

NOTE: The governor signed this measure on 6/10/2016.

An Act

HOUSE BILL 16-1324

BY REPRESENTATIVE(S) Ginal, McCann, Arndt, Becker K., Brown, Coram, Dore, Lebsock, Vigil, Court, Primavera, Becker J., Buckner, Conti, Duran, Klingenschmitt, Pabon, Priola, Ryden, Saine, Sias, Van Winkle, Wist, Hulinghorst, Humphrey, Tyler;
also SENATOR(S) Sonnenberg, Garcia, Baumgardner, Cooke, Crowder, Donovan, Grantham, Jahn, Jones, Lambert, Lundberg, Marble, Martinez Humenik, Neville T., Newell, Scott, Tate, Woods.

CONCERNING THE AVAILABILITY OF COMPOUNDED PHARMACEUTICAL DRUGS FOR USE BY A VETERINARIAN TO TREAT A PATIENT'S EMERGENCY CONDITION, AND, IN CONNECTION THEREWITH, MAKING AN APPROPRIATION.

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

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

12-42.5-118. Compounding - dispensing - sale of drugs and devices - rules - definition. (6) (b) (I) The board shall promulgate rules authorizing a prescription drug outlet located in this state to compound drugs for office use by a practitioner or for use by a hospital located in this state. The rules must limit the amount of drugs a prescription drug outlet

Capital letters indicate new material added to existing statutes; dashes through words indicate deletions from existing statutes and such material not part of act.

may compound and distribute to a practitioner or hospital pursuant to this paragraph (b) to no more than ten percent of the total number of drug dosage units dispensed and distributed on an annual basis by the outlet.

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

(B) FOR PURPOSES OF THIS SUBPARAGRAPH (II), A "PRESCRIPTION DRUG OUTLET" INCLUDES A NONRESIDENT PHARMACY OUTLET REGISTERED OR LICENSED PURSUANT TO THIS ARTICLE WHERE PRESCRIPTIONS ARE COMPOUNDED AND DISPENSED, BUT ONLY IF THE NONRESIDENT PHARMACY OUTLET HAS PROVIDED THE BOARD WITH A COPY OF THE MOST RECENT INSPECTION OF THE NONRESIDENT PHARMACY OUTLET BY THE AGENCY THAT REGULATES PHARMACEUTICALS IN THE STATE OF RESIDENCE AND A COPY OF THE MOST RECENT INSPECTION RECEIVED FROM A BOARD-APPROVED THIRD-PARTY ENTITY THAT INSPECTS PHARMACY OUTLETS, FOR WHICH THIRD-PARTY INSPECTION THE NONRESIDENT PHARMACY OUTLET SHALL OBTAIN AND PAY FOR ON AN ANNUAL BASIS, AND THE BOARD APPROVES THE INSPECTION REPORTS AS SATISFACTORILY DEMONSTRATING PROOF OF COMPLIANCE WITH THE BOARD'S OWN INSPECTION PROCEDURE AND STANDARDS.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CONSULTATION WITH THE BOARD OF PHARMACY.

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

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

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

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

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

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

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

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

(IV.5) "OFFICE STOCK" HAS THE SAME MEANING AS SET FORTH IN

SECTION 12-42.5-118.5 (5) (b).

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

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

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

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

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

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

(2) For the 2016-17 state fiscal year, \$9,501 is appropriated to the department of law. This appropriation is from reappropriated funds received from the department of regulatory agencies under paragraph (b) of subsection (1) of this section. To implement this act, the department of law may use this appropriation to provide legal services for the department of regulatory agencies.

SECTION 6. Act subject to petition - effective date. This act takes effect at 12:01 a.m. on the day following the expiration of the ninety-day period after final adjournment of the general assembly (August 10, 2016, if adjournment sine die is on May 11, 2016); except that, if a referendum petition is filed pursuant to section 1 (3) of article V of the state constitution against this act or an item, section, or part of this act within

such period, then the act, item, section, or part will not take effect unless approved by the people at the general election to be held in November 2016 and, in such case, will take effect on the date of the official declaration of the vote thereon by the governor.

Dickey Lee Hullinghorst
SPEAKER OF THE HOUSE
OF REPRESENTATIVES

Bill L. Cadman
PRESIDENT OF
THE SENATE

Marilyn Eddins
CHIEF CLERK OF THE HOUSE
OF REPRESENTATIVES

Effie Ameen
SECRETARY OF
THE SENATE

APPROVED _____

John W. Hickenlooper
GOVERNOR OF THE STATE OF COLORADO