

First Regular Session  
Seventy-fourth General Assembly  
STATE OF COLORADO

INTRODUCED

LLS NO. 23-0101.01 Kristen Forrestal x4217

SENATE BILL 23-041

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SENATE SPONSORSHIP

Ginal and Smallwood,

HOUSE SPONSORSHIP

Amabile,

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Senate Committees  
Health & Human Services

House Committees

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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.

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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.*

- 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.

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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 or dispensing drugs for off-label use -**  
5 **informed consent - 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 DRUG:

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

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

14           (c) "PRESCRIBER" MEANS:

15           (I) A PHYSICIAN OR PHYSICIAN ASSISTANT LICENSED PURSUANT TO  
16 ARTICLE 240 OF THIS TITLE 12; OR

17           (II) AN ADVANCED PRACTICE REGISTERED NURSE, AS DEFINED IN  
18 SECTION 12-255-104 (1), WITH PRESCRIPTIVE AUTHORITY PURSUANT TO  
19 SECTION 12-255-112.

20           (2) A PRESCRIBER MAY PRESCRIBE OR ADMINISTER AN

1 FDA-APPROVED DRUG FOR AN OFF-LABEL USE IF:

2 (a) THE OFF-LABEL USE OF THE DRUG FOR THE INDICATION FOR  
3 WHICH IT IS PRESCRIBED HAS LONGSTANDING, COMMON USE;

4 (b) THERE IS MEDICAL EVIDENCE TO SUPPORT THE OFF-LABEL USE  
5 AND NO KNOWN EVIDENCE CONTRAINDICATING SUCH USE, INCLUDING  
6 PEER-REVIEWED STUDIES AND PRACTICE GUIDELINES FROM RELEVANT  
7 MEDICAL SOCIETIES; AND

8 (c) THE PRESCRIBER HAS PROVIDED THE PATIENT, OR, IF THE  
9 PATIENT IS A MINOR, THE PATIENT'S PARENT OR GUARDIAN, WITH AN  
10 INFORMED CONSENT FORM, AND THE PATIENT OR PARENT OR GUARDIAN  
11 HAS SIGNED THE FORM.

12 (3) THE INFORMED CONSENT FORM REQUIRED PURSUANT TO  
13 SUBSECTION (2)(c) OF THIS SECTION MUST INCLUDE:

14 (a) THE KNOWN POTENTIAL BENEFITS AND THE KNOWN POTENTIAL  
15 RISKS FOR THE OFF-LABEL USE OF THE DRUG FOR THE INDICATION FOR  
16 WHICH IT IS PRESCRIBED;

17 (b) ANY ALTERNATIVE TREATMENT OPTIONS;

18 (c) THE EXPECTED PROGNOSIS WITHOUT TREATMENT; AND

19 (d) A DISCLOSURE THAT THE PRESCRIPTION IS FOR OFF-LABEL USE.

20 (4) THE SAME STANDARD OF CARE THAT APPLIES TO THE  
21 FDA-APPROVED USE OF A PRESCRIPTION DRUG APPLIES TO THE  
22 PRESCRIPTION AND ADMINISTRATION OF THE PRESCRIPTION DRUG FOR AN  
23 OFF-LABEL USE.

24 (5) THE PRESCRIBER SHALL KEEP THE SIGNED INFORMED CONSENT  
25 FORM REGARDING THE PRESCRIPTION FOR THE OFF-LABEL USE AS PART OF  
26 THE PATIENT'S MEDICAL RECORD.

27 **SECTION 2.** In Colorado Revised Statutes, **add** 12-280-141 as

1 follows:

2 **12-280-141. Dispensing prescription drugs for off-label use.** A  
3 PHARMACIST WHO DISPENSES A PRESCRIPTION FOR THE OFF-LABEL USE OF  
4 A DRUG PRESCRIBED PURSUANT TO SECTION 12-30-120 IS NOT SUBJECT TO  
5 DISCIPLINARY ACTION BY THE BOARD FOR DISPENSING THE PRESCRIPTION.

6 **SECTION 3. 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.