



# MEMORANDUM

<b>DATE</b>	July 8, 2022
<b>TO</b>	Veterinary Medical Board (Board)
<b>FROM</b>	Richard Sullivan, DVM, Chair Multidisciplinary Advisory Committee (MDC)
<b>SUBJECT</b>	<b>Agenda Item 5.E. Review, Discussion, and Possible Action on Recommendation Regarding Veterinary Drug Compounding Guidance</b>

## Background

The Board’s [drug compounding regulations](#) became effective on April 1, 2022. During the January 2022 meeting, the Board directed the MDC to create a guidance document to assist licensees and registrants in complying with the new regulations.

Dr. Sullivan and Ms. Ussery formed the Drug Compounding Subcommittee (Subcommittee) to draft the guidance for MDC discussion and consideration.

## Subcommittee Newly Identified Issues

This task was approached with the plan of developing an educational document to serve as an example on how to comply with the new regulations. The idea was to first explain the reasoning behind the new regulations and then to provide a step-by-step process on how to comply.

While working with Board staff on document drafts, it became apparent that there are two major deficiencies in the regulations that should be addressed:

1. Unique Identification Number and Prescription Number Not Currently Required  
 For each compounded drug preparation, a formula document shall be maintained and include the following information (California Code of Regulations (CCR), tit. 16, § [2092](#), subs.(b)):
- (1) Active ingredients to be used.
  - (2) Equipment to be used.
  - (3) Expiration date of the preparation.
  - (4) Inactive ingredients to be used.
  - (5) Specific compounding steps to be used to prepare the drug.
  - (6) Instructions for storage, handling, and administration of the compounded preparation.

The formula document may be included in the premises' Policies and Procedures Manual. (CCR, tit. 16, § [2092](#), subs. (c).)

However, each formula document is not required to have a unique identification number nor are individual preparations required to have prescription numbers. The Subcommittee believes these numbers are necessary to provide each individual compounded preparation with a proper paper trail from the time that it is compounded to the time that it is either dispensed to a patient or used as office stock.

Ideally, the unique identification number would be logged on a form or spreadsheet that would also include the following:

- date the preparation was compounded;
- prescription number
- the ingredients;
- individual ingredient expiration dates;
- client number;
- animal (or herd) name or number;
- initials of the veterinarian prescribing the preparation or directing the making of an office stock preparation;
- initials of the registered veterinary technician performing the drug compounding; and,
- expiration date of the final compounded preparation.

The Subcommittee believes CCR, title 16, section 2092, subsection (b), should be amended to require this information.

## 2. Medical Record Requirement Intended for Dispensed Compounded Drugs

For each compounded drug preparation prepared for an animal patient, the following information shall be included in the animal patient's medical record (CCR, tit. 16, § [2092](#), subs. (e)):

- (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.

This section was intended to apply only to those compounded medications that were dispensed to clients for animal patients. It was not intended to apply to office stock compounded medications for use on multiple patients. However, since the language states "prepared for a patient," it applies to all compounded medications – dispensed and prepared for office stock.

The Subcommittee believes it is not practical to list out items 1 through 5 in each animal patient's medical record for an office stock compounded preparation. To remedy this issue, the Subcommittee believes CCR, title 16, section 2092, subsection

(e), should be amended to apply solely to compounded drug preparations dispensed to a client for animal patient use.

The MDC will review the Subcommittee's proposal to resolve these issues at the MDC's July 2022 meeting. In the meantime, the Subcommittee prepared the Guidance on Veterinary Drug Compounding (Guidance) and suggested a courtesy formula form (Compounded Drug Preparation Formula Form) for use by practitioners to comply with CCR, title 16, section 2092, subsection (b).

### **Additional Concerns**

During MDC discussion and public comment at the April 2022 MDC meeting, significant concerns were raised that only veterinarians and registered veterinary technicians (RVTs) are allowed to compound. The concerns were focused on the inability for others to perform tabletop compounding, which includes adding potassium and various other items to intravenous (IV) fluids, and the paperwork that needed to be completed for each compound. Public comment also included concerns that limiting compounding to veterinarians and RVTs will negatively impact and delay patient care.

The Subcommittee explained the guidance document did not create any new requirements. The limitation for only veterinarians and RVTs to perform drug compounding was established in existing statute (Bus. & Prof. Code, § [4826.5](#)) and would require a legislative change to expand drug compounding authority to other veterinary care professionals. As reported during the April Board meeting, the Subcommittee will develop legislative and regulatory proposals to address the remaining concerns and present the proposals to the MDC at its July 2022 meeting.

### **MDC Recommendation**

After making minor edits to the Guidance during the April 2022 MDC meeting, the MDC approved a motion to recommend the Board approve the Guidance and courtesy Compounded Drug Preparation Formula Form for posting on its website and dissemination to all licensees and stakeholders.

Following the April 2022 MDC meeting, Board staff raised concerns with the inclusion of the tabletop definition in the Guidance (April 2022 MDC Agenda [Item 9](#), p. 6, list item 3). To resolve those concerns, the Guidance has been revised to delete the tabletop compounding definitions. The Subcommittee will propose definitions to be added to CCR, title 16, section [2090](#) to address tabletop compounding and immediate use of sterile compounded drug preparations and present those regulatory amendments to the MDC at its July meeting.

### **Action Requested**

Please review and discuss the attached Guidance and courtesy Compounded Drug Preparation Formula Form. If the Board approves of these documents, please entertain a motion to approve the Guidance on Veterinary Drug Compounding and courtesy Compounded Drug Preparation Formula Form for posting on the Board's website and dissemination to all licensees and stakeholders.

### **Attachments**

1. Guidance on Veterinary Drug Compounding

## 2. Compounded Drug Preparation Formula Form

**VETERINARY MEDICAL BOARD  
GUIDANCE ON VETERINARY DRUG COMPOUNDING  
PURSUANT TO CALIFORNIA CODE OF REGULATIONS, TITLE 16, SECTIONS [2090-2095](#)**

**I. INTRODUCTION:**

In 2016, US Pharmacopeia (USP) began revising USP <795> and <797>, which are the guidelines used for compounding non-sterile 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 ante room, 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), § 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 State 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.

**BEFORE READING THIS DOCUMENT, YOU SHOULD FIRST READ CCR, TITLE 16, SECTIONS [2090-2095](#) TO BETTER UNDERSTAND THE PROCESS OF COMPLYING WITH THE REGULATIONS. These Guidelines provide 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 Policies and Procedures 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](#), subsections (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).) In addition, for each compounded drug preparation prepared for a patient, specific information shall be recorded in the animal patient's medical record. (CCR, tit. 16, § [2092](#), subs. (e).)

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

## **IV. 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).)

## **V. 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](#).)

## **VI. 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 non-sterile 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 non-sterile 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 these guidelines may be deemed at any time to conflict with any statute or regulation, the statute or regulation shall prevail.

**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:

<b>NAME OF COMPOUNDED DRUG PREPARATION:</b>
<b>1. Active Ingredients to be Used:</b>
<b>2. Equipment to be Used:</b>
<b>3. Expiration Date of Preparation:</b>
<b>4. Inactive Ingredients to be Used:</b>
<b>5. Specific Compounding Steps to be Used to Prepare Drug:</b>
<b>6. Instructions for Storage, Handling, and Administration of Compounded Preparation</b>



**EXAMPLE:  
COMPOUNDED DRUG PREPARATION  
FORMULA FORM**

<b>NAME OF COMPOUNDED DRUG PREPARATION:</b>
Serum for Treatment of Corneal Ulcers
<b>1. Active Ingredients to be Used:</b>
Serum from patient
<b>2. Equipment to be Used:</b>
10 ml sterile syringe 2 red top blood collecting tubes 4 or 5 1 ml syringes to collect the separated serum
<b>3. Expiration Date of Preparation:</b>
30 days from day of collection of serum
<b>4. Inactive Ingredients to be Used:</b>
N/A
<b>5. Specific Compounding Steps to be Used to Prepare Drug:</b>
10 ml of blood drawn from patient with the corneal ulcer. Place 10 ml of blood into several serum separator tubes and let set for 20 minutes. Remove serum from tubes and place in 1 ml syringes and freeze until ready to use.
<b>6. Instructions for Storage, Handling, and Administration of Compounded Preparation</b>
Refrigerate the 1 ml syringe that is being used daily. Freeze 1 ml syringes that will be used later. Apply one drop of serum to the eye with the ulcer q 6 hrs.

**EXAMPLE:  
COMPOUNDED DRUG PREPARATION  
FORMULA FORM**

<b>NAME OF COMPOUNDED DRUG PREPARATION:</b>
Bovine LRS IV Solution
<b>1. Active Ingredients to be Used:</b>
0.83 g of CaCl <sub>2</sub> dihydrate 1.3 g of KCl 8.9 g of NaHCO <sub>3</sub> 22.56 g of NaCl 275 ml of 50% Dextrose (depending upon patient needs)
<b>2. Equipment to be Used:</b>
Gram scale Weighing tray Zip Lock bag or other type of sealed bag or container Bottle to mix active and inactive ingredients in for administration Simplex/Bell IV administration set 14 GA x 1 ½" needle
<b>3. Expiration Date of Preparation:</b>
180 days from date of compounding
<b>4. Inactive Ingredients to be Used:</b>
Distilled water
<b>5. Specific Compounding Steps to be Used to Prepare Drug:</b>
Mix ingredients to provide approximately equivalent to (in mEq/l): Na=130, Cl=109, K=4, Ca=3, HCO=28. Store in a zip lock bag or other type of sealed container to prevent moisture from coming into contact with the mixture until ready to use.
<b>6. Instructions for Storage, Handling, and Administration of Compounded Preparation</b>
For use: add mixture to 1 gal. of distilled water to make a non-sterile solution. Shake solution well and give IV for dehydration in any bovine. May add 275 ml of 50% dextrose to the final solution if needed.