

SENATE COMMITTEE OF REFERENCE AMENDMENT

Committee on Health & Human Services.

SB23-041 be amended as follows:

1 Amend printed bill, strike everything below the enacting clause and
2 substitute:

3 "SECTION 1. In Colorado Revised Statutes, **add** 12-30-120 as
4 follows:

5 **12-30-120. Prescribing, administering, or dispensing drugs for**
6 **off-label use - definitions.** (1) AS USED IN THIS SECTION:

7 (a) "FDA" MEANS THE FOOD AND DRUG ADMINISTRATION IN THE
8 UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, OR ANY
9 SUCCESSOR ENTITY.

10 (b) "OFF-LABEL USE" MEANS THE USE OF AN FDA-APPROVED
11 DRUG:

12 (I) FOR AN INDICATION THAT HAS NOT BEEN APPROVED BY THE
13 FDA; OR

14 (II) THAT IS A DIFFERENT DOSAGE OF THE DRUG THAN THE DOSAGE
15 THAT HAS BEEN APPROVED BY THE FDA.

16 (c) "PRESCRIBER" HAS THE SAME MEANING AS SET FORTH IN
17 SECTION 12-30-109 (4).

18 (2) (a) A PRESCRIBER MAY PRESCRIBE OR ADMINISTER AN
19 FDA-APPROVED DRUG FOR AN OFF-LABEL USE. THE PRESCRIPTION AND
20 ADMINISTRATION OF AN FDA-APPROVED DRUG FOR AN OFF-LABEL USE BY
21 A PRESCRIBER IS NOT, BY ITSELF, A VIOLATION OF, OR GROUNDS FOR
22 DISCIPLINE PURSUANT TO, A PRESCRIBER'S APPLICABLE PRACTICE ACT.

23 (b) A PHARMACIST WHO DISPENSES A PRESCRIPTION FOR THE
24 OFF-LABEL USE OF A DRUG PRESCRIBED PURSUANT TO THIS SECTION IS NOT
25 SUBJECT TO DISCIPLINARY ACTION BY THE STATE BOARD OF PHARMACY
26 PURSUANT TO SECTION 12-280-127 FOR DISPENSING THE PRESCRIPTION.

27 **SECTION 2. Act subject to petition - effective date.** This act
28 takes effect at 12:01 a.m. on the day following the expiration of the
29 ninety-day period after final adjournment of the general assembly; except
30 that, if a referendum petition is filed pursuant to section 1 (3) of article V
31 of the state constitution against this act or an item, section, or part of this
32 act within such period, then the act, item, section, or part will not take
33 effect unless approved by the people at the general election to be held in
34 November 2024 and, in such case, will take effect on the date of the
35 official declaration of the vote thereon by the governor."

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