

Second Regular Session
Seventy-fifth General Assembly
STATE OF COLORADO

REENGROSSED

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

LLS NO. 26-0540.01 Christopher McMichael x4775

SENATE BILL 26-066

SENATE SPONSORSHIP

Jodeh and Carson,

HOUSE SPONSORSHIP

Jackson,

Senate Committees
Health & Human Services

House Committees

A BILL FOR AN ACT

101 **CONCERNING THE REGULATION OF COMPOUNDED WEIGHT-LOSS**
102 **MEDICATIONS THAT HAVE NOT BEEN APPROVED BY THE UNITED**
103 **STATES FOOD AND DRUG ADMINISTRATION.**

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 establishes regulations for the sale, transfer, or distribution of compounded weight-loss medications, which are custom-made medications that, unlike mass-produced medications, are not subject to approval by the federal food and drug administration (FDA). A person may not sell, transfer, or distribute a compounded weight-loss medication

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 3rd Reading
April 17, 2026

SENATE
Amended 2nd Reading
March 16, 2026

unless the person confirms that the medication:

- Is made from bulk drug substances and drugs that are approved by the FDA when such approval is required;
- Was manufactured in compliance with FDA processes;
- Contains bulk drug substances that are pharmaceutical grade and are accompanied by a certificate of analysis containing information that is material to the safety and efficacy of the bulk drug substances;
- Was manufactured at a facility that is registered with the FDA and passed an FDA inspection within the previous 2 years; and
- Is verified for purity and accurate dosage.

Labels for compounded weight-loss medications must list all active and inactive ingredients, the quantity of those ingredients, and the ingredients' country of origin. There must also be a warning on the label stating that the compounded weight-loss medication has not been FDA-approved, has inadequate evidence of safety or efficacy, and has known and unknown side effects. A person must also provide certain disclosures to a patient when prescribing compounded weight-loss medications.

The bill prohibits the use of false or misleading claims, including unsubstantiated claims, when advertising or promoting compounded weight-loss medications.

A person that sells, transfers, or distributes compounded weight-loss medication must keep records related to the compounded weight-loss medication for at least 2 years after the date of expiration of the compounded weight-loss medication and make those records available for inspection by the state board of pharmacy.

The state board of pharmacy may issue fines of up to \$1,000 per dose of compounded weight-loss medications that are sold or distributed in violation of the bill and may revoke a pharmacy or business license for violations.

The attorney general has authority to enforce this bill as a deceptive trade practice under the "Colorado Consumer Protection Act".

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

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

4 (a) Compounding pharmacies play an important role in the United
5 States drug supply chain and allow patients to receive life-saving or

1 life-improving medication when the commercial market is unable to
2 support patients' needs;

3 (b) The United States food and drug administration, referred to in
4 this section as the "FDA", provides regulatory oversight and sets
5 internationally recognized standards for drug approval; however, there
6 has been an increase in the number of companies that develop, dispense,
7 and market non-FDA-approved compounded medications, notably
8 weight-loss drugs;

9 (c) Patients in Colorado are at risk of receiving compounded
10 weight-loss medications that are not approved by the FDA or are not
11 manufactured in compliance with the FDA's current good manufacturing
12 practice requirements; and

13 (d) Therefore, the general assembly should take action to protect
14 Coloradans by requiring that compounded weight-loss medications are
15 sourced from FDA-registered and -inspected facilities and that those
16 medications contain safe and pharmaceutical-grade ingredients.

17 **SECTION 2.** In Colorado Revised Statutes, add 6-1-741 as
18 follows:

19 **6-1-741. Regulation of compounded weight-loss medication -**
20 **prohibited conduct - enforcement by attorney general -**
21 **definitions.**

22 (1) **Definitions.** AS USED IN THIS SECTION, UNLESS THE CONTEXT
23 OTHERWISE REQUIRES:

24 (a) (I) "BULK DRUG SUBSTANCE" OR "ACTIVE PHARMACEUTICAL
25 INGREDIENT" MEANS A SUBSTANCE THAT IS INTENDED FOR
26 INCORPORATION INTO A FINISHED DRUG PRODUCT AND IS INTENDED TO
27 PROMOTE PHARMACOLOGICAL ACTIVITY OR OTHER DIRECT EFFECTS IN THE

1 DIAGNOSIS, CURE, MITIGATION, TREATMENT, OR PREVENTION OF DISEASE
2 OR TO AFFECT THE STRUCTURE OR FUNCTION OF THE BODY.

3 (II) "BULK DRUG SUBSTANCE" DOES NOT INCLUDE INTERMEDIATES
4 USED IN THE SYNTHESIS OF THE SUBSTANCE.

5 (b) "COMPOUNDED WEIGHT-LOSS MEDICATION" MEANS A DRUG
6 THAT:

7 (I) IS CREATED BY COMBINING, MIXING, OR ALTERING OTHER
8 DRUGS OR BULK DRUG SUBSTANCES;

9 (II) IS INTENDED TO BE USED BY HUMANS FOR OBESITY OR WEIGHT
10 MANAGEMENT OR CONTAINS, OR CLAIMS TO CONTAIN, AN ACTIVE
11 INGREDIENT THAT IS NAMED IN A DRUG APPROVED BY THE FDA FOR
12 OBESITY OR WEIGHT MANAGEMENT; AND

13 (III) IS A GLUCAGON-LIKE PEPTIDE-1 RECEPTOR AGONIST DRUG,
14 ALSO KNOWN AS A "GLP-1 DRUG".

15 (c) "DRUG" HAS THE MEANING SET FORTH IN SECTION 12-280-103
16 (16).

17 (d) "FDA" MEANS THE FEDERAL FOOD AND DRUG
18 ADMINISTRATION.

19 (2) **Prohibited conduct.** A PERSON ENGAGES IN A DECEPTIVE
20 TRADE PRACTICE WHEN, IN THE COURSE OF THE PERSON'S BUSINESS,
21 VOCATION, OR OCCUPATION, THE PERSON:

22 (a) MAKES A FALSE OR MISLEADING CLAIM, INCLUDING AN
23 UNSUBSTANTIATED CLAIM, ABOUT A COMPOUNDED WEIGHT-LOSS
24 MEDICATION WHEN THE PERSON IS ADVERTISING OR OTHERWISE
25 PROMOTING THE COMPOUNDED WEIGHT-LOSS MEDICATION;

26 (b) DISTRIBUTES A COMPOUNDED WEIGHT-LOSS MEDICATION TO A
27 PERSON WHEN THE DISTRIBUTOR IS NOT LEGALLY AUTHORIZED TO

1 DISTRIBUTE OR TRANSFER THE BULK DRUG SUBSTANCES USED IN THE
2 COMPOUNDED WEIGHT-LOSS MEDICATION;

3 (c) MAKES A MATERIALLY FALSE OR MISLEADING REPRESENTATION
4 THAT THE COMPOUNDED WEIGHT-LOSS MEDICATION IS APPROVED BY THE
5 FDA WHEN THE COMPOUNDED WEIGHT-LOSS MEDICATION IS NOT
6 APPROVED BY THE FDA; OR

7 (d) MAKES A MATERIALLY FALSE, MISLEADING, OR UNVERIFIED
8 CLAIM REGARDING THE EFFICACY, SAFETY, COMPARATIVE PERFORMANCE,
9 CLINICAL OUTCOMES, OR OTHER THERAPEUTIC BENEFITS OF THE
10 COMPOUNDED WEIGHT-LOSS MEDICATION WHEN THE PERSON IS
11 ADVERTISING OR OTHERWISE PROMOTING THE COMPOUNDED WEIGHT-LOSS
12 MEDICATION.

13 **(3) Enforcement.**

14 (a) PURSUANT TO SECTION 6-1-105 (1)(qqqq), THE ATTORNEY
15 GENERAL MAY ENFORCE THIS SECTION AS A DECEPTIVE TRADE PRACTICE.

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17 (b) NOTWITHSTANDING SECTION 6-1-103, THE ATTORNEY GENERAL
18 HAS EXCLUSIVE AUTHORITY TO ENFORCE THIS SECTION PURSUANT TO THIS
19 ARTICLE 1.

20 (c) NOTWITHSTANDING ANY OTHER PROVISION OF THIS ARTICLE 1,
21 NOTHING IN THIS SECTION PROVIDES THE BASIS FOR, OR IS THE SUBJECT OF,
22 A PRIVATE RIGHT OF ACTION FOR A VIOLATION OF THIS SECTION.

23 **(4) Applicability. THIS SECTION DOES NOT APPLY TO:**

24 (a) THE COMPOUNDING OF A DRUG ADMINISTERED BY A
25 PRACTITIONER AT AN ENTITY LICENSED PURSUANT TO SECTION 25-1.5-103
26 (1)(a)(I)(A);

27 (b) A LONG-TERM CARE FACILITY, AS DEFINED IN SECTION

1 12-280-103 (25);

2 (c) AN ASSISTED LIVING RESIDENCE, AS DEFINED IN SECTION
3 25-27-102 (1.3);

4 (d) A HOME CARE AGENCY, AS DEFINED IN SECTION 25-27.5-102
5 (3);

6 (e) THE PACE PROGRAM, AS DESCRIBED IN SECTION 25.5-5-412;

7 (f) AN ADULT DAY CARE FACILITY, AS DEFINED IN SECTION
8 25.5-6-303 (1); OR

9 (g) THE COMPOUNDING OF A DRUG FOR ANIMAL USE.

10 SECTION 3. In Colorado Revised Statutes, 6-1-105, add
11 (1)(qqqq) as follows:

12 **6-1-105. Unfair or deceptive trade practices - definitions.**

13 (1) A person engages in a deceptive trade practice when, in the
14 course of the person's business, vocation, or occupation, the person:

15 (qqqq) VIOLATES SECTION 6-1-741.

16 **SECTION 4. Act subject to petition - effective date -**

17 **applicability.** (1) This act takes effect at 12:01 a.m. on the day following
18 the expiration of the ninety-day period after final adjournment of the
19 general assembly (August 12, 2026, if adjournment sine die is on May 13,
20 2026); except that, if a referendum petition is filed pursuant to section 1
21 (3) of article V of the state constitution against this act or an item, section,
22 or part of this act within such period, then the act, item, section, or part
23 will not take effect unless approved by the people at the general election
24 to be held in November 2026 and, in such case, will take effect on the
25 date of the official declaration of the vote thereon by the governor.

26 (2) This act applies to conduct occurring on or after the applicable
27 effective date of this act.