Second Regular Session
Seventy-fifth General Assembly
STATE OF COLORADO

ENGROSSED

This Version Includes All Amendments Adopted on Second Reading 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

CONCERNING THE REGULATION OF COMPOUNDED WEIGHT-LOSS MEDICATIONS THAT HAVE NOT BEEN APPROVED BY THE UNITED 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

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-lost 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".

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(2) **Prohibited conduct.**

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

(I) USES BULK DRUG SUBSTANCES THAT:

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

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

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

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

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

(IV) VERIFIES THAT THE BULK DRUG SUBSTANCES IN THE

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(3) **Labeling requirements.**

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

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

(A) THE ESTABLISHED NAME OF THE INGREDIENT; AND

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

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

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

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

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

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

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

(4) **Deceptive advertising.**

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

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

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

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

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

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

(5) **Records and inspections.**

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

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

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

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

(6) **Enforcement.**

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

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

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

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

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

(7) **Applicability.**

(a) THIS SECTION APPLIES ONLY TO A PERSON THAT COMPOUNDS MORE THAN TWENTY UNITS OF WEIGHT-LOSS DRUGS PER MONTH OR COMPOUNDS WEIGHT-LOSS DRUGS IN BATCHES OF MORE THAN TWENTY UNITS.

(b) THIS SECTION DOES NOT APPLY TO:

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

(II) A LONG-TERM CARE FACILITY, AS DEFINED IN SECTION 12-280-103 (25);

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

(IV) A HOME CARE AGENCY, AS DEFINED IN SECTION 25-27.5-102

(3);

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

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

(VII) THE COMPOUNDING OF A DRUG FOR ANIMAL USE.

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

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