

# HOUSE BILL 1099

M4, J2

4lr1728

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By: **Delegate Guyton**

Introduced and read first time: February 7, 2024

Assigned to: Environment and Transportation

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## A BILL ENTITLED

1 AN ACT concerning

2 **Veterinary Practitioners and Veterinary Technicians – Compounding**  
3 **Prescription Drugs – Authorization and Requirements**

4 FOR the purpose of authorizing certain veterinary practitioners and veterinary technicians  
5 to compound prescription drugs under certain circumstances; requiring a veterinary  
6 clinic or hospital that carries out compounding to establish certain policies and keep  
7 certain records regarding certain compounded prescription drugs; authorizing an  
8 office manager or veterinary assistant to maintain certain records in a certain  
9 manner and update certain policies under certain circumstances; requiring a  
10 veterinary clinic or hospital that compounds drugs on-site to take certain actions for  
11 purposes of quality assurance; prohibiting a veterinary practitioner or veterinary  
12 technician from compounding a drug under certain circumstances; authorizing a  
13 veterinary practitioner to purchase, store, and distribute certain compounded drugs  
14 under certain circumstances; requiring the State Board of Veterinary Medical  
15 Examiners to establish certain safety standards and guidelines; and generally  
16 relating to the compounding of prescription drugs by veterinary practitioners and  
17 veterinary technicians.

18 BY repealing and reenacting, without amendments,  
19 Article – Agriculture  
20 Section 2–301(a), (i), and (j)  
21 Annotated Code of Maryland  
22 (2016 Replacement Volume and 2023 Supplement)

23 BY adding to  
24 Article – Agriculture  
25 Section 2–313.4  
26 Annotated Code of Maryland  
27 (2016 Replacement Volume and 2023 Supplement)

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EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



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 (i) “Veterinary practitioner” means a licensed and registered veterinarian  
7 engaged in the practice of veterinary medicine.

8 (j) “Veterinary technician” means a person who is registered with the Board as a  
9 veterinary technician.

10 **2–313.4.**

11 (A) (1) IN THIS SECTION THE FOLLOWING WORDS HAVE THE MEANINGS  
12 INDICATED.

13 (2) (I) “COMPOUNDING” MEANS:

- 14 1. ALTERING THE DOSAGE FORM OF A DRUG;  
15 2. ALTERING THE DELIVERY SYSTEM OF A DRUG;  
16 3. ALTERING THE STRENGTH OF A DRUG;  
17 4. COMBINING INGREDIENTS OF DIFFERENT DRUGS; OR  
18 5. PREPARING A COMPOUNDED DRUG PREPARATION  
19 FROM CHEMICALS.

20 (II) “COMPOUNDING” INCLUDES:

- 21 1. THE PREPARATION OF A COMPOUNDED DRUG FROM  
22 BULK SUBSTANCES; AND  
23 2. THE PREPARATION OF OFFICE-USE PRODUCTS  
24 APPROVED BY THE U.S. FOOD AND DRUG ADMINISTRATION THAT HAVE BEEN  
25 CREATED IN:

1                   **A. A PHARMACY EQUIPPED WITH A CLASS A**  
2 **PRESCRIPTION BALANCE AND WEIGHTS, OR A PRESCRIPTION BALANCE WITH**  
3 **EQUIVALENT OR SUPERIOR SENSITIVITY TO A CLASS A PRESCRIPTION BALANCE; OR**

4                   **B. AN OUTSOURCING FACILITY REGISTERED WITH THE**  
5 **U.S. FOOD AND DRUG ADMINISTRATION.**

6                   **(3) “OFFICE USE” MEANS PATIENT TREATMENT CARRIED OUT BY A**  
7 **VETERINARY PRACTITIONER OR A VETERINARY TECHNICIAN UNDER THE DIRECT OR**  
8 **INDIRECT SUPERVISION OF A VETERINARY PRACTITIONER.**

9                   **(4) “PATIENT TREATMENT” INCLUDES:**

10                   **(I) TREATMENT PROVIDED DURING A PATIENT’S OFFICE OR**  
11 **HOSPITAL VISIT;**

12                   **(II) TREATMENT PROVIDED DURING SURGERY;**

13                   **(III) EMERGENCY TREATMENT; AND**

14                   **(IV) PRESCRIBED AT-HOME TREATMENT.**

15                   **(B) COMPOUNDING MAY BE CARRIED OUT BY:**

16                   **(1) A VETERINARY PRACTITIONER WHO HAS AN ESTABLISHED**  
17 **RELATIONSHIP WITH THE CLIENT; OR**

18                   **(2) A VETERINARY TECHNICIAN UNDER THE DIRECT SUPERVISION OF**  
19 **A VETERINARY PRACTITIONER WHO HAS AN ESTABLISHED RELATIONSHIP WITH THE**  
20 **CLIENT.**

21                   **(C) A VETERINARY CLINIC OR HOSPITAL THAT CARRIES OUT COMPOUNDING**  
22 **SHALL:**

23                   **(1) ESTABLISH POLICIES AND CREATE A MANUAL ON COMPOUNDING**  
24 **THAT INCLUDE:**

25                   **(I) HOW EACH COMPOUNDED DRUG WAS CREATED,**  
26 **INCLUDING:**

27                   **1. THE MANUFACTURER’S NAME;**

28                   **2. THE ORIGINAL DOSAGE;**

1                                   **3. THE LOT NUMBER;**

2                                   **4. THE EXPIRATION DATE; AND**

3                                   **5. THE PURCHASE DATE; AND**

4                                   **(II) HOW VETERINARY TECHNICIANS SHALL BE TRAINED AT**  
5 **COMPOUNDING;**

6                                   **(2) MAINTAIN A RECORD OF:**

7                                   **(I) THE FORMULA USED WHEN COMPOUNDING;**

8                                   **(II) ALL ACTIVE AND INACTIVE INGREDIENTS;**

9                                   **(III) ANY EQUIPMENT USED;**

10                                  **(IV) THE EXPIRATION DATE OF:**

11                                  **1. THE COMPOUNDED DRUG; AND**

12                                  **2. ANY INGREDIENTS USED;**

13                                  **(V) THE SPECIFIC STEPS TAKEN WHILE COMPOUNDING;**

14                                  **(VI) INSTRUCTIONS ON PROPER STORAGE, HANDLING,**  
15 **ADMINISTRATION, AND DISPOSAL OF THE COMPOUNDED DRUG; AND**

16                                  **(VII) THE NAME OF THE INDIVIDUAL WHO PREPARED THE DRUG**  
17 **AND THE DATE OF PREPARATION;**

18                                  **(3) MAINTAIN THE FOLLOWING INFORMATION IN A PATIENT RECORD:**

19                                  **(I) THE NAME OF THE VETERINARY PRACTITIONER WHO**  
20 **COMPOUNDED, OR SUPERVISED THE COMPOUNDING OF, THE DRUG, AND THE NAME**  
21 **OF THE VETERINARY TECHNICIAN, IF APPLICABLE;**

22                                  **(II) THE EXPIRATION DATE OF THE COMPOUNDED DRUG;**

23                                  **(III) INSTRUCTIONS ON PROPER STORAGE, HANDLING,**  
24 **ADMINISTRATION, AND DISPOSAL OF THE COMPOUNDED DRUG;**

1 (IV) THE NAME, STRENGTH, AND QUANTITY OF THE  
2 COMPOUNDED DRUG; AND

3 (V) THE DATE THE DRUG WAS COMPOUNDED; AND

4 (4) MAINTAIN PROPER STORAGE FOR COMPOUNDED DRUGS.

5 (D) AN OFFICE MANAGER OR VETERINARY ASSISTANT, UNDER THE  
6 SUPERVISION OF A VETERINARY PRACTITIONER, MAY:

7 (1) MAINTAIN THE RECORDS REQUIRED UNDER SUBSECTION (C) OF  
8 THIS SECTION IN WRITTEN OR ELECTRONIC FORMAT; AND

9 (2) UPDATE THE POLICIES AND MANUAL REQUIRED UNDER  
10 SUBSECTION (C) OF THIS SECTION.

11 (E) A VETERINARY PRACTITIONER SHALL PROVIDE TRAINING FOR A  
12 VETERINARY TECHNICIAN WHO IS COMPOUNDING DRUGS OR HANDLING  
13 COMPOUNDED DRUGS UNDER THE SUPERVISION OF THE VETERINARY  
14 PRACTITIONER.

15 (F) A VETERINARY CLINIC OR HOSPITAL THAT COMPOUNDS DRUGS ON-SITE  
16 SHALL:

17 (1) CREATE A QUALITY ASSURANCE PROGRAM THAT DOCUMENTS  
18 AND ASSESSES MEDICATION ERRORS;

19 (2) DOCUMENT ANY CAUSES, REACTIONS, AND TREATMENTS  
20 RESULTING FROM MEDICATION ERRORS;

21 (3) CONTACT A CLIENT AS SOON AS POSSIBLE TO NOTIFY THEM OF  
22 ANY ERRORS AND THE STEPS REQUIRED TO FIX THE ERROR AND TO AVOID INJURY  
23 OR ILLNESS; AND

24 (4) BE SUBJECT TO QUESTIONS AND REVIEW FROM THE BOARD AND  
25 THE STATE BOARD OF PHARMACY.

26 (G) A VETERINARY PRACTITIONER OR VETERINARY TECHNICIAN MAY NOT  
27 COMPOUND A DRUG IF THE COMPLEXITY OF COMPOUNDING THE DRUG IS BEYOND  
28 THE VETERINARY PRACTITIONER'S OR VETERINARY TECHNICIAN'S KNOWLEDGE,  
29 SKILL, EXPERTISE, OR AVAILABLE FACILITIES OR EQUIPMENT.

1           **(H) A VETERINARY PRACTITIONER MAY PURCHASE COMPOUNDED DRUGS**  
2 **FOR OFFICE USE IF THE DRUGS WERE COMPOUNDED AT A LICENSED PHARMACY IN**  
3 **THE STATE OR AT AN OUTSOURCING FACILITY.**

4           **(I) A VETERINARY PRACTITIONER MAY STORE COMPOUNDED DRUGS FOR**  
5 **IN-OFFICE OR HOSPITAL USE:**

6                   **(1) IF COMPOUNDED AT A LICENSED PHARMACY IN THE STATE OR AT**  
7 **AN OUTSOURCING FACILITY, FOR A PERIOD OF 21 DAYS; AND**

8                   **(2) IF COMPOUNDED IN THE VETERINARY PRACTITIONER'S OFFICE**  
9 **OR HOSPITAL, FOR A PERIOD OF 14 DAYS.**

10           **(J) A VETERINARY PRACTITIONER MAY DISPENSE COMPOUNDED DRUGS**  
11 **IN-OFFICE:**

12                   **(1) FOR IMMEDIATE MEDICAL NEED;**

13                   **(2) WHEN THERE ARE LIMITED OR NO RETAIL OPTIONS AVAILABLE**  
14 **TO THE PATIENT; AND**

15                   **(3) WHEN THERE IS A POTENTIAL RISK OF HARM TO THE PATIENT IF**  
16 **THE COMPOUNDED DRUGS ARE NOT DISPENSED.**

17           **(K) THE BOARD SHALL ESTABLISH STANDARDS AND GUIDELINES FOR**  
18 **VETERINARY PRACTITIONERS AND VETERINARY TECHNICIANS TO ENSURE THE**  
19 **SAFETY OF COMPOUNDED DRUGS.**

20           SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect  
21 October 1, 2024.