

HB1462/456586/1

BY: Health and Government Operations Committee

AMENDMENTS TO HOUSE BILL 1462

(First Reading File Bill)

AMENDMENT NO. 1

On page 1, in the sponsor line, strike “and Sample-Hughes” and substitute “Sample-Hughes, Hammen, Angel, Barron, Cullison, Hayes, Hill, Kelly, Kipke, McDonough, McMillan, Miele, Morgan, Morhaim, Oaks, Pena-Melnyk, Pendergrass, Rose, Saab, West, and K. Young”; in line 3, strike “Companion” and substitute “Nonfarm”; strike beginning with “altering” in line 4 down through “circumstances;” in line 6; in line 6, strike “an exception” and substitute “certain exceptions”; in line 7, after “medication” insert “that is not in a certain manufacturer’s container for a person who sells or dispenses certain medication in a container with a label showing certain information for use by a certain nonfarm animal and”; in line 9, strike “companion” and substitute “certain nonfarm”; in the same line, after “animal” insert “under certain circumstances”; in line 15, after “circumstances;” insert “prohibiting a pharmacy from providing certain compounded preparations in certain amounts to a licensed veterinarian under certain circumstances;”; in line 20, strike “companion” and substitute “nonfarm”; and in line 28, strike “through (b-3)” and substitute “and (b-2)”.

AMENDMENT NO. 2

On pages 2 and 3, strike in their entirety the lines beginning with line 27 on page 2 through line 3 on page 3, inclusive.

On page 3, in lines 4, 6, and 8, strike “**(B-2)**”, “**(B-3)**”, and “**(B-4)**”, respectively, and substitute “**(B-1)**”, “**(B-2)**”, and “**(B-3)**”, respectively; in line 25, strike the brackets; and in line 29, strike “; OR”.

On page 4, strike beginning with “**(8)**” in line 1 down through “**ARTICLE**” in line 18; and in line 20, before “A” insert “**(A)**”.

(Over)

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On page 5, in line 4, strike “Practice” and substitute “EXCEPT AS PROVIDED IN SUBSECTIONS (B) AND (C) OF THIS SECTION, PRACTICE”; strike beginning with “labeled” in line 5 down through “ANIMAL” in line 16; after line 20, insert:

“(B) A PERSON MAY PRACTICE VETERINARY MEDICINE AND SELL OR DISPENSE MEDICATION THAT IS NOT IN THE ORIGINAL MANUFACTURER’S CONTAINER IF:

(1) THE MEDICATION IS FOR USE BY A NONFARM ANIMAL AS DEFINED IN REGULATIONS ADOPTED BY THE BOARD; AND

(2) THE PERSON AFFIXES TO THE CONTAINER IN WHICH THE MEDICATION IS SOLD OR DISPENSED, A LABEL CLEARLY SHOWING THE BRAND, GENERIC OR CHEMICAL NAME AND STRENGTH, IF INDICATED, OF THE MEDICATION, THE TYPE OF NONFARM ANIMAL FOR WHICH THE MEDICATION IS DESIGNATED, AND THE OWNER’S LAST NAME.

(C) A LICENSED VETERINARIAN MAY DISPENSE COMPOUNDED NONSTERILE PREPARATIONS OR COMPOUNDED STERILE PREPARATIONS IF:

(1) THE COMPOUNDED NONSTERILE PREPARATIONS OR COMPOUNDED STERILE PREPARATIONS ARE TO BE USED FOR A NONFARM ANIMAL AS DEFINED BY REGULATIONS ADOPTED BY THE BOARD THAT ARE CONSISTENT WITH STATE AND FEDERAL LAW;

(2) THE NONFARM ANIMAL IS A PATIENT OF THE LICENSED VETERINARIAN;

(3) THE QUANTITY OF THE COMPOUNDED NONSTERILE PREPARATIONS OR COMPOUNDED STERILE PREPARATIONS DISPENSED DOES NOT EXCEED A 7-DAY SUPPLY;

(4) THE LICENSED VETERINARIAN DETERMINES THAT TIMELY ACCESS TO A COMPOUNDING PHARMACY IS NOT AVAILABLE AND THAT THE COMPOUNDED NONSTERILE PREPARATIONS OR COMPOUNDED STERILE PREPARATIONS ARE NOT OTHERWISE COMMERCIALY AVAILABLE;

(5) THE COMPOUNDED NONSTERILE PREPARATIONS OR COMPOUNDED STERILE PREPARATIONS ARE PROVIDED TO THE LICENSED VETERINARIAN BY A PHARMACIST IN ACCORDANCE WITH § 12-510 OF THE HEALTH OCCUPATIONS ARTICLE; AND

(6) THE COMPOUNDED NONSTERILE PREPARATIONS OR COMPOUNDED STERILE PREPARATIONS ARE DISPENSED IN A CONTAINER WITH A LABEL CLEARLY SHOWING:

(i) THE BRAND, GENERIC OR CHEMICAL NAME AND STRENGTH, IF INDICATED, OF THE COMPOUNDED NONSTERILE PREPARATIONS OR COMPOUNDED STERILE PREPARATIONS, THE TYPE OF NONFARM ANIMAL FOR WHICH THE COMPOUNDED NONSTERILE PREPARATIONS OR COMPOUNDED STERILE PREPARATIONS ARE DESIGNATED, AND THE OWNER'S LAST NAME; AND

(ii) THE DISPENSING DATE AND THE EXPIRATION DATE OF THE COMPOUNDED NONSTERILE PREPARATIONS OR COMPOUNDED STERILE PREPARATIONS."

AMENDMENT NO. 3

(Over)

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On page 6 in line 18, on page 7 in line 17, and on page 8 in line 16, in each instance, strike “**§ 2-301(F)(8)**” and substitute “**§ 2-313(C)**”.

On page 7, in line 13, strike “A” and substitute:

“(A) EXCEPT AS PROVIDED IN SUBSECTION (B) OF THIS SECTION, A”;

in line 11, strike “**2-301(F)(8)**” and substitute “**2-313(C)**”; in line 33, after “PHARMACY” insert “**;AND**

(3) COMPLIES WITH APPLICABLE FEDERAL LAW AND REGULATIONS.

(B) (1) THIS SUBSECTION DOES NOT APPLY TO DISPENSING COMPOUNDED NONSTERILE PREPARATIONS OR COMPOUNDED STERILE PREPARATIONS DISPENSED FOR A PATIENT-SPECIFIC PRESCRIPTION.

(2) A PHARMACY MAY NOT PROVIDE COMPOUNDED NONSTERILE PREPARATIONS OR COMPOUNDED STERILE PREPARATIONS COMPOUNDED USING BULK DRUG SUBSTANCES TO A LICENSED VETERINARIAN:

(I) IN AN AMOUNT GREATER THAN 10% OF THE TOTAL AMOUNT OF DRUG PRODUCTS SOLD OR DISPENSED FROM THE PHARMACY; OR

(II) IF THE COMPOUNDED NONSTERILE PREPARATIONS OR COMPOUNDED STERILE PREPARATIONS ARE COPIES OR CLOSE APPROXIMATIONS TO PRODUCTS APPROVED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION.

(3) FOR PURPOSES OF THE LIMITATION ESTABLISHED IN PARAGRAPH (2)(I) OF THIS SUBSECTION:

(I) THE CALCULATION SHALL BE MADE ON AN ANNUAL BASIS AND USE THE NUMBER OF DOSAGE UNITS SOLD OR DISPENSED; AND

(II) FOR NONRESIDENT PHARMACIES, THE TOTAL AMOUNT OF DRUG PRODUCTS SOLD OR DISPENSED SHALL BE THE PHARMACY'S TOTAL BUSINESS WITHIN THE STATE".