

# HOUSE BILL 1462

J2, M4

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CF SB 614

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By: ~~Delegates Bromwell, Krebs, and Sample-Hughes~~ 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

Introduced and read first time: February 12, 2016

Assigned to: Environment and Transportation

Reassigned: Health and Government Operations, February 19, 2016

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Committee Report: Favorable with amendments

House action: Adopted

Read second time: March 16, 2016

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## CHAPTER \_\_\_\_\_

1 AN ACT concerning

2 **Veterinarians, Pharmacies, and Pharmacists – Dispensing Compounded**  
3 **Preparations for Use by ~~Companion~~ Nonfarm Animals**

4 FOR the purpose of ~~altering the definition of “practice of veterinary medicine” to include~~  
5 ~~the practice of any person who dispenses compounded nonsterile or sterile~~  
6 ~~preparations under certain circumstances; providing an exception~~ certain exceptions  
7 to a certain prohibition on the practice of veterinary medicine and dispensing certain  
8 medication that is not in a certain manufacturer’s container for a person who sells  
9 or dispenses certain medication in a container with a label showing certain  
10 information for use by a certain nonfarm animal and for a licensed veterinarian who  
11 dispenses certain compounded preparations to be used for a ~~companion~~ certain  
12 nonfarm animal under certain circumstances; providing that certain provisions of  
13 law do not prohibit a licensed veterinarian from dispensing, in accordance with a  
14 certain provision of this Act, certain compounded preparations provided by a certain  
15 pharmacy; authorizing a certain pharmacy to provide certain compounded  
16 preparations without a patient-specific prescription to a certain licensed  
17 veterinarian; authorizing a pharmacist to provide certain compounded preparations  
18 without a patient-specific prescription to a certain licensed veterinarian under  
19 certain circumstances; prohibiting a pharmacy from providing certain compounded  
20 preparations in certain amounts to a licensed veterinarian under certain  
21 circumstances; providing that a certain subtitle does not affect a certain person while

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EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.

Underlining indicates amendments to bill.

~~Strike out~~ indicates matter stricken from the bill by amendment or deleted from the law by amendment.



1 distributing certain compounded preparations; defining certain terms; making a  
2 stylistic change; repealing an obsolete provision of law; making a technical  
3 correction; and generally relating to veterinarians, pharmacies, pharmacists, and  
4 dispensing compounded preparations for use by ~~companion~~ nonfarm animals.

5 BY repealing and reenacting, without amendments,  
6 Article – Agriculture  
7 Section 2–301(a)  
8 Annotated Code of Maryland  
9 (2007 Replacement Volume and 2015 Supplement)

10 BY adding to  
11 Article – Agriculture  
12 Section 2–301(b–1) ~~through (b–3)~~ and (b–2)  
13 Annotated Code of Maryland  
14 (2007 Replacement Volume and 2015 Supplement)

15 BY repealing and reenacting, with amendments,  
16 Article – Agriculture  
17 Section 2–301(b–1) and (f) and 2–313  
18 Annotated Code of Maryland  
19 (2007 Replacement Volume and 2015 Supplement)

20 BY repealing and reenacting, without amendments,  
21 Article – Health Occupations  
22 Section 12–101(a), (d), and (aa) and 12–102(a)  
23 Annotated Code of Maryland  
24 (2014 Replacement Volume and 2015 Supplement)

25 BY adding to  
26 Article – Health Occupations  
27 Section 12–101(c–1), (z–1), and (z–2), 12–403(c)(23), and 12–510  
28 Annotated Code of Maryland  
29 (2014 Replacement Volume and 2015 Supplement)

30 BY repealing and reenacting, with amendments,  
31 Article – Health Occupations  
32 Section 12–102(c)(2)(i), 12–403(c)(21) and (22), and 12–6C–02  
33 Annotated Code of Maryland  
34 (2014 Replacement Volume and 2015 Supplement)

35 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND,  
36 That the Laws of Maryland read as follows:

37 **Article – Agriculture**

38 2–301.

1 (a) In this subtitle the following words have the meanings indicated.

2 ~~(B-1) (1) "COMPANION ANIMAL" MEANS:~~

3 ~~(I) A RABBIT, A BIRD, A RODENT, A FISH, A REPTILE, AN~~  
4 ~~AMPHIBIAN, A NONHUMAN PRIMATE, OR ANY SPECIES OF ANIMAL KEPT FOR~~  
5 ~~PLEASURE RATHER THAN UTILITY AND ACCUSTOMED TO LIVING IN OR ABOUT~~  
6 ~~HUMAN HABITATION; OR~~

7 ~~(II) A DOG OR CAT, REGARDLESS OF ANY UTILITARIAN~~  
8 ~~PURPOSE.~~

9 ~~(2) "COMPANION ANIMAL" DOES NOT INCLUDE:~~

10 ~~(I) CATTLE, SHEEP, GOATS, SWINE, OR POULTRY; OR~~

11 ~~(II) ANY OTHER ANIMALS KEPT FOR BONA FIDE RESEARCH OR~~  
12 ~~AGRICULTURAL USES.~~

13 ~~(B-2) (B-1) "COMPOUNDED NONSTERILE PREPARATIONS" HAS THE MEANING~~  
14 ~~STATED IN § 12-101 OF THE HEALTH OCCUPATIONS ARTICLE.~~

15 ~~(B-3) (B-2) "COMPOUNDED STERILE PREPARATIONS" HAS THE MEANING~~  
16 ~~STATED IN § 12-101 OF THE HEALTH OCCUPATIONS ARTICLE.~~

17 [(b-1)] ~~(B-4) (B-3)~~ "Convicted" includes:

18 (1) A finding of guilt by a court or a jury; and

19 (2) The acceptance by a court of a defendant's plea of guilty, nolo  
20 contendere, or Alford plea.

21 (f) "Practice of veterinary medicine" includes[, but is not limited to,] the practice  
22 by any person who:

23 (1) Diagnoses, advises, prescribes, or administers a drug, medicine,  
24 biological product, appliance, application, or treatment of any nature, for the prevention,  
25 cure, or relief of a wound, fracture, bodily injury, or disease of an animal;

26 (2) Performs a surgical operation, including cosmetic surgery, upon any  
27 animal;

28 (3) Performs dentistry on any animal;

1 (4) Performs any manual procedure upon an animal for the diagnosis or  
2 treatment of sterility or infertility of the animal;

3 (5) Represents himself as engaged in the practice of veterinary medicine;

4 (6) Offers, undertakes, or holds himself out as being able to diagnose, treat,  
5 operate, vaccinate, or prescribe for any animal disease, pain, injury, deformity, or physical  
6 condition; ~~for~~

7 (7) Uses any words, letters, or titles in connection or under circumstances  
8 as to induce the belief that the person using them is engaged in the practice of veterinary  
9 medicine. This use is prima facie evidence of the intention to represent himself as engaged  
10 in the practice of veterinary medicine; ~~OR~~

11 ~~(8) DISPENSES COMPOUNDED NONSTERILE PREPARATIONS OR~~  
12 ~~COMPOUNDED STERILE PREPARATIONS IF:~~

13 ~~(I) THE COMPOUNDED NONSTERILE PREPARATIONS OR~~  
14 ~~COMPOUNDED STERILE PREPARATIONS ARE TO BE USED FOR A COMPANION~~  
15 ~~ANIMAL;~~

16 ~~(II) THE COMPANION ANIMAL IS A PATIENT OF THE LICENSED~~  
17 ~~VETERINARIAN;~~

18 ~~(III) THE QUANTITY OF THE COMPOUNDED NONSTERILE~~  
19 ~~PREPARATIONS OR COMPOUNDED STERILE PREPARATIONS DISPENSED DOES NOT~~  
20 ~~EXCEED A 7-DAY SUPPLY; AND~~

21 ~~(IV) THE LICENSED VETERINARIAN DETERMINES THAT TIMELY~~  
22 ~~ACCESS TO A COMPOUNDING PHARMACY IS NOT AVAILABLE AND THAT THE~~  
23 ~~COMPOUNDED NONSTERILE PREPARATIONS OR COMPOUNDED STERILE~~  
24 ~~PREPARATIONS ARE NOT OTHERWISE COMMERCIALY AVAILABLE; AND~~

25 ~~(V) THE COMPOUNDED NONSTERILE PREPARATIONS OR~~  
26 ~~COMPOUNDED STERILE PREPARATIONS ARE PROVIDED TO THE LICENSED~~  
27 ~~VETERINARIAN BY A PHARMACIST IN ACCORDANCE WITH § 12-510 OF THE HEALTH~~  
28 ~~OCCUPATIONS ARTICLE.~~

29 2-313.

30 (A) A person may not:

31 (1) Practice veterinary medicine unless he is licensed, registered, and  
32 authorized to engage in the practice under the provisions of this subtitle;

1 (2) Practice veterinary medicine under a name other than the one on his  
2 license and registration, or induce any person to so practice in violation of this subtitle;

3 (3) Practice veterinary medicine unless his license and registration are  
4 displayed in his regularly established office and place of practice;

5 (4) Own, maintain, conduct, operate, or manage a veterinary office,  
6 veterinary dental office, veterinary hospital, or a dog, cat, or animal hospital, unless (i) he  
7 is a licensed veterinarian, or (ii) the office or hospital is under the direct supervision and  
8 control of a licensed and registered veterinarian and a licensed or registered veterinarian  
9 is employed in the office or hospital;

10 (5) Advertise any veterinary office, veterinary dental office, veterinary  
11 hospital, or a dog, cat, or animal hospital except in accordance with the rules and  
12 regulations of the Board;

13 (6) ~~Practice~~ **EXCEPT AS PROVIDED IN SUBSECTIONS (B) AND (C) OF**  
14 **THIS SECTION, PRACTICE** veterinary medicine and sell or dispense any medication, which  
15 is not in the original manufacturer's container ~~labeled with the information required below,~~  
16 ~~for use by a [household pet] COMPANION ANIMAL unless [he]:~~

17 ~~(I) THE PERSON affixes to the container in which the medication is~~  
18 ~~sold or dispensed, a label clearly showing the brand, generic or chemical name and strength,~~  
19 ~~if indicated, of the medication, the type of animal for whom designated and the owner's last~~  
20 ~~name]. However, this provision does not apply to the dispensing of any medication of any~~  
21 ~~kind for use in the treatment, care or cure of farm animals, poultry, fowl, or other animals,~~  
22 ~~used in the furtherance of farming activities]; OR~~

23 ~~(II) THE PERSON IS A LICENSED VETERINARIAN WHO~~  
24 ~~DISPENSES COMPOUNDED NONSTERILE PREPARATIONS OR COMPOUNDED STERILE~~  
25 ~~PREPARATIONS, IN ACCORDANCE WITH § 2-301(F)(8) OF THIS ARTICLE, TO BE USED~~  
26 ~~FOR A COMPANION ANIMAL;~~

27 (7) Advertise as a Board registered veterinary technician unless registered  
28 with the Board as required by this subtitle; or

29 (8) Practice as a veterinary technician unless employed by a veterinary  
30 practitioner.

31 **(B) A PERSON MAY PRACTICE VETERINARY MEDICINE AND SELL OR**  
32 **DISPENSE MEDICATION THAT IS NOT IN THE ORIGINAL MANUFACTURER'S**  
33 **CONTAINER IF:**

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

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

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

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

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

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

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

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

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

28           **(I) THE BRAND, GENERIC OR CHEMICAL NAME AND STRENGTH,**  
29 **IF INDICATED, OF THE COMPOUNDED NONSTERILE PREPARATIONS OR**  
30 **COMPOUNDED STERILE PREPARATIONS, THE TYPE OF NONFARM ANIMAL FOR**  
31 **WHICH THE COMPOUNDED NONSTERILE PREPARATIONS OR COMPOUNDED STERILE**  
32 **PREPARATIONS ARE DESIGNATED, AND THE OWNER'S LAST NAME; AND**

1                                    **(II) THE DISPENSING DATE AND THE EXPIRATION DATE OF THE**  
2 **COMPOUNDED NONSTERILE PREPARATIONS OR COMPOUNDED STERILE**  
3 **PREPARATIONS.**

4                                    **Article – Health Occupations**

5 12–101.

6            (a)    In this title the following words have the meanings indicated.

7            **(C–1) “COMPOUNDED NONSTERILE PREPARATIONS” MEANS PRODUCTS**  
8 **COMPOUNDED IN ACCORDANCE WITH USP 795.**

9            (d)    “Compounded sterile preparations” means biologics, diagnostics, drugs,  
10 nutrients, and radiopharmaceuticals that, under USP 797, must be compounded using  
11 aseptic techniques.

12            **(Z–1) “USP–NF” MEANS THE UNITED STATES PHARMACOPEIA AND THE**  
13 **NATIONAL FORMULARY.**

14            **(Z–2) “USP 795” MEANS THE STANDARDS SET FORTH IN THE UNITED STATES**  
15 **PHARMACOPEIA, GENERAL CHAPTER 795, “PHARMACEUTICAL COMPOUNDING –**  
16 **NONSTERILE PREPARATIONS”.**

17            (aa)    “USP 797” means the standards set forth in the United States Pharmacopeia,  
18 General Chapter 797, “Pharmaceutical Compounding – Sterile Preparations”.

19 12–102.

20            (a)    (1)    In this section the following terms have the meanings indicated.

21                                    (2)    “In the public interest” means the dispensing of drugs or devices by a  
22 licensed dentist, physician, or podiatrist to a patient when a pharmacy is not conveniently  
23 available to the patient.

24                                    (3)    “Personally preparing and dispensing” means that the licensed dentist,  
25 physician, or podiatrist:

26                                    (i)    Is physically present on the premises where the prescription is  
27 filled; and

28                                    (ii)   Performs a final check of the prescription before it is provided to  
29 the patient.

30            (c)    (2)    This title does not prohibit:

(i) A licensed veterinarian from [personally]:

1. **PERSONALLY** preparing and dispensing the veterinarian's prescriptions; **OR**

2. **DISPENSING, IN ACCORDANCE WITH ~~§ 2-301(F)(8)~~ § 2-313(C) OF THE AGRICULTURE ARTICLE, COMPOUNDED NONSTERILE PREPARATIONS OR COMPOUNDED STERILE PREPARATIONS PROVIDED BY A PHARMACY;**

12-403.

(c) Except as otherwise provided in this section, a pharmacy for which a pharmacy permit has been issued under this title:

(21) Shall dispense or dispose of prescription drugs or medical supplies in accordance with Title 15, Subtitle 6 of the Health – General Article; [and]

(22) (i) [Subject to § 12-4A-02 of this title, may] **MAY** provide to an ophthalmologist for office use, without a patient-specific prescription:

1. Compound antibiotics for the emergency treatment of bacterial endophthalmitis or viral retinitis; and

2. Compound antivasular endothelial growth factor agents for the emergency treatment of neovascular glaucoma, wet macular degeneration, or macular edema; and

(ii) Shall require the ophthalmologist to inform the pharmacy of the identity of any patient to whom the drugs are administered; **AND**

**(23) SUBJECT TO § 12-510 OF THIS TITLE, MAY PROVIDE COMPOUNDED NONSTERILE PREPARATIONS OR COMPOUNDED STERILE PREPARATIONS WITHOUT A PATIENT-SPECIFIC PRESCRIPTION TO A LICENSED VETERINARIAN WHO INTENDS TO DISPENSE THE COMPOUNDED NONSTERILE PREPARATIONS OR COMPOUNDED STERILE PREPARATIONS IN ACCORDANCE WITH ~~§ 2-301(F)(8)~~ 2-313(C) OF THE AGRICULTURE ARTICLE.**

12-510.

**(A) EXCEPT AS PROVIDED IN SUBSECTION (B) OF THIS SECTION, A PHARMACIST MAY PROVIDE COMPOUNDED NONSTERILE PREPARATIONS OR COMPOUNDED STERILE PREPARATIONS WITHOUT A PATIENT-SPECIFIC PRESCRIPTION TO A LICENSED VETERINARIAN WHO INTENDS TO DISPENSE THE COMPOUNDED NONSTERILE PREPARATIONS OR COMPOUNDED STERILE**

1 PREPARATIONS IN ACCORDANCE WITH ~~§ 2-301(F)(8)~~ § 2-313(C) OF THE  
2 AGRICULTURE ARTICLE IF THE PHARMACIST:

3 (1) COMPLIES WITH USP 795 OR USP 797, AS APPLICABLE; AND

4 (2) LABELS THE COMPOUNDED NONSTERILE PREPARATIONS OR  
5 COMPOUNDED STERILE PREPARATIONS WITH:

6 (I) THE NAME AND STRENGTH OF THE COMPOUNDED  
7 NONSTERILE PREPARATIONS OR COMPOUNDED STERILE PREPARATIONS OR A LIST  
8 OF THE ACTIVE INGREDIENTS AND THE STRENGTH OF THE ACTIVE INGREDIENTS IN  
9 THE COMPOUNDED NONSTERILE PREPARATIONS OR COMPOUNDED STERILE  
10 PREPARATIONS;

11 (II) AN APPROPRIATE BEYOND-USE DATE AS DETERMINED BY  
12 THE PHARMACIST IN ACCORDANCE WITH USP-NF STANDARDS FOR PHARMACY  
13 COMPOUNDING;

14 (III) THE QUANTITY OF COMPOUNDED NONSTERILE  
15 PREPARATIONS OR COMPOUNDED STERILE PREPARATIONS; AND

16 (IV) THE NAME, ADDRESS, AND LICENSE NUMBER OF THE  
17 PHARMACY; AND

18 (3) COMPLIES WITH APPLICABLE FEDERAL LAW AND REGULATIONS.

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

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

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

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

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

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

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

6 12-6C-02.

7           This subtitle does not affect any person while distributing:

8           (1)    Feed for livestock or poultry;

9           (2)    Fertilizers;

10          (3)    Fungicides;

11          (4)    Insecticide;

12          (5)    Land plaster;

13          (6)    Lime;

14          (7)    Seeds; [or]

15          (8)    Devices, drugs, or supplies of any kind for the treatment, care, or cure  
 16 of farm animals; **OR**

17           **(9) COMPOUNDED NONSTERILE PREPARATIONS OR COMPOUNDED**  
 18 **STERILE PREPARATIONS PROVIDED IN ACCORDANCE WITH § 12-510 OF THIS TITLE**  
 19 **TO A LICENSED VETERINARIAN WHO INTENDS TO DISPENSE THE COMPOUNDED**  
 20 **NONSTERILE PREPARATIONS OR COMPOUNDED STERILE PREPARATIONS IN**  
 21 **ACCORDANCE WITH ~~§ 2-301(F)(8)~~ § 2-313(C) OF THE AGRICULTURE ARTICLE.**

22           SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect  
 23 October 1, 2016.