Veterinary Medical Board
BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY • GAVIN NEWSOM, GOVERNOR
DEPARTMENT OF CONSUMER AFFAIRS • VETERINARY MEDICAL BOARD
1747 North Market Blvd., Suite 230, Sacramento, CA 95834-2987
P (916) 515-5520 | Toll-Free (866) 229-6849 | www.vmb.ca.gov

MEMORANDUM

DATE	April 5, 2022
TO	Multidisciplinary Advisory Committee (MDC)
FROM	Drug Compounding Subcommittee Richard Sullivan, DVM Marie Ussery, RVT
SUBJECT	**Agenda Item 9. Discussion and Potential Recommendation to the Board Regarding Veterinary Drug Compounding Guidance**

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 a subcommittee to draft the guidance for MDC discussion and consideration.

Subcommittee Update, Newly Identified Issues, and Recommendations

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.

In the meantime, the Subcommittee prepared the attached guidance and suggested a formula form to comply with CCR, title 16, section 2092, subsection (b).

Next Steps

The Subcommittee will develop proposed regulatory amendments to address the concerns raised and bring to the MDC at its next meeting.

Action Requested

Please review and discuss the attached Guidance on Veterinary Drug Compounding document and courtesy formula form. If the MDC approves of the educational material, please entertain a motion to recommend the Board approves the material for posting on its website and dissemination to all licensees and stakeholders.

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 2016, the California State Legislature passed Senate Bill 1193 (Hill, Chapter 484, Statutes of 2016), which added Business and Professions Code (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 mediation 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. "Tabletop compounding" means:
   (a) Tabletop compounding is when two or more sterile products are combined to make a compounded preparation and are used within four hours.
   (b) This preparation does not have to be documented in the Policies and Procedures Manual.
   (c) However, if you use this preparation again later in the day or use it the next day, then it no longer is a "tabletop" preparation.
4. "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.
5. 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.

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:
Serum for Treatment of Corneal Ulcers
1. Active Ingredients to be Used:
Serum from patient
2. Equipment to be Used:
10 ml sterile syringe 2 red top blood collecting tubes 4 or 5 1 ml syringes to collect the separated serum
3. Expiration Date of Preparation:
30 days from day of collection of serum
4. Inactive Ingredients to be Used:
N/A
5. Specific Compounding Steps to be Used to Prepare Drug:
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.
6. Instructions for Storage, Handling, and Administration of Compounded Preparation
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

NAME OF COMPOUNDED DRUG PREPARATION:
Bovine LRS IV Solution
1. Active Ingredients to be Used:
0.83 g of $CaCl_2$ dihydrate 1.3 g of KCl 8.9 g of $NaHCO_3$ 22.56 g of NaCl 275 ml of 50% Dextrose (depending upon patient needs)
2. Equipment to be Used:
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
3. Expiration Date of Preparation:
180 days from date of compounding
4. Inactive Ingredients to be Used:
Distilled water
5. Specific Compounding Steps to be Used to Prepare Drug:
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.
6. Instructions for Storage, Handling, and Administration of Compounded Preparation
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.