherwise maintained pursuant to subsection (b), a formula record for the compounded drug preparation ~~may~~ shall be kept in the medical record of the animal patient and shall include all information required in paragraphs (~~2~~1) through (~~7~~6) of subsection (b).

(e) Notwithstanding subsections (b) and (d), for intravenous (IV) or subcutaneous (SQ) compounded drug preparations for immediate use on an animal patient that contain a sterile solution ~~that is not otherwise compounded at the veterinary premises~~, the name and quantity of the sterile solution and the name, strength, and quantity of the ingredient(s) added to the sterile solution shall be recorded in the animal patient's medical record.

(~~e~~f) For each compounded drug preparation prepared for an animal patient, the following information shall be recorded in the animal patient's medical record:

(1) Name or initials of the veterinarian who made or supervised the making of a compounded drug preparation and the name or initials of the R.V.T. ~~or permit holder registered veterinary technician~~, if any, who made the compounded drug preparation.

(2) Expiration date of the compounded drug preparation.

~~(3) Directions for its storage and administration.~~

(4~~3~~) Name, amount, and strength of the active ingredient(s) compounded drug preparation.

(5~~4~~) Date the drug preparation was compounded.

(~~f~~g) The veterinarian performing or supervising the compounding of drug preparations is responsible for the following:

(1) Training and supervision of the R.V.T. ~~or permit holder registered veterinary technician~~ who is compounding the drug preparation.

(2) Proper storage of the drugs used in compounding and the compounded drug preparations.

Note: Authority cited: Sections 4808 and 4826.5, Business and Professions Code. Reference: Section 4826.5, Business and Professions Code.

§ 2093. Expiration Dates.

(a) For non-sterile compounding, the expiration date shall not exceed either of the following:

(1) 180 days from the date the preparation is compounded.

(2) The shortest expiration date of any ingredient in the non-sterile compounded drug preparation.

(b) For sterile compounding, the expiration date shall not exceed either of the following:

(1) 30 days from the date the preparation is compounded.

(2) The shortest expiration date or beyond use date of any ingredient in the sterile compounded drug preparation.

(c) For a compounded intravenous (IV) or subcutaneous (SQ) preparation that does not satisfy the definition of "immediate use," the preparation shall expire 24 hours after the preparation is initially compounded.

NOTE: Authority cited: Section 4826.5, Business and Professions Code. Reference: Section 4826.5, Business and Professions Code.

§ 2094. Labeling of Compounded Preparations.

(~~b~~a) All ~~other compounded drug preparations~~ office stock shall be labeled with the following information:

(1) Name assigned to the compounded drug preparation ~~pursuant to paragraph (7) of subsection (b) of section 2092~~.

(~~1~~2) Name, strength, and quantity of each active ingredient.

(~~2~~3) Expiration date.

~~(3) Lot number or control number assigned by the preparer.~~

(4) Name or initials of the preparer.

(5) Date of drug preparation.

(b) All intravenous (IV) and subcutaneous (SQ) compounded drug preparations for an animal patient that contain a sterile solution shall be labeled with the following information:

(1) Name, strength, and quantity of the ingredient(s) added to the sterile solution.

(2) Date and time of the initial preparation.

(3) Name or initials of the preparer.

(~~a~~c) In addition to the label specifications specified above, ~~A~~all labeling of any dispensed compounded drug preparation shall comply with subsection (b) of section 2032.2.

(~~c~~d) If the label or packaging of a component or ingredient in the compounded drug preparation indicates refrigeration is required, the label of the compounded drug preparation shall state refrigeration is required.

Note: Authority cited: Sections 4808 and 4826.5, Business and Professions Code. Reference: Section 4826.5, Business and Professions Code.

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TITLE 16. PROFESSIONAL AND VOCATIONAL REGULATIONS
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PROPOSED REGULATORY LANGUAGE

Veterinary Drug Compounding

Proposed amendments to the regulatory language are shown in single underline for added text and ~~single strikethrough~~ for deleted text.

Amend section 2036.5 of article 4 and sections 2090, 2091, 2092, 2093, and 2094 of article 11 of division 20 of title 16 of the California Code of Regulations as follows:

ARTICLE 4. PRACTICE

§ 2036.5. Animal ~~Hospital~~ Health Care Tasks for Permit Holders and Veterinary Assistants.

(a) Permit holders and veterinary assistants shall be prohibited from performing any of the functions or activities specified in subsections (a), (b), and (c) of ~~S~~section 2036 of these regulations, except that a permit holder under the direct or indirect supervision of a licensed veterinarian may administer a controlled substance.

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

Note: Authority cited: Sections 4808 and 4836, Business and Professions Code. Reference: Sections 4836 and 4840, Business and Professions Code.

ARTICLE 11. COMPOUNDING IN A VETERINARY PREMISES

§ 2090. Definitions.

(a) "Compounding" means any of the following activities performed in a registered veterinary premises by a licensed veterinarian, ~~that~~who has established the veterinarian-client-patient relationship for the animal patient(s), or an R.V.T. under the direct or indirect supervision 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.

(b) "Compounding" also means preparing a compounded drug preparation from bulk substances by a licensed veterinarian, who has established a veterinarian-client-patient relationship for the animal patient or prepares the compounded drug preparation for office stock, or by an ~~registered veterinary technician~~ R.V.T. under the direct supervision of that veterinarian.

(c) "Compounding" does not include:

(1) Reconstitution of a drug pursuant to a manufacturer's direction(s) for oral, rectal, topical, or injectable administration.

(2) The sole act of tablet splitting or crushing~~,~~ or capsule opening.

(3) Addition of flavoring agent(s) to enhance palatability.

(d) "Expiration date" means the date, or date and time, determined from the date the preparation is compounded, 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.

(e) "Immediate use" means administration of a sterile compounded drug preparation to an animal patient beginning within four hours from the time the drug preparation was compounded.

(~~e~~f) "Office stock" means a compounded drug prepared without a patient-specific prescription that may be administered to an animal patient within the registered veterinary premises where the drug preparation was compounded or administered in mobile units and vehicles operated from the registered veterinary premises in accordance with section 4853 of the code, or dispensed only to a client, client's ~~representative~~authorized agent, or other veterinarian at the same veterinary premises.

Note: Authority cited: Sections 4808 and 4826.5, Business and Professions Code. Reference: Section 4826.5, Business and Professions Code.

§ 2091. Veterinary Drug Compounding.

(a) A veterinarian shall ensure the safety and efficacy of a compounded drug preparation, through reliance on drug compounding standards in the profession and in accordance with section 2032.

(b) A veterinarian shall not perform or supervise the performance by an R.V.T. of either sterile or non-sterile drug compounding when the complexity of the drug compounding exceeds the veterinarian's knowledge, skill, facilities, or available equipment.

(c) A veterinarian shall not perform or supervise the performance by an R.V.T. of either sterile or non-sterile drug compounding unless there are no other human or animal drugs approved by the United States Food and Drug Administration (FDA) and available that satisfy the need for this preparation.

(d) Sterile drug 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 is historical documentation of the need, safety, and efficacy of the preparation.

(e) Only sterile drugs approved by the FDA shall be used as the ingredients in a sterile compounded drug preparation.

(f) For non-sterile compounded drug preparations, active pharmaceutical ingredients (APIs) shall be purchased from an FDA-registered facility, and all records of such purchases shall be maintained for three (3) years to prove the origin of the APIs.

Note: Authority cited: Sections 4808 and 4826.5, Business and Professions Code. Reference: Section 4826.5, Business and Professions Code.

§ 2092. Policies and Procedures.

(a) A veterinary premises that engages in compounding drug preparations shall develop and maintain a written policies and procedures manual, which shall include:

(1) A list of each of the requirements of subsections (b), (d), and (e), and (f) and sections 2093 and 2094.

(2) Policies and procedures for the training of an R.V.T. who may perform compounded drug preparations.

(3) Policies and procedures for a quality assurance program established pursuant to section 2095.

(b) For each compounded drug preparationExcept as provided under subsections (d) and (e), a master formula document shall be maintained for each compounded drug preparation and include all of the following:

(1) Name, strength, and quantity of each Aactive ingredients to be used.

(2) Equipment to be used.

(3) Calculation of Eexpiration date of the compounded drug preparation.

(4) Name, strength, and quantity of each Iinactive ingredients to be used.

(5) Specific compounding steps to be used to prepare the compounded drug preparation.

(6) Instructions for storage, handling, and administration of the compounded drug preparation.

(7) Name assigned to the compounded drug preparation.

(c) The master formula document may be included in the policies and procedures manual maintained pursuant to subsection (a).

(d) If the compounded drug preparation is not routinely compounded and a master formula document is not otherwise maintained pursuant to subsection (b), a formula record for the compounded drug preparation ~~may~~ shall be kept in the medical record of the animal patient and shall include all information required in paragraphs (1) through (6) of subsection (b).

(e) Notwithstanding subsections (b) and (d), for intravenous (IV) or subcutaneous (SQ) compounded drug preparations for immediate use on an animal patient that contain a sterile solution, the name and quantity of the sterile solution and the name, strength, and quantity of the ingredient(s) added to the sterile solution shall be recorded in the animal patient's medical record.

(~~e~~f) For each compounded drug preparation prepared for an animal patient, the following information shall be recorded in the animal patient's medical record:

(1) Name or initials of the veterinarian who made or supervised the making of a compounded drug preparation and the name or initials of the ~~registered veterinary technician~~R.V.T., if any, who made the compounded drug preparation.

(2) Expiration date of the compounded drug preparation.

~~(3) Directions for its storage and administration.~~

(43) Name, amount, and strength of the active ingredient(s) compounded drug preparation.

(~~5~~4) Date the drug preparation was compounded.

(~~f~~g) The veterinarian performing or supervising the compounding of drug preparations is responsible for the following:

(1) Training and supervision of the ~~registered veterinary technician~~R.V.T. who is compounding the drug preparation.

(2) Proper storage of the drugs used in compounding and the compounded drug preparations.

Note: Authority cited: Sections 4808 and 4826.5, Business and Professions Code. Reference: Section 4826.5, Business and Professions Code.

§ 2093. Expiration Dates.

(a) For non-sterile compounding, the expiration date shall not exceed either of the following:

(1) 180 days from the date the preparation is compounded.

(2) The shortest expiration date of any ingredient in the non-sterile compounded drug preparation.

(b) For sterile compounding, the expiration date shall not exceed either of the following:

(1) 30 days from the date the preparation is compounded.

(2) The shortest expiration date or beyond use date of any ingredient in the sterile compounded drug preparation.

(c) For a compounded intravenous (IV) or subcutaneous (SQ) drug preparation that does not satisfy the definition of "immediate use," the preparation shall expire 24 hours after the preparation is initially compounded.

NOTE: Authority cited: Section 4826.5, Business and Professions Code. Reference: Section 4826.5, Business and Professions Code.

§ 2094. Labeling of Compounded Preparations.

(~~b~~a) All ~~other compounded drug preparations~~ office stock shall be labeled with the following information:

(1) Name assigned to the compounded drug.

(~~1~~2) Name, strength, and quantity of each active ingredient.

(~~2~~3) Expiration date.

~~(3) Lot number or control number assigned by the preparer.~~

(4) Name or initials of the preparer.

(5) Date of drug preparation.

(b) All intravenous (IV) and subcutaneous (SQ) compounded drug preparations for an animal patient that contain a sterile solution shall be labeled with the following information:

(1) Name, strength, and quantity of the ingredient(s) added to the sterile solution.

(2) Date and time of the initial preparation.

(3) Name or initials of the preparer.

(~~a~~c) In addition to the label specifications specified above, ~~A~~all labeling of any dispensed compounded drug preparation shall comply with subsection (b) of section 2032.2.

(d) If the label or packaging of a component or ingredient in the compounded drug preparation indicates refrigeration is required, the label of the compounded drug preparation shall state refrigeration is required.

Note: Authority cited: Sections 4808 and 4826.5, Business and Professions Code. Reference: Section 4826.5, Business and Professions Code.