

**First Regular Session
Seventy-fourth General Assembly
STATE OF COLORADO**

ENGROSSED

*This Version Includes All Amendments Adopted
on Second Reading in the House of Introduction*

LLS NO. 23-0101.01 Kristen Forrestal x4217

SENATE BILL 23-041

SENATE SPONSORSHIP

Ginal and Smallwood,

HOUSE SPONSORSHIP

Amabile,

Senate Committees
Health & Human Services

House Committees

A BILL FOR AN ACT

101 **CONCERNING THE AUTHORIZATION OF PRESCRIPTION DRUGS**
102 **APPROVED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION**
103 **FOR OFF-LABEL USE.**

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 authorizes a physician, a physician assistant, and an advanced practice registered nurse (prescriber) to prescribe and administer a drug approved by the federal food and drug administration for an off-label use if:

- The off-label use of the drug for the indication has

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

SENATE
Amended 2nd Reading
February 7, 2023

- longstanding, common use;
- There is medical evidence to support the off-label use and no known evidence contraindicating such off-label use; and
- The prescriber has provided the patient or a minor patient's parent or guardian with an informed consent form, and the patient or parent or guardian has signed the form.

The bill applies the same standard of care for the off-label use of the drug as for the on-label use of the drug.

The bill clarifies that a pharmacist who fills a prescription for off-label use is not subject to discipline by the state board of pharmacy.

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

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

4 **12-30-120. Prescribing, administering, or dispensing drugs for**
5 **off-label use - definitions. (1) AS USED IN THIS SECTION:**

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

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

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

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

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

17 **(2) (a) A PRESCRIBER MAY PRESCRIBE OR ADMINISTER AN**
18 **FDA-APPROVED DRUG FOR AN OFF-LABEL USE. THE PRESCRIPTION AND**
19 **ADMINISTRATION OF AN FDA-APPROVED DRUG FOR AN OFF-LABEL USE BY**
20 **A PRESCRIBER IS NOT, BY ITSELF, A VIOLATION OF, OR GROUNDS FOR**

1 DISCIPLINE PURSUANT TO, A PRESCRIBER'S APPLICABLE PRACTICE ACT.

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

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