Veterinary Medical Board
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DEPARTMENT OF CONSUMER AFFAIRS • VETERINARY MEDICAL BOARD
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MEMORANDUM

DATE	October 6, 2022
TO	Multidisciplinary Advisory Committee (MDC)
FROM	Drug Compounding Subcommittee (Subcommittee) Richard Sullivan, DVM, Chair Marie Ussery, RVT
SUBJECT	**Agenda Item 7. Discussion and Potential Recommendation to the Board on Revisions to Guidance on Veterinary Drug Compounding Regarding Drug Consultation**

Background

The Veterinary Medical Board's (Board) 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 Subcommittee to draft the guidance, as well as a courtesy formula form for use by practitioners to comply with CCR, title 16, section 2092, subsection (b).

On April 19, 2022, the MDC reviewed and approved the Subcommittee's Guidance on Veterinary Drug Compounding (Guidance) and a courtesy formula form (Compounded Drug Preparation Formula Form). On July 20, 2022, the Board reviewed, revised, and approved the Guidance and Compounded Drug Preparation Formula Form.

Drug Consultations

Following the July 2022 Board meeting, the Subcommittee continued review of the drug compounding regulations and Guidance. The Subcommittee found additional revisions to be made to the Guidance to alert veterinarians of the requirement in Business and Professions Code (BPC) section 4829.5 to provide, in person or through electronic means, drug consultations to clients, or their agents, when the veterinarian initially dispenses or furnishes a compounded drug preparation. The statute does not specify whether the consultation must be oral or written, but the animal patient's medical record must reflect whether the consultation was provided or declined by the client or their agent.

BPC section 4829.5, subdivision (a), requires a veterinarian to offer to provide all of the following information to the client in the drug consultation:

(1) The name and description of the dangerous drug.

(2) Route of administration, dosage form, dosage, duration of drug therapy, the duration of the effects of the drug, and the common severe adverse effects associated with the use of a short-acting or long-acting drug.

(3) Any special directions for proper use and storage.

(4) Actions to be taken in the event of a missed dose.

(5) If available, precautions and relevant warnings provided by the drug's manufacturer, including common severe adverse effects of the drug.

If requested, the veterinarian must provide drug documentation, if available. (BPC, § 4829.5, subd. (b).) The veterinarian may delegate to a registered veterinary technician or veterinary assistant may provide the consultation and drug documentation. (BPC, § 4829.5, subd. (c).)

Plumb's is a resource for medication information commonly used by veterinarians to provide drug documentation to clients. Since Plumb's does not provide medication information on compounded drug preparations, and the veterinarian must provide drug documentation upon request, the veterinary clinic would have to develop a document that satisfies the requirements of BPC section 4829.5. The Subcommittee notes that providing to all clients, regardless of request, a medication information document is helpful because the drug label may not contain all of the details of the formula that may be needed if a animal patient is given an overdose, or a child accidentally is exposed to or ingests the compounded drug preparation, which may occur when the veterinary premises is closed.

To provide information regarding the statutory drug consultation requirement relating to compounded drug preparations in one resource document, the Subcommittee recommends the Guidance be amended to include the drug consultation information requirement. Attached hereto is the proposed revised Guidance (revisions shown in underlined text).

Action Requested

The MDC is asked to review and discuss the proposed revisions to the Guidance. If the MDC approves of the revisions to the Guidance, please entertain a motion to recommend the Board adopt the revised 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.

Attachment

1. Proposed Guidance on Veterinary Drug Compounding and 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.

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 his or her agent, a consultation that includes specified medication information. (BPC section 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 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 if the Poison Center needs to know the ingredient(s) and concentration(s).

BEFORE READING THIS DOCUMENT, YOU SHOULD FIRST READ 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 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).)

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 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).)

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 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 this Guidance 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:

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.