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DEPARTMENT OF CONSUMER AFFAIRS • VETERINARY MEDICAL BOARD
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MEMORANDUM

Date	October 5, 2023
To	Veterinary Medical Board (Board)
From	Jeffrey Olguin, Lead Administrative & Policy Analyst
Subject	**Agenda Item 7.B. Consideration of Previously Approved Text to Amend CCR, Title 16, Sections 2036.5, 2090, 2091, 2092, 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 (permit) 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 adopted language added the definition "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 the veterinarian's supervisory duties over a Registered Veterinary Technician (R.V.T.) and permit holder when drug compounding. The modifications also included a requirement for a master formula document and updates on the requirements for the compounded drug preparation for each compounded drug preparation be maintained by the veterinary premises. The Board also adopted amendments to change instances of "animal hospital" to the standardized term "registered veterinary premises." (See discussion in this portion of the minutes from that meeting available here: Board's minutes.)

Concerns Regarding Animal Health Care Tasks for Permit Holders Related to Drug Compounding

Upon Board staff's development of documentation of the regulatory package, a review of BPC section 4826.5 indicated the Board does not have the authority to allow permit holders with similar rights as an R.V.T. As a result, language that would allow permit holders with certain functions was re-reviewed and is recommended for removal by staff and Regulations Counsel. Board staff also notated, that while the Board approved language to replace instances of "animal hospital," which also included the title of Section 2036.5, the entire section of 2036.5 covers "animal health care tasks for permit holders and veterinary assistants," and is therefore recommending only removing the word "hospital" from the title, which will also mirror the format of California Code of Regulations (CCR), title 16, section 2036. In addition, minor corrections, including lowercasing the "s" in "Section" under 2036.5(a) and correcting the order of items (b)(1) and (b)(2) of section 2092 are recommended for consistency with existing language. Text showing changes from the prior meeting that are recommended by staff are

included in Attachment 1. A clean version of the proposed text is available for Board member consideration in Attachment 2.

Request for Consideration of Additional Changes from Regulations Counsel

Regulations Counsel was asked to review this item in July and upon review has additional concerns that she is requesting the Board discuss. These include:

Issue No. 1, Page 2 of Attachment 2, Section 2090(f) definition for “Office Stock”:

Regulations Counsel advises that the proposed amendments to this definition render the meaning less clear and should 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 (see Attachment 2) See also, Title 16, California Code of Regulations section 1735.2(c)(3), the “office use” exception applies to “the prescriber's *own veterinary patients* seen as part of regular treatment in the prescriber's office…”).

Current text reads:

(ef) ""Office stock" means a compounded drug prepared without a patient-specific prescription that may be used within the registered veterinary premises where the drug preparation was compounded, 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, or other veterinarian at the same veterinary premises.

Changes proposed by Regulations Counsel:

(ef) "Office stock" means a compounded drug prepared without a patient-specific prescription that may be 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 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.

Issue No. 2, Page 3 of Attachment 2, Section 2092(a)(1) written policies and procedures manual’s recordkeeping requirements:

Under this proposal, the Board proposes to revise and add new documentation and recordkeeping requirements in this subsection, including renumbering the current (e) to (f). However, those new requirements and renumbered subsections are not completely covered in existing Section 2092(a) relating to the Board’s requirements for the written policies and procedures manual. The recommendation would be to add those subsections to the currently proposed text, as follows.

Current text reads:

(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) and (e) and sections 2093 and 2094.

Changes proposed by Regulations Counsel:

(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.

Issue No. 3, Page 4 in Attachment 2, Section 2092(e) regarding newly proposed text for IV compounded drug preparations:

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. These issues should be addressed to avoid clarity concerns that could be raised by stakeholders and the Office of Administrative Law.

Current text reads:

(e) Notwithstanding subsections (b) and (d), 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, 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.

Changes proposed by Regulations Counsel:

(e) 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.

Issue No. 4, Page 4, Section 2092(e) regarding newly proposed text for IV compounded drug preparations:

For this item, Regulations Counsel recommends striking the phrase "pursuant to paragraph (7) of subsection (b) of section 2092" as redundant.

Current text reads:

(b) 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.

Changes proposed by Regulations Counsel:

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

(1) Name assigned to the compounded drug preparation.

Suggested revisions that include all of Regulations Counsel's recommendations are attached to this memorandum as Attachment 3.

Action Requested

The Board is asked to consider the language in Attachment Nos. 2 and 3 and consider one of the following motions:

Option A: (If the Board has no recommended changes and would like to approve either Attachment 2 or Attachment 3's proposed text):

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, and 2094 as set forth in (**Choose One**: Attachment No. 2 or Attachment 3). 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, and 2094.

Option B: (If the Board would like to work from either Attachment 2 or 3 and make other changes to the recommended text):

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, and 2094 as set forth in (**Choose One**: Attachment No. 2 or Attachment 3), with the following changes. (Describe the suggested changes to the proposed text).

Direct staff to submit the text, which includes the changes approved at this meeting, 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, and 2094.

Attachments

1. Attachment No. 1: Proposed Language Showing Changes since the January 2023 Board Meeting

2. Attachment No. 2: Proposed Language to Amend CCR, Title 16, Sections 2036.5, 2090, 2091, 2092, and 2094 (Regarding Drug Compounding)

3. Attachment No. 3: Proposed Language Suggested by Counsel to Amend CCR, Title 16, Sections 2036.5, 2090, 2091, 2092, and 2094 (Regarding Drug Compounding)

4. Attachment No.4: FDA Guidance Document Entitled "For Veterinarians: Prescribing Animal Drugs Compounded from Bulk Drug Substances"

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

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.

Changes to the approved language are shown in double underline for added text and ~~double strikeout~~ for deleted text.

Amend section 2036.5 of article 4 and sections 2090, 2091, 2092, 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~~~~Registered Veterinary Premises~~ 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 within the registered veterinary premises where the

drug preparation was compounded, in mobile units and vehicles operated from the registered veterinary premises in accordance with section ~~4353~~4853 of the code, or dispensed only to a client, client's representative, 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) and (e) 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) through (7) of subsection (b).

(e) Notwithstanding subsections (b) and (d), 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, 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.

§ 2094. Labeling of Compounded Preparations.

(a) All labeling of any dispensed compounded drug preparation shall comply with subsection (b) of section 2032.2.

(b) 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.

(c) 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.

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

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, 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. ~~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. ~~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 within the registered veterinary premises where the drug preparation was compounded, 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, 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) and (e) and sections 2093 and 2094.

(2) Policies and procedures for the training of an R.V.T. ~~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) through (7) of subsection (b).

(e) Notwithstanding subsections (b) and (d), 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, 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. ~~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.~~

(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 R.V.T. ~~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.

§ 2094. Labeling of Compounded Preparations.

(a) All labeling of any dispensed compounded drug preparation shall comply with subsection (b) of section 2032.2.

(b) 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.

(c) 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.

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

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, 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. ~~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. ~~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 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 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.

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. ~~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) through (7) of subsection (b).

(e) 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.

(~~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. ~~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.~~

(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 R.V.T. ~~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.

§ 2094. Labeling of Compounded Preparations.

(a) All labeling of any dispensed compounded drug preparation shall comply with subsection (b) of section 2032.2.

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

(1) Name assigned to the compounded drug preparation.

(~~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.

(c) 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.

For Veterinarians: Prescribing Animal Drugs Compounded from Bulk Drug Substances

As a veterinarian, you may sometimes prescribe compounded drugs for your patient.

FDA regulates animal drugs, including compounded drugs, under the Federal Food, Drug and Cosmetic Act (FD&C Act). Here is what you need to know about the FD&C Act and FDA policies when you prescribe compounded drugs for your patient.

There are two ways to compound animal drugs, based on the source of the active ingredient. One way uses FDA-approved finished animal or human drugs as the source of the active ingredient. Compounding with FDA-approved drug products is a legal extralabel use under the FD&C Act if the conditions of FDA's extralabel use regulations are met. See 21 CFR Part 530.

The other way to compound animal drugs uses bulk drug substances (BDS), also known as active pharmaceutical ingredients (APIs), as the source of the active ingredient. Compounding animal drugs from BDS creates drugs that violate the FD&C Act because they do not meet the law's requirements for approval, manufacturing under current good manufacturing practices (CGMPs), and adequate directions for use. Because compounded animal drugs are not FDA-approved, they do not have these same assurances of safety, efficacy, and quality as FDA-approved and indexed products.

FDA's *Guidance for Industry # 256, Compounding Animal Drugs from Bulk Drug Substances* (GFI #256 or "the guidance"), describes the circumstances under which, at this time, FDA does not generally intend to take enforcement action against drugs compounded from BDS for violations of the FD&C Act's requirements for approval, adequate directions for use, and CGMPs. FDA recognizes that veterinarians sometimes prescribe drugs compounded from BDS when the patient cannot be treated with an approved or indexed drug. This checklist is intended to summarize the circumstances in GFI #256.

General Recommendations When Prescribing Compounded Animal Drugs from BDS

Under the guidance, whenever you prescribe or administer a drug compounded from BDS you should:

- ☐ **Have a valid veterinary-client-patient relationship (VCPR)**
- ☐ **Consider other FDA-approved options first.**
  - Consider whether an FDA approved (animal or human) drug or indexed drug can be used as labeled or in an extralabel manner, including compounding with the approved or indexed product, to treat the patient. If so, the approved or indexed drug should be used, instead of a drug compounded from BDS.
- ☐ **Distribute appropriately.**
  - Distribute compounded drugs to the patient's owner or caretaker or another veterinarian in your practice at the same location
- ☐ **Report adverse events.**
  - Report adverse events and product defects associated with the compounded drug to the compounder and to FDA on Form FDA 1932a.

Prescribing drugs for specific animal patients that are to be compounded from BDS by a pharmacy

When you prescribe a compounded drug for a particular patient or group of patients you should also:

- ☐ **Confirm the patient(s) is not a food-producing animal.**
  - ➢ See below for limited circumstances for compounding from BDS for food-producing animals
- ☐ **Identify patient(s).**
  - ➢ Write a prescription that identifies the patient or group of patients at same location.
- ☐ **Determine if you are prescribing a copy.**
  - ➢ Determine if there is an approved product with the same active ingredient, that can be given via the same route of administration. If so, you should have a medical rationale in your records noting why the compounded copy will make a clinical difference for the patient.
- ☐ **Provide rationale if copy is needed.**
  - ➢ Provide the pharmacist compounding the drug with the rationale for making a copy, either by writing it on the prescription or verbally when the pharmacist contacts you to obtain it. The statement of the rationale can be brief; see GFI #256 for examples. Note: If the compounded drug is not a copy of an approved product, the guidance does not ask you to provide a rationale.[1]

Obtaining office stock (i.e., drugs ordered without a prescription to be kept on-hand in inventory) compounded from BDS by a pharmacy

For some conditions treatment is urgently needed, and the time needed to compound a drug in response to an individual patient prescription may result in animal suffering or death. Under GFI #256 FDA reviews BDS nominated for use in compounding drugs as office stock for these circumstances and lists them on the List of Bulk Drug Substances for Compounding Office Stock Drugs for Use in Nonfood-Producing Animals. When you prescribe a compounded drug for office stock, you should also:

- ☐ **Confirm the patient(s) is not a food-producing animal.**
  - ➢ See below for limited circumstances for compounding from BDS for food-producing animals
- ☐ **Confirm that the BDS is on the List of Bulk Drug Substances for Compounding Office Stock Drugs for Use in Nonfood-Producing Animals or the list of Bulk Drug Substances Currently Under Review**
- ☐ **Use the compounded office stock to treat the species of animals under the conditions identified for the BDS on the list.**

Note: If you would like FDA to consider adding other drugs to the list, you can nominate a BDS at any time by following the directions in the Appendix of the GFI #256. Or, see Nominating a Bulk Drug Substance (BDS) to a List: A Quick Reference.

Prescribing drugs for food-producing animals and free-ranging wildlife species to be compounded from BDS by a pharmacy

Drugs compounded from BDS for food-producing animals are a high priority for enforcement action because of the potential for harmful residues in food from treated animals. However, because of their critical role in veterinary medicine, FDA generally does not intend to take action when animal drugs are

[1] Certain recommendations constitute collections of information that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521). These recommendations are under OMB review and are not for current implementation. See PRA statement in section IV. *Paperwork Reduction Act of 1995* of this guidance for more information.

compounded from certain BDS as antidotes for food-producing animals or sedatives or anesthetics for free-ranging wildlife as long as additional measures are taken to protect the human and animal food supply. When you prescribe a compounded drug for food-producing animals or wildlife (for use in specific patients or as office stock), you should also**:**

- ☐ **Confirm that the BDS is on the List of Bulk Drug Substances for Compounding Drugs for Use in Food-Producing Animals or Free-Ranging Wildlife Species or the list of Bulk Drug Substances Currently Under Review**
- ☐ **Establish withdrawal time.**
  - ➢ Establish a scientifically based withdrawal time that ensures that residues of the antidote, sedative, or anesthetic are not present in the animal at the time of slaughter or harvest
- ☐ **Ensure withdrawal time is observed.**
  - ➢ Take steps to ensure that the treated animals do not enter the food supply before the end of the withdrawal time or do not enter the food supply at all.

Note: If you would like FDA to consider adding other drugs to the list, you can nominate a BDS at any time by following the directions in the Appendix of the GFI #256. Or, see Nominating a Bulk Drug Substance (BDS) to a List: A Quick Reference.