

# SENATE BILL 614

J2, M4

(6lr1583)

## ENROLLED BILL

— Education, Health, and Environmental Affairs/Health and Government Operations —

Introduced by **Senator Conway**

Read and Examined by Proofreaders:

\_\_\_\_\_  
Proofreader.

\_\_\_\_\_  
Proofreader.

Sealed with the Great Seal and presented to the Governor, for his approval this

\_\_\_\_\_ day of \_\_\_\_\_ at \_\_\_\_\_ o'clock, \_\_\_\_\_ M.

\_\_\_\_\_  
President.

### 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 or  
9 dispenses certain medication in a container with a label showing certain information  
10 for use by a certain nonfarm animal and for a licensed veterinarian who dispenses  
11 certain compounded preparations to be used for a ~~companion~~ certain nonfarm animal  
12 under certain circumstances; providing that certain provisions of law do not prohibit  
13 a licensed veterinarian from dispensing, in accordance with a certain provision of  
14 this Act, certain compounded preparations provided by a certain pharmacy;  
15 authorizing a certain pharmacy to provide certain compounded preparations without

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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.

*Italics indicate opposite chamber/conference committee amendments.*



1 a patient-specific prescription to a certain licensed veterinarian; authorizing a  
 2 pharmacist to provide certain compounded preparations without a patient-specific  
 3 prescription to a certain licensed veterinarian under certain circumstances;  
 4 prohibiting a pharmacy from providing certain compounded preparations in certain  
 5 amounts to a licensed veterinarian under certain circumstances; providing that a  
 6 certain subtitle does not affect a certain person while distributing certain  
 7 compounded preparations; defining certain terms; making a stylistic change;  
 8 repealing an obsolete provision of law; making a technical correction; and generally  
 9 relating to veterinarians, pharmacies, pharmacists, and dispensing compounded  
 10 preparations for use by ~~companion~~ nonfarm animals.

11 BY repealing and reenacting, without amendments,  
 12 Article – Agriculture  
 13 Section 2–301(a)  
 14 Annotated Code of Maryland  
 15 (2007 Replacement Volume and 2015 Supplement)

16 BY adding to  
 17 Article – Agriculture  
 18 Section 2–301(b–1) ~~through (b–3)~~ and (b–2)  
 19 Annotated Code of Maryland  
 20 (2007 Replacement Volume and 2015 Supplement)

21 BY repealing and reenacting, with amendments,  
 22 Article – Agriculture  
 23 Section 2–301(b–1) and (f) and 2–313  
 24 Annotated Code of Maryland  
 25 (2007 Replacement Volume and 2015 Supplement)

26 BY repealing and reenacting, without amendments,  
 27 Article – Health Occupations  
 28 Section 12–101(a), (d), and (aa) and 12–102(a)  
 29 Annotated Code of Maryland  
 30 (2014 Replacement Volume and 2015 Supplement)

31 BY adding to  
 32 Article – Health Occupations  
 33 Section 12–101(c–1), (z–1), and (z–2), 12–403(c)(23), and 12–510  
 34 Annotated Code of Maryland  
 35 (2014 Replacement Volume and 2015 Supplement)

36 BY repealing and reenacting, with amendments,  
 37 Article – Health Occupations  
 38 Section 12–102(c)(2)(i), 12–403(c)(21) and (22), and 12–6C–02  
 39 Annotated Code of Maryland  
 40 (2014 Replacement Volume and 2015 Supplement)

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

3 **Article – Agriculture**

4 2–301.

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

6 ~~(B-1) (1) “COMPANION ANIMAL” MEANS:~~

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

11 ~~(II) A DOG OR CAT, REGARDLESS OF ANY UTILITARIAN~~  
12 ~~PURPOSE.~~

13 ~~(2) “COMPANION ANIMAL” DOES NOT INCLUDE:~~

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

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

17 ~~(B-2) (B-1) “COMPOUNDED NONSTERILE PREPARATIONS” HAS THE MEANING~~  
18 ~~STATED IN § 12–101 OF THE HEALTH OCCUPATIONS ARTICLE.~~

19 ~~(B-3) (B-2) “COMPOUNDED STERILE PREPARATIONS” HAS THE MEANING~~  
20 ~~STATED IN § 12–101 OF THE HEALTH OCCUPATIONS ARTICLE.~~

21 [(b-1)] ~~(B-4) (B-3)~~ “Convicted” includes:

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

23 (2) The acceptance by a court of a defendant’s plea of guilty, nolo  
24 contendere, or Alford plea.

25 (f) “Practice of veterinary medicine” includes[, but is not limited to,] the practice  
26 by any person who:

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

- 1                   (2)    Performs a surgical operation, including cosmetic surgery, upon any  
2 animal;
- 3                   (3)    Performs dentistry on any animal;
- 4                   (4)    Performs any manual procedure upon an animal for the diagnosis or  
5 treatment of sterility or infertility of the animal;
- 6                   (5)    Represents himself as engaged in the practice of veterinary medicine;
- 7                   (6)    Offers, undertakes, or holds himself out as being able to diagnose, treat,  
8 operate, vaccinate, or prescribe for any animal disease, pain, injury, deformity, or physical  
9 condition; ~~for~~
- 10                  (7)    Uses any words, letters, or titles in connection or under circumstances  
11 as to induce the belief that the person using them is engaged in the practice of veterinary  
12 medicine. This use is prima facie evidence of the intention to represent himself as engaged  
13 in the practice of veterinary medicine; ~~OR~~

14                   ~~(8)    DISPENSES COMPOUNDED NONSTERILE PREPARATIONS OR~~  
15 ~~COMPOUNDED STERILE PREPARATIONS IF:~~

16                   ~~(i)    THE COMPOUNDED NONSTERILE PREPARATIONS OR~~  
17 ~~COMPOUNDED STERILE PREPARATIONS ARE TO BE USED FOR A COMPANION~~  
18 ~~ANIMAL;~~

19                   ~~(ii)   THE COMPANION ANIMAL IS A PATIENT OF THE LICENSED~~  
20 ~~VETERINARIAN;~~

21                   ~~(iii)   THE QUANTITY OF THE COMPOUNDED NONSTERILE~~  
22 ~~PREPARATIONS OR COMPOUNDED STERILE PREPARATIONS DISPENSED DOES NOT~~  
23 ~~EXCEED A 7-DAY SUPPLY; AND~~

24                   ~~(iv)   THE LICENSED VETERINARIAN DETERMINES THAT TIMELY~~  
25 ~~ACCESS TO A COMPOUNDING PHARMACY IS NOT AVAILABLE AND THAT THE~~  
26 ~~COMPOUNDED NONSTERILE PREPARATIONS OR COMPOUNDED STERILE~~  
27 ~~PREPARATIONS ARE NOT OTHERWISE COMMERCIALY AVAILABLE; AND~~

28                   ~~(v)    THE COMPOUNDED NONSTERILE PREPARATIONS OR~~  
29 ~~COMPOUNDED STERILE PREPARATIONS ARE PROVIDED TO THE LICENSED~~  
30 ~~VETERINARIAN BY A PHARMACIST IN ACCORDANCE WITH § 12-510 OF THE HEALTH~~  
31 ~~OCCUPATIONS ARTICLE.~~

1 2-313.

2 (A) A person may not:

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

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

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

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

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

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

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

27 ~~(H) THE PERSON IS A LICENSED VETERINARIAN WHO~~  
28 ~~DISPENSES COMPOUNDED NONSTERILE PREPARATIONS OR COMPOUNDED STERILE~~  
29 ~~PREPARATIONS, IN ACCORDANCE WITH § 2-301(F)(8) OF THIS ARTICLE, TO BE USED~~  
30 ~~FOR A COMPANION ANIMAL;~~

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

33 (8) Practice as a veterinary technician unless employed by a veterinary  
34 practitioner.

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

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

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

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

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

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

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

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

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

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

33           **(1) THE BRAND, GENERIC OR CHEMICAL NAME AND STRENGTH,**  
34 **IF INDICATED, OF THE COMPOUNDED NONSTERILE PREPARATIONS OR**

1 COMPOUNDED STERILE PREPARATIONS, THE TYPE OF NONFARM ANIMAL FOR WHICH  
2 THE COMPOUNDED NONSTERILE PREPARATIONS OR COMPOUNDED STERILE  
3 PREPARATIONS ARE DESIGNATED, AND THE OWNER'S LAST NAME; AND

4 (II) THE DISPENSING DATE AND THE EXPIRATION DATE OF THE  
5 COMPOUNDED NONSTERILE PREPARATIONS OR COMPOUNDED STERILE  
6 PREPARATIONS.

7 **Article – Health Occupations**

8 12–101.

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

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

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

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

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

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

22 12–102.

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

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

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

29 (i) Is physically present on the premises where the prescription is  
30 filled; and

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

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

4 (i) A licensed veterinarian from [personally]:

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

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

11 12-403.

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

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

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

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

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

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

25 **(23) SUBJECT TO § 12-510 OF THIS TITLE, MAY PROVIDE**  
26 **COMPOUNDED NONSTERILE PREPARATIONS OR COMPOUNDED STERILE**  
27 **PREPARATIONS WITHOUT A PATIENT-SPECIFIC PRESCRIPTION TO A LICENSED**  
28 **VETERINARIAN WHO INTENDS TO DISPENSE THE COMPOUNDED NONSTERILE**  
29 **PREPARATIONS OR COMPOUNDED STERILE PREPARATIONS IN ACCORDANCE WITH §**  
30 **~~2-301(F)(8)~~ 2-313(C) OF THE AGRICULTURE ARTICLE.**

31 **12-510.**



1           **(A) ~~A~~ EXCEPT AS PROVIDED IN SUBSECTION (B) OF THIS SECTION, A**  
2 PHARMACIST MAY PROVIDE COMPOUNDED NONSTERILE PREPARATIONS OR  
3 COMPOUNDED STERILE PREPARATIONS WITHOUT A PATIENT-SPECIFIC  
4 PRESCRIPTION TO A LICENSED VETERINARIAN WHO INTENDS TO DISPENSE THE  
5 COMPOUNDED NONSTERILE PREPARATIONS OR COMPOUNDED STERILE  
6 PREPARATIONS IN ACCORDANCE WITH ~~§ 2-301(F)(8)~~ **§ 2-313(C)** OF THE  
7 AGRICULTURE ARTICLE IF THE PHARMACIST:

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

9           **(2) LABELS THE COMPOUNDED NONSTERILE PREPARATIONS OR**  
10 **COMPOUNDED STERILE PREPARATIONS WITH:**

11           **(I) THE NAME AND STRENGTH OF THE COMPOUNDED**  
12 **NONSTERILE PREPARATIONS OR COMPOUNDED STERILE PREPARATIONS OR A LIST**  
13 **OF THE ACTIVE INGREDIENTS AND THE STRENGTH OF THE ACTIVE INGREDIENTS IN**  
14 **THE COMPOUNDED NONSTERILE PREPARATIONS OR COMPOUNDED STERILE**  
15 **PREPARATIONS;**

16           **(II) AN APPROPRIATE BEYOND-USE DATE AS DETERMINED BY**  
17 **THE PHARMACIST IN ACCORDANCE WITH USP-NF STANDARDS FOR PHARMACY**  
18 **COMPOUNDING;**

19           **(III) THE QUANTITY OF COMPOUNDED NONSTERILE**  
20 **PREPARATIONS OR COMPOUNDED STERILE PREPARATIONS; AND**

21           **(IV) THE NAME, ADDRESS, AND LICENSE NUMBER OF THE**  
22 **PHARMACY; AND**

23           **(3) COMPLIES WITH APPLICABLE FEDERAL LAW AND REGULATIONS.**

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

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

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

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

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

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

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

11 12-6C-02.

12 This subtitle does not affect any person while distributing:

- 13 (1) Feed for livestock or poultry;
- 14 (2) Fertilizers;
- 15 (3) Fungicides;
- 16 (4) Insecticide;
- 17 (5) Land plaster;
- 18 (6) Lime;
- 19 (7) Seeds; [or]
- 20 (8) Devices, drugs, or supplies of any kind for the treatment, care, or cure  
 21 of farm animals; OR

22 **(9) COMPOUNDED NONSTERILE PREPARATIONS OR COMPOUNDED**  
 23 **STERILE PREPARATIONS PROVIDED IN ACCORDANCE WITH § 12-510 OF THIS TITLE**  
 24 **TO A LICENSED VETERINARIAN WHO INTENDS TO DISPENSE THE COMPOUNDED**  
 25 **NONSTERILE PREPARATIONS OR COMPOUNDED STERILE PREPARATIONS IN**  
 26 **ACCORDANCE WITH ~~§ 2-301(F)(8)~~ § 2-313(C) OF THE AGRICULTURE ARTICLE.**

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