VETERINARY MEDICAL BOARD

GUIDANCE ON VETERINARY DRUG COMPOUNDING PURSUANT TO CALIFORNIA CODE OF REGULATIONS, TITLE 16, SECTIONS **2090–2095**

I. INTRODUCTION

In 2016, U.S. Pharmacopeia (USP) began revising USP <795> and <797>, which are the guidelines used for compounding nonsterile and sterile drug preparations. These revisions would eliminate the existing categories of simple, moderate, and complex compounding. The scope of the proposed changes would include veterinarians and veterinary facilities. These new guidelines would require veterinary clinicians to comply with the same standards to compound simple preparations, like combining two sterile products, as a veterinary compounding pharmacy that is making a complex preparation of making a sterile product from nonsterile ingredients. The requirements for the facility of a compounding pharmacy and a veterinary clinic would be the same and include a separate compounding room with an adjacent anteroom, air quality and air flow requirements, documented 24-hour temperature control, stability testing, sterility testing, etc. As of July 2021, the proposed revisions to USP <795> and <797> are still under consideration and have not been enacted.

In California, the Pharmacy Law was recently amended to require compounding of drug preparations by a pharmacy to be consistent with standards established under the USP (see Business and Professions Code (BPC), section 4126.8). Various provisions under the Pharmacy Law regarding prescriptions are applicable to veterinarians, so it was important to establish separate drug compounding requirements specific to veterinarian practice under the Veterinary Medicine Practice Act.

In 2016, the California Legislature passed **Senate Bill 1193** (Hill, Chapter 484, Statutes of 2016), which added BPC section **4826.5** to authorize veterinarians or supervised registered veterinary technicians to compound drugs for animal use.

In accordance with BPC section **4826.5**, the Veterinary Medical Board (VMB) developed regulations that allow veterinarians to continue to perform "simple" drug compounding and 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. These regulations also establish new documentation and procedure requirements.

Please note that each time a veterinarian initially prescribes, dispenses, or furnishes a dangerous drug*, as defined in BPC section **4022**, to an animal patient in an outpatient setting, the veterinarian shall offer to provide, in person or through electronic means, to the client responsible for the animal, or their agent, a consultation that includes specified medication information (see BPC § **4829.5**). As such, any new compounded drug preparation that is classified as a dangerous drug will require information to be provided to the client to satisfy BPC section **4829.5**. Although not required to be provided in writing unless requested by the client, it is recommended that every client be provided this information in writing and include the compounded drug preparation formula in case of emergency or adverse reaction.

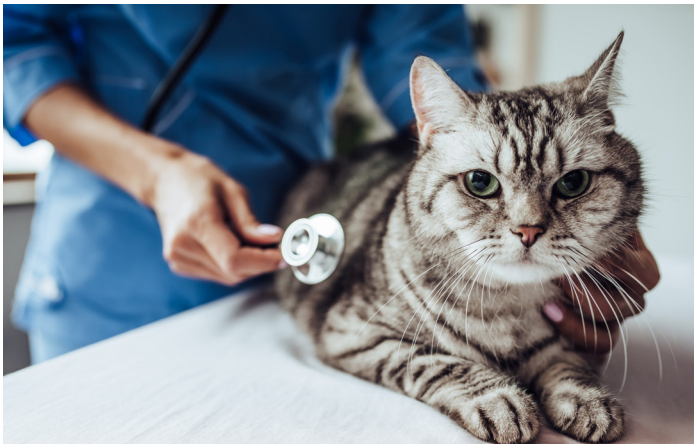
**"Dangerous drug" means any drug requiring a prescription. (BPC § 4022)*

BEFORE READING THIS DOCUMENT, YOU SHOULD FIRST READ CALIFORNIA CODE OF REGULATIONS (CCR), TITLE 16, SECTIONS 2090–2095 TO BETTER UNDERSTAND THE PROCESS OF COMPLYING WITH THE REGULATIONS.

This guidance provides discussion of some, but not all, of the drug compounding regulatory requirements.

II. DRUG COMPOUNDING POLICIES AND PROCEDURE MANUAL

As of April 1, 2022, a veterinary premises that engages in compounding drug preparations shall develop and maintain a written policies and procedures manual. The information that must be included in the manual is listed in CCR, title 16, section **2092**, subsection (a), and includes policies and procedures for the training of a registered veterinary technician who may perform compounded drug preparations and policies and procedures for a quality assurance program.



III. FORMULA DOCUMENT

For each compounded drug preparation, a formula document shall be maintained. The requirements for each formula document are provided in CCR, title 16, section **2092**, subsection (b). The formula document may be included in the premises' policies and procedures manual. (CCR, tit. 16, § **2092**, subs. (c))

If the compounded drug preparation is not routinely compounded, a formula record for the preparation may be kept in the animal patient's medical record. (CCR, tit. 16, § **2092**, subs. (d))

A courtesy Compounded Drug Preparation Formula form is provided at the end of this guidance, along with examples of completed forms.

IV. ANIMAL PATIENT MEDICAL RECORD DOCUMENTATION

For each compounded drug preparation prepared for a patient, the following information shall be recorded in the 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, if any, who made the compounded drug preparation.

(2) Expiration date of the compounded drug preparation.

(3) Directions for its storage and administration.

(4) Name, amount, and strength of the compounded drug preparation.

(5) Date the drug preparation was compounded.
(CCR, tit. 16, § **2092**, subs. (e))

V. QUALITY ASSURANCE PROGRAM

A veterinary premises that engages in compounding drug preparations shall establish a quality assurance program that documents and assesses medication errors to determine cause and appropriate response. The requirements for the quality assurance program are provided in CCR, title 16, section **2095**. The policies and procedures for the quality assurance program shall be included in the premises' policies and procedures manual. (CCR, tit. 16, § **2092**, subs. (a)(3))

VI. LABELING OF COMPOUNDED PREPARATIONS

All labeling of any dispensed compounded drug preparation shall comply with CCR, title 16, section **2032.2**, subsection (b), and include specified information. (CCR, tit. 16, § **2094**)

VII. DEFINITIONS

A. Compounding (CCR, tit. 16, § 2090):

1. Compounding is any of the following:

(a) Altering the dosage form or delivery system of a drug.

(b) Altering the strength of a drug.

(c) Combining components or active ingredients.

(d) Preparing a compounded drug preparation from bulk substances.

(e) Preparing a compounded drug preparation for office stock.

2. Compounding does not include:

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

(b) Tablet splitting.

(c) Tablet crushing.

(d) Capsule opening.

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

3. "Office stock" means a compounded drug prepared without a patient-specific prescription that may be dispensed only to a client, client's representative, or other veterinarian at the same veterinary premises.

4. For a specific compounded drug preparation that is rarely made, you may include all the pertinent information in the medical record of the patient, and you do not have to include it in the policies and procedures manual.

B. Expiration Dates:

(a) For nonsterile compounding, the expiration date shall not exceed either of the following (CCR, tit. 16, § **2093**, subs. (a)):

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

(ii) The shortest expiration date of any ingredient in the nonsterile compounded drug preparation.

(b) For sterile compounding, the expiration date shall not exceed either of the following (CCR, tit. 16, § **2093**, subs. (b)):

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

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

In the event that any portion of this guidance may be deemed at any time to conflict with any statute or regulation, the statute or regulation shall prevail.

VMB Veterinary Medical Board

CALIFORNIA DEPARTMENT OF CONSUMER AFFAIRS

COMPOUNDED DRUG PREPARATION FORMULA FORM

To assist veterinary professionals in compliance with the requirements of California Code of Regulations (CCR) section **2092**, subsection (b)(1)-(6), this form is provided as a courtesy by the Veterinary Medical Board. This form may be included in the policies and procedures manual maintained pursuant to CCR, section **2092**, subsection (a).

For each compounded drug preparation, document the following:

NAME OF COMPOUNDED DRUG PREPARATION:
1. ACTIVE INGREDIENTS TO BE USED:
2. EQUIPMENT TO BE USED:
3. EXPIRATION DATE OF PREPARATION:
4. INACTIVE INGREDIENTS TO BE USED:
5. SPECIFIC COMPOUNDING STEPS TO BE USED TO PREPARE DRUG:
6. INSTRUCTIONS FOR STORAGE, HANDLING, AND ADMINISTRATION OF COMPOUNDED PREPARATION:

EXAMPLE:

COMPOUNDED DRUG PREPARATION FORMULA FORM

NAME OF COMPOUNDED DRUG PREPARATION:
Laparoscopic AI Ewe Sedation Cocktail
1. ACTIVE INGREDIENTS TO BE USED:
10 ml ketamine 100 mg/ml 2 ml butorphanol 10 mg/ml 0.2 ml xylazine 100 mg/ml
2. EQUIPMENT TO BE USED:
Syringes and needles as needed
3. EXPIRATION DATE OF PREPARATION:
30 days from date of compounding or the shortest expiration date of any ingredient in the compounded drug preparation.
4. INACTIVE INGREDIENTS TO BE USED:
N/A
5. SPECIFIC COMPOUNDING STEPS TO BE USED TO PREPARE DRUG:
Mix 10 ml ketamine, 2 ml butorphanol, and 0.2 ml xylazine in a sterile bottle.
6. INSTRUCTIONS FOR STORAGE, HANDLING, AND ADMINISTRATION OF COMPOUNDED PREPARATION:
Store at room temperature according to controlled drug storage procedures. Give 1 ml of mixed solution IV per adult ewe for sedation.

EXAMPLE:

COMPOUNDED DRUG PREPARATION FORMULA FORM

NAME OF COMPOUNDED DRUG PREPARATION:
Enrofloxacin and Dexamethasone Otic Solution
1. ACTIVE INGREDIENTS TO BE USED:
4 oz TrizEDTA Aqueous Flush 10 ml enrofloxacin 100 mg/ml 4 ml dexamethasone SP 4 mg/ml
2. EQUIPMENT TO BE USED:
Syringes and needles as needed
3. EXPIRATION DATE OF PREPARATION:
180 days from date of compounding or the shortest expiration date of any ingredient in the compounded drug preparation.
4. INACTIVE INGREDIENTS TO BE USED:
N/A
5. SPECIFIC COMPOUNDING STEPS TO BE USED TO PREPARE DRUG:
Remove 14ml of TrizEDTA from the original bottle and dispose; add 10 ml enrofloxacin and 4 ml dexamethasone to the TrizEDTA bottle; shake bottle to combine ingredients.
6. INSTRUCTIONS FOR STORAGE, HANDLING, AND ADMINISTRATION OF COMPOUNDED PREPARATION:
Store at room temperature. Shake well before use. Apply in affected ear twice daily (every 12 hours) for 10 days.