

SENATE COMMITTEE OF REFERENCE REPORT

Chair of Committee

March 5, 2026
Date

Committee on Health & Human Services.

After consideration on the merits, the Committee recommends the following:

SB26-066 be amended as follows, and as so amended, be referred to the Committee of the Whole with favorable recommendation:

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

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

5 (a) Compounding pharmacies play an important role in the United
6 States drug supply chain and allow patients to receive life-saving or
7 life-improving medication when the commercial market is unable to
8 support patients' needs;

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

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

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

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

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

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

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

7 **6-1-741. Regulation of compounded weight-loss medication -**
8 **prohibited conduct - labeling requirements - deceptive advertising -**
9 **enforcement by attorney general - rules - definitions.**

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

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

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

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

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

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

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

30 (c) "DRUG" HAS THE MEANING SET FORTH IN SECTION 12-280-103
31 (16).

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

34 (2) **Prohibited conduct.**

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

40 (I) USES BULK DRUG SUBSTANCES THAT:

41 (A) COMPLY WITH THE STANDARDS OF AN APPLICABLE UNITED
42 STATES PHARMACOPEIA OR NATIONAL FORMULARY MONOGRAPH, IF A
43 MONOGRAPH EXISTS, AND THE UNITED STATES PHARMACOPEIA CHAPTER

1 ON PHARMACY COMPOUNDING;

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

4 (C) IF A NATIONAL FORMULARY MONOGRAPH DOES NOT EXIST AND
5 THE BULK DRUG SUBSTANCES ARE NOT COMPONENTS OF DRUGS APPROVED
6 BY THE FDA, APPEAR ON THE LIST DEVELOPED BY THE SECRETARY OF THE
7 FEDERAL DEPARTMENT OF HEALTH AND HUMAN SERVICES PURSUANT TO
8 21 U.S.C. SEC. 353a (b)(1)(A)(i)(III);

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

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

17 (IV) VERIFIES THAT THE BULK DRUG SUBSTANCES IN THE
18 COMPOUNDED WEIGHT-LOSS MEDICATION HAVE A VALID CERTIFICATE OF
19 ANALYSIS, INCLUDING THE IDENTIFICATION AND PURITY OF THOSE BULK
20 DRUG SUBSTANCES AND THE IDENTIFICATION OF EACH IMPURITY BY
21 CHEMICAL NAME AND AMOUNT PRESENT;

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

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

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

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

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

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

1 AND

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

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

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

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

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

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

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

27 (VI) MAKE A MATERIALLY FALSE, MISLEADING, OR UNVERIFIED
28 CLAIM REGARDING THE EFFICACY, SAFETY, COMPARATIVE PERFORMANCE,
29 CLINICAL OUTCOMES, OR OTHER THERAPEUTIC BENEFITS OF THE
30 COMPOUNDED WEIGHT-LOSS MEDICATION; OR

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

37 (3) **Labeling requirements.**

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

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

42 (A) THE ESTABLISHED NAME OF THE INGREDIENT; AND
43 (B) THE QUANTITY OR PROPORTION OF THE INGREDIENT; AND

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

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

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

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

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

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

18 (4) **Deceptive advertising.**

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

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

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

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

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

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

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

41 (a) (I) A PERSON THAT SELLS, TRANSFERS, OR DISTRIBUTES
42 COMPOUNDED WEIGHT-LOSS MEDICATION SHALL MAINTAIN ALL RECORDS
43 RELATED TO THE ACQUISITION, EXAMINATION, AND TESTING OF THE BULK

1 DRUG SUBSTANCES USED IN THE COMPOUNDED WEIGHT-LOSS MEDICATION
2 FOR AT LEAST TWO YEARS AFTER THE EXPIRATION DATE OF THE LAST LOT
3 OF COMPOUNDED WEIGHT-LOSS MEDICATION CONTAINING BULK DRUG
4 SUBSTANCES.

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

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

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

21 (6) **Enforcement.**

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

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

29 (II) PURSUE ANY OTHER REMEDY AVAILABLE UNDER THIS ARTICLE
30 1.

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

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

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

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

41 (b) A LONG-TERM CARE FACILITY, AS DEFINED IN SECTION
42 12-280-103 (25); OR

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

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

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

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