Legislative Council Staff
Nonpartisan Services for Colorado's Legislature

Fiscal Note Memorandum

TO: Members of the Senate Health and Human Services Committee

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Fiscal Assessment of L.003 to SB26-066

This memorandum is an assessment of the fiscal impact of the attached proposed amendment L.003 to SB26-066. This fiscal assessment is for the impact of the bill with inclusion of this amendment only. Any other added amendment could influence the fiscal impact.

Summary of Proposed Amendment

Amendment L.003 strikes everything in the bill below the enacting clause and places new requirements on compounded versions of weight-loss medication produced by 503A compounding pharmacies. Specifically, the amendment requires a person involved in the sale, transfer, or distribution of a weight-loss medication compounded under Section 503A of the Federal Food, Drug, and Cosmetic Act to:

- use bulk drug substances that comply with certain national standards and that have been tested for quality control;
- label the drug as a compounded drugs not approved by the FDA and not for resale; and
- list all ingredients and specific information about them, including the country of origin.

Additionally, Amendment L.003 places disclosure requirements on persons compounding weight-loss medication, specifies recordkeeping requirements and inspection procedures, and gives the Attorney General authority to inspect records. Violations are a deceptive trade practice.

The requirements of L.003 do not apply to the compounding of a drug administered by a practitioner at a licensed health facilities or a long-term care facility, or to drugs compounded for animal use.

Fiscal Impact of Amendment

Strike-below Amendment L.003 eliminates the expenditure and revenue impacts to the Division of Professions and Occupations in the Department of Regulatory Agencies shown in the published fiscal note dated March 3, 2026. Instead, the amendment will minimally increase state revenue and agency workload from creation of a new deceptive trade practice, as outlined in the section below.

Bill's Revised Fiscal Impact with Amendment

State Revenue

Strike-below Amendment L.003 increases state revenue from fees and penalties by a minimal amount, as discussed below.

Civil Penalties

Under the Colorado Consumer Protection Act, a person committing a deceptive trade practice may be subject to a civil penalty of up to $20,000 for each violation. Additional penalties may be imposed for subsequent violations of a court order or injunction. This revenue is classified as a damage award and not subject to TABOR. Given the uncertainty about the number of cases that may be pursued by the Attorney General and district attorneys, as well as the wide range in potential penalty amounts, the fiscal note cannot estimate the potential impact of these civil penalties.

Filing Fees

To the extent that the amended bill results in more civil filings with the trial courts, fee revenue to the Judicial Department may increase by a minimal amount. Revenue from filing fees is subject to TABOR.

State Expenditures

Strike-below Amendment L.003 minimally increases workload for the Department of Law and the Judicial Department, as discussed below.

Department of Law

With Amendment L.003, workload in the Department of Law will minimally increase to the extent that deceptive trade practice complaints are filed. The department will review complaints under the bill and prioritize investigations as necessary within the overall number of deceptive trade practice complaints and available resources.

Judicial Department

Amendment L.003 will increase workload for the trial courts in the Judicial Department to handle any cases filed under the Colorado Consumer Protection Act from the addition of a new deceptive trade practice. It is assumed that persons compounding drugs as allowed by the bill will abide by the law and that any violation of the legislation will result in minimal number of new cases; no change in appropriations is required.

Local Government

Similar to the state, to the extent district attorneys receive complaints related to the new deceptive trade practice under the bill, workload will increase to investigate complaints and seek relief when appropriate. It is assumed most such cases will be handled at the state level by the Attorney General.

Table 1
State Fiscal Impacts with Amendment L.003

Type of Impact	Budget Year FY 2025-26	Out Year FY 2026-27
State Revenue	$0	$0
State Expenditures	$0	$0
Transferred Funds	$0	$0
Change in TABOR Refunds	$0	$0
Change in State FTE	0.0 FTE	0.0 FTE

SB066_L.003

SENATE COMMITTEE OF REFERENCE AMENDMENT

Committee on Health & Human Services.

SB26-066 be amended as follows:

Amend printed bill, strike everything below the enacting clause and substitute:

"**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 AS A DECEPTIVE TRADE PRACTICE 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 OR A VIOLATION OF THIS ARTICLE 1.

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

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

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

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

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) FAILS TO COMPLY WITH SECTION 6-1-741.

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.".

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