

**Second Regular Session
Seventy-fifth General Assembly
STATE OF COLORADO**

PREAMENDED

*This Unofficial Version Includes Committee
Amendments Not Yet Adopted on Second Reading*

LLS NO. 26-0540.01 Christopher McMichael x4775

SENATE BILL 26-066

SENATE SPONSORSHIP

Jodeh and Carson,

HOUSE SPONSORSHIP

(None),

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.*

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;

13 (d) The safety and integrity of compounded weight-loss
14 medications and their ingredients are paramount for the health and
15 well-being of patients in Colorado;

16 (e) Patients in Colorado deserve to have clear information
17 regarding the safety of compounded weight-loss medications and their
18 ingredients;

19 (f) Preserving the physician-patient relationship is critical to
20 health outcomes and protecting a prescriber's scope of care with
21 individual patients helps to ensure the health of Coloradans; and

22 (g) Therefore, the general assembly should take action to protect
23 Coloradans by requiring that compounded weight-loss medications are
24 sourced from FDA-registered and -inspected facilities and that those
25 medications contain safe and pharmaceutical-grade ingredients.

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

1 **6-1-741. Regulation of compounded weight-loss medication -**
2 **prohibited conduct - labeling requirements - deceptive advertising -**
3 **enforcement by attorney general - rules - definitions.**

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

6 **(a) (I) "BULK DRUG SUBSTANCE" OR "ACTIVE PHARMACEUTICAL**
7 **INGREDIENT" MEANS A SUBSTANCE THAT IS INTENDED FOR**
8 **INCORPORATION INTO A FINISHED DRUG PRODUCT AND IS INTENDED TO**
9 **PROMOTE PHARMACOLOGICAL ACTIVITY OR OTHER DIRECT EFFECTS IN THE**
10 **DIAGNOSIS, CURE, MITIGATION, TREATMENT, OR PREVENTION OF DISEASE**
11 **OR TO AFFECT THE STRUCTURE OR FUNCTION OF THE BODY.**

12 **(II) "BULK DRUG SUBSTANCE" DOES NOT INCLUDE INTERMEDIATES**
13 **USED IN THE SYNTHESIS OF THE SUBSTANCE.**

14 **(b) "COMPOUNDED WEIGHT-LOSS MEDICATION" MEANS A DRUG**
15 **THAT:**

16 **(I) IS CREATED BY COMBINING, MIXING, OR ALTERING OTHER**
17 **DRUGS OR BULK DRUG SUBSTANCES;**

18 **(II) IS INTENDED TO BE USED BY HUMANS FOR OBESITY OR WEIGHT**
19 **MANAGEMENT OR CONTAINS, OR CLAIMS TO CONTAIN, AN ACTIVE**
20 **INGREDIENT THAT IS NAMED IN A DRUG APPROVED BY THE FDA FOR**
21 **OBESITY OR WEIGHT MANAGEMENT; AND**

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

24 **(c) "DRUG" HAS THE MEANING SET FORTH IN SECTION 12-280-103**
25 **(16).**

26 **(d) "FDA" MEANS THE FEDERAL FOOD AND DRUG**
27 **ADMINISTRATION.**

1 (2) Prohibited conduct.

2 (a) A PERSON SHALL NOT ENGAGE IN THE SALE, TRANSFER, OR
3 DISTRIBUTION OF A COMPOUNDED WEIGHT-LOSS MEDICATION
4 COMPOUNDED UNDER SECTION 503A OF THE "FEDERAL FOOD, DRUG, AND
5 COSMETIC ACT", 21 U.S.C. SEC. 353a, UNLESS THE PERSON COMPOUNDING
6 THE WEIGHT-LOSS MEDICATION:

7 (I) USES BULK DRUG SUBSTANCES THAT:

8 (A) COMPLY WITH THE STANDARDS OF AN APPLICABLE UNITED
9 STATES PHARMACOPEIA OR NATIONAL FORMULARY MONOGRAPH, IF A
10 MONOGRAPH EXISTS, AND THE UNITED STATES PHARMACOPEIA CHAPTER
11 ON PHARMACY COMPOUNDING;

12 (B) IF A NATIONAL FORMULARY MONOGRAPH DOES NOT EXIST, ARE
13 COMPONENTS OF DRUGS APPROVED BY THE FDA; OR

14 (C) IF A NATIONAL FORMULARY MONOGRAPH DOES NOT EXIST AND
15 THE BULK DRUG SUBSTANCES ARE NOT COMPONENTS OF DRUGS APPROVED
16 BY THE FDA, APPEAR ON THE LIST DEVELOPED BY THE SECRETARY OF THE
17 FEDERAL DEPARTMENT OF HEALTH AND HUMAN SERVICES PURSUANT TO
18 21 U.S.C. SEC. 353a (b)(1)(A)(i)(III);

19 (II) CONFIRMS THAT, IF A BULK DRUG SUBSTANCE IS USED IN
20 ACCORDANCE WITH SUBSECTION (2)(a)(I)(B) OF THIS SECTION, THE BULK
21 DRUG SUBSTANCE WAS REVIEWED AS PART OF A NEW DRUG APPLICATION
22 THAT THE FDA HAS APPROVED PURSUANT TO SECTION 505 OF THE
23 "FEDERAL FOOD, DRUG, AND COSMETIC ACT", 21 U.S.C. SEC. 355;

24 (III) VERIFIES THAT THE BULK DRUG SUBSTANCES IN THE
25 COMPOUNDED WEIGHT-LOSS MEDICATION ARE HUMAN
26 PHARMACEUTICAL-GRADE PRODUCTS;

27 (IV) VERIFIES THAT THE BULK DRUG SUBSTANCES IN THE

1 COMPOUNDED WEIGHT-LOSS MEDICATION HAVE A VALID CERTIFICATE OF
2 ANALYSIS, INCLUDING THE IDENTIFICATION AND PURITY OF THOSE BULK
3 DRUG SUBSTANCES AND THE IDENTIFICATION OF EACH IMPURITY BY
4 CHEMICAL NAME AND AMOUNT PRESENT;

5 (V) VERIFIES THAT THE BULK DRUG SUBSTANCES IN THE
6 COMPOUNDED WEIGHT-LOSS MEDICATION WERE MANUFACTURED BY A
7 MANUFACTURER THAT IS REGISTERED WITH THE FDA IN ACCORDANCE
8 WITH 21 U.S.C. SEC. 360; AND

9 (VI) VERIFIES THAT THE BULK DRUG SUBSTANCES IN THE
10 COMPOUNDED WEIGHT-LOSS MEDICATION WERE MANUFACTURED BY A
11 MANUFACTURER THAT HAS BEEN INSPECTED BY THE FDA AS A HUMAN
12 DRUG ESTABLISHMENT AND THE INSPECTION CONFIRMED THAT THE
13 MANUFACTURER WAS:

14 (A) IN COMPLIANCE WITH CURRENT GOOD MANUFACTURING
15 PRACTICE REQUIREMENTS THAT COVERED THE BULK DRUG SUBSTANCES;
16 AND

17 (B) CLASSIFIED AS "VOLUNTARY ACTION INDICATED" OR "NO
18 ACTION INDICATED" BY THE FDA.

19 (b) BEFORE A COMPOUNDED WEIGHT-LOSS MEDICATION
20 CONTAINING A BULK DRUG SUBSTANCE IS OFFERED FOR SALE IN THE STATE,
21 THE MANUFACTURER OR WHOLESALER OF THE COMPOUNDED WEIGHT-LOSS
22 MEDICATION SHALL CONDUCT AND DOCUMENT QUALITY CONTROL TESTING
23 OF THE BULK DRUG SUBSTANCE PRIOR TO USING THE BULK DRUG
24 SUBSTANCE IN THE COMPOUNDED WEIGHT-LOSS MEDICATION, WHICH
25 TESTING MUST CONFIRM:

26 (I) THE IDENTITY AND CONTENT OF THE BULK DRUG SUBSTANCE;
27 AND

1 (II) THAT ANY IMPURITIES PRESENT IN THE BULK DRUG SUBSTANCE
2 ARE IDENTIFIED, CHARACTERIZED, QUANTIFIED, AND JUSTIFIED GIVEN THE
3 PRODUCT AND ITS INTENDED USE.

4 (c) A PERSON THAT COMPOUNDS, SELLS, DISTRIBUTES, OR
5 TRANSFERS A COMPOUNDED WEIGHT-LOSS MEDICATION SHALL NOT:

6 (I) DISTRIBUTE A COMPOUNDED WEIGHT-LOSS MEDICATION TO A
7 PERSON WHEN THE DISTRIBUTOR IS NOT LEGALLY AUTHORIZED TO
8 DISTRIBUTE OR TRANSFER THE BULK DRUG SUBSTANCES USED IN THE
9 COMPOUNDED WEIGHT-LOSS MEDICATION;

10 (II) DISTRIBUTE, DISPENSE, OR ADMINISTER A COMPOUNDED
11 WEIGHT-LOSS MEDICATION THAT IS COUNTERFEIT, ADULTERATED,
12 MISBRANDED, DIVERTED, OR OTHERWISE IN VIOLATION OF FEDERAL OR
13 STATE LAW;

14 (III) FAIL TO MAINTAIN REASONABLE SAFEGUARDS TO PREVENT
15 CONTAMINATION, DIVERSION, THEFT, OR MISUSE OF THE COMPOUNDED
16 WEIGHT-LOSS MEDICATION IN VIOLATION OF APPLICABLE FEDERAL OR
17 STATE LAW;

18 (IV) SHIP OR DISTRIBUTE FINISHED COMPOUNDED WEIGHT-LOSS
19 MEDICATION OR ACTIVE PHARMACEUTICAL INGREDIENTS TO A PERSON NOT
20 LEGALLY AUTHORIZED UNDER FEDERAL OR STATE LAW TO RECEIVE,
21 COMPOUND, MANUFACTURE, DISTRIBUTE, OR DISPENSE SUCH DRUGS;

22 (V) MAKE A MATERIALLY FALSE OR MISLEADING REPRESENTATION
23 THAT THE COMPOUNDED WEIGHT-LOSS MEDICATION IS APPROVED BY THE
24 FDA WHEN THE COMPOUNDED WEIGHT-LOSS MEDICATION IS NOT
25 APPROVED BY THE FDA;

26 (VI) MAKE A MATERIALLY FALSE, MISLEADING, OR UNVERIFIED
27 CLAIM REGARDING THE EFFICACY, SAFETY, COMPARATIVE PERFORMANCE,

1 CLINICAL OUTCOMES, OR OTHER THERAPEUTIC BENEFITS OF THE
2 COMPOUNDED WEIGHT-LOSS MEDICATION; OR

3 (VII) REPRESENT DIRECTLY OR BY IMPLICATION THAT THE
4 COMPOUNDED WEIGHT-LOSS MEDICATION HAS SUPERIOR EFFICACY OR
5 SAFETY COMPARED TO ANOTHER MEDICALLY APPROPRIATE PRODUCT,
6 UNLESS THAT SUPERIORITY HAS BEEN DEMONSTRATED BY
7 WELL-CONTROLLED CLINICAL STUDIES AND IS SUPPORTED BY COMPETENT
8 SCIENTIFIC EVIDENCE.

9 **(3) Labeling requirements.**

10 (a) THE LABEL OF A COMPOUNDED WEIGHT-LOSS MEDICATION
11 MUST:

12 (I) LIST EACH OF THE ACTIVE INGREDIENTS IN THE MEDICATION
13 AND THE FOLLOWING INFORMATION ABOUT EACH INGREDIENT:

14 (A) THE ESTABLISHED NAME OF THE INGREDIENT; AND

15 (B) THE QUANTITY OR PROPORTION OF THE INGREDIENT; AND

16 (II) CONTAIN THE FOLLOWING STATEMENTS, PRINTED IN A CLEAR
17 AND CONSPICUOUS MANNER ON THE LABEL:

18 (A) "THIS IS A COMPOUNDED DRUG. COMPOUNDED DRUGS ARE NOT
19 APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION
20 AND HAVE NO EVIDENCE OF SAFETY OR EFFICACY."

21 (B) "THIS ITEM IS NOT FOR RESALE."

22 (b) A PERSON THAT SELLS, TRANSFERS, OR DISTRIBUTES A
23 COMPOUNDED WEIGHT-LOSS MEDICATION TO A PATIENT SHALL PROVIDE
24 THE PATIENT WITH THE FOLLOWING INFORMATION:

25 (I) ANY SIDE EFFECTS, ADVERSE REACTIONS, CONTRAINDICATIONS,
26 PRECAUTIONS, AND WARNINGS ASSOCIATED WITH THE COMPOUNDED
27 WEIGHT-LOSS MEDICATION; AND

1 (II) IF A COMPOUNDED WEIGHT-LOSS MEDICATION CONTAINS AN
2 ACTIVE INGREDIENT THAT IS LISTED OR IS CLAIMED TO BE THE SAME AS AN
3 ACTIVE INGREDIENT IN A DRUG THAT IS APPROVED BY THE FDA, A
4 SUMMARY OF THE RISK INFORMATION DESCRIBED IN SUBSECTION (3)(b)(I)
5 OF THIS SECTION THAT IS ON THE LABEL OF THE FDA-APPROVED DRUG.

6 **(4) Deceptive advertising.**

7 (a) A PERSON SHALL NOT MAKE A FALSE OR MISLEADING CLAIM,
8 INCLUDING AN UNSUBSTANTIATED CLAIM, ABOUT A COMPOUNDED
9 WEIGHT-LOSS MEDICATION WHEN THE PERSON IS ADVERTISING OR
10 OTHERWISE PROMOTING THE COMPOUNDED WEIGHT-LOSS MEDICATION.

11 (b) A CLAIM ABOUT A COMPOUNDED WEIGHT-LOSS MEDICATION IS
12 CONSIDERED MISLEADING IF THE CLAIM DOES NOT INCLUDE:

13 (I) A DISCLOSURE OF THE POTENTIAL SIDE EFFECTS, ADVERSE
14 REACTIONS, CONTRAINDICATIONS, PRECAUTIONS, AND WARNINGS
15 ASSOCIATED WITH ACTIVE INGREDIENTS IN THE COMPOUNDED
16 WEIGHT-LOSS MEDICATION;

17 (II) A SUMMARY OF THE SPECIFIED RISK INFORMATION FOR AN
18 ACTIVE INGREDIENT OF THE COMPOUNDED WEIGHT-LOSS MEDICATION
19 THAT IS LISTED OR CLAIMED TO BE THE SAME AS AN ACTIVE INGREDIENT
20 IN AN FDA-APPROVED DRUG, WHICH RISK INFORMATION IS CONTAINED ON
21 THE LABEL OF THE FDA-APPROVED DRUG;

22 (III) A CLEAR, CONSPICUOUS STATEMENT THAT THE PRODUCT IS A
23 COMPOUNDED MEDICATION, HAS NOT BEEN APPROVED BY THE FDA AND
24 HAS NOT BEEN EVALUATED BY THE FDA FOR SAFETY OR EFFICACY; AND

25 (IV) A DISCLOSURE OF THE ENTITIES, SUCH AS SPECIFIC
26 PHARMACIES AND OUTSOURCING FACILITIES, THAT ARE USED TO
27 COMPOUND THE COMPOUNDED WEIGHT-LOSS MEDICATION.

1 **(5) Records and inspections.**

2 (a) (I) A PERSON THAT SELLS, TRANSFERS, OR DISTRIBUTES
3 COMPOUNDED WEIGHT-LOSS MEDICATION SHALL MAINTAIN ALL RECORDS
4 RELATED TO THE ACQUISITION, EXAMINATION, AND TESTING OF THE BULK
5 DRUG SUBSTANCES USED IN THE COMPOUNDED WEIGHT-LOSS MEDICATION
6 FOR AT LEAST TWO YEARS AFTER THE EXPIRATION DATE OF THE LAST LOT
7 OF COMPOUNDED WEIGHT-LOSS MEDICATION CONTAINING BULK DRUG
8 SUBSTANCES.

9 (II) IF THE ATTORNEY GENERAL REQUESTS RECORDS FROM A
10 PERSON THAT SELLS, TRANSFERS, OR DISTRIBUTES COMPOUNDED
11 WEIGHT-LOSS MEDICATION, THE PERSON SHALL PROVIDE SUCH RECORDS
12 TO THE ATTORNEY GENERAL WITHIN ONE BUSINESS DAY AFTER RECEIVING
13 THE REQUEST OR WITHIN ANOTHER REASONABLE TIME FRAME AS
14 DETERMINED BY THE ATTORNEY GENERAL BASED ON THE CIRCUMSTANCES
15 OF THE REQUEST.

16 (b) (I) TO DETERMINE COMPLIANCE WITH THIS SECTION, THE
17 ATTORNEY GENERAL MAY INSPECT THE PREMISES OF A PERSON THAT
18 ENGAGES IN THE COMPOUNDING OF WEIGHT-LOSS MEDICATION, INCLUDING
19 A DOMESTIC SUPPLIER, WHOLESALER, REPACKAGER, OR OTHER PROVIDER
20 OF BULK DRUG SUBSTANCES USED FOR COMPOUNDING WEIGHT-LOSS
21 MEDICATIONS.

22 (II) A PERSON THAT REFUSES TO COMPLY WITH AN INSPECTION
23 CONDUCTED PURSUANT TO SUBSECTION (5)(b)(I) OF THIS SECTION IS IN
24 VIOLATION OF THIS SECTION.

25 **(6) Enforcement.**

26 (a) IF THE ATTORNEY GENERAL DETERMINES THAT A PERSON HAS
27 VIOLATED THIS SECTION, THE ATTORNEY GENERAL MAY:

1 (I) ASSESS A FINE IN THE AMOUNT OF UP TO ONE THOUSAND
2 DOLLARS PER COMPOUND PACKAGE UNIT OR VIAL OF A COMPOUNDED
3 WEIGHT-LOSS MEDICATION THAT IS SOLD, OFFERED FOR SALE, DISPENSED,
4 TRANSFERRED, DISTRIBUTED, ADVERTISED, OR PROMOTED IN VIOLATION
5 OF THIS SECTION; OR

6 (II) PURSUE ANY OTHER REMEDY AVAILABLE UNDER THIS ARTICLE
7 1.

8 (b) NOTWITHSTANDING SECTION 6-1-103, THE ATTORNEY GENERAL
9 HAS EXCLUSIVE AUTHORITY TO ENFORCE THIS SECTION PURSUANT TO THIS
10 ARTICLE 1.

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

14 (7) **Applicability.** THIS SECTION DOES NOT APPLY TO:

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

18 (b) A LONG-TERM CARE FACILITY, AS DEFINED IN SECTION
19 12-280-103 (25); OR

20 (c) THE COMPOUNDING OF A DRUG FOR ANIMAL USE.

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

23 **SECTION 4. Safety clause.** The general assembly finds,
24 determines, and declares that this act is necessary for the immediate
25 preservation of the public peace, health, or safety or for appropriations for
26 the support and maintenance of the departments of the state and state
27 institutions.