First Regular Session
Seventy-third General Assembly
STATE OF COLORADO

INTRODUCED

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

(None),

Senate Committees
Health & Human Services

House Committees

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

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;

- **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.

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

SECTION 1. In Colorado Revised Statutes, 12-280-104, **amend** (3) as follows:

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

~~of professions and occupations in accordance with parts 1 to 3 of article 280 of title 12;~~

(31) (a) The following agencies, functions, or both, are scheduled for repeal on September 1, 2030:

(VI) THE STATE BOARD OF PHARMACY AND THE REGULATION OF THE PRACTICE OF PHARMACY IN ACCORDANCE WITH PARTS 1 TO 3, 5, AND 6 OF ARTICLE 280 OF TITLE 12.

SECTION 3. In Colorado Revised Statutes, 12-280-103, **amend** (10), (27), (32)(a) introductory portion, (38.5)(a)(V), (38.5)(a)(VI), (39)(a), (39)(d), (40), (43), (48), (54)(b)(III), (54)(b)(XI), and (55); **repeal** (3), (4), (9), (34), (37), (54)(b)(IX), and (54)(b)(XII); and **add** (5.5), (15.5), (28.5), (35.5), (38.5)(a)(VII), (38.5)(a)(VIII), (39)(f), (39)(g), (39)(h), (39)(i), (39)(j), (46.5), (52.5), and (54)(b)(XVI) as follows:

12-280-103. Definitions - rules. As used in this article 280, unless the context otherwise requires or the term is otherwise defined in another part of this article 280:

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

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

~~(a) The wholesaler has a written agreement currently in effect~~

~~with the manufacturer evidencing the ongoing relationship; and~~

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

(5.5) "BIOSIMILAR", IN REFERENCE TO A BIOLOGICAL PRODUCT, MEANS "BIOSIMILAR" OR "BIOSIMILARITY", AS DEFINED IN 42 U.S.C. SEC. 262 (i)(2).

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

(10) (a) (I) "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or device:

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

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

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

(b) "COMPOUNDING" DOES NOT INCLUDE:

(I) RECONSTITUTING A CONVENTIONALLY MANUFACTURED DRUG IN ACCORDANCE WITH THE DIRECTIONS IN THE MANUFACTURER'S APPROVED LABELING;

(II) REPACKAGING OR TABLET SPLITTING OF A CONVENTIONALLY MANUFACTURED DRUG; OR

(III) ADDING STANDARD FLAVORING TO ORAL LIQUID DRUGS.

(15.5) "DQSA" MEANS THE FEDERAL "DRUG QUALITY AND SECURITY ACT", PUB.L. 113-54, AS AMENDED.

(27) ~~"Manufacturer's exclusive distributor" means a person who contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of a manufacturer and who takes 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 FACILITY THAT OPERATES A LICENSED SUBSTANCE USE DISORDER TREATMENT PROGRAM, 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 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 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~~

(VI) ~~Other activities as authorized and defined by the board by rule~~ GATHERING, DOCUMENTING, AND MAINTAINING PROPER CLINICAL AND NONCLINICAL INFORMATION FROM PATIENTS;

(VII) REPLENISHING AUTOMATED DISPENSING DEVICES WITHOUT THE NEED FOR PHARMACIST VERIFICATION AS LONG AS THE PHARMACY TECHNICIAN USES BAR CODE TECHNOLOGY THAT CHECKS THE ACCURACY OF THE MEDICATION OR A SECOND PHARMACY TECHNICIAN PERFORMS THE VERIFICATION; AND

(VIII) OTHER ACTIVITIES AS AUTHORIZED AND DEFINED BY THE BOARD BY RULE.

(39) "Practice of pharmacy" means:

(a) The interpretation, evaluation, implementation, and dispensing of orders; participation in drug and device selection, drug administration, drug regimen reviews, and drug or drug-related research; THE provision of patient counseling; and the provision of those acts or services

necessary to provide ~~pharmaceutical~~ PHARMACIST care SERVICES in all areas of patient care;

(d) The dispensing of chronic maintenance drugs pursuant to section 12-280-125.5 and board rules adopted in accordance with that section; ~~and~~

(f) PROVIDING CARE TO PATIENTS PURSUANT TO A COLLABORATIVE PHARMACY PRACTICE AGREEMENT AS DEFINED IN SECTION 12-280-601;

(g) EXERCISING INDEPENDENT PRESCRIPTIVE AUTHORITY:

(I) AS AUTHORIZED PURSUANT TO SECTION 25.5-5-322, ONLY WITH REGARD TO OVER-THE-COUNTER MEDICATIONS PRESCRIBED TO RECIPIENTS UNDER THE "COLORADO MEDICAL ASSISTANCE ACT", ARTICLES 4 TO 6 OF TITLE 25.5;

(II) IN ACCORDANCE WITH A COLLABORATIVE PHARMACY PRACTICE AGREEMENT AS DEFINED IN SECTION 12-280-601 (1)(b);

(III) AS AUTHORIZED PURSUANT TO SECTIONS 12-30-110 AND 12-280-123 (3) REGARDING OPIATE ANTAGONISTS; OR

(IV) FOR DRUGS, DRUG CATEGORIES, OR DEVICES THAT ARE PRESCRIBED IN ACCORDANCE WITH THE PRODUCT'S FDA-APPROVED LABELING AND THAT ARE LIMITED TO CONDITIONS THAT:

(A) DO NOT REQUIRE A NEW DIAGNOSIS;

(B) ARE MINOR AND GENERALLY SELF-LIMITING; OR

(C) HAVE A TEST THAT IS USED TO GUIDE DIAGNOSIS OR CLINICAL DECISION-MAKING AND IS WAIVED UNDER THE FEDERAL "CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988", PUB.L. 100-578, AS AMENDED;

(h) ORDERING AND EVALUATING LABORATORY TESTS AS RELATED TO MEDICATION THERAPY;

(i) PERFORMING LIMITED PHYSICAL ASSESSMENTS COMMENSURATE WITH EDUCATION AND TRAINING; AND

(j) PERFORMING OTHER TASKS DELEGATED BY A LICENSED PHYSICIAN.

(40) "Practitioner" means a person authorized by law to prescribe any drug or device, acting within the scope of the authority, including a pharmacist who is participating within the parameters of a statewide drug therapy protocol pursuant to a collaborative pharmacy practice agreement as defined in section 12-280-601 (1)(b), ~~or~~ prescribing over-the-counter medications pursuant to section 25.5-5-322, OR PRESCRIBING AN OPIATE ANTAGONIST PURSUANT TO SECTIONS 12-30-110 AND 12-280-123 (3).

(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;

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

SECTION 4. In Colorado Revised Statutes, 12-280-105, **amend** (1)(a), (1)(b), and (1)(c)(II) as follows:

12-280-105. Membership of board - removal - compensation - meetings - repeal. (1) (a) (I) The board is composed of five licensed pharmacists, each having at least five years' experience in this state and actively engaged in the practice of pharmacy in this state, and two nonpharmacists who have no financial interest in the practice of pharmacy.

(II) OF THE LICENSED PHARMACIST MEMBERS OF THE BOARD, ONE

MUST BE ENGAGED IN PRACTICE IN A HOSPITAL SETTING, ONE MUST BE ENGAGED IN PRACTICE IN A CHAIN PHARMACY, AND ONE MUST BE ENGAGED IN PRACTICE IN AN INDEPENDENT PHARMACY.

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

(II) (A) FOR THE LICENSED PHARMACIST MEMBERS OF THE BOARD WHOSE TERMS EXPIRE ON JULY 1, 2021, AND JULY 1, 2022, THE GOVERNOR SHALL APPOINT LICENSED PHARMACIST MEMBERS THAT SATISFY THE REQUIREMENTS OF SUBSECTION (1)(a)(II) OF THIS SECTION.

(B) THIS SUBSECTION (1)(b)(II) IS REPEALED, EFFECTIVE DECEMBER 31, 2022.

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

(II) The type of practice of the appointee so that various types of practices are represented on the board AND SO THAT THE LICENSED PHARMACIST MEMBERS OF THE BOARD SATISFY THE REQUIREMENTS OF SUBSECTION (1)(a)(II) OF THIS SECTION.

SECTION 5. In Colorado Revised Statutes, 12-280-106, **amend** (1)(a)(I)(B) and (2)(c) as follows:

12-280-106. Veterinary pharmaceutical advisory committee - creation - appointments - rules - repeal. (1) (a) (I) There is created in the department the veterinary pharmaceutical advisory committee comprised of three members, each appointed by the state veterinarian who serves under the commissioner of agriculture pursuant to section 35-50-104 as follows:

(B) One member who is either a ~~licensed pharmaceutical~~ wholesaler REGISTERED PURSUANT TO PART 3 OF THIS ARTICLE 280

engaged in the distribution of animal drugs, having at least five years' experience in this state, in good standing, and actively engaged in the practice of wholesale pharmacy or a licensed veterinarian, having at least five years' experience in this state, in good standing, and actively engaged in the practice of veterinary medicine, but who is not both a ~~pharmaceutical~~ wholesaler and a veterinarian; and

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

SECTION 6. In Colorado Revised Statutes, 12-280-108, **amend** (1)(a) and (1)(j); and **add** (1)(k) as follows:

12-280-108. Powers and duties - rules. (1) The board shall:

(a) (I) Inspect, or direct inspectors who are licensed pharmacists to inspect, all outlets and investigate violations of this article 280.

(II) THE BOARD'S AUTHORITY UNDER THIS SUBSECTION (1)(a) TO INSPECT ALL OUTLETS INCLUDES THE AUTHORITY, AFTER CONDUCTING A RISK-BASED ASSESSMENT, AS DEFINED BY THE BOARD BY RULE, TO INSPECT AN OUT-OF-STATE PHARMACY, A NONRESIDENT 503B OUTSOURCING FACILITY, OR AN OUT-OF-STATE WHOLESALER.

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

(k) SEND A QUARTERLY ELECTRONIC NEWSLETTER TO ALL LICENSEES BY E-MAIL THAT DETAILS CHANGES IN FEDERAL AND STATE LAW THAT AFFECT OR ARE PERTINENT TO THE PRACTICE OF PHARMACY.

SECTION 7. In Colorado Revised Statutes, **amend** 12-280-111 as follows:

12-280-111. Malpractice claims information - not public - exception. ~~(1) Each insurance company licensed to do business in this state and engaged in the writing of malpractice insurance for licensed pharmacists and pharmacies, and each pharmacist or pharmacy that self-insures, shall send to the board, in the form prescribed by the board, information relating to each malpractice claim against a licensed pharmacist that is settled or in which judgment is rendered against the insured.~~

~~(2) The insurance company or self-insured pharmacist or pharmacy shall provide information relating to each malpractice claim as is deemed necessary by the board to conduct a further investigation and hearing.~~

~~(3)~~ Information relating to each malpractice claim provided by insurance companies or self-insured pharmacists or pharmacies PURSUANT TO SECTION 10-1-125.3 is exempt from the provisions of any law requiring that the proceedings of the board be conducted publicly or that the minutes or records of the board be open to public inspection unless the board takes final disciplinary action. The board may use the information in any formal hearing involving a licensee or registrant.

SECTION 8. In Colorado Revised Statutes, 12-280-118, **amend** (5)(a)(I) and (5)(a)(II) as follows:

12-280-118. Prescription drug outlet under charge of

pharmacist - rules. (5) (a) Except as specified in subsection (5)(b) of this section, the pharmacist responsible for the prescription order or chart order may delegate the following tasks to the following individuals if, in the pharmacist's professional judgment, the delegation is appropriate:

(I) Specific tasks, excluding tasks described in section 12-280-103 (38.5)(a), ~~but which tasks may include delivery and proper and safe storage of drugs or devices,~~ to ancillary personnel, other than a pharmacist or pharmacy intern, who are under the pharmacist's supervision, WHICH TASKS MAY INCLUDE:

(A) DELIVERY AND PROPER AND SAFE STORAGE OF DRUGS OR DEVICES;

(B) CASHIER TRANSACTIONS;

(C) MEDICATION SHIPPING AND HANDLING;

(D) MEDICATION TRANSPORTATION;

(E) RECORD KEEPING;

(F) TELEPHONE OR COMMUNICATION TRIAGE;

(G) INVENTORY MANAGEMENT; OR

(H) OTHER ADMINISTRATIVE DUTIES; or

(II) Specific tasks described in section 12-280-103 (38.5)(a) or in board rules adopted pursuant to section 12-280-103 ~~(38.5)(a)(VI)~~ (38.5)(a)(VIII) to a pharmacy technician who is under the pharmacist's supervision.

SECTION 9. In Colorado Revised Statutes, 12-280-119, **amend** (7) and (11); and **repeal** (9) as follows:

12-280-119. Registration of facilities - rules. (7) A separate registration is required under this section for any area outside the outlet that is not a satellite where ~~pharmaceutical~~ PHARMACIST care ~~and~~ services

are provided and for any area outside the outlet that is under different ownership from the outlet.

(9) ~~(a) Subject to subsection (9)(b) of this section, a prescription drug outlet may register as a compounding prescription drug outlet.~~

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

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

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

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

(11) A prescription drug outlet may register as a specialized prescription drug outlet if it engages in the compounding, dispensing, and delivery of drugs and devices to, or the provision of ~~pharmaceutical~~ PHARMACIST care SERVICES to residents of, a long-term care facility. The board shall adopt rules as necessary to implement this subsection (11).

SECTION 10. In Colorado Revised Statutes, 12-280-120, **amend** (6)(b), (10), and (15)(b) introductory portion; and **repeal** (15)(a) as follows:

12-280-120. Compounding - dispensing - sale of drugs and devices - rules - definition. (6) (b) (I) ~~The board shall promulgate rules authorizing~~ A prescription drug outlet located in this state ~~to~~ MAY compound AND DISTRIBUTE drugs ~~for office use by a practitioner or for use by a hospital located in this state. The rules must limit the amount of~~

~~drugs a prescription drug outlet may compound and distribute to a practitioner or hospital~~ FOR VETERINARY USE pursuant to ~~this subsection (6)(b) to no more than~~ SECTION 12-280-121, BUT THE AMOUNT OF DRUGS THE PRESCRIPTION DRUG OUTLET MAY COMPOUND AND DISTRIBUTE FOR VETERINARY USE MUST NOT EXCEED ten percent of the total number of drug dosage units dispensed and distributed on an annual basis by the outlet.

(II) ~~(A) The ten percent limitation set forth in subsection (6)(b)(I) of this section applies to a compounded drug for veterinary use that a prescription drug outlet distributes in Colorado.~~

~~(B) For purposes of this subsection (6)(b)(II)~~ AS USED IN THIS SUBSECTION (6)(b), a "prescription drug outlet" includes a nonresident 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-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 TWENTY-FOUR 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 TWENTY-FOUR-HOUR 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 compounded drugs without limitation to practitioners or to prescription drug outlets under common ownership with the pharmacist who owns the compounding prescription drug outlet.~~

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

SECTION 11. In Colorado Revised Statutes, 12-280-121, **amend** (3), (4), and (6) as follows:

12-280-121. Compounding drugs for office use by a veterinarian - rules - definitions. (3) A licensed veterinarian shall not administer or dispense a compounded drug maintained for office stock pursuant to this section or for office use pursuant to ~~section 12-280-120 (6)(b)(II)~~ SECTION 12-280-120 (6)(b) without a valid veterinarian-client-patient relationship in place at the time of administering the compounded drug to an animal patient or dispensing the

compounded drug to a client.

(4) To compound and distribute a controlled substance pursuant to this section or ~~section 12-280-120 (6)(b)(II)~~ SECTION 12-280-120 (6)(b), a registered prescription drug outlet shall possess a valid manufacturing registration from the federal drug enforcement administration.

(6) The board may promulgate rules as necessary concerning compounded veterinary pharmaceuticals pursuant to this section and ~~section 12-280-120 (6)(b)(II)~~ SECTION 12-280-120 (6)(b).

SECTION 12. In Colorado Revised Statutes, 12-280-123, **amend** (3) as follows:

12-280-123. Prescription required - exception - prescribing and dispensing opiate antagonists - selling nonprescription syringes and needles. (3) A pharmacist may PRESCRIBE AND dispense an opiate antagonist in accordance with section 12-30-110.

SECTION 13. In Colorado Revised Statutes, 12-280-124, **amend** (1)(b) as follows:

12-280-124. Labeling - rules. (1) A prescription drug dispensed pursuant to an order must be labeled as follows:

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

~~(II) If the prescription is for any drug other than an anabolic steroid~~ The symptom or purpose for which the drug is being prescribed must appear on the label, if, after being advised by the practitioner, the patient or the patient's authorized representative so requests. If the practitioner does not provide the symptom or purpose for which a drug is being prescribed, the pharmacist may fill the prescription order without

contacting the practitioner, patient, or patient's representative. ~~unless the prescription is for an anabolic steroid.~~

SECTION 14. In Colorado Revised Statutes, 12-280-125, **amend** (1)(b)(I), (1)(b)(II), (2)(a) introductory portion, (3)(b), (4), (5), and (6); and **add** (1)(a.5) as follows:

12-280-125. Substitution of prescribed drugs and biological products authorized - when - conditions. (1) (a.5) (I) A PHARMACIST FILLING A PRESCRIPTION ORDER FOR A SPECIFIC DRUG MAY SUBSTITUTE A DRUG IN THE SAME THERAPEUTIC CLASS AS LONG AS THE PATIENT AGREES TO THE SUBSTITUTION AND THE SUBSTITUTION IS MADE TO REPLACE A DRUG THAT IS ON BACK ORDER, TO ENSURE FORMULARY COMPLIANCE WITH THE PATIENT'S HEALTH INSURANCE PLAN, OR, IN THE CASE OF AN UNINSURED PATIENT, TO LOWER THE COST TO THE PATIENT FOR THE DRUG WHILE MAINTAINING SAFETY.

(II) THIS SUBSECTION (1)(a.5) DOES NOT AUTHORIZE:

(A) THE SUBSTITUTION OF BIOLOGICAL PRODUCTS, NARROW THERAPEUTIC INDEX DRUGS, OR PSYCHOTROPIC DRUGS; OR

(B) A SUBSTITUTION WHEN THE PRACTITIONER HAS INDICATED, IN THE MANNER DESCRIBED IN SUBSECTION (2) OF THIS SECTION, THAT THE PHARMACIST SHALL NOT SUBSTITUTE A DRUG IN THE SAME THERAPEUTIC CLASS AS THE DRUG PRESCRIBED.

(b) (I) A pharmacist filling a prescription order for a specific biological product may substitute ~~an interchangeable~~ A biological product for the prescribed biologic only if THE PRACTITIONER HAS NOT INDICATED, IN THE MANNER DESCRIBED IN SUBSECTION (2) OF THIS SECTION, THAT THE PHARMACIST SHALL NOT SUBSTITUTE AN INTERCHANGEABLE OR BIOSIMILAR BIOLOGICAL PRODUCT FOR THE PRESCRIBED BIOLOGICAL

PRODUCT AND:

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

(B) ~~The practitioner has not indicated, in the manner described in subsection (2) of this section, that the pharmacist shall not substitute an interchangeable biological product for the prescribed biological product.~~ THE FDA HAS DETERMINED THAT THE BIOLOGICAL PRODUCT TO BE SUBSTITUTED IS BIOSIMILAR WITH THE PRESCRIBED BIOLOGICAL PRODUCT; OR

(C) THE SUBSTITUTION IS MADE PURSUANT TO A THERAPEUTIC INTERCHANGE APPROVED BY THE PHARMACY AND THERAPEUTICS COMMITTEE OF A HOSPITAL OR HEALTH CARE SYSTEM.

(II) Within a reasonable time after dispensing a biological product, the dispensing pharmacist or ~~his or her~~ THE DISPENSING PHARMACIST'S designee shall communicate to the prescribing practitioner the specific biological product dispensed to the patient, including the name and manufacturer of the biological product. The pharmacist or designee shall communicate the information to the prescribing practitioner by making an entry into an interoperable electronic medical records system, through electronic prescribing technology, or through a pharmacy record that the prescribing practitioner can access electronically. Otherwise, the pharmacist or ~~his or her~~ THE PHARMACIST'S designee shall communicate to the prescribing practitioner the name and manufacturer of the biological product dispensed to the patient using facsimile, telephone, electronic transmission, or other prevailing means. ~~except when:~~

~~(A) There is no FDA-approved interchangeable biological product~~

~~for the prescribed biological product; or~~

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

(2) (a) If, in the opinion of the practitioner, it is in the best interest of the patient that the pharmacist not substitute an equivalent drug, A DRUG IN THE SAME THERAPEUTIC CLASS, or AN interchangeable OR BIOSIMILAR biological product for the specific drug or biological product ~~he or she~~ THE PRACTITIONER prescribed, the practitioner may convey this information to the pharmacist in any of the following manners:

(3) (b) The pharmacist is not required to communicate a substitution to ~~institutionalized~~ patients IN AN INPATIENT SETTING, AN OUTPATIENT INFUSION CENTER, OR A CLINICAL SETTING.

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

(5) If a prescription drug outlet does not have in stock the prescribed drug or biological product and the only equivalent drug, DRUG IN THE SAME THERAPEUTIC CLASS, or interchangeable OR BIOSIMILAR biological product in stock is higher priced, the pharmacist, with the consent of the purchaser, may substitute the higher priced drug or interchangeable OR BIOSIMILAR biological product. This subsection (5) applies only to a prescription drug outlet located in a town, as defined in section 31-1-101 (13).

(6) The board shall maintain on its website a link to the FDA resource, if one is available, that identifies all biological products approved as interchangeable OR BIOSIMILAR with specific biological products.

SECTION 15. In Colorado Revised Statutes, **add** 12-280-125.3 as follows:

12-280-125.3. Pharmacists' authority - minor prescription adaptions. (1) EXCEPT AS PROVIDED IN SUBSECTION (3) OF THIS SECTION, A PHARMACIST WHO IS ACTING IN GOOD FAITH AND IS USING PROFESSIONAL JUDGMENT AND EXERCISING REASONABLE CARE MAY MAKE THE FOLLOWING MINOR ADAPTIONS TO AN ORDER IF THE PHARMACIST HAS THE INFORMED CONSENT OF THE PATIENT FOR WHOM THE PRESCRIPTION WAS PROVIDED:

(a) A CHANGE IN THE PRESCRIBED DOSAGE FORM OR DIRECTIONS FOR USE OF THE PRESCRIPTION DRUG IF THE CHANGE ACHIEVES THE INTENT OF THE PRESCRIBING PRACTITIONER;

(b) A CHANGE IN THE PRESCRIBED QUANTITY OF THE PRESCRIPTION DRUG IF THE PRESCRIBED QUANTITY IS NOT A PACKAGE SIZE COMMERCIALLY AVAILABLE FROM THE MANUFACTURER;

(c) AN EXTENSION OF THE QUANTITY OF A MAINTENANCE DRUG FOR THE LIMITED QUANTITY NECESSARY TO ACHIEVE MEDICATION REFILL SYNCHRONIZATION FOR THE PATIENT; AND

(d) COMPLETION OF MISSING INFORMATION ON THE ORDER IF THERE IS SUFFICIENT EVIDENCE TO SUPPORT THE CHANGE.

(2) A PHARMACIST WHO ADAPTS AN ORDER IN ACCORDANCE WITH SUBSECTION (1) OF THIS SECTION SHALL DOCUMENT THE ADAPTION AND THE JUSTIFICATION FOR THE CHANGE IN THE PATIENT'S PHARMACY RECORD

WITH THE ORIGINAL PRESCRIPTION AND SHALL NOTIFY THE PRESCRIBING PRACTITIONER OF THE ADAPTION.

(3) A PHARMACIST SHALL NOT ADAPT AN ORDER IF THE PRESCRIBING PRACTITIONER HAS WRITTEN "DO NOT ADAPT" ON THE PRESCRIPTION OR HAS OTHERWISE COMMUNICATED TO THE PHARMACIST THAT THE PRESCRIPTION MUST NOT BE ADAPTED.

SECTION 16. In Colorado Revised Statutes, 12-280-126, **amend** (1)(e); and **add** (1)(t) as follows:

12-280-126. Unprofessional conduct - grounds for discipline. (1) The board may take disciplinary or other action as authorized in section 12-20-404, after a hearing held in accordance with the provisions of sections 12-20-403 and 12-280-127, upon proof that the licensee, certificant, or registrant:

(e) ~~Has a substance use disorder, as defined in section 27-81-102, or~~ Engages in the habitual or excessive use or abuse of alcohol, a habit-forming drug, or a controlled substance, as defined in section 18-18-102 (5);

(t) HAS FAILED TO NOTIFY THE BOARD, IN WRITING AND WITHIN THIRTY DAYS AFTER A JUDGMENT OR SETTLEMENT IS ENTERED, OF A FINAL JUDGMENT BY A COURT OF COMPETENT JURISDICTION AGAINST THE LICENSEE OR REGISTRANT FOR MALPRACTICE IN THE PRACTICE OF PHARMACY OR A SETTLEMENT BY THE LICENSEE IN RESPONSE TO CHARGES OR ALLEGATIONS OF MALPRACTICE IN THE PRACTICE OF PHARMACY AND, IN THE CASE OF A JUDGMENT, HAS FAILED TO INCLUDE IN THE NOTICE THE NAME OF THE COURT, THE CASE NUMBER, AND THE NAMES OF ALL PARTIES TO THE ACTION;

SECTION 17. In Colorado Revised Statutes, 12-280-127, **amend**

(6) as follows:

12-280-127. Disciplinary actions. (6) The board may send a letter of admonition ~~by certified mail~~ to a licensee, certificant, or registrant under the circumstances specified in and in accordance with section 12-20-404 (4). In the case of a complaint, the board may send a copy of the letter of admonition to the person making the complaint.

SECTION 18. In Colorado Revised Statutes, **add** 12-280-133.5 and 12-280-133.7 as follows:

12-280-133.5. Nonresident 503B outsourcing facility - registration - requirements - denial, revocation, or suspension - rules. (1) A NONRESIDENT 503B OUTSOURCING FACILITY SHALL NOT CONDUCT THE BUSINESS OF DISTRIBUTING COMPOUNDED PRESCRIPTION DRUGS IN THIS STATE WITHOUT FIRST REGISTERING WITH THE BOARD AS A NONRESIDENT 503B OUTSOURCING FACILITY. A NONRESIDENT 503B OUTSOURCING FACILITY SHALL APPLY FOR A NONRESIDENT 503B OUTSOURCING FACILITY REGISTRATION ON A FORM FURNISHED BY THE BOARD AND SHALL SUBMIT THE FOLLOWING TO THE BOARD WITH THE APPLICATION:

(a) PROOF THAT THE FACILITY IS ACTIVELY REGISTERED WITH THE FDA AS A 503B OUTSOURCING FACILITY AND IS ACTIVELY LICENSED, PERMITTED, OR REGISTERED IN THE STATE IN WHICH IT IS A RESIDENT;

(b) THE LOCATION, NAMES, AND TITLES OF ALL PRINCIPAL ENTITY OFFICERS AND THE NAME OF THE PHARMACIST IN CHARGE OF THE OPERATIONS OF THE FACILITY;

(c) VERIFICATION THAT THE FACILITY COMPLIES WITH ALL LAWFUL DIRECTIONS AND REQUESTS FOR INFORMATION FROM THE FDA AND FROM THE REGULATORY OR LICENSING AGENCY OF THE STATE IN WHICH IT IS

LICENSED, PERMITTED, OR REGISTERED, AS WELL AS WITH ALL REQUESTS FOR INFORMATION MADE BY THE BOARD PURSUANT TO THIS SECTION;

(d) A COPY OF THE MOST RECENT INSPECTION REPORT RESULTING FROM AN INSPECTION CONDUCTED BY THE FDA; AND

(e) ANY OTHER INFORMATION THE BOARD DEEMS NECESSARY TO CARRY OUT THE PURPOSE OF THIS SECTION.

(2) A NONRESIDENT 503B OUTSOURCING FACILITY SHALL:

(a) MAINTAIN AT ALL TIMES A VALID, UNEXPIRED LICENSE, PERMIT, OR REGISTRATION TO OPERATE THE 503B OUTSOURCING FACILITY IN COMPLIANCE WITH THE LAWS OF THE STATE IN WHICH IT IS A RESIDENT; AND

(b) COMPLY WITH THE REQUIREMENTS OF THE "FEDERAL FOOD, DRUG, AND COSMETIC ACT", 21 U.S.C. SEC. 301 ET SEQ., AS AMENDED, OR THE DQSA OR WITH FDA REGULATIONS IMPLEMENTING EITHER ACT.

(3) THE BOARD MAY DENY, REVOKE, OR SUSPEND A NONRESIDENT 503B OUTSOURCING FACILITY REGISTRATION IF:

(a) THE FACILITY FAILS TO COMPLY WITH THIS SECTION OR WITH ANY RULE PROMULGATED BY THE BOARD;

(b) THE FDA HAS REVOKED OR REFUSED TO RENEW THE NONRESIDENT 503B OUTSOURCING FACILITY'S FDA REGISTRATION FOR FAILING TO COMPLY WITH THE REQUIREMENTS OF THE "FEDERAL FOOD, DRUG, AND COSMETIC ACT", 21 U.S.C. SEC. 301 ET SEQ., AS AMENDED, THE DQSA, OR FDA REGULATIONS IMPLEMENTING EITHER ACT OR THE FACILITY'S FDA REGISTRATION HAS EXPIRED OR IS NO LONGER ACTIVE; OR

(c) THE STATE IN WHICH THE NONRESIDENT 503B OUTSOURCING FACILITY RESIDES HAS REVOKED OR REFUSED TO RENEW THE FACILITY'S LICENSE, PERMIT, OR REGISTRATION FOR FAILING TO COMPLY WITH THE

LAWS OF THAT STATE OR THE FACILITY'S LICENSE, PERMIT, OR REGISTRATION IN ANOTHER STATE HAS EXPIRED OR IS NO LONGER ACTIVE.

(4) THE BOARD MAY ADOPT RULES AS NECESSARY TO IMPLEMENT THIS SECTION.

12-280-133.7. Third-party logistics providers - registration - denial, revocation, or suspension - rules. (1) A THIRD-PARTY LOGISTICS PROVIDER SHALL NOT CONDUCT BUSINESS IN THIS STATE WITHOUT FIRST REGISTERING WITH THE BOARD AS A THIRD-PARTY LOGISTICS PROVIDER. A THIRD-PARTY LOGISTICS PROVIDER SHALL APPLY FOR A REGISTRATION ON A FORM FURNISHED BY THE BOARD AND SHALL SUBMIT THE INFORMATION REQUIRED PURSUANT TO RULES ADOPTED BY THE BOARD. THE BOARD SHALL SPECIFY, BY RULE, THE INFORMATION A THIRD-PARTY LOGISTICS PROVIDER MUST SUBMIT WITH ITS APPLICATION FOR A REGISTRATION.

(2) A THIRD-PARTY LOGISTICS PROVIDER SHALL COMPLY WITH ALL LAWFUL DIRECTIONS AND REQUESTS FOR INFORMATION FROM THE FDA, THE REGULATORY OR LICENSING AGENCY OF THE STATE IN WHICH IT IS LICENSED, PERMITTED, OR REGISTERED, AND THE BOARD.

(3) THE BOARD MAY DENY, REVOKE, OR SUSPEND A THIRD-PARTY LOGISTICS PROVIDER REGISTRATION IF:

(a) THE THIRD-PARTY LOGISTICS PROVIDER FAILS TO COMPLY WITH THIS SECTION OR WITH ANY RULE PROMULGATED BY THE BOARD;

(b) THE FDA HAS REVOKED OR REFUSED TO RENEW THE THIRD-PARTY LOGISTICS PROVIDER'S FDA REGISTRATION FOR FAILING TO COMPLY WITH THE REQUIREMENTS OF THE "FEDERAL FOOD, DRUG, AND COSMETIC ACT", 21 U.S.C. SEC. 301 ET SEQ., AS AMENDED, OR THE DQSA OR WITH FDA REGULATIONS IMPLEMENTING EITHER ACT; OR

(c) THE STATE IN WHICH THE THIRD-PARTY LOGISTICS PROVIDER RESIDES HAS REVOKED OR REFUSED TO RENEW THE PROVIDER'S LICENSE, PERMIT, OR REGISTRATION FOR FAILING TO COMPLY WITH THE LAWS OF THAT STATE.

(4) THE BOARD MAY ADOPT RULES AS NECESSARY TO IMPLEMENT THIS SECTION.

SECTION 19. In Colorado Revised Statutes, 12-280-134, **add** (10) as follows:

12-280-134. Records - rules. (10) THE BOARD SHALL ADOPT RULES FOR THE ELECTRONIC STORAGE OF RECORDS REQUIRED TO BE MAINTAINED PURSUANT TO THIS SECTION.

SECTION 20. In Colorado Revised Statutes, **add** 12-280-137 and 12-280-138 as follows:

12-280-137. Investigations of suspicious drugs. ALL PRESCRIPTION DRUG OUTLETS, MANUFACTURERS, REPACKAGERS, AND WHOLESALERS SHALL INVESTIGATE ANY SUSPECT PRODUCT, AS DEFINED IN THE DQSA AND ANY FEDERAL REGULATIONS IMPLEMENTING THE DQSA, AND SHALL USE DOCUMENTATION AND REPORTING PROCEDURES RELATING TO THE INVESTIGATION IN ACCORDANCE WITH THE DQSA AND ANY FEDERAL REGULATIONS IMPLEMENTING THE DQSA.

12-280-138. Patient counseling - pharmacists required to perform - patient may decline - rules. (1) (a) EXCEPT IN THE CIRCUMSTANCES DESCRIBED IN SUBSECTION (2) OF THIS SECTION, A PHARMACIST SHALL PROVIDE PATIENT COUNSELING ON NEW MEDICATION THERAPY AND, BASED ON THE PHARMACIST'S PROFESSIONAL JUDGMENT AND DUE DILIGENCE, MAY PROVIDE PATIENT COUNSELING FOR ANY OTHER PRESCRIPTION. IF THE PHARMACIST IS UNABLE TO PROVIDE PATIENT

COUNSELING ORALLY DUE TO LANGUAGE BARRIERS, THE PHARMACIST MAY USE ALTERNATE MEANS TO PROVIDE THE PATIENT COUNSELING.

(b) ALL PHARMACIES, INCLUDING MAIL-ORDER PHARMACIES, MUST ENSURE THAT THEIR PHARMACISTS PROVIDE PATIENT COUNSELING IN ACCORDANCE WITH THIS SECTION.

(2) A PATIENT MAY DECLINE PATIENT COUNSELING OFFERED BY A PHARMACIST. A PHARMACIST SHALL DOCUMENT, IN THE FORM AND MANNER SPECIFIED IN BOARD RULES, WHEN A PATIENT DECLINES PATIENT COUNSELING.

(3) THE BOARD SHALL ADOPT RULES SPECIFYING:

(a) THE ALTERNATE MEANS BY WHICH PHARMACISTS MAY PROVIDE PATIENT COUNSELING WHEN LANGUAGE BARRIERS PRECLUDE PROVIDING PATIENT COUNSELING ORALLY; AND

(b) THE FORM AND MANNER FOR PHARMACISTS TO DOCUMENT WHEN A PATIENT DECLINES COUNSELING, WHICH RULES MUST SPECIFY A DOCUMENTATION PROCESS THAT IS SIMPLE AND ALLOWS THE DOCUMENTATION TO BE COMPLETED ELECTRONICALLY.

SECTION 21. In Colorado Revised Statutes, **amend** 12-280-201 as follows:

12-280-201. Legislative declaration. (1) The general assembly finds, determines, and declares that the creation of a pharmacy peer health assistance ~~diversion~~ program for those persons subject to the jurisdiction of the board will serve to safeguard the life, health, property, and public welfare of the people of this state. A pharmacy peer health assistance ~~diversion~~ program will help practitioners experiencing impaired practice due to psychiatric, psychological, or emotional problems; excessive alcohol or drug use; or alcohol or substance use disorders. The general

assembly further declares that a pharmacy peer health assistance ~~diversion~~ program will protect the privacy and welfare of those persons who provide services and at the same time assist the board in carrying out its duties and responsibilities to ensure that only qualified persons are allowed to engage in providing those services that are under the jurisdiction of the board.

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

SECTION 22. In Colorado Revised Statutes, 12-280-203, **amend** (2)(b) introductory portion as follows:

12-280-203. Pharmacy peer health assistance fund - rules. (2) (b) The board shall select one or more peer health assistance organizations as designated providers. To be eligible for designation by the board, a peer health assistance ~~diversion~~ program shall:

SECTION 23. In Colorado Revised Statutes, 12-280-204, **amend** (1), (2)(b), and (3) as follows:

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 of a licensee participating in or referred to a state-funded peer health assistance ~~diversion~~ program occurred while the licensee was performing

duties as an employee of the state.

SECTION 25. In Colorado Revised Statutes, 12-280-301, **amend** (3) and (7); **repeal** (1), (4), (6), and (8); and **add** (7.5) as follows:

12-280-301. Definitions. As used in this part 3, unless the context otherwise requires:

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

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

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

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

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

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

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

~~(IV) A pharmacy to a patient; or~~

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

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

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

(7) "Pedigree" means a document or electronic file containing information that records each distribution of any given prescription drug ~~that leaves the normal distribution channel~~ IN ACCORDANCE WITH THE DQSA AND ANY FEDERAL REGULATIONS IMPLEMENTING THE DQSA.

(7.5) "PRESCRIPTION DRUG" HAS THE SAME MEANING AS SET FORTH IN SECTION 12-280-103 (42); EXCEPT THAT "PRESCRIPTION DRUG" EXCLUDES ANY DRUG SPECIFICALLY EXEMPTED UNDER THE DQSA AND ANY FEDERAL REGULATIONS IMPLEMENTING THE DQSA.

(8) ~~"Third-party logistics provider" means anyone who 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.~~

SECTION 26. In Colorado Revised Statutes, **repeal** 12-280-302.

SECTION 27. In Colorado Revised Statutes, 12-280-303, **amend** (1), (2)(b), (2)(c), (3)(a) introductory portion, (3)(a)(VI), (3)(b), (4), (5) introductory portion, (5)(f), and (6) as follows:

12-280-303. Wholesaler registration requirements - rules. (1) ~~(a)~~ A wholesaler that resides in this state must ~~be licensed by~~ REGISTER WITH the board BEFORE ENGAGING IN THE WHOLESALE DISTRIBUTION OF PRESCRIPTION DRUGS IN THIS STATE. A wholesaler that does not reside in this state must be ~~licensed~~ REGISTERED in this state prior to engaging in the wholesale distribution of prescription drugs in this state. ~~The board shall exempt a manufacturer and that manufacturer's third-party logistics providers to the extent involving that manufacturer's drugs under contract from any licensing qualifications and other requirements, including the requirements in subsections (3)(a)(VI) and (3)(a)(VII) of this section, subsections (4) to (6) of this section, and section 12-280-304, to the extent the requirements are not required by federal law or regulation, unless the particular requirements are deemed necessary and appropriate following rule-making by the board.~~

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

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

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

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

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

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

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

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

(f) Serve in the capacity of a designated representative for only one applicant or wholesaler at a time, except where more than one ~~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;

(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 not knowingly return a medication that is not what it purports to be.~~

(4) ~~A manufacturer or wholesaler shall not accept payment for, or~~

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

SECTION 29. In Colorado Revised Statutes, **repeal and reenact, with amendments,** 12-280-306 as follows:

12-280-306. Records - pedigree - compliance with DQSA. A WHOLESALER SHALL ESTABLISH AND MAINTAIN INVENTORIES AND RECORDS OF ALL TRANSACTIONS REGARDING THE RECEIPT AND DISTRIBUTION OR OTHER DISPOSITION OF PRESCRIPTION DRUGS. THE RECORDS MUST INCLUDE THE PEDIGREE FOR EACH WHOLESALE DISTRIBUTION OF A PRESCRIPTION DRUG AS REQUIRED PURSUANT TO THE DQSA AND ANY FEDERAL REGULATIONS IMPLEMENTING THE DQSA.

SECTION 30. In Colorado Revised Statutes, 12-280-403, **amend** (2)(a) as follows:

12-280-403. Prescription drug use monitoring program - registration required. (2) (a) By January 1, 2015, or by an earlier date determined by the director, every practitioner in this state who holds a current registration issued by the federal drug enforcement administration and every pharmacist shall register and maintain a user account with the program. A PHARMACY TECHNICIAN WHO HAS SATISFIED THE REQUIREMENTS FOR CERTIFICATION SPECIFIED IN SECTION 12-280-115.5 (2) AND IS CERTIFIED PURSUANT TO SECTION 12-280-115.5 MAY REGISTER

AND MAINTAIN A USER ACCOUNT WITH THE PROGRAM.

SECTION 31. In Colorado Revised Statutes, 12-280-404, **amend** (3)(f) as follows:

12-280-404. Program operation - access - rules - definitions - repeal. (3) The program is available for query only to the following persons or groups of persons:

(f) A pharmacist, A PHARMACY TECHNICIAN REGISTERED WITH THE PROGRAM PURSUANT TO SECTION 12-280-403 (2)(a) WHO IS ACTING ON BEHALF OF A PHARMACIST, an individual designated by a pharmacist in accordance with section 12-280-403 (2)(b) to act on ~~his or her~~ THE PHARMACIST'S behalf, or a pharmacist licensed in another state, to the extent the information requested relates specifically to a current patient to whom the pharmacist is dispensing or considering dispensing a controlled substance or prescription drug or a patient to whom the pharmacist is currently providing clinical patient care services;

SECTION 32. In Colorado Revised Statutes, 12-30-110, **amend** (1)(a) introductory portion, (2)(a), (3) introductory portion, (4)(a), and (7)(h) as follows:

12-30-110. Prescribing or dispensing opiate antagonists - authorized recipients - definitions. (1) (a) A prescriber may prescribe or dispense, directly or in accordance with standing orders and protocols, ~~and a pharmacist may dispense, pursuant to an order or standing orders and protocols,~~ an opiate antagonist to:

(2) (a) A prescriber who prescribes or dispenses ~~or a pharmacist who dispenses,~~ an opiate antagonist pursuant to this section is strongly encouraged to educate persons receiving the opiate antagonist on the use of an opiate antagonist for overdose, including instruction concerning risk

factors for overdose, recognizing an overdose, calling emergency medical services, rescue breathing, and administering an opiate antagonist.

(3) ~~Neither~~ A prescriber described in ~~subsection (7)(h)(I)~~ SUBSECTION (7)(h) of this section ~~nor a pharmacist engages~~ DOES NOT ENGAGE in unprofessional conduct OR IS NOT SUBJECT TO DISCIPLINE pursuant to section 12-240-121, ***12-255-120***, or 12-280-126, ~~respectively, and a prescriber described in subsection (7)(h)(II) of this section does not engage in conduct that is grounds for discipline pursuant to section 12-255-120~~ AS APPLICABLE, if the prescriber issues standing orders and protocols regarding opiate antagonists or prescribes or dispenses, ~~or the pharmacist dispenses,~~ pursuant to an order or standing orders and protocols, an opiate antagonist in a good-faith effort to assist:

(4) (a) A prescriber ~~or pharmacist~~ who prescribes or dispenses an opiate antagonist in accordance with this section is not subject to civil liability or criminal prosecution, as specified in sections 13-21-108.7 (4) and 18-1-712 (3), respectively.

(7) As used in this section:

(h) "Prescriber" means:

(I) A physician or physician assistant licensed pursuant to article 240 of this title 12; ~~or~~

(II) An advanced practice registered nurse, as defined in section 12-255-104 (1), with prescriptive authority pursuant to section 12-255-112; OR

(III) A PHARMACIST.

SECTION 33. In Colorado Revised Statutes, **add with amended and relocated provisions** 10-1-125.3 as follows:

10-1-125.3. Reporting of malpractice claims against

pharmacists and pharmacies. (1) **[Formerly 12-280-111 (1)]** Each insurance company licensed to do business in this state and engaged in ~~the~~ writing ~~of~~ malpractice insurance for licensed pharmacists and REGISTERED pharmacies, and each pharmacist or pharmacy that self-insures, shall send to the STATE board OF PHARMACY, in the form prescribed by the ~~board~~ COMMISSIONER IN COLLABORATION WITH THE STATE BOARD OF PHARMACY, information relating to each malpractice claim against a licensed pharmacist OR REGISTERED PHARMACY that is settled or in which judgment is rendered against the insured.

(2) **[Formerly 12-280-111 (2)]** The insurance company or self-insured pharmacist or pharmacy shall provide information relating to each malpractice claim ~~as is deemed~~ THAT THE STATE BOARD OF PHARMACY DEEMS necessary ~~by the board~~ to conduct a further investigation and hearing.

SECTION 34. In Colorado Revised Statutes, **amend** 13-64-303 as follows:

13-64-303. Judgments and settlements - reported - penalties. Any final judgment, settlement, or arbitration award against any health care professional or health care institution for medical malpractice shall be reported within fourteen days by the professional's or institution's medical malpractice insurance carrier in accordance with section 10-1-120, 10-1-120.5, 10-1-121, 10-1-124, 10-1-125, ***10-1-125.3***, or 10-1-125.7, or by the professional or institution if there is no commercial medical malpractice insurance coverage to the licensing agency of the health care professional or health care institution for review, investigation, and, where appropriate, disciplinary or other action. Any health care professional, health care institution, or insurance carrier that

knowingly fails to report as required by this section shall be subject to a civil penalty of not more than two thousand five hundred dollars. Such penalty shall be determined and collected by the district court in the city and county of Denver. All penalties collected pursuant to this section shall be transmitted to the state treasurer, who shall credit the same to the general fund.

SECTION 35. In Colorado Revised Statutes, 25-51-104, **amend** (1)(c) and (1)(e) as follows:

25-51-104. Payment and financial resolution. (1) If a patient accepts an offer of compensation made pursuant to section 25-51-103 (5) and receives the compensation, the payment of compensation to the patient is not a payment resulting from:

(c) A malpractice claim settled or in which judgment is rendered against a professional for purposes of reporting by malpractice insurance companies under section 10-1-120, 10-1-120.5, 10-1-121, 10-1-124, 10-1-125, ***10-1-125.3***, 10-1-125.5, or 10-1-125.7;

(e) A judgment, administrative action, settlement, or arbitration award involving malpractice under section 12-200-106 (5), 12-210-105 (5), 12-215-115 (1)(i), 12-220-201 (1)(q) or (1)(r), 12-235-111 (1)(i), 12-240-125 (4)(b)(III), 12-245-226 (7), 12-250-116, 12-255-119 (3)(b)(II), 12-255-120 (1)(dd), 12-275-120 (1)(p) or (1)(v), 12-275-129, ~~12-280-111 (1)~~ ***12-280-126 (1)(t)***, 12-285-120 (1)(o), 12-285-127 (1)(a), 12-285-211 (1)(k), 12-285-216 (1)(a), or 12-290-113 (2)(b)(III).

SECTION 36. In Colorado Revised Statutes, 25.5-2.5-204, **amend** (3)(d) and (4)(a) as follows:

25.5-2.5-204. Eligible prescription drugs - eligible Canadian suppliers - eligible importers - distribution requirements. (3) The

following entities are eligible importers and may obtain imported prescription drugs:

(d) A licensed Colorado pharmacist or REGISTERED wholesaler approved by the state department.

(4) (a) The state department shall designate an office or division that must be a ~~licensed pharmaceutical~~ REGISTERED wholesaler or that shall contract with a ~~licensed pharmaceutical~~ wholesaler ~~licensed~~ REGISTERED pursuant to part 3 of article 280 of title 12.

SECTION 37. Effective date. This act takes effect September 1, 2021; except that section 4 of this act takes effect upon passage.

SECTION 38. Safety clause. The general assembly hereby finds, determines, and declares that this act is necessary for the immediate preservation of the public peace, health, or safety.