Basis and Purpose: Pursuant to CRS 12-42.5-105(2), on or before January 1, 2014, the Board shall amend or adopt rules as necessary to permit the dispensing of an opiate antagonist by a pharmacist to a person who is at increased risk of experiencing or likely to experience an opiate-related drug overdose event or to a family member, friend, or other person who is in a position to assist such a person, so long as the order for the opiate antagonist provides for the dispensing of the opiate antagonist to such a family member, friend, or other person.

Authority for Promulgation of Rules: Sections 12-42.5-101, 12-42.5-105, and 24-4-103, C.R.S.

3.00.21 A pharmacist shall make every reasonable effort to ensure that any order, regardless of the means of transmission, has been issued for a legitimate medical purpose by an authorized practitioner. A pharmacist shall not dispense a prescription drug if the pharmacist knows or should have known that the order for such drug was issued on the basis of an internet-based questionnaire, an internet-based consultation, or a telephonic consultation, all without a valid preexisting patient-practitioner relationship. A pharmacist may, in good faith, dispense an opiate antagonist pursuant to an order that was issued without a valid preexisting patient-practitioner relationship under the following conditions:

a. The opiate antagonist is not a controlled substance; and

b. The opiate antagonist is approved by the Federal Food and Drug Administration for the treatment of a drug overdose.

3.00.22 The dispensing of an opiate antagonist, as described in Rule 3.00.21, by a pharmacist shall not constitute unprofessional conduct pursuant to CRS 12-42.5-123 if he or she dispensed the opiate antagonist in good faith pursuant to an order issued to the following:

a. A person who is at increased risk of experiencing or likely to experience an opiate-related drug overdose event, which is defined as an acute condition, including but not limited to a decreased level of consciousness or respiratory depression resulting from the consumption or use of a controlled substance, or another substance with which a controlled substance was combined, and that a layperson would reasonably believe to be an opiate-related drug overdose event that requires medical attention; or

b. A family member, friend, or other person who is in a position to assist a person who is at increased risk of experiencing or likely to experience an opiate-related drug overdose event as defined in subsection a. of this Rule 3.00.22.

Basis and Purpose: The addition of this proposed Rule 3.00.55 is to state what is required when flavoring a prescription.

Authority for Promulgation of Rules: Sections 12-42.5-101, 12-42.5-105, 12-42.5-106, and 24-4-103, C.R.S.

3.00.55 Prescription Flavoring.A flavor additive may be incorporated into a non-sterile prescription under the following conditions:

a. The patient, patient's caregiver, or practitioner who authorized the original prescription shall authorize the flavoring of each new and, if applicable, refilled prescription;

b. The flavor additive shall in no way compromise the stability, safety, or efficacy of the dispensed drug.

c. No expired flavor additive shall be incorporated into a prescription. No flavor additive shall be incorporated which will expire prior to utilization by the patient, based on the practitioner's directions for use.

d. For flavoring additives that do not have expiration dates assigned by the manufacturer or supplier, a pharmacist shall clearly and legibly label the container with the date of receipt and assign a conservative expiration date, not to exceed three (3) years after receipt, to the flavoring additive. In no event shall the labeled date of receipt or assigned expiration date be later altered after originally labeling the container.

e. The following information shall be recorded and maintained in a suitable hard-copy or electronic dispensing record for a period of two years from the date of flavoring the corresponding new or refilled prescription. This record shall be made available, in printed form, for the Board or its representatives immediately upon the request of the Board or its representatives.

(1) Additive's flavor;

(2) Flavor additive's manufacturer

(3) Flavor additive's lot number (if available); and

(4) Flavor additive's expiration date.

f. The pharmacist responsible for conducting the final evaluation of a new or refilled prescription shall also be responsiblefor the flavoring of the prescription as specified in subsections a., b., and c. of this Rule 3.00.55.

g. The pharmacist manager shall be responsible for subsection d. of this Rule 3.00.55 and the maintenance of records as specified in subsection e. of this Rule 3.00.55.

Basis and Purpose: The amendment of this Rule 3.00.90 is to prohibit the return to stock of a compounded or flavored prescription at a pharmacy when compounded or flavored at another pharmacy.

Authority for Promulgation of Rules: Sections 12-42.5-101, 12-42.5-105, 12-42.5-106, and 24-4-103, C.R.S.

3.00.90 Prescriptions Dispensed but Not Delivered. When a drug has been dispensed pursuant to a prescription or LTCF chart order but has not been delivered to the ultimate consumer, the drug may be returned to stock for subsequent redispensing provided that:

a. It is stored in the container in which it was dispensed, with the original prescription label intact;

b. A separate written record or a separate record printable upon request is maintained for prescriptions returned to stock. Such record shall indicate only prescriptions returned to stock and shall list at minimum the following:

(1) Prescription number;

(2) Drug name and strength;

(3) Quantity returned to stock;

(4) Date of return; and

(5) If centrally filled, the location where filled.

c. The expiration date of the drug shall not be more than one year from the date it was dispensed. Unless it was dispensed in the manufacturer's original container and bears the manufacturer's original label and expiration date; and

d. The drug remains under the same ownership from which it was originally dispensed or is dispensed from a pharmacy in which the pharmacy has a contractual affiliation for central fill processing;

e. If the drug was delivered to another prescription drug outlet for delivery to the ultimate consumer, the following apply:

(1) The lot number and manufacturer's expiration date must be placed on the label of the drug container by the original dispensing prescription drug outlet; or

(2) The original dispensing prescription drug outlet can access and provide the expiration date and lot number upon request.

(3) No controlled substance prescriptions may be returned to stock.

(4) No compounded or flavored prescriptions may be returned to stock.

Basis and Purpose: The proposed amendment to Rule 3.01.20(c) is being promulgated to clarify, by reference to the addition of proposed Rule 3.01.30, the labeled beyond-use date of a repackaged sterile product. The addition of proposed Rule 3.01.30 is to state what is required when repackaging a sterile product from a manufacturer's stock container or device into another suitable container or device in advance of immediate need for the purpose of future dispensing or distribution.

Authority for Promulgation of Rules: Sections 12-42.5-101, 12-42.5-105, 12-42.5-106, and 24-4-103, C.R.S.

3.01.00 Packaging.

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 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; and

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

3.01.20 Each packaged container, whether for use in a unit dose distribution system or a traditional dispensing system, shall be labeled in accordance with this rule. Any packaged unit dose, single dose or unit of issue container for which return for restocking and redispensing, pursuant to 3.00.80, is anticipated, shall be labeled in accordance with this rule. Additionally, any packaged container from which subsequent dispensing may occur, shall be labeled in accordance with this rule. Such labeling shall include at least the following:

a. If a suitable internal record is maintained in the prescription drug outlet or other outlet, the requirements of (d), (e), (f), (g), and (h) of this rule may be omitted from the labeling and maintained in such record. An internal lot number shall be assigned and shall appear in the labeling. In a prescription drug outlet the record shall be signed by the pharmacist responsible for each lot packaged. In another outlet the record shall be signed by the person specified in the Board approved protocol. The record shall be retained for two years from the date of packaging unless otherwise required by law or rule.

b. Name and strength of the medication, and, in the case of a single dose package, the total number of individual tablets or capsules per dose;

c. A suitable expiration date, which shall be not later than the expiration date on the

manufacturer's container, or one year from the date the drug is packaged, whichever is less. Sterile packaged product beyond-use dating shall comply with Rule 3.01.34(h)(3));

d. The identity of the manufacturer or distributor;

e. The manufacturer's or distributor's lot number;

f. The manufacturer's or distributor's expiration date;

g. The date the product was packaged;

h. The identity of the pharmacist responsible for packaging in a prescription drug outlet, or, in the case of an other outlet, the identity of the non-pharmacist permitted to do so pursuant to protocols approved by the Board.

i. The name and address of the packaging pharmacy if the drug is distributed by a prescription drug outlet owned and operated by a hospital that is accredited by the Joint Commission of Accreditation of Healthcare Organizations or a successor organization or by a prescription drug outlet operated by a health maintenance organization as defined in section 10-16-102, C.R.S. Such drugs may only be distributed to prescription drug outlets under common ownership.

3.01.21 If the unit dose package or unit of issue package is obtained from the manufacturer or distributor and complies with applicable federal requirements, such package may be dispensed without additional labeling as required in 3.01.20 above.

3.01.22 Filling of automated cassettes.

a. If a multi-source drug, the outlet may not use drugs in the same cassette from multiple manufacturers or distributors;

b. Schedule II controlled substances may not be packaged into automated cassettes.

c. Automated cassettes, without electronic maintenance or records, shall be labeled with the following:

1. If a suitable internal record is maintained in the prescription drug outlet or other outlet, the requirements of 4, 5, 6, 7, and 8 of this rule may be omitted from the labeling and maintained in such record. An internal lot number shall be assigned and shall appear in the labeling. In a prescription drug outlet the record shall be signed by the pharmacist responsible for each lot packaged. In an other outlet the record shall be signed by the person specified in the Board approved protocol. The record shall be retained for two years from the date of packaging, unless otherwise required by law or rule.

2. Name and strength of the medication;

3. A suitable expiration date, which shall be not later than the expiration date on the manufacturer's container, or one year from the date the drug is packaged, whichever is sooner;

4. The identity of the manufacturer or distributor;

5. **The manufacturer's or distributor's lot number(s);**

6. **The manufacturer's or distributor's expiration date;**

7. **The date the product was packaged;**

8. **The identity of the pharmacist responsible for packaging in a prescription drug outlet, or, in the case of another outlet, the identity of the non-pharmacist permitted to do so pursuant to protocols approved by the Board;**

9. **All records detailing item 1-8 above, shall be retained at the pharmacy for at least two years.**

d. **In the event that the automation associated with the cassettes deactivates the cassette when the suitable expiration date is reached, and the outlet either prints packaging printouts on a daily basis or is capable of electronically maintaining the packaging information, the cassette need only be labeled with the name and strength of the drug.**

e. **In the event of a product recall, the pharmacist manager shall reasonably ensure that all recalled drug has been removed from the cassette.**

3.01.23 Maintenance of automated cassette records.

A prescription drug outlet may utilize a computer (automated data processing system) for storage and retrieval of information regarding packaging in automated cassettes. The following requirements shall be met:

a. **All information required by rule 3.01.22 c (1-8) shall be entered into the system at the time of the transaction.**

b. **Every 24 hours the system must produce a hard-copy document that, for the purposes of these rules, shall be known as the "packaging printout". It shall consist of a single, uniform, complete document. The packaging printout shall list, separately, each packaging transaction for the previous 24 hours and shall contain all information required by this rule. Packaging printouts shall be retained in a chronological manner. If the printouts are bound, the sheets shall be separated into individual pages that are then placed in the same order as printed and bound uniformly. If the pages are bound in any other manner so that they are not uniform in placement or appearance, they shall be deemed not readily retrievable and available.**

3.01.24 Electronic Maintenance of Packaging Records.

A prescription drug outlet which utilizes a computer (automated data processing system) for storage and retrieval of information regarding packaging transactions need not print the packaging printout required by rule 3.01.23 if the prescription drug outlet and the computer system utilized are capable of complying with the following requirements:

a. **The prescription drug outlet must be able to provide on-line retrieval of all information required by this rule for all packaging transactions during the two years preceding the request.**

b. **The prescription drug outlet must ensure a daily (i.e., every twenty-four hours) back up is performed for use in restoring required information in case of a system failure.**

c. **The prescription drug outlet must:**

(1) **Have and maintain a complete on-line transaction file that is printable on the inspector's request,**

or

(2) **Have a "lock-out" feature that prevents editing of packaging information.**

d. **The Board or its inspectors must be able to inspect and review the packaging transactions of the prescription drug outlet. Therefore, immediately upon the oral or written request of the Board or its inspectors, the prescription drug outlet shall either:**

(1) **Print a report of all packaging transactions for such period of time as the Board or its inspector(s) may specify. The system must be capable of retrieving and printing such a report within a limited time not to exceed two hours. Additionally within 72 hours, the system must be capable of retrieving and printing the information sorted according to the variables which include, but are not limited to, date packaged; drug name, strength and dosage form; lot number, manufacturer/distributor; or expiration date.**

(2) **Provide a computer terminal and monitor for the sole use of the Board or its inspector(s) to inspect and review packaging transactions, and, if necessary, provide a person to assist the Board or its inspector(s) for a period of time not to exceed two hours in operating the system. If the prescription drug outlet elects to comply with this subparagraph (d), the system must also be capable of printing the same reports described in subparagraph (1).**

(3) **It is the responsibility of the prescription drug outlet manager to ensure that all prescription drug outlet staff are aware of the requirements of subparagraphs (1) and (2). Any failure or refusal by the prescription drug outlet manager and/or a staff pharmacist to comply with a request by the Board or its inspector(s) will be deemed to be a willful violation of these rules.**

e. **Whether the prescription drug outlet elects to comply with rule3.01.24(d), the system and any reports printed on request shall contain, as a minimum, the following information for each transaction:**

1. **Name and strength of the medication;**

2. **A suitable expiration date, which shall be not later than the expiration date on the manufacturer's container, or one year from the date the drug is packaged, whichever is sooner;**

3. **The identity of the manufacturer or distributor;**

4. **The manufacturer's or distributor's lot number(s);**

5. The manufacturer's or distributor's expiration date;

6. The date the product was packaged;

7. The identity of the pharmacist responsible for packaging in a prescription drug outlet, or, in the case of an other outlet, the identity of the non-pharmacist permitted to do so pursuant to protocols approved by the Board;

3.01.25 Maintenance and cleaning of automated cassettes

a. The outlet must maintain, on-site and available for inspection, the manufacturer's guidelines for maintenance and cleaning of the cassettes.

b. The maintenance and cleaning schedule recommended by the manufacturer shall be adhered to and records of performed maintenance shall be available for inspection for a period of at least two years.

c. If the outlet changes the drug used in a cassette, the cassette must be thoroughly cleaned per manufacturer's recommendations prior to using the cassette for a different drug.

3.01.26 Responsibility for unit-dose medications packaged with automated cassettes is the responsibility of the pharmacist responsible for loading the cassette.

3.01.27 The pharmacist responsible for the final evaluation of any prescriptions dispensed using drugs packaged in automated cassettes shall be held accountable for the accuracy of the product.

3.01.30 Sterile Product Packaging.

3.01.32 "Sterile product packaging" means the transfer of a sterile drug, in part or in whole, from one container or device to another container or device in advance of immediate need for the purposes of future dispensing or distribution.

3.01.34 a. Each packaged container shall be labeled according to Rule 3.01.20(a) through (i).

b. All sterile products shall be packaged under the environmental quality, controls and monitoring specified in Rules 21.20.60through 21.60.90.

c. Each outlet engaged in sterile product packaging shall maintain a policy and procedure manual that shall be reviewed, signed and dated by the pharmacist manager at least once annually, and within 30 days of a new pharmacist manager assuming that position. The manual shall at least address the following:

(1) Responsibilities of sterile product packaging personnel;

(2) Verification of packaging sterilization if not using packagingthat is sterile

(3) Personnel training and evaluation in aseptic manipulation skills;

(4) Environmental quality and control;

(5) Aseptic processing;

(6) Labeling and recordkeeping;

(7) Finished preparation release check;

(8) Storage and beyond-use dating;

(9) Maintaining product quality and control during transportation and delivery after the packaged sterile product leaves the pharmacy;

(10) Patient or caregiver training;

(11) Adverse event reporting and recalls;

(12) Quality assurance program;

(13) Quality control procedures; and

(15) Manner by which storage excursions are handled and documented.

d. All pharmacy personnel engaged in sterile product packaging shall receive suitable didactic and experiential training which, at minimum, includes aseptic processing, environmental testing, as well as the selection and use of containers, equipment and closures.

e. Written procedures outlining equipment used in sterile product packaging, calibration, appropriate maintenance, monitoring for proper function, controlled procedures for use of the equipment, and specified time frames for these activities shall be established and followed. Results of equipment calibration and appropriate maintenancereports shall be maintained on file at the outlet for at least two years from the report date and shall be available for inspection.

f. Accuracy assessments of automated sterile packaging devices shall be conducted daily for each day used. At least annually, the pharmacist manager, or his or her designee, shall review these assessments to avoid potentially significant errors. These assessments shall be documented and available for inspection at the outlet for at least two years.

g. All sterile product packaging shall by individually inspected pursuant to written procedures. Immediately after packaging, and prior to dispensing or distribution, each packaged product shall be inspected for evidence of particulates or other foreign matter, container-closure integrity, precipitation, cloudiness, and any other apparent visual defect. Defective product shall be segregated from other product and shall not be dispensed or distributed.

h. Storage and Beyond-Use Dating (BUD).

(1) All sterile packaged products shall be stored in accordance to the corresponding manufacturers' storage directions. The temperature of drug storage areas of sterile packaged products shall be monitored and recorded daily, either manually or electronically. Temperature records shall be maintained and available for inspection at the outlet for at least two years.

(2) Finished packaged sterile products that are not immediately dispensed, distributed, or administered shall be refrigerated or frozen unless their

chemical and physical stability are known to be adversely affected by cold or freezing temperatures.

(3) In the absenceof sterility testing compliant with the most current United States Pharmacopeia/National Formulary Chapter 71 <Sterility Tests>, the BUD of all sterile product packaging shall not exceed the following:

(a) Low risk packaged sterile products with greater than 12-hour BUD:

Room temperature:	**No more than 48 hours**
Refrigerated temperature:	**No more than 14 days**
Frozen:	**No more than 45 days**

(b) Low risk packaged sterile products with 12-hour or less BUD:

Room temperature:	**No more than 12 hours**
Refrigerated temperature:	**No more than 12 hours**
Frozen:	**Not applicable**

i. If, after tests or observations, a sterile packaged product is believed to be defective in any way, the outlet shall immediately recall any product dispensed or distributed. Any product remaining in the outlet shall be immediately quarantined and shall not be dispensed or distributed. Recall records shall be maintained and available for inspection at the outlet for at least two years and shall include at least the following:

(1) Product name, strength, dosage form;

(2) Reason for recall;

(3) Amount of product packaged;

(4) Date packaged; and

(5) Amount of product dispensed and/or distributed.

Basis and Purpose: The purpose of amending Rules 4.00.10 and 4.00.20 is to reflect an amendment made to CRS 12-42.5-102(17), which no longer defines an "Intern" to mean a licensed pharmacist in Colorado or another state or territory of the United States who is making clinical rotations of the nontraditional pharmacy program at the University of Colorado or a substantially equivalent program as determined by the Board.

Authority for Promulgation of Rules: Sections 12-42.5-101, 12-42.5-102, 12-42.5-105, and 24-4-103, C.R.S.

4.00.00 LICENSING.

4.00.10 Definitions

a. "Academic examination" is the North American Pharmacist Licensure Examination.

b. "Board-approved foreign pharmacy graduate certification" means the Foreign Pharmacy Graduate Equivalency Certification.

c. "Board-approved jurisprudence examination" means the Colorado-specific Multistate Pharmacy Jurisprudence Examination.

d. "Board-approved school or college of pharmacy" is a professional degree program of a school or college of pharmacy that has an accredited or preaccredited status from the Accreditation Council for Pharmacy Education ("ACPE").

e. "Board-designated clearinghouse for license transfer" means the National Association of Boards of Pharmacy Clearinghouse operated by the National Association of Boards of Pharmacy.

f. "Intern" means a person who is:

(1) Enrolled in a professional degree program of a Board-approved school or college of pharmacy, licensed by the Board to engage in the practice of pharmacy, and satisfactorily progressing toward meeting the requirements for licensure as a pharmacist;

(2) A graduate of a Board-approved school or college of pharmacy or a graduate who has established education equivalency by obtaining a Board-approved foreign pharmacy graduate certification and who is currently licensed by the Board for the purpose of obtaining practical experience as a requirement for licensure as a pharmacist; or

(3) A qualified pharmacist applicant awaiting examination for licensure as a pharmacist or meeting Board requirements for pharmacist licensure.

4.00.20 Requirements for Intern Licensure include the following;

a) Submission of a completed application form provided by the Division of Professions and Occupations with the appropriate fee.

b) Submission of one of the following:

1) Proof of enrollment in a Board-approved school or college of pharmacy. A person on suspension from a Board-approved school or college of pharmacy may not be licensed as an intern. A person in good standing with a Board-approved school or college of pharmacy may be licensed as an intern.

2) If a graduate of a foreign school or college of pharmacy, a Foreign Pharmacy Graduate Equivalency Certification;

3) Proof of graduation within the prior two years from a Board-approved school or college of pharmacy. If the applicant ceased to be enrolled in a Board-approved school or college of pharmacy more than two years prior to application, the applicant shall include an explanation of "good cause" for licensure which the Board or its designee shall review and act on in the normal course of business.

4) If a pharmacist in another state awaiting pharmacist licensure in Colorado, verification of an active, unrestricted license in another state.

Basis and Purpose: The proposed amendment to Rule 5.01.31 is being promulgated to allow prescription drug outlets to utilize a locked door or doors to separate parts of a prescription drug outlet's compounding/dispensing area provided the locked door or doors is unlocked upon the request of the Board or its representatives.

Authority for Promulgation of Rules: Sections 12-42.5-101, 12-42.5-105, 12-42.5-106, and 24-4-103, C.R.S.

5.01.31 Within every prescription drug outlet as defined in CRS 12-22-102(30.2), there shall be one area designated as the principal compounding/dispensing area. In addition to the principal compounding/dispensing area there may be one or more satellite compounding/dispensing areas ("satellites") which are located in the same building as the principal compounding/dispensing area. The principal compounding/dispensing area and any satellite shall comply with the following conditions:

a. The principal compounding/dispensing area shall not be less than 225 continuous square feet, except that prescription drug outlets registered by the Board prior to the effective date of this regulation that do not meet this space requirement are hereby exempted from such requirement. However, any new prescription drug outlet shall comply with this requirement prior to the granting of the initial registration. Any existing prescription drug outlet which is being remodeled or is being moved from one location to another, whether or not there is a change of address, shall submit documentation required by the Board prior to remodeling or relocation. Satellite compounding/dispensing areas at the same location must not be less than 100 continuous square feet and must be approved by the Board prior to use for compounding/dispensing.

(1) Any room or rooms included within or adjacent to the principal compounding / dispensing area that are separated from the principal compounding / dispensing area by a door must meet the following:

(A) The prescription drug outlet shall submit documentation required by the board to remodel the principal compounding / dispensing area prior to the utilizing the room or rooms for the purposes of compounding and dispensing or for the storage of prescription drugs and controlled substance stocks;

(B) The door must have a conspicuously displayed sign attached to it, and facing the principal compounding / dispensing area, that states "This room is part of the Board-approved designated principal compounding / dispensing area";

(C) If a locked or otherwise secured door is used to separate parts of the compounding / dispensing area, it shall be unlocked immediately upon the request of the Board or of its inspectors and be available for inspection.

Basis and Purpose: The purpose of amending Rule 15.01.14 is to reflect CRS 12-42.5-118(3)(b), which requires a practitioner-written order issued for an animal to be provided to a wholesaler after receiving an oral order for a schedule III, IV or V controlled substance. Written orders would no longer have to be provided to wholesalers for animals following an oral order for prescription drugs that are not a schedule III, IV or V controlled substance.

Authority for Promulgation of Rules: Sections 12-42.5-101, 12-42.5-105, 12-42.5-118, and 24-4-103, C.R.S.

15.10.14 A wholesaler may sell or deliver to a person responsible for the control of an animal a drug intended for veterinary use provided the following conditions are met:

a. A licensed veterinarian has issued, prior to such sale or delivery, either a written or oral prescription order for the drug in the course of an existing, valid veterinarian-client-patient relationship. If the order is for a Schedule III, IV or V controlled substance and it is transmitted orally, it must be immediately transcribed to writing and the practitioner's written prescription order shall be transmitted to the wholesaler within three business days of the oral order;

b. If the order was transmitted orally, the practitioner's written prescription order shall be attached to the oral order and retained as the original order;

c. The drugs, prior to distribution, may not be packaged or dispensed by the registrant;

d. The drugs, once distributed, may not be returned to the registrant for resale or redistribution;

e. The prescription order issued by the veterinarian becomes void after one year if for a non-controlled drug or a schedule II controlled substance, unless the veterinarian specifies a shorter expiration date. The registrant may not distribute larger quantities than the order authorizes.

f. If a schedule III, IV, or V controlled substance, the prescription order becomes void after six months from date of issue, unless the veterinarian specifies a shorter expiration date. The registrant may not distribute larger quantities than the order authorizes.

g. The original order must be retained on the premises of the registrant filed by client name. The invoices for each distribution authorized by the order must be attached to the order.

h. A drug distribution log must be retained on the premises of the registrant. It shall include the following information:

(1) Date sold/delivered;

(2) Client and patient name;

(3) Veterinarian name;

(4) Veterinarian's Drug Enforcement Administration registration if a controlled substance;

(5) Drug sold/delivered;

(6) Quantity drug;

(7) Date of issue of order;

(8) Expiration of order; and

(9) Invoice number.

Basis and Purpose: The purpose of amending Rule 23.00.90 is to add an exemption for interventional research entities dispensing controlled substances part of investigational dispensing transactions using investigational products from the data submission requirements of the Prescription Drug Monitoring Program, in order to allow double-blind studies without disclosure to study participants as to whether they are receiving a drug or a placebo.

Authority for Promulgation of Rules: Sections 12-42.5-101, 12-42.5-105, and 24-4-103, C.R.S.

23.00.90 Exemptions

a. The following individuals or entities are exempt from reporting controlled substance dispensing transactions to the Prescription Drug Monitoring Program:

1. Hospitals licensed or certified pursuant to CRS 25-1.5-103;

2. A prescription drug outlet located within a hospital licensed or certified pursuant to CRS 25-1.5-103 that dispenses controlled substances only pursuant to chart orders or dispenses no more than a 24-hour supply of a controlled substance to an outpatient;

3. Emergency medical services personnel certified pursuant to CRS 25-3.5-203; and

4. A prescription drug outlet which has applied to the Board and received a waiver from the Board. Waivers will only be considered if the pharmacy has no electronic automation. Such requests must be submitted in writing to the Board and will be considered in the normal course of business.

b. Controlled substance dispensing transactions that occur solely for Institutional Review Board (IRB) approved interventional research trials using investigational drug products that are regulated by the Federal Food and Drug Administration shall be exempt from the data submission requirements of the PDMP.