

HOUSE COMMITTEE OF REFERENCE REPORT

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Chairman of Committee

March 8, 2012  
Date

Committee on Health and Environment.

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

HB12-1311 be amended as follows, and as so amended, be referred to the Committee on Finance with favorable recommendation:

1 Amend printed bill, page 5, line 13, strike "part 1," and substitute "~~part 1~~  
2 ARTICLE,".

3 Page 5, line 15, strike "part 1 shall be" and substitute "~~part 1 shall be~~  
4 ARTICLE".

5 Page 6, after line 10 insert:

6 "(3.5) [**Formerly 12-22-801 (1) (b)**] "Authorized distributor of  
7 record" means a wholesaler with whom a manufacturer has established an  
8 ongoing relationship to distribute the manufacturer's prescription drug.  
9 FOR PURPOSES OF THIS SUBSECTION (3.5), an ongoing relationship is  
10 deemed to exist between a wholesaler and a manufacturer when the  
11 wholesaler, including any affiliated group of the wholesaler as defined in  
12 section 1504 of the federal "Internal Revenue Code of 1986", complies  
13 with the following:

14 ~~(H)~~ (a) The wholesaler has a written agreement currently in effect  
15 with the manufacturer evidencing such ongoing relationship; and

16 ~~(H)~~ (b) The wholesaler is listed on the manufacturer's current list  
17 of authorized distributors of record, which list is updated by the  
18 manufacturer on no less than a monthly basis."

19 Page 6, after line 21 insert:

20 "(6.5) [**Formerly 12-22-801 (1) (d)**] "Chain pharmacy

1 warehouse" means a physical location for prescription drugs that acts  
2 SERVES as a central warehouse and performs intracompany sales or  
3 transfers of such PRESCRIPTION drugs to a group of chain pharmacies or  
4 other chain pharmacy warehouses that are under common ownership or  
5 control. Notwithstanding any other provision of this ~~part 8~~ ARTICLE, a  
6 chain pharmacy warehouse receiving distributions on behalf of, or  
7 making distributions to, an intracompany pharmacy is ~~not required to~~  
8 NEED NOT be an authorized distributor of record to be ~~considered~~ part of  
9 the normal distribution channel."

10 Page 8, line 19, strike ""INPATIENT HOSPITAL" and substitute  
11 ""HOSPITAL".

12 Page 8, line 20, strike "IS ELIGIBLE TO REGISTER" and substitute  
13 "REGISTERS".

14 Page 8, strike line 21 and substitute "12-42.5-117 (10) FOR THE PURPOSE  
15 OF ADMINISTRATION OF DRUGS TO PATIENTS WHILE BEING TREATED IN THE  
16 FACILITY."

17 Page 8, line 22, strike "who is attending, or who is in" and substitute  
18 "who is: ~~attending, or who is in~~".

19 Page 8, strike lines 23 through 25 and substitute "~~good standing with, an~~  
20 ~~accredited school of pharmacy, who has graduated from an accredited~~  
21 ~~school of pharmacy and is completing an internship to satisfy board~~  
22 ~~requirements for licensure, or who is licensed~~

23 (a) (I) ENROLLED IN A PROFESSIONAL DEGREE PROGRAM OF A  
24 SCHOOL OR COLLEGE OF PHARMACY THAT HAS BEEN APPROVED BY THE  
25 BOARD;

26 (II) CURRENTLY LICENSED BY THE BOARD TO ENGAGE IN THE  
27 PRACTICE OF PHARMACY; AND

28 (III) IS SATISFACTORILY PROGRESSING TOWARD MEETING THE  
29 REQUIREMENTS FOR LICENSURE AS A PHARMACIST;

30 (b) LICENSED AS A PHARMACIST IN COLORADO OR ANOTHER STATE  
31 OR TERRITORY OF THE UNITED STATES and in good".

32 Page 9, line 1, strike "board." and substitute "board;".

33 Page 9, after line 1 insert:

1           "(c) A GRADUATE OF AN APPROVED PROFESSIONAL DEGREE  
2 PROGRAM OF A SCHOOL OR COLLEGE OF PHARMACY OR A GRADUATE WHO  
3 HAS ESTABLISHED EDUCATION EQUIVALENCY BY OBTAINING A  
4 BOARD-APPROVED FOREIGN PHARMACY GRADUATE CERTIFICATION AND  
5 WHO IS CURRENTLY LICENSED BY THE BOARD FOR THE PURPOSE OF  
6 OBTAINING PRACTICAL EXPERIENCE AS A REQUIREMENT FOR LICENSURE AS  
7 A PHARMACIST; OR  
8           (d) A QUALIFIED APPLICANT AWAITING EXAMINATION FOR  
9 LICENSURE AS A PHARMACIST OR MEETING BOARD REQUIREMENTS FOR  
10 LICENSURE."

11 Page 9, after line 8 insert:

12           "(19.5) "LONG-TERM CARE FACILITY" MEANS A NURSING FACILITY,  
13 AS DEFINED IN SECTION 25.5-4-103 (14), C.R.S., THAT IS LICENSED  
14 PURSUANT TO SECTION 25-1.5-103, C.R.S."

15 Page 9, after line 14 insert:

16           "(20.5) [**Formerly 12-22-801 (1) (h)**] "Manufacturer's exclusive  
17 distributor" means ~~anyone~~ A PERSON who contracts with a manufacturer  
18 to provide or coordinate warehousing, distribution, or other services on  
19 behalf of a manufacturer and who takes title to the manufacturer's  
20 prescription drug but who does not have general responsibility to direct  
21 the sale or disposition of the manufacturer's prescription drug. ~~Such~~  
22 ~~manufacturer's exclusive distributor shall be licensed as a wholesaler~~  
23 ~~under this part 8 and~~, To be considered part of the normal distribution  
24 channel, AS DEFINED IN SECTION 12-42.5-301 (6), A MANUFACTURER'S  
25 EXCLUSIVE DISTRIBUTOR shall ~~also~~ be an authorized distributor of  
26 record."

27 Page 10, line 11, strike "hospital" and substitute "hospital, MEDICAL  
28 CLINIC OPERATED BY A HOSPITAL, AMBULATORY SURGICAL CENTER,  
29 HOSPICE,".

30 Page 10, line 17, strike "pharmacy;" and substitute "pharmacy,".

31 Page 10, strike lines 18 and 19 and substitute "any rural health clinic,  
32 FEDERALLY QUALIFIED HEALTH CENTER, AS DEFINED IN SECTION 1861 (aa)  
33 (4) OF THE FEDERAL "SOCIAL SECURITY ACT", 42 U.S.C. SEC. 1395x (aa)  
34 (4), family planning clinic, school, jail,".

1 Page 10, strike lines 21 through 24 and substitute "university, or college  
2 that:"

3 Page 10, strike line 27 and substitute "drugs or devices; OR  
4 (b) AN AMBULATORY SURGICAL CENTER LICENSED PURSUANT TO  
5 PART 1 OF ARTICLE 3 OF TITLE 25, C.R.S., A MEDICAL CLINIC OPERATED BY  
6 A HOSPITAL, OR A HOSPICE LICENSED PURSUANT TO PART 1 OF ARTICLE 3  
7 OF TITLE 25, C.R.S., THAT:

8 (I) HAS FACILITIES IN THIS STATE REGISTERED PURSUANT TO THIS  
9 ARTICLE; AND

10 (II) ENGAGES IN THE COMPOUNDING, DISPENSING, AND DELIVERY  
11 OF DRUGS OR DEVICES FOR ADMINISTRATION TO PATIENTS WHILE BEING  
12 TREATED IN THE FACILITY."

13 Page 11, after line 24 insert:

14 "(29.5) [~~Formerly 12-22-801 (1) (k)~~] "Pharmacy buying  
15 cooperative warehouse" means a permanent physical location that acts as  
16 a central warehouse for prescription drugs and from which sales of ~~such~~  
17 PRESCRIPTION drugs are made to an exclusive group of pharmacies that  
18 are members or member owners of the buying cooperative operating the  
19 warehouse. ~~that shall be licensed as a wholesaler."~~

20 Page 12, line 21, strike "that, prior" and substitute "that:

21 (a) IS REQUIRED BY ANY APPLICABLE FEDERAL OR STATE LAW OR  
22 RULE TO BE DISPENSED ONLY PURSUANT TO AN ORDER;

23 (b) IS RESTRICTED BY ANY APPLICABLE FEDERAL OR STATE LAW OR  
24 RULE TO USE BY PRACTITIONERS ONLY; OR

25 (c) Prior".

26 Page 12, line 22, after "required" insert "UNDER FEDERAL LAW" and after  
27 "with" insert "ONE OF".

28 Page 12, strike lines 23 and 24 and substitute "~~statement: "Caution:  
29 Federal law prohibits dispensing without a prescription."~~; STATEMENTS:

30 (I) "Rx only"; or

31 (II) "Caution: Federal law restricts this drug to".

32 Page 13, line 3, strike "12-42.5-118 (9)." and substitute "12-42.5-117 (9)  
33 OR SPECIALIZED PRESCRIPTION DRUG OUTLET REGISTERED PURSUANT TO  
34 SECTION 12-42.5-117 (11)."

1 Page 13, after line 6 insert:

2 "(36.3) [**Formerly 12-22-801 (1) (m)**] "Repackage" means  
3 repackaging or otherwise changing the container, wrapper, or labeling to  
4 further the distribution of a prescription drug, excluding that  
5 REPACKAGING OR LABELING completed by the pharmacist responsible for  
6 dispensing product to the patient.

7 (36.5) [**Formerly 12-22-801 (1) (n)**] "Repackager" means a  
8 person who repackages prescription drugs."

9 Page 14, strike lines 2 through 5 and substitute:

10 "(42) [**Formerly 12-22-801 (2)**] (a) ~~For the purposes of this part~~  
11 ~~8~~; "Wholesale distribution" means distribution of prescription drugs to  
12 persons or entities other than a consumer or patient.

13 (b) "Wholesale distribution" does not include:

14 ~~(a)~~ (I) Intracompany sales or transfers of prescription drugs,  
15 including a transaction or transfer between a division, subsidiary, parent,  
16 or affiliated or related company under common ownership or control of  
17 an entity;

18 ~~(b)~~ (II) The sale, purchase, distribution, trade, or transfer of a  
19 prescription drug or offer to sell, purchase, distribute, trade, or transfer a  
20 prescription drug for emergency medical reasons or during a state or  
21 national declaration of emergency;

22 ~~(c)~~ (III) The sale or transfer of a drug for medical reasons by a  
23 retail pharmacy to another retail pharmacy to alleviate a temporary  
24 shortage; ~~pursuant to Colorado law;~~

25 ~~(d)~~ (IV) The distribution of prescription drug samples by a  
26 manufacturer's representative;

27 ~~(e)~~ (V) Drug returns, when conducted by a hospital, health care  
28 entity, or charitable institution in accordance with 21 CFR 203.23;

29 ~~(f)~~ (VI) The sale of minimal quantities of prescription drugs by  
30 retail pharmacies to licensed practitioners for office use;

31 ~~(g)~~ (VII) A retail pharmacy's delivery of prescription drugs to a  
32 patient or patient's agent pursuant to the lawful order of a licensed  
33 practitioner;

34 ~~(h)~~ (VIII) The sale, transfer, merger, or consolidation of all or part  
35 of the business of a pharmacy or pharmacies from or with another  
36 pharmacy or pharmacies, whether accomplished as a purchase and sale of  
37 stock or business assets;

38 ~~(i)~~ (IX) The direct sale, purchase, distribution, trade, or transfer

1 of a prescription drug from a manufacturer to an authorized distributor of  
2 record to one additional authorized distributor of record but only if an  
3 authorized distributor of record that purchases a prescription drug from  
4 an authorized distributor of record that purchased the prescription drug  
5 directly from the manufacturer:

6       (†) (A) Provides the supplying authorized distributor of record  
7 with a verifiable statement that the product is unavailable from the  
8 manufacturer; and

9       (†) (B) Receives a verifiable statement from the supplying  
10 authorized distributor of record that the product was purchased directly  
11 from the manufacturer;

12       (j) ~~(Deleted by amendment, L. 2007, p. 1246, § 1, effective~~  
13 ~~August 3, 2007.)~~

14       (†) (X) The delivery of, or offer to deliver, a prescription drug by  
15 a common carrier solely in the common carrier's usual course of business  
16 of transporting prescription drugs where the common carrier does not  
17 store, warehouse, or take legal ownership of the prescription drug;

18       (†) (XI) The sale or transfer from a retail pharmacy or chain  
19 pharmacy warehouse of expired, damaged, returned, or recalled  
20 prescription drugs to the original manufacturer or to a third-party returns  
21 processor;

22       (†) (XII) The sale or transfer of compounded drugs compounded  
23 by a retail pharmacy as defined in ~~section 12-22-102 (6)~~ SUBSECTION (7)  
24 OF THIS SECTION and as authorized by section ~~12-22-121~~ 12-42.5-119 (6)  
25 (b);

26       (†) (XIII) The transfer of prescription drugs within Colorado  
27 purchased with public funds by the department of public health and  
28 environment, created in section 25-1-102, C.R.S., or a district or county  
29 public health agency, created pursuant to section 25-1-506, C.R.S., and  
30 procured by a physician licensed in Colorado who is either the executive  
31 director or the chief medical officer appointed pursuant to section  
32 25-1-105, C.R.S., or a public health director or medical officer of a  
33 county or district public health agency selected pursuant to section  
34 25-1-508 (5) (c) (I), C.R.S. The transfers may only be made to the  
35 department of public health and environment pursuant to the Colorado  
36 medical license of the executive director or chief medical officer, a  
37 district or county public health agency pursuant to the Colorado medical  
38 license of the public health director or medical officer, or a physician  
39 licensed in Colorado.

40       (34) (43) "Wholesaler" means a ~~corporation, individual, or other~~  
41 ~~entity with facilities in this state that buys drugs or devices for resale or~~

1 ~~distributes drugs or devices to corporations, individuals, or entities~~  
2 ~~entitled to possess such drugs or devices, other than consumers~~ PERSON  
3 ENGAGED IN THE WHOLESALE DISTRIBUTION OF PRESCRIPTION DRUGS TO  
4 PERSONS, OTHER THAN CONSUMERS, WHO ARE ENTITLED TO POSSESS  
5 PRESCRIPTION DRUGS, INCLUDING: REPACKAGERS; OWN-LABEL  
6 DISTRIBUTORS; PRIVATE-LABEL DISTRIBUTORS; JOBBERS; BROKERS;  
7 WAREHOUSES, INCLUDING MANUFACTURERS' AND DISTRIBUTORS'  
8 WAREHOUSES; MANUFACTURERS' EXCLUSIVE DISTRIBUTORS; AUTHORIZED  
9 DISTRIBUTORS OF RECORD; DRUG WHOLESALERS OR DISTRIBUTORS;  
10 INDEPENDENT WHOLESALE DRUG TRADERS; PHARMACY BUYING  
11 COOPERATIVE WAREHOUSES; RETAIL PHARMACIES THAT CONDUCT  
12 WHOLESALE DISTRIBUTION; AND CHAIN PHARMACY WAREHOUSES THAT  
13 CONDUCT WHOLESALE DISTRIBUTION."

14 Page 14, line 8, strike "part 1" and substitute "~~part 1~~ ARTICLE".

15 Page 14, line 11, strike "part 1," and substitute "~~part 1~~ ARTICLE,".

16 Page 14, line 17, strike "part 1" and substitute "~~part 1~~ ARTICLE".

17 Page 17, line 8, strike "grant and renew" and substitute "grant, ~~and~~ renew,  
18 REACTIVATE, AND REINSTATE".

19 Page 17, line 17, strike "renewals" and substitute "renewals,  
20 REACTIVATIONS, AND REINSTATEMENTS".

21 Page 21, strike lines 19 through 27.

22 Strike page 22.

23 Page 23, strike lines 1 through 15.

24 Renumber succeeding C.R.S. sections accordingly.

25 Page 24, line 8, strike "pharmacists," and substitute "pharmacists AND  
26 PHARMACIES,".

27 Page 25, line 4, strike "12-42.5-113" and substitute "12-42.5-112".

28 Page 25, line 7, strike "12-42.5-113" and substitute "12-42.5-112".

- 1 Page 25, line 9, strike "12-42.5-115" and substitute "12-42.5-114".
- 2 Page 25, line 11, strike "12-42.5-115" and substitute "12-42.5-114".
- 3 Page 25, line 13, strike "12-42.5-117" and substitute "12-42.5-116".
- 4 Page 25, line 15, strike "12-42.5-117" and substitute "12-42.5-116".
- 5 Page 25, line 22, strike "12-42.5-117" and substitute "12-42.5-116".
- 6 Page 25, line 25, strike "12-42.5-117" and substitute "12-42.5-116".
- 7 Page 26, line 1, strike "12-42.5-117" and substitute "12-42.5-116".
- 8 Page 26, line 5, strike "12-42.5-118" and substitute "12-42.5-117".
- 9 Page 26, line 7, strike "12-42.5-131;" and substitute "12-42.5-130;".
- 10 Page 26, line 10, strike "12-42.5-118 (11)." and substitute "12-42.5-117
- 11 (12).".
- 12 Page 26, line 13, strike "part 1 ~~but shall be~~" and substitute "part 1 ~~but~~
- 13 ~~shall be~~ ARTICLE".
- 14 Page 27, line 1, strike "part 1 ~~shall apply~~" and substitute "part 1 ~~shall~~
- 15 ~~apply~~ ARTICLE".
- 16 Page 27, line 3, after "manufacture," insert "DISPENSING,".
- 17 Page 27, line 6, strike "part 1" and substitute "~~part 1~~".
- 18 Page 27, line 7, after "~~to~~" insert "ARTICLE".
- 19 Page 27, line 17, strike "part 3 1" and substitute "~~part 3~~ ARTICLE".
- 20 Page 28, line 10, strike "part 1" and substitute "~~part 1~~ ARTICLE".
- 21 Page 29, line 6, after "license," insert "REACTIVATION,".
- 22 Page 29, strike lines 23 and 24 and substitute "manufactures drugs as
- 23 ~~defined in section 12-22-102(17); and any wholesaler of drugs as defined~~



- 1 ~~in section 12-22-102 (34);~~".
- 2 Page 29, line 25, strike "12-42.5-102 (42);".
- 3 Page 30, line 6, strike "12-42.5-118" and substitute "12-42.5-117".
- 4 Page 30, line 16, strike "part 1" and substitute "~~part 1~~ ARTICLE".
- 5 Page 31, line 24, strike "PART 1." and substitute "ARTICLE."
- 6 Page 32, line 18, strike "12-42.5-111" and substitute "12-42.5-110".
- 7 Page 32, line 26, strike "renew" and substitute "renew, REINSTATE,".
- 8 Page 37, line 9, strike "part 1" and substitute "~~part 1~~ ARTICLE".
- 9 Page 37, line 13, strike "12-42.5-118" and substitute "12-42.5-117".
- 10 Page 37, line 24, strike "part 1," and substitute "~~part 1~~ ARTICLE,".
- 11 Page 38, line 13, strike "12-42.5-127" and substitute "12-42.5-126".
- 12 Page 38, line 26, strike "12-42.5-113" and substitute "12-42.5-112".
- 13 Page 39, line 5, strike "specification of forms for use in applying" and  
14 substitute "~~specification of forms~~ SPECIFICATIONS for use in applying  
15 APPLICATION".
- 16 Page 39, line 14, strike "part 1 which" and substitute "~~part 1 which~~  
17 ARTICLE".
- 18 Page 40, line 20, strike "AN INPATIENT" and substitute "A".
- 19 Page 40, line 22, strike "BUILDING" and substitute "FACILITY".
- 20 Page 40, line 23, strike "OWNERSHIP" and substitute "MANAGEMENT".
- 21 Page 41, line 2, strike "AN INPATIENT" and substitute "A".
- 22 Page 41, after line 4 insert:

1           "(11) ON OR AFTER JANUARY 1, 2013, A PRESCRIPTION DRUG  
2 OUTLET MAY REGISTER AS A SPECIALIZED PRESCRIPTION DRUG OUTLET IF  
3 IT ENGAGES IN THE COMPOUNDING, DISPENSING, AND DELIVERY OF DRUGS  
4 AND DEVICES TO, OR THE PROVISION OF PHARMACEUTICAL CARE TO  
5 RESIDENTS OF, A LONG-TERM CARE FACILITY. THE BOARD SHALL ADOPT  
6 RULES AS NECESSARY TO IMPLEMENT THIS SUBSECTION (11).".

7           Renummer succeeding subsections accordingly.

8           Page 42, line 6, strike "12-42.5-119" and substitute "12-42.5-118".

9           Page 42, line 8, strike "(11)" and substitute "(12)".

10          Page 42, line 9, strike "12-42.5-119" and substitute "12-42.5-118".

11          Page 42, line 15, strike "(11)" and substitute "(12)".

12          Page 43, line 25, strike "OR AN ORAL".

13          Page 43, line 27, strike "(15.5)."

14          and substitute "(15.5); EXCEPT THAT, IF  
15          THE PRESCRIPTION ORDER IS FOR A DRUG THAT IS NOT A CONTROLLED  
16          SUBSTANCE OR IS A CONTROLLED SUBSTANCE LISTED ON SCHEDULE III, IV,  
17          OR V, THE LICENSED VETERINARIAN MAY ISSUE AN ORAL PRESCRIPTION  
18          ORDER FOR THAT DRUG.".

18          Page 44, line 1, strike "ORDER," and substitute "ORDER FOR A  
19          CONTROLLED SUBSTANCE LISTED ON SCHEDULE III, IV, OR V,".

20          Page 44, line 6, strike "12-42.5-118" and substitute "12-42.5-117".

21          Page 44, line 8, after "~~12-22-120(1)(e)~~." add "INITIAL INTERPRETATION  
22          AND FINAL EVALUATION, AS DEFINED BY THE BOARD, MAY BE CONDUCTED  
23          AT A LOCATION OTHER THAN A REGISTERED PRESCRIPTION DRUG OUTLET  
24          OR OTHER OUTLET REGISTERED PURSUANT TO THIS ARTICLE IN  
25          ACCORDANCE WITH RULES ADOPTED BY THE BOARD.".

26          Page 44, line 15, after "kit" insert "OR STARTER DOSE, AS DEFINED BY THE  
27          BOARD BY RULE,".

28          Page 44, line 18, strike "certified" and substitute "~~certified~~ LICENSED".

- 1 Page 45, line 20, strike "part 1" and substitute "~~part 1~~ ARTICLE".
- 2 Page 45, strike line 21 and substitute "12-42.5-126."
- 3 Page 47, strike lines 18 through 20 and substitute "supervision of a  
4 pharmacist".
- 5 Page 47, line 21, strike "BOARD," and after "pharmacy." add "AN INTERN,  
6 AS DEFINED IN SECTION 12-42.5-102 (17) (a), ENGAGED IN THE PRACTICE  
7 OF PHARMACY WITHIN THE CURRICULUM OF A SCHOOL OR COLLEGE OF  
8 PHARMACY IN ACCORDANCE WITH SECTION 12-42.5-102 (17) (a), MAY BE  
9 SUPERVISED BY A MANUFACTURER REGISTERED PURSUANT TO SECTION  
10 12-42.5-112 OR BY ANOTHER REGULATED INDIVIDUAL AS PROVIDED FOR  
11 IN RULES ADOPTED BY THE BOARD."
- 12 Page 48, line 5, strike "12-42.5-118" and substitute "12-42.5-117".
- 13 Page 49, line 13, strike "12-42.5-118 (11)" and substitute "12-42.5-117  
14 (12)".
- 15 Page 49, line 23, strike "12-42.5-118 (11)" and substitute "12-42.5-117  
16 (12)".
- 17 Page 55, line 22, strike "part 1," and substitute "~~part 1~~ ARTICLE,".
- 18 Page 55, line 24, strike "12-42.5-127;" and substitute "12-42.5-126;".
- 19 Page 57, line 17, strike "12-42.5-135;" and substitute "12-42.5-134;".
- 20 Page 58, line 3, strike "12-42.5-118 (11)" and substitute "12-42.5-117  
21 (12)".
- 22 Page 58, line 6, strike "12-42.5-118(11) AND 12-42.5-119" and substitute  
23 "12-42.5-117 (12) AND 12-42.5-118".
- 24 Page 58, line 18, strike "12-42.5-124" and substitute "12-42.5-123".
- 25 Page 65, line 14, strike "12-42.5-126." and substitute "12-42.5-125."
- 26 Page 66, line 10, strike "12-42.5-119" and substitute "12-42.5-118".

- 1 Page 66, line 11, strike "12-42.5-123;" and substitute "12-42.5-122;".
- 2 Page 66, line 12, strike "12-42.5-123," and substitute "12-42.5-122,".
- 3 Page 67, line 6, strike "12-42.5-117" and substitute "12-42.5-116".
- 4 Page 69, line 20, strike "PART 1" and substitute "ARTICLE".
- 5 Page 71, line 23, strike "PART 1" and substitute "ARTICLE".
- 6 Page 72, line 17, strike "part 1," and substitute "~~part 1~~ ARTICLE,".
- 7 Page 72, line 18, strike "part 1 shall be" and substitute "~~part 1 shall be~~  
8 ARTICLE".
- 9 Page 72, line 26, strike "part 1 shall be" and substitute "~~part 1 shall be~~  
10 ARTICLE".
- 11 Page 76, line 20, strike "12-42.5-124." and substitute "12-42.5-123.".
- 12 Page 76, line 24, strike "12-42.5-124" and substitute "12-42.5-123".
- 13 Page 76, line 26, strike "12-42.5-125." and substitute "12-42.5-124.".
- 14 Page 77, line 2, strike "12-42.5-124" and substitute "12-42.5-123".
- 15 Page 84, strike lines 5 through 16 and substitute:
- 16 ~~"(b) "Authorized distributor of record" means a wholesaler with~~  
17 ~~whom a manufacturer has established an ongoing relationship to~~  
18 ~~distribute the manufacturer's prescription drug. An ongoing relationship~~  
19 ~~is deemed to exist between a wholesaler and a manufacturer when the~~  
20 ~~wholesaler, including any affiliated group of the wholesaler as defined in~~  
21 ~~section 1504 of the federal "Internal Revenue Code of 1986", complies~~  
22 ~~with the following:~~
- 23 ~~(I) The wholesaler has a written agreement currently in effect with~~  
24 ~~the manufacturer evidencing such ongoing relationship; and~~
- 25 ~~(H) The wholesaler is listed on the manufacturer's current list of~~  
26 ~~authorized distributors of record, which list is updated by the~~  
27 ~~manufacturer on no less than a monthly basis."~~

1    Renumber succeeding subsections accordingly.

2    Page 84, strike lines 21 through 27.

3    Page 85, strike lines 1 and 2 and substitute:

4           ~~"(d) "Chain pharmacy warehouse" means a physical location for~~  
5 ~~prescription drugs that acts as a central warehouse and performs~~  
6 ~~intracompany sales or transfers of such drugs to a group of chain~~  
7 ~~pharmacies or other chain pharmacy warehouses that are under common~~  
8 ~~ownership or control. Notwithstanding any other provision of this part 8,~~  
9 ~~a chain pharmacy warehouse receiving distributions on behalf of, or~~  
10 ~~making distributions to, an intracompany pharmacy is not required to be~~  
11 ~~an authorized distributor of record to be considered part of the normal~~  
12 ~~distribution channel."~~

13   Renumber succeeding subsections accordingly.

14   Page 85, strike lines 17 through 25 and substitute:

15           ~~"(h) "Manufacturer's exclusive distributor" means anyone who~~  
16 ~~contracts with a manufacturer to provide or coordinate warehousing,~~  
17 ~~distribution, or other services on behalf of a manufacturer and who takes~~  
18 ~~title to the manufacturer's prescription drug but who does not have~~  
19 ~~general responsibility to direct the sale or disposition of the~~  
20 ~~manufacturer's prescription drug. Such manufacturer's exclusive~~  
21 ~~distributor shall be licensed as a wholesaler under this part 8 and, to be~~  
22 ~~considered part of the normal distribution channel, shall also be an~~  
23 ~~authorized distributor of record."~~

24   Renumber succeeding subsections accordingly.

25   Page 87, strike lines 2 through 20 and substitute:

26           ~~"(k) "Pharmacy buying cooperative warehouse" means a~~  
27 ~~permanent physical location that acts as a central warehouse for~~  
28 ~~prescription drugs and from which sales of such drugs are made to an~~  
29 ~~exclusive group of pharmacies that are members or member owners of the~~  
30 ~~buying cooperative operating the warehouse that shall be licensed as a~~  
31 ~~wholesaler.~~

32           ~~(l) "Prescription drug" means any drug, including any biological~~

1 product, except for blood and blood components, including factor,  
2 intended for transfusion or biological products that are also medical  
3 devices, required by federal law or regulation to be dispensed only by a  
4 prescription, including finished dosage forms and bulk drug substances  
5 subject to section 503(b) of the "Federal Food, Drug, and Cosmetic Act".

6 (m) "Repackage" means repackaging or otherwise changing the  
7 container, wrapper, or labeling to further the distribution of a prescription  
8 drug, excluding that completed by the pharmacist responsible for  
9 dispensing product to the patient.

10 (n) "Repackager" means a person who repackages prescription  
11 drugs:".

12 Renumber succeeding subsections accordingly.

13 Page 88, strike lines 16 through 27.

14 Strike page 89 and 90.

15 Page 91, strike lines 1 through 9 and substitute:

16 ~~"(2) For the purposes of this part 8, "wholesale distribution"~~  
17 ~~means distribution of prescription drugs to persons or entities other than~~  
18 ~~a consumer or patient. "Wholesale distribution" does not include:~~

19 ~~(a) Intracompany sales or transfers of prescription drugs,~~  
20 ~~including a transaction or transfer between a division, subsidiary, parent,~~  
21 ~~or affiliated or related company under common ownership or control of~~  
22 ~~an entity;~~

23 ~~(b) The sale, purchase, distribution, trade, or transfer of a~~  
24 ~~prescription drug or offer to sell, purchase, distribute, trade, or transfer a~~  
25 ~~prescription drug for emergency medical reasons or during a state or~~  
26 ~~national declaration of emergency;~~

27 ~~(c) The sale or transfer of a drug for medical reasons by a retail~~  
28 ~~pharmacy to another retail pharmacy to alleviate a temporary shortage~~  
29 ~~pursuant to Colorado law;~~

30 ~~(d) The distribution of prescription drug samples by a~~  
31 ~~manufacturer's representative;~~

32 ~~(e) Drug returns, when conducted by a hospital, health care entity,~~  
33 ~~or charitable institution in accordance with 21 CFR 203.23;~~

34 ~~(f) The sale of minimal quantities of prescription drugs by retail~~  
35 ~~pharmacies to licensed practitioners for office use;~~

36 ~~(g) A retail pharmacy's delivery of prescription drugs to a patient~~

1 or patient's agent pursuant to the lawful order of a licensed practitioner;  
2 (h) The sale, transfer, merger, or consolidation of all or part of the  
3 business of a pharmacy or pharmacies from or with another pharmacy or  
4 pharmacies, whether accomplished as a purchase and sale of stock or  
5 business assets;  
6 (i) The direct sale, purchase, distribution, trade, or transfer of a  
7 prescription drug from a manufacturer to an authorized distributor of  
8 record to one additional authorized distributor of record but only if an  
9 authorized distributor of record that purchases a prescription drug from  
10 an authorized distributor of record that purchased the prescription drug  
11 directly from the manufacturer;  
12 (I) Provides the supplying authorized distributor of record with a  
13 verifiable statement that the product is unavailable from the  
14 manufacturer; and  
15 (H) Receives a verifiable statement from the supplying authorized  
16 distributor of record that the product was purchased directly from the  
17 manufacturer;  
18 (j) ~~(Deleted by amendment, L. 2007, p. 1246, § 1, effective~~  
19 ~~August 3, 2007.)~~  
20 (k) The delivery of, or offer to deliver, a prescription drug by a  
21 common carrier solely in the common carrier's usual course of business  
22 of transporting prescription drugs where the common carrier does not  
23 store, warehouse, or take legal ownership of the prescription drug;  
24 (l) The sale or transfer from a retail pharmacy or chain pharmacy  
25 warehouse of expired, damaged, returned, or recalled prescription drugs  
26 to the original manufacturer or to a third-party returns processor;  
27 (m) The sale or transfer of compounded drugs compounded by a  
28 retail pharmacy as defined in section 12-22-102 (6) and as authorized by  
29 section 12-22-121 (6) (b);  
30 (n) The transfer of prescription drugs within Colorado purchased  
31 with public funds by the department of public health and environment,  
32 created in section 25-1-102, C.R.S., or a district or county public health  
33 agency, created pursuant to section 25-1-506, C.R.S., and procured by a  
34 physician licensed in Colorado who is either the executive director or the  
35 chief medical officer appointed pursuant to section 25-1-105, C.R.S., or  
36 a public health director or medical officer of a county or district public  
37 health agency selected pursuant to section 25-1-508 (5) (c) (I), C.R.S. The  
38 transfers may only be made to the department of public health and  
39 environment pursuant to the Colorado medical license of the executive  
40 director or chief medical officer, a district or county public health agency  
41 pursuant to the Colorado medical license of the public health director or

- 1 ~~medical officer, or a physician licensed in Colorado.~~
- 2 Page 91, line 10, strike "**Exemption for**" and substitute "**Exemptions.**".
- 3 Page 91, line 11, strike "**pharmacy benefits entity.**".
- 4 Page 107, line 1, strike "12-42.5-113" and substitute "12-42.5-112".
- 5 Page 107, line 15, strike "12-22-306.1" and substitute "12-22-111,
- 6 12-22-306.1,".
- 7 Page 109, line 10, strike "12-42.5-119" and substitute "12-42.5-118".
- 8 Page 135, line 25, strike "12-42.5-119" and substitute "12-42.5-118".
- 9 Page 136, line 16, strike "12-42.5-119" and substitute "12-42.5-118".
- 10 Page 140, line 22, strike "12-42.5-119," and substitute "12-42.5-118,".
- 11 Page 141, line 10, strike "12-42.5-119," and substitute "12-42.5-118,".
- 12 Page 142, line 12, strike "12-42.5-119" and substitute "12-42.5-118".
- 13 Page 145, line 16, strike "12-42.5-126," and substitute "12-42.5-125,".
- 14 Page 151, line 16, strike "12-42.5-118(11)," and substitute "12-42.5-117
- 15 (12),".
- 16 Page 152, line 27, strike "~~parts~~ PART 1" and substitute "~~parts~~ 1".
- 17 Page 153, line 1, strike the first "of" and substitute "~~of~~".
- 18 Page 153, line 21, strike "part 1 of" and substitute "~~part 1 of~~".
- 19 Page 156, line 11, strike "12-42.5-132," and substitute "12-42.5-131,".
- 20 Page 156, line 13, strike "12-42.5-132" and substitute "12-42.5-131".
- 21 Page 157, line 22, strike "12-42.5-132" and substitute "12-42.5-131".
- 22 Page 164, line 2, strike "part 1 of" and substitute "~~part 1 of~~".



1 Page 166, line 3, strike "12-42.5-134" and substitute "12-42.5-133".

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