

**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

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House Committees

Health, Insurance, & Environment
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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 (3) (b) and (6) (b) as follows:

4 **12-42.5-118. Compounding - dispensing - sale of drugs and**
5 **devices - rules - definition.** (3) (b) (I) EXCEPT AS PERMITTED IN
6 SUBPARAGRAPH (II) OF THIS PARAGRAPH (b), a wholesaler may sell or
7 deliver to a person responsible for the control of an animal a drug
8 intended for veterinary use for that animal only if a licensed veterinarian
9 has issued, ~~prior to such~~ BEFORE sale or delivery, a written prescription
10 order for the drug in the course of an existing, valid
11 veterinarian-client-patient relationship as defined in section 12-64-103
12 (15.5); except that, if the prescription order is for a drug that is not a
13 controlled substance or is a controlled substance listed on schedule III,
14 IV, or V, the licensed veterinarian may issue an oral prescription order for
15 that drug. If the licensed veterinarian issues an oral prescription order for
16 a controlled substance listed on schedule III, IV, or V, the licensed
17 veterinarian shall provide a written prescription to the wholesaler within
18 three business days after issuing the oral order.

19 (II) (A) WHETHER A COMPOUNDED DRUG IS A CONTROLLED
20 SUBSTANCE OR A NONCONTROLLED SUBSTANCE, A WHOLESALER MAY SELL

1 OR DELIVER THE COMPOUNDED DRUG TO A LICENSED VETERINARIAN
2 WITHOUT THE LICENSED VETERINARIAN HAVING A
3 VETERINARIAN-CLIENT-PATIENT RELATIONSHIP IN PLACE AT THE TIME OF
4 THE SALE OR DISTRIBUTION IF THE COMPOUNDED DRUG IS SOLD OR
5 DISTRIBUTED FOR OFFICE USE PURSUANT TO PARAGRAPH (b) OF
6 SUBSECTION (6) OF THIS SECTION OR FOR OFFICE STOCK PURSUANT TO
7 SECTION 12-42.5-118.5.

8 (B) A LICENSED VETERINARIAN SHALL NOT ADMINISTER OR
9 DISPENSE A COMPOUNDED DRUG PURSUANT TO THIS SUBPARAGRAPH (II)
10 WITHOUT A VALID VETERINARIAN-CLIENT-PATIENT RELATIONSHIP IN PLACE
11 AT THE TIME OF ADMINISTERING THE COMPOUNDED DRUG TO AN ANIMAL
12 PATIENT OR DISPENSING THE COMPOUNDED DRUG TO A CLIENT.

13 (6) (b) (I) The board shall promulgate rules authorizing a
14 prescription drug outlet located in this state to compound drugs for office
15 use by a practitioner or for use by a hospital located in this state. The
16 rules must limit the amount of drugs a prescription drug outlet may
17 compound and distribute to a practitioner or hospital pursuant to this
18 paragraph (b) to no more than ten percent of the total number of drug
19 dosage units dispensed and distributed on an annual basis by the outlet.

20 (II) (A) THE TEN PERCENT LIMITATION SET FORTH IN
21 SUBPARAGRAPH (I) OF THIS PARAGRAPH (b) APPLIES TO A COMPOUNDED
22 DRUG FOR VETERINARY USE THAT A PRESCRIPTION DRUG OUTLET
23 DISTRIBUTES IN COLORADO.

24 (B) FOR PURPOSES OF THIS SUBPARAGRAPH (II), A "PRESCRIPTION
25 DRUG OUTLET" INCLUDES A NONRESIDENT PHARMACY OUTLET REGISTERED
26 OR LICENSED PURSUANT TO THIS ARTICLE WHERE PRESCRIPTIONS ARE
27 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
4 INFORMATION ABOUT THE PROCEDURE AND CRITERIA OF INSPECTIONS IN
5 THAT STATE, AND THE BOARD APPROVES THE INSPECTION REPORT AND THE
6 STATE'S INSPECTION PROCEDURE AND CRITERIA AS SATISFACTORILY
7 DEMONSTRATING PROOF OF COMPLIANCE WITH THE BOARD'S OWN
8 INSPECTION PROCEDURE AND CRITERIA. THE BOARD MAY PROMULGATE
9 RULES CONCERNING ITS REVIEW OF NONRESIDENT PHARMACY OUTLET
10 INSPECTIONS.

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 OR OTHER OUTLET REGISTERED PURSUANT TO SECTION
16 12-42.5-117 (1) (d) MAY COMPOUND AND DISTRIBUTE A DRUG TO A
17 LICENSED VETERINARIAN SO THAT THE VETERINARIAN MAY MAINTAIN THE
18 DRUG AS PART OF THE VETERINARIAN'S OFFICE STOCK.

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

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

24 (II) AS DETERMINED BY THE VETERINARIAN, THE VETERINARIAN
25 CANNOT ACCESS, IN A TIMELY MANNER, THE COMPOUNDED DRUG
26 THROUGH A REGISTERED PRESCRIPTION DRUG OUTLET OR OTHER OUTLET
27 REGISTERED PURSUANT TO SECTION 12-42.5-117 (1) (d).

1 (b) A VETERINARIAN SHALL NOT DISPENSE A COMPOUNDED DRUG
2 PURSUANT TO THIS SECTION IN AN AMOUNT GREATER THAN THE AMOUNT
3 REQUIRED TO TREAT A PATIENT'S EMERGENCY CONDITION FOR FIVE DAYS.

4 (3) AS USED IN THIS SECTION, UNLESS THE CONTEXT OTHERWISE
5 REQUIRES:

6 (a) "CLIENT" HAS THE SAME MEANING AS SET FORTH IN SECTION
7 12-64-103 (4.3).

8 (b) "OFFICE STOCK" MEANS THE STORAGE OF A COMPOUNDED
9 DRUG:

10 (I) THAT WAS DISTRIBUTED OR SOLD BY A REGISTERED
11 PRESCRIPTION DRUG OUTLET OR OTHER OUTLET REGISTERED PURSUANT TO
12 SECTION 12-42.5-117 (1) (d) TO A VETERINARIAN;

13 (II) WITHOUT A SPECIFIC PATIENT INDICATED TO RECEIVE THE
14 COMPOUNDED DRUG; AND

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

17 (c) "PATIENT" HAS THE SAME MEANING AS SET FORTH IN SECTION
18 12-64-103 (9.7).

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

20 (A) RESIDENT OR NONRESIDENT PHARMACY OUTLET REGISTERED
21 OR LICENSED PURSUANT TO THIS ARTICLE WHERE PRESCRIPTIONS ARE
22 COMPOUNDED AND DISPENSED; OR

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

25 (II) NOTWITHSTANDING SUBPARAGRAPH (I) OF THIS PARAGRAPH
26 (d), "PRESCRIPTION DRUG OUTLET" DOES NOT INCLUDE A NONRESIDENT
27 PHARMACY OUTLET UNLESS THE NONRESIDENT PHARMACY OUTLET HAS

1 PROVIDED THE BOARD WITH A COPY OF THE MOST RECENT INSPECTION OF
2 THE NONRESIDENT PHARMACY BY THE AGENCY THAT REGULATES
3 PHARMACEUTICALS IN THE STATE OF RESIDENCE AND INFORMATION ABOUT
4 THE PROCEDURE AND CRITERIA FOR INSPECTIONS IN THAT STATE, AND THE
5 BOARD HAS APPROVED THE INSPECTION REPORT AND THE STATE'S
6 INSPECTION PROCEDURE AND CRITERIA AS SATISFACTORILY
7 DEMONSTRATING PROOF OF COMPLIANCE WITH THE BOARD'S OWN
8 INSPECTION PROCEDURE AND CRITERIA.

9 (4) THE BOARD MAY PROMULGATE RULES AS NECESSARY TO
10 IMPLEMENT THIS SECTION.

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

13 **12-64-104. License requirements and exceptions - definitions**
14 **- rules.** (2.5) IF A VETERINARIAN COMPLIES WITH THE REQUIREMENTS OF
15 SECTION 12-42.5-118.5, THE VETERINARIAN MAY MAINTAIN AN OFFICE
16 STOCK OF COMPOUNDED DRUGS.

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

19 (IV.5) "OFFICE STOCK" HAS THE SAME MEANING AS SET FORTH IN
20 SECTION 12-42.5-118.5 (3) (b).

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

23 **12-64-111. Discipline of licensees.** (1) Upon receipt of a signed
24 complaint by a complainant or upon its own motion, the board may
25 proceed to a hearing in conformity with section 12-64-112. After a
26 hearing, and by a concurrence of a majority of members, the board may
27 deny a license to an applicant or revoke or suspend the license of, place

1 on probation, or otherwise discipline or fine, a licensed veterinarian for
2 any of the following reasons:

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

5 **SECTION 5. Effective date.** This act takes effect January 1,
6 2017.

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