

SENATE COMMITTEE OF REFERENCE AMENDMENT

Committee on Health & Human Services.

SB26-066 be amended as follows:

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

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

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

34 **6-1-741. Regulation of compounded weight-loss medication -**
35 **prohibited conduct - labeling requirements - deceptive advertising -**
36 **enforcement by attorney general - rules - definitions.**

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

39 (a) (I) "BULK DRUG SUBSTANCE" OR "ACTIVE PHARMACEUTICAL
40 INGREDIENT" MEANS A SUBSTANCE THAT IS INTENDED FOR

1 INCORPORATION INTO A FINISHED DRUG PRODUCT AND IS INTENDED TO
2 PROMOTE PHARMACOLOGICAL ACTIVITY OR OTHER DIRECT EFFECTS IN THE
3 DIAGNOSIS, CURE, MITIGATION, TREATMENT, OR PREVENTION OF DISEASE
4 OR TO AFFECT THE STRUCTURE OR FUNCTION OF THE BODY.

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

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

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

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

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

17 (c) "DRUG" HAS THE MEANING SET FORTH IN SECTION 12-280-103
18 (16).

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

21 (2) **Prohibited conduct.**

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

27 (I) USES BULK DRUG SUBSTANCES THAT:

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

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

34 (C) IF A NATIONAL FORMULARY MONOGRAPH DOES NOT EXIST AND
35 THE BULK DRUG SUBSTANCES ARE NOT COMPONENTS OF DRUGS APPROVED
36 BY THE FDA, APPEAR ON THE LIST DEVELOPED BY THE SECRETARY OF THE
37 FEDERAL DEPARTMENT OF HEALTH AND HUMAN SERVICES PURSUANT TO
38 21 U.S.C. SEC. 353a (b)(1)(A)(i)(III);

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

44 (III) VERIFIES THAT THE BULK DRUG SUBSTANCES IN THE
45 COMPOUNDED WEIGHT-LOSS MEDICATION ARE HUMAN

1 PHARMACEUTICAL-GRADE PRODUCTS;

2 (IV) VERIFIES THAT THE BULK DRUG SUBSTANCES IN THE
3 COMPOUNDED WEIGHT-LOSS MEDICATION HAVE A VALID CERTIFICATE OF
4 ANALYSIS, INCLUDING THE IDENTIFICATION AND PURITY OF THOSE BULK
5 DRUG SUBSTANCES AND THE IDENTIFICATION OF EACH IMPURITY BY
6 CHEMICAL NAME AND AMOUNT PRESENT;

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

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

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

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

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

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

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

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

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

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

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

1 STATE LAW;

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

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

10 (VI) MAKE A MATERIALLY FALSE, MISLEADING, OR UNVERIFIED
11 CLAIM REGARDING THE EFFICACY, SAFETY, COMPARATIVE PERFORMANCE,
12 CLINICAL OUTCOMES, OR OTHER THERAPEUTIC BENEFITS OF THE
13 COMPOUNDED WEIGHT-LOSS MEDICATION; OR

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

20 (3) **Labeling requirements.**

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

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

25 (A) THE ESTABLISHED NAME OF THE INGREDIENT; AND
26 (B) THE QUANTITY OR PROPORTION OF THE INGREDIENT; AND

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

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

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

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

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

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

44 (4) **Deceptive advertising.**

45 (a) A PERSON SHALL NOT MAKE A FALSE OR MISLEADING CLAIM,

1 INCLUDING AN UNSUBSTANTIATED CLAIM, ABOUT A COMPOUNDED
2 WEIGHT-LOSS MEDICATION WHEN THE PERSON IS ADVERTISING OR
3 OTHERWISE PROMOTING THE COMPOUNDED WEIGHT-LOSS MEDICATION.

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

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

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

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

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

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

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

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

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

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

45 (6) **Enforcement.**

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

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

8 (II) PURSUE ANY OTHER REMEDY AVAILABLE UNDER THIS ARTICLE
9 1.

10 (b) NOTWITHSTANDING SECTION 6-1-103, THE ATTORNEY GENERAL
11 HAS EXCLUSIVE AUTHORITY TO ENFORCE THIS SECTION AS A DECEPTIVE
12 TRADE PRACTICE PURSUANT TO THIS ARTICLE 1.

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

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

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

21 (b) A LONG-TERM CARE FACILITY, AS DEFINED IN SECTION
22 12-280-103 (25); OR

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

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

26 **6-1-105. Unfair or deceptive trade practices - definitions.**

27 (1) A person engages in a deceptive trade practice when, in the
28 course of the person's business, vocation, or occupation, the person:
29 (qqqq) FAILS TO COMPLY WITH SECTION 6-1-741.

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

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

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