Second Regular Session Seventieth General Assembly STATE OF COLORADO

PREAMENDED

This Unofficial Version Includes Committee Amendments Not Yet Adopted on Second Reading

LLS NO. 16-0671.01 Jennifer Berman x3286

SENATE BILL 16-062

SENATE SPONSORSHIP

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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, AND, IN CONNECTION THEREWITH, MAKING

103 <u>AN APPROPRIATION.</u>

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 <u>http://www.leg.state.co.us/billsummaries</u>.)

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



Amended 2nd Reading

SENATE

March 9, 2016

regulatory purview.

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.

1 Be it enacted by the General Assembly of the State of Colorado: 2 SECTION 1. In Colorado Revised Statutes, add 12-42.5-104.5 3 as follows: 4 12-42.5-104.5. Veterinary pharmaceutical advisory committee 5 - creation - appointments - rules. (1) (a) THERE IS CREATED IN THE 6 DEPARTMENT OF REGULATORY AGENCIES THE VETERINARY 7 PHARMACEUTICAL ADVISORY COMMITTEE COMPRISED OF THREE MEMBERS, 8 ONE MEMBER OF WHICH IS ONE OF THE NONPHARMACIST MEMBERS OF THE 9 BOARD WHOM THE BOARD WILL APPOINT TO THE ADVISORY COMMITTEE, 10 WITH THE OTHER TWO MEMBERS APPOINTED BY THE EXECUTIVE DIRECTOR 11 OF THE DEPARTMENT OF REGULATORY AGENCIES, IN CONSULTATION WITH 12 THE BOARD OF VETERINARY MEDICINE CREATED IN SECTION 12-64-105, AS 13 FOLLOWS: 14 (I)ONE MEMBER WHO IS A LICENSED VETERINARIAN WHO 15 PREDOMINANTLY WORKS ON LARGE ANIMALS, HAVING AT LEAST FIVE 16 YEARS' EXPERIENCE IN THIS STATE AND ACTIVELY ENGAGED IN THE 17 PRACTICE OF VETERINARY MEDICINE; AND 18 (II) ONE LICENSED PHARMACEUTICAL WHOLESALER ENGAGED IN 19 THE DISTRIBUTION OF ANIMAL DRUGS, HAVING AT LEAST FIVE YEARS' 20 EXPERIENCE IN THIS STATE AND ACTIVELY ENGAGED IN THE PRACTICE OF 21 WHOLESALE PHARMACY. 22 (b) (I) THE TWO MEMBERS OF THE ADVISORY COMMITTEE WHO ARE 23 NOT ON THE BOARD SERVE THREE-YEAR TERMS. OF THE TWO MEMBERS

1 INITIALLY APPOINTED TO THE ADVISORY COMMITTEE WHO DO NOT SERVE 2 ON THE BOARD, THE EXECUTIVE DIRECTOR OF THE DEPARTMENT OF 3 REGULATORY AGENCIES SHALL APPOINT ONE MEMBER FOR A TWO-YEAR 4 TERM AND ONE MEMBER FOR A THREE-YEAR TERM. THE BOARD MEMBER 5 INITIALLY APPOINTED TO THE ADVISORY COMMITTEE SERVES FOR THE 6 DURATION OF HIS OR HER BOARD TERM, AND THE BOARD SHALL APPOINT 7 HIS OR HER SUCCESSOR OR THE OTHER NONPHARMACIST BOARD MEMBER 8 AS A REPLACEMENT MEMBER OF THE ADVISORY COMMITTEE, WHO SHALL 9 SERVE ON THE ADVISORY COMMITTEE FOR THE DURATION OF HIS OR HER 10 TERM ON THE BOARD. 11 (II) IF THERE IS A VACANCY ON THE ADVISORY COMMITTEE, THE 12 EXECUTIVE DIRECTOR, IN CONSULTATION WITH THE BOARD OF 13 VETERINARY MEDICINE, SHALL APPOINT A SUCCESSOR TO FILL THE 14 UNEXPIRED PORTION OF THE MEMBER'S TERM; EXCEPT THAT A VACANCY 15 OF THE SEAT ON THE ADVISORY BOARD THAT WAS FILLED BY ONE OF THE 16 NONPHARMACIST BOARD MEMBERS SHALL BE FILLED BY THE BOARD WITH 17 EITHER THE OTHER NONPHARMACIST BOARD MEMBER OR, IF THE VACANCY 18 WAS CAUSED BY A VACANCY ON THE BOARD, BY ANY SUCCESSOR 19 NONPHARMACIST BOARD MEMBER. 20 (c) (I) THE ADVISORY COMMITTEE SHALL ELECT A MEMBER TO 21 SERVE AS CHAIR OF THE ADVISORY COMMITTEE. THE ADVISORY 22 COMMITTEE SHALL MEET AS REQUIRED BY THE BOARD IN ACCORDANCE 23 WITH SUBSECTION (2) OF THIS SECTION.

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

26 (III) PURSUANT TO SECTION 24-18-108.5, C.R.S., A MEMBER OF
27 THE ADVISORY COMMITTEE SHALL NOT PERFORM AN OFFICIAL ACT THAT

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2 UNDERTAKING IN WHICH THE MEMBER HAS A DIRECT OR SUBSTANTIAL 3 FINANCIAL INTEREST. 4 (d) THE DEPARTMENT OF REGULATORY AGENCIES SHALL PROVIDE 5 STAFF ASSISTANCE TO THE ADVISORY COMMITTEE. 6 (2)(a) UNLESS A MATTER PRESENTED TO THE BOARD CONSTITUTES 7 AN EMERGENCY REQUIRING PROMPT RESOLUTION, THE BOARD SHALL 8 REFER THE FOLLOWING MATTERS THAT CONCERN VETERINARY 9 PHARMACEUTICALS TO THE ADVISORY COMMITTEE FOR A 10 RECOMMENDATION ON HOW THE BOARD SHOULD PROCEED ON THE 11 MATTER: 12 (I) WHETHER AND TO WHAT EXTENT ACTION, IF ANY, SHOULD BE 13 TAKEN ON AN INVESTIGATION INTO OR COMPLAINT OF AN ALLEGED 14 VIOLATION OF THIS ARTICLE, INCLUDING WHETHER TO: 15 (A) SUSPEND OR REVOKE A LICENSE OR REGISTRATION; 16 (B) IMPOSE A FINE AGAINST A LICENSEE OR REGISTRANT, WHETHER 17 THE VIOLATION IS EGREGIOUS, AND THE AMOUNT OF ANY FINE 18 RECOMMENDED; 19 (C) SEEK A RESTRAINING ORDER OR INJUNCTION IN CIVIL COURT 20 AGAINST A PERSON; OR 21 (D) PURSUE OTHER DISCIPLINARY ACTION AGAINST A LICENSEE, 22 REGISTRANT, OR OTHER PERSON; 23 (II) REVIEW OF LICENSE AND REGISTRATION APPLICATIONS AND 24 RENEWAL, REACTIVATION, AND REINSTATEMENT APPLICATIONS; AND 25 (III) PROMULGATION OF RULES. 26 UPON BEING REFERRED A MATTER BY THE BOARD, THE (b) 27 ADVISORY COMMITTEE SHALL MEET AS SOON AS PRACTICABLE TO REVIEW

MAY HAVE A DIRECT ECONOMIC BENEFIT ON A BUSINESS OR OTHER

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1 THE MATTER. THE BOARD SHALL SHARE ALL DOCUMENTS, RECORDINGS, 2 AND OTHER MATERIALS THAT ARE RELEVANT TO THE MATTER REFERRED 3 WITH THE ADVISORY COMMITTEE FOR THE ADVISORY COMMITTEE'S REVIEW 4 OF THE MATTER. THE ADVISORY COMMITTEE SHALL TREAT ALL SHARED 5 MATERIALS AS CONFIDENTIAL. THE ADVISORY COMMITTEE SHALL PROVIDE 6 THE BOARD A WRITTEN RECOMMENDATION ON HOW THE BOARD SHOULD 7 PROCEED ON THE MATTER REFERRED, SETTING FORTH ITS FINDINGS AND 8 CONCLUSIONS.

9 (c) THE BOARD SHALL ADOPT THE ADVISORY COMMITTEE'S 10 RECOMMENDATION ON A REFERRED MATTER UNLESS THE BOARD 11 DETERMINES THAT THERE EXISTS MATERIAL AND SUBSTANTIAL EVIDENCE 12 OR INFORMATION RELATED TO THE MATTER THAT WARRANTS A 13 RESOLUTION OF THE MATTER THAT IS DISTINCT FROM THE ADVISORY 14 COMMITTEE'S RECOMMENDATION. IF THE BOARD DEVIATES FROM THE 15 ADVISORY COMMITTEE'S RECOMMENDATION, THE BOARD SHALL MAKE A 16 RECORD OF THE REASONS FOR THE DEVIATION.

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

20 (4) (a) THIS SECTION IS REPEALED, EFFECTIVE SEPTEMBER 1, 2026.
21 (b) BEFORE THE REPEAL OF THIS SECTION, THE DEPARTMENT OF
22 REGULATORY AGENCIES SHALL REVIEW THE ADVISORY COMMITTEE
23 PURSUANT TO SECTION 2-3-1203, C.R.S.

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

26 12-42.5-107. Drugs, devices, and other materials. (2) The
27 board is responsible for the control and regulation of the sale of devices

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1	at retail; EXCEPT THAT THE BOARD SHALL NOT REGULATE THE SALE OF ANY
2	DISPOSABLE VETERINARY DEVICE. THE BOARD MAY ALSO EXEMPT FROM
3	REGULATION VETERINARY DEVICES:
4	(a) THAT ARE REGULATED BY THE FDA; OR
5	(b) For which the board determines regulation is
6	UNNECESSARY.
7	SECTION 3. In Colorado Revised Statutes, 12-42.5-124, amend
8	(5) (a) (I); and add (5) (a) (III) as follows:
9	12-42.5-124. Disciplinary actions. (5) (a) (I) Except as provided
10	in subparagraph SUBPARAGRAPHS (II) AND (III) of this paragraph (a), in
11	addition to any other penalty the board may impose pursuant to this
12	section, the board may fine any registrant violating this article or any rules
13	promulgated pursuant to this article not less than five hundred dollars and
14	not more than five thousand dollars for each violation.
15	(III) (A) The board, after providing notice and an
16	OPPORTUNITY TO BE HEARD, MAY FINE A REGISTRANT WHO DISTRIBUTES
17	\underline{A} VETERINARY DRUG IN VIOLATION OF THIS ARTICLE NOT LESS THAN FIFTY
18	DOLLARS NOR MORE THAN FIVE HUNDRED DOLLARS FOR EACH VIOLATION,
19	WITH A MAXIMUM AGGREGATED FINE OF FIVE THOUSAND DOLLARS FOR
20	MULTIPLE VIOLATIONS; EXCEPT THAT, IF, AFTER CONSIDERING THE
21	RECOMMENDATIONS OF THE ADVISORY COMMITTEE CREATED IN SECTION
22	12-42.5-104.5, THE BOARD DETERMINES THAT THE REGISTRANT HAS
23	COMMITTED ONE OR MORE EGREGIOUS VIOLATIONS, THE BOARD MAY FINE
24	THE REGISTRANT IN ACCORDANCE WITH SUBPARAGRAPH (I) of this
25	PARAGRAPH (a).
26	(B) IN SETTING A FINE, THE BOARD SHALL CONSIDER THE
27	REGISTRANT'S ABILITY TO PAY. IF THE BOARD DETERMINES THAT PAYING

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1 THE FINE WOULD CAUSE THE REGISTRANT AN UNDUE HARDSHIP, THE 2 BOARD SHALL WAIVE THE FINE. 3 **SECTION 4.** In Colorado Revised Statutes, 2-3-1203, add (3) 4 (mm) (II) as follows: 5 2-3-1203. Sunset review of advisory committees. (3) The 6 following dates are the dates on which the statutory authorization for the 7 designated advisory committee is scheduled for repeal: 8 (mm) September 1, 2026: 9 (II) THE VETERINARY PHARMACEUTICAL ADVISORY COMMITTEE, 10 CREATED IN SECTION 12-42.5-104.5, C.R.S. 11 **SECTION 5.** Appropriation. For the 2016-17 state fiscal year, 12 \$5,220 is appropriated to the department of regulatory agencies for use by 13 the division of professions and occupations. This appropriation is from 14 the division of professions and occupations cash fund created in section 15 24-34-105 (2) (b) (I), C.R.S. To implement this act, the division may use 16 this appropriation for operating expenses. 17 **SECTION 6. Effective date - applicability.** This act takes effect 18 July 1, 2016, and applies to offenses committed on or after said date. 19 **SECTION 7.** Safety clause. The general assembly hereby finds, 20 determines, and declares that this act is necessary for the immediate 21 preservation of the public peace, health, and safety.