

SENATE COMMITTEE OF REFERENCE REPORT

Chair of Committee

February 2, 2023
Date

Committee on Health & Human Services.

After consideration on the merits, the Committee recommends the following:

SB23-041 be amended as follows, and as so amended, be referred to the Committee of the Whole with favorable recommendation:

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

1 takes effect at 12:01 a.m. on the day following the expiration of the
2 ninety-day period after final adjournment of the general assembly; except
3 that, if a referendum petition is filed pursuant to section 1 (3) of article V
4 of the state constitution against this act or an item, section, or part of this
5 act within such period, then the act, item, section, or part will not take
6 effect unless approved by the people at the general election to be held in
7 November 2024 and, in such case, will take effect on the date of the
8 official declaration of the vote thereon by the governor."

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