Basis and Purpose: The purpose of repealing Board Rules 1.00.15 and 5.00.55 (a)(6) is to remove the restriction on prescriber ownership of a pharmacy. The purpose of the amendment to Board Rule 3.01.10 is to implement HB 17-1371, which allows pharmacies owned and operated by hospitals accredited by the Joint Commission on Accreditation of Healthcare Organizations, a health maintenance organization as defined in Section 10-16-102, C.R.S., or the Colorado Department of Corrections to distribute prepackaged drugs, without limitation, to other pharmacies or other outlets under common ownership and/or control. The purpose of the amendment to Board Rule 7.00.30 is to implement SB 17-268, which amends the technician to pharmacist ratio at a Colorado-based prescription drug outlet and therefore amends the pharmacy technician posting requirements. The purpose of the amendments to Board Rules 21.00.20 and 21.00.30 is to implement HB 17-1274, which allows an in-state or nonresident pharmacy to distribute compounded products to Colorado-based licensed veterinarians for office use under certain limitations and conditions, and to implement HB 17-1371, which allows pharmacies owned and operated by hospitals accredited by the Joint Commission on Accreditation of Healthcare Organizations, a health maintenance organization as defined in Section 10-16-102, C.R.S., or the Colorado Department of Corrections to distribute compounded drugs, without limitation, to other pharmacies or other outlets under common ownership and/or control. The purpose of the amendments to Board Rules 23.00.10 and 23.00.70 is to implement SB 17-146, which clarifies under what conditions prescribers and pharmacists may access Colorado's Electronic Prescription Drug Monitoring Program ("PDMP").

Authority for Promulgation of Rules: Sections 12-42.5-101, 12-42.5-105, 12-42.5-106(2) and (3), 12-42.5-118, 12-42.5-118.5, 12-42.5-119, 12-42.5-130, 12-42.5-404 and 24-4-103, C.R.S.

1.00.00 RULES OF PROFESSIONAL CONDUCT.

1.00.11 **A pharmacist shall at all times conduct his/her profession in conformity with all federal and state drug laws, rules and regulations; and shall uphold the legal standards of the current official compendia.**

1.00.12 **A pharmacist shall not be a party or accessory to nor engage in any fraudulent or deceitful practice or transaction in pharmacy, nor knowingly participate in any practice which detrimentally affects the patient, nor discredit his/her profession.**

1.00.13 **A pharmacist shall not enter into any agreement or arrangement with anyone for the compounding of secret formula or coded orders, except for investigational drugs.**

~~**1.00.15** **A pharmacist shall not, directly or indirectly, be employed as a pharmacist to dispense drugs by a person authorized to prescribe drugs. For the purpose of this rule, the term person shall include any person or persons, partnership or business entity in which the person or persons authorized to prescribe drugs has an ownership interest individually or jointly greater than 10 percent.~~

3.01.10 a. **In a prescription drug outlet packaging shall only be done by a pharmacist, or by an intern or pharmacy technician under the supervision of a pharmacist. In an other outlet, packaging may be done by a person not licensed as a pharmacist pursuant to protocols approved by the Board.**

b. **Such packaged drugs shall only be dispensed or distributed from the premises where packaged. Such packaged drugs shall only be distributed as provided in 3.01.10(d).**

c. **Any container used for packaging shall meet compendia requirements.**

d. **The following prescription drug outlets may distribute packaged medications without limitation to prescription drug outlets and other outlets under common ownership:**

1. **Prescription drug outlets owned and operated by a hospital that is accredited by the joint commission on accreditation of healthcare organizations or a successor organization pursuant to 12-42.5-118((15)(b), C.R.S;**

2. **Prescription drug outlets operated by a health maintenance organization as defined in section 10-16-102, C.R.S.; and**

3. **The Colorado Department of Corrections.**

5.00.55 Reinstatement of an In-State or Non-Resident Prescription Drug Outlet Registration.

a. In-state Prescription Drug Outlet. If a registration has expired, a facility seeking to reinstate such registration shall submit the following:

(1) The current reinstatement application with the required fee;

(2) If the owner of the in-state prescription drug outlet is a corporation, submit either a copy of the articles of incorporation as they were filed with the Colorado Secretary of State or a Certificate of Good Standing issued by the Colorado Secretary of State;

(3) A letter stating whether the corporation is public or private as follows:

(A) If the corporation is a public corporation, submit a list of all stockholders owning five percent or more of the stock; or

(B) If the corporation is a private corporation, submit a list of all stockholders;

(4) An accurate drawn-to-scale floor plan of the prescription drug outlet's compounding / dispensing area detailing all counters, bays, sinks, refrigerators and, if applicable, sterile and non-sterile compounding hoods; and

(5) A completed, dated and signed minimum equipment self-inspection form as provided with the reinstatement application.~~; and~~

(6) ~~A statement, signed by the pharmacist manager, stating whether or not greater than ten percent of the business is owned by a person or persons authorized by law to prescribe drugs.~~

7.00.30 Compliance of Outlet:

b. The manager shall be responsible for posting the following information for each pharmacy technician working in the compounding/dispensing area:

1. Certificate indicating the technician is certified by a nationally recognized certification Board; or

2. Diploma indicating the technician has graduated from an accredited pharmacy technician training program; or

3. Documentation that the pharmacy technician has completed five hundred hours of experiential training at the pharmacy. This documentation must be certified by the pharmacist manager of the prescription drug outlet; or

4. Documentation that the pharmacy technician does not have certification from a nationally recognized certification Board, has not graduated from an accredited pharmacy technician training program, and has not completed 500 hours of experiential training at the pharmacy. Within 18 months of beginning employment at the pharmacy, each pharmacy technician shall meet the requirements of either subparagraph 1, 2 or 3 of this Rule 7.00.30(b).

21.00.20 Casual Sales/Distribution of Compounded Products.

a. An in-state prescription drug outlet shall only distribute a compounded product to:

(1) Practitioners licensed and located in Colorado and authorized by law to prescribe the drug;

(2) Colorado licensed/registered acupuncturists, direct-entry midwives, or naturopathic doctors who are located in Colorado and authorized by law to obtain the drug;

(3) Hospital prescription drug outlets registered and located in Colorado; or

(4) ~~Hospital other~~ Other outlets registered and located in Colorado pursuant to Board Rule 3.01.10(d).

Except as provided by Rule 21.00.20(d), distribution of the compounded product pursuant to this rule shall be for the sole purpose of drug administration. In-state Prescription Drug Outlets shall not distribute compounded products outside of the state. In-state Prescription Drug Outlets shall dispense compounded products and ship them out of the state only pursuant to patient-specific prescription orders.

b. Unless otherwise allowed by state and federal law, nonresident prescription drug outlets shall not distribute compounded products into Colorado pursuant to 21 U.S.C. secs. 331(a), 353(b) and 355(a).

c. Unless otherwise allowed by state and federal law, nonresident prescription drug outlets registered in Colorado may dispense compounded products and ship them into Colorado only pursuant to valid, patient-specific prescription orders.

d. A nonresident prescription drug outlet may distribute a compounded product to a Colorado-licensed veterinarian who is located in Colorado and authorized by law to prescribe the drug only if:

i) The nonresident prescription drug outlet provides the Board with a copy of the outlet's most recent report detailing an inspection by the National Association of Boards of Pharmacy Verified Pharmacy Program, for which third-party inspection the nonresident prescription drug outlet shall obtain and pay for on an annual basis, and the Board approves the inspection report as satisfactorily demonstrating proof of compliance with the Board's own inspection procedures and standards; and

ii) The nonresident prescription drug outlet provides the Board, on an annual basis, with a copy of the outlet's current manufacturer registration obtained from the Drug Enforcement Administration.

e. Distribution of a compounded product to a Colorado-licensed veterinarian may be for the purpose of dispensing by the receiving veterinarian only if:

i) The compounded product is necessary for the treatment of a ~~companion animal's~~ animal patient's emergency medical condition;

ii) As determined by the veterinarian, the veterinarian cannot access, in a timely manner, the compounded product from a prescription drug outlet or nonresident prescription drug outlet.

f. Except as provided under CRS 12-42.5-118(15)(a), (b)(I) and (b)(II), the amount of compounded drug product a prescription drug outlet compounds and distributes shall be no more than ten (10) percent of the total number of drug dosage units the prescription drug outlet dispenses and distributes on an annual basis, and no more than ten (10) percent of the total number of drug dosage units the nonresident prescription drug outlet dispenses and distributes into Colorado on an annual basis pursuant to Board Rules 21.00.20(d) and (e). An in-state compounding prescription drug outlet registered pursuant to CRS 12-42.5-117(9) may distribute compounded product pursuant to CRS 12-42.5-118(15)(a), (b)(I) and (II). All prescription drug outlets shall comply with all applicable federal laws and rules pertaining to the distribution of controlled substance preparations.

g. The distributing prescription drug outlet or compounding prescription drug outlet must retain the following information on a current basis for each practitioner, hospital prescription drug outlet or hospital other outlet or, when allowable, each prescription drug outlet, to whom it distributes compounded products:

(1) Verification of practitioner's license, or hospital prescription drug outlet's or hospital other outlet's registration; and

(2) Verification of practitioner's or hospital prescription drug outlet's or hospital other outlet's current Drug Enforcement Administration registration, if controlled substances are distributed;

h. Labeling of compounded products which are distributed shall comply with rule 21.11.10(c) or (d) or 21.21.70(c) or (d), whichever is applicable.

i. Records of distribution shall comply with rule 11.07.10 or 11.07.20, whichever is applicable.

21.00.30 Definitions. When used in this Rule 21.00.00, the following words and terms shall have the following meanings, unless the context clearly indicates otherwise.

a. Active Pharmaceutical Ingredient (API): Chemicals, substances or other components of preparations intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases in human or other animals or for use as dietary supplements.

b. Batch (Lot): Multiple units of the same compounded preparation in a single discrete process, by the same individuals, carried out during one limited time period.

c. Beyond-Use Date (BUD): A date after which a compounded preparation should not be stored, used or transferred and is determined from the date the preparation is compounded.

~~**d. Companion animal: An animal, other than a food animal, as defined by the Colorado Board of Veterinary Medicine.**~~

~~e~~d. Component (ingredient): Any substance which is contained in a compounded preparation.

~~f~~e. Compounding:

(1) The preparation, mixing, or assembling, of one or more active ingredients with one or more other substances, or the assembling of a finished device:

(a) Formulated for use on or for the patient 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

(b) For the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing; or

(c) In anticipation of prescription orders based on routine, regularly-observed prescribing patterns.

(2) Compounding does not include the preparation of copies of commercially available drug products. Compounded preparations that produce, for the patient, a significant difference between the compounded drug and the comparable commercially available drug product as determined, by the prescriber, as necessary for the medical best interest of the patient are not copies of commercially available products. "Significant differences" may include, but are not limited to, the removal of a dye for medical reasons (such as allergic reaction), changes in strength, and changes in dosage form or delivery mechanism. Price differences are not a "significant" difference to justify compounding.

~~g~~f. Preparation or Product: A compounded drug dosage form, a compounded dietary supplement, or a finished device.

~~h~~g. **Quality Assurance (QA): Set of activities used to ensure that the processes used in the preparation of non-sterile or sterile drug products lead to products that meet predetermined standards of quality.**

~~i~~h. **Quality Control (QC): Set of testing activities used to determine that the ingredients, components and final non-sterile or sterile drug products prepared meet pre-determined requirements with respect to strength, identity, quality, and purity.**

~~j~~i. **Repackaging: The subdivision or transfer of a product from one container or device to a different container or device. Repackaging does not constitute compounding, whether or not the product being repackaged was previously compounded.**

~~k~~j. **SOPS: Standard operating procedures.**

~~l~~k. **Stability: Extent to which a preparation retains, within specified limits, and throughout its period of storage and use, the same properties and characteristics that it possessed at the time of compounding.**

~~m~~l. **USP/NF: The current edition of the United States Pharmacopeia/National Formulary.**

~~n~~m. **Validation: Documented evidence providing a high degree of assurance that specific processes will consistently produce a product meeting predetermined specifications and quality attributes.**

~~o~~n. **Vehicle: A component for internal or external use that is used as a carrier or diluent in which liquids, semisolids, or solids are dissolved or suspended. Examples include, but are not limited to, water, syrups, elixirs, oleaginous liquids, solid and semisolid carriers, and proprietary products.**

23.00.00 ELECTRONIC PRESCRIPTION MONITORING PROGRAM.

23.00.10 Definitions:

a. "Bona fide investigation," for purposes of an investigation of an individual prescriber under investigation by a state regulatory board, means:

1. Any investigation conducted by any state regulatory board within the Colorado Division of Professions and Occupations, or the Director of the Colorado Division of Professions and Occupations and

2. Investigations pertaining to matters which are the subject of a complaint or notice of charges pending in the Office of Administrative Courts so long as the information obtained from the PDMP is made available by the state regulatory board to the respondent in the pending case.

b. "Bona fide research or education" means research conducted by qualified entities whose recognized primary purpose is scientific inquiry; the results of which would likely contribute to the basic knowledge of prescribing practitioners, dispensing pharmacists, or entities for the purpose of curtailing substance abuse of consumers. The Board shall determine in its discretion on a case-by-case basis whether an individual or entity seeking access to the PDMP pursuant to CRS 12-42.5-404(5) constitutes "bona fide research or education" conducted by qualified personnel for purposes of satisfying the statutory limitations therein.

c. "Client", as it pertains to a licensed veterinarian's use of the PDMP, means the patient's owner, the owner's agent, or a person responsible for the patient.

~~c~~d. "Clinical patient care services" means pharmaceutical care provided in a clinical setting. The pharmacist providing clinical patient care services must be working closely with the physician/prescriber responsible for the patient's care. "Clinical patient care services" do not include monitoring previously dispensed prescriptions for any purpose in the absence of a current assessment of a patient whether in a clinical setting or not.

~~d~~e. "Law Enforcement Official" means any of the following:

1. Sheriff;

2. Undersheriff;

3. Certified deputy sheriff;

4. Coroner;

5. Police Officer;

6. Southern Ute Police Officer;

7. Ute Mountain Ute police officer;

8. Town marshall;

9. CBI director and agents;

10. Colorado state patrol officer;

11. Colorado attorney general and any entity designated as "peace officers" by the Attorney General or acting on behalf of a state agency;

12. Attorney general criminal investigator;

13. District attorney and all assistants, deputies, etc. statutorily defined as "peace officers;"

14. District Attorney chief investigator and investigators;

15. Police administrator and police officers employed by the Colorado State Hospital in Pueblo; and

16. Federal special agents.

~~e~~f. "Legitimate program to monitor a patient's controlled substance abuse" means a program in which prescribers actively monitor a patient's controlled substance use. Such programs shall only involve patients in pain management or other controlled substance management programs. Such programs shall actively monitor the patient's controlled substance usage by means of urine or other drug screens in addition to the use of the PDMP. The patient must be informed in writing that his/her controlled substance usage is being actively screened by various methods, including review of the PDMP.

g. "Mistreat", as it pertains to a licensed veterinarian's use of the PDMP, means every act or omission which causes or unreasonably permits the continuation of unnecessary or unjustifiable pain or suffering.

h. "Patient", as it pertains to a licensed veterinarian's use of the PDMP, means an animal that is examined or treated by a licensed veterinarian and includes herds, flocks, litters and other groups of animals.

~~f~~i. "PDMP" means the Electronic Prescription Drug Monitoring Program.

~~g~~j. "Prescriber" or "practitioner" means a licensed health care professional with authority to prescribe a controlled substance.

~~h~~k. "Prescription Drug Outlet" or "Dispenser" means any resident or nonresident pharmacy registered with the Board.

~~i~~l. "Qualified personnel" means persons who are appropriately trained to collect and analyze data for the purpose of conducting bona fide research or education.

~~j~~m. "Valid photographic identification" means any of the following forms of identification which include an identifying photograph:

1. A valid driver's license, or identification issued by any United States state;

2. An official passport issued by any nation; or

3. A United States armed forces identification card issued to active duty, reserve, and retired personnel and the personnel's dependents.

23.00.70 PDMP Access

The PDMP shall be available for query only to the following persons or groups of persons:

a. Board staff responsible for administering the PDMP;

b. Any licensed practitioner, or up to three (3) trained individuals designated by the practitioner by way of registered PDMP sub-accounts of the prescriber to act on the prescriber's behalf in accordance with 12-42.5-403(1.5)(b), (c) and (d), C.R.S., with the statutory authority to prescribe controlled substances to the extent the query relates to a current patient of the practitioner to whom the practitioner ~~is prescribing or considering prescribing a controlled substance~~;

c. Any licensed veterinarian with statutory authority to prescribe controlled substances, to the extent the query relates to a current patient or to a client and if the veterinarian, in the exercise of professional judgment, has a reasonable basis to suspect the client has committed drug abuse or has mistreated an animal.

d. Licensed pharmacists, or up to three (3) trained individuals designated by the pharmacist by way of registered PDMP sub-accounts of the pharmacist to act on the pharmacist's behalf in accordance with 12-42.5-403(1.5)(b), (c) and (d), C.R.S., or a pharmacist licensed in another state, with statutory authority to dispense controlled substances 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;

e. Practitioners engaged in a legitimate program to monitor a patient's controlled substance abuse;

f. Law enforcement officials so long as the information released is specific to an individual patient, prescriber, or prescription drug outlet and part of a bona fide investigation and the request for information is accompanied by an official court order or subpoena. Such official court orders or subpoenas shall be submitted with the Board-provided form;

g. The individual who is the recipient of a controlled substance prescription so long as the information released is specific to such individual. The procedure for individuals to obtain such information is as follows:

1. The individual shall submit a written, signed request to the Board on the Board-provided form;

2. The individual shall provide valid photographic identification prior to obtaining the PDMP information;

3. An individual submitting a request on behalf of another individual who is the recipient of a controlled substance prescription may only obtain PDMP information if the following documents are provided:

(A) The original document establishing medical durable power of attorney of the individual submitting the request as power of attorney for the individual who is the recipient of the controlled substance prescription, and

(B) Valid photographic identification of the individual submitting the request.

h. State regulatory boards within the Colorado Division of Professions and Occupations and the Director of the Colorado Division or Professions and Occupations so long as the information released is specific to an individual prescriber and is part of a bona fide investigation and the request for information is accompanied by an official court order or subpoena. Such official court orders or subpoenas shall be submitted with the Board-provided form; and

i. A resident physician with an active physician training license issued by the Colorado medical board pursuant to section 12-36-122 and under the supervision of a licensed physician to the extent the query relates to a current patient of the resident physician to whom the resident physician is prescribing or considering prescribing a controlled substance.

j. The Department of Public Health and Environment for purposes of population-level analysis, but any use of the program data by the department is subject to the federal "Health Insurance Portability and Accountability Act of 1996 (HIPAA) and any rules promulgated pursuant to HIPAA, including the requirement to remove any identifying data unless exempted from the requirement.

k. A person authorized to access the PDMP may knowingly release PDMP information specific to an individual or to the individual's treating providers in accordance with HIPAA, Pub.L. 104-191, as amended, and any rules promulgated pursuant to HIPAA without violating Part 4 of Title 12, Article 42.5.