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

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 <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 regulatory purview.



Shading denotes HOUSE amendment. <u>Double underlining denotes SENATE amendment</u>. Capital letters indicate new material to be added to existing statute. Dashes through the words indicate deletions from existing statute. **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
24	INITIALLY APPOINTED TO THE ADVISORY COMMITTEE WHO DO NOT SERVE

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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.

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

- 23 (II) MEMBERS OF THE ADVISORY COMMITTEE SERVE WITHOUT
 24 COMPENSATION OR REIMBURSEMENT OF EXPENSES.
- (III) PURSUANT TO SECTION 24-18-108.5, C.R.S., A MEMBER OF
 THE ADVISORY COMMITTEE SHALL NOT PERFORM AN OFFICIAL ACT THAT
 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) P ROMULGATION 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.

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

8 THE BOARD SHALL ADOPT THE ADVISORY COMMITTEE'S (c) 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.

(4) (a) THIS SECTION IS REPEALED, EFFECTIVE SEPTEMBER 1, 2026.
(b) BEFORE THE REPEAL OF THIS SECTION, THE DEPARTMENT OF
REGULATORY AGENCIES SHALL REVIEW THE ADVISORY COMMITTEE
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:

12-42.5-107. Drugs, devices, and other materials. (2) The
board is responsible for the control and regulation of the sale of devices
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	\underline{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	<u>REGISTRANT'S ABILITY TO PAY. IF THE BOARD DETERMINES THAT PAYING</u>
27	THE FINE WOULD CAUSE THE REGISTRANT AN UNDUE HARDSHIP, THE

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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.

SECTION <u>6.</u> Safety clause. The general assembly hereby finds,
determines, and declares that this act is necessary for the immediate
preservation of the public peace, health, and safety.