

Second Regular Session
Seventy-first General Assembly
STATE OF COLORADO

INTRODUCED

LLS NO. 18-0239.01 Kristen Forrestal x4217

SENATE BILL 18-023

SENATE SPONSORSHIP

Martinez Humenik,

HOUSE SPONSORSHIP

Ginal, Landgraf

Senate Committees
Health & Human Services

House Committees

A BILL FOR AN ACT

101 CONCERNING THE PROMOTION OF THE OFF-LABEL USE OF
102 PHARMACEUTICAL PRODUCTS.

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://leg.colorado.gov>.)

The bill allows a pharmaceutical manufacturer or its representative to promote the off-label use of a prescription drug, biological product, or device approved by the United States food and drug administration.

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

Shading denotes HOUSE amendment. Double underlining denotes SENATE amendment.
Capital letters or bold & italic numbers indicate new material to be added to existing statute.
Dashes through the words indicate deletions from existing statute.

1 **SECTION 1.** In Colorado Revised Statutes, 12-42.5-102, **amend**
2 the introductory portion; and **add** (23.5) and (40.5) as follows:

3 **12-42.5-102. Definitions.** As used in this ~~article~~ ARTICLE 42.5,
4 unless the context otherwise requires or the term is otherwise defined in
5 another part of this ~~article~~ ARTICLE 42.5:

6 (23.5) "OFF-LABEL USE" MEANS THE USE OF AN FDA-APPROVED
7 PRESCRIPTION DRUG, BIOLOGICAL PRODUCT, OR DEVICE IN A MANNER
8 OTHER THAN THE USE APPROVED BY THE FDA.

9 (40.5) "TRUTHFUL PROMOTION" MEANS THE SHARING OF
10 INFORMATION THAT IS NOT MISLEADING, NOT CONTRARY TO THE FACTS,
11 AND CONSISTENT WITH THE GENERALLY ACCEPTED SCIENTIFIC PRINCIPLES
12 BETWEEN MANUFACTURERS AND PRACTITIONERS.

13 **SECTION 2.** In Colorado Revised Statutes, **add** 12-42.5-135 as
14 follows:

15 **12-42.5-135. Off-label use of drug, biological product, or**
16 **device - promotion by manufacturer - short title.** (1) THE SHORT TITLE
17 OF THIS SECTION IS THE "FREE SPEECH IN MEDICINE ACT".

18 (2) (a) NOTWITHSTANDING ANY OTHER LAW TO THE CONTRARY, A
19 MANUFACTURER OR ITS REPRESENTATIVE MAY ENGAGE IN THE TRUTHFUL
20 PROMOTION OF AN OFF-LABEL USE OF A PRESCRIPTION DRUG, BIOLOGICAL
21 PRODUCT, OR DEVICE.

22 (b) THE BOARD SHALL NOT REVOKE, FAIL TO RENEW, OR TAKE ANY
23 ACTION AGAINST THE REGISTRATION OF A MANUFACTURER OR ITS
24 REPRESENTATIVE FOR ENGAGING IN THE TRUTHFUL PROMOTION OF THE
25 OFF-LABEL USE OF A PRESCRIPTION DRUG, BIOLOGICAL PRODUCT, OR
26 DEVICE.

27 (3) A CARRIER, AS DEFINED IN SECTION 10-16-102 (8), OR A

1 THIRD-PARTY PAYER IS NOT REQUIRED TO PROVIDE COVERAGE FOR THE
2 COST OF THE OFF-LABEL USE OF A PRESCRIPTION DRUG, BIOLOGICAL
3 PRODUCT, OR DEVICE.

4 **SECTION 3. Act subject to petition - effective date.** This act
5 takes effect at 12:01 a.m. on the day following the expiration of the
6 ninety-day period after final adjournment of the general assembly (August
7 8, 2018, if adjournment sine die is on May 9, 2018); except that, if a
8 referendum petition is filed pursuant to section 1 (3) of article V of the
9 state constitution against this act or an item, section, or part of this act
10 within such period, then the act, item, section, or part will not take effect
11 unless approved by the people at the general election to be held in
12 November 2018 and, in such case, will take effect on the date of the
13 official declaration of the vote thereon by the governor.