

Second Regular Session  
Seventy-fifth General Assembly  
STATE OF COLORADO

INTRODUCED

LLS NO. 26-0456.01 Sarah Lozano x3858

HOUSE BILL 26-1262

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HOUSE SPONSORSHIP

Stewart K. and Stewart R.,

SENATE SPONSORSHIP

Ball and Roberts,

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House Committees  
Health & Human Services

Senate Committees

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A BILL FOR AN ACT

101 CONCERNING PRESERVING PATIENT ACCESS TO COMPOUNDED  
102 MEDICAL ITEMS.

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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 provides that, if the action is undertaken in accordance with applicable federal and state law:

- A licensed person may compound a drug or device in the state;
- A state-licensed pharmacy or a distribution facility registered with the federal food and drug administration

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.*

(licensed 503B outsourcing facility) may supply a compounded drug or device to a licensed health-care provider, pharmacy, facility, or organization; and

- A licensed health-care provider, pharmacy, facility, or organization may obtain, dispense, or administer a compounded drug or device supplied by a state-licensed pharmacy or a licensed 503B outsourcing facility.

In addition, the bill prohibits the state board of pharmacy from adopting rules that are more restrictive than federal or state law regarding the compounding of drugs or devices.

Current law exempts drugs that are intended solely for investigational use by experts qualified by scientific training and experience and that are plainly labeled for investigational use only from the sales and delivery prohibition for new drugs. The bill also exempts from the prohibition:

- Drugs that are reviewed by an institutional review board and plainly labeled for investigational use only; and
- Compounded drugs and devices if the compounding of the drug or device is undertaken in accordance with applicable federal and state law.

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

2       **SECTION 1. Short title.** The short title of this act is the  
3 "Colorado Patient Access and Compounding Clarity Act".

4       **SECTION 2. Legislative declaration.** (1) The general assembly  
5 finds and declares that:

6       (a) Sterile and nonsterile compounded medical items are used and  
7 relied upon on a daily basis in hospitals, surgical centers, behavioral  
8 health treatment facilities, and other care settings across Colorado;

9       (b) Federal standards for sterile and nonsterile compounding have  
10 evolved in recent years, and state law should reflect that framework to  
11 ensure clarity and continuity;

12       (c) Modernizing Colorado's laws regarding compounding  
13 promotes patient safety, reduces unnecessary regulatory duplication, and  
14 supports uninterrupted access to essential medications; and

1 (d) Preserving the availability of high-quality compounded  
2 medical items is vital for Colorado patients and the providers that serve  
3 them.

4 **SECTION 3.** In Colorado Revised Statutes, 12-280-120, **add**  
5 (1.5) as follows:

6 **12-280-120. Compounding - dispensing - sale of drugs and**  
7 **devices - rules - definition.**

8 (1.5) (a) IF THE ACTION IS UNDERTAKEN IN ACCORDANCE WITH  
9 APPLICABLE FEDERAL AND STATE LAW:

10 (I) A LICENSED PERSON MAY COMPOUND A DRUG OR DEVICE IN THE  
11 STATE, INCLUDING THE COMPOUNDING OF A DRUG OR DEVICE IN A STERILE  
12 OR NONSTERILE ENVIRONMENT;

13 (II) A STATE-LICENSED RESIDENT PHARMACY, LICENSED RESIDENT  
14 503B OUTSOURCING FACILITY, STATE-LICENSED NONRESIDENT PHARMACY,  
15 OR NONRESIDENT 503B OUTSOURCING FACILITY MAY SUPPLY A  
16 COMPOUNDED DRUG OR DEVICE TO A LICENSED HEALTH-CARE PROVIDER,  
17 PHARMACY, FACILITY, OR ORGANIZATION; AND

18 (III) A LICENSED HEALTH-CARE PROVIDER, PHARMACY, FACILITY,  
19 OR ORGANIZATION MAY OBTAIN, DISPENSE, OR ADMINISTER A  
20 COMPOUNDED DRUG OR DEVICE SUPPLIED BY A STATE-LICENSED RESIDENT  
21 PHARMACY, LICENSED RESIDENT 503B OUTSOURCING FACILITY,  
22 STATE-LICENSED NONRESIDENT PHARMACY, OR NONRESIDENT 503B  
23 OUTSOURCING FACILITY.

24 (b) IN ADOPTING RULES TO IMPLEMENT THIS SECTION OR  
25 OTHERWISE REGULATE THE COMPOUNDING OF DRUGS OR DEVICES IN THE  
26 STATE, THE BOARD SHALL NOT ADOPT RULES THAT ARE MORE RESTRICTIVE  
27 THAN APPLICABLE FEDERAL AND STATE LAW.

1 (c) NOTHING IN THIS SECTION SHALL BE CONSTRUED TO CLASSIFY  
2 LAWFUL COMPOUNDING PRACTICES AS MANUFACTURING OR TO EXPAND OR  
3 ALTER THE BOARD'S ENFORCEMENT AUTHORITY AS OF THE EFFECTIVE  
4 DATE OF THIS SUBSECTION (1.5).

5 (d) THE FEDERAL LAW DESCRIBED IN THIS SECTION INCLUDES THE  
6 STANDARDS RECOGNIZED BY THE FDA FOR STATE-LICENSED RESIDENT  
7 PHARMACIES, LICENSED RESIDENT 503B OUTSOURCING FACILITIES,  
8 STATE-LICENSED NONRESIDENT PHARMACIES, AND NONRESIDENT 503B  
9 OUTSOURCING FACILITIES, INCLUDING INCORPORATED UNITED STATES  
10 PHARMACOPEIA STERILE OR NONSTERILE PROCESSING STANDARDS.

11 **SECTION 4.** In Colorado Revised Statutes, 12-280-131, **amend**  
12 (2) as follows:

13 **12-280-131. New drugs - when sales permissible - exemptions.**

14 (2) This section does not apply:

15 (a) To a drug THAT IS PLAINLY LABELED TO BE FOR  
16 INVESTIGATIONAL USE ONLY AND THAT IS:

17 (I) Intended solely for investigational use by experts qualified by  
18 scientific training and experience to investigate the safety and  
19 effectiveness of drugs; ~~if the drug is plainly labeled to be for~~  
20 ~~investigational use only~~ OR

21 (II) REVIEWED BY AN INSTITUTIONAL REVIEW BOARD;

22 (b) TO A COMPOUNDED DRUG OR DEVICE IF THE COMPOUNDING OF  
23 THE DRUG OR DEVICE IS UNDERTAKEN IN ACCORDANCE WITH APPLICABLE  
24 FEDERAL AND STATE LAW, INCLUDING THE STANDARDS RECOGNIZED BY  
25 THE FDA FOR STATE-LICENSED RESIDENT PHARMACIES, LICENSED  
26 RESIDENT 503B OUTSOURCING FACILITIES, STATE-LICENSED NONRESIDENT  
27 PHARMACIES, AND NONRESIDENT 503B OUTSOURCING FACILITIES,

1 INCLUDING INCORPORATED UNITED STATES PHARMACOPEIA STERILE OR  
2 NONSTERILE PROCESSING STANDARDS.

3           **SECTION 5. Applicability.** This act applies to conduct occurring  
4 on or after the effective date of this act.

5           **SECTION 6. Safety clause.** The general assembly finds,  
6 determines, and declares that this act is necessary for the immediate  
7 preservation of the public peace, health, or safety or for appropriations for  
8 the support and maintenance of the departments of the state and state  
9 institutions.