

**Second Regular Session
Seventieth General Assembly
STATE OF COLORADO**

PREAMENDED

*This Unofficial Version Includes Committee
Amendments Not Yet Adopted on Second Reading*

LLS NO. 16-0881.01 Jennifer Berman x3286

HOUSE BILL 16-1324

HOUSE SPONSORSHIP

Ginal, McCann, Arndt, Becker K., Brown, Coram, Dore, Lebsock, Vigil, Court, Primavera

SENATE SPONSORSHIP

Sonnenberg, Garcia

House Committees

Health, Insurance, & Environment
Finance
Appropriations

Senate Committees

A BILL FOR AN ACT

101 **CONCERNING THE AVAILABILITY OF COMPOUNDED PHARMACEUTICAL**
102 **DRUGS FOR USE BY A VETERINARIAN TO TREAT A PATIENT'S**
103 **EMERGENCY CONDITION.**

Bill Summary

(Note: This summary applies to this bill as introduced and does not reflect any amendments that may be subsequently adopted. If this bill passes third reading in the house of introduction, a bill summary that applies to the reengrossed version of this bill will be available at <http://www.leg.state.co.us/bills summaries>.)

Under current law, a veterinarian cannot maintain an office stock of compounded drugs, which are drugs that are combined, mixed, or otherwise altered to create a specific drug or formulation, for later distribution or administration to patients. The bill authorizes:

! A compounding pharmacy to compound and distribute a

Shading denotes HOUSE amendment. Double underlining denotes SENATE amendment.
Capital letters indicate new material to be added to existing statute.
Dashes through the words indicate deletions from existing statute.

drug to a veterinarian without a specific patient indicated to receive the compounded drug; and

- ! A veterinarian to dispense a compounded drug, maintained as part of the veterinarian's office stock, in an amount not to exceed 5 days' worth of doses, if a patient has an emergency condition that the compounded drug is necessary to treat and the veterinarian cannot access, in a timely manner, the compounded drug through a compounding pharmacy.

1 *Be it enacted by the General Assembly of the State of Colorado:*

2 **SECTION 1.** In Colorado Revised Statutes, 12-42.5-118, **amend**
3 (6) (b) as follows:

4 **12-42.5-118. Compounding - dispensing - sale of drugs and**
5 **devices - rules - definition.** (6) (b) (I) The board shall promulgate rules
6 authorizing a prescription drug outlet located in this state to compound
7 drugs for office use by a practitioner or for use by a hospital located in
8 this state. The rules must limit the amount of drugs a prescription drug
9 outlet may compound and distribute to a practitioner or hospital pursuant
10 to this paragraph (b) to no more than ten percent of the total number of
11 drug dosage units dispensed and distributed on an annual basis by the
12 outlet.

13 (II) (A) THE TEN PERCENT LIMITATION SET FORTH IN
14 SUBPARAGRAPH (I) OF THIS PARAGRAPH (b) APPLIES TO A COMPOUNDED
15 DRUG FOR VETERINARY USE THAT A PRESCRIPTION DRUG OUTLET
16 DISTRIBUTES IN COLORADO.

17 (B) FOR PURPOSES OF THIS SUBPARAGRAPH (II), A "PRESCRIPTION
18 DRUG OUTLET" INCLUDES A NONRESIDENT PHARMACY OUTLET REGISTERED
19 OR LICENSED PURSUANT TO THIS ARTICLE WHERE PRESCRIPTIONS ARE
20 COMPOUNDED AND DISPENSED, BUT ONLY IF THE NONRESIDENT PHARMACY

1 OUTLET HAS PROVIDED THE BOARD WITH A COPY OF THE MOST RECENT
2 INSPECTION OF THE NONRESIDENT PHARMACY OUTLET BY THE AGENCY
3 THAT REGULATES PHARMACEUTICALS IN THE STATE OF RESIDENCE AND A
4 COPY OF THE MOST RECENT INSPECTION RECEIVED FROM A
5 BOARD-APPROVED THIRD-PARTY ENTITY THAT INSPECTS PHARMACY
6 OUTLETS, FOR WHICH THIRD-PARTY INSPECTION THE NONRESIDENT
7 PHARMACY OUTLET SHALL OBTAIN AND PAY FOR ON AN ANNUAL BASIS,
8 AND THE BOARD APPROVES THE INSPECTION REPORTS AS SATISFACTORILY
9 DEMONSTRATING PROOF OF COMPLIANCE WITH THE BOARD'S OWN
10 INSPECTION PROCEDURE AND STANDARDS.

11 **SECTION 2.** In Colorado Revised Statutes, **add** 12-42.5-118.5
12 as follows:

13 **12-42.5-118.5. Compounding drugs for office use by a**
14 **veterinarian - rules - definitions.** (1) A REGISTERED PRESCRIPTION
15 DRUG OUTLET MAY COMPOUND AND DISTRIBUTE A DRUG TO A LICENSED
16 VETERINARIAN SO THAT THE VETERINARIAN MAY MAINTAIN THE DRUG AS
17 PART OF THE VETERINARIAN'S OFFICE STOCK.

18 (2) (a) A VETERINARIAN MAY DISPENSE A COMPOUNDED DRUG
19 MAINTAINED AS PART OF THE VETERINARIAN'S OFFICE STOCK PURSUANT TO
20 SUBSECTION (1) OF THIS SECTION ONLY IF:

21 (I) THE COMPOUNDED DRUG IS NECESSARY FOR THE TREATMENT
22 OF A PATIENT'S EMERGENCY CONDITION; AND

23 (II) AS DETERMINED BY THE VETERINARIAN, THE VETERINARIAN
24 CANNOT ACCESS, IN A TIMELY MANNER, THE COMPOUNDED DRUG
25 THROUGH A REGISTERED PRESCRIPTION DRUG OUTLET.

26 (b) A VETERINARIAN SHALL NOT DISPENSE A COMPOUNDED DRUG
27 PURSUANT TO THIS SECTION IN AN AMOUNT GREATER THAN THE AMOUNT

1 REQUIRED TO TREAT A PATIENT'S EMERGENCY CONDITION FOR FIVE DAYS.

2 (3) A LICENSED VETERINARIAN SHALL NOT ADMINISTER OR
3 DISPENSE A COMPOUNDED DRUG MAINTAINED FOR OFFICE STOCK
4 PURSUANT TO THIS SECTION OR FOR OFFICE USE PURSUANT TO SECTION
5 12-42.5-118 (6) (b) (II) WITHOUT A VALID VETERINARIAN-CLIENT-PATIENT
6 RELATIONSHIP IN PLACE AT THE TIME OF ADMINISTERING THE
7 COMPOUNDED DRUG TO AN ANIMAL PATIENT OR DISPENSING THE
8 COMPOUNDED DRUG TO A CLIENT.

9 (4) TO COMPOUND AND DISTRIBUTE A CONTROLLED SUBSTANCE
10 PURSUANT TO THIS SECTION OR SECTION 12-42.5-118 (6) (b) (II), A
11 REGISTERED PRESCRIPTION DRUG OUTLET SHALL POSSESS A VALID
12 MANUFACTURING REGISTRATION FROM THE FEDERAL DRUG ENFORCEMENT
13 ADMINISTRATION.

14 (5) AS USED IN THIS SECTION, UNLESS THE CONTEXT OTHERWISE
15 REQUIRES:

16 (a) "CLIENT" HAS THE SAME MEANING AS SET FORTH IN SECTION
17 12-64-103 (4.3).

18 (b) "OFFICE STOCK" MEANS THE STORAGE OF A COMPOUNDED
19 DRUG:

20 (I) THAT WAS DISTRIBUTED OR SOLD BY A REGISTERED
21 PRESCRIPTION DRUG OUTLET TO A VETERINARIAN;

22 (II) WITHOUT A SPECIFIC PATIENT INDICATED TO RECEIVE THE
23 COMPOUNDED DRUG; AND

24 (III) THAT THE VETERINARIAN MAY SUBSEQUENTLY ADMINISTER
25 TO A PATIENT OR DISPENSE TO A CLIENT.

26 (c) "PATIENT" MEANS A COMPANION ANIMAL, AS THAT TERM IS
27 DEFINED BY RULE BY THE BOARD OF VETERINARY MEDICINE, IN

1 CONSULTATION WITH THE BOARD OF PHARMACY.

2 (d) (I) "PRESCRIPTION DRUG OUTLET" MEANS ANY:

3 (A) RESIDENT OR NONRESIDENT PHARMACY OUTLET REGISTERED
4 OR LICENSED PURSUANT TO THIS ARTICLE WHERE PRESCRIPTIONS ARE
5 COMPOUNDED AND DISPENSED; OR

6 (B) FEDERALLY OWNED AND OPERATED PHARMACY REGISTERED
7 WITH THE FEDERAL DRUG ENFORCEMENT ADMINISTRATION.

8 (II) NOTWITHSTANDING SUBPARAGRAPH (I) OF THIS PARAGRAPH
9 (d), "PRESCRIPTION DRUG OUTLET" DOES NOT INCLUDE A NONRESIDENT
10 PHARMACY OUTLET UNLESS THE NONRESIDENT PHARMACY OUTLET HAS
11 PROVIDED THE BOARD WITH A COPY OF THE MOST RECENT INSPECTION OF
12 THE NONRESIDENT PHARMACY BY THE AGENCY THAT REGULATES
13 PHARMACEUTICALS IN THE STATE OF RESIDENCE AND A COPY OF THE MOST
14 RECENT INSPECTION RECEIVED FROM A BOARD-APPROVED THIRD-PARTY
15 ENTITY THAT INSPECTS PHARMACY OUTLETS, FOR WHICH THIRD-PARTY
16 INSPECTION THE NONRESIDENT PHARMACY OUTLET SHALL OBTAIN AND
17 PAY FOR ON AN ANNUAL BASIS, AND THE BOARD APPROVES THE
18 INSPECTION REPORTS AS SATISFACTORILY DEMONSTRATING PROOF OF
19 COMPLIANCE WITH THE BOARD'S OWN INSPECTION PROCEDURE AND
20 STANDARDS.

21 (6) THE BOARD MAY PROMULGATE RULES AS NECESSARY
22 CONCERNING COMPOUNDED VETERINARY PHARMACEUTICALS PURSUANT
23 TO THIS SECTION AND SECTION 12-42.5-118 (6) (b) (II).

24 **SECTION 3.** In Colorado Revised Statutes, 12-64-104, **add** (2.5)
25 and (3) (a) (IV.5) as follows:

26 **12-64-104. License requirements and exceptions - definitions**
27 **- rules.** (2.5) IF A VETERINARIAN COMPLIES WITH THE REQUIREMENTS OF

1 SECTION 12-42.5-118.5, THE VETERINARIAN MAY MAINTAIN AN OFFICE
2 STOCK OF COMPOUNDED DRUGS.

3 (3) (a) As used in this subsection (3), unless the context otherwise
4 requires:

5 (IV.5) "OFFICE STOCK" HAS THE SAME MEANING AS SET FORTH IN
6 SECTION 12-42.5-118.5 (5) (b).

7 **SECTION 4.** In Colorado Revised Statutes, 12-64-111, **add** (1)
8 (a.5) as follows:

9 **12-64-111. Discipline of licensees.** (1) Upon receipt of a signed
10 complaint by a complainant or upon its own motion, the board may
11 proceed to a hearing in conformity with section 12-64-112. After a
12 hearing, and by a concurrence of a majority of members, the board may
13 deny a license to an applicant or revoke or suspend the license of, place
14 on probation, or otherwise discipline or fine, a licensed veterinarian for
15 any of the following reasons:

16 (a.5) VIOLATION OF SECTION 12-42.5-118.5 OR ANY RULES OF THE
17 PHARMACY BOARD PROMULGATED PURSUANT TO THAT SECTION;

18 **SECTION 5. Effective date.** This act takes effect January 1,
19 2017.

20 **SECTION 6. Safety clause.** The general assembly hereby finds,
21 determines, and declares that this act is necessary for the immediate
22 preservation of the public peace, health, and safety.