Second Regular Session
Seventy-fifth General Assembly
STATE OF COLORADO

INTRODUCED

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

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) 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 have been increasing attempts to circumvent these regulations by companies that develop, dispense, and market non-FDA-approved compounded medications, notably weight-loss drugs, which undermines public trust and patient safety;

(b) Compounded medications should only be prescribed and dispensed when a patient's medical needs cannot be met by drugs that have been approved by the FDA;

(c) Compounded weight-loss medications are not approved by the FDA and therefore do not carry the same assurances of safety and efficacy as FDA-approved products, resulting in increased risks to patients;

(d) Compounded weight-loss medications, such as compounded GLP-1 medications, have demonstrated that a high demand can lead to the proliferation of illicit, substandard, and potentially harmful pharmaceutical substances in weight-loss ingredients and medications, which jeopardizes patient health and safety;

(e) 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 FDA good manufacturing practice requirements, including compounded weight-loss medications made with ingredients that are imported into the United States from foreign countries with less stringent regulations;

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

(g) Patients in Colorado deserve to have clear information

regarding the origin and preparation of compounded weight-loss ingredients and medications;

(h) Even though FDA-approved GLP-1 medications are widely available, certain actors continue to violate federal and state laws by mass compounding products under the guise of personalization; and

(i) Therefore, the general assembly should take action to protect Coloradans by ensuring that compounded weight-loss medications are sourced from reputable, licensed, and inspected establishments and that those medications contain safe and pharmaceutical-grade ingredients.

SECTION 2. In Colorado Revised Statutes, **add** 12-280-120.5 as follows:

12-280-120.5. Regulation of compounded weight-loss medication - prohibited conduct - labeling requirements - deceptive advertising - enforcement - rules - definitions.

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

(a) (I) "BULK DRUG SUBSTANCE", ALSO REFERRED TO AS AN "ACTIVE PHARMACEUTICAL INGREDIENT", MEANS A SUBSTANCE THAT IS INTENDED FOR INCORPORATION INTO A FINISHED DRUG PRODUCT AND IS INTENDED TO FURNISH 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 IS:

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

(II) INTENDED TO BE USED BY HUMANS FOR WEIGHT LOSS.

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

(a) USES BULK DRUG SUBSTANCES THAT:

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

(II) IF A MONOGRAPH FOR ANY OF THE BULK DRUG SUBSTANCES DOES NOT EXIST, ARE COMPONENTS OF A DRUG APPROVED BY THE FDA; OR

(III) IF A MONOGRAPH FOR ANY OF THE BULK DRUG SUBSTANCES DOES NOT EXIST AND THE BULK DRUG SUBSTANCE IS NOT A COMPONENT OF A DRUG APPROVED BY THE FDA, ARE ON THE LIST DEVELOPED BY THE FDA PURSUANT TO 21 U.S.C. SEC. 353a (b)(1)(A)(i)(III);

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

(c) CONFIRMS THAT THE BULK DRUG SUBSTANCES IN THE

COMPOUNDED WEIGHT-LOSS MEDICATION ARE HUMAN PHARMACEUTICAL-GRADE PRODUCTS;

(d) VERIFIES THAT THE BULK DRUG SUBSTANCES IN THE COMPOUNDED WEIGHT- LOSS MEDICATION HAVE A VALID CERTIFICATE OF ANALYSIS CONTAINING INFORMATION MATERIAL TO THE SAFETY AND EFFECTIVENESS OF THE DRUGS MADE FROM THE BULK DRUG SUBSTANCES THAT ARE USED IN THE COMPOUNDED WEIGHT-LOSS MEDICATION, INCLUDING THE IDENTIFICATION AND PURITY OF THOSE BULK DRUG SUBSTANCES;

(e) OBTAINS PROOF THAT THE BULK DRUG SUBSTANCES USED IN THE COMPOUNDED WEIGHT-LOSS MEDICATION WERE MANUFACTURED BY A MANUFACTURER THAT:

(I) IS REGISTERED WITH THE FDA IN ACCORDANCE WITH 21 U.S.C. SEC. 360; AND

(II) HAS BEEN INSPECTED BY THE FDA AS A HUMAN DRUG ESTABLISHMENT WITHIN THE PREVIOUS TWO YEARS FROM THE DATE ON WHICH THE COMPOUNDED WEIGHT-LOSS MEDICATION WAS COMPOUNDED AND THE INSPECTION:

(A) INCLUDED CURRENT GOOD MANUFACTURING PRACTICE REQUIREMENTS COMPLIANCE RELEVANT TO THE BULK DRUG SUBSTANCES; AND

(B) WAS CLASSIFIED AS "VOLUNTARY ACTION INDICATED" OR "NO ACTION INDICATED" BY THE FDA; AND

(f) CONDUCTS AND DOCUMENTS QUALITY CONTROL TESTING OF A BULK DRUG SUBSTANCE PRIOR TO USING THE BULK DRUG SUBSTANCE IN A COMPOUNDED WEIGHT- LOSS MEDICATION, WHICH TESTING CONFIRMS:

(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.

(3) **Labeling requirements.**

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

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

(A) THE ESTABLISHED NAME OF THE INGREDIENT;

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

(C) THE COUNTRY OF ORIGIN 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, HAVE NO EVIDENCE OF SAFETY OR EFFICACY, AND HAVE KNOWN AND UNKNOWN POTENTIAL SIDE EFFECTS."

(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, INCLUDING ANY SIDE EFFECTS, REACTIONS, CONTRAINDICATIONS, PRECAUTIONS, OR WARNINGS NOTED FROM CLINICAL

TRIALS, RESEARCH, OR OTHER APPROPRIATE INFORMATION SOURCES; AND

(II) IF A COMPOUNDED WEIGHT-LOSS MEDICATION CONTAINS AN ACTIVE INGREDIENT THAT IS LISTED 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 CONTAINED IN THE LABELING INFORMATION FOR 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, INCLUDING ANY SIDE EFFECTS, ADVERSE REACTIONS, CONTRAINDICATIONS, PRECAUTIONS, AND WARNINGS NOTED IN CLINICAL TRIALS, RESEARCH, OR OTHER APPROPRIATE INFORMATION SOURCES;

(II) A SUMMARY OF THE SPECIFIED RISK INFORMATION FOR AN ACTIVE INGREDIENT OF THE COMPOUNDED WEIGHT-LOSS MEDICATION THAT IS NAMED AS AN ACTIVE INGREDIENT IN AN FDA-APPROVED DRUG, WHICH RISK INFORMATION IS CONTAINED IN THE LABELING OF THE FDA-APPROVED DRUG;

(III) A CLEAR, CONSPICUOUS STATEMENT THAT THE PRODUCT IS A COMPOUNDED MEDICATION, HAS NOT BEEN APPROVED BY THE FDA, HAS

INADEQUATE EVIDENCE OF SAFETY AND EFFICACY, AND HAS POTENTIAL UNKNOWN SIDE EFFECTS; 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 BOARD REQUESTS RECORDS FROM A PERSON THAT SELLS, TRANSFERS, OR DISTRIBUTES COMPOUNDED WEIGHT-LOSS MEDICATION, THE PERSON SHALL PROVIDE SUCH RECORDS TO THE BOARD WITHIN ONE BUSINESS DAY AFTER RECEIVING THE REQUEST, OR WITHIN ANOTHER REASONABLE TIME AS DETERMINED BY THE BOARD BASED ON THE CIRCUMSTANCES OF THE REQUEST.

(b) (I) TO DETERMINE COMPLIANCE WITH THIS SECTION, THE BOARD MAY INSPECT THE BUSINESS RECORDS AND PREMISES OF ANY PERSON THAT ENGAGES IN THE COMPOUNDING OF COMPOUNDED WEIGHT-LOSS MEDICATION, INCLUDING ANY DOMESTIC SUPPLIER, WHOLESALER, REPACKAGER, OR OTHER PROVIDER OF BULK DRUG SUBSTANCES USED FOR COMPOUNDED WEIGHT-LOSS MEDICATION.

(II) A PERSON THAT REFUSES TO COMPLY WITH AN INSPECTION BY THE BOARD VIOLATES THIS SECTION.

(6) **Enforcement.**

(a) IF THE BOARD DETERMINES THAT A PERSON VIOLATES THIS SECTION, THE BOARD MAY:

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

(II) REVOKE THE PERSON'S PHARMACY OR BUSINESS LICENSE ISSUED IN ACCORDANCE WITH THIS ARTICLE 280.

(b) NOTWITHSTANDING SECTION 6-1-103, THE ATTORNEY GENERAL MAY ENFORCE THIS SECTION AS A DECEPTIVE TRADE PRACTICE PURSUANT TO SECTIONS 6-1-105 (1)(e) AND 6-1-105 (1)(qqqq).

(7) **Rules.** THE BOARD MAY ADOPT RULES NECESSARY TO IMPLEMENT THIS SECTION.

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

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

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

(qqqq) VIOLATES SECTION 12-280-120.5.

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

SECTION 5. 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.