

Second Regular Session
Seventieth General Assembly
STATE OF COLORADO

REVISED

*This Version Includes All Amendments Adopted
on Second Reading in the Second House*

LLS NO. 16-0671.01 Jennifer Berman x3286

SENATE BILL 16-062

SENATE SPONSORSHIP

Marble, Grantham, Neville T., Lambert, Woods, Holbert, Lundberg, Scheffel, Cooke, Crowder, Hill, Martinez Humenik, Sonnenberg, Tate

HOUSE SPONSORSHIP

Becker J. and Vigil, Saine, Brown, Everett, Willett, Ransom, Wist, Sias, Nordberg, Joshi, Lundeen, Klingenschmitt, Buck, Navarro, Neville P., Humphrey

Senate Committees

Agriculture, Natural Resources, & Energy
Appropriations

House Committees

State, Veterans, & Military Affairs
Appropriations

A BILL FOR AN ACT

101 CONCERNING MODIFICATIONS TO THE REGULATION OF VETERINARY
102 PHARMACEUTICALS.

Bill Summary

(Note: This summary applies to this bill as introduced and does not reflect any amendments that may be subsequently adopted. If this bill passes third reading in the house of introduction, a bill summary that applies to the reengrossed version of this bill will be available at <http://www.leg.state.co.us/billsummaries>.)

Section 1 of the bill requires the governor to appoint at least 2 members to the state board of pharmacy (board) who are engaged in the practice of, or otherwise professionally interested in, veterinary medicine or animal agriculture.

Section 2 removes the sale of veterinary devices from the board's regulatory purview.

Shading denotes HOUSE amendment. Double underlining denotes SENATE amendment.

Capital letters indicate new material to be added to existing statute.

Dashes through the words indicate deletions from existing statute.

HOUSE
Amended 2nd Reading
April 22, 2016

SENATE
3rd Reading Unamended
March 10, 2016

SENATE
Amended 2nd Reading
March 9, 2016

Section 3 reduces the civil penalty a person faces for unlawfully distributing a veterinary drug to a civil penalty of \$50 to \$500 for a single violation and a maximum of \$5,000 for multiple violations.

Be it enacted by the General Assembly of the State of Colorado:

SECTION 1. In Colorado Revised Statutes, **add 12-42.5-104.5** as follows:

12-42.5-104.5. Veterinary pharmaceutical advisory committee - creation - appointments - rules. (1) (a) THERE IS CREATED IN THE DEPARTMENT OF REGULATORY AGENCIES THE VETERINARY PHARMACEUTICAL ADVISORY COMMITTEE COMPRISED OF THREE MEMBERS, ONE MEMBER OF WHICH IS ONE OF THE NONPHARMACIST MEMBERS OF THE BOARD WHOM THE BOARD WILL APPOINT TO THE ADVISORY COMMITTEE, WITH THE OTHER TWO MEMBERS APPOINTED BY THE EXECUTIVE DIRECTOR OF THE DEPARTMENT OF REGULATORY AGENCIES, IN CONSULTATION WITH THE BOARD OF VETERINARY MEDICINE CREATED IN SECTION 12-64-105, AS FOLLOWS:

(I) ONE MEMBER WHO IS A LICENSED VETERINARIAN WHO PREDOMINANTLY WORKS ON LARGE ANIMALS, HAVING AT LEAST FIVE YEARS' EXPERIENCE IN THIS STATE AND ACTIVELY ENGAGED IN THE PRACTICE OF VETERINARY MEDICINE; AND

(II) ONE LICENSED PHARMACEUTICAL WHOLESALER ENGAGED IN THE DISTRIBUTION OF ANIMAL DRUGS, HAVING AT LEAST FIVE YEARS' EXPERIENCE IN THIS STATE AND ACTIVELY ENGAGED IN THE PRACTICE OF WHOLESAL PHARMACY.

(b) (I) THE TWO MEMBERS OF THE ADVISORY COMMITTEE WHO ARE NOT ON THE BOARD SERVE THREE-YEAR TERMS. OF THE TWO MEMBERS INITIALLY APPOINTED TO THE ADVISORY COMMITTEE WHO DO NOT SERVE

1 ON THE BOARD, THE EXECUTIVE DIRECTOR OF THE DEPARTMENT OF
2 REGULATORY AGENCIES SHALL APPOINT ONE MEMBER FOR A TWO-YEAR
3 TERM AND ONE MEMBER FOR A THREE-YEAR TERM. THE BOARD MEMBER
4 INITIALLY APPOINTED TO THE ADVISORY COMMITTEE SERVES FOR THE
5 DURATION OF HIS OR HER BOARD TERM, AND THE BOARD SHALL APPOINT
6 HIS OR HER SUCCESSOR OR THE OTHER NONPHARMACIST BOARD MEMBER
7 AS A REPLACEMENT MEMBER OF THE ADVISORY COMMITTEE, WHO SHALL
8 SERVE ON THE ADVISORY COMMITTEE FOR THE DURATION OF HIS OR HER
9 TERM ON THE BOARD.

10 (II) IF THERE IS A VACANCY ON THE ADVISORY COMMITTEE, THE
11 EXECUTIVE DIRECTOR, IN CONSULTATION WITH THE BOARD OF
12 VETERINARY MEDICINE, SHALL APPOINT A SUCCESSOR TO FILL THE
13 UNEXPIRED PORTION OF THE MEMBER'S TERM; EXCEPT THAT A VACANCY
14 OF THE SEAT ON THE ADVISORY BOARD THAT WAS FILLED BY ONE OF THE
15 NONPHARMACIST BOARD MEMBERS SHALL BE FILLED BY THE BOARD WITH
16 EITHER THE OTHER NONPHARMACIST BOARD MEMBER OR, IF THE VACANCY
17 WAS CAUSED BY A VACANCY ON THE BOARD, BY ANY SUCCESSOR
18 NONPHARMACIST BOARD MEMBER.

19 (c) (I) THE ADVISORY COMMITTEE SHALL ELECT A MEMBER TO
20 SERVE AS CHAIR OF THE ADVISORY COMMITTEE. THE ADVISORY
21 COMMITTEE SHALL MEET AS REQUIRED BY THE BOARD IN ACCORDANCE
22 WITH SUBSECTION (2) OF THIS SECTION.

23 (II) MEMBERS OF THE ADVISORY COMMITTEE SERVE WITHOUT
24 COMPENSATION OR REIMBURSEMENT OF EXPENSES.

25 (III) PURSUANT TO SECTION 24-18-108.5, C.R.S., A MEMBER OF
26 THE ADVISORY COMMITTEE SHALL NOT PERFORM AN OFFICIAL ACT THAT
27 MAY HAVE A DIRECT ECONOMIC BENEFIT ON A BUSINESS OR OTHER

1 UNDERTAKING IN WHICH THE MEMBER HAS A DIRECT OR SUBSTANTIAL
2 FINANCIAL INTEREST.

3 (d) THE DEPARTMENT OF REGULATORY AGENCIES SHALL PROVIDE
4 STAFF ASSISTANCE TO THE ADVISORY COMMITTEE.

5 (2)(a) UNLESS A MATTER PRESENTED TO THE BOARD CONSTITUTES
6 AN EMERGENCY REQUIRING PROMPT RESOLUTION, THE BOARD SHALL
7 REFER THE FOLLOWING MATTERS THAT CONCERN VETERINARY
8 PHARMACEUTICALS TO THE ADVISORY COMMITTEE FOR A
9 RECOMMENDATION ON HOW THE BOARD SHOULD PROCEED ON THE
10 MATTER:

11 (I) WHETHER AND TO WHAT EXTENT ACTION, IF ANY, SHOULD BE
12 TAKEN ON AN INVESTIGATION INTO OR COMPLAINT OF AN ALLEGED
13 VIOLATION OF THIS ARTICLE, INCLUDING WHETHER TO:

14 (A) SUSPEND OR REVOKE A LICENSE OR REGISTRATION;

15 (B) IMPOSE A FINE AGAINST A LICENSEE OR REGISTRANT, WHETHER
16 THE VIOLATION IS EGREGIOUS, AND THE AMOUNT OF ANY FINE
17 RECOMMENDED;

18 (C) SEEK A RESTRAINING ORDER OR INJUNCTION IN CIVIL COURT
19 AGAINST A PERSON; OR

20 (D) PURSUE OTHER DISCIPLINARY ACTION AGAINST A LICENSEE,
21 REGISTRANT, OR OTHER PERSON;

22 (II) REVIEW OF LICENSE AND REGISTRATION APPLICATIONS AND
23 RENEWAL, REACTIVATION, AND REINSTATEMENT APPLICATIONS; AND

24 (III) PROMULGATION OF RULES.

25 (b) UPON BEING REFERRED A MATTER BY THE BOARD, THE
26 ADVISORY COMMITTEE SHALL MEET AS SOON AS PRACTICABLE TO REVIEW
27 THE MATTER. THE BOARD SHALL SHARE ALL DOCUMENTS, RECORDINGS,

1 AND OTHER MATERIALS THAT ARE RELEVANT TO THE MATTER REFERRED
2 WITH THE ADVISORY COMMITTEE FOR THE ADVISORY COMMITTEE'S REVIEW
3 OF THE MATTER. THE ADVISORY COMMITTEE SHALL TREAT ALL SHARED
4 MATERIALS AS CONFIDENTIAL. THE ADVISORY COMMITTEE SHALL PROVIDE
5 THE BOARD A WRITTEN RECOMMENDATION ON HOW THE BOARD SHOULD
6 PROCEED ON THE MATTER REFERRED, SETTING FORTH ITS FINDINGS AND
7 CONCLUSIONS.

8 (c) THE BOARD SHALL ADOPT THE ADVISORY COMMITTEE'S
9 RECOMMENDATION ON A REFERRED MATTER UNLESS THE BOARD
10 DETERMINES THAT THERE EXISTS MATERIAL AND SUBSTANTIAL EVIDENCE
11 OR INFORMATION RELATED TO THE MATTER THAT WARRANTS A
12 RESOLUTION OF THE MATTER THAT IS DISTINCT FROM THE ADVISORY
13 COMMITTEE'S RECOMMENDATION. IF THE BOARD DEVIATES FROM THE
14 ADVISORY COMMITTEE'S RECOMMENDATION, THE BOARD SHALL MAKE A
15 RECORD OF THE REASONS FOR THE DEVIATION.

16 (3) THE BOARD, IN CONSULTATION WITH THE BOARD OF
17 VETERINARY MEDICINE, MAY PROMULGATE RULES TO IMPLEMENT THIS
18 SECTION.

19 (4) (a) THIS SECTION IS REPEALED, EFFECTIVE SEPTEMBER 1, 2026.

20 (b) BEFORE THE REPEAL OF THIS SECTION, THE DEPARTMENT OF
21 REGULATORY AGENCIES SHALL REVIEW THE ADVISORY COMMITTEE
22 PURSUANT TO SECTION 2-3-1203, C.R.S.

23 **SECTION 2.** In Colorado Revised Statutes, 12-42.5-107, **amend**
24 (2) as follows:

25 **12-42.5-107. Drugs, devices, and other materials.** (2) The
26 board is responsible for the control and regulation of the sale of devices
27 at retail; EXCEPT THAT THE BOARD SHALL NOT REGULATE THE SALE OF ANY

1 DISPOSABLE VETERINARY DEVICE. THE BOARD MAY ALSO EXEMPT FROM
2 REGULATION VETERINARY DEVICES:

3 (a) THAT ARE REGULATED BY THE FDA; OR

4 (b) FOR WHICH THE BOARD DETERMINES REGULATION IS
5 UNNECESSARY.

6 **SECTION 3.** In Colorado Revised Statutes, 12-42.5-124, **amend**
7 (5) (a) (I); and **add** (5) (a) (III) as follows:

8 **12-42.5-124. Disciplinary actions.** (5) (a) (I) Except as provided
9 in ~~subparagraph~~ SUBPARAGRAPHS (II) AND (III) of this paragraph (a), in
10 addition to any other penalty the board may impose pursuant to this
11 section, the board may fine any registrant violating this article or any rules
12 promulgated pursuant to this article not less than five hundred dollars and
13 not more than five thousand dollars for each violation.

14 (III) (A) THE BOARD, AFTER PROVIDING NOTICE AND AN
15 OPPORTUNITY TO BE HEARD, MAY FINE A REGISTRANT WHO DISTRIBUTES
16 A VETERINARY DRUG IN VIOLATION OF THIS ARTICLE NOT LESS THAN FIFTY
17 DOLLARS NOR MORE THAN FIVE HUNDRED DOLLARS FOR EACH VIOLATION,
18 WITH A MAXIMUM AGGREGATED FINE OF FIVE THOUSAND DOLLARS FOR
19 MULTIPLE VIOLATIONS; EXCEPT THAT, IF, AFTER CONSIDERING THE
20 RECOMMENDATIONS OF THE ADVISORY COMMITTEE CREATED IN SECTION
21 12-42.5-104.5, THE BOARD DETERMINES THAT THE REGISTRANT HAS
22 COMMITTED ONE OR MORE EGREGIOUS VIOLATIONS, THE BOARD MAY FINE
23 THE REGISTRANT IN ACCORDANCE WITH SUBPARAGRAPH (I) OF THIS
24 PARAGRAPH (a).

25 (B) IN SETTING A FINE, THE BOARD SHALL CONSIDER THE
26 REGISTRANT'S ABILITY TO PAY. IF THE BOARD DETERMINES THAT PAYING
27 THE FINE WOULD CAUSE THE REGISTRANT AN UNDUE HARDSHIP, THE

1 BOARD SHALL WAIVE THE FINE.

2 **SECTION 4.** In Colorado Revised Statutes, 2-3-1203, **add** (3)
3 (mm) (II) as follows:

4 **2-3-1203. Sunset review of advisory committees.** (3) The
5 following dates are the dates on which the statutory authorization for the
6 designated advisory committee is scheduled for repeal:

7 (mm) September 1, 2026:

8 (II) THE VETERINARY PHARMACEUTICAL ADVISORY COMMITTEE,
9 CREATED IN SECTION 12-42.5-104.5, C.R.S.

10

11 **SECTION 5. Effective date - applicability.** This act takes effect
12 July 1, 2016, and applies to offenses committed on or after said date.

13 **SECTION 6. Safety clause.** The general assembly hereby finds,
14 determines, and declares that this act is necessary for the immediate
15 preservation of the public peace, health, and safety.