

ARTICLE ~~42.5~~ 280
PHARMACISTS, PHARMACY BUSINESSES,
AND PHARMACEUTICALS

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1 **12-280-101. [Formerly 12-42.5-101] Public interest - rules.** The practice of

1 pharmacy is a professional practice affecting the public health, safety, and welfare and is
2 subject to regulation and control in the public interest. It is a matter of public interest and
3 concern that the practice of pharmacy, as defined in this article **280**, merits and receives the
4 confidence of the public, and that only qualified persons be permitted to practice pharmacy
5 in this state. This article **280** is liberally construed to carry out these objects and purposes.
6 Pursuant to these standards and obligations, the state board of pharmacy may adopt rules of
7 professional conduct in accordance with article 4 of title 24. ~~C.R.S.~~

8
9 **12-280-102. Applicability of common provisions. ARTICLES 1, 20, AND 30 OF THIS**
10 **TITLE 12 APPLY, ACCORDING TO THEIR TERMS, TO THIS ARTICLE 280.**

11
12 **12-280-103. [Formerly 12-42.5-102] Definitions - rules.** As used in this article ~~42.5~~
13 **280**, unless the context otherwise requires or the term is otherwise defined in another part
14 of this article ~~42.5~~ **280**:

15 (1) "Administer" means the direct application of a drug to the body of a patient or
16 research subject by injection, inhalation, ingestion, or any other method.

17 (2) "Advertise" means to publish or display information about prescription prices or
18 drugs in any medium.

19 (3) "Anabolic steroid" has the same meaning as set forth in section 18-18-102 (3).
20 ~~C.R.S.~~

21 ~~(3.5)~~ (4) "Authorized distributor of record" means a wholesaler with whom a
22 manufacturer has established an ongoing relationship to distribute the manufacturer's
23 prescription drug. For purposes of this subsection ~~(3.5)~~ (4), an ongoing relationship is
24 deemed to exist between a wholesaler and a manufacturer when the wholesaler, including
25 any affiliated group of the wholesaler as defined in section 1504 of the federal "Internal
26 Revenue Code of 1986", complies with the following:

27 (a) The wholesaler has a written agreement currently in effect with the manufacturer
28 evidencing ~~such~~ THE ongoing relationship; and

29 (b) The wholesaler is listed on the manufacturer's current list of authorized
30 distributors of record, which list is updated by the manufacturer on no less than a monthly
31 basis.

32 ~~(3.7)~~ (5) "Biological product" has the same meaning as "~~biological product~~", as
33 ~~defined~~ SET FORTH in 42 U.S.C. sec. 262 (i)(1).

34 ~~(4)~~ (6) "Board" means the state board of pharmacy.

35 ~~(5)~~ (7) "Bureau" means the drug enforcement administration, or its successor agency,
36 of the United States department of justice.

37 ~~(6)~~ (8) "Casual sale" means a transfer, delivery, or distribution to a corporation,
38 individual, or other entity, other than a consumer, entitled to possess prescription drugs;
39 except that the amount of drugs transferred, delivered, or distributed in ~~such~~ THE manner by

1 any registered prescription drug outlet or hospital other outlet shall not exceed ten percent
2 of the total number of dosage units of drugs dispensed and distributed on an annual basis by
3 ~~such~~ THE outlet.

4 ~~(6.5)~~ (9) "Chain pharmacy warehouse" means a physical location for prescription
5 drugs that serves as a central warehouse and performs intracompany sales or transfers of
6 prescription drugs to a group of chain pharmacies or other chain pharmacy warehouses that
7 are under common ownership or control. Notwithstanding any other provision of this article
8 **280**, a chain pharmacy warehouse receiving distributions on behalf of, or making
9 distributions to, an intracompany pharmacy need not be an authorized distributor of record
10 to be part of the normal distribution channel.

11 ~~(7)~~ (10) (a) "Compounding" means the preparation, mixing, assembling, packaging,
12 or labeling of a drug or device:

13 (I) As the result of a practitioner's prescription drug order, chart order, or initiative,
14 based on the relationship between the practitioner, patient, and pharmacist in the course of
15 professional practice; or

16 (II) For the purpose of, or as an incident to, research, teaching, or chemical analysis
17 and not for sale or dispensing.

18 (b) "Compounding" also includes the preparation of drugs or devices in anticipation
19 of prescription drug orders based on routine, regularly observed prescribing patterns.

20 ~~(8)~~ (11) "Controlled substance" shall have the same meaning as in section 18-18-102
21 (5). ~~C.R.S.~~

22 ~~(9)~~ (12) "Delivery" means the actual, constructive, or attempted transfer of a drug or
23 device from one person to another, whether or not for consideration.

24 ~~(10)~~ (13) "Device" means an instrument, apparatus, implement, machine,
25 contrivance, implant, or similar or related article that is required under federal law to bear
26 the label, "**Caution: federal law requires dispensing by or on the order of a physician.**"
27 "Device" also includes any component part of, or accessory or attachment to, any such
28 article, whether or not the component part, accessory, or attachment is separately so labeled.

29 ~~(11)~~ (14) "Dispense" means to interpret, evaluate, and implement a prescription drug
30 order or chart order, including the preparation of a drug or device for a patient or patient's
31 agent in a suitable container appropriately labeled for subsequent administration to or use
32 by a patient.

33 ~~(12)~~ (15) "Distribution" means the transfer of a drug or device other than by
34 administering or dispensing.

35 ~~(13)~~ (16) (a) "Drug" means:

36 (I) Substances recognized as drugs in the official compendia;

37 (II) Substances intended for use in the diagnosis, cure, mitigation, treatment, or
38 prevention of disease in individuals or animals;

39 (III) Substances, other than food, intended to affect the structure or any function of

1 the body of individuals or animals; and

2 (IV) Substances intended for use as a component of any substance specified in
3 ~~subparagraph (I), (II), or (III) of this paragraph~~ (a) SUBSECTION (16)(a)(I), (16)(a)(II), OR
4 (16)(a)(II) OF THIS SECTION.

5 (b) "Drug" does not include devices or their components, parts, or accessories.

6 ~~(13.5)~~ (17) "FDA" means the federal food and drug administration.

7 ~~(14)~~ (18) "Generic drug type" means the chemical or generic name, as determined
8 by the United States adopted names (USAN) and accepted by the ~~federal food and drug~~
9 ~~administration (FDA)~~ FDA, of those drug products having exactly the same active chemical
10 ingredients in exactly the same strength and quantity.

11 ~~(15)~~ (19) "Hospital" means a general hospital or specialty hospital having a license
12 or certificate of compliance issued by the department of public health and environment.

13 ~~(16)~~ (20) "Hospital satellite pharmacy" means a satellite that registers pursuant to
14 section ~~12-42.5-117~~ ~~(10)~~ **12-280-119 (10)** for the purpose of administration of drugs to
15 patients while being treated in the facility.

16 ~~(16.5)~~ (21) "Interchangeable", in reference to a biological product, means:

17 (a) "Interchangeable" or "interchangeability", as determined by the FDA pursuant to
18 42 U.S.C. sec. 262 (k)(4); or

19 (b) That the FDA has deemed the biological product therapeutically equivalent to
20 another biological product, as set forth in the latest edition or supplement of the FDA
21 Approved Drug Products with Therapeutic Equivalence Evaluations, also referred to as the
22 "Orange Book".

23 ~~(17)~~ (22) "Intern" means a person who is:

24 (a) (I) Enrolled in a professional degree program of a school or college of pharmacy
25 that has been approved by the board;

26 (II) Currently licensed by the board to engage in the practice of pharmacy; and

27 (III) Satisfactorily progressing toward meeting the requirements for licensure as a
28 pharmacist;

29 ~~(b) Repealed.~~

30 ~~(c)~~ (b) A graduate of an approved professional degree program of a school or college
31 of pharmacy or a graduate who has established education equivalency by obtaining a
32 board-approved foreign pharmacy graduate certification and who is currently licensed by the
33 board for the purpose of obtaining practical experience as a requirement for licensure as a
34 pharmacist; or

35 ~~(d)~~ (c) A qualified applicant awaiting examination for licensure as a pharmacist or
36 meeting board requirements for licensure.

37 ~~(18)~~ (23) "Labeling" means the process of preparing and affixing a label to any drug
38 container, exclusive, however, of the labeling by a manufacturer, packer, or distributor of
39 a nonprescription drug or commercially packaged legend drug or device. Any such label

1 shall include all information required by federal and state law or regulation.

2 ~~(19)~~ (24) "Location" means the physical confines of an individual building or at the
3 same address.

4 ~~(19.5)~~ (25) "Long-term care facility" means a nursing facility, as defined in section
5 25.5-4-103 (14), ~~C.R.S.~~, that is licensed pursuant to section 25-1.5-103. ~~C.R.S.~~

6 ~~(20)~~ (26) "Manufacture" means to cultivate, grow, or prepare by other process drugs
7 for sale to wholesalers or other persons entitled to purchase drugs other than the ultimate
8 user, but "manufacture" does not include the compounding and dispensing of a prescription
9 drug pursuant to a prescription order.

10 ~~(20.5)~~ (27) "Manufacturer's exclusive distributor" means a person who contracts with
11 a manufacturer to provide or coordinate warehousing, distribution, or other services on
12 behalf of a manufacturer and who takes title to the manufacturer's prescription drug but who
13 does not have general responsibility to direct the sale or disposition of the manufacturer's
14 prescription drug. To be considered part of the normal distribution channel, as defined in
15 section ~~12-42.5-301~~ ~~(6)~~ **12-280-301 (6)**, a manufacturer's exclusive distributor shall be an
16 authorized distributor of record.

17 ~~(21)~~ (28) "Nonprescription drug" means a drug that may be sold without a
18 prescription and that is labeled for use by the consumer in accordance with the requirements
19 of the law and rules of this state and the federal government.

20 ~~(22)~~ (29) "Nuclear pharmacy" means a specialized pharmacy that deals with the
21 preparation and delivery of radioactive material as defined in section 25-11-101. ~~C.R.S.~~

22 ~~(23)~~ (30) "Official compendia" means the official United States pharmacopeia,
23 national formulary, homeopathic pharmacopoeia of the United States, or any supplements
24 thereto.

25 ~~(24)~~ (31) "Order" means:

26 (a) A prescription order that is any order, other than a chart order, authorizing the
27 dispensing of a single drug or device that is written, mechanically produced, computer
28 generated and signed by the practitioner, transmitted electronically or by facsimile, or
29 produced by other means of communication by a practitioner to a licensed pharmacy or
30 pharmacist and that includes the name or identification of the patient, the date, the symptom
31 or purpose for which the drug is being prescribed, if included by the practitioner at the
32 patient's authorization, and sufficient information for compounding, dispensing, and
33 labeling; or

34 (b) A chart order, which is an order for inpatient drugs or medications that are to be
35 dispensed by a pharmacist, or by a pharmacy intern under the direct supervision of a
36 pharmacist, and administered by an authorized person only during the patient's stay in a
37 hospital, medical clinic operated by a hospital, ambulatory surgical center, hospice, or
38 long-term care facility. The chart order shall contain the name of the patient and the
39 medicine ordered and ~~such~~ THE directions as the practitioner may prescribe concerning

1 strength, dosage, frequency, and route of administration.

2 ~~(25)~~ (32) "Other outlet" means:

3 (a) A hospital that does not operate a registered pharmacy, a rural health clinic, a
4 federally qualified health center, as defined in section 1861 (aa)(4) of the federal "Social
5 Security Act", 42 U.S.C. sec. 1395x (aa)(4), a family planning clinic, an acute treatment unit
6 licensed by the department of public health and environment, a school, a jail, a county or
7 district public health agency, a community health clinic, a university, or a college that:

8 (I) Has facilities in this state registered pursuant to this article **280**; and

9 (II) Engages in the compounding, dispensing, and delivery of drugs or devices;

10 (b) An ambulatory surgical center licensed pursuant to part 1 of article 3 of title 25,
11 ~~C.R.S.~~, a medical clinic operated by a hospital, or a hospice licensed pursuant to part 1 of
12 article 3 of title 25 ~~C.R.S.~~, that:

13 (I) Has facilities in this state registered pursuant to this article **280**; and

14 (II) Engages in the compounding, dispensing, and delivery of drugs or devices for
15 administration to patients while being treated in the facility; or

16 (c) A telepharmacy outlet.

17 ~~(26)~~ (33) "Patient counseling" means the oral communication by a pharmacist or
18 intern of information to the patient or caregiver in order to improve therapy by ensuring
19 proper use of drugs and devices.

20 ~~(27)~~ (34) "Pharmaceutical care" means the provision of drug therapy and other
21 pharmaceutical patient care services by a pharmacist intended to achieve outcomes related
22 to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or
23 arresting or slowing of a disease process. In addition to the preparation, dispensing, and
24 distribution of medications, "pharmaceutical care" may include assessment and evaluation
25 of the patient's medication-related needs and development and communication of a
26 therapeutic plan with defined outcomes in consultation with the patient and the patient's
27 other health care professionals to attain the desired outcome. This function includes efforts
28 to prevent, detect, and resolve medication-related problems for individual patients.
29 "Pharmaceutical care" does not include prescriptive authority; except that a pharmacist may
30 prescribe only over-the-counter medications to a recipient under the "Colorado Medical
31 Assistance Act" as authorized pursuant to section 25.5-5-322 or pursuant to a collaborative
32 pharmacy practice agreement as defined in section ~~12-42.5-601(1)(b)~~ **12-280-601 (1)(b)**.

33 ~~(28)~~ (35) "Pharmacist" means an individual licensed by this state to engage in the
34 practice of pharmacy.

35 ~~(29)~~ (36) "Pharmacist manager" means an individual, licensed in this state as a
36 pharmacist, who has direct control of the pharmaceutical affairs of a prescription drug outlet,
37 and who is not the manager of any other prescription drug outlet.

38 ~~(29.5)~~ (37) "Pharmacy buying cooperative warehouse" means a permanent physical
39 location that acts as a central warehouse for prescription drugs and from which sales of

1 prescription drugs are made to an exclusive group of pharmacies that are members or
2 member owners of the buying cooperative operating the warehouse.

3 ~~(30)~~ (38) "Pharmacy technician" means an unlicensed person who performs those
4 functions set forth in ~~paragraph (b) of subsection (31)~~ SUBSECTION (39)(b) of this section
5 under the supervision of a pharmacist.

6 ~~(31)~~ (39) "Practice of pharmacy" means:

7 (a) The interpretation, evaluation, implementation, and dispensing of orders;
8 participation in drug and device selection, drug administration, drug regimen reviews, and
9 drug or drug-related research; provision of patient counseling; and the provision of those
10 acts or services necessary to provide pharmaceutical care in all areas of patient care;

11 (b) (I) The preparation, mixing, assembling, packaging, labeling, or delivery of a
12 drug or device;

13 (II) Proper and safe storage of drugs or devices; and

14 (III) The maintenance of proper records for ~~such~~ THE drugs and devices; and

15 (c) The provision of a therapeutic interchange selection or a therapeutically
16 equivalent selection to a patient if, during the patient's stay at a nursing care facility or a
17 long-term acute care hospital licensed under part 1 of article 3 of title 25, ~~C.R.S.~~, the
18 selection has been approved for the patient:

19 (I) In accordance with written guidelines and procedures for making therapeutic
20 interchange or therapeutically equivalent selections, as developed by a quality assessment
21 and assurance committee that includes a pharmacist licensed under this article **280** and is
22 formed by the nursing care facility or the long-term acute care hospital in accordance with
23 42 CFR 483.75 (o); and

24 (II) By one of the following health care providers:

25 (A) A physician licensed under article ~~36~~ **240** of this title **12**;

26 (B) A physician assistant licensed under section ~~12-36-107.4~~ **12-240-113**, if the
27 physician assistant is under the supervision of a licensed physician; or

28 (C) An advanced practice nurse prescriber licensed as a professional nurse under
29 section ~~12-38-111~~ **12-255-110**, registered as an advanced practice nurse under section
30 ~~12-38-111.5~~ **12-255-111**, and authorized to prescribe controlled substances or prescription
31 drugs pursuant to section ~~12-38-111.6~~ **12-255-112**, if the advanced practice nurse prescriber
32 has developed an articulated plan to maintain ongoing collaboration with physicians and
33 other health care professionals.

34 ~~(32)~~ (40) "Practitioner" means a person authorized by law to prescribe any drug or
35 device, acting within the scope of ~~such~~ THE authority, including a pharmacist who is
36 participating within the parameters of a statewide drug therapy protocol pursuant to a
37 collaborative pharmacy practice agreement as defined in section ~~12-42.5-601(1)(b)~~ **12-280-**
38 **601 (1)(b)**, or prescribing over-the-counter medications pursuant to section 25.5-5-322.

39 ~~(33)~~ (41) "Prescription" means the finished product of the dispensing of a

1 prescription order in an appropriately labeled and suitable container.

2 ~~(34)~~ (42) "Prescription drug" means a drug that:

3 (a) Is required by any applicable federal or state law or rule to be dispensed only
4 pursuant to an order;

5 (b) Is restricted by any applicable federal or state law or rule to use by practitioners
6 only; or

7 (c) Prior to being dispensed or delivered, is required under federal law to be labeled
8 with one of the following statements:

9 (I) "Rx only"; or

10 (II) "Caution: Federal law restricts this drug to use by or on the order of a licensed
11 veterinarian."

12 ~~(35)~~ (43) "Prescription drug outlet" or "pharmacy" means any pharmacy outlet
13 registered pursuant to this article **280** where prescriptions are compounded and dispensed.
14 "Prescription drug outlet" includes, without limitation, a compounding prescription drug
15 outlet registered pursuant to section ~~12-42.5-117 (9)~~ **12-280-119 (9)** or specialized
16 prescription drug outlet registered pursuant to section ~~12-42.5-117 (11)~~ **12-280-119 (11)**.

17 ~~(36)~~ (44) "Refill" means the compounding and dispensing of any drug pursuant to
18 a previously executed order.

19 ~~(36.3)~~ (45) "Repackage" means repackaging or otherwise changing the container,
20 wrapper, or labeling to further the distribution of a prescription drug, excluding repackaging
21 or labeling completed by the pharmacist responsible for dispensing product to the patient.

22 ~~(36.5)~~ (46) "Repackager" means a person who repackages prescription drugs.

23 ~~(37)~~ (47) "Sample" means any prescription drug given free of charge to any
24 practitioner for any reason except for a bona fide research program.

25 ~~(38)~~ (48) "Satellite" means an area outside the prescription drug outlet where
26 pharmaceutical care and services are provided and that is in the same location.

27 ~~(39)~~ (49) "Supervision" means that a licensed pharmacist is on the location and
28 readily available to consult with and assist unlicensed personnel performing tasks described
29 in ~~paragraph (b) of subsection (31)~~ SUBSECTION (39)(b) of this section. If the unlicensed
30 person is a pharmacy technician located at a registered telepharmacy outlet, the licensed
31 pharmacist need not be physically present at the telepharmacy outlet as long as the licensed
32 pharmacist is connected to the telepharmacy outlet via computer link, video link, and audio
33 link, or via other telecommunication equipment of equivalent functionality, and is readily
34 available to consult with and assist the pharmacy technician in performing tasks described
35 in ~~paragraph (b) of subsection (31)~~ SUBSECTION (39)(b) of this section.

36 ~~(39.5)~~ (50) (a) "Telepharmacy outlet" means a remote pharmacy site that:

37 (I) Is registered as an other outlet under this article **280**;

38 (II) At the time of registration, is located more than twenty miles from the nearest
39 prescription drug outlet and from any other telepharmacy outlet registered under this article

1 280;

2 (III) Is connected via computer link, video link, and audio link, or via other
3 functionally equivalent telecommunication equipment, with a central pharmacy that is
4 registered under this article 280; and

5 (IV) Has a pharmacy technician on site who, under the remote supervision of a
6 licensed pharmacist located at the central pharmacy, performs the tasks described in
7 ~~paragraph (b) of subsection (31)~~ SUBSECTION (39)(b) of this section.

8 (b) The board may adopt rules as necessary to specify additional criteria for a
9 telepharmacy outlet that the board deems necessary.

10 ~~(39.7)~~ (51) "Therapeutic interchange" means the substitution of one drug for another
11 drug with similar therapeutic effects.

12 ~~(40)~~ (52) "Therapeutically equivalent" or "equivalent" means those compounds
13 containing the identical active chemical ingredients of identical strength, quantity, and
14 dosage form and of the same generic drug type, which, when administered in the same
15 amounts, will provide the same therapeutic effect as evidenced by the control of a symptom
16 or disease.

17 ~~(41)~~ (53) "Ultimate user" means a person who lawfully possesses a prescription drug
18 for his or her own use, for the use of a member of the person's household, or for use in
19 administering to an animal owned by the person or a member of his or her household.

20 ~~(42)~~ (54) (a) "Wholesale distribution" means distribution of prescription drugs to
21 persons or entities other than a consumer or patient.

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

23 (I) Intracompany sales or transfers of prescription drugs, including a transaction or
24 transfer between a division, subsidiary, parent, or affiliated or related company under
25 common ownership or control of an entity;

26 (II) The sale, purchase, distribution, trade, or transfer of a prescription drug or offer
27 to sell, purchase, distribute, trade, or transfer a prescription drug for emergency medical
28 reasons or during a state or national declaration of emergency;

29 (III) The sale or transfer of a drug for medical reasons by a retail pharmacy to another
30 retail pharmacy to alleviate a temporary shortage;

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

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

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

36 (VII) A retail pharmacy's delivery of prescription drugs to a patient or patient's agent
37 pursuant to the lawful order of a licensed practitioner;

38 (VIII) The sale, transfer, merger, or consolidation of all or part of the business of a
39 pharmacy or pharmacies from or with another pharmacy or pharmacies, whether

1 accomplished as a purchase and sale of stock or business assets;

2 (IX) The direct sale, purchase, distribution, trade, or transfer of a prescription drug
3 from a manufacturer to an authorized distributor of record to one additional authorized
4 distributor of record but only if an authorized distributor of record that purchases a
5 prescription drug from an authorized distributor of record that purchased the prescription
6 drug directly from the manufacturer:

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

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

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

15 (XI) The sale or transfer from a retail pharmacy or chain pharmacy warehouse of
16 expired, damaged, returned, or recalled prescription drugs to the original manufacturer or
17 to a third-party returns processor;

18 (XII) The sale or transfer of compounded drugs compounded by a retail pharmacy
19 as defined in subsection ~~(7)~~ (10) of this section and as authorized by section ~~12-42.5-118~~
20 ~~(6)(b)~~ 12-280-120 (6)(b);

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

32 (XIV) The distribution of naloxone;

33 (XV) The distribution, donation, or sale by a manufacturer or wholesaler of a stock
34 supply of epinephrine auto-injectors to public schools or nonpublic schools for emergency
35 use by designated school personnel in accordance with the requirements of section
36 22-1-119.5, ~~€R.S.~~, or to other entities for emergency use in accordance with the
37 requirements of article 47 of title 25. ~~€R.S.~~

38 ~~(43)~~ (55) "Wholesaler" means a person engaged in the wholesale distribution of
39 prescription drugs to persons, other than consumers, who are entitled to possess prescription

1 drugs, including: Repackagers; own-label distributors; private-label distributors; jobbers;
2 brokers; warehouses, including manufacturers' and distributors' warehouses; manufacturers'
3 exclusive distributors; authorized distributors of record; drug wholesalers or distributors;
4 independent wholesale drug traders; pharmacy buying cooperative warehouses; retail
5 pharmacies that conduct wholesale distribution; and chain pharmacy warehouses that
6 conduct wholesale distribution.

7
8 **12-280-104. [Formerly 12-42.5-103] State board of pharmacy - creation - subject**
9 **to termination - repeal of parts.** (1) The responsibility for enforcement of this article **280**
10 is vested in the state board of pharmacy, which is hereby created. The board has all of the
11 duties, powers, and authority specifically granted by and necessary to the enforcement of this
12 article **280**, as well as other duties, powers, and authority as may be granted by statute from
13 time to time. Except as otherwise provided to the contrary, the board shall exercise all its
14 duties, powers, and authority in accordance with the "State Administrative Procedure Act",
15 article 4 of title 24. ~~C.R.S.~~

16 (2) The board shall exercise its powers, and perform its duties, and functions
17 specified by this article under the department of regulatory agencies and the executive
18 director of the department as if the same were transferred to the department by AS a **type 1**
19 transfer, as is defined in the "Administrative Organization Act of 1968", article 1 of title 24,
20 ~~C.R.S.~~ ENTITY, AS DEFINED IN SECTION 24-1-105. <{*Amended to reflect language in a*
21 *Statutory Revision Committee bill that is updating type 1 and type 2 entity language*
22 *throughout the statutes*}>

23 (3) (a) ~~Section 24-34-104, C.R.S., concerning the termination schedule for regulatory~~
24 ~~bodies of the state, unless extended as provided in that section, applies to the state board of~~
25 ~~pharmacy created by this section.~~

26 (b) Parts 1 to 3 of this article **280** are repealed, effective September 1, 2021. ~~Prior~~
27 ~~to BEFORE the repeal, the department of regulatory agencies shall review the board and the~~
28 ~~regulation of the practice of pharmacy pursuant to parts 1 to 3 of this article as provided in~~
29 ~~**280** ARE SCHEDULED FOR REVIEW IN ACCORDANCE WITH section 24-34-104. C.R.S.~~

30
31 **12-280-105. [Formerly 12-42.5-104] Membership of board - removal -**
32 **compensation - meetings.** (1) (a) The board is composed of five licensed pharmacists, each
33 having at least five years' experience in this state and actively engaged in the practice of
34 pharmacy in this state, and two nonpharmacists who have no financial interest in the practice
35 of pharmacy.

36 (b) The governor shall make all appointments to the board in accordance with this
37 section.

38 (c) For purposes of achieving a balance in the membership on the board, the
39 governor shall consider:

1 (I) Whether the appointee's home is in:

2 (A) An urban or rural location; and

3 (B) An area already represented geographically by another appointee on the board;
4 and

5 (II) The type of practice of the appointee so that various types of practices are
6 represented on the board.

7 (d) (I) The term of office of each member is four years.

8 (II) In the case of an appointment to fill a vacancy, the appointee shall complete the
9 unexpired term of the former board member.

10 (III) No member of the board may serve more than two consecutive full terms.

11 (e) No more than four members of the board shall be members of the same major
12 political party.

13 (f) The governor shall appoint the pharmacist members in a manner to ensure that
14 the term of one member expires July 1 of each year.

15 (2) The governor may remove any board member for misconduct, incompetence, or
16 neglect of duty.

17 (3) Each member of the board shall receive the compensation provided for in section
18 ~~24-34-102 (13), C.R.S. 12-20-103 (6).~~

19 (4) The board shall hold meetings at least once every four months at the times and
20 places fixed by the board. At one meeting, the board shall elect a president and a
21 vice-president. A majority of the members of the board constitutes a quorum for the conduct
22 of business, and, except as otherwise provided in this part 1, all actions of the board must
23 be by a majority of a quorum. The board shall give full and timely notice of all meetings of
24 the board pursuant to any requirements of state laws. All board meetings and hearings are
25 open to the public; except that the board may conduct any portion of its meetings in
26 executive session closed to the public, as may be permitted by law.

27
28 **12-280-106. [Formerly 12-42.5-104.5] Veterinary pharmaceutical advisory**
29 **committee - creation - appointments - rules - repeal.** (1) (a) (I) There is created in the
30 department of ~~regulatory agencies~~ the veterinary pharmaceutical advisory committee
31 comprised of three members, each appointed by the state veterinarian who serves under the
32 commissioner of agriculture pursuant to section 35-50-104 ~~C.R.S.~~, as follows:

33 (A) One member who is a licensed veterinarian who predominantly works on large
34 animals, having at least five years' experience in this state, in good standing, and actively
35 engaged in the practice of veterinary medicine;

36 (B) One member who is either a licensed pharmaceutical wholesaler engaged in the
37 distribution of animal drugs, having at least five years' experience in this state, in good
38 standing, and actively engaged in the practice of wholesale pharmacy or a licensed
39 veterinarian, having at least five years' experience in this state, in good standing, and actively

1 engaged in the practice of veterinary medicine, but who is not both a pharmaceutical
2 wholesaler and a veterinarian; and

3 (C) One member who has a background in agriculture and who is not a pharmacist,
4 pharmaceutical wholesaler, or veterinarian.

5 (II) The state veterinarian shall choose a person who does not do business along the
6 front range for at least one of the professional appointments on the advisory committee.

7 (b) The members of the advisory committee serve three-year terms; except that the
8 state veterinarian shall appoint one of the initial members of the advisory committee for a
9 two-year term. If there is a vacancy on the advisory committee, the state veterinarian shall
10 appoint a successor to fill the unexpired portion of the member's term.

11 (c) (I) The advisory committee shall elect a member to serve as chair of the advisory
12 committee. The advisory committee shall meet as required by the board in accordance with
13 subsection (2) of this section.

14 (II) Members of the advisory committee serve without compensation or
15 reimbursement of expenses.

16 (III) A member of the advisory committee shall not perform an official act that:

17 (A) May provide a direct economic benefit to a business or other undertaking in
18 which the member has a direct or substantial financial interest; or

19 (B) Involves a person with whom the member has engaged in a substantial number
20 of business transactions.

21 (d) ~~The department of regulatory agencies~~ shall provide staff assistance to the
22 advisory committee.

23 (2) (a) Unless a matter presented to the board constitutes an emergency requiring
24 prompt resolution, the board shall refer the following matters that concern veterinary
25 pharmaceuticals to the advisory committee for a recommendation on how the board should
26 proceed on the matter:

27 (I) Whether and to what extent action, if any, should be taken on an investigation
28 into or complaint of an alleged violation of this article **280**, including whether to:

29 (A) Suspend or revoke a license or registration;

30 (B) Impose a fine against a licensee or registrant, whether the violation is egregious,
31 and the amount of any fine recommended;

32 (C) Seek a restraining order or injunction in civil court against a person; or

33 (D) Pursue other disciplinary action against a licensee, registrant, or other person;

34 (II) Review of license and registration applications and renewal, reactivation, and
35 reinstatement applications; and

36 (III) Promulgation of rules.

37 (b) Upon being referred a matter by the board, the advisory committee shall meet,
38 in person or by teleconference, as soon as practicable to review the matter. The board shall
39 share all documents, recordings, and other materials that are relevant to the matter referred

1 ~~with~~ TO the advisory committee for the advisory committee's review of the matter. The
2 advisory committee shall treat all shared materials as confidential. The advisory committee
3 shall provide the board a written recommendation on how the board should proceed on the
4 matter referred, setting forth its findings and conclusions. At the advisory committee's
5 discretion, the advisory committee may also present its recommendations to the board in
6 person or by teleconference.

7 (c) The board shall adopt the advisory committee's recommendation on a referred
8 matter unless the board determines that there exists material and substantial evidence or
9 information related to the matter that warrants a resolution of the matter that is distinct from
10 the advisory committee's recommendation. If the board deviates from the advisory
11 committee's recommendation, the board shall make a record of the reasons for the deviation.

12 (3) The board, in consultation with the state veterinarian, may promulgate rules to
13 implement this section.

14 (4) (a) This section is repealed, effective September 1, 2026.

15 (b) Before ~~the ITS repeal, of this section, the department of regulatory agencies shall~~
16 ~~review~~ the advisory committee pursuant to IS SCHEDULED FOR REVIEW IN ACCORDANCE WITH
17 section 2-3-1203. ~~C.R.S.~~

18
19 **12-280-107. [Formerly 12-42.5-105] Rules.** (1) The board shall make, adopt,
20 amend, or repeal rules in accordance with article 4 of title 24 ~~C.R.S.~~, AND 12-20-204 that the
21 board deems necessary for the proper administration and enforcement of the responsibilities
22 and duties delegated to the board by this article **280**, including those relating to nuclear
23 pharmacies.

24 (2) On or before January 1, 2016, the board shall adopt or amend rules as necessary
25 to permit the dispensing of an opiate antagonist in accordance with section ~~12-42.5-120 (3)~~
26 **SECTIONS 12-30-110 AND 12-280-123 (3)**. <{*Adding reference to opiate antagonists*
27 *common provision, 12-20-110.*}>

28
29 **12-280-108. [Formerly 12-42.5-106] Powers and duties.** (1) The board shall:

30 (a) Inspect, or direct inspectors who are licensed pharmacists to inspect, all outlets
31 and investigate violations of this article **280**;

32 (b) Prescribe forms and receive applications for licensure and registration and grant,
33 renew, reactivate, and reinstate licenses and registrations;

34 (c) Deny, suspend, or revoke licenses or registrations **IN ACCORDANCE WITH SECTION**
35 **12-20-404 (1)(d)**; <{*Suggest adding a cross reference to disciplinary actions common*
36 *provision, 12-20-404.*}>

37 (d) Apply to the courts for and obtain ~~in accordance with the Colorado rules of civil~~
38 ~~procedure~~ restraining orders and injunctions **IN ACCORDANCE WITH SECTION 12-20-406** to
39 enjoin violations of the laws that the board is empowered to enforce; <{*Suggest adding a*

1 *cross reference to injunction common provision, 12-20-406.*>

2 (e) Administer examinations to, and determine the qualifications and fitness of,
3 applicants for licensure or registration;

4 (f) Keep a record of:

5 (I) All licenses, registrations, and license and registration renewals, reactivations, and
6 reinstatements for a reasonable period;

7 (II) All suspensions, revocations, and any other disciplinary actions; and

8 (III) Its own proceedings;

9 (g) Collect all fees prescribed by this article **280** AND SECTION 12-20-105; <{*Adding*
10 *reference to fees common provision, 12-20-105.*>

11 (h) Fine registrants when consistent with the provisions of this article **280** and the
12 rules adopted pursuant to this article **280**;

13 (i) ~~(H)~~ Conduct investigations, hold hearings, and take evidence in all matters relating
14 to the exercise and performance of the powers and duties of the board IN ACCORDANCE WITH
15 SECTION 12-20-403. <{*Suggest adding a cross reference to disciplinary procedures*
16 *common provision, 12-20-403.*>

17 ~~(H) (A) The board or an administrative law judge may administer oaths, take~~
18 ~~affirmations of witnesses, and issue subpoenas to compel the attendance of witnesses and~~
19 ~~the production of all relevant papers, books, records, documentary evidence, and materials~~
20 ~~in any hearing, investigation, accusation, or other matter before the board.~~

21 ~~(B) The board may appoint an administrative law judge pursuant to part 10 of article~~
22 ~~30 of title 24, C.R.S., to take evidence, make findings, and report the findings to the board.~~

23 ~~(H) Upon failure of any witness to comply with a subpoena or process, the district~~
24 ~~court of the county in which the subpoenaed person or licensee resides or conducts business,~~
25 ~~upon application by the board with notice to the subpoenaed person or licensee, may issue~~
26 ~~to the person or licensee an order requiring that person or licensee to appear before the~~
27 ~~board; to produce the relevant papers, books, records, documentary evidence, or materials~~
28 ~~if so ordered; or to give evidence touching the matter under investigation or in question. The~~
29 ~~court may hold the person or licensee in contempt of court for failure to obey the order of~~
30 ~~the court.~~ <{*Redundant with discipline/ALJ/subpoena powers common provision,*
31 *12-20-403. Recommend amendment as indicated.*>

32 (j) Review and approve or reject applications for participation in the pharmacy peer
33 health assistance diversion program pursuant to part 2 of this article **280** and perform any
34 other functions that were performed by the rehabilitation evaluation committee prior to its
35 repeal.

36 (2) The board has other duties, powers, and authority as may be necessary to enforce
37 this article **280** and the rules adopted pursuant to this article **280**.

38 (3) The board may:

39 (a) Adopt a seal to be used only in the manner the board prescribes;

1 (b) Promulgate rules governing the compounding of pharmaceutical products, which
2 rules must address the following:

- 3 (I) Training and qualifications;
4 (II) Quality control;
5 (III) Internal operating procedures;
6 (IV) Procurement of compounding materials;
7 (V) Formulation, documentation, and testing requirements;
8 (VI) Equipment standards;
9 (VII) Facility standards; and
10 (VIII) A recall system.

11 (4) (a) (I) Whenever a duly authorized agent of the board finds or has probable cause
12 to believe that, in any registered outlet, any drug, nonprescription drug, or device is
13 adulterated or misbranded within the meaning of the "Colorado Food and Drug Act", part
14 4 of article 5 of title 25, ~~C.R.S.~~, the agent shall affix to the article a tag or other appropriate
15 marking giving notice:

16 (A) That the article is, or is suspected of being, adulterated or misbranded;

17 (B) That the article has been detained or embargoed; and

18 (C) Warning all persons not to remove or dispose of the article by sale or otherwise
19 until the board, its agent, or the court gives provision for removal or disposal.

20 (II) No person shall remove or dispose of an embargoed article by sale or otherwise
21 without the permission of the board or its agent or, after summary proceedings have been
22 instituted, without permission from the court.

23 (b) If the board or the court removes the embargo, neither the board nor the state is
24 liable for damages because of the embargo if the court finds that there was probable cause
25 for the embargo.

26 (c) When an agent finds that an article detained or embargoed under ~~paragraph (a)~~
27 ~~of this subsection~~ (4) SUBSECTION (4)(a) OF THIS SECTION is adulterated or misbranded, the
28 agent shall petition the judge of the district court in whose jurisdiction the article is detained
29 or embargoed for an order for condemnation of the article. When the agent finds that an
30 article so detained or embargoed is not adulterated or misbranded, he or she shall remove
31 the tag or other marking.

32 (d) (I) If the court finds that a detained or embargoed article is adulterated or
33 misbranded, except as provided in ~~subparagraph (H) of this paragraph (d)~~ SUBSECTION
34 (4)(d)(II) OF THIS SECTION, the court shall order the article, after entry of the decree, to be
35 destroyed at the expense of the owner of the article under the supervision of the agent. The
36 owner of the article or the owner's agent shall bear all court costs and fees, storage, and other
37 proper expense.

38 (II) When the owner can correct the adulteration or misbranding by proper labeling
39 or processing of the article, after entry of the decree and after the owner has paid the costs,

1 fees, and expenses and has posted a good and sufficient bond, conditioned that the article
2 be properly labeled or processed, the court may direct, by order, that the article be delivered
3 to the owner for proper labeling or processing under the supervision of an agent. The owner
4 shall pay the expense of the agent's supervision. The bond must be returned to the owner of
5 the article once the board represents to the court that the article is no longer in violation of
6 the embargo and that the owner has paid the expenses of supervision.

7 (e) It is the duty of the attorney general or the district attorney to whom the board
8 reports any violation of this subsection (4) to institute appropriate proceedings in the proper
9 courts without delay and to prosecute the matter in the manner required by law. Nothing in
10 this paragraph (e) SUBSECTION (4)(e) requires the board to report violations when the board
11 believes the public interest will be adequately served in the circumstances by a suitable
12 written notice or warning.

13
14 **12-280-109. [Formerly 12-42.5-107] Drugs, devices, and other materials.** (1) The
15 board is responsible for the control and regulation of drugs, including the following:

16 (a) The regulation of the sale at retail and the dispensing of drugs;

17 (b) The specification of minimum professional and technical equipment,
18 environment, supplies, and procedures for the compounding or dispensing of medications
19 and drugs;

20 (c) The control of the purity and quality of drugs.

21 (2) The board is responsible for the control and regulation of the sale of devices at
22 retail; except that the board shall not regulate the sale of any disposable veterinary device.
23 The board may also exempt from regulation veterinary devices:

24 (a) That are regulated by the FDA; or

25 (b) For which the board determines regulation is unnecessary.

26
27 **12-280-110. [Formerly 12-42.5-108] Publications.** The board shall issue its
28 publications that are circulated in quantity outside the executive branch in accordance with
29 section 24-1-136. ~~C.R.S.~~ The board shall circulate its publications to all registered
30 prescription drug outlets that will be directly affected by the publications.

31
32 **12-280-111. [Formerly 12-42.5-109] Reporting - malpractice claims.** (1) Each
33 insurance company licensed to do business in this state and engaged in the writing of
34 malpractice insurance for licensed pharmacists and pharmacies, and each pharmacist or
35 pharmacy that self-insures, shall send to the board, in the form prescribed by the board,
36 information relating to each malpractice claim against a licensed pharmacist that is settled
37 or in which judgment is rendered against the insured.

38 (2) The insurance company or self-insured pharmacist or pharmacy shall provide
39 information relating to each malpractice claim as is deemed necessary by the board to

1 conduct a further investigation and hearing.

2 (3) Information relating to each malpractice claim provided by insurance companies
3 or self-insured pharmacists or pharmacies is exempt from the provisions of any law requiring
4 that the proceedings of the board be conducted publicly or that the minutes or records of the
5 board be open to public inspection unless the board takes final disciplinary action. The board
6 may use the information in any formal hearing involving a licensee or registrant.

7
8 **12-280-112. [Formerly 12-42.5-110] Fees.** (1) The director of the division of
9 professions and occupations shall determine, and the board shall collect, fees pursuant to
10 section ~~24-34-105, C.R.S., 12-20-105~~ for the following licenses and registrations:

11 (a) For certifying to another state the grades of a person who has taken the
12 pharmacist examination in this state;

13 (b) For the initial licensure, upon examination, as a pharmacist, as provided in
14 section ~~12-42.5-112(4)~~ **12-280-114 (4)**;

15 (c) For the initial licensure, without examination and upon presentation of evidence
16 of licensure in another state, as a pharmacist, as provided in section ~~12-42.5-112(8)~~ **12-280-**
17 **114 (8)**;

18 (d) For the renewal of a license as a licensed pharmacist, as provided in section
19 ~~12-42.5-114(1)~~ **12-280-116 (1)**;

20 (e) For reinstatement as a licensed pharmacist, as provided in section ~~12-42.5-114~~
21 ~~(2)~~ **12-280-116 (2)**;

22 (f) For the transfer of a prescription drug outlet registration to a new owner, as
23 provided in section ~~12-42.5-116(2)~~ **12-280-118 (2)**;

24 (g) For the transfer of a manager's name, as provided in section ~~12-42.5-116(1)~~ **12-**
25 **280-118 (1)**;

26 (h) For the issuance of a duplicate certificate to a licensed pharmacist;

27 (i) For the initial licensure as a pharmacy intern;

28 (j) For the issuance of a duplicate license of a pharmacy intern;

29 (k) For the transfer of a prescription drug outlet registration to a new location, as
30 provided in section ~~12-42.5-116(2)~~ **12-280-118 (2)**;

31 (l) For reissuing a prescription drug outlet registration in a new store name, without
32 change of owner or manager, as provided in section ~~12-42.5-116(2)~~ **12-280-118 (2)**;

33 (m) For the initial registration or the renewal of the registration of a prescription drug
34 outlet, as provided in section ~~12-42.5-116(2)~~ **12-280-118 (2)**;

35 (n) For the initial certificate evidencing licensure for all pharmacists;

36 (o) For the initial and renewal registration of all other outlets under section
37 ~~12-42.5-117~~ **12-280-119** not covered in this section;

38 (p) For the initial and renewal registration of all nonresident prescription drug outlets
39 under section ~~12-42.5-130~~ **12-280-133**;

1 (q) For the initial and renewal registration of humane societies and animal control
2 agencies pursuant to section ~~12-42.5-117~~ (12) **12-280-119** (12).

3 (2) Any pharmacist licensed in Colorado for fifty years or more as a pharmacist is
4 exempt from the payment of fees under this article **280** and is allowed to practice as a
5 licensed pharmacist.

6
7 **12-280-113. [Formerly 12-42.5-111] Approval of schools.** (1) A school or college
8 of pharmacy that is approved by the board as a school or college of pharmacy from which
9 graduation is required in order for the graduate of the school or college of pharmacy to apply
10 for a license as a pharmacist must meet the requirements set forth by the board.

11 (2) The board may utilize the facilities, reports, requirements, and recommendations
12 of any recognized accrediting organization in determining the requirements for a school or
13 college of pharmacy.

14 (3) The board shall maintain a list of approved schools or colleges.

15
16 **12-280-114. [Formerly 12-42.5-112] Licensure or registrations - applicability -**
17 **applications - licensure requirements - rules.** (1) This article **280** applies to all persons
18 in this state engaged in the practice of pharmacy and to all outlets in this state engaged in the
19 manufacture, dispensing, production, sale, and distribution of drugs, devices, and other
20 materials used in the treatment of injury, illness, and disease.

21 (2) (a) Every applicant for a license under this article **280** must read and write the
22 English language, or if the applicant is a partnership, each member of the partnership must
23 read and write the English language. If the applicant is a Colorado corporation, the
24 corporation must be in good standing, and if the applicant is a foreign corporation, it must
25 be qualified to do business in this state.

26 (b) The board shall issue the appropriate registration to each manufacturer and
27 wholesaler that meets the requirements of this article **280** unless the board determines that
28 the issuance of the registration would be inconsistent with the public interest. In determining
29 the public interest, the board shall consider the following factors:

30 (I) Maintenance of effective controls against diversion of controlled substances into
31 illegitimate medical, scientific, or industrial channels;

32 (II) Compliance with applicable state and local laws;

33 (III) Any conviction of the applicant under any federal or state law relating to a
34 controlled substance;

35 (IV) Past experience in the manufacture or distribution of controlled substances and
36 the existence in the applicant's establishment of effective controls against diversion;

37 (V) Any false or fraudulent information in an application filed under this part 1;

38 (VI) Suspension or revocation of the applicant's federal registration to manufacture,
39 distribute, or dispense a controlled substance as authorized by federal law; and

1 (VII) Any other factors relevant to and consistent with the public peace, health, and
2 safety.

3 (3) Every applicant for a license or registration under this article **280** shall make
4 written application in the manner and form prescribed by the board, setting forth the
5 applicant's name and address, the applicant's qualifications for the license or registration, and
6 other information required by the board. The applicant shall submit with the application the
7 required fee, and, if the applicant is required to take an examination, the applicant shall
8 appear for examination at the time and place fixed by the board.

9 (4) (a) (I) An applicant who has graduated from a school or college of pharmacy
10 approved by the board may take an examination before the board.

11 (II) The examination must be designed fairly to test the applicant's knowledge of
12 pharmacy and other related subjects and must be in a form approved by the board. The
13 examination cannot be administered orally.

14 (III) An applicant for licensure by examination shall have completed an internship
15 as prescribed by the board.

16 (b) A person who produces evidence satisfactory to the board that the person has
17 graduated and obtained a degree from a school of pharmacy outside the United States and
18 has passed a foreign graduate equivalency test given or approved by the board may apply
19 to take the examination set forth in ~~paragraph (a) of this subsection (4)~~ SUBSECTION (4)(a)
20 OF THIS SECTION.

21 (5) Every applicant for licensure as a pharmacist, whether by examination, transfer
22 of license, reactivation, or reinstatement, shall take a jurisprudence examination approved
23 by the board that tests ~~such~~ THE applicant's knowledge of the laws of this state.

24 (6) No applicant shall exercise the privileges of licensure or registration until the
25 board grants the license or registration.

26 (7) The board may require any applicant for licensure to display written or oral
27 competency in English. The board may utilize a standardized test to determine language
28 proficiency.

29 (8) A person licensed by examination and in good standing in another state may
30 apply for a license transfer. The board shall designate a clearinghouse for license transfer
31 applicants, and a person applying for a license transfer shall apply through the clearinghouse
32 designated by the board.

33 (9) The board shall adopt rules as necessary to ensure that any person who
34 manufactures drugs and any wholesaler of drugs possesses the minimum qualifications
35 required for wholesale drug distributors pursuant to the federal "Prescription Drug
36 Marketing Act of 1987", 21 U.S.C. sec. 353, as amended.

37 ~~(10) A person whose license has been revoked shall not reapply for licensure earlier~~
38 ~~than two years after the effective date of the revocation.~~ <{***Redundant with***
39 ***discipline/waiting period common provision, 12-20-404 (3). Recommend repeal.***>

1 ~~(H)~~ (10) Issuance of a license or registration under this section and section
2 ~~12-42.5-117~~ **12-280-119** does not entitle a licensee or registered facility or outlet to
3 wholesale, manufacture, distribute, dispense, or professionally use controlled substances
4 beyond the scope of ~~his or her~~ THE LICENSEE'S OR REGISTRANT'S federal registration.
5

6 **12-280-115. [Formerly 12-42.5-113] Exemptions from licensure - hospital**
7 **residency programs - home renal dialysis - research companies.** (1) The board is
8 authorized to approve hospital residency programs in the practice of pharmacy. Persons
9 accepted into an approved hospital residency program who are licensed to practice pharmacy
10 in another state are exempt from the licensing requirements of this article **280** so long as
11 their practice is limited to participation in the residency program.

12 (2) This article **280** does not apply to the sale or delivery of a dialysis solution if all
13 of the following conditions are met:

14 (a) The sale or delivery is made directly by the manufacturer to a person with chronic
15 kidney failure or to the designee of the person;

16 (b) The sale or delivery is for the purpose of self-administration by the person
17 pursuant to an order by a physician lawfully practicing in this state; and

18 (c) The solution is sold or delivered in original packages, properly labeled, and
19 unadulterated in accordance with the requirements of the "Colorado Food and Drug Act",
20 part 4 of article 5 of title 25, ~~C.R.S.~~, and the "Federal Food, Drug, and Cosmetic Act".

21 (3) A manufacturer that must obtain a prescription drug or device solely for use in
22 its research, development, or testing procedures and that does not further distribute the drug
23 or device may apply to the board for a waiver of registration pursuant to this subsection (3).
24 The board may grant a waiver if the manufacturer submits to the board the name of the drug
25 or device it requires and an affidavit certifying that the drug or device will only be used for
26 necessary research, development, or testing procedures and will not be further distributed.
27 A waiver granted pursuant to this subsection (3) does not apply to a controlled substance,
28 as defined in section 18-18-102 (5), ~~C.R.S.~~, or in federal law.

29 (4) An employee of a facility, as defined in section 25-1.5-301, ~~C.R.S.~~, who is
30 administering and monitoring medications to persons under the care or jurisdiction of the
31 facility pursuant to part 3 of article 1.5 of title 25 ~~C.R.S.~~, need not be licensed by the board
32 to lawfully possess controlled substances under this article **280**.
33

34 **12-280-116. [Formerly 12-42.5-114] Expiration and renewal of licenses or**
35 **registrations.** (1) ~~All licenses and registrations expire pursuant to a schedule established~~
36 ~~by the director of the division of professions and occupations within the department of~~
37 ~~regulatory agencies and must be renewed or reinstated pursuant to section 24-34-102 (8),~~
38 ~~C.R.S. The director of the division of professions and occupations may establish renewal~~
39 ~~fees and delinquency fees for reinstatement pursuant to section 24-34-105, C.R.S. If a~~

1 person fails to renew his or her license or registration pursuant to the schedule established
 2 by the director of the division of professions and occupations, the license or registration
 3 expires ISSUED PURSUANT TO THIS ARTICLE 280 ARE SUBJECT TO THE RENEWAL, EXPIRATION,
 4 REINSTATEMENT, AND DELINQUENCY FEE PROVISIONS SPECIFIED IN SECTION 12-20-202 (1)
 5 AND (2). Any person whose license or registration expires is subject to the penalties provided
 6 in this article 280 or section ~~24-34-102 (8)~~, C.R.S. 12-20-202 (1). <{*Redundant with the*
 7 *renewal / reinstatement common provision, 12-20-202 (1) & (2). Recommend amending*
 8 *as indicated.*>

9 (2) A pharmacist who fails to renew his or her license on or before the applicable
 10 renewal time may have his or her license reinstated for the remainder of the current renewal
 11 period by filing a proper application, satisfying the board that the pharmacist is fully
 12 qualified to practice, and paying the reinstatement fee as provided in section ~~12-42.5-110~~
 13 ~~(1)(e)~~ 12-280-112 (1)(e) and all delinquent fees. <{*Is this provision different from the*
 14 *reinstatement common provision, 12-20-202 (2)? Can this subsection (2) be repealed?*>

15 (3) Except for good cause shown, the board shall not grant a license to a pharmacy
 16 intern more than two years after the applicant has ceased to be an enrolled student in a
 17 college or school of pharmacy approved by the board.

18
 19 **12-280-117. [Formerly 12-42.5-115] Continuing education - exceptions - inactive**
 20 **status.** (1) Except as permitted in subsections (2) and (3) of this section, the board shall not
 21 renew, reinstate, or reactivate the license of any pharmacist until the pharmacist presents
 22 evidence that he or she has completed twenty-four hours of approved continuing
 23 pharmaceutical education within the preceding two years. Subject to subsection (9) of this
 24 section, the evidence may be provided by checking a sign-off box on the license renewal
 25 application.

26 (2) (a) The board may renew the license of a pharmacist who presents acceptable
 27 evidence that the pharmacist was unable to comply with subsection (1) of this section.

28 (b) The board may grant a six-month compliance extension to pharmacists who are
 29 unable to comply with subsection (1) of this section.

30 (3) The board may renew the license for the first renewal period following the
 31 issuance of the original license without requiring a pharmacist to complete any continuing
 32 pharmaceutical education if the pharmacist obtains a license within one year after the
 33 completion of the pharmacist's pharmaceutical education.

34 (4) To qualify for continuing education credit, a program of continuing
 35 pharmaceutical education must be currently approved by the Accreditation Council on FOR
 36 Pharmaceutical Education or an equivalent accrediting body as determined by the board.

37 (5) Each program of continuing pharmaceutical education must consist of at least one
 38 continuing education unit, which is one hour of participation in an organized continuing
 39 educational experience, including postgraduate studies, institutes, seminars, lectures,

1 conferences, workshops, correspondence courses, cassette programs, programmed learning
2 courses, audiovisual programs, internet programs, and any other form of presentation that
3 is accredited.

4 (6) Any aspect of the practice of pharmacy may be the subject of a program of
5 continuing pharmaceutical education, including pharmaceutics, compounding,
6 pharmacology, pharmaceutical chemistry, biochemistry, physiology, microbiology, pharmacy
7 administration, and professional practice management.

8 (7) A program of continuing pharmaceutical education may include the following:

9 (a) A definite stated objective;

10 (b) Presentation in an organized manner; and

11 (c) A method of program evaluation that is suitable to the type of program being
12 presented.

13 (8) A program of continuing pharmaceutical education must meet the requirements
14 as established by the accrediting body.

15 (9) The board may annually audit up to five percent of the pharmacists licensed and
16 residing in Colorado to determine compliance with this section.

17 (10) If a licensed pharmacist fails to obtain the twenty-four hours of approved
18 continuing pharmaceutical education, the pharmacist's license becomes inactive IN
19 ACCORDANCE WITH SECTION 12-20-203. An inactive licensee, ~~is not required to comply with~~
20 ~~any continuing pharmaceutical education requirement so long as the licensee remains~~
21 ~~inactive, but the licensee~~ WHILE ON INACTIVE STATUS, must continue to pay applicable fees,
22 including renewal fees. ~~The board shall note "inactive status" on the face of any license it~~
23 ~~issues to a licensee while the licensee remains inactive. Should an inactive pharmacist wish~~
24 To resume the practice of pharmacy after being placed on an inactive list, the pharmacist
25 shall file an application to activate his or her license, pay the license renewal fee, and,
26 subject to subsections (2) and (3) of this section, meet the twenty-four-hour continuing
27 education requirement. ~~If a licensed pharmacist engages in the practice of pharmacy while~~
28 ~~on inactive status, that conduct may be grounds for license revocation under this article.~~
29 <{***Redundant with inactive status common provision, 12-20-203. Recommend amending***
30 ***as indicated.***>
31

32 **12-280-118. [Formerly 12-42.5-116] Prescription drug outlet under charge of**
33 **pharmacist.** (1) (a) A prescription drug outlet must be under the direct charge of a
34 pharmacist manager. A proprietor who is not a pharmacist shall comply with this
35 requirement and shall provide a manager who is a pharmacist.

36 (b) The registration of any prescription drug outlet becomes void if the pharmacist
37 manager in whose name the prescription drug outlet registration was issued ceases to be
38 engaged as the manager. The owner shall close the prescription drug outlet unless the owner:

39 (I) Employs a new pharmacist manager; and

1 (II) Within thirty days after termination of the former manager's employment:

2 (A) Applies to transfer the registration to the new pharmacist manager; and

3 (B) Pays the registration transfer fee.

4 (c) At the time the pharmacist manager in whose name the registration was obtained
5 ceases to be employed as the pharmacist manager, he or she shall immediately report to the
6 board the fact that he or she is no longer manager of the prescription drug outlet. The
7 pharmacist manager is responsible as the manager until the cessation of employment is
8 reported. The proprietor of the prescription drug outlet shall also notify the board of the
9 termination of managership.

10 (2) A prescription drug outlet shall not commence business until it applies to the
11 board for a registration and receives from the board a registration showing the name of the
12 proprietor and the name of the manager. Upon transfer of the ownership of a prescription
13 drug outlet, the new proprietor shall submit to the board an application to transfer the
14 registration of the prescription drug outlet, and, upon approval of the transfer by the board,
15 the board shall transfer the registration to the new proprietor. Upon the change of name or
16 location of a prescription drug outlet, the registrant shall submit an application to change the
17 name or location and the applicable fee, and, upon approval of the application, the board
18 shall issue a new registration showing the new name or new location.

19 (3) (a) A prescription drug outlet operated by the state of Colorado or any political
20 subdivision of the state is not required to be registered but, in lieu of a registration, must
21 apply to the board, on a form approved by the board, for a certificate of compliance. The
22 board shall determine whether the prescription drug outlet is operated in accordance with
23 the laws of this state and the rules of the board. If the board determines that the prescription
24 drug outlet is operated in accordance with state laws and board rules, except for the holding
25 of a prescription drug outlet registration, the board shall issue a certificate of compliance,
26 which certificate expires and may be renewed in accordance with section ~~24-34-102(8)~~;
27 *C.R.S. 12-20-202 (1)*. Once the board issues the certificate of compliance, the prescription
28 drug outlet has the rights and privileges of, and is treated in all respects as, a registered
29 prescription drug outlet. The provisions of this article **280** with respect to the denial,
30 suspension, or revocation of a prescription drug outlet registration apply to a certificate of
31 compliance.

32 (b) An outlet as recognized in section ~~12-42.5-117(1)(d)~~ **12-280-119 (1)(d)** need not
33 be under the direct charge of a pharmacist, but a licensed pharmacist shall either initially
34 interpret all prescription orders compounded or dispensed from the outlet or provide written
35 protocols for compounding and dispensing by unlicensed persons. An outlet qualifying for
36 registration under this ~~paragraph (b)~~ SUBSECTION (3)(b) may also apply to the board for a
37 waiver of the requirements concerning physical space, equipment, inventory, or business
38 hours as necessary and consistent with the outlet's limited public welfare purpose. In
39 determining the granting or denial of a waiver application, the board shall ensure that the

1 public interest criteria set forth in section ~~12-42.5-101~~ **12-280-101** are satisfied. All other
2 provisions of this article **280**, except as specifically waived by the board, apply to the outlet.

3 (4) Every outlet and every pharmacist and pharmacy intern regularly practicing shall
4 conspicuously display the registration and license, respectively, within the premises of the
5 place of practice or outlet.

6 (5) The pharmacist responsible for the prescription order or chart order may delegate
7 certain specific tasks described in section ~~12-42.5-102 (31)(b)~~ **12-280-103 (39)(b)** to a
8 person who is not a pharmacist or pharmacy intern but who is an unlicensed assistant under
9 the pharmacist's supervision if, in the pharmacist's professional judgment, the delegation is
10 appropriate; except that the pharmacist shall not make the delegation if the delegation
11 jeopardizes the public health, safety, or welfare, is prohibited by rule of the board, or
12 violates section ~~12-42.5-126 (1)~~ **12-280-129 (1)**.

13
14 **12-280-119. [Formerly 12-42.5-117] Registration of facilities - rules.** (1) All
15 outlets with facilities in this state shall register with the board in one of the following
16 classifications:

17 (a) Prescription drug outlet;

18 (b) Wholesale drug outlet;

19 (c) Manufacturing drug outlet;

20 (d) Any other outlet, as may be authorized by this article **280** or that meets the
21 definition of outlet as set forth in section ~~12-42.5-102 (25)~~ **12-280-103 (32)**.

22 (2) The board shall establish, by rule, criteria, consistent with section ~~12-42.5-112~~
23 **12-280-114** and with the public interest as set forth in section ~~12-42.5-101~~ **12-280-101**, that
24 an outlet that has employees or personnel engaged in the practice of pharmacy must meet to
25 qualify for registration in each classification.

26 (3) The board shall specify by rule the registration procedures applicants must
27 follow, including the specifications for application for registration and the information
28 needed.

29 (4) Registrations issued by the board pursuant to this section are transferable or
30 assignable only pursuant to this article **280** and rules established by the board.

31 (5) It is lawful for a person to sell and distribute nonprescription drugs. Any person
32 engaged in the sale and distribution of nonprescription drugs is not improperly engaged in
33 the practice of pharmacy, and the board shall not promulgate any rule pursuant to this article
34 **280** that permits the sale of nonprescription drugs only by a licensed pharmacist or only
35 under the supervision of a licensed pharmacist or that would otherwise apply to or interfere
36 with the sale and distribution of nonprescription drugs.

37 (6) The board shall accept the licensure or certification of nursing care facilities and
38 intermediate care facilities required by the department of public health and environment as
39 sufficient registration under this section.

1 (7) A separate registration is required under this section for any area outside the
2 outlet that is not a satellite where pharmaceutical care and services are provided and for any
3 area outside the outlet that is under different ownership from the outlet.

4 (8) No hospital outlet filling inpatient chart orders shall sell or otherwise transfer any
5 portion of its prescription drug inventory to another registered outlet for sale or dispensing
6 at retail. This subsection (8) does not limit any transfer of prescription drugs for the
7 hospital's own use or limit the ability of a hospital outlet to engage in a casual sale.

8 (9) (a) Subject to ~~paragraph (b) of this subsection~~ (9) SUBSECTION (9)(b) OF THIS
9 SECTION, a prescription drug outlet may register as a compounding prescription drug outlet.

10 (b) The board shall not register a facility as a compounding prescription drug outlet
11 unless:

12 (I) The facility has been accredited by a board-approved compounding accreditation
13 entity to be within acceptable parameters to compound more than ten percent of the facility's
14 total sales; and

15 (II) Ownership of the facility is vested solely in a pharmacist.

16 (c) To be approved by the board to accredit a compounding prescription drug outlet,
17 a compounding accreditation entity shall be, at a minimum, a scientific organization with
18 expertise in compounding medications.

19 (10) (a) **On or after January 1, 2013**, a satellite shall register as a hospital satellite
20 pharmacy if the satellite:

21 (I) Is located in a facility that is under the same management and control as the
22 building or site where the prescription drug outlet is located; and

23 (II) Has a different address than the prescription drug outlet.

24 (b) The board shall adopt rules as necessary to implement this subsection (10). At a
25 minimum, the rules must set forth the manner in which a satellite is to apply for a hospital
26 satellite pharmacy registration and the limits on the distance of satellites from the main
27 prescription drug outlet.

28 (11) **On or after January 1, 2013**, a prescription drug outlet may register as a
29 specialized prescription drug outlet if it engages in the compounding, dispensing, and
30 delivery of drugs and devices to, or the provision of pharmaceutical care to residents of, a
31 long-term care facility. The board shall adopt rules as necessary to implement this subsection
32 (11).

33 (12) (a) A humane society that is duly registered with the secretary of state and has
34 been in existence and in business for at least five years in this state as a nonprofit
35 corporation, or an animal control agency that is operated by a unit of government, shall
36 register with the board.

37 (b) The board may issue a limited license to a humane society or animal control
38 agency to perform the activities described in section ~~12-42.5-118~~ (17) **12-280-120** (17).

39 (c) The board shall adopt rules as necessary to ensure strict compliance with this

1 subsection (12) and section ~~12-42.5-118~~ (17) **12-280-120** (17) and, in conjunction with the
2 state board of veterinary medicine, shall develop criteria for training individuals in the
3 administration of the drug or combination of drugs.

4 (d) Nothing in this subsection (12) applies to a licensed veterinarian.

5 (13) A facility or outlet applying for a registration under this section shall have
6 adequate and proper facilities for the handling and storage of controlled substances and shall
7 maintain proper control over the controlled substances to ensure the controlled substances
8 are not illegally dispensed or distributed.

9 (14) The board shall not issue a registration under this section to a manufacturer or
10 distributor of marijuana or marijuana concentrate, as those terms are defined in section
11 27-80-203 (15) and (16), ~~C.R.S.~~, respectively.

12
13 **12-280-120. [Formerly 12-42.5-118] Compounding - dispensing - sale of drugs
14 and devices - rules - definition.** (1) Except as otherwise provided in this section or part 2
15 of article 80 of title 27, ~~C.R.S.~~, no drug, controlled substance, or device shall be sold,
16 compounded, dispensed, given, received, or held in possession unless it is sold,
17 compounded, dispensed, given, or received in accordance with this section.

18 (2) Except as provided in subsection (7) of this section, a manufacturer of drugs may
19 sell or give any drug to:

- 20 (a) Any wholesaler of drugs;
21 (b) A licensed hospital;
22 (c) An other outlet;
23 (d) A registered prescription drug outlet; or
24 (e) Any practitioner authorized by law to prescribe the drugs.

25 (3) (a) A wholesaler may sell or give any drug or device to:

- 26 (I) Another wholesaler of drugs or devices;
27 (II) Any licensed hospital;
28 (III) A registered prescription drug outlet;
29 (IV) An other outlet; or
30 (V) Any practitioner authorized by law to prescribe the drugs or devices.

31 (b) A wholesaler may sell or deliver to a person responsible for the control of an
32 animal a drug intended for veterinary use for that animal only if a licensed veterinarian has
33 issued, prior to such THE sale or delivery, a written prescription order for the drug in the
34 course of an existing, valid veterinarian-client-patient relationship as defined in section
35 ~~12-64-103~~ (15.5) **12-315-___** (___); except that, if the prescription order is for a drug that
36 is not a controlled substance or is a controlled substance listed on schedule III, IV, or V, the
37 licensed veterinarian may issue an oral prescription order for that drug. If the licensed
38 veterinarian issues an oral prescription order for a controlled substance listed on schedule
39 III, IV, or V, the licensed veterinarian shall provide a written prescription to the wholesaler

1 within three business days after issuing the oral order.

2 (4) Only a registered prescription drug outlet or other outlet registered pursuant to
3 section ~~12-42.5-117 (1)(d)~~ **12-280-119 (1)(d)** may compound or dispense a prescription.
4 Initial interpretation and final evaluation, as defined by the board, may be conducted at a
5 location other than a registered prescription drug outlet or other outlet registered pursuant
6 to this article **280** in accordance with rules adopted by the board.

7 (5) (a) A registered prescription drug or licensed hospital other outlet may:

8 (I) Make a casual sale or loan of or give a drug to another registered outlet or to a
9 wholesaler of drugs;

10 (II) Sell or give a drug to a practitioner authorized by law to prescribe the drug;

11 (III) Supply an emergency kit or starter dose, as defined by the board by rule, to:

12 (A) Any facility approved by the board for receipt of an emergency kit;

13 (B) Any home health agency licensed by the department of public health and
14 environment and approved by the board for receipt of an emergency kit;

15 (C) Any licensed hospice approved by the board for receipt of an emergency kit in
16 compliance with subsection (12) of this section; and

17 (D) Any acute treatment unit licensed by the department of public health and
18 environment and approved by the board for receipt of an emergency kit.

19 (b) In the case of a county or district public health agency that operates registered
20 other outlets, one registered other outlet may make a casual sale of a drug to another
21 registered other outlet if:

22 (I) The drug is sold in the original sealed container in which it was originally
23 received from the wholesaler;

24 (II) A casual sale is not made to a registered other outlet that is not owned or
25 operated by that county or district public health agency; and

26 (III) The amount sold does not exceed the ten percent limit established by section
27 ~~12-42.5-102 (6)~~ **12-285-103 (8)**.

28 (c) Pursuant to section 17-1-113.1, ~~C.R.S.~~, the department of corrections may
29 transfer, deliver, or distribute to a corporation, individual, or other entity entitled to possess
30 prescription drugs, other than a consumer, prescription drugs in an amount that is less than,
31 equal to, or in excess of five percent of the total number of dosage units of drugs dispensed
32 and distributed on an annual basis.

33 (6) (a) A practitioner may personally compound and dispense for any patient under
34 the practitioner's care any drug that the practitioner is authorized to prescribe and that the
35 practitioner deems desirable or necessary in the treatment of any condition being treated by
36 the practitioner, and the practitioner is exempt from all provisions of this article **280** except
37 section ~~12-42.5-126~~ **12-280-129**.

38 (b) (I) The board shall promulgate rules authorizing a prescription drug outlet located
39 in this state to compound drugs for office use by a practitioner or for use by a hospital

1 located in this state. The rules must limit the amount of drugs a prescription drug outlet may
2 compound and distribute to a practitioner or hospital pursuant to this ~~paragraph (b)~~
3 SUBSECTION (6)(b) to no more than ten percent of the total number of drug dosage units
4 dispensed and distributed on an annual basis by the outlet.

5 (II) (A) The ten percent limitation set forth in ~~subparagraph (I) of this paragraph (b)~~
6 SUBSECTION (6)(b)(I) OF THIS SECTION applies to a compounded drug for veterinary use that
7 a prescription drug outlet distributes in Colorado.

8 (B) For purposes of this ~~subparagraph (II)~~ SUBSECTION (6)(b)(II), a "prescription
9 drug outlet" includes a nonresident pharmacy outlet registered or licensed pursuant to this
10 article **280** where prescriptions are compounded and dispensed, but only if the nonresident
11 pharmacy outlet has provided the board with a copy of the most recent inspection of the
12 nonresident pharmacy outlet by the agency that regulates pharmaceuticals in the state of
13 residence and a copy of the most recent inspection received from a board-approved
14 third-party entity that inspects pharmacy outlets, for which third-party inspection the
15 nonresident pharmacy outlet shall obtain and pay for on an annual basis, and the board
16 approves the inspection reports as satisfactorily demonstrating proof of compliance with the
17 board's own inspection procedure and standards.

18 (c) Nothing in this section prohibits an optometrist licensed pursuant to article ~~40~~
19 **275** of this title **12** or a physician licensed pursuant to article ~~36~~ **240** of this title **12** from
20 charging a fee for prescribing, adjusting, fitting, adapting, or dispensing drugs for
21 ophthalmic purposes and ophthalmic devices, such as contact lenses, that are classified by
22 the ~~federal food and drug administration~~ FDA as a drug or device, as long as the activity is
23 within the scope of practice of the optometrist pursuant to article ~~40~~ **275** of this title **12** or
24 the scope of practice of the physician pursuant to article ~~36~~ **240** of this title **12**.

25 (7) Distribution of any sample may be made only upon written receipt from a
26 practitioner, and the receipt must be given specifically for each drug or drug strength
27 received.

28 (8) It is lawful for the vendor of any drug or device to repurchase the drug or device
29 from the vendee to correct an error, to retire an outdated article, or for other good reason,
30 under rules the board may adopt to protect consumers of drugs and devices against the
31 possibility of obtaining unsafe or contaminated drugs or devices.

32 (9) A duly authorized agent or employee of an outlet registered by the board is not
33 deemed to be in possession of a drug or device in violation of this section if he or she is in
34 possession of the drug or device for the sole purpose of carrying out the authority granted
35 by this section to his or her principal or employer.

36 (10) Any hospital employee or agent authorized by law to administer or dispense
37 medications may dispense a twenty-four-hour supply of drugs on the specific order of a
38 practitioner to a registered emergency room patient.

39 (11) The original, duplicate, or electronic or mechanical facsimile of a chart order

1 by the physician or lawfully designated agent constitutes a valid authorization to a
2 pharmacist or pharmacy intern to dispense to a hospitalized patient for administration the
3 amounts of the drugs as will enable an authorized person to administer to the patient the
4 drug ordered by the practitioner. The practitioner is responsible for verifying the accuracy
5 of any chart order he or she transmitted to anyone other than a pharmacist or pharmacist
6 intern within forty-eight hours of the transmittal.

7 (12) Any facility approved by the board, any home health agency certified by the
8 department of public health and environment and approved by the board, and any licensed
9 hospice approved by the board may maintain emergency drugs provided and owned by a
10 prescription drug outlet, consisting of drugs and quantities as established by the board.

11 (13) An intern under the direct and immediate supervision of a pharmacist may
12 engage in the practice of pharmacy. An intern, as defined in section ~~12-42.5-102(17)(a)~~
13 **12-280-103 (22)(a)**, engaged in the practice of pharmacy within the curriculum of a school
14 or college of pharmacy in accordance with section ~~12-42.5-102(17)(a)~~ **12-280-103 (22)(a)**,
15 may be supervised by a manufacturer registered pursuant to section ~~12-42.5-112~~ **12-280-114**
16 or by another regulated individual as provided for in rules adopted by the board.

17 (14) A manufacturer or wholesaler of prescription drugs shall not sell or give any
18 prescription drug, as provided in subsections (2) and (3) of this section, to a licensed hospital
19 or registered outlet or to any practitioner unless the prescription drug stock container bears
20 a label containing the name and place of business of the manufacturer of the finished dosage
21 form of the drug and, if different from the manufacturer, the name and place of business of
22 the packer or distributor.

23 (15) (a) A compounding prescription drug outlet registered pursuant to section
24 ~~12-42.5-117(9)~~ **12-280-119 (9)** may dispense and distribute compounded drugs without
25 limitation to practitioners or to prescription drug outlets under common ownership with the
26 pharmacist who owns the compounding prescription drug outlet.

27 (b) The following may distribute compounded and prepackaged medications, without
28 limitation, to pharmacies and other outlets under common ownership of the entity:

29 (I) A prescription drug outlet owned and operated by a hospital that is accredited by
30 the Joint Commission on Accreditation of Healthcare Organizations <{***Now just referred***
31 ***to as the Joint Commission. Wait to fix in sunset process?***> or a successor organization;

32 (II) A prescription drug outlet operated by a health maintenance organization, as
33 defined in section 10-16-102; ~~C.R.S.~~; and

34 (III) The Colorado department of corrections.

35 (c) (I) A prescription drug outlet shall not compound drugs that are commercially
36 available except as provided in ~~subparagraph (H) of this paragraph~~ (c) SUBSECTION
37 (15)(c)(II) OF THIS SECTION.

38 (II) A pharmacist may compound a commercially available drug if the compounded
39 drug is significantly different from the commercially available drug or if use of the

1 compounded drug is in the best medical interest of the patient, based upon the practitioner's
2 drug order, including the removal of a dye that causes an allergic reaction. If the pharmacist
3 compounds a drug in lieu of a commercially available product, the pharmacist shall notify
4 the patient of that fact.

5 (16) A prescription drug outlet may allow a licensed pharmacist to remove
6 immunizations and vaccines from the prescription drug outlet for the purpose of
7 administration by a licensed pharmacist, or an intern under the supervision of a pharmacist
8 certified in immunization, pursuant to rules promulgated by the board. The board shall
9 promulgate rules regarding the storage, transportation, and record keeping of immunizations
10 and vaccines that are administered off-site.

11 (17) (a) A humane society or animal control agency that is registered with the board
12 pursuant to section ~~12-42.5-117~~ (12) **12-280-119** (12) is authorized to:

13 (I) Purchase, possess, and administer sodium pentobarbital, or sodium pentobarbital
14 in combination with other prescription drugs that are medically recognized for euthanasia,
15 to euthanize injured, sick, homeless, or unwanted pets and animals; and

16 (II) Purchase, possess, and administer drugs commonly used for the chemical capture
17 of animals for control purposes or to sedate or immobilize pet animals immediately prior to
18 euthanasia.

19 (b) A society or agency registered pursuant to section ~~12-42.5-117~~ (12) **12-280-119**
20 (12) shall not permit a person to administer scheduled controlled substances, sodium
21 pentobarbital, or sodium pentobarbital in combination with other noncontrolled prescription
22 drugs that are medically recognized for euthanasia unless the person has demonstrated
23 adequate knowledge of the potential hazards and proper techniques to be used in
24 administering the drug or combination of drugs.

25 (18) Persons registered as required under this part 1, or otherwise licensed or
26 registered as required by federal law, may possess, manufacture, distribute, dispense, or
27 administer controlled substances only to the extent authorized by their registrations or
28 federal registrations or licenses and in conformity with this article **280** and with article 18
29 of title 18. ~~C.R.S.~~

30
31 **12-280-121. [Formerly 12-42.5-118.5] Compounding drugs for office use by a**
32 **veterinarian - rules - definitions.** (1) A registered prescription drug outlet may compound
33 and distribute a drug to a licensed veterinarian so that the veterinarian may maintain the drug
34 as part of the veterinarian's office stock.

35 (2) (a) A veterinarian may dispense a compounded drug maintained as part of the
36 veterinarian's office stock pursuant to subsection (1) of this section only if:

37 (I) The compounded drug is necessary for the treatment of an animal patient's
38 emergency condition; and

39 (II) As determined by the veterinarian, the veterinarian cannot access, in a timely

1 manner, the compounded drug through a registered prescription drug outlet.

2 (b) A veterinarian shall not dispense a compounded drug pursuant to this section in
3 an amount greater than the amount required to treat an animal patient's emergency condition
4 for five days.

5 (3) A licensed veterinarian shall not administer or dispense a compounded drug
6 maintained for office stock pursuant to this section or for office use pursuant to section
7 ~~12-42.5-118 (6)(b)(H)~~ **12-280-120 (6)(b)(II)** without a valid veterinarian-client-patient
8 relationship in place at the time of administering the compounded drug to an animal patient
9 or dispensing the compounded drug to a client.

10 (4) To compound and distribute a controlled substance pursuant to this section or
11 section ~~12-42.5-117(12)~~ **12-280-119 (12)**, a registered prescription drug outlet shall possess
12 a valid manufacturing registration from the federal drug enforcement administration.

13 (5) As used in this section, unless the context otherwise requires:

14 (a) "Client" has the same meaning as set forth in section ~~12-64-103 (4.3)~~ **12-315-**
15 **()**.

16 (b) "Office stock" means the storage of a compounded drug:

17 (I) That was distributed or sold by a registered prescription drug outlet to a
18 veterinarian;

19 (II) Without a specific animal patient indicated to receive the compounded drug; and

20 (III) That the veterinarian may subsequently administer to an animal patient or
21 dispense to a client.

22 ~~(c) Repealed.~~

23 ~~(d)~~ (c) (I) "Prescription drug outlet" means any:

24 (A) Resident or nonresident pharmacy outlet registered or licensed pursuant to this
25 article **280** where prescriptions are compounded and dispensed; or

26 (B) Federally owned and operated pharmacy registered with the federal drug
27 enforcement administration.

28 (II) Notwithstanding ~~subparagraph (I) of this paragraph (d)~~ SUBSECTION (5)(c)(I) OF
29 THIS SECTION, "prescription drug outlet" does not include a nonresident pharmacy outlet
30 unless the nonresident pharmacy outlet has provided the board with a copy of the most
31 recent inspection of the nonresident pharmacy by the agency that regulates pharmaceuticals
32 in the state of residence and a copy of the most recent inspection received from a
33 board-approved third-party entity that inspects pharmacy outlets, for which third-party
34 inspection the nonresident pharmacy outlet shall obtain and pay for on an annual basis, and
35 the board approves the inspection reports as satisfactorily demonstrating proof of
36 compliance with the board's own inspection procedure and standards.

37 (6) The board may promulgate rules as necessary concerning compounded veterinary
38 pharmaceuticals pursuant to this section and section ~~12-42.5-118 (6)(b)(H)~~ **12-280-120**
39 **(6)(b)(II)**.

1 **12-280-122. [Formerly 12-42.5-119] Limited authority to delegate activities**
2 **constituting practice of pharmacy to pharmacy interns or pharmacy technicians.** (1) A
3 pharmacist may supervise up to six persons who are either pharmacy interns or pharmacy
4 technicians, of whom no more than two may be pharmacy interns. If three or more pharmacy
5 technicians are on duty, the majority must be certified by a nationally recognized
6 certification board, possess a degree from an accredited pharmacy technician training
7 program, or have completed five hundred hours of experiential training in duties described
8 in section ~~12-42.5-102 (31)(b)~~ **12-280-103 (39)(b)** at the pharmacy as certified by the
9 pharmacist manager within eighteen months of hire.

10 (2) The pharmacy shall retain documentation verifying the training for review by the
11 pharmacist responsible for the final check on prescriptions filled by the pharmacy technician
12 and shall make the documentation available for inspection by the board.

13 (3) The supervision ratio specified in subsection (1) of this section does not include
14 other ancillary personnel who may be in the prescription drug outlet but who are not
15 performing duties described in section ~~12-42.5-102 (31)(b)~~ **12-280-103 (39)(b)** that are
16 delegated to the interns or pharmacy technicians.

17
18 **12-280-123. [Formerly 12-42.5-120] Prescription required - exception -**
19 **dispensing opiate antagonists.** (1) Except as provided in section 18-18-414 C.R.S., and
20 subsections (2) and (3) of this section, an order is required prior to dispensing any
21 prescription drug. Orders shall be readily retrievable within the appropriate statute of
22 limitations.

23 (2) A pharmacist may refill a prescription order for any prescription drug without the
24 practitioner's authorization when all reasonable efforts to contact the practitioner have failed
25 and when, in the pharmacist's professional judgment, continuation of the medication is
26 necessary for the patient's health, safety, and welfare. The prescription refill may only be in
27 an amount sufficient to maintain the patient until the practitioner can be contacted, but in no
28 event may a refill under this subsection (2) continue medication beyond seventy-two hours.
29 However, if the practitioner states on the prescription that no emergency filling of the
30 prescription is permitted, then the pharmacist shall not issue any medication that is not
31 authorized by the prescription. Neither a prescription drug outlet nor a pharmacist is liable
32 as a result of refusing to refill a prescription pursuant to this subsection (2).

33 (3) (a) A pharmacist may dispense pursuant to an order or standing orders and
34 protocols, an opiate antagonist to IN ACCORDANCE WITH SECTION 12-30-110.

- 35 (I) An individual at risk of experiencing an opiate-related drug overdose event;
36 (II) A family member, friend, or other person in a position to assist an individual at
37 risk of experiencing an opiate-related drug overdose event;
38 (III) An employee or volunteer of a harm reduction organization; or
39 (IV) A first responder.

1 (b) A pharmacist who dispenses an opiate antagonist pursuant to this subsection (3)
2 is strongly encouraged to educate persons receiving the opiate antagonist on the use of an
3 opiate antagonist for overdose, including instruction concerning risk factors for overdose,
4 recognizing an overdose, calling emergency medical services, rescue breathing, and
5 administering an opiate antagonist.

6 (c) (I) A pharmacist does not engage in unprofessional conduct pursuant to section
7 12-42.5-123 if the pharmacist dispenses, pursuant to an order or standing orders and
8 protocols, an opiate antagonist in a good-faith effort to assist:

9 (A) An individual who is at risk of experiencing an opiate-related drug overdose
10 event;

11 (B) A family member, friend, or other person who is in a position to assist an
12 individual who is at risk of experiencing an opiate-related drug overdose event; or

13 (C) A first responder or an employee or volunteer of a harm reduction organization
14 in responding to, treating, or otherwise assisting an individual who is experiencing or is at
15 risk of experiencing an opiate-related drug overdose event or a friend, family member, or
16 other person in a position to assist an at-risk individual.

17 (H) A pharmacist who dispenses an opiate antagonist in accordance with this section
18 is not subject to civil liability or criminal prosecution, as specified in sections 13-21-108.7
19 (4) and 18-1-712 (3), C.R.S., respectively.

20 (HH) This subsection (3) does not establish a duty or standard of care regarding the
21 dispensing of an opiate antagonist.

22 (d) (I) A first responder or an employee or volunteer of a harm reduction
23 organization may, pursuant to an order or standing orders and protocols:

24 (A) Possess an opiate antagonist;

25 (B) Furnish an opiate antagonist to a family member, friend, or other person who is
26 in a position to assist an individual who is at risk of experiencing an opiate-related drug
27 overdose event; or

28 (C) Administer an opiate antagonist to an individual experiencing, or who a
29 reasonable person would believe is experiencing, an opiate-related drug overdose event.

30 (H) A first responder or harm reduction organization is strongly encouraged to
31 educate its employees and volunteers, as well as persons receiving an opiate antagonist from
32 the first responder or harm reduction organization, on the use of an opiate antagonist for
33 overdose, including instruction concerning risk factors for overdose, recognizing an
34 overdose, calling emergency medical services, rescue breathing, and administering an opiate
35 antagonist.

36 (HH) A first responder or an employee or volunteer of a harm reduction organization
37 acting in accordance with this paragraph (d) is not subject to civil liability or criminal
38 prosecution, as specified in sections 13-21-108.7 (3) and 18-1-712 (2), C.R.S., respectively.

39 (e) As used in this section:

1 ~~(I) "First responder" means:~~

2 ~~(A) A peace officer, as defined in section 16-2.5-101, C.R.S.;~~

3 ~~(B) A firefighter, as defined in section 29-5-203 (10), C.R.S.; or~~

4 ~~(C) A volunteer firefighter, as defined in section 31-30-1102 (9), C.R.S.~~

5 ~~(H) "Harm reduction organization" means an organization that provides services,~~
6 ~~including medical care, counseling, homeless services, or drug treatment, to individuals at~~
7 ~~risk of experiencing an opiate-related drug overdose event or to the friends and family~~
8 ~~members of an at-risk individual.~~

9 ~~(III) "Opiate" has the same meaning as set forth in section 18-18-102 (21), C.R.S.~~

10 ~~(IV) "Opiate antagonist" means naloxone hydrochloride or any similarly acting drug~~
11 ~~that is not a controlled substance and that is approved by the federal food and drug~~
12 ~~administration FDA for the treatment of a drug overdose.~~

13 ~~(V) "Opiate-related drug overdose event" means an acute condition, including a~~
14 ~~decreased level of consciousness or respiratory depression, that:~~

15 ~~(A) Results from the consumption or use of a controlled substance or another~~
16 ~~substance with which a controlled substance was combined;~~

17 ~~(B) A layperson would reasonably believe to be caused by an opiate-related drug~~
18 ~~overdose event; and~~

19 ~~(C) Requires medical assistance.~~

20 ~~(VI) "Protocol" means a specific written plan for a course of medical treatment~~
21 ~~containing a written set of specific directions created by a physician, group of physicians,~~
22 ~~hospital medical committee, pharmacy and therapeutics committee, or other similar~~
23 ~~practitioners or groups of practitioners with expertise in the use of opiate antagonists.~~

24 ~~(VII) "Standing order" means a prescription order written by a practitioner that is not~~
25 ~~specific to and does not identify a particular patient.~~

26 <{*Redundant with opiate antagonists common provision, 12-30-110. Recommend*
27 *repealing and adding reference to common provision.*>

28
29 **12-280-124. [Formerly 12-42.5-121] Labeling.** (1) A prescription drug dispensed
30 pursuant to an order must be labeled as follows:

31 (a) Drugs compounded and dispensed pursuant to a chart order for a patient in a
32 hospital must bear a label containing the name of the outlet, the name and location of the
33 patient, the identification of the drug, and, when applicable, any suitable control numbers,
34 the expiration date, any warnings, and any precautionary statements.

35 (b) (I) If the prescription is for an anabolic steroid, the purpose for which the
36 anabolic steroid is being prescribed must appear on the label.

37 (II) If the prescription is for any drug other than an anabolic steroid, the symptom or
38 purpose for which the drug is being prescribed must appear on the label, if, after being
39 advised by the practitioner, the patient or the patient's authorized representative so requests.

1 If the practitioner does not provide the symptom or purpose for which a drug is being
2 prescribed, the pharmacist may fill the prescription order without contacting the practitioner,
3 patient, or patient's representative, unless the prescription is for an anabolic steroid.

4 (2) Except as otherwise required by law, any drug dispensed pursuant to a
5 prescription order must bear a label prepared and placed on or securely attached to the
6 medicine container stating at least the name and address of the prescription drug outlet, the
7 serial number and the date of the prescription or of its dispensing, the name of the drug
8 dispensed unless otherwise requested by the practitioner, the name of the practitioner, the
9 name of the patient, and, if stated in the prescription, the directions for use and cautionary
10 statements, if any, contained in the prescription.

11
12 **12-280-125. [Formerly 12-42.5-122] Substitution of prescribed drugs authorized**
13 **- when - conditions.** (1) (a) A pharmacist filling a prescription order for a specific drug by
14 brand or proprietary name may substitute an equivalent drug product if the substituted drug
15 product is the same generic drug type and, in the pharmacist's professional judgment, the
16 substituted drug product is therapeutically equivalent, is interchangeable with the prescribed
17 drug, and is permitted to be moved in interstate commerce. A pharmacist making a
18 substitution shall assume the same responsibility for selecting the dispensed drug product
19 as he or she would incur in filling a prescription for a drug product prescribed by a generic
20 name; except that the pharmacist is charged with notice and knowledge of the FDA list of
21 approved drug substances and manufacturers that is published periodically.

22 (b) (I) A pharmacist filling a prescription order for a specific biological product may
23 substitute an interchangeable biological product for the prescribed biologic only if:

24 (A) The FDA has determined that the biological product to be substituted is
25 interchangeable with the prescribed biological product; and

26 (B) The practitioner has not indicated, in the manner described in subsection (2) of
27 this section, that the pharmacist shall not substitute an interchangeable biological product
28 for the prescribed biological product.

29 (II) Within a reasonable time after dispensing a biological product, the dispensing
30 pharmacist or his or her designee shall communicate to the prescribing practitioner the
31 specific biological product dispensed to the patient, including the name and manufacturer
32 of the biological product. The pharmacist or designee shall communicate the information to
33 the prescribing practitioner by making an entry into an interoperable electronic medical
34 records system, through electronic prescribing technology, or through a pharmacy record
35 that the prescribing practitioner can access electronically. Otherwise, the pharmacist or his
36 or her designee shall communicate to the prescribing practitioner the name and manufacturer
37 of the biological product dispensed to the patient using facsimile, telephone, electronic
38 transmission, or other prevailing means except when:

39 (A) There is no FDA-approved interchangeable biological product for the prescribed

1 biological product; or

2 (B) A refill prescription is not changed from the biological product dispensed on the
3 prior filling of the prescription.

4 (III) The pharmacy from which the biological product was dispensed must retain a
5 written or electronic record of the dispensed biological product for at least two years after
6 the substitution.

7 (IV) This ~~paragraph (b)~~ SUBSECTION (1)(b) does not apply to the administration of
8 vaccines and immunizations as outlined in board rules.

9 (2) (a) If, in the opinion of the practitioner, it is in the best interest of the patient that
10 the pharmacist not substitute an equivalent drug or interchangeable biological product for
11 the specific drug or biological product he or she prescribed, the practitioner may convey this
12 information to the pharmacist in any of the following manners:

13 (I) Initialing by hand or electronically a preprinted box that states "dispense as
14 written" or "DAW";

15 (II) Signing by hand or electronically a preprinted box stating "do not substitute" or
16 "dispense as written"; or

17 (III) Orally, if the practitioner communicates the prescription orally to the
18 pharmacist.

19 (b) The practitioner shall not transmit by facsimile his or her handwritten signature,
20 nor preprint his or her initials, to indicate "dispense as written".

21 (3) (a) If a pharmacist makes a substitution pursuant to subsection (1) of this section,
22 the pharmacist shall communicate the substitution to the purchaser in writing and orally,
23 label the container with the name of the drug or biological product dispensed, and indicate
24 on the file copy of the prescription both the name of the prescribed drug or biological
25 product and the name of the drug or biological product dispensed in lieu of the prescribed
26 drug or prescribed biological product.

27 (b) The pharmacist is not required to communicate a substitution to institutionalized
28 patients.

29 (4) Except as provided in subsection (5) of this section, the pharmacist shall not
30 substitute a drug or interchangeable biological product as provided in this section unless the
31 drug or interchangeable biological product substituted costs the purchaser less than the drug
32 or biological product prescribed. The prescription shall be priced for a drug, other than a
33 biological product, as if it had been prescribed generically.

34 (5) If a prescription drug outlet does not have in stock the prescribed drug or
35 biological product and the only equivalent drug or interchangeable biological product in
36 stock is higher priced, the pharmacist, with the consent of the purchaser, may substitute the
37 higher priced drug or interchangeable biological product. This subsection (5) applies only
38 to a prescription drug outlet located in a town, as defined in section 31-1-101 (13). ~~C.R.S.~~

39 (6) The board shall maintain on its website a link to the FDA resource, if one is

1 available, that identifies all biological products approved as interchangeable with specific
2 biological products.

3
4 **12-280-126. [Formerly 12-42.5-123] Unprofessional conduct - grounds for**
5 **discipline.** (1) The board may suspend, revoke, refuse to renew, or otherwise discipline any
6 license or registration issued by it TAKE DISCIPLINARY OR OTHER ACTION AS AUTHORIZED IN
7 SECTIONS 12-20-404, after a hearing held in accordance with the provisions of this section
8 SECTIONS 12-20-203 AND 12-280-127, upon proof that the licensee or registrant:
9 <{*Updated to include references to disciplinary procedures and disciplinary actions*

10 *common provisions, 12-20-403 and 12-20-404.*>
11 (a) Is guilty of misrepresentation, fraud, or deceit in procuring, attempting to procure,
12 or renewing a license or registration;

13 (b) Is guilty of the commission of a felony or has had accepted by a court a plea of
14 guilty or nolo contendere to a felony or has received a deferred judgment and sentence for
15 a felony;

16 (c) Has violated:

17 (I) Any of the provisions of this article ~~280~~, including commission of an act declared
18 unlawful in section ~~12-42.5-126~~ **12-280-129**;

19 (II) The lawful rules of the board; or

20 (III) Any state or federal law pertaining to drugs;

21 (d) Is unfit or incompetent by reason of negligence or habits, or for any other cause,
22 to practice pharmacy;

23 (e) Has an alcohol use disorder, as defined in section 27-81-102, or a substance use
24 disorder, as defined in section 27-82-102, or engages in the habitual or excessive use or
25 abuse of alcohol, a habit-forming drug, or a controlled substance, as defined in section
26 18-18-102 (5);

27 (f) Knowingly permits a person not licensed as a pharmacist or pharmacy intern to
28 engage in the practice of pharmacy;

29 (g) Has had his or her license to practice pharmacy in another state revoked or
30 suspended, or is otherwise disciplined or has committed acts in any other state that would
31 subject him or her to disciplinary action in this state;

32 (h) Has engaged in advertising that is misleading, deceptive, or false;

33 (i) Has dispensed a schedule III, IV, or V controlled substance order as listed in
34 sections 18-18-205 to 18-18-207 ~~C.R.S.~~, more than six months after the date of issue of the
35 order;

36 (j) Has engaged in the practice of pharmacy while on inactive status;

37 (k) Has failed to meet generally accepted standards of pharmacy practice;

38 (l) Fails or has failed to permit the board or its agents to conduct a lawful inspection;

39 (m) Has violated any lawful board order;

1 (n) Has committed any fraudulent insurance act as defined in section 10-1-128;
2 ~~C.R.S.~~;

3 (o) Has willfully deceived or attempted to deceive the board or its agents with regard
4 to any matter under investigation by the board;

5 (p) Has failed to notify the board of any criminal conviction or deferred judgment
6 within thirty days after the conviction or judgment;

7 (q) Has failed to notify the board of any discipline against his or her license in
8 another state within thirty days after the discipline;

9 (r) (I) Has failed to notify the board of a physical illness; a physical condition; or a
10 behavioral, mental health, or substance use disorder that affects the person's ability to treat
11 clients with reasonable skill and safety or that may endanger the health or safety of persons
12 under his or her care;

13 (II) Has failed to act within the limitations created by a physical illness; a physical
14 condition; or a behavioral, mental health, or substance use disorder that renders the person
15 unable to practice pharmacy with reasonable skill and safety or that may endanger the health
16 or safety of persons under his or her care; or

17 (III) Has failed to comply with the limitations agreed to under a confidential
18 agreement entered pursuant to section ~~12-42.5-134~~ SECTIONS 12-30-107 AND 12-280-136;
19 <{*Adding reference to confidential agreements common provision, 12-30-107.*}>

20 (s) Has had his or her federal registration to manufacture, distribute, or dispense a
21 controlled substance suspended or revoked.

22 (2) In considering the conviction of a crime, the board is governed by section
23 SECTIONS 12-20-202 (5) AND 24-5-101. ~~C.R.S.~~ <{*Updated with cross reference to criminal*
24 *conviction common provision, 12-20-202 (5).*}>

25 (3) Repeated.

26
27 **12-280-127. [Formerly 12-42.5-124] Disciplinary actions.** (1) (a) The board may
28 ~~deny or discipline an applicant, licensee, or registrant~~ TAKE DISCIPLINARY OR OTHER ACTION
29 AS AUTHORIZED IN SECTION 12-20-404 when the board determines that the applicant,
30 licensee, or registrant has engaged in activities that are grounds for discipline UNDER
31 SECTION 12-280-126. <{*Updated to include citation to disciplinary actions common*
32 *provision, 12-20-404.*}>

33 (b) The board may suspend or revoke a registration issued pursuant to section
34 ~~12-42.5-117 (12)~~ 12-280-119 (12) upon determination that the person administering a drug
35 or combination of drugs to an animal has not demonstrated adequate knowledge required
36 by sections ~~12-42.5-117 (12)~~ 12-280-119 (12) and ~~12-42.5-118 (17)~~ 12-280-120 (17).

37 (2) (a) Proceedings for the denial, suspension, or revocation of a license or
38 registration and any judicial review of a suspension or revocation must be conducted in
39 accordance with article 4 of title 24 ~~C.R.S.~~, and the board or, at the board's discretion, an

1 administrative law judge, shall conduct the hearing and opportunity for review AND
2 SECTIONS 12-20-403 AND 12-20-408. <{*Redundant with disciplinary procedures common*
3 *provision, 12-20-403, and judicial review common provision, 12-20-408.*}>

4 (b) Upon finding that grounds for discipline pursuant to section ~~12-42.5-123~~
5 *12-280-126* exist, **IN ADDITION TO THE DISCIPLINARY ACTIONS SPECIFIED IN SECTION 12-20-**
6 **404 (1)**, the board may impose one or more of the following penalties on a person who holds
7 or is seeking a new or renewal license or registration:

8 ~~(I) Suspension of the offender's license or registration for a period to be determined~~
9 ~~by the board;~~

10 ~~(H) Revocation of the offender's license or registration;~~

11 ~~(HH) (I) Restriction of the offender's license or registration to prohibit the offender~~
12 ~~from performing certain acts or from practicing pharmacy in a particular manner for a period~~
13 ~~to be determined by the board;~~

14 ~~(IV) Refusal to renew the offender's license or registration;~~

15 ~~(V) (II) Placement of the offender on probation and supervision by the board for a~~
16 ~~period to be determined by the board; OR~~

17 ~~(VT) (III) Suspension of the registration of the outlet that is owned by or employs the~~
18 ~~offender for a period to be determined by the board. <{*Some redundancy with disciplinary*~~
19 ~~*actions common provision, 12-20-404 (1). Recommend amending as indicated.*}>~~

20 (c) The board may limit revocation or suspension of a registration to the particular
21 controlled substance which was the basis for revocation or suspension.

22 (d) If the board suspends or revokes a registration, the board may place all controlled
23 substances owned or possessed by the registrant at the time of the suspension or on the
24 effective date of the revocation order under seal. The board may not dispose of substances
25 under seal until the time for making an appeal has elapsed or until all appeals have been
26 concluded, unless a court orders otherwise or orders the sale of any perishable controlled
27 substances and the deposit of the proceeds with the court. When a revocation becomes final,
28 all controlled substances may be forfeited to the state.

29 (e) The board shall promptly notify the bureau and the appropriate professional
30 licensing agency, if any, of all charges and the final disposition of the charges and of all
31 forfeitures of a controlled substance.

32 (3) The board may also include in any disciplinary order that allows the licensee or
33 registrant to continue to practice conditions that the board deems appropriate to assure that
34 the licensee or registrant is physically, mentally, morally, and otherwise qualified to practice
35 pharmacy in accordance with the generally accepted professional standards of practice,
36 including any or all of the following:

37 (a) Requiring the licensee or registrant to submit to examinations that the board may
38 order to determine the licensee's physical or mental condition or professional qualifications;

39 (b) Requiring the licensee to take therapy courses of training or education that the

1 board deems necessary to correct deficiencies found either in the hearing or by examinations
2 required pursuant to ~~paragraph (a) of this subsection~~ (3) SUBSECTION (3)(a) OF THIS SECTION;

3 (c) Requiring the review or supervision of the licensee's practice to determine the
4 quality of and correct deficiencies in his or her practice; and

5 (d) Imposing restrictions upon the nature of the licensee's practice to assure that he
6 or she does not practice beyond the limits of his or her capabilities.

7 (4) Upon failure of the licensee or registrant to comply with any conditions imposed
8 by the board pursuant to subsection (3) of this section, unless due to conditions beyond the
9 licensee's or registrant's control, the board may order suspension of the license or registration
10 in this state until the licensee or registrant complies with the conditions.

11 (5) (a) ~~(H)~~ Except as provided in ~~subparagraphs (H) and (HH) of this paragraph~~ (a)
12 SUBSECTIONS (5)(b) AND (5)(c) OF THIS SECTION, in addition to any other penalty the board
13 may impose pursuant to this section, the board may fine any registrant violating this article
14 **280** or any rules promulgated pursuant to this article **280** not less than five hundred dollars
15 and not more than five thousand dollars for each violation.

16 ~~(H)~~ (b) In addition to any other penalty the board may impose pursuant to this
17 section, the board may fine a registrant violating part 4 of this article **280** not less than five
18 hundred dollars and not more than one thousand dollars for the first time the board imposes
19 a fine, not more than two thousand dollars for the second time the board imposes a fine, and
20 not more than five thousand dollars for a third or subsequent time the board imposes a fine.
21 If a registrant violates an agreement to refrain from committing subsequent violations of part
22 4 of this article **280**, the board may impose a fine of not more than one thousand dollars for
23 each violation of the agreement.

24 ~~(HH)(A)~~ (c) (I) The board, after providing notice and an opportunity to be heard, may
25 fine a registrant who distributes a veterinary drug in violation of this article **280** not less than
26 fifty dollars nor more than five hundred dollars for each violation, with a maximum
27 aggregated fine of five thousand dollars for multiple violations; except that, if, after
28 considering the recommendations of the advisory committee created in section
29 ~~12-42.5-104.5~~ **12-280-106**, the board determines that the registrant has committed one or
30 more egregious violations, the board may fine the registrant in accordance with
31 ~~subparagraph (F) of this paragraph~~ (a) SUBSECTION (5)(a) OF THIS SECTION.

32 ~~(B)~~ (II) In setting a fine, the board shall consider the registrant's ability to pay. If the
33 board determines that paying the fine would cause the registrant an undue hardship, the
34 board shall waive the fine.

35 ~~(b) The board shall transmit any moneys collected as administrative fines pursuant~~
36 ~~to this subsection (5) to the state treasurer for credit to the general fund. <{~~ ***Redundant with***
37 ***disposition of fines common provision, 12-20-404 (6)*** ~~>~~

38 ~~(6) (a) When a complaint or an investigation discloses an instance of misconduct~~
39 ~~that, in the opinion of the board, does not warrant formal action by the board but should not~~

1 ~~be dismissed as being without merit, The board may send a letter of admonition by certified~~
2 ~~mail to the A licensee or registrant against whom the complaint was made or who was the~~
3 ~~subject of investigation and IN ACCORDANCE WITH SECTION 12-20-404 (4). In the case of a~~
4 ~~complaint, THE BOARD may send a copy of the letter of admonition to the person making the~~
5 ~~complaint.~~

6 ~~(b) When the board sends a letter of admonition to a licensee or registrant~~
7 ~~complained against, the board shall include in the letter a statement advising the licensee or~~
8 ~~registrant that the licensee or registrant has the right to request in writing, within twenty days~~
9 ~~after receipt of the letter, that the board initiate formal disciplinary proceedings to adjudicate~~
10 ~~the propriety of the conduct upon which the letter of admonition is based.~~

11 ~~(c) If the licensee or registrant timely requests adjudication, the letter of admonition~~
12 ~~is vacated, and the board shall process the matter by means of formal disciplinary~~
13 ~~proceedings. <{Redundant with letters of admonition common provision, 12-20-404 (4).~~
14 ~~Recommend amending as indicated. }>~~

15 ~~(7) (a) When a complaint or an investigation discloses an instance of conduct that~~
16 ~~does not warrant formal action by the board but the board determines that the conduct could~~
17 ~~warrant action if continued, The board may send a confidential letter of concern to the A~~
18 ~~licensee or registrant against whom the complaint was made or who was the subject of~~
19 ~~investigation IN ACCORDANCE WITH SECTION 12-20-404 (5). If a complaint precipitated the~~
20 ~~investigation, the board shall send a response to the person making the complaint.~~
21 ~~<{Redundant with confidential letters of concern common provision, 12-20-404 (5).~~
22 ~~Recommend amending as indicated. }>~~

23 ~~(b) A confidential letter of concern is not discipline.~~

24 ~~(8) When a complaint or an investigation discloses an instance of misconduct that,~~
25 ~~in the opinion of the board, warrants formal action, the board shall not resolve the complaint~~
26 ~~by a deferred settlement, action, judgment, or prosecution. <{Redundant with no deferment~~
27 ~~common provision, 12-20-404 (2). Recommend repealing. }>~~

28 ~~(9) (a) If it appears to the board, based upon credible evidence as presented in a~~
29 ~~written complaint by any person, that a licensee or registrant is acting in a manner that is an~~
30 ~~imminent threat to the health and safety of the public or a person is acting or has acted~~
31 ~~without the required license or registration, the board may issue an order to cease and desist~~
32 ~~the activity. The board shall set forth in the order the statutes and rules alleged to have been~~
33 ~~violated, the facts alleged to have constituted the violation, and the requirement that all~~
34 ~~unlawful acts or unlicensed or unregistered practices immediately cease.~~

35 ~~(b) Within ten days after service of the order to cease and desist pursuant to~~
36 ~~paragraph (a) of this subsection (9), the respondent may request a hearing on the question~~
37 ~~of whether acts or practices in violation of this article have occurred. The board shall~~
38 ~~conduct the hearing pursuant to sections 24-4-104 and 24-4-105, C.R.S.~~

39 ~~(10) (a) If it appears to the board, based upon credible evidence as presented in a~~

1 written complaint by any person, that a person has violated any other portion of this article,
2 then, in addition to any specific powers granted pursuant to this article, the board may issue
3 to the person an order to show cause as to why the board should not issue a final order
4 directing the person to cease and desist from the unlawful act or unlicensed or unregistered
5 practice:

6 (b) ~~The board shall promptly notify a person against whom the board has issued an~~
7 ~~order to show cause pursuant to paragraph (a) of this subsection (10) of the issuance of the~~
8 ~~order and shall include in the notice a copy of the order, the factual and legal basis for the~~
9 ~~order, and the date set by the board for a hearing on the order. The board may serve the~~
10 ~~notice upon the person against whom the order is issued by personal service, by first-class~~
11 ~~United States mail, postage prepaid, or as may be practicable. Personal service or mailing~~
12 ~~of an order or document pursuant to this subsection (10) constitutes notice to the person.~~

13 (c) (I) ~~The board shall commence the hearing on an order to show cause no sooner~~
14 ~~than ten and no later than forty-five calendar days after the date of transmission or service~~
15 ~~of the notification by the board as provided in paragraph (b) of this subsection (10). The~~
16 ~~board may continue the hearing by agreement of all parties based upon the complexity of the~~
17 ~~matter, number of parties to the matter, and legal issues presented in the matter, but in no~~
18 ~~event shall the board commence the hearing later than sixty calendar days after the date of~~
19 ~~transmission or service of the notification.~~

20 (H) ~~If a person against whom an order to show cause has been issued pursuant to~~
21 ~~paragraph (a) of this subsection (10) does not appear at the hearing, the board may present~~
22 ~~evidence that notification was properly sent or served upon the person pursuant to paragraph~~
23 ~~(b) of this subsection (10) and such other evidence related to the matter as the board deems~~
24 ~~appropriate. The board shall issue the order within ten days after the board's determination~~
25 ~~related to reasonable attempts to notify the respondent, and the order becomes final as to that~~
26 ~~person by operation of law. The hearing must be conducted pursuant to sections 24-4-104~~
27 ~~and 24-4-105, C.R.S.~~

28 (HH) ~~If the board reasonably finds that the person against whom the order to show~~
29 ~~cause was issued is acting or has acted without the required license or registration or has or~~
30 ~~is about to engage in acts or practices constituting violations of this article, the board may~~
31 ~~issue a final cease-and-desist order directing the person to cease and desist from further~~
32 ~~unlawful acts or unlicensed or unregistered practices.~~

33 (IV) ~~The board shall provide notice, in the manner set forth in paragraph (b) of this~~
34 ~~subsection (10), of the final cease-and-desist order within ten calendar days after the hearing~~
35 ~~conducted pursuant to this paragraph (c) to each person against whom the final order has~~
36 ~~been issued. The final order issued pursuant to subparagraph (H) of this paragraph (c) is~~
37 ~~effective when issued and is a final order for purposes of judicial review.~~

38 (11) ~~If it appears to the board, based upon credible evidence presented to the board,~~

1 that a person has engaged in or is about to engage in any unlicensed or unregistered act or
2 practice, any act or practice constituting a violation of this article, any rule promulgated
3 pursuant to this article, or any order issued pursuant to this article, or any act or practice
4 constituting grounds for administrative sanction pursuant to this article, the board may enter
5 into a stipulation with the person.

6 (12) If any person fails to comply with a final cease-and-desist order or a stipulation,
7 the board may request the attorney general or the district attorney for the judicial district in
8 which the alleged violation exists to bring, and if so requested such attorney shall bring, suit
9 for a temporary restraining order and for injunctive relief to prevent any further or continued
10 violation of the final order.

11 (13) A person aggrieved by the final cease-and-desist order may seek judicial review
12 of the board's determination or of the board's final order as provided in section 12-42.5-125.

13 (8) **THE BOARD MAY ISSUE CEASE-AND-DESIST ORDERS UNDER THE CIRCUMSTANCES**
14 **AND IN ACCORDANCE WITH THE PROCEDURES SPECIFIED IN SECTION 12-20-405.**
15 *<{Subsections (9) - (13) redundant with cease-and-desist orders common provision,*
16 *12-20-405. Recommend repealing subsections (9) - (13) and replacing with*
17 *cross-reference to cease-and-desist orders common provisions.}>*

18
19 **12-280-128. [Formerly 12-42.5-125] Judicial review.** **The court of appeals has**
20 **initial jurisdiction to SECTION 12-20-408 GOVERNS JUDICIAL review all final actions and**
21 **orders OF THE BOARD that are subject to judicial review. of the board and shall conduct the**
22 **judicial review proceedings in accordance with section 24-4-106(11), C.R.S. <{Redundant**
23 **with judicial review common provision, 12-20-408. Recommend amending as**
24 **indicated.}>**

25
26 **12-280-129. [Formerly 12-42.5-126] Unlawful acts - civil fines.** (1) It is unlawful:
27 (a) To practice pharmacy without a license;
28 (b) To obtain or dispense or to procure the administration of a drug by fraud, deceit,
29 misrepresentation, or subterfuge, by the forgery or alteration of an order, or by the use of a
30 false name or the giving of a false address;
31 (c) To willfully make a false statement in any order, report, application, or record
32 required by this article **280**;
33 (d) To falsely assume the title of or falsely represent that one is a pharmacist,
34 practitioner, or registered outlet;
35 (e) To make or utter a false or forged order;
36 (f) To affix a false or forged label to a package or receptacle containing drugs;
37 (g) To sell, compound, dispense, give, receive, or possess any drug or device unless
38 it was sold, compounded, dispensed, given, or received in accordance with sections

1 ~~12-42.5-118~~ **12-280-120** to ~~12-42.5-122~~ **12-280-125**;

2 (h) Except as provided in section ~~12-42.5-122~~ **12-280-125**, to dispense a different
3 drug or brand of drug in place of the drug or brand ordered or prescribed without the oral
4 or written permission of the practitioner ordering or prescribing the drug;

5 (i) To manufacture, process, pack, distribute, sell, dispense, or give a drug, or the
6 container or labeling of the drug, that, without authorization, bears the trademark, trade
7 name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug
8 manufacturer, processor, packer, or distributor other than the person who in fact
9 manufactured, processed, packed, or distributed ~~such~~ THE drug, container, or label and that
10 thereby falsely purports or is represented to be the product of or to have been packed or
11 distributed by ~~such~~ THE other drug manufacturer, processor, packer, or distributor;

12 (j) For an employer or an employer's agent or employee to coerce a pharmacist to
13 dispense a prescription drug against the professional judgment of the pharmacist;

14 (k) For an employer, an employer's agent or employee, or a pharmacist to use or
15 coerce to be used nonpharmacist personnel in any position or task that would require the
16 nonpharmacist to practice pharmacy or to make a judgmental decision using pharmaceutical
17 knowledge or in violation of the delegatory restrictions enumerated in section ~~12-42.5-116~~
18 ~~(5)~~ **12-280-118 (5)**;

19 (l) To dispense any drug without complying with the labeling, drug identification,
20 and container requirements imposed by law;

21 (m) (I) To possess, sell, dispense, give, receive, or administer a drug or device that
22 is adulterated or misbranded within the meaning of the "Colorado Food and Drug Act", part
23 4 of article 5 of title 25, or is a counterfeit drug.

24 (II) As used in this subsection (1)(m), "counterfeit drug" means a drug, or the
25 container or labeling of a drug, that, without authorization, bears the trademark, trade name,
26 or other identifying mark, imprint, or device or any likeness thereof of a drug manufacturer,
27 processor, packer, or distributor other than the person who in fact manufactured, processed,
28 packed, or distributed the drug and that falsely purports or is represented to be the product
29 of, or to have been packed or distributed by, the drug manufacturer, processor, packer, or
30 distributor whose trademark, trade name, or other identifying mark, imprint, or device or
31 likeness thereof appears on the drug or its container or labeling.

32 (2) In addition to any other penalties that may be imposed under this part 1, a person
33 who engages in an unlawful act under this section may be punished by a civil fine of not less
34 than one thousand dollars and not more than ten thousand dollars for each violation. **Fines**
35 **imposed and paid under this section shall be deposited in the general fund.** <{*Since these*
36 *are "civil" fines that presumably are imposed by a court, it appears that this direction to*
37 *deposit the fines in the GF should be retained.*}>
38

1 **12-280-130. [Formerly 12-42.5-127] Unauthorized practice - penalties.** Any
2 person who practices or offers or attempts to practice pharmacy without an active license
3 issued under this article commits a class 2 misdemeanor and shall be punished as provided
4 in section 18-1.3-501, C.R.S., for the first offense, and any person committing a second or
5 subsequent offense commits a class 6 felony and shall be punished as provided in section
6 ~~18-1.3-401, C.R.S.~~ **280** IS SUBJECT TO PENALTIES PURSUANT TO SECTION 12-20-407 (1)(a).
7 <{*Redundant with unauthorized practice common provision. Recommend amending as*
8 *indicated.*}>
9

10 **12-280-131. [Formerly 12-42.5-128] New drugs - when sales permissible.** (1) No
11 person shall sell, deliver, offer for sale, hold for sale, or give away any new drug not
12 authorized to move in interstate commerce under appropriate federal law.

13 (2) This section does not apply to a drug intended solely for investigational use by
14 experts qualified by scientific training and experience to investigate the safety and
15 effectiveness of drugs if the drug is plainly labeled to be for investigational use only.
16

17 **12-280-132. [Formerly 12-42.5-129] Advertising of prescription drug prices.** A
18 prescription drug outlet may advertise its prices for prescription drugs. If the drug is
19 advertised by its brand or proprietary name, the prescription drug outlet shall also include
20 its generic name in the advertisement.
21

22 **12-280-133. [Formerly 12-42.5-130] Nonresident prescription drug outlet -**
23 **registration - rules.** (1) Any prescription drug outlet located outside this state that ships,
24 mails, or delivers, in any manner, drugs or devices into this state is a nonresident prescription
25 drug outlet and shall register with the board and disclose to the board the following:

26 (a) The location, names, and titles of all principal entity officers and all pharmacists
27 who are dispensing drugs or devices to the residents of this state. The nonresident
28 prescription drug outlet shall submit a report containing this information to the board on an
29 annual basis and within thirty days after any change of office, officer, or pharmacist.

30 (b) A verification that it complies with all lawful directions and requests for
31 information from the regulatory or licensing agency of the state in which it is licensed as
32 well as with all requests for information made by the board pursuant to this section. The
33 nonresident prescription drug outlet shall maintain at all times a valid, unexpired license,
34 permit, or registration to conduct the prescription drug outlet in compliance with the laws
35 of the state in which it is a resident. As a prerequisite to registering with the board, the
36 nonresident prescription drug outlet shall submit a copy of the most recent inspection report
37 resulting from an inspection conducted by the regulatory or licensing agency of the state in
38 which it is located.

1 (2) The registration requirements of this section apply only to a nonresident
2 prescription drug outlet that only ships, mails, or delivers, in any manner, drugs and devices
3 into this state pursuant to a prescription order.

4 (3) A nonresident prescription drug outlet doing business in this state that has not
5 obtained a registration shall not conduct the business of selling or distributing drugs in this
6 state without first registering as a nonresident prescription drug outlet. A nonresident
7 prescription drug outlet shall make application for a nonresident prescription drug outlet
8 registration on a form furnished by the board. The board may require ~~such~~ THE information
9 as it deems necessary to carry out the purpose of this section.

10 (4) (a) The board may deny, revoke, or suspend a nonresident prescription drug
11 outlet registration for failure to comply with this section or with any rule promulgated by the
12 board.

13 (b) The board may deny, revoke, or suspend a nonresident prescription drug outlet
14 registration if the nonresident prescription drug outlet's license or registration has been
15 revoked or not renewed for noncompliance with the laws of the state in which it is a
16 resident.

17
18 **12-280-134. [Formerly 12-42.5-131] Records.** (1) (a) All persons licensed or
19 registered under this article **280** shall keep and maintain records of the receipt, distribution,
20 or other disposal of prescription drugs or controlled substances, shall make the records
21 available to the board upon request for inspection, copying, verification, or any other
22 purpose, and shall retain the records for two years or for a period otherwise required by law.

23 (b) The board may permit a wholesaler to maintain a portion of its records at a central
24 location that is different from the storage facility of the wholesaler. If the board grants the
25 permission, the wholesaler shall make available all relevant records within forty-eight hours
26 after a request for inspection, copying, verification, or any other purpose by the board. The
27 wholesaler shall make all other records that are available for immediate access readily
28 available to the board.

29 (2) A wholesaler shall establish and maintain inventories and records of all
30 transactions regarding the receipt and distribution of prescription drugs. A wholesaler shall
31 make its records available to the board in accordance with subsection (1) of this section. A
32 wholesaler shall include the following information in its records:

33 (a) The source of the prescription drugs, including the name and principal address
34 of the seller or transferor of the prescription drugs and the address of the location from
35 which the prescription drugs were shipped;

36 (b) The identity and quantity of the drugs received, distributed, or disposed of by the
37 wholesale distributor; and

38 (c) The dates of receipt, distribution, or other disposition of the prescription drugs.

1 (3) The record of any controlled substance distributed, administered, dispensed, or
2 otherwise used must show the date the controlled substance was distributed, administered,
3 dispensed, used, or otherwise disposed of, the name and address of the person to whom or
4 for whose use the controlled substance was distributed, administered, dispensed, used, or
5 otherwise disposed of, and the kind and quantity of the controlled substance.

6 (4) Manufacturing records of controlled substances must include the kind and
7 quantity of controlled substances produced or removed from process of manufacture and the
8 dates of production or removal from process of manufacture.

9 (5) A person who maintains a record required by federal law that contains
10 substantially the same information as set forth in subsections (1) to (4) of this section is
11 deemed to comply with the record-keeping requirements of this section.

12 (6) A person required to maintain records pursuant to this section shall keep a record
13 of any controlled substance lost, destroyed, or stolen, the kind and quantity of the controlled
14 substance, and the date of the loss, destruction, or theft.

15 (7) Prescription drug outlets shall report thefts of controlled substances to the proper
16 law enforcement agencies and to the board within thirty days after the occurrence of the
17 thefts.

18 (8) A person licensed, registered, or otherwise authorized under this article **280** or
19 other laws of this state shall distribute, administer, dispense, use, or otherwise dispose of
20 controlled substances listed in schedule I or II of part 2 of article 18 of title 18 ~~C.R.S.~~, only
21 pursuant to an order form. Compliance with the provisions of federal law respecting order
22 forms is deemed compliance with this section.

23 (9) Prescriptions, orders, and records required by this part 1 and stocks of controlled
24 substances are open for inspection only to federal, state, county, and municipal officers
25 whose duty it is to enforce the laws of this state or of the United States relating to controlled
26 substances or the regulation of practitioners. No officer having knowledge by virtue of his
27 or her office, of a prescription, order, or record shall divulge his or her knowledge, except
28 in connection with a prosecution or proceeding in court or before a licensing or registration
29 board or officer to which prosecution or proceeding the person to whom the prescriptions,
30 orders, or records relate is a party.

31
32 **12-42.5-132. Immunity.** Any member of the board, any member of the board's staff,
33 any person acting as a witness or consultant to the board, any witness testifying in a
34 proceeding authorized under this article, and any person who lodges a complaint pursuant
35 to this article is immune from liability in any civil action brought against him or her for acts
36 occurring while acting in his or her capacity as board member, staff, consultant, or witness,
37 respectively, if the individual was acting in good faith within the scope of his or her
38 respective capacity, made a reasonable effort to obtain the facts of the matter as to which he

1 or she acted, and acted in the reasonable belief that the action taken by him or her was
2 warranted by the facts. Any person participating in good faith in lodging a complaint or
3 participating in any investigative or administrative proceeding pursuant to this article is
4 immune from any civil or criminal liability that may result from participation.
5 <{***Recommend repealing as redundant with immunity common provision, 12-20-402.***>

6
7 **12-280-135. [Formerly 12-42.5-133] Unused medication - licensed facilities -**
8 **correctional facilities - reuse - definitions - rules.** (1) As used in this section, unless the
9 context otherwise requires:

10 (a) "Correctional facility" means a facility under the supervision of the United States,
11 the department of corrections, or a similar state agency or department in a state other than
12 Colorado in which persons are or may be lawfully held in custody as a result of conviction
13 of a crime; a jail or an adult detention center of a county, city, or city and county; and a
14 private contract prison operated by a state, county, city, or city and county.

15 ~~(a.5)~~ (b) "Licensed facility" means a hospital, hospital unit, community mental health
16 center, acute treatment unit, hospice, nursing care facility, assisted living residence, or any
17 other facility that is required to be licensed pursuant to section 25-3-101, ~~C.R.S.~~, or a
18 licensed long-term care facility as defined in section 25-1-124 (2.5)(b). ~~C.R.S.~~

19 ~~(b)~~ (c) "Medical device" means an instrument, apparatus, implement, machine,
20 contrivance, implant, or similar or related article that is required to be labeled pursuant to
21 21 CFR part 801.

22 ~~(c)~~ (d) "Medical supply" means a consumable supply item that is disposable and not
23 intended for reuse.

24 ~~(d)~~ (e) "Medication" means a prescription that is not a controlled substance.

25 (2) (a) (I) If donated by the patient, resident, or the patient's or resident's next of kin,
26 a licensed facility may return unused medications or medical supplies, and used or unused
27 medical devices to a pharmacist within the licensed facility or a prescription drug outlet in
28 order for the materials to be redispensed to another patient or donated to a nonprofit entity
29 that has the legal authority to possess the materials or to a practitioner authorized by law to
30 dispense the materials.

31 (II) (A) A licensed facility or a prescription drug outlet may donate materials to a
32 nonprofit entity that has legal authority to possess the materials or to a person legally
33 authorized to dispense the materials. A licensed pharmacist shall review the process of
34 donating the unused medications to the nonprofit entity.

35 (B) Nothing in this ~~subparagraph~~ ~~(H)~~ SUBSECTION (2)(a)(II): Creates or abrogates any
36 liability on behalf of a prescription drug manufacturer for the storage, donation, acceptance,
37 or dispensing of a medication or product; or creates any civil cause of action against a
38 prescription drug manufacturer in addition to that which is available under applicable law.

1 (C) A person or entity is not subject to civil or criminal liability or professional
2 disciplinary action for donating, accepting, dispensing, or facilitating the donation of
3 materials in good faith, without negligence, and in compliance with this section.

4 (III) A correctional facility may return unused medications or medical supplies, and
5 used or unused medical devices to the pharmacist within the correctional facility or a
6 prescription drug outlet in order for the medication to be redispensed to another patient or
7 donated to a nonprofit entity that has the legal authority to possess the materials or to a
8 practitioner authorized by law to prescribe the materials.

9 (b) Medications are only available to be dispensed to another person or donated to
10 a nonprofit entity under this section if the medications are:

11 (I) Liquid and the vial is still sealed and properly stored;

12 (II) Individually packaged and the packaging has not been damaged; or

13 (III) In the original, unopened, sealed, and tamper-evident unit dose packaging.

14 (c) The following medications may not be donated:

15 (I) Medications packaged in traditional brown or amber pill bottles;

16 (II) Controlled substances;

17 (III) Medications that require refrigeration, freezing, or special storage;

18 (IV) Medications that require special registration with the manufacturer; or

19 (V) Medications that are adulterated or misbranded, as determined by a person
20 legally authorized to dispense the medications on behalf of the nonprofit entity.

21 (3) Medication dispensed or donated pursuant to this section must not be expired.
22 A medication shall not be dispensed that will expire before the use by the patient based on
23 the prescribing practitioner's directions for use.

24 ~~(3.5)~~ (4) Medication, medical supplies, and medical devices donated pursuant to this
25 section may not be resold for profit. The entity that receives the donated materials may
26 charge the end user a handling fee, which FEE shall not exceed the amount specified by rule
27 of the board.

28 ~~(4)~~ (5) The board shall adopt rules that allow a pharmacist to redispense medication
29 pursuant to this section and section 25.5-5-502, ~~C.R.S.~~, and to donate medication pursuant
30 to this section.

31 ~~(5)~~ (6) Nothing in this section or section 25.5-5-502 ~~C.R.S.~~, creates or abrogates any
32 liability on behalf of a prescription drug manufacturer for the storage, donation, acceptance,
33 or dispensing of an unused donated medication or creates any civil cause of action against
34 a prescription drug manufacturer in addition to that which is available under applicable law.

35
36 **12-280-136. [Formerly 12-42.5-134] Confidential agreement to limit practice.**

37 **(1) If a pharmacist or intern has a physical illness; a physical condition; or a behavioral or**
38 **mental health disorder that renders the person unable to practice pharmacy with reasonable**

1 skill and safety to clients, the pharmacist or intern shall notify the board of the physical
2 illness; the physical condition; or the behavioral or mental health disorder in a manner and
3 within a period determined by the board. The board may require the pharmacist or intern to
4 submit to an examination or refer the pharmacist or intern to the pharmacy peer health
5 assistance diversion program established in part 2 of this article 42.5 to evaluate the extent
6 of the physical illness; the physical condition; or the behavioral or mental health disorder
7 and its impact on the pharmacist's or intern's ability to practice pharmacy with reasonable
8 skill and safety to clients.

9 (2) (a) Upon determining that a pharmacist or intern with a physical illness; a
10 physical condition; or a behavioral or mental health disorder is able to render limited
11 services with reasonable skill and safety to clients, the board may enter into a confidential
12 agreement with the pharmacist or intern in which the pharmacist or intern agrees to limit his
13 or her practice based on the restrictions imposed by the physical illness; the physical
14 condition; or the behavioral or mental health disorder, as determined by the board.

15 (b) As part of the agreement, the pharmacist or intern is subject to periodic
16 reevaluations or monitoring as determined appropriate by the board. The board may refer
17 the pharmacist or intern to the pharmacy peer health assistance diversion program for
18 reevaluation or monitoring.

19 (c) The parties may modify or dissolve the agreement as necessary based on the
20 results of a reevaluation or of monitoring.

21 (3) By entering into an agreement with the board pursuant to this section to limit his
22 or her practice, a pharmacist or intern is not engaging in activities prohibited pursuant to
23 section 12-42.5-123. The agreement does not constitute a restriction or discipline by the
24 board. However, if the pharmacist or intern fails to comply with the terms of an agreement
25 entered into pursuant to this section, the failure constitutes a prohibited activity pursuant to
26 section 12-42.5-123 (1)(r), and the pharmacist or intern is subject to discipline in accordance
27 with section 12-42.5-124.

28 (1) EXCEPT AS SPECIFIED IN SUBSECTION (2) OF THIS SECTION, SECTION 12-30-107
29 CONCERNING CONFIDENTIAL AGREEMENTS TO LIMIT PRACTICE APPLIES TO THIS ARTICLE 280.

30 (4) (2) This section does AND SECTION 12-30-107 DO not apply to a pharmacist or
31 intern subject to discipline for prohibited activities as described in section 12-42.5-123 (1)(e)
32 *12-280-126 (1)(e)*. <{*Largely redundant with confidential agreement common provision,*
33 *12-30-107. Recommend amendment as indicated.*}>

34
35 PART 2

36 PHARMACY PEER HEALTH ASSISTANCE DIVERSION PROGRAM

37
38 **12-280-201. [Formerly 12-42.5-201] Legislative declaration.** (1) The general

1 assembly finds, determines, and declares that the creation of a pharmacy peer health
2 assistance diversion program for those persons subject to the jurisdiction of the board will
3 serve to safeguard the life, health, property, and public welfare of the people of this state.
4 A pharmacy peer health assistance diversion program will help practitioners experiencing
5 impaired practice due to **psychiatric, psychological, or emotional problems; excessive**
6 **alcohol or drug use; or alcohol or substance use disorders**. The general assembly further
7 declares that a pharmacy peer health assistance diversion program will protect the privacy
8 and welfare of those persons who provide services and at the same time assist the board in
9 carrying out its duties and responsibilities to ensure that only qualified persons are allowed
10 to engage in providing those services that are under the jurisdiction of the board. <{***Noting***
11 ***variances in terminology throughout this part.***}>

12 (2) It is the intent of the general assembly that the pharmacy peer health assistance
13 diversion program and its related procedures be utilized by the board in conjunction with,
14 or as an alternative to, the use of disciplinary proceedings by the board, which proceedings
15 are by their nature time-consuming and costly to the people of this state. The pharmacy peer
16 health assistance diversion program is hereby established to alleviate the need for
17 disciplinary proceedings, while at the same time providing safeguards that protect the public
18 health, safety, and welfare. The general assembly further declares that it intends that the
19 board will act to implement the provisions of this article **280**.

20
21 **12-280-202. [Formerly 12-42.5-202] Definitions.** As used in this part 2, unless the
22 context otherwise requires:

23 (1) "Impaired practice" means a licensee's inability to meet the requirements of the
24 laws of this state and the rules of the board governing his or her practice when the licensee's
25 cognitive, interpersonal, or psychomotor skills are affected by **psychiatric, psychological,**
26 **or emotional problems; excessive alcohol or drug use; or alcohol or substance use disorders.**
27 <{***Noting variances in terminology throughout this part.***}>

28 ~~(2) "Licensee" means any pharmacist or intern who is licensed by the board.~~
29 <{***Redundant with definitions common provision, 12-20-102 (10).***}>

30 ~~(3)~~ (2) "Peer health assistance organization" means an organization that provides a
31 formal, structured program that meets the requirements specified in this part 2 and is
32 administered by appropriate professionals for the purpose of assisting licensees experiencing
33 impaired practice to obtain evaluation, treatment, short-term counseling, monitoring of
34 progress, and ongoing support for the purpose of arresting and treating the licensee's
35 **psychiatric, psychological, or emotional problems; excessive alcohol or drug use; or alcohol**
36 **or substance use disorders**. <{***Noting variances in terminology throughout this part.***}>

37
38 **12-280-203. [Formerly 12-42.5-203] Pharmacy peer health assistance fund.**

1 (1) There is hereby created in the state treasury the pharmacy peer health assistance fund.
2 The fund consists of ~~moneys~~ MONEY collected by the board and credited to the fund pursuant
3 to subsection (2) of this section. Any interest earned on the investment of ~~moneys~~ MONEY
4 in the fund must be credited at least annually to the fund.

5 (2) (a) As a condition of licensure and licensure renewal in this state, every applicant
6 shall pay to the administering entity that has been selected by the board pursuant to this
7 section an amount set by the board not to exceed fifty-six dollars biennially. The amount
8 must be used to support designated providers that have been selected by the board to provide
9 assistance to pharmacists and interns needing help in dealing with **physical, emotional,**
10 **psychiatric, or psychological problems** or behavioral, mental health, or substance use
11 **disorders** that may be detrimental to their ability to practice. <{***Noting variances in***
12 ***terminology throughout this part.***>

13 (b) The board shall select one or more peer health assistance organizations as
14 designated providers. To be eligible for designation by the board a peer health assistance
15 diversion program shall:

16 (I) Provide for the education of pharmacists and interns with respect to the
17 recognition and prevention of **physical, emotional, and psychological problems** and provide
18 for intervention when necessary or under circumstances that may be established by rules
19 promulgated by the board; <{***Noting variances in terminology throughout this part.***>

20 (II) Offer assistance to a pharmacist or intern in identifying **physical, emotional, or**
21 **psychological problems**; <{***Noting variances in terminology throughout this part.***>

22 (III) Evaluate the extent of **physical, emotional, or psychological problems** and refer
23 the pharmacist or intern for appropriate treatment; <{***Noting variances in terminology***
24 ***throughout this part.***>

25 (IV) Monitor the status of a pharmacist or intern who has been referred for treatment;

26 (V) Provide counseling and support for the pharmacist or intern and for the family
27 of any pharmacist or intern referred for treatment;

28 (VI) Agree to receive referrals from the board;

29 (VII) Agree to make their services available to all licensed Colorado pharmacists and
30 interns.

31 (c) The administering entity must be a qualified, nonprofit, private foundation that
32 is qualified under section 501 (c)(3) of the federal "Internal Revenue Code of 1986", as
33 amended, and must be dedicated to providing support for charitable, benevolent,
34 educational, and scientific purposes that are related to pharmaceutical education,
35 pharmaceutical research and science, and other pharmaceutical charitable purposes.

36 (d) The responsibilities of the administering entity are:

37 (I) To collect the required annual payments, directly or through the board;

38 (II) To verify to the board, in a manner acceptable to the board, the names of all

1 pharmacist and intern applicants who have paid the fee set by the board;

2 (III) To distribute the ~~moneys~~ MONEY collected, less expenses, to the designated
3 provider, as directed by the board;

4 (IV) To provide an annual accounting to the board of all amounts collected, expenses
5 incurred, and amounts disbursed; and

6 (V) To post a surety performance bond in an amount specified by the board to secure
7 performance under the requirements of this section. The administering entity may recover
8 the actual administrative costs incurred in performing its duties under this section in an
9 amount not to exceed ten percent of the total amount collected.

10 (e) The board, at its discretion, may collect the required annual payments payable to
11 the administering entity for the benefit of the administering entity and shall transfer all ~~such~~
12 THE payments to the administering entity. All required annual payments collected or due to
13 the board for each fiscal year are custodial funds that are not subject to appropriation by the
14 general assembly, and the funds do not constitute state fiscal year spending for purposes of
15 section 20 of article X of the state constitution.

16
17 **12-280-204. [Formerly 12-42.5-204] Eligibility - participants.** (1) Any licensee
18 may apply to the board for participation in a qualified peer health assistance diversion
19 program.

20 (2) In order to be eligible for participation, a licensee shall:

21 (a) Acknowledge the existence or the potential existence of a **psychiatric,**
22 **psychological, or emotional problem; excessive alcohol or drug use; or an alcohol use**
23 **disorder, as defined in section 27-81-102, or a substance use disorder, as defined in section**
24 **27-82-102;** <{*Noting variances in terminology throughout this part.*}>

25 (b) After a full explanation of the operation and requirements of the peer health
26 assistance diversion program, agree to voluntarily participate in the program and agree in
27 writing to participate in the program of the peer health assistance organization designated
28 by the board.

29 (3) Notwithstanding the provisions of this section, the board may summarily suspend
30 the license of any licensee who is referred to a peer health assistance diversion program by
31 the board and who fails to attend or to complete the program. If the board summarily
32 suspends the license, the board shall schedule a hearing on the suspension, which shall be
33 conducted in accordance with section 24-4-105. ~~C.R.S.~~

34
35 **12-280-205. [Formerly 12-42.5-205] Liability.** Nothing in this part 2 creates any
36 liability of the board, members of the board, or the state of Colorado for the actions of the
37 board in making awards to pharmacy peer health assistance organizations or in designating
38 licensees to participate in the programs of pharmacy peer health assistance organizations.

1 No civil action may be brought or maintained against the board, its members, or the state for
 2 an injury alleged to have been the result of an act or omission of a licensee participating in
 3 or referred to a state-funded program provided by a pharmacy peer health assistance
 4 organization. However, the state remains liable under the "Colorado Governmental
 5 Immunity Act", article 10 of title 24, C.R.S., if an injury alleged to have been the result of
 6 an act or omission of a licensee participating in or referred to a state-funded peer health
 7 assistance diversion program occurred while the licensee was performing duties as an
 8 employee of the state.
 9

10 **12-280-206. [Formerly 12-42.5-206] Immunity.** Any member of the board acting
 11 pursuant to this part 2 is immune from suit in any civil action ~~if the member acted in good~~
 12 ~~faith within the scope of the function of the board, made a reasonable effort to obtain the~~
 13 ~~facts of the matter as to which the member acted, and acted in the reasonable belief that the~~
 14 ~~action taken by the member was warranted by the facts~~ UNDER THE SAME CONDITIONS FOR
 15 IMMUNITY AS SPECIFIED IN SECTION 12-20-402 (1). <{Some redundancy with immunity
 16 common provision, 12-20-402. Recommend amending as indicated.}>
 17

18 PART 3
 19 WHOLESALERS
 20

21 **12-280-301. [Formerly 12-42.5-301] Definitions.** As used in this part 3, unless the
 22 context otherwise requires:

23 (1) "Authentication" means the process of affirmatively verifying that each
 24 transaction listed on a pedigree has occurred before any wholesale distribution of a
 25 prescription drug occurs.

26 (2) "Board-registered outlet" means a prescription drug outlet, an other outlet, a
 27 nonresident prescription drug outlet, a wholesaler, or a manufacturer.

28 (3) "Designated representative" means a person authorized by a licensed wholesaler
 29 to act as a representative for the wholesaler.

30 (4) "Drop shipment" means the sale by a manufacturer of the manufacturer's
 31 prescription drug, that manufacturer's third-party logistics provider, or that manufacturer's
 32 exclusive distributor to a wholesaler whereby the wholesaler takes title to, but not possession
 33 of, the prescription drug and the wholesaler invoices the board-registered outlet or
 34 practitioner authorized by law to prescribe the prescription drug and the board-registered
 35 outlet or the practitioner authorized by law to prescribe the prescription drug receives
 36 delivery of the prescription drug directly from the manufacturer of ~~such~~ THE drug, that
 37 manufacturer's third-party logistics provider, or that manufacturer's exclusive distributor.

38 (5) "Facility" means a facility of a wholesaler where prescription drugs are stored,

1 handled, repackaged, or offered for sale.

2 (6) "Normal distribution channel" means a chain of custody for a prescription drug
3 that goes directly or by drop shipment from a manufacturer of the prescription drug to:

4 (a) (I) A wholesaler to a pharmacy to a patient or other designated persons authorized
5 by law to dispense or administer a prescription drug to a patient;

6 (II) A wholesaler to a chain pharmacy warehouse to their intracompany pharmacies
7 to a patient;

8 (III) A chain pharmacy warehouse to its intracompany pharmacies to a patient; or

9 (IV) A pharmacy to a patient; or

10 (b) A manufacturer's colicensed partner, third-party logistics provider, or exclusive
11 distributor to a wholesaler to a pharmacy to a patient or other designated persons authorized
12 by law to dispense or administer ~~such~~ A PRESCRIPTION drug to a patient; or

13 (c) A manufacturer's colicensed partner, or that manufacturer's third-party logistics
14 provider, or exclusive distributor to a wholesaler to a chain pharmacy warehouse to that
15 chain pharmacy warehouse's intracompany pharmacy to a patient or other designated persons
16 authorized by law to dispense or administer ~~such~~ A PRESCRIPTION drug to a patient; or

17 (d) A wholesaler to a pharmacy buying cooperative warehouse to a pharmacy that
18 is a member or member owner of the cooperative to a patient or other designated person
19 authorized by law to dispense or administer the prescription drug to a patient.

20 (7) "Pedigree" means a document or electronic file containing information that
21 records each distribution of any given prescription drug that leaves the normal distribution
22 channel.

23 (8) "Third-party logistics provider" means anyone who contracts with a manufacturer
24 to provide or coordinate warehousing, distribution, or other services on behalf of a
25 manufacturer but does not take title to a prescription drug or have general responsibility to
26 direct the prescription drug's sale or disposition.

27
28 **12-280-302. [Formerly 12-42.5-302] Exemptions - definition.** (1) (a) The board
29 may exempt a pharmacy benefits entity from the requirements of sections ~~12-42.5-303~~
30 **12-280-303** and ~~12-42.5-304~~ **12-280-304** if the entity's purchases are solely from a
31 manufacturer or a wholesale distributor in the normal distribution channel, and any
32 subsequent sales or further distributions are to entities other than a wholesaler within the
33 normal distribution channel.

34 (b) For the purposes of this section, "pharmacy benefits entity" means an entity that
35 is not engaged in the activities of a chain pharmacy warehouse but that assists in the
36 administration of pharmacy benefits under contracts with insurers or to a company under
37 common ownership with that entity.

38 (2) The board may exempt a wholesaler from any requirement of this part 3 if the

1 wholesaler exclusively distributes animal health medicines. The board may exempt a
2 wholesaler that distributes animal health medicines from the requirements of section
3 ~~12-42.5-306~~ **12-280-306**.

4 (3) The board shall exempt from the requirements of sections ~~12-42.5-303~~
5 **12-280-303** and ~~12-42.5-304~~ **12-280-304**:

6 (a) A licensed wholesaler operated by a nonprofit organization exempt from taxation
7 under section 501 (c)(3) of the federal "Internal Revenue Code of 1986", as amended, that
8 engages only in intracompany sales or transfers of prescription drugs to licensed other
9 outlets or pharmacies that are controlled by, or under common ownership or control with,
10 the wholesaler and that purchase drugs directly from the manufacturer or the manufacturer's
11 authorized distributor of record for distribution or transfer to the wholesaler's licensed other
12 outlets, pharmacies, or other areas authorized by state law;

13 (b) A licensed wholesaler operated by a hospital, a state agency, or a political
14 subdivision if the entity purchases drugs directly from a manufacturer or a manufacturer's
15 authorized distributor of record and if any further distribution is to authorized licensed
16 entities within its own network.

17
18 **12-280-303. [Formerly 12-42.5-303] Wholesaler license requirements - rules.**

19 (1) (a) A wholesaler that resides in this state must be licensed by the board. A wholesaler
20 that does not reside in this state must be licensed in this state prior to engaging in the
21 wholesale distribution of prescription drugs in this state. The board shall exempt a
22 manufacturer and that manufacturer's third-party logistics providers to the extent involving
23 that manufacturer's drugs under contract from any licensing qualifications and other
24 requirements, including the requirements in ~~subparagraphs (VI) and (VII) of paragraph (a)~~
25 ~~of subsection (3)~~ SUBSECTIONS (3)(a)(VI) AND (3)(a)(VII) of this section, subsections (4) to
26 (6) of this section, and section ~~12-42.5-304~~ **12-280-304**, to the extent the requirements are
27 not required by federal law or regulation, unless the particular requirements are deemed
28 necessary and appropriate following rule-making by the board.

29 (b) A manufacturer's exclusive distributor and pharmacy buying cooperative
30 warehouse must be licensed by the board as a wholesaler pursuant to this part 3. A
31 third-party logistics provider must be licensed by the board as a wholesale distributor
32 pursuant to this part 3.

33 (2) (a) The board may adopt rules to approve an accreditation body to evaluate a
34 wholesaler's operations to determine compliance with professional standards and any other
35 applicable laws and to perform inspections of each facility and location where the
36 wholesaler conducts wholesale distribution operations.

37 (b) An applicant for a license shall pay any fee required by the accreditation body or
38 the board and comply with any rules promulgated by the board.

1 (c) The board shall not issue or renew a license to a wholesaler who does not comply
2 with this part 3.

3 (3) (a) An applicant for a wholesaler license shall provide to the board the following
4 information, and any other information deemed appropriate by the board on a form provided
5 by the board:

6 (I) The name, full business address, and telephone number of the applicant;

7 (II) The trade and business names used by the applicant;

8 (III) The addresses, telephone numbers, and names of the contact persons for all
9 facilities used by the applicant for the storage, handling, and distribution of prescription
10 drugs;

11 (IV) The type of ownership or operation of the applicant;

12 (V) The names of the owner and the operator of the applicant, including:

13 (A) The name of each partner if the applicant is a partnership;

14 (B) The name and title of each officer and director, the name of the corporation, and
15 the state of incorporation, if the applicant is a corporation;

16 (C) The name of the limited liability company, if the applicant is a limited liability
17 company, and the name of the parent company, if any, and the state of incorporation or
18 formation of both; or

19 (D) The name of the sole proprietor and the business entity if the applicant is a sole
20 proprietorship;

21 (VI) A list of the licenses and permits issued to the applicant by any other state that
22 authorizes the applicant to purchase or possess prescription drugs; and

23 (VII) The name of the applicant's designated representative for the facility, the
24 fingerprints of the designated representative, and a personal information statement for the
25 designated representative that includes information as required by the board, including but
26 not limited to the information in subsection (5) of this section.

27 (b) A licensee shall complete and return a form approved by the board at each
28 renewal period. The board may suspend or revoke the license of a wholesaler if the board
29 determines that the wholesaler no longer qualifies for a license.

30 (4) Prior to issuing a wholesaler license to an applicant, the board, the regulatory
31 oversight body from another state, or board-approved accreditation body may conduct a
32 physical inspection of the facility at the business address provided by the applicant. Nothing
33 in this subsection (4) shall preclude the board from inspecting a wholesaler.

34 (5) The designated representative of an applicant for a wholesaler license shall:

35 (a) Be at least twenty-one years of age;

36 (b) Have at least three years of full-time employment history with a pharmacy or a
37 wholesaler in a capacity related to the dispensing and distribution of and the record keeping
38 related to prescription drugs;

1 (c) Be employed by the applicant in a full-time managerial position;

2 (d) Be actively involved in and aware of the actual daily operation of the wholesaler;

3 (e) Be physically present at the facility of the applicant during regular business hours,
4 except when the absence of the designated representative is authorized BY, including, but
5 not limited to, sick leave and vacation leave;

6 (f) Serve in the capacity of a designated representative for only one applicant or
7 wholesaler at a time, except where more than one licensed wholesaler is co-located in the
8 same facility and the wholesalers are members of an affiliated group as defined by section
9 1504 of the federal "Internal Revenue Code of 1986";

10 (g) Not have any convictions under federal, state, or local law relating to wholesale
11 or retail prescription drug distribution or a controlled substance, as defined in section
12 18-18-102 (5); ~~C.R.S.~~;

13 (h) Not have any felony convictions pursuant to federal, state, or local law; and

14 (i) Update all of the information required in this part 3 whenever changes occur.

15 (6) A wholesaler shall obtain a license for each facility it uses for the distribution of
16 prescription drugs.

17
18 **12-280-304. [Formerly 12-42.5-304] Criminal history record check.** Prior to
19 submission of an application, each designated representative must have his or her
20 fingerprints taken by a local law enforcement agency or any third party approved by the
21 Colorado bureau of investigation for the purpose of obtaining a fingerprint-based criminal
22 history record check. If an approved third party takes the person's fingerprints, the
23 fingerprints may be electronically captured using Colorado bureau of investigation-approved
24 livescan equipment. Third-party vendors shall not keep the applicant information for more
25 than thirty days unless requested to do so by the applicant. The designated representative
26 shall submit payment by certified check or money order for the fingerprints and for the
27 actual costs of the record check at the time the fingerprints are submitted to the Colorado
28 bureau of investigation. Upon receipt of fingerprints and receipt of the payment for costs,
29 the Colorado bureau of investigation shall conduct a state and national fingerprint-based
30 criminal history record check utilizing records of the Colorado bureau of investigation and
31 the federal bureau of investigation.

32
33 **12-280-305. [Formerly 12-42.5-305] Restrictions on transactions.** (1) A
34 wholesaler shall accept prescription drug returns or exchanges from a pharmacy or a chain
35 pharmacy warehouse pursuant to the terms and conditions of the agreement between the
36 wholesale distributor and the pharmacy or chain pharmacy warehouse. The receiving
37 wholesale distributor shall distribute returns or exchanges of expired, damaged, recalled, or
38 otherwise unsaleable pharmaceutical product only to the original manufacturer or to a

1 third-party returns processor. The returns or exchanges of prescription drugs, saleable or
2 unsaleable, including any redistribution by a receiving wholesaler, are not subject to the
3 pedigree requirements of section ~~12-42.5-306~~ **12-280-306** so long as the drugs are exempt
4 from the pedigree requirement of the federal food and drug administration's currently
5 applicable "Prescription Drug Marketing Act of 1987" guidance. The pharmacies, chain
6 pharmacy warehouses, and pharmacy buying cooperative warehouses are responsible for
7 ensuring that the prescription drugs returned are what they purport to be and shall ensure that
8 those returned prescription drugs were stored under proper conditions since their receipt.
9 Wholesalers are responsible for policing their returns process and helping to ensure that their
10 operations are secure and do not permit the entry of adulterated or counterfeit product. A
11 pharmacist shall not knowingly return a medication that is not what it purports to be.

12 (2) A manufacturer or wholesaler shall furnish prescription drugs only to a
13 board-registered outlet or practitioner authorized by law to prescribe the drugs. Before
14 furnishing prescription drugs to a person or entity not known to the manufacturer or
15 wholesaler, the manufacturer or wholesaler shall affirmatively verify that the person or entity
16 is legally authorized to receive the prescription drugs by contacting the board.

17 (3) A manufacturer or wholesaler may furnish prescription drugs to a hospital
18 pharmacy receiving area if a pharmacist or authorized receiving agent signs, at the time of
19 delivery, a receipt showing the type and quantity of the prescription drug received. The
20 pharmacist or authorized receiving agent shall report any discrepancy between the receipt
21 and the type and quantity of the prescription drug actually received to the delivering
22 manufacturer or wholesaler by the next business day after the delivery to the pharmacy
23 receiving area.

24 (4) A manufacturer or wholesaler shall not accept payment for, or allow the use of,
25 a person's or entity's credit to establish an account for the purchase of prescription drugs
26 from any person other than the owner of record, the chief executive officer, or the chief
27 financial officer listed on the license of a person or entity legally authorized to receive
28 prescription drugs. An account established for the purchase of prescription drugs must bear
29 the name of the licensee. This subsection (4) does not apply to standard ordering and
30 purchasing business practices between a chain pharmacy warehouse, a wholesaler, and a
31 manufacturer.

32
33 **12-280-306. [Formerly 12-42.5-306] Records - study - authentication - pedigree**
34 **- rules.** (1) A wholesaler shall establish and maintain inventories and records of all
35 transactions regarding the receipt and distribution or other disposition of prescription drugs.
36 The records must include the pedigree for each wholesale distribution of a prescription drug
37 that occurs outside the normal distribution channel.

38 (2) A wholesaler in the possession of a pedigree for a prescription drug shall verify

1 that each transaction on the pedigree has occurred prior to distributing the prescription drug.

2 (3) A pedigree shall include all necessary identifying information concerning each
3 sale in the chain of distribution of the product from the manufacturer or the first authorized
4 distributor of record through the acquisition and sale by a wholesaler until final sale to a
5 pharmacy or other person dispensing or administering the prescription drug. The pedigree
6 shall include, at a minimum:

7 (a) The name, address, telephone number, and, if available, the electronic mail
8 address of each owner of the prescription drug and each wholesaler of the drug;

9 (b) The name and address of each location from which the prescription drug was
10 shipped, if different from that of the owner;

11 (c) The transaction dates;

12 (d) Certification that each recipient has authenticated the pedigree;

13 (e) The name of the prescription drug;

14 (f) The dosage form and strength of the prescription drug;

15 (g) The size and number of containers;

16 (h) The lot number of the prescription drug; and

17 (i) The name of the manufacturer of the finished dosage form.

18 (4) A purchaser or wholesaler shall maintain each pedigree for three years after the
19 date of the sale or transfer of the prescription drug and shall make the pedigree available for
20 inspection or use within five business days upon the request of an authorized law
21 enforcement officer or an authorized agent of the board.

22 (5) This section does not apply to a retail pharmacy or chain pharmacy warehouse
23 if the retail pharmacy or chain pharmacy warehouse does not engage in the wholesale
24 distribution of prescription drugs.

25 (6) The board shall adopt rules as necessary for the implementation of this part 3.

26
27 **12-280-307. [Formerly 12-42.5-307] Penalty.** (1) A person who engages in the
28 wholesale distribution of prescription drugs in violation of this part 3 is subject to a penalty
29 of up to fifty thousand dollars.

30 (2) A person who knowingly engages in the wholesale distribution of prescription
31 drugs in violation of this part 3 is subject to a penalty of up to five hundred thousand dollars.

32 33 PART 4

34 ELECTRONIC MONITORING OF PRESCRIPTION DRUGS

35
36 **12-42.5-401. [Formerly 12-42.5-401] Legislative declaration.** (1) The general
37 assembly finds, determines, and declares that:

38 (a) Prescription drug misuse occurs in this country to an extent that exceeds or rivals

1 the abuse of illicit drugs;

2 (b) Prescription drug misuse occurs at times due to the deception of the authorized
3 practitioners where patients seek controlled substances for treatment and the practitioner is
4 unaware of the patient's other medical providers and treatments;

5 (c) Electronic monitoring of prescriptions for controlled substances provides a
6 mechanism whereby practitioners can discover the extent of each patient's requests for drugs
7 and whether other providers have prescribed similar substances during a similar period of
8 time;

9 (d) Electronic monitoring of prescriptions for controlled substances provides a
10 mechanism for law enforcement officials and regulatory boards to efficiently investigate
11 practitioner behavior that is potentially harmful to the public.

12
13 **12-42.5-402. Definitions.** As used in this part 4, unless the context otherwise
14 requires:

15 ~~(1) "Board" means the state board of pharmacy created in section 12-42.5-103.~~
16 <{***Board is defined in part 1 for entire article.***}>

17 ~~(1.5) (1) "Controlled substance" means any schedule II, III, IV, or V drug as listed~~
18 ~~in sections 18-18-204, 18-18-205, 18-18-206, and 18-18-207. C.R.S.~~

19 ~~(2) "Division" means the division of professions and occupations in the department~~
20 ~~of regulatory agencies.~~ <{***Redundant with definitions common provision, 12-20-102 (7).***}>

21 ~~(3) (2) "Drug abuse" or "abuse" means utilization of a controlled substance for~~
22 ~~nonmedical purposes or in a manner that does not meet generally accepted standards of~~
23 ~~medical practice.~~

24 ~~(4) (3) "Prescription drug outlet" or "pharmacy" means:~~

25 (a) Any resident or nonresident pharmacy outlet registered or licensed pursuant to
26 this article **280** where prescriptions are compounded and dispensed; and

27 (b) Any federally owned and operated pharmacy registered with the federal drug
28 enforcement administration.

29 ~~(5) (4) "Program" means the electronic prescription drug monitoring program~~
30 ~~developed or procured by the board in accordance with section ~~12-42.5-403~~ **12-280-403**.~~

31
32 **12-280-403. [Formerly 12-42.5-403] Prescription drug use monitoring program**
33 **- registration required - rules.** (1) The board shall develop or procure a prescription
34 controlled substance electronic program to track information regarding prescriptions for
35 controlled substances dispensed in Colorado, including the following information:

36 (a) The date the prescription was dispensed;

37 (b) The name of the patient and the practitioner;

38 (c) The name and amount of the controlled substance;

1 (d) The method of payment;

2 (e) The name of the dispensing pharmacy; and

3 (f) Any other data elements necessary to determine whether a patient is visiting
4 multiple practitioners or pharmacies, or both, to receive the same or similar medication.

5 ~~(1.5)~~ (2) (a) By January 1, 2015, or by an earlier date determined by the director, ~~of~~
6 ~~the division~~, every practitioner in this state who holds a current registration issued by the
7 federal drug enforcement administration and every pharmacist shall register and maintain
8 a user account with the program.

9 (b) When registering with the program or at any time thereafter, a practitioner or
10 pharmacist may authorize up to three designees to access the program under section
11 ~~12-42.5-404~~ **12-280-404** (3)(b), ~~(3)(c)~~ **(3)(d)**, or ~~(3)(d)~~ **(3)(f)**, as applicable, on behalf of the
12 practitioner or pharmacist if:

13 (I) (A) The authorized designee of the practitioner is employed by, or is under
14 contract with, the same professional practice as the practitioner; or

15 (B) The authorized designee of the pharmacist is employed by, or is under contract
16 with, the same prescription drug outlet as the pharmacist; and

17 (II) The practitioner or pharmacist takes reasonable steps to ensure that the designee
18 is sufficiently competent in the use of the program; and

19 (III) The practitioner or pharmacist remains responsible for:

20 (A) Ensuring that access to the program by the practitioner's designee is limited to
21 the purposes authorized in section ~~12-42.5-404~~ (3)(b) or ~~(3)(c)~~ **12-280-404** (3)(d) OR **(3)(f)**
22 or that access to the program by the pharmacist's designee is limited to the purposes
23 authorized in section ~~12-42.5-404~~ (3)(d) **12-280-404** (3)(f), as the case may be, and that
24 access to the program occurs in a manner that protects the confidentiality of the information
25 obtained from the program; and

26 (B) Any negligent breach of confidentiality of information obtained from the
27 program by the practitioner's or pharmacist's designee.

28 (c) A practitioner or pharmacist is subject to penalties pursuant to section
29 ~~12-42.5-406~~ **12-280-406** for violating the requirements of ~~paragraph (b) of this subsection~~
30 ~~(1.5)~~ SUBSECTION (2)(b) OF THIS SECTION.

31 (d) Any individual authorized as a designee of a practitioner or pharmacist pursuant
32 to ~~paragraph (b) of this subsection~~ ~~(1.5)~~ SUBSECTION (2)(b) OF THIS SECTION shall register
33 as a designee of a practitioner or pharmacist with the program for program data access in
34 accordance with section ~~12-42.5-404~~ **12-280-404** (3)(b), ~~(3)(c)~~ **(3)(d)**, or ~~(3)(d)~~ **(3)(f)**, as
35 applicable, and board rules.

36 ~~(2)~~ (3) Each practitioner and each dispensing pharmacy shall disclose to a patient
37 receiving a controlled substance that his or her identifying prescription information will be
38 entered into the program database and may be accessed for limited purposes by specified

1 individuals.

2 ~~(3)~~ (4) The board shall establish a method and format for prescription drug outlets
3 to convey the necessary information to the board or its designee. The method must not
4 require more than a one-time entry of data per patient per prescription by a prescription drug
5 outlet.

6 ~~(4)~~ (5) The division may contract with any individual or public or private agency or
7 organization in carrying out the data collection and processing duties required by this part
8 4.

9
10 **12-280-404. [Formerly 12-42.5-404] Program operation - access - rules -**
11 **definitions - repeal.** (1) The board shall operate and maintain the program.

12 (2) The board shall adopt all rules necessary to implement the program.

13 (3) The program is available for query only to the following persons or groups of
14 persons:

15 (a) Board staff responsible for administering the program;

16 (b) Any practitioner with the statutory authority to prescribe controlled substances,
17 or an individual designated by the practitioner to act on his or her behalf in accordance with
18 section ~~12-42.5-403 (1.5)(b)~~ **12-280-403 (2)(b)**, to the extent the query relates to a current
19 patient of the practitioner. The practitioner or his or her designee shall identify his or her
20 area of health care specialty or practice upon the initial query of the program.

21 ~~(b.5)~~ (c) (I) Any veterinarian with statutory authority to prescribe controlled
22 substances, to the extent the query relates to a current patient or to a client and if the
23 veterinarian, in the exercise of professional judgment, has a reasonable basis to suspect the
24 client has committed drug abuse or has mistreated an animal.

25 (II) As used in this subsection ~~(3)(b.5)~~ **(3)(c)**:

26 (A) "Client" has the same meaning as set forth in section ~~12-64-103 (4.3)~~ **12-315-**
27 **___ (___)**.

28 (B) "Mistreat" has the same meaning as set forth in section 35-42-103 (9).

29 (C) "Patient" has the same meaning as set forth in section ~~12-64-103 (9.7)~~ **12-315-**
30 **___ (___)**.

31 ~~(e)~~ (d) A practitioner, or an individual designated by the practitioner to act on his or
32 her behalf in accordance with section ~~12-42.5-403 (1.5)(b)~~ **12-280-403 (2)(b)**, engaged in
33 a legitimate program to monitor a patient's drug abuse;

34 ~~(e.5)~~ (e) The medical director, or his or her designee, at a facility that treats substance
35 use disorders with controlled substances, if an individual in treatment at the facility gives
36 permission to the facility to access his or her program records;

37 ~~(d)~~ (f) A pharmacist, an individual designated by a pharmacist in accordance with
38 section ~~12-42.5-403 (1.5)(b)~~ **12-280-403 (2)(b)** to act on his or her behalf, or a pharmacist

1 licensed in another state, to the extent the information requested relates specifically to a
2 current patient to whom the pharmacist is dispensing or considering dispensing a controlled
3 substance or prescription drug or a patient to whom the pharmacist is currently providing
4 clinical patient care services;

5 (e) (g) Law enforcement officials so long as the information released is specific to
6 an individual patient, pharmacy, or practitioner and is part of a bona fide investigation, and
7 the request for information is accompanied by an official court order or subpoena;

8 (f) (h) The individual who is the recipient of a controlled substance prescription so
9 long as the information released is specific to the individual;

10 (g) (i) ~~State regulatory boards within the division and the director of the division~~
11 **REGULATORS**, so long as the information released is specific to an individual practitioner and
12 is part of a bona fide investigation, and the request for information is accompanied by an
13 official court order or subpoena; <{ "**Regulator**" defined in common definitions, 12-20-102
14 **(14) to include the DPO boards and the DPO director. Recommend using defined term.** }>

15 (h) (j) A resident physician with an active physician training license issued by the
16 Colorado medical board pursuant to section ~~12-36-122~~ **12-240-128** and under the
17 supervision of a licensed physician.

18 (i) (k) The department of public health and environment for purposes of
19 population-level analysis, but any use of program data by the department is subject to the
20 federal "Health Insurance Portability and Accountability Act of 1996", Pub.L. 104-191, as
21 amended, and implementing federal regulations, including the requirement to remove any
22 identifying data unless exempted from the requirement.

23 (3.6) (4) (a) Each practitioner or his or her designee shall query the program prior to
24 prescribing the second fill for an opioid unless the patient receiving the prescription:

25 (I) Is receiving the opioid in a hospital, skilled nursing facility, residential facility,
26 or correctional facility;

27 (II) Has been diagnosed with cancer and is experiencing cancer-related pain;

28 (III) Is undergoing palliative care or hospice care;

29 (IV) Is experiencing post-surgical pain that, because of the nature of the procedure,
30 is expected to last more than fourteen days;

31 (V) Is receiving treatment during a natural disaster or during an incident where mass
32 casualties have taken place; or

33 (VI) Has received only a single dose to relieve pain for a single test or procedure.

34 (b) The program must use industry standards to allow providers or their designees
35 direct access to data from within an electronic health record to the extent that the query
36 relates to a current patient of the practitioner.

37 (c) A practitioner or his or her designee complies with this subsection (3.6) (4) if he
38 or she attempts to access the program prior to prescribing the second fill for an opioid, and

1 the program is not available or is inaccessible due to technical failure.

2 (d) A violation of this subsection ~~(3.6)~~ (4) does not create a private right of action
3 or serve as the basis of a cause of action. A violation of this section does not constitute
4 negligence per se or contributory negligence per se and does not alone establish a standard
5 of care. Compliance with this section does not alone establish an absolute defense to any
6 alleged breach of the standard of care. <{Reference to "section" should be limited to
7 "subsection (4). Same issue that came up in dental practice act, per SB18-022.}>

8 (e) This subsection ~~(3.6)~~ (4) is repealed, effective September 1, 2021.

9 ~~(4)~~ (5) The board shall not charge a practitioner or pharmacy who transmits data in
10 compliance with the operation and maintenance of the program a fee for the transmission
11 of the data.

12 ~~(5)~~ (6) The board, the department of public health and environment, or the
13 department of health care policy and financing, pursuant to a written agreement that ensures
14 compliance with this part 4, may provide data to qualified personnel of a public or private
15 entity for the purpose of bona fide research or education so long as the data does not identify
16 a recipient of, a practitioner who prescribed, or a prescription drug outlet that dispensed, a
17 prescription drug.

18 ~~(6)~~ (7) The board shall provide a means of sharing information about individuals
19 whose information is recorded in the program with out-of-state health care practitioners and
20 law enforcement officials that meet the requirements of ~~paragraph (b), (c), or (e) of~~
21 ~~subsection (3)~~ SUBSECTION (3)(b), (3)(d), OR (3)(g) of this section.

22 ~~(7)~~ (8) The board shall develop criteria for indicators of misuse, abuse, and diversion
23 of controlled substances and, based on those criteria, provide unsolicited reports of
24 dispensed controlled substances to prescribing practitioners and dispensing pharmacies for
25 purposes of education and intervention to prevent and reduce occurrences of controlled
26 substance misuse, abuse, and diversion. In developing the criteria, the board shall consult
27 with the Colorado dental board, Colorado medical board, state board of nursing, state board
28 of optometry, Colorado podiatry board, and state board of veterinary medicine.

29 ~~(8)~~ (9) Reports generated by the program and provided to prescribing practitioners
30 for purposes of information, education, and intervention to prevent and reduce occurrences
31 of controlled substance misuse, abuse, and diversion are:

32 (a) Not public records under the "Colorado Open Records Act", part 2 of article 72
33 of title 24;

34 (b) Not discoverable in any criminal or administrative proceeding against a
35 prescribing practitioner; and

36 (c) Not admissible in any civil, criminal, or administrative proceeding against a
37 prescribing practitioner.

1 **12-280-405. [Formerly 12-42.5-405] Prescription drug monitoring fund -**
 2 **creation - gifts, grants, and donations - fee.** (1) The board may seek and accept funds
 3 MONEY from any public or private entity for the purposes of implementing and maintaining
 4 the program. The board shall transmit any funds MONEY it receives to the state treasurer,
 5 who shall credit the same MONEY to the prescription drug monitoring fund, which fund is
 6 hereby created. The moneys MONEY in the fund are IS subject to annual appropriation by the
 7 general assembly for the sole purpose of implementing and maintaining the program. The
 8 moneys MONEY in the fund must not be transferred to or revert to the general fund at the end
 9 of any fiscal year.

10 (2) After implementing the program, the board shall seek gifts, grants, and donations
 11 on an annual basis for the purpose of maintaining the program. The board shall report
 12 annually to the health and human services committee of the senate and the health,
 13 INSURANCE, and environment committee of the house of representatives, or any successor
 14 committees, regarding the gifts, grants, and donations requested, of whom they were
 15 requested, and the amounts received. <{*Ongoing report, but no exception made to 24-1-*
 16 *136 (11). SRC issue?*}>

17 (3) If, based upon the appropriations for the direct and indirect costs of the program,
 18 there are insufficient funds to maintain the program, the division may collect an annual fee
 19 of no more than seventeen dollars and fifty cents for the fiscal years 2011-12 and 2012-13,
 20 twenty dollars for the fiscal years 2013-14 and 2014-15, and twenty-five dollars for each
 21 fiscal year thereafter, from an individual who holds a license from the division that
 22 authorizes him or her to prescribe a controlled substance, as defined in section 18-18-102
 23 (5). ~~C.R.S.~~ The division shall set the fee pursuant to section ~~24-34-105, C.R.S., 12-20-105~~
 24 and shall collect the fee in conjunction with the license renewal fees collected pursuant to
 25 section ~~24-34-105, C.R.S. Moneys 12-20-105.~~ MONEY collected pursuant to this subsection
 26 (3) are IS credited to the prescription drug monitoring fund created in subsection (1) of this
 27 section.

29 **12-280-406. [Formerly 12-42.5-406] Violations - penalties.** A person who
 30 knowingly releases, obtains, or attempts to obtain information from the program in violation
 31 of this part 4 shall be punished by a civil fine of not less than one thousand dollars and not
 32 more than ten thousand dollars for each violation. **Fines paid shall be deposited in the**
 33 **general fund.** <{*Since these are "civil" fines that presumably are imposed by a court, it*
 34 *appears that this direction to deposit the fines in the GF should be retained.*}>

36 **12-280-407. [Formerly 12-42.-5-407] Prescription drug outlets - prescribers -**
 37 **responsibilities - liability.** (1) A prescription drug outlet shall submit information in the
 38 manner required by the board.

1 (2) A practitioner who has, in good faith, written a prescription for a controlled
2 substance to a patient is not liable for information submitted to the program. A practitioner
3 or prescription drug outlet who has, in good faith, submitted the required information to the
4 program is not liable for participation in the program.
5

6 **12-280-408. [Formerly 12-42.5-408] Exemption - waiver.** (1) A hospital licensed
7 or certified pursuant to section 25-1.5-103, ~~C.R.S.~~, a prescription drug outlet located within
8 the hospital that is dispensing a controlled substance for a chart order or dispensing less than
9 or equal to a twenty-four-hour supply of a controlled substance, and emergency medical
10 services personnel certified pursuant to section 25-3.5-203 ~~C.R.S.~~, are exempt from the
11 reporting provisions of this part 4. A hospital prescription drug outlet licensed pursuant to
12 section ~~12-42.5-112~~ **12-280-114** shall comply with the provisions of this part 4 for
13 controlled substances dispensed for outpatient care that have more than a twenty-four-hour
14 supply.

15 (2) A prescription drug outlet that does not report controlled substance data to the
16 program due to a lack of electronic automation of the outlet's business may apply to the
17 board for a waiver from the reporting requirements.
18

19 **12-280-409. [Formerly 12-42.5-408.5] Examination and analysis of prescription**
20 **drug monitoring program - recommendations to executive director.** (1) The executive
21 director of the department of regulatory agencies shall create a prescription drug monitoring
22 program task force or consult with and request assistance from the **Colorado team assembled**
23 **by the governor's office to develop a strategic plan to reduce prescription drug misuse,**
24 **<{Assume this is the Colorado Consortium for Prescription drug Abuse Prevention.**
25 **Should name be inserted/updated?}>** or its successor group, in order to:

26 (a) Examine issues, opportunities, and weaknesses of the program, including how
27 personal information is secured in the program and whether inclusion of personal identifying
28 information in the program and access to that information is necessary; and

29 (b) Make recommendations to the executive director on ways to make the program
30 a more effective tool for practitioners and pharmacists in order to reduce prescription drug
31 misuse in this state.

32 (2) If the executive director convenes a task force or obtains assistance from the
33 **Colorado team**, the applicable group shall submit annual reports to the executive director
34 and the general assembly detailing its findings and recommendations. Notwithstanding
35 section 24-1-136 (11), ~~C.R.S.~~, the requirement in this section to report to the general
36 assembly continues indefinitely.

37 (3) If the executive director convenes a task force, the members of the task force
38 serve on a voluntary basis and are not entitled to compensation or expense reimbursement.

1 physician assistant is under the supervision of a licensed physician; or

2 (III) An advanced practice nurse prescriber licensed as a professional nurse under
3 section ~~12-38-111~~ **12-255-110**, registered as an advanced practice nurse under section
4 ~~12-38-111.5~~ **12-255-111**, and authorized to prescribe controlled substances or prescription
5 drugs pursuant to section ~~12-38-111.6~~ **12-255-112**, if the advanced practice nurse prescriber
6 has developed an articulated plan to maintain ongoing collaboration with physicians and
7 other health care professionals.

8 (2) The board may adopt rules as necessary to implement this part 5.
9

10 PART 6
11 COLLABORATIVE PHARMACY PRACTICE
12

13 **12-280-601. [Formerly 12-42.5-601] Definitions.** As used in this part 6:

14 (1) (a) "Collaborative pharmacy practice agreement" means a written and signed
15 agreement entered into voluntarily between one or more pharmacists licensed pursuant to
16 this article **280** and one or more physicians or advanced practice nurses licensed in this state,
17 which statement grants authority to the pharmacist or pharmacists to provide evidence-based
18 health care services to one or more patients pursuant to a specific treatment protocol
19 delegated to a pharmacist or pharmacists by the physician or advanced practice nurse.

20 (b) A "collaborative pharmacy practice agreement" may also mean a statewide drug
21 therapy protocol developed by the board, the Colorado medical board, and the state board
22 of nursing in collaboration with the department of public health and environment for public
23 health care services.
24

25 **12-280-602. [Formerly 12-42.5-602] Collaborative pharmacy practice**
26 **agreements - pharmacist requirements.** (1) A pharmacist may enter into a collaborative
27 pharmacy practice agreement with one or more physicians if:

28 (a) The pharmacist:

29 (I) Holds a current license to practice in Colorado;

30 ~~(b)~~ (II) ~~The pharmacist~~ Is engaged in the practice of pharmacy;

31 ~~(c)~~ (III) ~~The pharmacist~~ Has earned a doctorate of pharmacy degree or completed at
32 least five years of experience as a licensed pharmacist;

33 ~~(d)~~ (IV) ~~The pharmacist~~ Carries adequate professional liability insurance as
34 determined by the board; AND

35 ~~(e)~~ (V) ~~The pharmacist~~ Agrees to devote a portion of his or her practice to
36 collaborative pharmacy practice; and

37 ~~(f)~~ (b) There is a process in place for the physician or advanced practice nurse and
38 the pharmacist to communicate and document changes to the patient's medical record.

1 (2) Unless a statewide protocol is in place, a pharmacist may not enter into a
2 collaborative pharmacy practice agreement with a physician or advanced practice nurse if
3 the physician or advanced practice nurse does not have an established relationship with the
4 patient or patients who will be served by the pharmacist under the collaborative pharmacy
5 practice agreement.

6 (3) For a pharmacist to provide health care services under a statewide protocol, a
7 process must be in place for the pharmacist to communicate with a patient's primary care
8 provider and document changes to the patient's medical record. If the patient does not have
9 a primary care provider, or is unable to provide contact information for his or her primary
10 care provider, the pharmacist shall provide the patient with a written record of the drugs or
11 devices furnished and advise the patient to consult an appropriate health care professional
12 of the patient's choice.

13 (4) A collaborative practice agreement **between a physician** <{or APN?}> **and a**
14 **pharmacist**, as permitted by this article **280**, does not change the employment status of any
15 party to the agreement, does not create an employer-employee relationship under any
16 circumstance, and may not be used to confer upon or deny to any person the status of a
17 public employee as described in the "Colorado Governmental Immunity Act", created in
18 article 10 of title 24. ~~C.R.S.~~

19 (5) A pharmacist or pharmacy shall not employ a physician or advanced practice
20 nurse for the sole purpose of forming a collaborative practice agreement.

21
22 **12-280-603. [Formerly 12-42.5-603] Rules.** The board, in conjunction with the
23 Colorado medical board created in section ~~12-36-103~~ **12-240-105** and the state board of
24 nursing created in section ~~12-38-104~~ **12-255-105**, shall promulgate rules to implement this
25 section. The rules must include the health care services and any statewide protocols that are
26 authorized to be part of the collaborative pharmacy practice agreements.