

SENATE BILL 614

J2, M4

6lr1583
CF HB 1462

By: **Senator Conway**

Introduced and read first time: February 5, 2016

Assigned to: Education, Health, and Environmental Affairs

Committee Report: Favorable

Senate action: Adopted

Read second time: March 15, 2016

CHAPTER _____

1 AN ACT concerning

2 **Veterinarians, Pharmacies, and Pharmacists – Dispensing Compounded**
3 **Preparations for Use by Companion 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 to a certain
7 prohibition on the practice of veterinary medicine and dispensing certain medication
8 for a licensed veterinarian who dispenses certain compounded preparations to be
9 used for a companion animal; providing that certain provisions of law do not prohibit
10 a licensed veterinarian from dispensing, in accordance with a certain provision of
11 this Act, certain compounded preparations provided by a certain pharmacy;
12 authorizing a certain pharmacy to provide certain compounded preparations without
13 a patient-specific prescription to a certain licensed veterinarian; authorizing a
14 pharmacist to provide certain compounded preparations without a patient-specific
15 prescription to a certain licensed veterinarian under certain circumstances;
16 providing that a certain subtitle does not affect a certain person while distributing
17 certain compounded preparations; defining certain terms; making a stylistic change;
18 repealing an obsolete provision of law; making a technical correction; and generally
19 relating to veterinarians, pharmacies, pharmacists, and dispensing compounded
20 preparations for use by companion animals.

21 BY repealing and reenacting, without amendments,
22 Article – Agriculture
23 Section 2–301(a)
24 Annotated Code of Maryland

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 (2007 Replacement Volume and 2015 Supplement)

2 BY adding to

3 Article – Agriculture

4 Section 2–301(b–1) through (b–3)

5 Annotated Code of Maryland

6 (2007 Replacement Volume and 2015 Supplement)

7 BY repealing and reenacting, with amendments,

8 Article – Agriculture

9 Section 2–301(b–1) and (f) and 2–313

10 Annotated Code of Maryland

11 (2007 Replacement Volume and 2015 Supplement)

12 BY repealing and reenacting, without amendments,

13 Article – Health Occupations

14 Section 12–101(a), (d), and (aa) and 12–102(a)

15 Annotated Code of Maryland

16 (2014 Replacement Volume and 2015 Supplement)

17 BY adding to

18 Article – Health Occupations

19 Section 12–101(c–1), (z–1), and (z–2), 12–403(c)(23), and 12–510

20 Annotated Code of Maryland

21 (2014 Replacement Volume and 2015 Supplement)

22 BY repealing and reenacting, with amendments,

23 Article – Health Occupations

24 Section 12–102(c)(2)(i), 12–403(c)(21) and (22), and 12–6C–02

25 Annotated Code of Maryland

26 (2014 Replacement Volume and 2015 Supplement)

27 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND,

28 That the Laws of Maryland read as follows:

29 **Article – Agriculture**

30 2–301.

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

32 **(B–1) (1) “COMPANION ANIMAL” MEANS:**

33 **(I) A RABBIT, A BIRD, A RODENT, A FISH, A REPTILE, AN**
34 **AMPHIBIAN, A NONHUMAN PRIMATE, OR ANY SPECIES OF ANIMAL KEPT FOR**

1 PLEASURE RATHER THAN UTILITY AND ACCUSTOMED TO LIVING IN OR ABOUT
2 HUMAN HABITATION; OR

3 (II) A DOG OR CAT, REGARDLESS OF ANY UTILITARIAN
4 PURPOSE.

5 (2) "COMPANION ANIMAL" DOES NOT INCLUDE:

6 (I) CATTLE, SHEEP, GOATS, SWINE, OR POULTRY; OR

7 (II) ANY OTHER ANIMALS KEPT FOR BONA FIDE RESEARCH OR
8 AGRICULTURAL USES.

9 (B-2) "COMPOUNDED NONSTERILE PREPARATIONS" HAS THE MEANING
10 STATED IN § 12-101 OF THE HEALTH OCCUPATIONS ARTICLE.

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

13 [(b-1)] (B-4) "Convicted" includes:

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

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

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

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

22 (2) Performs a surgical operation, including cosmetic surgery, upon any
23 animal;

24 (3) Performs dentistry on any animal;

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

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

1 (6) Offers, undertakes, or holds himself out as being able to diagnose, treat,
2 operate, vaccinate, or prescribe for any animal disease, pain, injury, deformity, or physical
3 condition; [or]

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

8 **(8) DISPENSES COMPOUNDED NONSTERILE PREPARATIONS OR**
9 **COMPOUNDED STERILE PREPARATIONS IF:**

10 **(I) THE COMPOUNDED NONSTERILE PREPARATIONS OR**
11 **COMPOUNDED STERILE PREPARATIONS ARE TO BE USED FOR A COMPANION**
12 **ANIMAL;**

13 **(II) THE COMPANION ANIMAL IS A PATIENT OF THE LICENSED**
14 **VETERINARIAN;**

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

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

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

26 2-313.

27 A person may not:

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

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

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

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

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

9 (6) Practice veterinary medicine and sell or dispense any medication,
10 which is not in the original manufacturer's container labeled with the information required
11 below, for use by a [household pet] **COMPANION ANIMAL** unless [he]:

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

18 **(II) THE PERSON IS A LICENSED VETERINARIAN WHO**
19 **DISPENSES COMPOUNDED NONSTERILE PREPARATIONS OR COMPOUNDED STERILE**
20 **PREPARATIONS, IN ACCORDANCE WITH § 2-301(F)(8) OF THIS ARTICLE, TO BE USED**
21 **FOR A COMPANION ANIMAL;**

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

24 (8) Practice as a veterinary technician unless employed by a veterinary
25 practitioner.

26 Article – Health Occupations

27 12-101.

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

29 **(C-1) “COMPOUNDED NONSTERILE PREPARATIONS” MEANS PRODUCTS**
30 **COMPOUNDED IN ACCORDANCE WITH USP 795.**

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

1 (Z-1) “USP-NF” MEANS THE UNITED STATES PHARMACOPEIA AND THE
2 NATIONAL FORMULARY.

3 (Z-2) “USP 795” MEANS THE STANDARDS SET FORTH IN THE UNITED STATES
4 PHARMACOPEIA, GENERAL CHAPTER 795, “PHARMACEUTICAL COMPOUNDING –
5 NONSTERILE PREPARATIONS”.

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

8 12–102.

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

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

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

15 (i) Is physically present on the premises where the prescription is
16 filled; and

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

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

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

21 1. **PERSONALLY** preparing and dispensing the
22 veterinarian’s prescriptions; **OR**

23 2. **DISPENSING, IN ACCORDANCE WITH § 2–301(F)(8) OF**
24 **THE AGRICULTURE ARTICLE, COMPOUNDED NONSTERILE PREPARATIONS OR**
25 **COMPOUNDED STERILE PREPARATIONS PROVIDED BY A PHARMACY;**

26 12–403.

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

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

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

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

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

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

10 **(23) SUBJECT TO § 12-510 OF THIS TITLE, MAY PROVIDE**
11 **COMPOUNDED NONSTERILE PREPARATIONS OR COMPOUNDED STERILE**
12 **PREPARATIONS WITHOUT A PATIENT-SPECIFIC PRESCRIPTION TO A LICENSED**
13 **VETERINARIAN WHO INTENDS TO DISPENSE THE COMPOUNDED NONSTERILE**
14 **PREPARATIONS OR COMPOUNDED STERILE PREPARATIONS IN ACCORDANCE WITH §**
15 **2-301(F)(8) OF THE AGRICULTURE ARTICLE.**

16 **12-510.**

17 **A PHARMACIST MAY PROVIDE COMPOUNDED NONSTERILE PREPARATIONS OR**
18 **COMPOUNDED STERILE PREPARATIONS WITHOUT A PATIENT-SPECIFIC**
19 **PRESCRIPTION TO A LICENSED VETERINARIAN WHO INTENDS TO DISPENSE THE**
20 **COMPOUNDED NONSTERILE PREPARATIONS OR COMPOUNDED STERILE**
21 **PREPARATIONS IN ACCORDANCE WITH § 2-301(F)(8) OF THE AGRICULTURE**
22 **ARTICLE IF THE PHARMACIST:**

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

24 **(2) LABELS THE COMPOUNDED NONSTERILE PREPARATIONS OR**
25 **COMPOUNDED STERILE PREPARATIONS WITH:**

26 **(I) THE NAME AND STRENGTH OF THE COMPOUNDED**
27 **NONSTERILE PREPARATIONS OR COMPOUNDED STERILE PREPARATIONS OR A LIST**
28 **OF THE ACTIVE INGREDIENTS AND THE STRENGTH OF THE ACTIVE INGREDIENTS IN**
29 **THE COMPOUNDED NONSTERILE PREPARATIONS OR COMPOUNDED STERILE**
30 **PREPARATIONS;**

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

1 **(III) THE QUANTITY OF COMPOUNDED NONSTERILE**
2 **PREPARATIONS OR COMPOUNDED STERILE PREPARATIONS; AND**

3 **(IV) THE NAME, ADDRESS, AND LICENSE NUMBER OF THE**
4 **PHARMACY.**

5 12-6C-02.

6 This subtitle does not affect any person while distributing:

7 (1) Feed for livestock or poultry;

8 (2) Fertilizers;

9 (3) Fungicides;

10 (4) Insecticide;

11 (5) Land plaster;

12 (6) Lime;

13 (7) Seeds; [or]

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

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

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