First Regular Session Seventy-third General Assembly STATE OF COLORADO

ENGROSSED

This Version Includes All Amendments Adopted on Second Reading in the House of Introduction

LLS NO. 21-0371.02 Christy Chase x2008

SENATE BILL 21-094

SENATE SPONSORSHIP

Ginal and Winter, Buckner, Fields, Jaquez Lewis, Kirkmeyer, Simpson

HOUSE SPONSORSHIP

Roberts,

Senate Committees

House Committees

Health & Human Services Appropriations

A BILL FOR AN ACT CONCERNING THE CONTINUATION OF THE STATE BOARD OF PHARMACY, AND, IN CONNECTION THEREWITH, IMPLEMENTING RECOMMENDATIONS CONTAINED IN THE 2020 SUNSET REPORT BY THE DEPARTMENT OF REGULATORY AGENCIES AND MAKING OTHER CHANGES REGARDING THE PRACTICE OF PROFESSIONS REGULATED BY THE BOARD.

Bill Summary

(Note: This summary applies to this bill as introduced and does not reflect any amendments that may be subsequently adopted. If this bill passes third reading in the house of introduction, a bill summary that applies to the reengrossed version of this bill will be available at http://leg.colorado.gov/.)

Sunset Process - Senate Health and Human Services

Committee. The bill implements recommendations of the department of regulatory agencies in its sunset review of and report on the state board of pharmacy (board) and its regulation of the practice of pharmacy and makes other modifications to the laws regulating the practice. Specifically:

- Sections 1 and 2 of the bill continue the board and its functions for 9 years, until 2030, and consolidate within the sunset review the board's functions regarding the regulation of therapeutic interchange and therapeutically equivalent selections and of collaborative pharmacy practice agreements;
- Sections 3, 9, 10, 11, 18, 20, and 25 to 29 align the pharmacy practice act with the federal "Drug Quality and Security Act";
- Section 3 also:
 - Clarifies that an out-of-state pharmacy need not register with the board when distributing prescription drugs to in-state pharmacies under common ownership with the out-of-state pharmacy if the drugs remain in the original manufacturer's packaging and are not compounded and the transfer is necessary to address an inventory shortage;
 - Excludes from the definition of "compounding" activities such as repackaging or tablet splitting a drug or adding standard flavoring to oral liquid drugs;
 - Includes in the definition of "other outlet" a community mental health clinic and a facility operating a licensed substance use disorder treatment program, thereby allowing those facilities to register with the board and operate as a pharmacy outlet;
 - Repeals the term "pharmaceutical care" and replaces it with "pharmacist care services" to reflect the services pharmacists provide in addition to compounding and dispensing drugs;
 - Adds functions to the scope of practice of a pharmacy technician, such as documenting medical history and replenishing automated dispensing devices; and
 - Adds functions to the scope of practice of a pharmacist, such as prescribing drugs for limited conditions, ordering and evaluating laboratory tests, and performing limited physical assessments;
- Section 4 specifies that, of the pharmacist members of the

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- board, one must be practicing in a hospital setting, one must be practicing in a chain pharmacy, and one must be practicing in an independent pharmacy;
- Section 5 repeals the requirement that the board justify its reasons for deviating from a recommendation from the veterinary pharmaceutical advisory committee;
- Sections 5, 6, 21 to 25, and 36 make technical amendments to the pharmacy practice act, such as eliminating references to "diversion" in the peer health assistance program and correcting erroneous references to wholesalers as "licensed" rather than "registered";
- Section 6 grants the board authority, after conducting a risk-based assessment, to inspect out-of-state pharmacies, out-of-state wholesalers, and nonresident 503B outsourcing facilities and requires the board to send quarterly electronic newsletters to pharmacists regarding updates in the law that affect the practice;
- Sections 7, 16, and 33 to 35 require pharmacists and pharmacies, as well as insurance companies that underwrite professional liability insurance for pharmacists and pharmacies, to report malpractice settlements and judgments to the board;
- Section 8 specifies tasks that a pharmacist may delegate to ancillary pharmacy personnel under the pharmacist's supervision;
- Section 10 increases the amount of medication that may be dispensed to an emergency room patient from a 24-hour supply to a 72-hour supply and allows a hospital to dispense a prescription drug to a hospitalized patient who leaves the hospital on a day pass;
- Sections 3, 12, and 32 authorize pharmacists to prescribe opiate antagonists;
- Sections 3 and 13 repeal the requirement that the label on an anabolic steroid prescription indicate the purpose for which the prescription was written;
- Sections 3 and 14 authorize a pharmacist, under specified circumstances, to substitute a drug in the same therapeutic class as the prescribed drug or a biological product that is a biosimilar to the prescribed biological product;
- Section 15 authorizes pharmacists to make specified types of minor adaptions to prescriptions;
- **Section 16** specifies that a licensee, certificant, or registrant may be disciplined for habitual or excessive use or abuse of alcohol, habit-forming drugs, or controlled substances, but not for having a substance use disorder;

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- **Section 17** eliminates the requirement that the board send letters of admonition by certified mail;
- Section 19 directs the board to adopt rules regarding electronic storage of pharmacy records;
- Section 20 requires a pharmacist to provide patient counseling in new medication therapy and authorizes a pharmacist, in the pharmacist's professional judgment, to provide patient counseling for any other prescription; and
- Sections 30 and 31 allow a pharmacy technician to register with and access, on behalf of a pharmacist supervising the pharmacy technician, the prescription drug monitoring program.

1 Be it enacted by the General Assembly of the State of Colorado:

2 **SECTION 1.** In Colorado Revised Statutes, 12-280-104, amend

3 (3) as follows:

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4 12-280-104. State board of pharmacy - creation - subject to

5 review - repeal of parts. (3) Parts 1 to 3 Parts 1 to 3, 5, AND 6 of this

article 280 are repealed, effective September 1, 2021 SEPTEMBER 1, 2030.

7 Before the repeal, the board and the regulation of the practice of

pharmacy pursuant to parts 1 to 3 PARTS 1 TO 3, 5, AND 6 of this article

280 including the regulation of the practice as a pharmacy technician, are

scheduled for review in accordance with section 24-34-104.

SECTION 2. In Colorado Revised Statutes, 24-34-104, **repeal** (21)(a)(II); and **add** (31)(a)(VI) as follows:

24-34-104. General assembly review of regulatory agencies and functions for repeal, continuation, or reestablishment - legislative declaration - repeal. (21) (a) The following agencies, functions, or both, will repeal on September 1, 2021:

(II) The state board of pharmacy and the regulation of the practice of pharmacy, including the regulation of the practice as a pharmacy technician, by the department of regulatory agencies through the division

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I	of professions and occupations in accordance with parts 1 to 3 of article
2	280 of title 12;
3	(31) (a) The following agencies, functions, or both, are scheduled
4	for repeal on September 1, 2030:
5	(VI) THE STATE BOARD OF PHARMACY AND THE REGULATION OF
6	THE PRACTICE OF PHARMACY IN ACCORDANCE WITH PARTS 1 TO 3, 5, AND
7	6 of article 280 of title 12.
8	SECTION 3. In Colorado Revised Statutes, 12-280-103, amend
9	(3), (4), (27), (32)(a) introductory portion, (38.5)(a)(V), (38.5)(a)(VI),
10	(39)(a), (39)(d), (40), (43), (48), (54)(b)(III), (54)(b)(XI), and (55); repeal
11	(9), (34), (37), (54)(b)(IX), and (54)(b)(XII); and add (9.7),
12	(15.5), (28.5), (35.5), (38.5)(a)(VII), (38.5)(a)(VIII), (39)(f), (39)(g),
13	(39)(h), (39)(i), (39)(j), (46.5), (52.5), and (54)(b)(XVI) as follows:
14	12-280-103. Definitions - rules. As used in this article 280, unless
15	the context otherwise requires or the term is otherwise defined in another
16	part of this article 280:
17	(3) "Anabolic steroid" has the same meaning as set forth in section
18	18-18-102 (3) "APPROVED TREATMENT FACILITY" MEANS AN APPROVED
19	PRIVATE OR PUBLIC TREATMENT FACILITY, AS DESCRIBED IN SECTION
20	27-81-102 (2) AND (3) THAT ADHERES TO THE STANDARDS SET FORTH IN
21	<u>SECTION 27-81-106.</u>
22	(4) "Authorized distributor of record" means a wholesaler with
23	whom a manufacturer has established an ongoing relationship to
24	distribute the manufacturer's prescription drug. For purposes of this
25	subsection (4), an ongoing relationship is deemed to exist between a
26	wholesaler and a manufacturer when the wholesaler, including any
27	affiliated group of the wholesaler as defined in section 1504 of the federal

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1	"Internal Revenue Code of 1986", as amended, complies with the
2	following:
3	(a) The wholesaler has a written agreement currently in effect
4	with the manufacturer evidencing the ongoing relationship; and
5	(b) The wholesaler is listed on the manufacturer's current list of
6	authorized distributors of record, which list is updated by the
7	manufacturer on no less than a monthly basis "Behavioral Health
8	ENTITY" MEANS A BEHAVIORAL HEALTH ENTITY, AS DEFINED IN SECTION
9	25-27.6-102 (6), LICENSED PURSUANT TO ARTICLE 27.6 OF TITLE 25.
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11	(9) "Chain pharmacy warehouse" means a physical location for
12	prescription drugs that serves as a central warehouse and performs
13	intracompany sales or transfers of prescription drugs to a group of chain
14	pharmacies or other chain pharmacy warehouses that are under common
15	ownership or control. Notwithstanding any other provision of this article
16	280, a chain pharmacy warehouse receiving distributions on behalf of, or
17	making distributions to, an intracompany pharmacy need not be an
18	authorized distributor of record to be part of the normal distribution
19	channel.
20	(9.7) "COMMUNITY MENTAL HEALTH CLINIC" HAS THE SAME
21	MEANING AS SET FORTH IN SECTION 25-27.6-102 (9).
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23	(15.5) "DQSA" MEANS THE FEDERAL "DRUG QUALITY AND
24	SECURITY ACT", Pub.L. 113-54, as amended.
25	(27) "Manufacturer's exclusive distributor" means a person who
26	contracts with a manufacturer to provide or coordinate warehousing,
27	distribution, or other services on behalf of a manufacturer and who takes

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title to the manufacturer's prescription drug but who does not have general responsibility to direct the sale or disposition of the manufacturer's prescription drug. To be considered part of the normal distribution channel, as defined in section 12-280-301 (6), a manufacturer's exclusive distributor shall be an authorized distributor of record "Manufacturer" or "Manufacturing drug outlet" means a person who manufactures drugs and includes a resident 503B outsourcing facility.

(28.5) "Nonresident 503B outsourcing facility" means a facility that is registered by the FDA, that is located outside the state, and that distributes compounded drugs into the state without a prescription order.

(32) "Other outlet" means:

(a) A hospital that does not operate a registered pharmacy, a rural health clinic, a federally qualified health center, as defined in the federal "Social Security Act", 42 U.S.C. sec. 1395x (aa)(4), a family planning clinic, an acute treatment unit licensed by the department of public health and environment, a school, a jail, a county or district public health agency, a community health clinic, A COMMUNITY MENTAL HEALTH CLINIC, A BEHAVIORAL HEALTH ENTITY, AN APPROVED TREATMENT FACILITY, a university, or a college that:

(34) "Pharmaceutical care" means the provision of drug therapy and other pharmaceutical patient care services by a pharmacist intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process. In addition to the preparation, dispensing, and distribution of medications, "pharmaceutical care" may include

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assessment and evaluation of the patient's medication-related needs and
development and communication of a therapeutic plan with defined
outcomes in consultation with the patient and the patient's other
health-care professionals to attain the desired outcome. This function
includes efforts to prevent, detect, and resolve medication-related
problems for individual patients. "Pharmaceutical care" does not include
prescriptive authority; except that a pharmacist may prescribe only
over-the-counter medications to a recipient under the "Colorado Medical
Assistance Act" as authorized pursuant to section 25.5-5-322 or pursuant
to a collaborative pharmacy practice agreement as defined in section
12-280-601 (1)(b).
(35.5) "PHARMACIST CARE SERVICES" MEANS PATIENT CARE
ACTIVITIES PROVIDED BY A PHARMACIST, WITH OR WITHOUT DISPENSING
A DRUG, THAT ARE INTENDED TO ACHIEVE OUTCOMES RELATED TO CURING
OR PREVENTING DISEASE, ELIMINATING OR REDUCING A PATIENT'S
SYMPTOMS, OR ARRESTING OR SLOWING THE PROCESS OF A DISEASE.
"PHARMACIST CARE SERVICES" INCLUDES EFFORTS TO PREVENT, DETECT,
AND RESOLVE MEDICATION-RELATED PROBLEMS.
(37) "Pharmacy buying cooperative warehouse" means a
permanent physical location that acts as a central warehouse for

(37) "Pharmacy buying cooperative warehouse" means a permanent physical location that acts as a central warehouse for prescription drugs and from which sales of prescription drugs are made to an exclusive group of pharmacies that are members or member owners of the buying cooperative operating the warehouse.

(38.5) (a) "Practice as a pharmacy technician" means engaging in any of the following activities involved in the practice of pharmacy, under the supervision and delegation of a supervising pharmacist:

(V) Transferring prescriptions; and

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1	(VI) Other activities as authorized and defined by the board by
2	rule Gathering, documenting, and maintaining proper clinical
3	AND NONCLINICAL INFORMATION FROM PATIENTS;
4	(VII) REPLENISHING AUTOMATED DISPENSING DEVICES WITHOUT
5	THE NEED FOR PHARMACIST VERIFICATION AS LONG AS THE PHARMACY
6	TECHNICIAN USES BAR CODE TECHNOLOGY THAT CHECKS THE ACCURACY
7	OF THE MEDICATION OR A SECOND PHARMACY TECHNICIAN PERFORMS THE
8	VERIFICATION; AND
9	(VIII) OTHER ACTIVITIES AS AUTHORIZED AND DEFINED BY THE
10	BOARD BY RULE.
11	(39) "Practice of pharmacy" means:
12	(a) The interpretation, evaluation, implementation, and dispensing
13	of orders; participation in drug and device selection, drug administration,
14	drug regimen reviews, and drug or drug-related research; THE provision
15	of patient counseling; and the provision of those acts or services
16	necessary to provide pharmaceutical PHARMACIST care SERVICES in all
17	areas of patient care;
18	(d) The dispensing of chronic maintenance drugs pursuant to
19	section 12-280-125.5 and board rules adopted in accordance with that
20	section; and
21	(f) Providing care to patients pursuant to a collaborative
22	PHARMACY PRACTICE AGREEMENT AS DEFINED IN SECTION 12-280-601;
23	(g) Exercising independent prescriptive authority:
24	(I) As authorized pursuant to section 25.5-5-322, only with
25	REGARD TO OVER-THE-COUNTER MEDICATIONS PRESCRIBED TO RECIPIENTS
26	UNDER THE "COLORADO MEDICAL ASSISTANCE ACT", ARTICLES 4 TO 6 OF
27	TITLE 25.5;

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1	(II) IN ACCORDANCE WITH A COLLABORATIVE PHARMACY
2	PRACTICE AGREEMENT AS DEFINED IN SECTION 12-280-601 (1)(b);
3	(III) AS AUTHORIZED PURSUANT TO SECTIONS 12-30-110 AND
4	12-280-123 (3) REGARDING OPIATE ANTAGONISTS; OR
5	(IV) FOR <u>DRUGS THAT ARE NOT CONTROLLED SUBSTANCES</u> , DRUG
6	CATEGORIES, OR DEVICES THAT ARE PRESCRIBED IN ACCORDANCE WITH
7	THE PRODUCT'S FDA-APPROVED LABELING AND THAT ARE LIMITED TO
8	CONDITIONS THAT:
9	(A) DO NOT REQUIRE A NEW DIAGNOSIS;
10	(B) ARE MINOR AND GENERALLY SELF-LIMITING; OR
11	(C) HAVE A TEST THAT IS USED TO GUIDE DIAGNOSIS OR CLINICAL
12	DECISION-MAKING AND IS WAIVED UNDER THE FEDERAL "CLINICAL
13	LABORATORY IMPROVEMENT AMENDMENTS OF 1988", Pub.L. 100-578,
14	AS AMENDED;
15	(h) Ordering and evaluating laboratory tests as related
16	TO MEDICATION THERAPY;
17	(i) PERFORMING LIMITED PHYSICAL ASSESSMENTS COMMENSURATE
18	WITH EDUCATION AND TRAINING; AND
19	(j) Performing other tasks delegated by a licensed
20	PHYSICIAN.
21	(40) "Practitioner" means a person authorized by law to prescribe
22	any drug or device, acting within the scope of the authority, including a
23	pharmacist who is participating within the parameters of a statewide drug
24	therapy protocol pursuant to a collaborative pharmacy practice agreement
25	as defined in section 12-280-601 (1)(b), or prescribing over-the-counter
26	medications pursuant to section 25.5-5-322, OR PRESCRIBING AN OPIATE
27	ANTAGONIST PURSUANT TO SECTIONS 12-30-110 AND 12-280-123 (3).

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

- (46.5) "RESIDENT 503B OUTSOURCING FACILITY" MEANS A FACILITY THAT IS REGISTERED BY THE FDA, THAT IS LOCATED IN THE STATE, AND THAT DISTRIBUTES COMPOUNDED DRUGS WITHIN THE STATE.
- (48) "Satellite" means an area outside the prescription drug outlet where pharmaceutical care and PHARMACIST CARE services are provided and that is in the same location.
- (52.5) "THIRD-PARTY LOGISTICS PROVIDER" MEANS A PERSON THAT CONTRACTS WITH A MANUFACTURER TO PROVIDE OR COORDINATE WAREHOUSING, DISTRIBUTION, OR OTHER SERVICES ON BEHALF OF A MANUFACTURER BUT DOES NOT TAKE TITLE TO A PRESCRIPTION DRUG OR HAVE GENERAL RESPONSIBILITY TO DIRECT THE PRESCRIPTION DRUG'S SALE OR DISPOSITION.
 - (54) (b) "Wholesale distribution" does not include:
- (III) The sale or transfer of a PRESCRIPTION drug THAT IS NOT COMPOUNDED OR PREPACKAGED BY THE SELLING OR TRANSFERRING PHARMACY, EXCEPT AS ALLOWED PURSUANT TO SECTION 12-280-120 (15)(b), for medical reasons by a retail AN IN-STATE OR UNREGISTERED NONRESIDENT pharmacy to another retail A SEPARATE IN-STATE pharmacy UNDER COMMON OWNERSHIP WITH THE SELLING OR TRANSFERRING IN-STATE OR UNREGISTERED NONRESIDENT PHARMACY to alleviate a temporary shortage;

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(IX) The direct sale, purchase, distribution, trade, or transfer of a
prescription drug from a manufacturer to an authorized distributor of
record to one additional authorized distributor of record but only if an
authorized distributor of record that purchases a prescription drug from
an authorized distributor of record that purchased the prescription drug
directly from the manufacturer:
(A) Provides the supplying authorized distributor of record with
a verifiable statement that the product is unavailable from the
manufacturer; and
(B) Receives a verifiable statement from the supplying authorized
distributor of record that the product was purchased directly from the
manufacturer;
(XI) The sale or transfer from a retail pharmacy or chain
pharmacy warehouse of expired, damaged, returned, or recalled
prescription drugs to the original manufacturer or to a third-party returns
processor;
(XII) The sale or transfer of compounded drugs compounded by
a retail pharmacy as defined in subsection (10) of this section and as
authorized by section 12-280-120 (6)(b);
(XVI) THE SALE, PURCHASE, OR TRADE OF A DRUG OR AN OFFER TO
SELL, PURCHASE, OR TRADE A DRUG BY A CHARITABLE ORGANIZATION
DESCRIBED IN SECTION 501 (c)(3) OF THE FEDERAL "INTERNAL REVENUE
Code of 1986", as amended, to a nonprofit affiliate of the
ORGANIZATION TO THE EXTENT OTHERWISE PERMITTED BY LAW.
(55) "Wholesaler" means a person engaged in the wholesale
distribution of prescription drugs to persons, other than consumers, who

are entitled THAT ARE AUTHORIZED BY LAW to possess prescription drugs.

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1	including: Repackagers; own-label distributors; private-label distributors;
2	jobbers; brokers; warehouses, including manufacturers' and distributors'
3	warehouses; manufacturers' exclusive distributors; authorized distributors
4	of record; drug wholesalers or distributors; independent wholesale drug
5	traders; pharmacy buying cooperative warehouses; retail pharmacies that
6	conduct wholesale distribution; and chain pharmacy warehouses that
7	conduct wholesale distribution.
8	SECTION 4. In Colorado Revised Statutes, 12-280-105, amend
9	(1)(a), (1)(b), and (1)(c)(II) as follows:
10	12-280-105. Membership of board - removal - compensation
11	- meetings - repeal. (1) (a) (I) The board is composed of five licensed
12	pharmacists, each having at least five years' experience in this state and
13	actively engaged in the practice of pharmacy in this state, and two
14	nonpharmacists who have no financial interest in the practice of
15	pharmacy.
16	(II) OF THE LICENSED PHARMACIST MEMBERS OF THE BOARD, ONE
17	MUST BE ENGAGED IN PRACTICE IN A HOSPITAL SETTING, ONE MUST BE
18	ENGAGED IN PRACTICE IN A CHAIN PHARMACY, AND ONE MUST BE
19	ENGAGED IN PRACTICE IN AN INDEPENDENT PHARMACY.
20	(b) (I) The governor shall make all appointments to the board in
21	accordance with this section.
22	$\mathrm{(II)}\mathrm{(A)}$ For the licensed pharmacist members of the board
23	whose terms expire on July 1, 2021, and July 1, 2022, the governor
24	SHALL APPOINT LICENSED PHARMACIST MEMBERS THAT SATISFY THE
25	REQUIREMENTS OF SUBSECTION (1)(a)(II) OF THIS SECTION.
26	(B) This subsection (1)(b)(II) is repealed, effective
27	DECEMBER 31, 2022.

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1	(c) For purposes of achieving a balance in the membership on the
2	board, the governor shall consider:
3	(II) The type of practice of the appointee so that various types of
4	practices are represented on the board AND SO THAT THE LICENSED
5	PHARMACIST MEMBERS OF THE BOARD SATISFY THE REQUIREMENTS OF
6	SUBSECTION (1)(a)(II) OF THIS SECTION.
7	SECTION 5. In Colorado Revised Statutes, 12-280-106, amend
8	(1)(a)(I)(B) and (2)(c) as follows:
9	12-280-106. Veterinary pharmaceutical advisory committee
10	- creation - appointments - rules - repeal. (1) (a) (I) There is created in
11	the department the veterinary pharmaceutical advisory committee
12	comprised of three members, each appointed by the state veterinarian who
13	serves under the commissioner of agriculture pursuant to section
14	35-50-104 as follows:
15	(B) One member who is either a licensed pharmaceutical
16	wholesaler registered pursuant to part 3 of this article 280
17	engaged in the distribution of animal drugs, having at least five years'
18	experience in this state, in good standing, and actively engaged in the
19	practice of wholesale pharmacy or a licensed veterinarian, having at least
20	five years' experience in this state, in good standing, and actively engaged
21	in the practice of veterinary medicine, but who is not both a
22	pharmaceutical wholesaler and a veterinarian; and
23	(2) (c) The board shall adopt the advisory committee's
24	recommendation on a referred matter unless the board determines that
25	there exists material and substantial evidence or information related to the
26	matter that warrants a resolution of the matter that is distinct from the
27	advisory committee's recommendation. If the board deviates from the

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1	advisory committee's recommendation, the board shall make a record of
2	the reasons for the deviation.
3	SECTION 6. In Colorado Revised Statutes, 12-280-108, amend
4	(1)(a) and (1)(j); and add (1)(k) as follows:
5	12-280-108. Powers and duties - rules. (1) The board shall:
6	(a) (I) Inspect, or direct inspectors who are licensed pharmacists
7	to inspect, all outlets and investigate violations of this article 280.
8	(II) THE BOARD'S AUTHORITY UNDER THIS SUBSECTION (1)(a) TO
9	INSPECT ALL OUTLETS INCLUDES THE AUTHORITY, AFTER CONDUCTING A
10	RISK-BASED ASSESSMENT, AS DEFINED BY THE BOARD BY RULE, TO INSPECT
11	AN OUT-OF-STATE PHARMACY, A NONRESIDENT 503B OUTSOURCING
12	FACILITY, OR AN OUT-OF-STATE WHOLESALER.
13	(j) Review and approve or reject applications for participation in
14	the pharmacy peer health assistance diversion program pursuant to part
15	2 of this article 280 and perform any other functions that were performed
16	by the rehabilitation evaluation committee prior to its repeal;
17	(k) SEND A QUARTERLY ELECTRONIC NEWSLETTER TO ALL
18	LICENSEES BY E-MAIL THAT DETAILS CHANGES IN STATE LAW THAT
19	AFFECT OR ARE PERTINENT TO THE PRACTICE OF PHARMACY.
20	SECTION 7. In Colorado Revised Statutes, amend 12-280-111
21	as follows:
22	12-280-111. Malpractice claims information - not public -
23	exception. (1) Each insurance company licensed to do business in this
24	state and engaged in the writing of malpractice insurance for licensed
25	pharmacists and pharmacies, and each pharmacist or pharmacy that
26	self-insures, shall send to the board, in the form prescribed by the board,
27	information relating to each malpractice claim against a licensed

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1	pharmacist that is settled or in which judgment is rendered against the
2	insured.
3	(2) The insurance company or self-insured pharmacist or
4	pharmacy shall provide information relating to each malpractice claim as
5	is deemed necessary by the board to conduct a further investigation and
6	hearing.
7	(3) Information relating to each malpractice claim provided by
8	insurance companies or self-insured pharmacists or pharmacies
9	PURSUANT TO SECTION 10-1-125.3 is exempt from the provisions of any
10	law requiring that the proceedings of the board be conducted publicly or
11	that the minutes or records of the board be open to public inspection
12	unless the board takes final disciplinary action. The board may use the
13	information in any formal hearing involving a licensee or registrant.
14	SECTION 8. In Colorado Revised Statutes, 12-280-118, amend
15	(5)(a)(I) and (5)(a)(II) as follows:
16	12-280-118. Prescription drug outlet under charge of
17	pharmacist - rules. (5) (a) Except as specified in subsection (5)(b) of
18	this section, the pharmacist responsible for the prescription order or chart
19	order may delegate the following tasks to the following individuals if, in
20	the pharmacist's professional judgment, the delegation is appropriate:
21	(I) Specific tasks, excluding tasks described in section 12-280-103
22	(38.5)(a), but which tasks may include delivery and proper and safe
23	storage of drugs or devices, to ancillary personnel, other than a
24	pharmacist or pharmacy intern, who are under the pharmacist's
25	supervision, WHICH TASKS MAY INCLUDE:
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27	(A) CASHIER TRANSACTIONS;

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1	(B) MEDICATION SHIPPING AND HANDLING;
2	(C) MEDICATION TRANSPORTATION;
3	(D) RECORD KEEPING;
4	(E) TELEPHONE OR COMMUNICATION TRIAGE; OR
5	(F) INVENTORY MANAGEMENT; or
6	
7	(II) Specific tasks described in section 12-280-103 (38.5)(a) or in
8	board rules adopted pursuant to section 12-280-103 (38.5)(a)(VI)
9	(38.5)(a)(VIII) to a pharmacy technician who is under the pharmacist's
10	supervision.
11	SECTION 9. In Colorado Revised Statutes, 12-280-119, amend
12	(7) and (11); and repeal (9) as follows:
13	12-280-119. Registration of facilities - rules. (7) A separate
14	registration is required under this section for any area outside the outlet
15	that is not a satellite where pharmaceutical PHARMACIST care and services
16	are provided and for any area outside the outlet that is under different
17	ownership from the outlet.
18	(9) (a) Subject to subsection (9)(b) of this section, a prescription
19	drug outlet may register as a compounding prescription drug outlet.
20	(b) The board shall not register a facility as a compounding
21	prescription drug outlet unless:
22	(I) The facility has been accredited by a board-approved
23	compounding accreditation entity to be within acceptable parameters to
24	compound more than ten percent of the facility's total sales; and
25	(II) Ownership of the facility is vested solely in a pharmacist.
26	(c) To be approved by the board to accredit a compounding
27	prescription drug outlet, a compounding accreditation entity shall be, at

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1	a minimum, a scientific organization with expertise in compounding
2	medications.
3	(11) A prescription drug outlet may register as a specialized
4	prescription drug outlet if it engages in the compounding, dispensing, and
5	delivery of drugs and devices to, or the provision of pharmaceutical
6	PHARMACIST care SERVICES to residents of, a long-term care facility. The
7	board shall adopt rules as necessary to implement this subsection (11).
8	SECTION 10. In Colorado Revised Statutes, 12-280-120, amend
9	(6)(b), (10), and (15)(b) introductory portion; and repeal (15)(a) as
10	follows:
11	12-280-120. Compounding - dispensing - sale of drugs and
12	devices - rules - definition. (6) (b) (I) The board shall promulgate rules
13	authorizing A prescription drug outlet located in this state to MAY
14	compound AND DISTRIBUTE drugs for office use by a practitioner or for
15	use by a hospital located in this state. The rules must limit the amount of
16	drugs a prescription drug outlet may compound and distribute to a
17	practitioner or hospital FOR VETERINARY USE pursuant to this subsection
18	(6)(b) to no more than SECTION 12-280-121, BUT THE AMOUNT OF DRUGS
19	THE PRESCRIPTION DRUG OUTLET MAY COMPOUND AND DISTRIBUTE FOR
20	VETERINARY USE MUST NOT EXCEED ten percent of the total number of
21	drug dosage units dispensed and distributed on an annual basis by the
22	outlet.
23	(II) (A) The ten percent limitation set forth in subsection (6)(b)(I)
24	of this section applies to a compounded drug for veterinary use that a
25	prescription drug outlet distributes in Colorado.
26	(B) For purposes of this subsection (6)(b)(II) AS USED IN THIS
27	SUBSECTION (6)(b), a "prescription drug outlet" includes a nonresident

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pharmacy outlet registered or licensed pursuant to this article 280 where
prescriptions are compounded and dispensed, but only if the nonresident
pharmacy outlet has provided the board with a copy of the most recent
inspection of the nonresident pharmacy outlet by the agency that regulates
pharmaceuticals in the state of residence and a copy of the most recent
inspection received from a board-approved third-party entity that inspects
pharmacy outlets, for which third-party inspection the nonresident
pharmacy outlet shall obtain and pay for on an annual basis, and the board
approves the inspection reports as satisfactorily demonstrating proof of
compliance with the board's own inspection procedure and standards.
(10) (a) Any hospital employee or agent authorized by law to
administer or dispense medications may dispense a twenty-four-hour
SEVENTY TWO HOLD supply of drugs on the specific order of a

- SEVENTY-TWO-HOUR supply of drugs on the specific order of a practitioner to a registered emergency room patient.
- (b) A HOSPITAL MAY DISPENSE A PRESCRIPTION DRUG PURSUANT TO A CHART ORDER FOR A HOSPITALIZED PATIENT FOR USE BY THE PATIENT DURING A TEMPORARY LEAVE FROM THE HOSPITAL OF LESS THAN <u>SEVENTY-TWO</u> HOURS IF THE PRESCRIPTION DRUG:
- (I) IS LABELED IN ACCORDANCE WITH SECTION 12-280-124(1) AND (2);
- (II) IS ADMINISTERED BY AN AUTHORIZED PERSON;
- (III) IS DISPENSED PURSUANT TO A CURRENT, ACTIVE ORDER; AND
- (IV) IS LIMITED TO A <u>SEVENTY-TWO-HOUR</u> SUPPLY OR, IF THE TEMPORARY LEAVE IS FOR LESS THAN TWENTY-FOUR HOURS, THE QUANTITY THE PATIENT REQUIRES DURING THE TEMPORARY LEAVE.
- (15) (a) A compounding prescription drug outlet registered pursuant to section 12-280-119 (9) may dispense and distribute

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1	compounded drugs without initiation to practitioners of to prescription
2	drug outlets under common ownership with the pharmacist who owns the
3	compounding prescription drug outlet.
4	(b) The following may distribute compounded and prepackaged
5	medications, without limitation, to pharmacies and other outlets under
6	common ownership of the entity:
7	SECTION 11. In Colorado Revised Statutes, 12-280-121, amend
8	(3), (4), and (6) as follows:
9	12-280-121. Compounding drugs for office use by a
10	veterinarian - rules - definitions. (3) A licensed veterinarian shall not
11	administer or dispense a compounded drug maintained for office stock
12	pursuant to this section or for office use pursuant to section 12-280-120
13	(6)(b)(II) SECTION 12-280-120 (6)(b) without a valid
14	veterinarian-client-patient relationship in place at the time of
15	administering the compounded drug to an animal patient or dispensing the
16	compounded drug to a client.
17	(4) To compound and distribute a controlled substance pursuant
18	to this section or section 12-280-120 (6)(b)(II) SECTION 12-280-120
19	(6)(b), a registered prescription drug outlet shall possess a valid
20	manufacturing registration from the federal drug enforcement
21	administration.
22	(6) The board may promulgate rules as necessary concerning
23	compounded veterinary pharmaceuticals pursuant to this section and
24	section 12-280-120 (6)(b)(II) SECTION 12-280-120 (6)(b).
25	SECTION 12. In Colorado Revised Statutes, 12-280-123, amend
26	(3) as follows:
27	12-280-123. Prescription required - exception - prescribing

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1	and dispensing opiate antagonists - selling nonprescription syringes
2	and needles. (3) A pharmacist may PRESCRIBE AND dispense an opiate
3	antagonist in accordance with section 12-30-110.
4	SECTION 13. In Colorado Revised Statutes, 12-280-124, amend
5	(1)(b) as follows:
6	12-280-124. Labeling - rules. (1) A prescription drug dispensed
7	pursuant to an order must be labeled as follows:
8	(b) (I) If the prescription is for an anabolic steroid, the purpose for
9	which the anabolic steroid is being prescribed must appear on the label.
10	(II) If the prescription is for any drug other than an anabolic
11	steroid The symptom or purpose for which the drug is being prescribed
12	must appear on the label, if, after being advised by the practitioner, the
13	patient or the patient's authorized representative so requests. If the
14	practitioner does not provide the symptom or purpose for which a drug is
15	being prescribed, the pharmacist may fill the prescription order without
16	contacting the practitioner, patient, or patient's representative. unless the
17	prescription is for an anabolic steroid.
18	SECTION 14. In Colorado Revised Statutes, 12-280-125, amend
19	(2)(a) introductory portion, (3)(b), and (5); and add (1)(a.5) as follows:
20	12-280-125. Substitution of prescribed drugs and biological
21	products authorized - when - conditions. (1) (a.5) (I) A PHARMACIST
22	FILLING A PRESCRIPTION ORDER FOR A SPECIFIC DRUG MAY SUBSTITUTE A
23	DRUG IN THE SAME THERAPEUTIC CLASS AS LONG AS THE PATIENT AGREES
24	TO THE SUBSTITUTION AND THE SUBSTITUTION IS MADE TO REPLACE A
25	DRUG THAT IS ON BACK ORDER, TO ENSURE FORMULARY COMPLIANCE
26	WITH THE PATIENT'S HEALTH INSURANCE PLAN, OR, IN THE CASE OF AN
27	UNINSURED PATIENT, TO LOWER THE COST TO THE PATIENT FOR THE DRUG

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1	WHILE MAINTAINING SAFETY.
2	(II) This subsection (1)(a.5) does not authorize:
3	(A) THE SUBSTITUTION OF BIOLOGICAL PRODUCTS, NARROW
4	THERAPEUTIC INDEX DRUGS, OR PSYCHOTROPIC DRUGS; OR
5	(B) A SUBSTITUTION WHEN THE PRACTITIONER HAS INDICATED, IN
6	THE MANNER DESCRIBED IN SUBSECTION (2) OF THIS SECTION, THAT THE
7	PHARMACIST SHALL NOT SUBSTITUTE A DRUG IN THE SAME THERAPEUTIC
8	CLASS AS THE DRUG PRESCRIBED.
9	
10	(2) (a) If, in the opinion of the practitioner, it is in the best interest
11	of the patient that the pharmacist not substitute an equivalent drug, A
12	DRUG IN THE SAME THERAPEUTIC CLASS, or AN interchangeable
13	biological product for the specific drug or biological product he or she
14	THE PRACTITIONER prescribed, the practitioner may convey this
15	information to the pharmacist in any of the following manners:
16	(3) (b) The pharmacist is not required to communicate a
17	substitution to institutionalized patients IN AN INPATIENT SETTING OR AN
18	OUTPATIENT INFUSION <u>CENTER.</u>
19	_
20	(5) If a prescription drug outlet does not have in stock the
21	prescribed drug or biological product and the only equivalent drug, DRUG
22	IN THE SAME THERAPEUTIC CLASS, or interchangeable biological
23	product in stock is higher priced, the pharmacist, with the consent of the
24	purchaser, may substitute the higher priced drug or interchangeable
25	biological product. This subsection (5) applies only to a prescription drug
26	outlet located in a town, as defined in section 31-1-101 (13).
27	

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1	SECTION 15. In Colorado Revised Statutes, add 12-280-125.3
2	as follows:
3	12-280-125.3. Pharmacists' authority - minor prescription
4	adaptions. (1) Except as provided in subsection (3) of this section,
5	A PHARMACIST WHO IS ACTING IN GOOD FAITH AND IS USING PROFESSIONAL
6	JUDGMENT AND EXERCISING REASONABLE CARE MAY MAKE THE
7	FOLLOWING MINOR ADAPTIONS TO AN ORDER IF THE PHARMACIST HAS THE
8	INFORMED CONSENT OF THE PATIENT FOR WHOM THE PRESCRIPTION WAS
9	PROVIDED:
10	(a) A CHANGE IN THE PRESCRIBED DOSAGE FORM OR DIRECTIONS
11	FOR USE OF THE PRESCRIPTION DRUG IF THE CHANGE ACHIEVES THE INTENT
12	OF THE PRESCRIBING PRACTITIONER;
13	(b) A CHANGE IN THE PRESCRIBED QUANTITY OF THE PRESCRIPTION
14	DRUG IF THE PRESCRIBED QUANTITY IS NOT A PACKAGE SIZE
15	COMMERCIALLY AVAILABLE FROM THE MANUFACTURER;
16	(c) AN EXTENSION OF THE QUANTITY OF A MAINTENANCE DRUG
17	FOR THE LIMITED QUANTITY NECESSARY TO ACHIEVE MEDICATION REFILL
18	SYNCHRONIZATION FOR THE PATIENT; AND
19	(d) Completion of missing information on the order if
20	THERE IS SUFFICIENT EVIDENCE TO SUPPORT THE CHANGE.
21	(2) A PHARMACIST WHO ADAPTS AN ORDER IN ACCORDANCE WITH
22	SUBSECTION (1) OF THIS SECTION SHALL DOCUMENT THE ADAPTION AND
23	THE JUSTIFICATION FOR THE CHANGE IN THE PATIENT'S PHARMACY RECORD
24	WITH THE ORIGINAL PRESCRIPTION AND SHALL NOTIFY THE PRESCRIBING
25	PRACTITIONER OF THE ADAPTION.
26	(3) A PHARMACIST SHALL NOT ADAPT AN ORDER IF THE
2.7	PRESCRIBING PRACTITIONER HAS WRITTEN "DO NOT ADAPT" ON THE

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1	PRESCRIPTION OR HAS OTHERWISE COMMUNICATED TO THE PHARMACIST
2	THAT THE PRESCRIPTION MUST NOT BE ADAPTED.
3	SECTION 16. In Colorado Revised Statutes, 12-280-126, amend
4	(1)(e); and add (1)(t) as follows:
5	12-280-126. Unprofessional conduct - grounds for discipline.
6	(1) The board may take disciplinary or other action as authorized in
7	section 12-20-404, after a hearing held in accordance with the provisions
8	of sections 12-20-403 and 12-280-127, upon proof that the licensee,
9	certificant, or registrant:
10	(e) Has a substance use disorder, as defined in section 27-81-102,
11	or Engages in the habitual or excessive use or abuse of alcohol, a
12	habit-forming drug, or a controlled substance, as defined in section
13	18-18-102 (5);
14	(t) Has failed to notify the board, in writing and within
15	THIRTY DAYS AFTER A JUDGMENT OR SETTLEMENT IS ENTERED, OF A FINAL
16	JUDGMENT BY A COURT OF COMPETENT JURISDICTION AGAINST THE
17	LICENSEE OR REGISTRANT FOR MALPRACTICE IN THE PRACTICE OF
18	PHARMACY OR A SETTLEMENT BY THE LICENSEE IN RESPONSE TO CHARGES
19	OR ALLEGATIONS OF MALPRACTICE IN THE PRACTICE OF PHARMACY AND,
20	IN THE CASE OF A JUDGMENT, HAS FAILED TO INCLUDE IN THE NOTICE THE
21	NAME OF THE COURT, THE CASE NUMBER, AND THE NAMES OF ALL PARTIES
22	TO THE ACTION;
23	SECTION 17. In Colorado Revised Statutes, 12-280-127, amend
24	(6) as follows:
25	12-280-127. Disciplinary actions. (6) The board may send a
26	letter of admonition by certified mail to a licensee, certificant, or
27	registrant under the circumstances specified in and in accordance with

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1	section 12-20-404 (4). In the case of a complaint, the board may send a
2	copy of the letter of admonition to the person making the complaint.
3	SECTION 18. In Colorado Revised Statutes, add 12-280-133.5
4	and 12-280-133.7 as follows:
5	12-280-133.5. Nonresident 503B outsourcing facility -
6	registration - requirements - denial, revocation, or suspension - rules.
7	(1) A NONRESIDENT 503B OUTSOURCING FACILITY SHALL NOT CONDUCT
8	THE BUSINESS OF DISTRIBUTING COMPOUNDED PRESCRIPTION DRUGS IN
9	THIS STATE WITHOUT FIRST REGISTERING WITH THE BOARD AS A
10	NONRESIDENT 503B OUTSOURCING FACILITY. A NONRESIDENT 503B
11	OUTSOURCING FACILITY SHALL APPLY FOR A NONRESIDENT 503B
12	OUTSOURCING FACILITY REGISTRATION ON A FORM FURNISHED BY THE
13	BOARD AND SHALL SUBMIT THE FOLLOWING TO THE BOARD WITH THE
14	APPLICATION:
15	(a) PROOF THAT THE FACILITY IS ACTIVELY REGISTERED WITH THE
16	FDA AS A 503B OUTSOURCING FACILITY AND IS ACTIVELY LICENSED,
17	PERMITTED, OR REGISTERED IN THE STATE IN WHICH IT IS A RESIDENT;
18	(b) THE LOCATION, NAMES, AND TITLES OF ALL PRINCIPAL ENTITY
19	OFFICERS AND THE NAME OF THE PHARMACIST IN CHARGE OF THE
20	OPERATIONS OF THE FACILITY;
21	(c) VERIFICATION THAT THE FACILITY COMPLIES WITH ALL LAWFUL
22	DIRECTIONS AND REQUESTS FOR INFORMATION FROM THE FDA and from
23	THE REGULATORY OR LICENSING AGENCY OF THE STATE IN WHICH IT IS
24	LICENSED, PERMITTED, OR REGISTERED, AS WELL AS WITH ALL REQUESTS
25	FOR INFORMATION MADE BY THE BOARD PURSUANT TO THIS SECTION;
26	(d) A COPY OF THE MOST RECENT INSPECTION REPORT RESULTING
27	FROM AN INSPECTION CONDUCTED BY THE FDA; AND

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1	(e) ANY OTHER INFORMATION THE BOARD DEEMS NECESSARY TO
2	CARRY OUT THE PURPOSE OF THIS SECTION.
3	(2) A nonresident 503B outsourcing facility shall:
4	(a) MAINTAIN AT ALL TIMES A VALID, UNEXPIRED LICENSE, PERMIT,
5	OR REGISTRATION TO OPERATE THE 503B OUTSOURCING FACILITY IN
6	COMPLIANCE WITH THE LAWS OF THE STATE IN WHICH IT IS A RESIDENT;
7	AND
8	(b) Comply with the requirements of the "Federal Food,
9	Drug, and Cosmetic Act", 21 U.S.C. sec. 301 et seq., as amended, or
10	THE DQSA OR WITH FDA REGULATIONS IMPLEMENTING EITHER ACT.
11	(3) THE BOARD MAY DENY, REVOKE, OR SUSPEND A NONRESIDENT
12	503B OUTSOURCING FACILITY REGISTRATION IF:
13	(a) THE FACILITY FAILS TO COMPLY WITH THIS SECTION OR WITH
14	ANY RULE PROMULGATED BY THE BOARD;
15	(b) The FDA has revoked or refused to renew the
16	NONRESIDENT 503B OUTSOURCING FACILITY'S FDA REGISTRATION FOR
17	FAILING TO COMPLY WITH THE REQUIREMENTS OF THE "FEDERAL FOOD,
18	Drug, and Cosmetic Act", 21 U.S.C. sec. 301 et seq., as amended,
19	THE DQSA, OR FDA REGULATIONS IMPLEMENTING EITHER ACT OR THE
20	FACILITY'S FDA REGISTRATION HAS EXPIRED OR IS NO LONGER ACTIVE; OR
21	(c) The state in which the nonresident $503B$ outsourcing
22	FACILITY RESIDES HAS REVOKED OR REFUSED TO RENEW THE FACILITY'S
23	LICENSE, PERMIT, OR REGISTRATION FOR FAILING TO COMPLY WITH THE
24	LAWS OF THAT STATE OR THE FACILITY'S LICENSE, PERMIT, OR
25	REGISTRATION IN ANOTHER STATE HAS EXPIRED OR IS NO LONGER ACTIVE.
26	(4) THE BOARD MAY ADOPT RULES AS NECESSARY TO IMPLEMENT
27	THIS SECTION

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1	12-280-133.7. Third-party logistics providers - registration -
2	denial, revocation, or suspension - rules. (1) A THIRD-PARTY LOGISTICS
3	PROVIDER SHALL NOT CONDUCT BUSINESS IN THIS STATE WITHOUT FIRST
4	REGISTERING WITH THE BOARD AS A THIRD-PARTY LOGISTICS PROVIDER.
5	A THIRD-PARTY LOGISTICS PROVIDER SHALL APPLY FOR A REGISTRATION
6	ON A FORM FURNISHED BY THE BOARD AND SHALL SUBMIT THE
7	INFORMATION REQUIRED PURSUANT TO RULES ADOPTED BY THE BOARD.
8	THE BOARD SHALL SPECIFY, BY RULE, THE INFORMATION A THIRD-PARTY
9	LOGISTICS PROVIDER MUST SUBMIT WITH ITS APPLICATION FOR A
10	REGISTRATION.
11	(2) A THIRD-PARTY LOGISTICS PROVIDER SHALL COMPLY WITH ALL
12	LAWFUL DIRECTIONS AND REQUESTS FOR INFORMATION FROM THE FDA,
13	THE REGULATORY OR LICENSING AGENCY OF THE STATE IN WHICH IT IS
14	LICENSED, PERMITTED, OR REGISTERED, AND THE BOARD.
15	(3) THE BOARD MAY DENY, REVOKE, OR SUSPEND A THIRD-PARTY
16	LOGISTICS PROVIDER REGISTRATION IF:
17	(a) THE THIRD-PARTY LOGISTICS PROVIDER FAILS TO COMPLY WITH
18	THIS SECTION OR WITH ANY RULE PROMULGATED BY THE BOARD;
19	(b) The FDA has revoked or refused to renew the
20	THIRD-PARTY LOGISTICS PROVIDER'S FDA REGISTRATION FOR FAILING TO
21	COMPLY WITH THE REQUIREMENTS OF THE "FEDERAL FOOD, DRUG, AND
22	COSMETIC ACT", 21 U.S.C. SEC. 301 ET SEQ., AS AMENDED, OR THE DQSA
23	OR WITH FDA REGULATIONS IMPLEMENTING EITHER ACT; OR
24	(c) THE STATE IN WHICH THE THIRD-PARTY LOGISTICS PROVIDER
25	RESIDES HAS REVOKED OR REFUSED TO RENEW THE PROVIDER'S LICENSE,
26	PERMIT, OR REGISTRATION FOR FAILING TO COMPLY WITH THE LAWS OF
2.7	THAT STATE

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1	(4) THE BOARD MAY ADOPT RULES AS NECESSARY TO IMPLEMENT
2	THIS SECTION.
3	SECTION 19. In Colorado Revised Statutes, 12-280-134, add
4	(10) as follows:
5	12-280-134. <u>Records.</u> (10) The board shall <u>allow</u>
6	ELECTRONIC STORAGE OF RECORDS REQUIRED TO BE MAINTAINED
7	PURSUANT TO THIS SECTION.
8	SECTION 20. In Colorado Revised Statutes, add 12-280-137 and
9	12-280-138 as follows:
10	12-280-137. Investigations of suspicious drugs. ALL
11	PRESCRIPTION DRUG OUTLETS, MANUFACTURERS, REPACKAGERS, AND
12	WHOLESALERS SHALL INVESTIGATE ANY SUSPECT PRODUCT, AS DEFINED
13	IN THE DQSA AND ANY FEDERAL REGULATIONS IMPLEMENTING THE
14	DQSA, AND SHALL USE DOCUMENTATION AND REPORTING PROCEDURES
15	RELATING TO THE INVESTIGATION IN ACCORDANCE WITH THE DQSA AND
16	ANY FEDERAL REGULATIONS IMPLEMENTING THE DQSA.
17	12-280-138. Patient counseling - pharmacists required to
18	perform - patient may decline - rules. (1) (a) EXCEPT IN THE
19	CIRCUMSTANCES DESCRIBED IN SUBSECTION (2) OF THIS SECTION, A
20	PHARMACIST SHALL PROVIDE PATIENT COUNSELING ON NEW MEDICATION
21	THERAPY AND, BASED ON THE PHARMACIST'S PROFESSIONAL JUDGMENT
22	AND DUE DILIGENCE, MAY PROVIDE PATIENT COUNSELING FOR ANY OTHER
23	PRESCRIPTION. IF THE PHARMACIST IS UNABLE TO PROVIDE PATIENT
24	COUNSELING ORALLY DUE TO LANGUAGE BARRIERS, THE PHARMACIST MAY
25	USE ALTERNATE MEANS TO PROVIDE THE PATIENT COUNSELING.
26	(b) (I) EXCEPT AS PROVIDED IN SUBSECTION (1)(b)(II) OF THIS
2.7	SECTION ALL IN-STATE PHARMACIES MUST ENSURE THAT THEIR

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1	PHARMACISTS PROVIDE PATIENT COUNSELING IN ACCORDANCE WITH THIS
2	SECTION.
3	(II) This subsection (1)(b) does not apply to an other
4	OUTLET.
5	(2) A PATIENT MAY DECLINE PATIENT COUNSELING OFFERED BY A
6	PHARMACIST. A PHARMACIST SHALL DOCUMENT, IN THE FORM AND
7	MANNER SPECIFIED IN BOARD RULES, WHEN A PATIENT DECLINES PATIENT
8	COUNSELING.
9	(3) THE BOARD SHALL ADOPT RULES SPECIFYING:
10	(a) THE ALTERNATE MEANS BY WHICH PHARMACISTS MAY PROVIDE
11	PATIENT COUNSELING WHEN LANGUAGE BARRIERS PRECLUDE PROVIDING
12	PATIENT COUNSELING ORALLY; AND
13	(b) The form and manner for pharmacists to document
14	WHEN A PATIENT DECLINES COUNSELING, WHICH RULES MUST SPECIFY A
15	DOCUMENTATION PROCESS THAT IS SIMPLE AND ALLOWS THE
16	DOCUMENTATION TO BE COMPLETED ELECTRONICALLY.
17	(4) This section does not apply to pharmacists who
18	DISPENSE PRESCRIPTION DRUGS TO PERSONS IN THE CUSTODY OF THE
19	DEPARTMENT OF CORRECTIONS.
20	SECTION 21. In Colorado Revised Statutes, amend 12-280-201
21	as follows:
22	12-280-201. Legislative declaration. (1) The general assembly
23	finds, determines, and declares that the creation of a pharmacy peer health
24	assistance diversion program for those persons subject to the jurisdiction
25	of the board will serve to safeguard the life, health, property, and public
26	welfare of the people of this state. A pharmacy peer health assistance
27	diversion program will help practitioners experiencing impaired practice

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1 due to psychiatric, psychological, or emotional problems; excessive 2 alcohol or drug use; or alcohol or substance use disorders. The general 3 assembly further declares that a pharmacy peer health assistance diversion 4 program will protect the privacy and welfare of those persons who 5 provide services and at the same time assist the board in carrying out its 6 duties and responsibilities to ensure that only qualified persons are 7 allowed to engage in providing those services that are under the 8 jurisdiction of the board. 9 (2) It is the intent of the general assembly that the pharmacy peer 10 health assistance diversion program and its related procedures be utilized 11 by the board in conjunction with, or as an alternative to, the use of 12 disciplinary proceedings by the board, which proceedings are by their 13 nature time-consuming and costly to the people of this state. The 14 pharmacy peer health assistance diversion program is hereby established 15 to alleviate the need for disciplinary proceedings, while at the same time 16 providing safeguards that protect the public health, safety, and welfare. 17 The general assembly further declares that it intends that the board will 18 act to implement the provisions of this article 280. 19 SECTION 22. In Colorado Revised Statutes, 12-280-203, amend 20 (2)(b) introductory portion as follows: 21 12-280-203. Pharmacy peer health assistance fund - rules. 22 (2) (b) The board shall select one or more peer health assistance 23 organizations as designated providers. To be eligible for designation by 24 the board, a peer health assistance diversion program shall: 25 **SECTION 23.** In Colorado Revised Statutes, 12-280-204, amend 26 (1), (2)(b), and (3) as follows:

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12-280-204. Eligibility - participants. (1) Any licensee may

apply to the board for participation in a qualified peer health assistance diversion program.

- (2) In order to be eligible for participation, a licensee shall:
- (b) After a full explanation of the operation and requirements of the peer health assistance diversion program, agree to voluntarily participate in the program and agree in writing to participate in the program of the peer health assistance organization designated by the board.
- (3) Notwithstanding the provisions of this section, the board may summarily suspend the license of any licensee who is referred to a peer health assistance diversion program by the board and who fails to attend or to complete the program. If the board summarily suspends the license, the board shall schedule a hearing on the suspension, which shall be conducted in accordance with section 24-4-105.
- **SECTION 24.** In Colorado Revised Statutes, **amend** 12-280-205 as follows:

12-280-205. Liability. Nothing in this part 2 creates any liability of the board, members of the board, or the state of Colorado for the actions of the board in making awards to pharmacy peer health assistance organizations or in designating licensees to participate in the programs of pharmacy peer health assistance organizations. No civil action may be brought or maintained against the board, its members, or the state for an injury alleged to have been the result of an act or omission of a licensee participating in or referred to a state-funded program provided by a pharmacy peer health assistance organization. However, the state remains liable under the "Colorado Governmental Immunity Act", article 10 of title 24, if an injury alleged to have been the result of an act or omission

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1	of a licensee participating in or referred to a state-funded peer health
2	assistance diversion program occurred while the licensee was performing
3	duties as an employee of the state.
4	SECTION 25. In Colorado Revised Statutes, 12-280-301, amend
5	(3) and (7); repeal (1), (4), (6), and (8); and add (7.5) as follows:
6	12-280-301. Definitions. As used in this part 3, unless the context
7	otherwise requires:
8	(1) "Authentication" means the process of affirmatively verifying
9	that each transaction listed on a pedigree has occurred before any
10	wholesale distribution of a prescription drug occurs.
11	(3) "Designated representative" means a person authorized by a
12	licensed REGISTERED wholesaler to act as a representative for the
13	wholesaler.
14	(4) "Drop shipment" means the sale by a manufacturer of the
15	manufacturer's prescription drug, that manufacturer's third-party logistics
16	provider, or that manufacturer's exclusive distributor to a wholesaler
17	whereby the wholesaler takes title to, but not possession of, the
18	prescription drug and the wholesaler invoices the board-registered outlet
19	or practitioner authorized by law to prescribe the prescription drug and
20	the board-registered outlet or the practitioner authorized by law to
21	prescribe the prescription drug receives delivery of the prescription drug
22	directly from the manufacturer of the drug, that manufacturer's third-party
23	logistics provider, or that manufacturer's exclusive distributor.
24	(6) "Normal distribution channel" means a chain of custody for a
25	prescription drug that goes directly or by drop shipment from a
26	manufacturer of the prescription drug to:
27	(a) (I) A wholesaler to a pharmacy to a patient or other designated

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I	persons authorized by law to dispense or administer a prescription drug
2	to a patient;
3	(II) A wholesaler to a chain pharmacy warehouse to their
4	intracompany pharmacies to a patient;
5	(HI) A chain pharmacy warehouse to its intracompany pharmacies
6	to a patient; or
7	(IV) A pharmacy to a patient; or
8	(b) A manufacturer's colicensed partner, third-party logistics
9	provider, or exclusive distributor to a wholesaler to a pharmacy to a
10	patient or other designated persons authorized by law to dispense or
11	administer the prescription drug to a patient; or
12	(c) A manufacturer's colicensed partner, or that manufacturer's
13	third-party logistics provider, or exclusive distributor to a wholesaler to
14	a chain pharmacy warehouse to that chain pharmacy warehouse's
15	intracompany pharmacy to a patient or other designated persons
16	authorized by law to dispense or administer the prescription drug to a
17	patient; or
18	(d) A wholesaler to a pharmacy buying cooperative warehouse to
19	a pharmacy that is a member or member owner of the cooperative to a
20	patient or other designated person authorized by law to dispense or
21	administer the prescription drug to a patient.
22	(7) "Pedigree" means a document or electronic file containing
23	information that records each distribution of any given prescription drug
24	that leaves the normal distribution channel IN ACCORDANCE WITH THE
25	DQSA AND ANY FEDERAL REGULATIONS IMPLEMENTING THE DQSA.
26	(7.5) "Prescription drug" has the same meaning as set forth
27	IN SECTION 12-280-103 (42); EXCEPT THAT "PRESCRIPTION DRUG"

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1	EXCLUDES ANY DRUG SPECIFICALLY EXEMPTED UNDER THE DQSA AND
2	ANY FEDERAL REGULATIONS IMPLEMENTING THE DQSA.
3	(8) "Third-party logistics provider" means anyone who contracts
4	with a manufacturer to provide or coordinate warehousing, distribution,
5	or other services on behalf of a manufacturer but does not take title to a
6	prescription drug or have general responsibility to direct the prescription
7	drug's sale or disposition.
8	SECTION 26. In Colorado Revised Statutes, repeal 12-280-302.
9	SECTION 27. In Colorado Revised Statutes, 12-280-303, amend
10	(1), (2)(b), (2)(c), (3)(a) introductory portion, (3)(a)(VI), (3)(b), (4), (5)
11	introductory portion, (5)(f), and (6) as follows:
12	12-280-303. Wholesaler registration requirements - rules.
13	(1) (a) A wholesaler that resides in this state must be licensed by
14	REGISTER WITH the board BEFORE ENGAGING IN THE WHOLESALE
15	DISTRIBUTION OF PRESCRIPTION DRUGS IN THIS STATE. A wholesaler that
16	does not reside in this state must be licensed REGISTERED in this state
17	prior to engaging in the wholesale distribution of prescription drugs in
18	this state. The board shall exempt a manufacturer and that manufacturer's
19	third-party logistics providers to the extent involving that manufacturer's
20	drugs under contract from any licensing qualifications and other
21	requirements, including the requirements in subsections (3)(a)(VI) and
22	(3)(a)(VII) of this section, subsections (4) to (6) of this section, and
23	section 12-280-304, to the extent the requirements are not required by
24	federal law or regulation, unless the particular requirements are deemed
25	necessary and appropriate following rule-making by the board.
26	(b) A manufacturer's exclusive distributor and pharmacy buying
27	cooperative warehouse must be licensed by the board as a wholesaler

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1	pursuant to this part 3. A third-party logistics provider must be licensed
2	by the board as a wholesale distributor pursuant to this part 3.
3	(2) (b) An applicant for a license REGISTRATION shall pay any fee
4	required by the accreditation body or the board and comply with any rules
5	promulgated by the board.
6	(c) The board shall not issue or renew a license REGISTRATION to
7	a wholesaler who does not comply with this part 3.
8	(3) (a) An applicant for a wholesaler license REGISTRATION shall
9	provide to the board the following information, and any other information
10	deemed appropriate by the board, on a form provided by the board:
11	(VI) A list of the licenses, and REGISTRATIONS, OR permits issued
12	to the applicant by any other state that authorizes the applicant to
13	purchase or possess prescription drugs; and
14	(b) A licensee REGISTRANT shall complete and return a form
15	approved by the board at each renewal period. The board may suspend or
16	revoke the license REGISTRATION of a wholesaler if the board determines
17	that the wholesaler no longer qualifies for a license REGISTRATION.
18	(4) Prior to issuing a wholesaler license REGISTRATION to an
19	applicant, the board, the regulatory oversight body from another state, or
20	a board-approved accreditation body may conduct a physical inspection
21	of the facility at the business address provided by the applicant. Nothing
22	in this subsection (4) shall preclude PRECLUDES the board from inspecting
23	a wholesaler.
24	(5) The designated representative of an applicant for a wholesaler
25	license REGISTRATION shall:
26	(f) Serve in the capacity of a designated representative for only
27	one applicant or wholesaler at a time, except where more than one

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licensed REGISTERED wholesaler is co-located in the same facility and the wholesalers are members of an affiliated group as defined by section 1504 of the federal "Internal Revenue Code of 1986", as amended;

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

SECTION 28. In Colorado Revised Statutes, 12-280-305, **repeal** (1) and (4) as follows:

12-280-305. Restrictions on transactions. (1) A wholesaler shall accept prescription drug returns or exchanges from a pharmacy or a chain pharmacy warehouse pursuant to the terms and conditions of the agreement between the wholesale distributor and the pharmacy or chain pharmacy warehouse. The receiving wholesale distributor shall distribute returns or exchanges of expired, damaged, recalled, or otherwise unsaleable pharmaceutical product only to the original manufacturer or to a third-party returns processor. The returns or exchanges of prescription drugs, saleable or unsaleable, including any redistribution by a receiving wholesaler, are not subject to the pedigree requirements of section 12-280-306 so long as the drugs are exempt from the pedigree requirement of the federal food and drug administration's currently applicable "Prescription Drug Marketing Act of 1987" guidance. The pharmacies, chain pharmacy warehouses, and pharmacy buying cooperative warehouses are responsible for ensuring that the prescription drugs returned are what they purport to be and shall ensure that those returned prescription drugs were stored under proper conditions since their receipt. Wholesalers are responsible for policing their returns process and helping to ensure that their operations are secure and do not permit the entry of adulterated or counterfeit product. A pharmacist shall

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1	not knowingly return a medication that is not what it purports to be.
2	(4) A manufacturer or wholesaler shall not accept payment for, or
3	allow the use of, a person's or entity's credit to establish an account for the
4	purchase of prescription drugs from any person other than the owner of
5	record, the chief executive officer, or the chief financial officer listed on
6	the license of a person or entity legally authorized to receive prescription
7	drugs. An account established for the purchase of prescription drugs must
8	bear the name of the licensee. This subsection (4) does not apply to
9	standard ordering and purchasing business practices between a chain
10	pharmacy warehouse, a wholesaler, and a manufacturer.
11	SECTION 29. In Colorado Revised Statutes, repeal and reenact,
12	with amendments, 12-280-306 as follows:
13	12-280-306. Records - pedigree - compliance with DQSA. A
14	WHOLESALER SHALL ESTABLISH AND MAINTAIN INVENTORIES AND
15	RECORDS OF ALL TRANSACTIONS REGARDING THE RECEIPT AND
16	DISTRIBUTION OR OTHER DISPOSITION OF PRESCRIPTION DRUGS. THE
17	RECORDS MUST INCLUDE THE PEDIGREE FOR EACH WHOLESALE
18	DISTRIBUTION OF A PRESCRIPTION DRUG AS REQUIRED PURSUANT TO THE
19	DQSA AND ANY FEDERAL REGULATIONS IMPLEMENTING THE DQSA.
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21	SECTION 30. In Colorado Revised Statutes, 12-280-403, amend
22	(2)(b) introductory portion as follows:
23	12-280-403. Prescription drug use monitoring program -
24	registration required. (2) (b) When registering with the program or at
25	any time thereafter, a practitioner or pharmacist may authorize up to three
26	designees to access the program under section 12-280-404 (3)(b) OR

(3)(d) or (3)(f), as applicable, on behalf of the practitioner, or AND A

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1	pharmacist MAY AUTHORIZE UP TO SIX DESIGNEES TO ACCESS THE
2	PROGRAM UNDER SECTION 12-280-404 (3)(f), if:
3	SECTION 31. In Colorado Revised Statutes, 12-30-110, amend
4	(1)(a) introductory portion, (2)(a), (3) introductory portion, (4)(a), and
5	(7)(h) as follows:
6	12-30-110. Prescribing or dispensing opiate antagonists -
7	authorized recipients - definitions. (1) (a) A prescriber may prescribe
8	or dispense, directly or in accordance with standing orders and protocols,
9	and a pharmacist may dispense, pursuant to an order or standing orders
10	and protocols, an opiate antagonist to:
11	(2) (a) A prescriber who prescribes or dispenses or a pharmacist
12	who dispenses, an opiate antagonist pursuant to this section is strongly
13	encouraged to educate persons receiving the opiate antagonist on the use
14	of an opiate antagonist for overdose, including instruction concerning risk
15	factors for overdose, recognizing an overdose, calling emergency medical
16	services, rescue breathing, and administering an opiate antagonist.
17	(3) Neither A prescriber described in subsection (7)(h)(I)
18	SUBSECTION (7)(h) of this section nor a pharmacist engages DOES NOT
19	ENGAGE in unprofessional conduct OR IS NOT SUBJECT TO DISCIPLINE
20	pursuant to section 12-240-121, <i>12-255-120</i> , or 12-280-126, respectively,
21	and a prescriber described in subsection (7)(h)(II) of this section does not
22	engage in conduct that is grounds for discipline pursuant to section
23	12-255-120 AS APPLICABLE, if the prescriber issues standing orders and
24	protocols regarding opiate antagonists or prescribes or dispenses, or the
25	pharmacist dispenses, pursuant to an order or standing orders and
26	protocols, an opiate antagonist in a good-faith effort to assist:
27	(4) (a) A prescriber or pharmacist who prescribes or dispenses an

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1 opiate antagonist in accordance with this section is not subject to civil 2 liability or criminal prosecution, as specified in sections 13-21-108.7 (4) 3 and 18-1-712 (3), respectively. 4 (7) As used in this section: 5 (h) "Prescriber" means: 6 (I) A physician or physician assistant licensed pursuant to article 7 240 of this title 12; or 8 (II) An advanced practice registered nurse, as defined in section 9 12-255-104 (1), with prescriptive authority pursuant to section 10 12-255-112; OR 11 (III) A PHARMACIST. 12 SECTION 32. In Colorado Revised Statutes, add with amended 13 and relocated provisions 10-1-125.3 as follows: 14 Reporting of malpractice claims against 10-1-125.3. 15 pharmacists and pharmacies. (1) [Formerly 12-280-111 (1)] Each 16 insurance company licensed to do business in this state and engaged in 17 the writing of malpractice insurance for licensed pharmacists and 18 REGISTERED pharmacies, and each pharmacist or pharmacy that 19 self-insures, shall send to the STATE board OF PHARMACY, in the form 20 prescribed by the board COMMISSIONER IN COLLABORATION WITH THE 21 STATE BOARD OF PHARMACY, information relating to each malpractice 22 claim against a licensed pharmacist OR REGISTERED PHARMACY that is 23 settled or in which judgment is rendered against the insured. 24 (2) [Formerly 12-280-111 (2)] The insurance company or 25 self-insured pharmacist or pharmacy shall provide information relating to 26 each malpractice claim as is deemed THAT THE STATE BOARD OF

PHARMACY DEEMS necessary by the board to conduct a further

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1	investigation and hearing.
2	SECTION 33. In Colorado Revised Statutes, amend 13-64-303
3	as follows:
4	13-64-303. Judgments and settlements - reported - penalties.
5	Any final judgment, settlement, or arbitration award against any health
6	care professional or health care institution for medical malpractice shall
7	be reported within fourteen days by the professional's or institution's
8	medical malpractice insurance carrier in accordance with section
9	10-1-120, 10-1-120.5, 10-1-121, 10-1-124, 10-1-125, <i>10-1-125.3</i> , or
10	10-1-125.7, or by the professional or institution if there is no commercial
11	medical malpractice insurance coverage to the licensing agency of the
12	health care professional or health care institution for review,
13	investigation, and, where appropriate, disciplinary or other action. Any
14	health care professional, health care institution, or insurance carrier than
15	knowingly fails to report as required by this section shall be subject to a
16	civil penalty of not more than two thousand five hundred dollars. Such
17	penalty shall be determined and collected by the district court in the city
18	and county of Denver. All penalties collected pursuant to this section
19	shall be transmitted to the state treasurer, who shall credit the same to the
20	general fund.
21	SECTION 34. In Colorado Revised Statutes, 25-51-104, amend
22	(1)(c) and (1)(e) as follows:
23	25-51-104. Payment and financial resolution. (1) If a patient
24	accepts an offer of compensation made pursuant to section 25-51-103 (5)
25	and receives the compensation, the payment of compensation to the
26	patient is not a payment resulting from:
27	(c) A malpractice claim settled or in which judgment is rendered

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1 against a professional for purposes of reporting by malpractice insurance 2 companies under section 10-1-120, 10-1-120.5, 10-1-121, 10-1-124, 3 10-1-125, *10-1-125.3*, 10-1-125.5, or 10-1-125.7; 4 (e) A judgment, administrative action, settlement, or arbitration 5 award involving malpractice under section 12-200-106 (5), 12-210-105 6 (5), 12-215-115 (1)(i), 12-220-201 (1)(q) or (1)(r), 12-235-111 (1)(i), 7 12-240-125 (4)(b)(III), 12-245-226 (7), 12-250-116, 12-255-119 8 (3)(b)(II), 12-255-120 (1)(dd), 12-275-120 (1)(p) or (1)(v), 12-275-129, 9 12-280-111 (1) **12-280-126 (1)(t)**, 12-285-120 (1)(o), 12-285-127 (1)(a), 10 12-285-211 (1)(k), 12-285-216 (1)(a), or 12-290-113 (2)(b)(III). 11 **SECTION 35.** In Colorado Revised Statutes, 25.5-2.5-204, 12 **amend** (3)(d) and (4)(a) as follows: 13 25.5-2.5-204. Eligible prescription drugs - eligible Canadian 14 suppliers - eligible importers - distribution requirements. (3) The 15 following entities are eligible importers and may obtain imported 16 prescription drugs: 17 (d) A licensed Colorado pharmacist or REGISTERED wholesaler 18 approved by the state department. 19 (4) (a) The state department shall designate an office or division 20 that must be a licensed pharmaceutical REGISTERED wholesaler or that 21 shall contract with a licensed pharmaceutical wholesaler licensed 22 REGISTERED pursuant to part 3 of article 280 of title 12. 23 **SECTION 36.** Effective date. This act takes effect September 1, 24 2021; except that section 4 of this act takes effect upon passage. 25 **SECTION 37. Safety clause.** The general assembly hereby finds, 26 determines, and declares that this act is necessary for the immediate 27 preservation of the public peace, health, or safety.

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