

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

REVISED

*This Version Includes All Amendments Adopted
on Second Reading in the Second House*

LLS NO. 16-0881.01 Jennifer Berman x3286

HOUSE BILL 16-1324

HOUSE SPONSORSHIP

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SENATE SPONSORSHIP

Sonnenberg, Garcia

House Committees

Health, Insurance, & Environment
Finance
Appropriations

Senate Committees

Agriculture, Natural Resources, & Energy
Appropriations

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, AND, IN CONNECTION THEREWITH,**
104 **MAKING AN APPROPRIATION.**

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/billsummaries>.)

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

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.

SENATE
Amended 2nd Reading
April 29, 2016

HOUSE
3rd Reading Unamended
April 25, 2016

HOUSE
Amended 2nd Reading
April 22, 2016

distribution or administration to patients. The bill authorizes:

- ! A compounding pharmacy to compound and distribute a 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

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

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

14 **12-42.5-118.5. Compounding drugs for office use by a**
15 **veterinarian - rules - definitions.** (1) A REGISTERED PRESCRIPTION
16 DRUG OUTLET MAY COMPOUND AND DISTRIBUTE A DRUG TO A LICENSED
17 VETERINARIAN SO THAT THE VETERINARIAN MAY MAINTAIN THE DRUG AS
18 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.

27 (b) A VETERINARIAN SHALL NOT DISPENSE A COMPOUNDED DRUG

1 PURSUANT TO THIS SECTION IN AN AMOUNT GREATER THAN THE AMOUNT
2 REQUIRED TO TREAT A PATIENT'S EMERGENCY CONDITION FOR FIVE DAYS.

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

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

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

17 (a) "CLIENT" HAS THE SAME MEANING AS SET FORTH IN SECTION
18 12-64-103 (4.3).

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

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

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

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

27 (c) "PATIENT" MEANS A COMPANION ANIMAL, AS THAT TERM IS

1 DEFINED BY RULE BY THE BOARD OF VETERINARY MEDICINE, IN
2 CONSULTATION WITH THE BOARD OF PHARMACY.

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

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

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

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

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

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

27 **12-64-104. License requirements and exceptions - definitions**

1 - **rules.** (2.5) IF A VETERINARIAN COMPLIES WITH THE REQUIREMENTS OF
2 SECTION 12-42.5-118.5, THE VETERINARIAN MAY MAINTAIN AN OFFICE
3 STOCK OF COMPOUNDED DRUGS.

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

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

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

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

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

19 **SECTION 5. Appropriation.** (1) For the 2016-17 state fiscal
20 year, \$12,941 is appropriated to the department of regulatory agencies.
21 This appropriation is from the division of professions and occupations
22 cash fund created in section 24-34-105 (2) (b) (I), C.R.S. To implement
23 this act, the department may use this appropriation as follows:

24 (a) \$3,440 for use by the division of professions and occupations
25 for operating expenses; and

26 (b) \$9,501 for the purchase of legal services.

27 (2) For the 2016-17 state fiscal year, \$9,501 is appropriated to the

1 department of law. This appropriation is from reappropriated funds
2 received from the department of regulatory agencies under paragraph (b)
3 of subsection (1) of this section. To implement this act, the department of
4 law may use this appropriation to provide legal services for the
5 department of regulatory agencies.

6 **SECTION 6. Act subject to petition - effective date.** This act
7 takes effect at 12:01 a.m. on the day following the expiration of the
8 ninety-day period after final adjournment of the general assembly (August
9 10, 2016, if adjournment sine die is on May 11, 2016); except that, if a
10 referendum petition is filed pursuant to section 1 (3) of article V of the
11 state constitution against this act or an item, section, or part of this act
12 within such period, then the act, item, section, or part will not take effect
13 unless approved by the people at the general election to be held in
14 November 2016 and, in such case, will take effect on the date of the
15 official declaration of the vote thereon by the governor.