Basis and Purpose: The purpose of this amendment is clarify the required content of prescription orders, LTCF chart orders, and hospital chart orders.

Authority for Promulgation of Rules: Sections 12-42.5-101, 12-42.5-105, 12-42.5-106(2), 12-42.5-131(1)(a) and 24-4-103, C.R.S.

2.00.00 ORDERS.

2.01.10 Information to Appear on Each Order. The following information must appear on each written or oral order except as provided for chart orders for hospitalized patients (hospital chart orders):

a. The date the order was compounded and dispensed; ~~and~~

b. ~~In the case of a prescription or chart order for a resident of a long term care facility (LTCF chart order), the~~ THE assigned serial number (HOSPITAL CHART ORDERS ARE EXEMPT FROM THIS REQUIREMENT)~~.~~;

c. The quantity dispensed if differs from the quantity ordered (LTCF CHART ORDERS ARE EXEMPT FROM THIS REQUIREMENT PROVIDED THIS INFORMATION IS RECORDED WITHIN ANOTHER APPROPRIATE UNIFORMLY MAINTAINED AND READILY RETRIEVABLE PERMANENT RECORD OF THE DISPENSING PHARMACY)~~.~~; AND

d. In the case of a controlled substance order, the patient address, prescriber address, and prescriber's Drug Enforcement Administration registration.

Basis and Purpose: The purpose of the addition of this Rule 3.00.25 is to codify the practice of "first dose dispensing" and to specify the limitations and record-keeping requirements of such.

Authority for Promulgation of Rules: Sections 12-42.5-101, 12-42.5-105, 12-42.5-106(2), 12-42.5-131(1)(a) and 24-4-103, C.R.S.

3.00.25 FIRST DOSE DISPENSING. A PHARMACIST AT A PRESCRIPTION DRUG OUTLET MAY DISPENSE UP TO A SEVENTY TWO (72) HOUR SUPPLY OF A NON-CONTROLLED SUBSTANCE PRESCRIPTION DRUG TO AN LTCF RESIDENT PURSUANT TO A DUPLICATE COPY OF AN LTCF CHART ORDER PROVIDED BY ANOTHER PRESCRIPTION DRUG OUTLET FOR THE PURPOSE OF PROVIDING IMMEDIATE PATIENT CARE, ON A ONE TIME PER ORDER BASIS, IF THE FOLLOWING CONDITIONS ARE MET:

A. THE RECEIVING PRESCRIPTION DRUG OUTLET RECORDS ON THE PRESCRIPTION ORDER THE NAME AND ADDRESS OF THE ORIGINATING PRESCRIPTION DRUG OUTLET AND THE DATE THE ORDER WAS RECEIVED BY THE RECEIVING PRESCRIPTION DRUG OUTLET;

B. THE RECEIVING PRESCRIPTION DRUG OUTLET MAINTAINS THE ORDER AS A PRESCRIPTION ORDER AND COMPLIES WITH ALL REQUIREMENTS FOR PRESCRIPTION ORDERS SPECIFIED IN BOARD RULES 2.01.10 THROUGH 2.01.40, 3.00.10 THROUGH 3.00.51, AND 11.04.10; AND

C. THE ORIGINATING PRESCRIPTION DRUG OUTLET RECORDS ON THE LTCF CHART ORDER THE NAME AND ADDRESS OF THE RECEIVING PRESCRIPTION DRUG OUTLET AND THE DATE THE ORDER WAS PROVIDED TO THE RECEIVING PRESCRIPTION DRUG OUTLET.

Basis and Purpose: The purpose of the addition of this Rule 3.00.91 is to codify the practice of returning prescriptions back into stock at an original dispensing pharmacy after previously being delivered at a Board-registered other outlet, and to specify the limitations and record-keeping requirements of such.

Authority for Promulgation of Rules: Sections 12-42.5-101, 12-42.5-105, 12-42.5-106(2), 12-42.5-133(4) and 24-4-103, C.R.S.

3.00.91 PRESCRIPTIONS DISPENSED BY PRESCRIPTION DRUG OUTLETS FOR DELIVERY TO CONSUMERS IN OTHER OUTLET SETTINGS. WHEN A DRUG HAS BEEN DISPENSED PURSUANT TO A PRESCRIPTION ORDER AT A PRESCRIPTION DRUG OUTLET BUT HAS NOT BEEN DELIVERED TO THE ULTIMATE CONSUMER AT AN OTHER OUTLET, THE DRUG MAY BE RETURNED TO STOCK ONLY AT THE ORIGINATING PRESCRIPTION DRUG OUTLET FOR SUBSEQUENT REDISPENSING PROVIDED THAT:

A. THE PRESCRIPTION DRUG OUTLET COMPLIES WITH BOARD RULES 3.00.90(A), (B), AND (C);

B. THE STORAGE CONDITIONS DURING THE TRANSPORT OF THE PRESCRIPTION TO AND FROM THE OTHER OUTLET DOES NOT IN ANY WAY COMPROMISE THE INTEGRITY OR STABILITY OF THE DRUG;

C. NO CONTROLLED SUBSTANCE PRESCRIPTIONS MY BE RETURNED TO STOCK; AND

D. NO COMPOUNDED OR FLAVORED PRESCRIPTIONS MAY BE RETURNED TO STOCK.

Basis and Purpose: The purpose of the addition of this Rule 5.00.15 is to specifically outline the requirements for obtaining a nonresident pharmacy registration, and to offer an alternative remedy to applicant businesses that are unable to provide a report detailing an inspection of a business by the business' resident state board of pharmacy.

Authority for Promulgation of Rules: Sections 12-42.5-101, 12-42.5-105, 12-42.5-106(2), 12-42.5-130(1)(b) and (3) and 24-4-103, C.R.S.

5.00.15 REGISTRATION FOR NONRESIDENT PRESCRIPTION DRUG OUTLET. AN APPLICANT FOR A NEW NONRESIDENT PRESCRIPTION DRUG OUTLET REGISTRATION SHALL SUBMIT THE FOLLOWING:

A. THE CURRENT APPLICATION WITH REQUIRED FEE;

B. A VERIFICATION OF THE CURRENT PHARMACY LICENSE OR REGISTRATION ISSUED BY THE APPLICANT'S RESIDENT STATE BOARD OF PHARMACY;

C. A COPY OF THE MOST RECENT REPORT DETAILING AN INSPECTION OF THE NONRESIDENT PRESCRIPTION DRUG OUTLET BY EITHER ITS RESIDENT STATE BOARD OF PHARMACY OR THE NATIONAL ASSOCIATION OF BOARDS OF PHARMACY'S VERIFIED PHARMACY PROGRAM DATED WITHIN TWO (2) YEARS OF SUBMISSION OF THE APPLICATION; AND

D. AN AFFIDAVIT ATTESTING THAT THE NON-RESIDENT PRESCRIPTION DRUG OUTLET SHALL NOT SHIP COMPOUNDED OR OTHER PRESCRIPTION DRUGS INTO THE STATE OF COLORADO WITHOUT A PRESCRIPTION ORDER FOR A SPECIFIC PATIENT.

Basis and Purpose: The purpose of the amendment to this rule is to offer an alternative remedy to pharmacists who wish to practice drug therapy management while still addressing the requirement of education and training in order to perform such practice.

Authority for Promulgation of Rules: Sections 12-42.5-101, 12-42.5-105, 12-42.5-106(1)(e) and (2), and 24-4-103, C.R.S.

6.00.30 Pharmacist Qualifications.

Any pharmacist engaged in drug therapy management shall meet the following qualifications:

a. Have and maintain an unrestricted license in good standing to practice pharmacy in Colorado; and

b. Meet one of the following qualifications:

(1). Proof of completion of a pharmacy residency accredited by the American Society of Health Systems Pharmacists or the American Pharmacists Association in the specialty being practiced; or

(2). PROOF OF COMPLETION OF ONE (1) YEAR OF PRACTICE EXPERIENCE IN PHARMACOTHERAPY, AND 40 HOURS OF ONSITE SUPERVISED CLINICAL PRACTICE AND TRAINING IN EACH AREA IN WHICH THE PHARMACIST IS CHOOSING TO PRACTICE; OR

~~2~~(3). Completion of a certificate program accredited by the Accreditation Council for Pharmacy Education in each area of practice, and 40 hours of on-site supervised clinical practice and training in each area in which the pharmacist is choosing to practice; or

~~3~~(4). Completion of at least 40 hours of ACPE approved continuing education regarding clinical practice and 40 hours of onsite supervised clinical practice and training in the area in which the pharmacist is choosing to practice; or

~~4~~(5). Current Board specialty certification from the Board of Pharmaceutical Specialties, current certification from the National Institute for Standards in Pharmacist Credentialing, or current certification from the Commission for Certification in Geriatric Pharmacy. Such credentials must be in the area of pharmacy practice undertaken in the drug therapy management; or

~~5~~(6). In an inpatient or group model integrated closed HMO setting, all of the following criteria shall be met in order to practice drug therapy management:

(a). Forty (40) hours of onsite supervised clinical practice and training in the area(s) in which the pharmacist is choosing to practice;

(b). Protocols must be approved by the health-system's medical committee, or pharmacy and therapeutics committee; and

(c). Documented competency of each area of practice in which the pharmacist is choosing to practice shall be maintained on site.

c. Licensed Colorado pharmacists practicing drug therapy management prior to August 1, 2005, must attest and certify that they were provided clinical training, experience, and oversight practicing in the disease state(s) that they work in, and the physician with whom they are currently practicing must attest that they are practicing to the standard of care required for management of the specific disease. Such attestations must be on file at the site of practice. ~~Copies of their written agreement must be submitted to the Board.~~ Documentation of their employment dates must be on file as proof of practice prior to August 2, 2005.

Basis and Purpose: The purpose of the amendment to this rule is incorporate acute treatment units into the use of emergency kits to implement HB-1083.

Authority for Promulgation of Rules: Sections 12-42.5-101, 12-42.5-105, 12-42.5-106(2), 12-42.5-118(5)(a)(III)(A) and 24-4-103, C.R.S.

10.00.00 EMERGENCY KITS.

10.00.05 Definitions.

a. "Emergency kit" or "kit" means a tamper-evident sealed and secured container or secured electronic system containing drugs which are used for either immediate administration to patients of facilities delineated in 10.00.10 or in an emergency situation or as a starter dose.

b. "Starter dose" means a dose of medication contained in an emergency kit for the purpose of starting the initial therapy for a patient residing in a facility delineated in 10.00.10.

10.00.10 A prescription drug outlet or a hospital other outlet may provide an emergency kit to any of the following facilities that are licensed or certified by the Colorado Department of Public Health and Environment: Long-Term Care Facilities, Hospices, ACUTE TREATMENT UNITS and Home Health Agencies. Such kit is to provide an emergency supply of drugs, both controlled and non-controlled as provided below. The drugs maintained in the emergency drug supply shall remain the property of the prescription drug outlet or the hospital other outlet who supplied the drugs.

a. Only one prescription drug outlet or hospital other outlet may provide a kit to any of the above facilities. Multiple pharmacies or hospital other outlets may not supply emergency kits to the same facility.

b. The pharmacist manager of the prescription drug outlet supplying the kit or the consultant pharmacist of the hospital other outlet supplying the kit shall be responsible for the accurate stocking or restocking of the kit. He/she may delegate this function to non-pharmacist personnel, but the pharmacist manager or other outlet consultant pharmacist assumes responsibility for the accuracy of the contents of the kit.

10.00.20 Categories and Limits

a. For Long-Term Care Facilities, ACUTE TREATMENT UNITS, and Inpatient Hospices, the medical director of the facility, or equivalent, and the consulting pharmacist shall determine the specific drugs to be kept in the kit. The number of drugs allowed in the kit shall be limited to sixty (60). Of the 60, twelve (12) may be controlled substances. The kit may contain no more than thirty (30) doses of any separate drug dosage form or strength for each drug. The container size for each drug shall be limited to unit dose or unit of issue packaging.

b. In the case of a Certified Home Health Agency or an Outpatient Hospice, the director of nursing of the Certified Home Health Agency or of the Licensed Hospice, and a pharmacist employed and designated by the prescription drug outlet or hospital other outlet providing the kit shall determine the specific drugs to be kept in the kit. A Certified Home Health Agency or Outpatient Hospice may not have oral dosage forms or controlled substances in the kit. The container size for each injectable drug shall be limited to unit dose or unit of issue

packaging. The number of drugs allowed in the kit shall be limited to sixty (60). The kit may contain only thirty (30) doses of any separate drug dosage form or strength for each drug.

10.00.30 The kit shall be sealed with a tamper-evident seal or an electronic system which notifies the pharmacy when the kit has been accessed. Paper or tape seals are unacceptable. If an electronic system is utilized, the pharmacy and facility must maintain a written procedure for how the kit can be accessed in the event of downtime.

10.00.40 The following information shall be readily retrievable and up-dated as required:

a. Name, address and telephone number of the prescription drug outlet or hospital other outlet providing the contents of the kit;

b. The date of sealing of the kit;

c. A suitable expiration date which shall be the earliest expiration date of any drug in the kit, but in no event shall it be more than one year from the date of sealing; and

d. In the case of a Long-Term Care Facility, ACUTE TREATMENT UNIT or Inpatient Hospice, the name of the consulting pharmacist, or, in the case of a Certified Home Health Agency or an Outpatient Hospice, the name of the designated pharmacist.

10.00.41 A copy of the kit contents shall also be attached to the kit.

10.00.50 Access. Access to the contents of the kit shall be limited as follows:

a. In the case of a Long-Term Care Facility, ACUTE TREATMENT UNIT, or Inpatient Hospice, only a pharmacist employed by the prescription drug outlet or hospital other outlet which provides the kit or his/her designee, the consulting pharmacist, and any nurse employed at the facility shall have access.

b. In the case of a Certified Home Health Agency or an Outpatient Hospice, only a pharmacist employed by the prescription drug outlet or hospital other outlet which provides the kit or a nurse employed by the Certified Home Health Agency or an Outpatient Hospice shall have access.

10.00.51 Notification. A prescription drug outlet or hospital other outlet which supplies an emergency drug kit to a Long-Term Care Facility, ACUTE TREATMENT UNIT, Hospice, or home health agency shall notify the Board in writing within seven days that it has done so, specifying the name and address of the facility.

Notification must be repeated, within 30 days:

a. If there is any change of ownership of the kit,

or

b. If there is a change of the consulting pharmacist, in the case of a Long-Term Care Facility, ACUTE TREATMENT UNIT, or Inpatient Hospice, or of the designated pharmacist in the case of a Certified Home Health Agency or a Outpatient Hospice.

10.00.60 Inspection. A pharmacist employed by the prescription drug outlet or hospital other outlet providing the kit or that pharmacist's designee shall inspect and inventory the contents of the kit at least annually and within 72 hours after being notified that the kit

has been accessed. Inspection shall be documented by that pharmacist, and such documentation shall be maintained and available for inspection at the prescription drug outlet or hospital other outlet for a period of two years.

10.00.70 A separate record of use for each drug placed in the kit, and for each kit provided, which shall state the following Records. The prescription drug outlet or hospital other outlet providing the kit shall maintain:

a. The name and address of the ACUTE TREATMENT UNIT, Long-Term Care Facility, Certified Home Health Agency, or Hospice;

b. The name and strength of the drug; and

c. The container size and the quantity initially placed in the kit.

10.00.71 When a drug is removed for administration the prescription drug outlet or hospital other outlet shall obtain a prescription order or LTCF chart order for the drug within 72 hours after being notified that the kit was opened and the drug was used. The order shall indicate the total number of doses administered. The order shall be assigned a serial number and the order shall be retained as required by rule 11.04.10. Additionally, the separate record required for each drug in the kit shall reflect the following information:

a. Date and quantity administered;

b. Names of both the patient and practitioner;

c. Date the drug was replaced in the kit;

d. The quantity of the drug replaced, which shall not exceed the quantity administered or removed for administration; and

e. The prescription order number assigned.

10.00.80 Use. The drugs shall only be administered to patients of the ACUTE TREATMENT UNIT, long term care facility, certified home health care agency, or Hospice pursuant to the order of a practitioner.

Basis and Purpose: The purpose of the amendment to this rule is to require pharmacies owned and operated by a health maintenance organization (as defined in 10-16-102, C.R.S.) that maintain secured controlled substance floor stock within the same building of the pharmacy to incorporate the available quantities of controlled substance floor stock into the pharmacy's biennial controlled substance inventory.

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

11.03.00 Inventories of Controlled Substances. Any inventory of controlled substances shall comply with the following:

a. If the outlet is registered with the Drug Enforcement Administration as a "hospital/clinic" OR IS OWNED AND OPERATED BY A HEALTH MAINTENANCE ORGANIZATION (AS DEFINED IN SECTION 10-16-102, C.R.S.), the inventory shall include all drugs located throughout the facility, excluding any drug which has been dispensed pursuant to a lawful chart order but which has not yet been administered to the patient.

b. Each inventory shall contain a complete and accurate records of all controlled substances (including outdated controlled substances) on hand on the date the inventory is taken. The inventory shall be maintained in written, typewritten or printed form at the prescription drug outlet. Schedule II drugs shall be separated from schedule III, IV, and V drugs. Controlled substances shall be deemed to be "on hand" if they are in the possession of or under the control of the registrant. However, the inventory shall exclude any drug that has been dispensed pursuant to a lawful prescription order but which has not yet been delivered.

c. The inventory shall be taken either as of opening of business or as of the close of business on the inventory date and it shall be recorded on the inventory. In the event the prescription drug outlet is open 24 hours per day, the inventory shall specify the time the inventory was conducted.

d. After the initial inventory is taken, the prescription drug outlet shall take new inventory of all stocks of controlled substances on hand at least every two years.

e. On the effective date of a law or rule on which a previously non-scheduled drug is added to any schedule of controlled substances, every prescription drug outlet that possesses that drug shall take an inventory of all stocks of the drug on hand. Thereafter, that drug shall be included in each inventory made by the prescription drug outlet.

f. The following information shall be recorded on the inventory.

(1) The name of the drug;

(2) Each finished form of the drug (strength and dosage form);

(3) The number of units or volume of each finished form.

(4) All outdated controlled substances.

g. In determining the number of units of each finished form of a controlled substance in a commercial container which has been opened, the prescription drug outlet shall do as follows:

(1) If the drug is a schedule II drug, an exact count of the contents shall be made.

(2) If the substance is listed in schedule III, IV, or V, and estimated count of the measure of the contents may be made, unless the container holds more than 1,000 tablets or capsules, in which case an exact count of the contents must be made.

h. All controlled substance inventories shall be retained at the prescription drug outlet for at least two years from the date of such inventory.

Basis and Purpose: The purpose of the amendment to this rule is to allow pharmacies owned and operated by a health maintenance organization (as defined in 10-16-102, C.R.S.) to maintain secured prescription drug and controlled substance floor stock within the same building of the pharmacy and to outline the requirements of appropriate record-keeping when maintaining such floor stock.

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

11.07.10 Records of distribution of controlled substances and prescription drugs within hospitals AND FACILITIES OWNED AND OPERATED BY HEALTH MAINTENANCE ORGANIZATIONS (AS DEFINED IN SECTION 10-16-102, C.R.S.). Records of distribution of controlled substances and prescription drugs shall comply with the following:

a. In a hospital OR A FACILITY OWNED AND OPERATED BY HEALTH MAINTENANCE ORGANIZATION which ~~operate~~ OPERATES a registered prescription drug outlet, a controlled substance or prescription drug may be distributed for floor stock to appropriate areas ~~of~~ WITHIN the HOSPITAL OR facility. A record of any such distribution shall be made and retained BY THE PRESCRIPTION DRUG OUTLET for a period of time not less than two years and shall include the following information:

(1) The location receiving the drug;

(2) The name of the drug;

(3) The strength of the drug;

(4) The quantity of the drug;

(5) The dosage form if appropriate;

(6) The date the drug was supplied;

(7) The identity of the person in the prescription drug outlet who issued the drug;

(8) The identity of the person who placed the drug into floor stock.

b. These records of distribution may be retained electronically provided the following requirements are met:

(1) 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.

(2) The prescription drug outlet must:

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

or

(b) Have a "lock-out" feature that prevents editing of distribution information.

(3) The Board and its inspectors must be able to inspect and review the distribution 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:

(a) Print a report of all distribution 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, the system must be capable of retrieving and printing the information sorted according to variables which include, but are not limited to, date distributed, drug name, strength and dosage form, or

(b) Provide a computer terminal and monitor for the sole use of the Board or its inspector(s) to inspect and review distribution 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 (2), the system must also be capable of printing the same reports described in subparagraph (1)

(c) 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.

(4) If the prescription drug outlet chooses to maintain records of distribution electronically, any reports printed upon request shall contain, as a minimum, the following information for each transaction:

(a) The location receiving the drug;

(b) The name of the drug;

(c) The strength of the drug;

(d) The quantity of the drug;

(e) The dosage form if appropriate;

(f) The date the drug was supplied;

(g) The identity of the person in the prescription drug outlet who issued the drug;

(h) The identity of the person who placed the drug into floor stock.

Basis and Purpose: The purpose of the amendments to this rule is to: (1) require corresponding consultant pharmacists of other outlets to assure that other outlets comply with all applicable provisions of Board Rule 21.00.00 when compounding non-sterile and sterile preparations; and (2) incorporate acute treatment units and telepharmacies into the rules governing other outlets pursuant to HB 14-1083 and HB 14-1290, respectively.

Authority for Promulgation of Rules: Sections 12-42.5-101, 12-42.5-105, 12-42.5-106(2), 12-42.5-117(1)(d) and (2) and 24-4-103, C.R.S.

14.00.00 OTHER OUTLETS.

14.00.05 Eligibility for registration. The following facilities may register as other outlets provided all requirements are met:

a. Hospitals that do not operate registered prescription drug outlets. For such hospitals, dispensing shall be limited as provided in CRS 12-42.5-118(10);

b. Federal Qualified Health Centers, as defined in section 1861(aa)(4) of the federal "Social Security Act", 42 U.S.C. sec. 1395x(aa)(4);

c. Family Planning Clinics;

d. Colleges, universities and schools (grades kindergarten through twelve) which operate a school-based clinic for students and faculty of that school. Schools must submit any contractual affiliations to the Board prior to registration;

e. Jails. A jail which obtains prescription drugs solely on the basis of individual prescription orders which have been compounded in and dispensed from a registered prescription drug outlet do not need registration;

f. County or district public health agencies;

g. Community and Rural Health Clinics, registered, certified, or licensed as such as by the Colorado Department of Public Health and Environment;

h. Ambulatory Surgical Centers licensed pursuant to Part 1 of Article 3 of Title 25, C.R.S. that engage in the compounding, dispensing, and delivery of drugs or devices for administration to patients while being treated in the facility;

i. Medical Clinics operated by a hospital that engage in the compounding, dispensing, and delivery of drugs or devices for administration to patients while being treated in the facility; and

j. Hospices licensed pursuant to Part 1 of Article 3 of Title 25, C.R.S. that engage in the compounding, dispensing, and delivery of drugs or devices for administration to patients while being treated in the facility.

K. ACUTE TREATMENT UNITS, REGISTERED, CERTIFIED, OR LICENSED AS SUCH BY THE COLORADO DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT.

L. TELEPHARMACIES AS DEFINED PURSUANT TO 12-42.5-102(25).

14.00.10 General Criteria. Unless otherwise exempted, the general criteria, which shall be met by other outlets herein enumerated, which are seeking to be registered by the Board pursuant to CRS 12-42.5-117(1)(d) are stated below.

a. **For the purpose of this section, the consultant pharmacist is the pharmacist responsible for the other outlet registration and the overall operation pertaining to drug receipt and distribution.**

b. **Except as provided in rule 14.07.00, all prescription drugs utilized by the outlet shall be obtained from an entity or individual registered with the Board or a state or local health agency.**

c. **For the purposes of this rule, "dispensing unit" means a container or containers of a drug, either packaged pursuant to rule 3.01.00 or the manufacturer's original container(s), containing a quantity suitable for the prescribed treatment or condition.**

14.00.20 **Protocols. Written protocols shall be developed by the consultant pharmacist and submitted to the Board for approval. These protocols shall be submitted on form(s) provided by the Board and shall establish:**

a. **A system of recordkeeping to document the procurement, administration, compounding, dispensing, and/or distribution, including the return to the original source, of all prescription drugs and devices, including recalled items.**

b. **A system to ensure that no drug or device shall be dispensed which will be outdated prior to utilization by the consumer, based on the practitioner's directions for use.**

c. **A system by which drugs are dispensed complying with the labeling, drug identification and container requirements imposed by law.**

d. **The duties of the consulting pharmacist.**

14.00.30 **Revisions to other outlet protocols. Revisions to other outlet protocols shall be submitted as a complete set in duplicate for approval by the Board. Prior to becoming effective, the protocol changes must be approved by the Board or its designee.**

14.00.40 **Application Procedure.**

a. **Original application. Original application for registration as an other outlet shall be made on a form provided by the Board. This application shall be accompanied by the appropriate fee and two copies of the protocols.**

b. **Other outlet relocation.**

(1) **When an other outlet changes location, the outlet shall submit an application on a form provided by the Board prior to outlet relocation.**

(2) **The consultant pharmacist for the other outlet shall submit two copies of revised protocols to the Board within 30 days of relocation.**

c. **Change of ownerships of other outlet. Application to transfer registration of an other outlet shall be submitted on a form provided by the Board. This application shall be accompanied by the appropriate fee and two copies of protocols. Transfer of ownership shall be deemed to have occurred:**

(1) **In the event the other outlet is owned by a corporation, upon sale or transfer of 20 percent or more of the shares of said corporation to a single individual or entity.**

(2) **In the event the other outlet is owned by a partnership, upon sale or transfer of 20 percent or more of any ownership interest.**

(3) In the event the other outlet is owned by a limited liability company (LLC), upon sale or transfer of 20 percent or more of the membership interests.

(4) Upon incorporation of an existing other outlet.

d. Change of name of other outlet. Changes in the name of an other outlet shall be submitted to the Board on a form provided by the Board. Two copies of protocols shall be submitted to the Board within 30 days of the other outlet changing its name.

e. Change of consultant pharmacist.

(1) A new application shall be submitted to the Board within 30 days after the former consultant pharmacist ceases to be the consultant pharmacist.

(2) If an application is not submitted within 30 days, the other outlet registration shall become void and the Board shall be informed in writing by the person responsible for the overall operation of the other outlet of the disposition of all drug stock possessed by the other outlet.

(3) The other outlet registration shall be issued in the name of the consultant pharmacist. At such time as the consultant pharmacist ceases to be engaged in said position, he/she shall immediately upon knowledge thereof, notify the Board in writing. The person responsible for the overall operation of the other outlet shall immediately notify the Board in writing when the consultant pharmacist ceases to function as such.

(4) A pharmacist assuming the duties as a consultant pharmacist for an other outlet shall notify the Board in writing within seven days of assuming said position.

(5) A pharmacist assuming duties as a consultant pharmacist for an other outlet shall review the current protocols and document the review within 30 days of assuming said position. Documentation shall include the date of review and the consultant pharmacist's signature. Said documentation shall be retained with the consultant pharmacist's record of inspection or the current Board approved protocols.

f. Change of Registration.

(1) Any other outlet located in a community health clinic, rural health clinic, college, or university which dispenses more than 25,000 dispensing units in a calendar year shall register with the Board as a prescription drug outlet.

(2) Any other outlet located in a hospital which has greater than 25 beds as stated on its license with the Colorado Department of Public Health and Environment shall register as a prescription drug outlet.

g. Reinstatement of Registration. If an Other Outlet registration has expired, a registrant wishing to reinstate such registration shall submit the following:

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

(2) Two complete and duplicate copies of written protocols, on forms provided by the Board, which are signed and dated by the individual who is the consultant pharmacist at the time the reinstatement application is submitted to the Board.

14.00.50 Board request that protocols be submitted. When the Board requests that protocols be submitted, the consultant pharmacist shall comply within 30 days of said request.

14.00.60 **Registration posting. Every other outlet shall display in the primary drug storage area, or other readily accessible area, all licenses and registrations applicable to the possession and distribution of prescription drugs and controlled substances. Furthermore, every other outlet shall display in the primary drug storage area, or other readily accessible area, the report of the last inspection conducted by the Board and have readily available Board approved protocols, consultant pharmacist reports of inspections and any other documents sent by the Board to clarify or assist in the legal operation of the other outlet.**

14.00.70 **Other required registrations. The other outlet shall obtain such state and/or federal registrations as may be required.**

14.00.80 **Consultant pharmacist.**

a. **A consultant pharmacist shall either:**

(1) **Initially interpret all prescription orders dispensed from the other outlet, or**

(2) **Provide written protocols for dispensing by unlicensed persons.**

b. **A consultant pharmacist shall be available for professional consultation.**

c. **A consultant pharmacist shall annually review the protocols for compliance with this rule 14.00.00. The review shall be documented in writing, signed, and dated by the consultant pharmacist. The consultant pharmacist shall record on the protocols at least annually the number of dispensing units dispensed in a calendar year for the following facility types: community clinics, rural health clinics, colleges, and universities. A calendar year is considered to run from January 1 through December 31.**

d. **The consultant pharmacist shall develop an inspection form to document the visit and the results thereof. Such form shall be dated and signed by the consultant pharmacist and shall be maintained and available for inspection at the other outlet by the Board for a period of two years.**

e. **The consultant pharmacist shall inspect and document the inspection in writing as detailed in 14.00.80(d) the following other outlets at the following frequencies:**

(1) **Quarterly inspections and visits shall be conducted for the following:**

(a) **Jails;**

(b) **County health departments;**

(c) **Schools, grade kindergarten through twelve;**

(d) **Hospitals;**

(e) **Family planning clinics;**

(f) **Hospices;**

(g) **Medical clinics operated by hospitals; and**

(h) **Ambulatory Surgical Centers.**

(2) **Community clinics, federally qualified health centers, rural health clinics, colleges, ACUTE TREATMENT UNITS, TELEPHARMACIES, and universities shall be inspected and visited as follows:**

(a) Monthly if 2,500 or less dispensing units are dispensed in a calendar year. A calendar year is considered to run from January 1 through December 31.

(b) Every other week if more than 2,500 but less than 7,501 dispensing units are dispensed in a calendar year; A calendar year is considered to run from January 1 through December 31.

(c) Each week if 7,501 dispensing units but less than 12,501 dispensing units are dispensed in a calendar year. A calendar year is considered to run from January 1 through December 31.

(d) Twice each week if 12,501 dispensing units but less than 25,001 dispensing units are dispensed in a calendar year. A calendar year is considered to run from January 1 through December 31.

f. The consultant pharmacist shall be responsible for the accuracy of records pertaining to drug stock returned to the original supplier, the manufacturer, or via a reverse distributor. The record of any returned drug stock shall indicate, as a minimum, the name and address of the original supplier, manufacturer or reverse distributor, the date of return, and the name, strength, and quantity of the drug returned. This record shall be signed by the consultant pharmacist, and shall be maintained on the premises for a minimum of two years.

g. The consultant pharmacist for a licensed hospital other outlet shall be notified of any casual sale or loan of a drug made by the licensed hospital other outlet to a practitioner authorized by law to prescribe the same prior to the transaction. The consultant pharmacist for a licensed hospital other outlet shall be notified within 72 hours of any casual sale or loan of a drug to a registered other outlet, a prescription drug outlet, or a mobile emergency care unit.

h. The consultant pharmacist is responsible for ensuring all prescription drugs obtained by the other outlet are procured from an individual or entity registered b the Board or a state or local health agency.

i. The consultant pharmacist shall be responsible for ensuring any significant errors related to the practice of pharmacy, such as those that result in significant harm to a patient or the death of a patient, are reported to the Board.

J. THE CONSULTANT PHARMACIST SHALL BE RESPONSIBLE FOR ASSURING THAT THE OTHER OUTLET COMPLIES WITH ALL APPLICABLE PROVISIONS OF BOARD RULE 21.00.00 WHEN COMPOUNDING NON-STERILE AND STERILE PRODUCTS.

14.01.00 Interim designated consultant pharmacist. In the event the consultant pharmacist in whose name the other outlet registration is issued is unable to perform the duties of a consultant pharmacist, the consultant pharmacist shall designate an individual pharmacist to assume the consultant pharmacist's duties for no more than 90 consecutive days. The consultant pharmacist in whose name the other outlet registration is issued shall notify the Board in writing within ten days of designating an individual pharmacist to assume said consultant pharmacist's duties. Said written notification shall include, as a minimum, the name and license number of the individual pharmacist, the beginning and ending dates for which said individual pharmacist assumes the consultant pharmacist's duties, and the reason for which said individual pharmacist is designated to assume the consultant pharmacist's duties. In the event the consultant pharmacist in whose name the other outlet registration is issued is unable to perform the duties of a consultant pharmacist for a period exceeding 90 days, an application identifying a new consultant pharmacist shall be submitted to the Board no later than 30 days following the end of the original 90 day period.

14.02.00 Records and recordkeeping in other outlets.

14.02.10 Records in general. All other outlets registered and/or licensed by the Board shall maintain such records and inventories of prescription drugs as may be required by these rules or any other state or federal law or rule pertaining to such drugs. Such records shall be maintained on a current basis and shall be complete and accurate for all drugs which the outlet manufactures, receives, dispenses, distributes or otherwise disposes of in any other manner. Records and inventories of controlled substances shall be deemed to be "complete" only if each individual record and inventory contains all required information regarding each specific transaction, and if the set of records and inventories contains all information and documents required to be kept by state and federal laws, rules, and rules. A record or inventory shall be deemed to be "accurate" only if it is a complete, true and factual statement regarding or reflecting each specific transaction. A set of records or inventories shall be deemed to be "accurate" only if they are complete, and, when considered as a whole, they demonstrate that the controlled substances and/or the records and inventories pertaining thereto have been handled in compliance with all applicable laws or rules and that all such controlled substances are properly accounted for.

14.02.20 Retrievability of records. For the purposes of these rules, records and inventories shall be deemed "readily retrievable" if they meet the following requirements:

a. For all other outlets:

(1) The following records shall be maintained on the premises of the other outlet at all times and shall be made available for inspection by the Board or its inspectors immediately upon request.

(a) All DEA-222 forms executed during the two years preceding the request;

(b) All inventories of controlled substances required to be taken during the two years preceding the request;

(c) All records of dispensing, receipt (invoices for drugs received and drugs credited), distribution, loss, surrender or disposal in any other manner of prescription drugs and controlled substances during the two years preceding the request;

(2) The following records shall be made available within 48 hours or two business days, whichever is longer, on request by the Board or its inspectors:

(a) All unexecuted DEA-222 forms.

b. In the case of a request by the inspector for specific records:

(1) Records shall be maintained in such a manner as to permit the inspector to retrieve specific records immediately.

(2) If the inspector determines the records are not maintained in the manner specified in (1) above, the inspector may give the consultant pharmacist or outlet staff a list of the items to be retrieved. The requested records shall be made available to the inspector within 48 hours of the request.

14.02.30 Inventories of controlled substances. Any inventory of controlled substances shall comply with the following:

a. If the outlet is registered with the Drug Enforcement Administration as a "hospital/clinic", the inventory shall include all drugs located throughout the facility, excluding any drug

which has been dispensed pursuant to a lawful chart order but which has not yet been administered to the patient.

b. Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken. The inventory shall be maintained in written, typewritten or printed form at the other outlet. Schedule II drugs shall be separated from schedule III, IV, and V drugs. Controlled substances shall be deemed to be "on hand"if they are in the possession of or under the control of the outlet. However, the inventory shall exclude any drug that has been dispensed pursuant to a lawful order but which has not yet been delivered.

c. The inventory shall be taken either as of opening of business or as of the close of business on the inventory date and this shall be recorded on the inventory. In the event the other outlet is open 24-hours per day, the inventory shall specify the time the inventory was conducted.

d. After the initial inventory is taken, the other outlet shall take a new inventory of all stocks of controlled substances on hand at least every two years.

e. On the effective date of a law or rule on which a previously non-scheduled drug is added to any schedule of controlled substances, every other outlet that possesses that drug shall take an inventory of all stocks of the drug on hand. Thereafter, that drug shall be included in each inventory made by the other outlet.

f. The following information shall be recorded on the inventory.

(1) The name of the drug;

(2) Each finished form of the drug (strength and dosage form);

(3) The number of units or volume of each finished form;

(4) All outdated controlled substances.

g. In determining the number of units of each finished form of a controlled substance in a commercial container which has been opened, the other outlet shall do as follows:

(1) If the drug is a schedule II drug, an exact count of the contents shall be made.

(2) If the substance is listed in schedule III, IV, or V, an estimated count of the measure of the contents may be made, unless the container holds more than 1000 tablets or capsules, in which case an exact count of the contents must be made.

h. All controlled substance inventories shall be retained at the other outlet for at least two years from the date of such inventory.

14.03.00 Dispensing records.

a. At minimum, dispensing records must include the following information for every transaction:

(1) Unique serial number;

(2) Patient name;

(3) Prescriber;

(4) Date dispensed;

(5) Name and strength of drug dispensed;

(6) Quantity dispensed;

(7) Whether the transaction is a new or refill transaction;

(8) If refill transaction, the date of the initial order;

(9) Number of refills authorized;

(10) Number of refills dispensed to date;

(11) Identification of individual responsible for dispensing;

(12) If a controlled substance, the Drug Enforcement Administration registration number of the prescriber;

Records must be current and show all dispensing transactions, new and refill.

14.03.10 Computer use for dispensing transactions. An other outlet may utilize a computer (automated data processing system) for storage and retrieval of information regarding dispensing transactions. The following requirements shall be met:

a. All new and refill transactions shall be entered into the system at the time of the transaction, except as provided in rule 14.03.10 i..

b. Every 24 hours, except as provided in rule 14.03.20, the system must produce a hard-copy document which, for the purposes of these rules, shall be known as the "daily printout". It shall consist of a single, uniform, complete document, except as otherwise permitted by this rule. The daily printout shall list, separately, each prescription order transaction for the previous 24 hours and shall contain all information required by this rule. Daily printouts shall be retained in a chronological manner. If the printouts are bound, the sheets shall be separated into individual pages which 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.

c. The daily printout shall contain all of the following information for each dispensing transaction and shall differentiate between new and refill transactions. As an alternative, new and refill transactions may be separated into two separate uniform and complete documents which contain the following:

(1) The serial number;

(2) The name of the patient;

(3) The name of the practitioner;

(4) For each controlled substance dispensed, the practitioner's Drug Enforcement Administration registration number;

(5) The date of issue by the practitioner. If the date is omitted by the practitioner, the date dispensed shall be presumed to be the date of issue;

(6) The total number of refills authorized;

(7) The date dispensed;

(8) The initials, name, or secure electronic identifier of the individual making the final evaluation;

(9) The name and strength of the drug dispensed;

(10) The quantity of the drug dispensed;

(11) In the case of a refill, the total number of refills dispensed to date.

d. Records of dispensing transactions involving controlled substances shall be identifiable from those involving non-controlled substances. Alternatively, a separate complete printout listing only controlled substance transactions may be produced.

e. The daily printout shall be available for inspection by the Board within 72 hours from the most recent date recorded on the printout.

f. Documentation of the fact that the refill information entered into the automated data processing system each time a person refills an original prescription order for a schedule III, IV, or V controlled substance is correct must be provided by the individual who makes the final evaluation. This documentation may be retained in the following manner:

(1) If such a system provides a hard-copy printout of each day's controlled substance prescription order refill data, the controlled substance refill information shall be verified, dated, and signed by the person making the final evaluation. This individual shall verify that the date indicated is correct and then sign this document in the same manner as he/she should sign a check or legal document. This document shall be maintained in a separate file at the other outlet for a period of two years from the dispensing date. The printout of the day's controlled substance dispensing transaction must be generated by the other outlet within 72 hours of the date on which the refill was dispensed. It must be verified and signed by each person who is involved in dispensing controlled substance refills.

OR

(2) The other outlet shall maintain a bound log book, or separate file, in which each person involved in dispensing controlled substance refills shall sign attesting to the fact that the refill information entered into the computer that day has been reviewed by him/her and is correct as shown. Such a book or file must be maintained at the other outlet for a period of two years after the date of dispensing the appropriately authorized refill.

g. The daily printout shall contain all information as required by this rule except that the identity of the person who makes the final evaluation may appear either on the daily printout or on another separate, uniformly maintained and readily retrievable record. The consultant pharmacist shall determine which of the two methods for identifying the responsible person is more appropriate for the outlet, and only that method for recording such information shall be used.

h. Because of the potential for a system malfunction or failure, the other outlet must have a manual procedure for recording all dispensing transactions during the system failure or malfunction. All recoverable transaction data and all manually recorded transaction data shall be entered or restored into the system within a reasonable period of time not to exceed seven days following the restoration of operation of the system.

i. **Any automated data processing system used by an outlet shall maintain the confidentiality of records in accordance with applicable laws, rules and regulations.**

14.03.20 **Electronic maintenance of dispensing records. An other outlet which utilizes a computer (automated data processing system) for storage and retrieval of information regarding dispensing transactions need not print the daily printout required by rule 14.03.10 if the other outlet and the computer system utilized are capable of complying with the following requirements:**

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

b. **The other 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 other 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 dispensing information.

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

(1) **Print a report of all dispensing 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, the system must be capable of retrieving and printing the information sorted according to variables which include, but are not limited to, date dispensed; drug name, strength and dosage form; patient name, and practitioner name;**

or

(2) **Provide a computer terminal and monitor for the sole use of the Board or its inspector(s) to inspect and review dispensing 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 other 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 consultant pharmacist to ensure that all outlet staff are aware of the requirements of subparagraphs (1) and (2). Any failure or refusal by the consultant pharmacist and/or outlet staff 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 other outlet elects to comply with rule 14.03.20(d), the system and any reports printed on request shall contain, as a minimum, the following information for each transaction:**

(1) **The prescription order serial number;**

(2) **The name of the patient;**

(3) **The name of the practitioner;**

(4) **For each controlled substance dispensed, the practitioner's Drug Enforcement Administration registration number;**

(5) **The date of issue by the practitioner; if the date is omitted by the practitioner, the date dispensed shall be presumed to be the date of issue;**

(6) **The total number of refills authorized;**

(7) **Date dispensed;**

(8) **The initials or other means of identification of the individual dispensing the order;**

(9) **The name and strength of the drug dispensed;**

(10) **The quantity of the drug dispensed;**

(11) **In the case of a refill, the total number of refills dispensed to date;**

(12) **Whether the prescription order is a new or refill transaction;**

(13) **In the case of a controlled substance, a means of visually identifying orders for such substances and differentiating them from non-controlled substances.**

14.04.00 **Receipts.**

14.04.10 **Records of receipts of prescription drugs and controlled substances shall contain the following information for each such substance received:**

a. **Name of the drug;**

b. **Strength of the drug;**

c. **Dosage form if appropriate;**

d. **Quantity received;**

e. **Date received if a controlled substance;**

f. **Name of the labeler of the drug if it is labeled only with its generic name;**

g. **Name of the distributor;**

h. **Drug Enforcement Administration number of distributor if a controlled substance.**

i. **The DEA form 222 or a copy of the DEA form 222 and the corresponding invoice shall be attached to each other.**

14.04.20 **All records of receipt of prescription drugs and controlled substances shall be maintained at the other outlet for a period of time not less than two years from the date the drugs were received.**

14.04.30 **All credit invoices of prescription drugs and controlled substances shall be maintained at the other outlet for a period of time not less than two years from the date of the invoice.**

14.04.40 **All records of receipt of schedule II controlled substances shall be maintained separately from all other records.**

14.04.50 **Records of receipt of schedule III, IV, and V controlled substances may be maintained with other records of receipt. However, the record shall be readily identifiable from the records of receipt of non-controlled drugs.**

14.05.00 **Distribution.**

14.05.10 **Records of distribution of controlled substances and prescription drugs within hospital other outlets. Records of distribution of controlled substances and prescription drugs shall comply with the following:**

a. **In a hospital which operates a registered hospital other outlet, a controlled substance or prescription drug may be distributed for floor stock to appropriate areas of the facility. A record of any such distribution shall be made and retained for a period of time not less than two years and shall include the following information:**

(1) **The location receiving the drug;**

(2) **The name of the drug;**

(3) **The strength of the drug;**

(4) **The quantity of the drug;**

(5) **The dosage form if appropriate;**

(6) **The date the drug was supplied;**

(7) **The identity of the person in the prescription drug outlet who issued the drug;**

(8) **The identity of the person who received the drug into floor stock.**

b. **These records of distribution may be retained electronically provided the following requirements are met:**

(1) **The other 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.**

(2) **The other outlet must:**

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

or

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

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

(a) **Print a report of all distribution 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, the system must be capable of retrieving and**

printing the information sorted according to variables which include, but are not limited to, date distributed, drug name, strength and dosage form;

or

(b) Provide a computer terminal and monitor for the sole use of the Board or its inspector(s) to inspect and review distribution 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 other outlet elects to comply with this subparagraph (2), the system must also be capable of printing the same reports described in subparagraph (1).

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

(4) If the other outlet chooses to maintain records of distribution electronically, any reports printed upon request shall contain, as a minimum, the following information for each transaction:

(a) The location receiving the drug;

(b) The name of the drug;

(c) The strength of the drug;

(d) The quantity of the drug;

(e) The dosage form if appropriate;

(f) The date the drug was supplied;

(g) The identity of the person in the prescription drug outlet who issued the drug;

(h) The identity of the person who received the drug into floor stock.

14.05.11 A county health department registered as an other outlet may distribute prescription drugs to another registered other outlet owned or operated by that county health department. The drug shall be distributed in the original sealed container in which it was received from the wholesaler.

14.05.20 Records of distribution (casual sales) of controlled substances and prescription drugs. A hospital or county health department other outlet which distributes prescription drugs and/or controlled substances shall record the following:

a. The name of the drug;

b. The strength of the drug;

c. The dosage form if appropriate;

d. The quantity of the drug;

e. The manufacturer name or NDC number of the labeler of the drug if labeled only with its generic name;

f. The date of distribution;

g. The name, and address of the distributing outlet;

h. The name, and address of the receiving practitioner or registered outlet.

i. If a controlled substance is distributed, the record shall also indicate the Drug Enforcement registration number of the distributing outlet and the receiving practitioner or registered outlet.

j. A schedule II controlled substance shall only be distributed pursuant to receipt of a properly executed DEA-222 form.

14.05.21 These records of distribution (casual sales) required by 14.05.20 shall be retained for a period of time not less than two years from the date of the distribution.

14.05.22 Records of distribution (casual sales) required by rule 14.04.20 may be maintained electronically if the following requirements are met:

a. The other 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.

b. Have and maintain a complete on-line distribution file that is printable on the inspector's request,

or

c. Have a "lock-out" feature that prevents editing of distribution information.

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

(1) Print a report of all distribution 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, the system must be capable of retrieving and printing the information sorted according to variables which include, but are not limited to, date of distribution; drug name, strength and dosage form; and licensee receiving the distribution;

or

(2) Provide a computer terminal and monitor for the sole use of the Board or its inspector(s) to inspect and review distribution 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 other outlet elects to comply with this subparagraph (2), the system must also be capable of printing the same reports described in subparagraph (1).

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

e. **If the other outlet chooses to maintain records of distribution electronically, any reports printed upon request shall contain, as a minimum, the following information for each transaction:**

(1) **The name of the drug;**

(2) **The strength of the drug;**

(3) **The dosage form if appropriate;**

(4) **The quantity of the drug;**

(5) **The manufacturer name or NDC number of the labeler of the drug if labeled only with its generic name;**

(6) **The date of distribution;**

(7) **The name, and address of the distributing outlet;**

(8) **The name, and address of the receiving practitioner or registered outlet;**

(9) **If a controlled substance is distributed, the record shall also indicate the Drug Enforcement registration number of the distributing outlet and the receiving practitioner or registered outlet.**

14.05.24 **Advertising.**

a. **Only one address shall appear on a prescription label and that shall be the address of the other outlet from which the prescription was dispensed.**

b. **An other outlet shall only use, operate or advertise under the name that appears on the current registration issued by the Board.**

c. **An other outlet may not advertise, either orally or in writing, that it is a prescription drug outlet (pharmacy).**

14.06.00 **Petition for a Reduced /Inspection Schedule.**

a. **The consultant pharmacist of an other outlet may petition the Board for a reduced inspection schedule by submitting a written request to the Board detailing the procedures or technology the other outlet has in place which eliminate the need for the required frequency of inspection. The Board will review these requests in the ordinary course of business. No other outlet may change its inspection schedule without receiving written notification from the Board approving the outlet's alternative inspection schedule. Such written notification shall be maintained in the other outlet posted next to the other outlet registration.**

14.07.00 **Emergency Redistribution of Prescription Drugs**

a. **In the event of a shortage of medication or state or national emergency as dictated by either the Centers for Disease Control and Prevention (CDC) or the Colorado Department of Public Health and Environment (CDPHE), an other outlet located in a county health department or public health agency as defined in CRS 25-1-502 may obtain medications from facilities, physicians, and other entities in possession of the drugs, and redistribute the medication as directed by the CDC or CDPHE. The other outlet shall not be required to become licensed as a wholesaler to conduct distribution of drugs for the limited**

purpose set forth in this rule. The other outlet shall maintain written records of the distributions detailing the following:

a. The name of the drug;

b. The strength of the drug;

c. The dosage form if appropriate;

d. The quantity of the drug;

e. Lot number of the drug;

f. Expiration date of the drug;

g. The name of the manufacturer or the NDC number of the drug if labeled only with its generic name.

h. The date of distribution;

i. The name and address of the distributing outlet;

j. The name and address of the receiver;

k. If a controlled substance is distributed, the record shall also indicate the drug enforcement administration registration number of the distributing outlet and the receiver.

l. A schedule II controlled substance shall only be distributed pursuant to receipt of a properly executed DEA-222 form.

Basis and Purpose: The purpose of the amendments to this rule is to incorporate facilities operated by the Colorado Division of Wildlife into this rule as it pertains to the capture and/or immobilization of wildlife for animal control purposes, and to expand the list of drugs that may be obtained by limited license facilities for this purpose.

Authority for Promulgation of Rules: Sections 12-42.5-101, 12-42.5-105, 12-42.5-106, 12-42.5-117(12)(b), 12-42.5-118(17) and 24-4-103, C.R.S.

16.00.00 LIMITED LICENSE.

16.00.10 General Criteria. The Board may issue a limited license to THE FOLLOWING FACILITIES ("OUTLETS") TO PURCHASE, POSSESS, STORE AND ADMINISTER DRUGS ENUMERATED IN THIS RULE 16.00.00 IN A MANNER APPROPRIATE TO THE OUTLET AS AUTHORIZED BY LAW.

A. FOR THE PURPOSE OF THE CAPTURE, SEDATION OR IMMOBILIZATION OF ANIMALS PRIOR TO, AND INCLUDING, EUTHANASIA OF INJURED, SICK, HOMELESS, OR UNWANTED PETS AND ANIMALS:

1. a humane society which is duly registered with the Secretary of State and has been in existence and in business for at least five years in this state as a nonprofit corporation; or

2. an animal control agency which is operated by a unit of government.

B. WHERE THE EMPLOYEES, AGENTS OR CONTRACTORS OF COLORADO DIVISION OF WILDLIFE LOCATIONS ARE AUTHORIZED BY THE AGENCY TO CAPTURE OR IMMOBILIZE WILDLIFE FOR ANIMAL CONTROL, MANAGEMENT OR RESEARCH PURPOSES, THOSE LOCATIONS ARE CONSIDERED "ANIMAL CONTROL AGENCIES" FOR PURPOSES OF 12-42.5-118(17) AND THIS RULE 16.00.00.

~~**for purposes of being authorized to purchase, possess, and administer sodium pentobarbital or sodium pentobarbital in combination with other prescription drugs which are medically recognized for euthanasia, to euthanize injured, sick, homeless, or unwanted pets and animals. Such may also purchase, possess, and administer drugs commonly used for the chemical capture of animals for control purposes or to sedate or immobilize immediately prior to euthanasia.**~~

~~a~~C. All drugs PURCHASED, POSSSED, STORED AND ADMINISTERED ~~utilized~~ by the ~~limited license registrant~~ OUTLET shall be obtained from an individual or entity registered by the Board.

16.00.20 Application Procedure.

a. Original Application.

Original application for registration as a limited license OUTLET shall be made on a form provided by the Board .

b. Limited License OUTLET Relocation

When a limited license OUTLET changes location, the ~~facility~~ OUTLET shall submit an application on a form provided by the Board prior to relocation.

c. Change of Name of Limited License OUTLET.

Changes in the name of a limited license OUTLET shall be submitted to the Board on a form provided by the Board.

d. Reinstatement of Limited License.

If a registration has expired, a registrant wishing to reinstate such registration shall submit the following:

(1) The reinstatement application that is current at the time submitted with the required fee; and

(2) A copy of the applicant's current registration with the Drug Enforcement Administration (DEA).

16.00.30 Security. ~~Limited~~ OUTLETS SHALL MAINTAIN LIMITED access to controlled substances AND OTHER DRUGS~~shall be maintained~~. ~~Drugs~~ ALL DRUGS shall be stored in locked cabinets, ~~or~~ a safe bolted to the floor, OR AN EQUIVALENT SECURE LOCATION. Drugs shall be stored at the address registered with the Drug Enforcement Administration, OR WHEN BEING TRANSPORTED FOR USE IN THE FIELD, DRUG SHALL BE SECURED AND IN THE IMMEDIATE POSSESSION OF THE EMPLOYEES, AGENTS OR CONTRACTORS OF THE OUTLET WHO ARE AUTHORIZED BY THE AGENCY TO CAPTURE OR IMMOBILIZE WILDLIFE.

16.00.40 Training. Staff shall receive adequate training to properly administer all drugs referenced in this section.

16.00.50 Records in General. All outlets registered and/or licensed by the Board shall maintain such records and inventories of prescription drugs as may be required by these rules or any other state or federal law or rule pertaining to such drugs. Such records shall be maintained on a current basis and shall be complete and accurate for all drugs which the outlet manufactures, receives, dispenses, distributes or otherwise disposes of in any other manner. Records and inventories of controlled substances shall be deemed to be "complete" only if each individual record and inventory contains all required information regarding each specific transaction, and if the set of records and inventories contains all information and documents required to be kept by state and federal laws, rules, and regulations. A record or inventory shall be deemed to be "accurate" only if it is a complete, true and factual statement regarding or reflecting each specific transaction. A set of records or inventories shall be deemed to be "accurate" only if they are complete, and, when considered as a whole, they demonstrate that the controlled substances and/or the records and inventories pertaining thereto have been handled in compliance with all applicable laws or rules and that all such controlled substances are properly accounted for.

16.00.60 Retrievability of records. For the purposes of these rules, records and inventories shall be deemed "readily retrievable" if they meet the following requirements:

a. For all limited licenses:

(1) The following records shall be maintained on the premises of the limited license at all times and shall be made available for inspection by the Board or its inspectors immediately upon request:

(a) All official DEA 222 forms executed during the two years preceding the request;

(b) All inventories of controlled substances required to be taken during the two years preceding the request;

(c) All records of administration, receipt (invoices for drugs received and drugs credited), distribution, loss, surrender or disposal in any other manner of prescription drugs and controlled substances during the two years preceding the request;

(2) The following records shall be made available within 48 hours or two business days, whichever is longer, on request by the Board or its inspectors:

(a) All unexecuted DEA-222 forms.

b. In the case of a request by the inspector for specific records:

(1) Records shall be maintained in such a manner as to permit the inspector to retrieve specific records immediately.

(2) If the inspector determines the records are not maintained in the manner specified in (1) above, the inspector may give the ~~facility~~ OUTLET a list of the items to be retrieved. The requested records shall be made available to the inspector within 48 hours of the request.

16.00.70 Inventories of controlled substances. Any inventory of controlled substances shall comply with the following:

a. Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken. The inventory shall be maintained in written, typewritten or printed form at the other outlet. Schedule II drugs shall be separated from schedule III, IV, and V drugs. Controlled substances shall be deemed to be "on hand" if they are in the possession of or under the control of the outlet.

b. The inventory shall be taken either as of opening of business or as of the close of business on the inventory date and this shall be recorded on the inventory.

c. After the initial inventory is taken, the ~~facility~~ OUTLET shall take a new inventory of all stocks of controlled substances on hand at least every two years.

d. The following information shall be recorded on the inventory.

(1) The name of the drug;

(2) Each finished form of the drug (strength and dosage form);

(3) The number of units or volume of each finished form;

(4) All outdated controlled substances.

e. In determining the number of units of each finished form of a controlled substance in a commercial container which has been opened, the other outlet shall do as follows:

(1) If the drug is a schedule II drug, an exact count of the contents shall be made.

(2) If the substance is listed in schedule III, IV, or V, an estimated count of the measure of the contents may be made, unless the container holds more than 1000 tablets or capsules, in which case an exact count of the contents must be made.

f. All controlled substance inventories shall be retained at the ~~facility~~ OUTLET for at least two years from the date of such inventory.

16.00.80 Records of use. Records of use of sodium pentobarbital, sodium pentobarbital in combination with other prescription drugs, or drugs used for the purposes of chemical capture or immobilization of animals OR WILDLIFE shall contain the following information:

a. Animal OR WILDLIFE number, if available, or general description.

b. Animal OR WILDLIFE weight, if available, or estimate.

c. Amount of drug administered, and method if drug was administered for the purposes of chemical capture or control.

d. Identification of individual administering drug.

e. Amount of drug wasted (if applicable).

f. Date administered.

Records of use shall be maintained for a period of at least two years from the date of administration.

16.01.00 Receipts.

16.01.10 Records of receipts of prescription drugs and controlled substances shall contain the following information for each such substance received:

a. Name of the drug;

b. Strength of the drug;

c. Dosage form if appropriate;

d. Quantity received;

e. Date received if a controlled substance;

f. Name of the labeler of the drug if it is labeled only with its generic name;

g. Name of the distributor;

h. Drug Enforcement Administration number of distributor if a controlled substance;

i. The DEA form 222 or a copy of the DEA form 222 and the corresponding invoice shall be attached to each other.

16.01.20 All records of receipt of prescription drugs and controlled substances shall be maintained at the ~~facility~~ OUTLET for a period of time not less than two years from the date the drugs were received.

16.01.30 All credit invoices of prescription drugs and controlled substances shall be maintained at the ~~facility~~ OUTLET for a period of time not less than two years from the date of the invoice.

16.01.40 All records of receipt of schedule II controlled substances shall be maintained separately from all other records.

16.01.50 All records of receipt of schedule III, IV, and V controlled substances may be maintained with other records of receipt. However, the record shall be readily identifiable from the records of receipt of non-controlled drugs.

16.02.00 Chemical capture and sedation of animals OR WILDLIFE for euthanasia or immobilization.

16.02.01. Outlets are authorized to purchase, possess and administer drugs commonly used for the chemical capture of animals OR WILDLIFE for control, MANAGEMENT OR RESEARCH purposes or to sedate or immobilize pet animals prior to euthanasia IN A MANNER APPROPRIATE TO THE OUTLET AS AUTHORIZED BY LAW. The drugs acceptable for this use are:

a. Acepromazine.

b. Ketamine.

c. Xylazine.

d. Tiletamine and Zolazepam.

e. Sodium Pentobarbital.

F. BUTORPHANOL.

G. AZAPERONE.

H. MEDETOMIDINE.

I. MIDAZOLAM.

J. HALOPERIDOL.

K. NALBUPHINE.

L. ATIPAMEZOLE.

M. TOLAZOLINE.

N. NALTREXONE.

O. DOXAPRAM.

P. YOHIMBINE.

Q. DIPHENHYDRAMINE.

16.02.02. Outlets must maintain records of the receipt, distribution, loss, surrender and/or disposal of these drugs in the manner specified in rules 16.00.50 – 16.01.50.

16.02.03. Outlets must demonstrate that staff are trained and capable of using the drugs as intended. Staff must demonstrate training as follows:

a. Certification of successful completion of the chemical immobilization workshop provided by the Law Enforcement Training Institute of the University of Missouri at Columbia, Missouri; or

b. Certification of successful completion of the Chemical Immobilization Workshop (the level I or III workshop) provided by the National Animal Control Association; or

c. Certification of successful completion of other training programs that provide at least 6 hours of didactic classroom instruction which covers animal behavior, drug delivery equipment, drug delivery, drugs for immobilization, calculating drug dosages, dosage guidelines, post immobilization procedures, emergencies, records, and laws and safety. In addition, the course must provide a minimum of two hours of field training on the use of instruments used for chemical immobilization. Credentials of instructors at these courses must demonstrate their knowledge, experience and expertise in the field of chemical immobilization of animals; and

d. In the case of euthanasia training, the consultant or staff veterinarian must certify that staff has received thorough and adequate training on the proper administration of the medications that comply with the dosage and routes guidelines of the American Veterinary Medical Association. Furthermore, the veterinarian must certify that he/she has provided direct supervision of staff administration of such drugs for at least 3 hours prior to staff administration without supervision.

Basis and Purpose: The purpose of the amendments to this rule is to refer the Pharmacy Peer Health Assistance Diversion Program as the Pharmacy Peer Health Assistance Program because the Program now provides support services beyond those required in instances of substance abuse or diversion by licensees, and to remove outdated language from the rule.

Authority for Promulgation of Rules: Sections 12-42.5-101, 12-42.5-105, 12-42.5-106(2), 12-42.5-201 through 12-42.5-206 and 24-4-103, C.R.S.

18.00.00 PHARMACY PEER HEALTH ASSISTANCE ~~DIVERSION~~ PROGRAM.

18.00.10 Definitions.

a. "Board" means the Colorado State Board of Pharmacy.

b. "Board-ordered" means a Licensee or Program Participant who has been ordered by the Board to enter or complete a ~~Diversion~~ Program Contract pursuant to:

1) a Stipulation and Final Agency Order,

2) a Final Agency Order issued subsequent to an Initial Decision entered by an Administrative Law Judge following a disciplinary hearing pursuant to CRS 24-4-105, or

3) a Board order entered pursuant to CRS 12-42.5-204(3) directing a Licensee to be evaluated and/or participate in the ~~Diversion~~ Program.

~~**c. "Diversion Program" means the treatment program and all associated services provided by the PHAO to the Program Participant.**~~

~~**d. "Diversion Program Contract" means a contract between the PHAO and a Program Participant to detail a treatment/recovery plan and provide other program services as outlined in the contract.**~~

~~e~~C. "Licensee" means a person who is a pharmacist or pharmacist intern, who possess an active license issued by the Board, or has applied for licensure and paid all required fees.

~~f~~D. "PHAO" means a Peer Health Assistance Organization under contract with the Board which provides a formal, structured program that meets the requirements specified in Title 12, Article 42.5, Part 2 of the Colorado Revised Statutes. Such program shall be administered by appropriate professionals for the purpose of assisting Licensees and Program Participants experiencing impaired practice to obtain evaluation, treatment, short-term counseling, monitoring of progress, and ongoing support for the purpose of arresting and treating the Licensee's or Program Participant's psychiatric, psychological, or emotional conditions or excessive alcohol or drug use or addiction.

~~g~~E. "PHAO Contract" means the contract between a Peer Health Assistance Organization ("PHAO") and the Department of Regulatory Agencies, as awarded in accordance with State law, for operation of the Pharmacy Peer Health Assistance ~~Diversion~~ Program.

F. "PHARMACY PEER HEALTH ASSISTANCE PROGRAM" MEANS, AND REFERS TO, THE PHARMACY PEER HEALTH ASSISTANCE DIVERSION PROGRAM UNDER 12-42.5-201, ET SEQ., C.R.S..

G. "PROGRAM" MEANS THE TREATMENT PROGRAM AND ALL ASSOCIATED SERVICES PROVIDED BY THE PHAO TO THE PROGRAM PARTICIPANT.

H. "PROGRAM CONTRACT" MEANS A CONTRACT BETWEEN THE PHAO AND A PROGRAM PARTICIPANT TO DETAIL A TREATMENT/RECOVERY PLAN OR OTHER KIND OF SUPPORT SERVICES PLAN AS DETERMINED NECESSARY BY THE PHAO, AND TO PROVIDE OTHER PROGRAM SERVICES AS OUTLINED IN THE CONTRACT.

~~h~~I. **"Program Participant" means a Licensee who is enrolled in the ~~Diversion~~ Program and has a ~~Diversion~~ Program Contract with the PHAO.**

~~i~~J. **"Program Participants with active cases" means those Licensees who are currently Board-ordered to receive an evaluation, treatment referral and/or monitoring with the PHAO, and those Licensees whose cases have been referred for discipline or a confidential agreement.**

18.01.00 Peer Health Assistance Organizations (PHAO).

18.01.10 General Responsibilities.

Each PHAO which enters a PHAO Contract to provide ~~Diversion~~ Program services for the Board shall be responsible for the following:

a. Performing assessments and evaluations of licensees who self-refer or are referred to the PHAO by the Board, and such additional evaluations and assessments as are deemed necessary by the PHAO or requested by the Board.

b. Entering into a ~~Diversion~~ Program Contract with Licensees admitted into the program ("Program Participants").

c. Informing each Program Participant of his/her rights and responsibilities under the ~~Diversion~~ Program Contract and the possible consequences of non-compliance.

d. Corresponding with Program Participants regarding Board actions relevant to the Program Participants.

e. Notifying a Program Participant and the Board of instances of noncompliance by the Program Participant or of the termination of the Program Participant from the program.

f. Destruction of all material maintained by the PHAO three years after a Program Participant's successful completion of or termination from the program.

g. Other duties as set forth in the PHAO Contract.

18.01.11 Quarterly Reports to the Board by PHAO's.

~~On the 15th days of April, July, October, and January of each year, each~~ THE PHAO shall submit compliance reports for the previous quarter DURING THE MONTHS OF APRIL,

JULY, OCTOBER AND JANUARY for participants ordered to participate in the ~~Diversion~~ Program. Compliance reports may include summaries of, but are not be limited to:

a. Records of attendance by Program Participants at all prescribed therapeutic activities including, but not limited to, counseling sessions, group meetings, and drug urine screens.

b. Records of attendance and performance from the Program Participants' supervisors/employers.

c. Records of monitored Antabuse or other relevant prescribed medications/agents.

d. Reports by treatment provider(s).

e. Evaluations and assessments.

f. Self-status reports.

g. Reports as required by the Program Participants' ~~Diversion~~ Program Contracts.

h. Other details as required in the PHAO Contract.

18.01.12 Confidentiality.

a. Any compliance report submitted by a PHAO to the Board regarding the progress of a Program Participant in the ~~Diversion~~ Program shall be reported to the Board by case number only, except as specified in paragraphs b through d below.

b. Whenever any Program Participant tests positive for alcohol or drugs, or otherwise chronically and/or substantially fails to comply with his/her ~~Diversion~~ Program Contract, the PHAO shall report the Program Participant by name to the Board.

c. When THE PHAO REPORTS a PARTICIPANT'S failure to comply with the ~~Diversion~~ Program Contract ~~has been reported to the Board~~, the Program Participant's treatment records and reports will no longer be kept confidential from the Board. Such reports and records shall remain confidential and be subject to protection from further disclosure pursuant to CRS 24-72-204(3)(a)(I).

d. The PHAO shall maintain and keep confidential a Program Participant's ~~Diversion~~ Program records for three years after completion of or termination from the Program and then destroy them.

18.03.00 ~~Diversion~~ Program - Eligibility, Participation, Program Completion or Termination of Individual Licensees.

18.03.10 Program Participation.

a. Voluntary Participation. To be eligible for voluntary participation in the ~~Diversion~~ Program, a Licensee shall:

1) Be a pharmacist or intern who possesses a currently active license in this state.

2) Have a psychiatric, psychological or emotional condition, or abuse alcohol and/or drugs, in a manner which may affect the Licensee's ability to practice with reasonable skill and safety.

3) Voluntarily request admission into the program.

4) Agree to undergo reasonable evaluation and examination necessary for the determination of need and ability to participate in the program.

5) Bear the cost of the program.

6) Cooperate by providing such evaluation and treatment information, disclosure authorizations and releases of liability as may be requested by the PHAO.

7) Sign a written ~~Diversion~~ Program Contract with the PHAO including a treatment/recovery plan in which the Licensee agrees to comply with all elements of the ~~Diversion~~ Program.

b. Mandatory Participation. A Licensee is eligible for ~~Diversion~~ Program participation and services if the Licensee:

1) Enters into a Stipulation and Final Agency Order wherein the Licensee agrees to participate in the ~~Diversion~~ Program as a term of disciplinary probation; or

2) Is ordered into the ~~Diversion~~ Program for treatment pursuant to a Final Agency Order following a disciplinary hearing; or

3) Is Board-ordered to enter into the ~~Diversion~~ Program for treatment pursuant to CRS 12-42.5-204(3).

4) Has a psychiatric, psychological or emotional condition, or abuses alcohol and/or drugs, in a manner which may affect the Licensee's ability to practice with reasonable skill and safety.

5) Bears the cost of the program.

6) Cooperates by providing such evaluation and treatment information, disclosure authorizations and releases of liability as may be requested by the PHAO.

7) Signs a written ~~Diversion~~ Program Contract with the PHAO including a treatment/recovery plan in which the Licensee agrees to comply with all elements of the ~~Diversion~~ Program.

c. In the event that a previously voluntary Program Participant is subsequently Board-ordered to participate in and/or complete the ~~Diversion~~ Program, the Program Participant shall enter into a new ~~Diversion~~ Program Contract with the PHAO in which it is indicated that the Program Participant's participation in the ~~Diversion~~ Program was Board-ordered.

18.03.11 Admission Procedures.

a. Each Licensee requesting admission into the ~~Diversion~~ Program shall submit an application to the PHAO.

~~b. For each Licensee who applies for admission into the Diversion Program, the PHAO shall make a recommendation to the Board for admission or denial of admission into the Diversion Program.~~

~~c. In the case of a denial of any Licensee's application for admission into the Diversion Program, the Board shall specify to the PHAO, in writing, grounds for the denial of a Licensee's application. At the time of application for admission to the Diversion Program, should the Licensee request to continue practicing while participating in the program, such request shall be evaluated by the PHAO, and a recommendation shall be made to the Board.~~

~~e. Upon consideration of the PHAO's recommendations, the Board may grant or deny the Licensee's request to continue practicing.~~

~~f~~B. Each Program Participant will be assigned a case number by the PHAO for the purpose of confidential identification during the Program Participant's participation in the program in a manner consistent with Rule 18.01.13, below.

~~g~~C. The Program Participant shall enter into a ~~Diversion~~ Program Contract with the PHAO signed by Program Participant and an authorized representative of the PHAO. The ~~Diversion~~ Program Contract is to be kept in the confidential files of the PHAO with a copy provided to the Program Participant and any other lawfully authorized parties.

~~h~~D. The term of any ~~Diversion~~ Program Contract between the Program Participant and the PHAO shall be determined by the PHAO ~~as recommended to the Board by the REC,~~ unless superseded by Board order. The term of the ~~Diversion~~ Program Contract may be extended and/or retroactive credit may be given at the discretion of the PHAO unless superseded by Board order.

~~i~~E. In any case where the Program Participant has been Board-ordered into the ~~Diversion~~ Program, the PHAO shall submit a copy of the ~~Diversion~~ Program Contract to the Board for inclusion in the Board's files.

18.03.12 Reports to the Board for Non-Compliance.

Notwithstanding any other provision of these Rules, if the PHAO determines that any applicant, Licensee, or Program Participant is unable to practice with reasonable skill and safety, the applicant, Licensee, or Program Participant shall be reported by name with supporting written documentation to the Board by the next business day.

18.03.13 Successful Discharge of a Program Participant from the ~~Diversion~~ Program.

A Program Participant shall be considered to have completed the ~~Diversion~~ Program when the Program Participant has complied with all of the terms and conditions of the ~~Diversion~~ Program Contract, has completed the contractual treatment program, and the PHAO has determined that the Program Participant can safely practice pharmacy without further treatment or monitoring.

18.03.14 Termination of a Program Participant from the ~~Diversion~~ Program.

A Program Participant may be terminated from his/her ~~Diversion~~ Program Contract with the PHAO for failure to comply with the treatment/recovery plan or any terms of the ~~Diversion~~ Program Contract with the PHAO.

Basis and Purpose: The purpose of the amendments to this rule is to define and address the practice of "shared pharmacy services" and to incorporate such practice into the rule where applicable, and to make the prescription labeling requirements for prescriptions dispensed pursuant to this rule consistent with the prescription labeling requirements outlined in Board Rule 8.00.00.

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

20.00.00 CENTRAL PRESCRIPTION PROCESSING.

20.00.10 **"Central prescription processing" means the dispensing of an order when more than one registered prescription drug outlet (pharmacy) is involved in the transaction. It is the processing by one pharmacy of a request from another pharmacy to fill or refill an order or to perform one or more dispensing functions, such as preparation, mixing, labeling, initial interpretation, and refill authorizations.**

20.00.11 **"Central prescription processing contract" means a written contract which outlines the services to be provided and the responsibilities and accountabilities of each pharmacy that is a party to the central prescription processing contract in compliance with federal and state laws and rules.**

20.00.12 **"Contract pharmacy" means a pharmacy that is a party to the same central prescription processing contract as another pharmacy performing a portion of the fulfillment of a given prescription in a shared pharmacy services arrangement.**

20.00.20 **"Initial interpretation" means the review of an order accompanied by order entry. The pharmacist(s) conducting the initial interpretation shall be held accountable for the accuracy of the electronic order entry/ manual transcription and for appropriateness of therapy (e.g. known allergies, reasonable dose, duration of use, and route of administration, considering age, gender, and other patient factors; reasonable directions for use; potential or actual adverse drug reactions; drug-drug interactions; drug-food interactions; drug-disease contraindications; therapeutic duplication; proper utilization (including over- or under-utilization) and optimum therapeutic outcomes; and abuse/misuse.)**

20.00.30 **"Fulfillment" means the preparation, mixing, and placement of the ordered medication in a suitable container with appropriate labeling.**

20.00.31 **"Fulfillment pharmacy" means the pharmacy where fulfillment ~~occurs~~is completed.**

20.00.40 **"Originating pharmacy" means the pharmacy or hospital where the order is initially presented.**

20.00.41 **"Network pharmacies" means pharmacies that are under common ownership, or are parties to a central prescription processing contract, which pharmacies may perform one or more parts of the fulfillment of a given prescription.**

20.00.43 **"SHARED PHARMACY SERVICES" MEANS A SYSTEM THAT ALLOWS A COMMON OWNERSHIP OR CONTRACT PHARMACY TO REQUEST ANOTHER COMMON OWNERSHIP OR CONTRACT PHARMACY TO CONDUCT THE INITIAL INTERPRETATION OF A PRESCRIPTION ORDER OR CHART ORDER.**

PHARMACIES PARTICIPATING IN SHARED PHARMACY SERVICES SHALL COMPLY WITH ALL PROVISIONS OF THIS BOARD RULE 20.00.00 UNLESS OTHERWISE SPECIFICALLY STATED IN THIS RULE.

20.00.50 **The dispensing, delivery, and return of prescriptions by one pharmacy for another pursuant to this section shall not be construed as the filling of a transferred prescription or as a wholesale distribution.**

20.00.60 **Operational Standards.**

a. **A pharmacy may outsource one or more portions of the dispensing of an order to other pharmacies provided the pharmacies:**

1. **Have the same owner or have entered into a central prescription processing contract~~written central prescription processing contract which outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws and rules~~; and**

2. **Share a common electronic file or have appropriate technology/interface to allow access to information required to process the order; and**

3. **Are registered with the Board as either prescription drug outlets or non-resident prescription drug outlets, depending on the pharmacy's location, EXCEPT THAT A NONRESIDENT PHARMACY THAT DOES NOT PHYSICALLY SHIP, MAIL OR DELIVER DISPENSED PRESCRIPTIONS DIRECTLY INTO THIS STATE FROM THE NONRESIDENT PHARMACY LOCATION SHALL BE EXEMPT FROM THE REQUIREMENT OF OBTAINING A NONRESIDENT PRESCRIPTION DRUG OUTLET REGISTRATION PURSUANT TO 12-42.5-130(2). All pharmacies participating in the central prescription processing contract, OR WHO ARE ENGAGED IN SHARED PHARMACY SERVICES, must be located within the United States REGARDLESS OF THE REQUIREMENT OF A COLORADO REGISTRATION.**

b. **The pharmacist manager of the fulfillment pharmacy shall assure that:**

1. **The pharmacy maintains and uses adequate storage or shipment containers and shipping processes to ensure drug stability and potency. Such shipping processes shall include the use of appropriate packaging material and/or devices to ensure that the drug is maintained at an appropriate temperature range to maintain the integrity of the medication throughout the delivery process; and**

2. **The filled prescriptions are shipped in containers, which are sealed in a manner as to show evidence of opening or tampering.**

20.00.70 **Notification to Patients.**

a. **Prior to the outsourcing of any portion of the dispensing process to another pharmacy that is a contract pharmacy or pharmacy under common ownership, ~~a~~the pharmacy shall:**

1. Notify the patient~~s~~ that the~~ir~~ prescription may be outsourced to the ~~an~~other pharmacy; and

2. Give the name of the~~at~~ contract pharmacy or common ownership pharmacy. ~~i~~If the pharmacy is part of a network of pharmacies ~~under common ownership and any of the network pharmacies~~that may participate in dispens~~e~~ing the prescription, the patient shall be notified of this fact. Such notification may be provided through a one-time written notice to the patient or through use of a sign in the pharmacy.

b. Prescription drug outlets in hospitals are exempt from this requirement.

20.00.80 Prescription Labeling.

a. Prescriptions shall be labeled with all information required by CRS 12-42.5-121. In addition, the following shall be included on the label of any prescription dispensed via central processing:

1. The name and address of EITHER the originating OR FULFILLMENT pharmacy involved in the dispensing; and

2. The telephone number of the pharmacy that the patient or caregiver should contact regarding refills or questions about the prescription.

20.00.90 Responsibilities of Originating Pharmacy.

a. The originating pharmacy, when transmitting a controlled substance order to a contract~~ed~~ or common ownership pharmacy, shall write "Central Fill" on the face of the original order and record the following:

1. The name, and address of the pharmacy to whom the order is transmitted;

2. The Drug Enforcement Administration registration of the pharmacy if a controlled substance order;

3. Name of pharmacist transmitting the order; and

4. The date of transmission.

5. SUBSEQUENT DISPENSING TRANSACTIONS IN THE SHARED PHARMACY SERVICES PROCESS ARE EXEMPT FROM THE REQUIREMENT OF WRITING "CENTRAL FILL" ON THE FACE OF THE ORIGINAL ORDER.

b. The originating pharmacy, when transmitting a non-controlled substance order to a contract~~ed~~ or common ownership pharmacy, shall maintain records of the following:

1. The name, and address of the pharmacy to whom the order is transmitted;

2. Name of pharmacist transmitting the order; and

3. The date of transmission.

c. Upon receipt of the prescription from the fulfillment pharmacy, the originating pharmacy shall record the following:

1. Date of receipt;

2. Method of delivery (private, common, or contract carrier); and

3. Name of pharmacy employee accepting delivery.

d. The above records shall be retained for a period not less than two years.

e. The originating pharmacy is responsible for the maintenance of the original order in accordance with rule 11.00.00.

20.01.00 Responsibilities of Fulfillment Pharmacy.

a. The fulfillment pharmacy shall:

1. Retain an electronic record of all information transmitted by the originating pharmacy, including the name, address, and Drug Enforcement Administration registration (for controlled substances only) of originating pharmacy.

2. Retain a record detailing the following:

i) Date the transmitted order was received;

ii) Identity of the pharmacist responsible for the final evaluation;

iii) Date the order was fulfilled;

iv) Date prescription delivered to the originating pharmacy; and

v) The method of delivery.

20.01.10 Records.

a. Each pharmacy shall comply with all the laws and rules relating to the maintenance of records as required by rule 11.00.00 and be able to produce an audit trail showing all prescriptions dispensed by the pharmacy.

b. The originating pharmacy is responsible for retaining the order in the manner specified in rule 11.00.00.

c. All involved pharmacies shall maintain appropriate records which identify the identity, date, and location of each individual performing any processing function for an order.

20.01.20 Policies and Procedures.

a. A policy and procedure manual as it relates to central prescription processing or shared pharmacy services shall be maintained and

complied with ~~at~~ by all pharmacies involved in the dispensing of the prescriptions. This policy and procedure manual shall be readily available for inspection. The manual shall:

1. Outline the responsibilities of each involved pharmacy;

2. Include a list of the names, addresses, telephone numbers, and all license/registration numbers (including Drug Enforcement Administration registrations) of involved pharmacies;

3. Delineate which pharmacy name and address appears on the prescription label.

4. Include policies and procedures for:

i) Notifying patients that their prescription may be outsourced to another pharmacy for centralized prescription processing and the name of that pharmacy or pharmacies;

ii) Protecting the confidentiality and integrity of patient information;

iii) Dispensing prescriptions when the filled prescription has not been received from the fulfillment pharmacy;

iv) Maintaining appropriate records to identify the location and pharmacist responsible for all aspects of dispensing of any order;

v) Complying with federal and state laws and rules;

vi) Identifying the pharmacist responsible for each aspect of prescription preparation including, but not limited to, the drug regimen review, the initial electronic entry, any changes or modifications of the prescription record or patient profile, and the final evaluation of the completed prescription;

vii) Reviewing the policy and procedure at least annually. Such review shall be done by the pharmacist manager and documented as to the date of the review accompanied by the signature of the pharmacist manager.

Basis and Purpose: The purpose of the amendments to this rule is to: (1) implement the recommendations of the Colorado Pharmacy Task Force; and (2) implement SB 14-095 which codifies that, within limitations as specified, in-state prescription drug outlets may distribute compounded preparations to either individual practitioners located in this state who are authorized by law to prescribe the preparations in this state or to hospitals located in this state.

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

21.00.00 COMPOUNDING.

The purpose of this rule is to codify the compounding of preparations to assure that they are of acceptable strength, quality and purity.

If the pharmacist compounds a preparation according to the manufacturer's labeling instructions, then further documentation is not required. All other compounded preparations require further documentation as set forth in this rule.

Compounding of investigational products may be exempt from sections of rule 21.00.00 when compounding is restricted to utilizing ingredients that are regulated by the Federal Food and Drug Administration through an Investigational Review Board (IRB) and when the IRB- approved protocol requires deviation from this rule.

21.00.10 Limitations.

a. No preparation shall be compounded in advance in such quantity as may exceed a 90-day supply or is necessary to accurately compound the preparation. A 90-day supply shall be determined by the average number of dosage units dispensed or distributed of said preparation during the previous 6 month period.

b. No expired components may be used in compounding. No component may be used which will expire prior to the beyond-use date of the final compounded product. No expired final compounded product shall be dispensed or distributed.

21.00.20 Casual Sales/Distribution of Compounded Products.

a. An in-state prescription drug outlet SHALL only distribute a compounded product to a practitioner LICENSED AND LOCATED IN COLORADO AND authorized by law to prescribe the drug, TO A HOSPITAL PRESCRIPTION DRUG OUTLET REGISTERED AND LOCATED IN COLORADO, OR TO A HOSPITAL OTHER OUTLET REGISTERED AND LOCATED IN COLORADO. DISTRIBUTION OF COMPOUNDED PRODUCT PURSUANT TO THIS RULE SHALL BE for the SOLE purpose~~s~~ of DRUG administration. ~~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) and (b)(I) and (II). Nonresident prescription drug outlets may not distribute compounded products into Colorado.~~ PURSUANT TO 21 U.S.C. secs.331(a), 353(b) and 355(a), nonresident prescription drug outlets SHALL not distribute compounded products into Colorado. Nonresident prescription drug outlets REGISTERED IN COLORADO SHALL dispense compounded products and ship them into COLORADO ONLY pursuant to VALID, PATIENT-SPECIFIC prescription orders. 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. 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 OR COMPOUNDING PRESCRIPTION DRUG OUTLET COMPOUNDS AND DISTRIBUTES SHALL BE NO MORE THAN TEN PERCENT OF THE TOTAL NUMBER OF DRUG DOSAGE UNITS THE PRESCRIPTION DRUG OUTLET OR COMPOUNDING PRESCRIPTION DRUG OUTLET DISPENSES AND DISTRIBUTES ON AN ANNUAL BASIS. 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).

c. 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 ~~from the jurisdiction in which licensed~~;

(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 ~~to the practitioner~~;

~~(3) If the products are distributed to practitioners located outside of Colorado, the pharmacy shall verify that the practitioner is legally authorized to prescribe the drug in the jurisdiction in which the practitioner is licensed;~~

~~(4) If the products are distributed outside of the United States, the pharmacy shall maintain written documentation of the above in English; and~~

~~(5) Controlled substances may not be distributed outside of the United States unless the pharmacy has obtained registration with the Drug Enforcement Administration (DEA) as an exporter.~~ I

~~c~~d. 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.

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

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.**

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

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.**

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.**

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.**

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

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.**

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

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

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.**

21.10.00 Compounding of Non-Sterile Products.

21.10.10 Policy and Procedure Manual.

a. **A manual, outlining policies and procedures encompassing all aspects of non-sterile compounding shall be available for inspection at the pharmacy. The manual shall be complied with and shall be reviewed on an annual basis. Such review shall be signed and dated by the pharmacist manager. In the event the pharmacist manager changes, the new manager shall review, sign, and date the manual within 30 days of becoming pharmacist manager. The pharmacist manager shall ensure compliance with the manual.**

b. **The policy and procedure manual shall address at least the following:**

(1) **Responsibility of compounding personnel;**

(2) **Verification of compounding accuracy;**

(3) **Personnel training and evaluation in compounding skills;**

(4) **Environmental quality and control;**

(5) **Labeling and recordkeeping;**

(6) **Finished preparation release check;**

(7) **Quality control procedures, as appropriate;**

(8) **Storage and beyond-use dating;**

(9) **Adverse event reporting and recalls; and**

(10) **Quality assurance program.**

21.10.20 Personnel Education, Training and Evaluation.

a. **All pharmacy personnel preparing non-sterile compounded products must receive suitable training.**

b. **Documentation of training of personnel shall be retained at the pharmacy and be available for inspection.**

21.10.30 Environmental Quality and Controls.

a. **The area used for compounding shall have adequate space for the orderly placement of equipment and materials to prevent mix-ups between ingredients, containers, labels, in-process materials, and finished preparations.**

b. **The compounding area shall be designed, arranged, used, and maintained to prevent adventitious cross-contamination.**

c. **Non-sterile compounding areas shall be separate and distinct from any sterile compounding area.**

d. **The entire compounding area is to be well-lighted. Heating, ventilation, and air conditioning systems are to be controlled to avoid decomposition of chemicals.**

e. **Storage areas shall provide an environment suitably controlled to ensure quality and stability of bulk chemicals and finished preparations.**

f. **All components, non-freestanding equipment, and containers shall be stored off of the floor and in a manner to prevent contamination and permit inspection and cleaning of the compounding / dispensing area.**

g. **Compounding areas shall be maintained in a clean and sanitary condition. Adequate washing facilities are to be provided, including hot and cold running water, soap or detergent, and air driers or single-service towels. The plumbing system shall be free of defects that could contribute to contamination of any compounded preparation.**

h. **Purified water shall be used for compounding nonsterile preparations when formulations indicate the inclusion of water. Purified water shall also be used for rinsing equipment and utensils used in compounding.**

i. **Sewage, trash, and other refuse in the compounding area are to be disposed of in a safe, sanitary, and timely manner.**

j. **Special precautions shall be taken to clean equipment and compounding areas meticulously after compounding preparations that contain allergenic ingredients.**

21.10.40 **Equipment.**

a. **Equipment shall be of appropriate design and capacity, and be operated within designed operational limits.**

b. **Equipment shall be of suitable composition so that surfaces that contact components, in-process material, or drug products shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug product beyond the desired result.**

c. **Appropriate cleaning processes shall be in place to insure cleanliness of equipment.**

d. **Written procedures outlining required equipment, 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 maintenance reports shall be kept on file at the outlet for at least two years from the report date. These results shall be available for inspection.**

21.10.60 **Components.**

a. **Compounding personnel shall ascertain that ingredients for compounded products are in compliance with rule 21.00.10(b) and are of the correct identity and appropriate quality using the following information: vendors' labels, labeling, certificates of analysis, direct chemical analysis, and knowledge of compounding**

facility storage conditions. No expired components may be used in compounding. No component may be used which will expire prior to the beyond-use date of the preparation.

b. Ingredients used in a compounded preparation shall either originate from FDA-approved sources, if available, or be USP/NF grade substances.

c. If neither USP/NF grade substances nor FDA-approved substances are available, or when food, cosmetics, or other substances are, or must be used, the substance shall be of a chemical grade in one of the following categories:

(1) Chemically Pure (CP);

(2) Analytical Reagent (AR); or

(3) American Chemical Society (ACS); or

(4) Food Chemical Codex.

d. For all ingredients, unless FDA-approved, the pharmacist shall establish purity and stability by obtaining a certificate of analysis from the supplier. The certificate of analysis, when applicable, shall be maintained at the prescription drug outlet for at least two years from the date of preparation.

e. For components 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 component based on the nature of the component and its degradation mechanism, the container in which it is packaged, and the storage conditions. A pharmacist shall clearly and legibly label the container with the assigned expiration date. In no event shall the labeled date of receipt or assigned expiration date be later altered after originally labeling the container.

f. A manufactured drug product may be a source of active ingredient. Only manufactured drugs from containers labeled with a lot number and an expiration date are acceptable as a potential source of active ingredients. When compounding with manufactured drug products, the compounder must consider all ingredients present in the drug product relative to the intended use of a compounded preparation.

g. Drug preparations that have been withdrawn or removed from the market for safety reasons shall not be compounded. Such preparations may be compounded exclusively for veterinary use provided no documentation exists which indicates that the preparation is unsafe for such use.

h. Any ingredient regulated by the FDA through an Investigational Review Board (IRB) is exempt from rule 21.10.60 provided the research requirements for the receipt of the ingredient is followed and meets the requirements of CRS 12-42.5-128(2).

21.10.65 Packaging and Drug Preparation Containers

a. Pharmacy personnel shall ensure that the containers and container closures used in the packaging of compounded preparations meet all applicable USP requirements and, when available, compounding monographs.

b. The containers and closures shall be made of suitable clean material in order not to alter the quality, strength, or purity of the compounded preparation in any way.

c. **The containers and closures shall be stored off of the floor, handled and stored to prevent contamination, and rotated so that the oldest stock is used first. The containers and closures shall be stored in such a way as to permit inspection and cleaning of the compounding / dispensing area.**

21.10.70 Finished Preparation Release Checks.

a. Physical Inspection

(1) Written procedures for physical inspection of compounded preparations shall be followed. Immediately after compounding, and prior to dispensing or distribution, each product shall be inspected for evidence of particulates or other foreign matter, container-closure integrity, and any other apparent visual defect. Defective product shall be segregated from other product and shall not be dispensed or distributed.

b. Compounding Accuracy Checks

(1) Written procedures for double-checking compounding accuracy shall be followed for every compounded product during preparation and immediately prior to release. Outlets which compound shall have at least the following written procedures for verifying the correct identity and quality of compounded products prior to dispensing or distribution:

(a) Verification of label for accuracy; and

(b) Correct identities, purities, and amounts of ingredients have been used by comparing the original written order to the written compounding record for the compounded product.

21.10.80 Storage and Beyond-Use Dating.

a. Completed compounded preparations that are not immediately dispensed or distributed shall be stored according to the guidelines in the formulation record.

b. In the absence of stability information that is applicable to ~~a specific drug and~~ THE LOWEST AND HIGHEST DOSE OR CONCENTRATION OF A SPECIFIC preparation COMPOUNDED AT THE OUTLET, the following maximum beyond-use dates are to be used for non-sterile compounded preparations that are packaged in tight, light-resistant containers and stored at controlled room temperature unless otherwise indicated.

(1) For non-aqueous liquids and solid formulations

(a) Where the manufactured drug product is the source of the active ingredient, the beyond-use date shall not exceed 25% of the time remaining until the product's expiration date or 6 months, whichever is earlier;

(b) Where a USP/NF substance is the source of active ingredient, the beyond-use date shall not be greater than 6 months;

(2) For water-containing ORAL formulations prepared from ingredients in solid form, REGARDLESS OF WHETHER AN INGREDIENT CONTAINS WATER OR WATER BY ITSELF IS AN INGREDIENT, the beyond-use date shall not be greater than 14 days when stored at cold temperatures;

(3) FOR INTRANASAL FORMULATIONS, THE BEYOND-USE DATE SHALL NOT BE GREATER THAN 30 DAYS;

(~~3~~4) For all other formulations, INCLUDING TOPICAL, DERMAL, MUCOSAL, LIQUIDS AND SEMI-SOLID FORMULATIONS, the beyond-use date shall not be greater than ~~the intended duration of therapy or 30~~ 90 days~~, whichever is earlier~~;

(~~4~~5) The beyond-use date limits may be exceeded when there is supporting valid scientific stability information that is directly applicable to the specific preparation. This information shall be retained on-site at the outlet and be available for inspection.

21.10.90 Formulation Record.

a. For each compounded preparation, a uniform, readily retrievable formulation record shall be maintained and available for inspection for two years from the date last utilized, documenting:

(1) The official or assigned name, strength, dosage form, and route of administration of the compounded preparation;

(2) Calculations needed to determine and verify quantities or concentrations of components and doses of APIs;

(3) All ingredients and their quantities;

(4) Compatibility and stability information, including references when available;

(5) The equipment used to compound the preparation;

(6) Mixing instructions that shall include:

(a) order of mixing;

(b) mixing temperatures or other environmental controls:

(c) duration of mixing; and

(d) other factors pertinent to the replication of the preparation as compounded;

(7) Sample labeling information which shall include, in addition to other required information;

(a) generic name and quantity or concentration of each API;

(b) assigned BUD;

(c) storage conditions; and

(d) assigned prescription or control number, whichever is applicable;

(8) The assigned BUD;

(9) The containers used in dispensing;

(10) Packaging and storage requirements;

(11) Physical description of final product; and

(12) Procedures for quality control, if applicable.

21.11.00 Compounding Record.

a. For each compounded product prepared, a record shall be maintained and available for inspection for two years on the original order, or on a separate, uniform, and readily retrievable record documenting the following:

(1) The official or assigned name and strength of the compounded preparation;

(2) Formulation record reference for the preparation;

(3) Names and corresponding quantities of all components used in the preparation;

(4) Sources, lot numbers, and expiration dates of each component;

(5) Total number of dosage units compounded;

(6) Name of the person who compounded the preparation;

(7) Name of the pharmacist who approved the preparation;

(8) Batch (lot) number assigned, if multiple units compounded;

(9) Date prepared;

(10) Assigned BUD;

(11) Assigned prescription number(s) or control number(s), whichever is applicable;

(12) ~~Duplicate label as described in the corresponding formulation record~~ STORAGE CONDITIONS;

(13) Physical description of the final product;

(14) Results of quality control procedures, if applicable; and

(15) Documentation of any quality control issues and any adverse reactions or preparation problems reported by the patient or caregiver.

21.11.10 Labeling of Non-Sterile Compounded Preparations.

a. Labeling of non-sterile compounded products dispensed pursuant to a prescription order or LTCF chart order shall include at least the following:

(1) All requirements of CRS 12-42.5-121;

(2) Batch (lot) number, if appropriate;

(3) Assigned BUD;

(4) Storage directions when appropriate; and

(5) A clear statement that this product was compounded by the pharmacy.

b. Labeling of non-sterile compounded products dispensed pursuant to a hospital chart order shall include at least the following:

(1) All requirements of CRS 12-42.5-121;

(2) Batch (lot) number, if appropriate;

(3) Assigned BUD; and

(4) Storage directions, when appropriate.

c. Labeling of non-sterile compounded products distributed to practitioners, ~~or~~ other prescription drug outlets, OR OTHER OUTLETS allowed by law or made in anticipation of orders shall include at least the following:

(1) Name and address of the outlet;

(2) Name and strength of the drug(s) / active ingredient(s) in the final product;

(3) Total quantity in package;

(4) Assigned BUD;

(5) Batch (lot) number;

(6) Specific route of administration;

(7) Storage directions, when appropriate;

(8) "Rx only"; and

(9) "This product was compounded by the pharmacy".

d. Labeling of non-sterile compounded products distributed within hospitals as floor stock shall include at least the following:

(1) Name of the outlet;

(2) Name and strength of the drug(s);

(3) Total quantity in package;

(4) Quantity of active ingredient in each dosage unit;

(5) Assigned BUD;

(6) Batch (lot) number;

(7) Specific route of administration; and

(8) Storage directions, if appropriate.

21.11.20 Patient Monitoring, Adverse Events Reporting, and Product Recall.

a. **Outlets which compound shall provide patients and other recipients of compounded preparations with a way to address their questions and report any concerns that they may have with these preparations.**

b. **The outlet shall have written policies describing specific instructions for receiving, acknowledging; and for recording, or filing, and evaluating reports of adverse events and of the quality of preparation claimed to be associated with compounded preparations.**

c. **The pharmacist manager shall report to the Board in writing significant errors related to compounded preparations such as those that result in serious personal injury or death of a patient.**

d. **If a compounded preparation 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 include at least the following:**

(1) **Product name, strength, dosage form;**

(2) **Reason for recall;**

(3) **Amount of product made;**

(4) **Date made; and**

(5) **Amount of product dispensed or distributed.**

e. **The outlet shall conduct tests, as appropriate, on the recalled product to identify reason product was defective. Results of these tests shall be retained at the outlet.**

f. **Adverse event reports and product recall records shall be retained and available for inspection at the outlet for at least two years.**

21.20.00 **Compounding of Sterile Products (CSPs).**

21.20.10 **Definitions. In addition to the definitions set forth above in rule 21.00.30, when used in these rules 21.20.00 et seq., 21.21.00 et seq. and 21.22.00 et seq., the following words and terms shall have the following meanings, unless the context clearly indicates otherwise.**

a. **Anteroom: An ISO Class 8 (Class 100,000) or better area where personnel perform hand hygiene and garbing procedures, staging of components, order entry, labeling, and other activities which generate particulates. It is a transition area that provides assurance that air flows from clean to dirty areas.**

b. **Aseptic Processing: A mode of processing pharmaceutical and medical products that involves the separate sterilization of the product and of the packaging and the transfer of the product into the container and its closure under at least ISO Class 5 conditions.**

c. **Biological Safety Cabinet (BSC): A ventilated containment unit for personnel, product, and environmental protections having an open front with inward airflow for personnel protection, downward HEPA filtered laminar airflow for product protections, and HEPA filtered exhausted air for environmental protections.**

d. **Buffer Area: An ISO Class 7 (Class 10,000) area where the primary engineering control is physically located. Activities conducted in this area include the preparation and staging of components and supplies when compounding sterile products. This area may also be referred to as a buffer or core room, buffer or cleanroom areas, buffer room area, buffer or clean area.**

e. **Class 100 Environment (ISO Class 5): An atmospheric environment which contains less than one hundred (100) particles 0.5 microns in diameter per cubic foot of air, according to federal standards.**

f. **Class 10,000 Environment (ISO Class 7): An atmospheric environment which contains less than ten thousand (10,000) particles 0.5 microns in diameter per cubic foot of air, according to federal standards.**

g. **Class 100,000 Environment (ISO Class 8): An atmospheric environment which contains less than one hundred thousand (100,000) particles 0.5 microns in diameter per cubic foot of air according to federal standards.**

h. **Clean Room: A room in which the concentration of airborne particles is controlled to meet a specified airborne particulate cleanliness class. Microorganisms in the environment are monitored so that a microbial level for air, surface, and personnel is not exceeded for a specified cleanliness class.**

i. **Compounding Aseptic Containment Isolator (CACI): A compounding aseptic isolator (CAI) designed to provide worker protection from exposure to undesirable levels of airborne drug throughout the compounding and material transfer process and to provide an aseptic environment for compounding sterile preparations. Air exchange with the surrounding environment should not occur unless the air is first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Where volatile drugs are prepared, the exhaust air from the isolator should be appropriately removed by properly designed building ventilation.**

j. **Compounding Aseptic Isolator (CAI): A closed system made up of solid walls, an air-handling system, and transfer and interaction devices. The walls are constructed so as to provide surfaces that are cleanable with covering between wall junctures. The air-handling system provides HEPA filtration of inlet air. Transfer of materials is accomplished through air locks, glove rings, or ports. Transfers are designed to minimize the entry of contamination. Manipulations can take place through either glove ports or half suits. A barrier isolator is designed for compounding sterile products. It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer process. Air exchange into the isolator from the surrounding environment should not occur unless it has first passed through a HEPA filter.**

k. **Compounded Sterile Products (CSPs): A sterile drug or nutrient compounded in a registered prescription drug outlet or other outlet. Such products may include, but are not limited to, implants, injectables, parenteral nutrition solutions, irrigation solutions, inhalation solutions, intravenous solutions and ophthalmic preparations.**

l. **Critical Area: An ISO Class 5 environment.**

m. **Critical Sites: Include sterile ingredients of CSPs and locationson devices and components used to prepare, package, and transfer CSPs that provide opportunity for contamination.**

n. **Cytotoxic Drugs: A pharmaceutical product that has the capability of direct toxic action on living tissue that can result in severe leucopenia and thrombocytopenia, depression of the immune system and the alteration of a host's inflammatory response system.**

o. **Disinfectant: An agent that frees from infections. It is usually a chemical agent but sometimes a physical one. It destroys disease-causing pathogens or other harmful microorganisms but may or may not kill bacterial spores. It refers to substances applied to inanimate objects.**

p. **High-Efficiency Particulate Air (HEPA) filter: A filter composed of pleats of filter medium separated by rigid sheets of corrugated paper or aluminum foil that direct the flow of air forced through the filter in a uniform parallel flow. HEPA filters remove 99.97% of all particles three-tenths (0.3) microns or larger. When HEPA filters are used as a component of a horizontal or vertical-laminar-airflow workbench, an environment can be created consistent with standards for a class 100 clean room.**

q. **Media-Fill Test: A test which is used to qualify aseptic technique of compounding personnel or processes and to ensure that the processes used are able to produce sterile product without microbial contamination. A microbiological growth medium such as soybean-casein digest medium (SCDM) is substituted for the actual drug product to simulate admixture compounding.**

r. **Multiple-Dose Container: A multiple-unit container for articles or preparations intended for parenteral administration only. These containers usually contain antimicrobial preservatives. The beyond-use date (BUD) for an opened or entered multi-dose container with antimicrobial preservatives is 28 days, unless otherwise specified by the manufacturer.**

s. **Parenteral: A sterile preparation of drugs for injection through one or more layers of skin.**

t. **Pharmacy Bulk Package: A container of a sterile preparation for parenteral use that contains multiple single doses. The contents of the package are intended for use in a pharmacy admixture program and are restricted to the preparation of admixtures for infusion or, through a sterile transfer device, for the filling of empty sterile syringes. The closure shall by penetrated only one time after constitution with a suitable sterile transfer device or dispensing set, which allows measured dispensing of the contents. The pharmacy bulk package is to be used only in a suitable work area such as a laminar flow hood or an equivalent clean air compounding area. Such container shall be labeled with the following:**

(1) The name, strength and quantity of drug or base solution;

(2) The statement "Pharmacy Bulk Package—Not For Direct Infusion;"

(3) Information on the proper technique to assure safe use of the product; and

(4) A statement limiting the time frame in which the container may be used once it has been entered, provided it is held under the labeled storage conditions.

u. **Primary Engineering Control (PEC): A device or room that provides an ISO Class 5 environment for the exposure of critical sites when compounding CSPs. Such devices include, but are not limited to, laminar airflow workbenches (LAFWs), biological safety cabinets (BSCs) and compounding aseptic isolators (CAIs), and compounding aseptic containment isolators (CACIs).**

v. **Process Validation or Simulation: Microbiological simulation of an aseptic process with growth medium processed in a manner similar to the processing of the product and with the same container or closure system.**

w. **Segregated Compounding Area: A part of the designated compounding / dispensing area that is a specifically designated space, either a demarcated area or room, and that is restricted to preparing low-risk level CSPs with a 12-hour or less BUD. Such area shall contain a device that provides unidirectional airflow of ISO Class 5 air quality for preparation of CSPs and shall be void of activities and materials that are extraneous to sterile compounding.**

x. **Single-Dose Container: A single-unit container for articles or preparations intended for parenteral administration only. It is intended for single use and is labeled as such. Examples include, but are not limited to, prefilled syringes, cartridges, fusion-sealed containers, and closure-sealed containers when so labeled.**

y. **Sterile Pharmaceutical: A dosage form free from living microorganisms.**

z. **Sterilization: A validated process used to render a product free of viable organisms.**

aa. **Sterilizing Grade Filter Membranes: Filter membranes that are documented to retain 100% of a culture of 10_7 microorganisms of a strain of Brevundimonas (Pseudomonas) diminuta per square centimeter of membrane surface under a pressure of not less than 30 psi (2.0 bar). Such filter membranes are nominally at 0.22 or 0.2 micrometer porosity, depending on the manufacturer's practice.**

bb. **Sterilization by Filtration: Passage of a fluid or solution through a sterilizing grade filter to produce a sterile effluent.**

cc. **Terminal Sterilization: The application of a lethal process (e.g. steam under pressure or autoclaving) to sealed containers for the purpose of achieving a predetermined sterile assurance level of usually less than 10^{-6}, or a probability of less than one in one million of a non-sterile unit.**

dd. **Temperatures:**

1. **Frozen means temperatures between twenty five degrees below zero and ten degrees below zero Celsius (-25 and -10 degrees C.) or thirteen degrees below zero and fourteen degrees Fahrenheit (-13 and 14 degrees F.).**

2. **Refrigerated means temperatures between two and eight degrees Celsius (2 and 8 degrees C.) or thirty-six and forty-six degrees Fahrenheit (36 and 46 degrees F.).**

3. **Room temperatures mean room temperatures between fifteen and thirty degrees Celsius (15 and 30 degrees C.) or fifty-nine and eighty-six degrees Fahrenheit (59 and 86 degrees F.).**

ee. **Unidirectional Flow: An airflow moving in a single direction, in a robust and uniform manner, and at sufficient speed to reproducibly sweep particles away from the critical processing or testing area.**

21.20.20 Definitions of Sterile Compounded Products by Risk Level.

A. IMMEDIATE USE CSPS:

(1) IMMEDIATE USE CSPS ARE INTENDED ONLY FOR EMERGENCY OR IMMEDIATE PATIENT ADMINISTRATION OF A CSP, AND ARE EXEMPT FROM THE REQUIREMENTS FOR LOW-RISK CSPS IF:

(A) THE COMPOUNDING PROCESS INVOLVES A TRANSFER OF NOT MORE THAN THREE (3) COMMERCIALLY MANUFACTURED STERILE NONHAZARDOUS PRODUCTS FROM THE MANUFACTURERS' ORIGINAL CONTAINERS AND NOT MORE THAN TWO (2) ENTRIES INTO ANY ONE (1) CONTAINER;

(B) THE COMPOUNDING PROCESS TAKES LESS THAN ONE (1) HOUR;

(C) ASEPTIC TECHNIQUE IS FOLLOWED WHEN COMPOUNDING OCCURS OUTSIDE OF CLASS 5 AIR QUALITY;

(D) PRODUCT ADMINISTRATION BEGINS NO LATER THAN ONE (1) HOUR AFTER PRODUCT PREPARATION; AND

(E) THE PRODUCT IS LABELED WITH A ONE (1) HOUR BUD.

~~a~~B. Low Risk CSPs;

(1) Low risk CSPs with greater than 12-hour BUD: Applies to compounding sterile products that exhibit characteristics (a) and (b) stated below. All low risk CSPs shall be compounded with aseptic manipulations entirely within ISO Class 5 or better air quality. The products shall be prepared with sterile equipment, sterile ingredients and solutions and sterile contact surfaces for the final product. Low risk includes the following:

(a) The compounding involves only transfer, measuring, and mixing manipulations using no more than three commercially manufactured sterile products and entries into one container package of sterile product to make the CSP; and

(b) Manipulations are limited to aseptically opening ampules, penetrating sterile stoppers on vials with sterile needles and syringes, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile products, and containers for storage and dispensing.

(2) Low risk CSPs with 12-hour or less BUD: Applies to CSPs if the PEC is a CAI, CACI, LAFW, or BSC that cannot be located within an ISO Class 7 buffer area and that exhibit characteristics (a) through (e) as stated below:

(a) This subsection (a) shall only apply to low risk level non-hazardous and radiopharmaceuticals which are compounded pursuant to a patient-specific order. Administration must occur only within the same location where prepared, except in the case or radiopharmaceuticals, and shall begin within 12 hours of preparation or as recommended in the manufacturer's package insert, whichever is less. This subsection (a) shall not apply to anti-neoplastic preparations;

(b) PECs (LAFWs, BSCs, CAIs, CACIs) shall be certified as required and shall maintain ISO Class 5 air quality;

(c) PECs shall be in a segregated compounding area restricted to sterile compounding activities that minimize the risk of CSP contamination;

(d) The segregated compounding area shall not be in a location that has unsealed windows or doors that connect to the outdoors or high traffic flow, or that is adjacent to construction sites, warehouses, or food preparation or any area that could cause contamination. The segregated area shall not be located next to a sink; and

(e) ~~Personnel shall follow garbing and cleaning requirements~~ THE SPECIFICATIONS IN CLEANING AND DISINFECTING THE STERILE COMPOUNDING AREA, PERSONNEL TRAINING AND COMPETENCY EVALUATION OF GARBING, ASEPTIC WORK PRACTICES AND CLEANING/DISINFECTION PROCEDURES, AND VIABLE AND NON-VIABLE ENVIRONMENTAL SAMPLING TESTING SHALL BE FOLLOWED.

~~b~~C. Medium Risk CSPs: Sterile products exhibit characteristics (1), (2), or (3) stated below. When CSPs are compounded aseptically under low risk conditions, and one or more of the following conditions exists, such CSPs are at a medium risk level of contamination:

(1) Multiple individual or small doses of sterile products are combined or pooled to prepare a CSP that will be administered either to multiple patients or to one patient on multiple occasions; or

(2) The compounding process includes complex aseptic manipulations other than the single volume transfer; or

(3) The compounding process requires unusually long duration, such as that required to complete dissolution or homogeneous mixing.

~~c~~D. High Risk CSPs: CSPs compounded under any of the following conditions are either contaminated or at high risk to become contaminated with infectious microorganisms:

(1) Products compounded from non-sterile ingredients or compounded with non-sterile components, containers or equipment before terminal sterilization; or

(2) Sterile contents of commercially manufactured products, CSPs that lack effective antimicrobial preservatives, and sterile surfaces of devices and containers for the preparation, transfer, sterilization, and packaging of CSPs are exposed to air quality worse than ISO Class 5 for more than 1 hour; or

(3) Before sterilization, non-sterile procedures such as weighing and mixing are conducted in air quality worse than ISO Class 7, compounding personnel are improperly garbed and gloved; or water–containing preparations are stored for more than 6 hours; or

(4) It is assumed, and not verified by examination of labeling and documentation from suppliers or by direct determination, that the chemical

purity and content strength of ingredients meet their original or compendial specifications in unopened or in opened packages of bulk ingredients.

21.20.23 Single-Dose and Multiple-Dose Containers.

a. Opened or needle-punctured single-dose containers shall be used within 1 hour if opened in worse than ISO Class 5 air quality. Single-dose containers exposed to ISO Class 5 air quality or cleaner air may be used up to 6 hours after initial puncture.

b. If multiple-dose containers include antimicrobial preservatives, the BUD shall not exceed 28 days from the initial date of entering or opening, unless otherwise specified by the manufacturer.

21.20.25 Radiopharmaceuticals as CSPs.

a. Production of radiopharmaceuticals for positron emission tomography (PET) shall comply with the most current Chapter 823 of the USP/NF <Radiopharmaceuticals for Positron Emission>.

b. All other radiopharmaceuticals shall be compounded in conformity to rules 21.20.25(b)(1) through (5) below, rule 12.00.00, and all other applicable sections of rule 21.00.00.

(1) Radiopharmaceuticals compounded from sterile components in closed sterile containers and with a volume of 100 ml or less for a single-dose injection or not more than 30 ml taken from a multiple-dose container shall be designated as, and conform to, the standards for low risk CSPs.

(2) Radiopharmaceuticals shall be compounded using appropriately shielded vials and syringes in a properly functioning and certified ISO Class 5 PEC located in an ISO Class 8 or cleaner air environment to permit compliance with special handling, shielding, and negative air flow requirements.

(3) Radiopharmaceutical vials designated for multiple use, compounded with technetium-99m, exposed to an ISO Class 5 environment, and punctured by needles with no direct contact contamination may be used up to the time indicated by the manufacturer's recommendations.

(4) Technetium-99m/molybdenum-99 generator systems shall be stored and operated under conditions recommended by the manufacturer and applicable state and federal rules. Such generator systems shall be operated in an ISO Class 8 or cleaner air environment to permit special handling, shielding, and air flow requirements. To limit acute and chronic radiation exposure of inspecting personnel to a level that is as low as reasonably achievable (ALARA), direct visual inspection of radiopharmaceutical CSPs containing high concentrations of doses of radioactivity shall be conducted in accordance with ALARA.

(5) Radiopharmaceuticals prepared as low risk CSPs with 12-hour or less BUD shall be prepared in a segregated compounding area. A line of demarcation defining the segregated compounding area shall be established. Materials and garbing exposed in a patient care and treatment area shall not cross a line of demarcation into the segregated compounding area.

21.20.30 Policy and Procedure Manual.

a. A manual, outlining policies and procedures encompassing all aspects of compounding low, medium or high risk products, shall be available for inspection at the pharmacy. This manual shall be complied with and shall be reviewed on an annual basis. Such review shall be signed and dated by the pharmacist manager. In the event the pharmacist manager changes, the new manager shall review, sign, and date the manual within 30 days of becoming pharmacist manager. The pharmacist manager shall ensure compliance with the manual.

b. The policy and procedure manual shall address at least the following:

(1) Responsibility of compounding personnel;

(2) Verification of compounding accuracy and sterilization;

(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 CSP leaves the pharmacy;

(10) Patient or caregiver training;

(11) Adverse event reporting and recalls;

(12) Quality assurance program; ~~and~~

(13) Quality control procedures, as appropriate~~.~~; AND

(14) VERIFICATION OF WORK AREA CLEANING EFFECTIVENESS.

21.20.40 Personnel Education and Training.

a. Low risk: All pharmacy personnel preparing sterile products must receive suitable didactic and experiential training.

b. Medium risk: In addition to low risk requirements, personnel training includes assessment of competency in all medium risk procedures.

c. High risk: In addition to low and medium risk requirements, operators have specific education, training and experience to prepare high risk products. The pharmacist knows principles of good compounding practice for risk level products, including:

(1) Aseptic processing;

(2) Quality assurance of environmental, component, and end-product testing;

(3) Sterilization; and

(4) Selection and use of containers, equipment, and closures.

21.20.50 Personnel Evaluation in Aseptic Manipulation Skills.

a. Personnel who prepare CSPs shall be provided appropriate training before they begin preparing CSPs.

b. Compounding personnel shall perform didactic review and pass written and media-fill testing of aseptic manipulative skills initially; at least annually thereafter for low and medium risk products; and every six months, thereafter, for high risk products.

c. Personnel who fail written tests, or whose media-fill test vials result in gross microbial colonization, must be immediately reinstructed and re-evaluated by expert compounding personnel to ensure correction of all aseptic practice deficiencies.

d. Results of these tests shall be retained and be available for inspection at the outlet for at least two years.

21.20.60 Environmental Quality and Controls.

a. All CSPs shall be compounded in air quality of a Class 100 (ISO Class 5) environment or better.

b. For the compounding of non-radiopharmaceuticals, all primary engineering controls shall be placed in a buffer area that is of air quality Class 10,000 (ISO Class 7) or better. For the compounding of radiopharmaceuticals, all primary engineering controls shall be placed in a buffer area that is of air quality Class 100,000 (ISO Class 8) or better.

c. The surfaces of the ceiling, walls, floor, fixtures, shelving, counters, and cabinets in the buffer area or clean room shall be smooth, impervious, free from cracks and crevices and non-shedding. Junctures of ceilings to walls shall be covedor caulked. There shall be no sink or floor drains in the buffer area or clean room.

d. An anteroom shall be physically isolated from the buffer area or clean room. In this area, supplies are uncartoned and disinfected. Hand sanitizing and gowning occurs in this area. A demarcation line or barrier identifies the separation of the buffer area from the anteroom area. The air quality of the anteroom shall be Class 100,000 (ISO Class 8) or better.

21.20.70 Environmental Monitoring.

a. Class 100 or better clean rooms and/or primary engineering controls shall be certified by qualified operators at least every six months and whenever the device or room is relocated or major service to the facility is performed. Certification records shall be maintained and be available for inspection at the outlet for at least two years from the certification date.

b. Certification that each ISO classified area is within established guidelines shall be performed no less than every six months and whenever the primary engineering control is relocated or the physical structure of the buffer area or anteroom has been altered. The testing shall be performed by qualified operators using state-of-the-art electronic equipment with the following results:

(1) Not more than 3,520 particles 0.5 micrometer size and larger per cubic meter of air for any primary engineering control (ISO Class 5).

(2) Not more than 352,000 particles of 0.5 micrometer size and larger per cubic meter of air (ISO Class 7) for any buffer room; and

(3) Not more than 3,520,000 particles of 0.5 micrometer size and larger per cubic meter of air (ISO Class 8) for any anteroom/area.

c. Certification records shall be maintained and be available for inspection at the outlet for at least two years from the certification date.

d. Tests shall be done for airborne microorganisms. Electronic air samplers are the preferred method. The instructions in the manufacturer's user manual for verification and use of the electronic air sample that actively collects volumes of air for evaluation must be followed. The sampling is performed at locations judged by compounding personnel to be the most prone to contamination. These tests shall be done at least every six months. The outlet shall have written policies to reevaluate cleaning procedures, operational procedures, and air filtration efficiency if the number of colony forming units increases over the normal baseline level. Records of these tests shall be maintained and be available for inspection at the outlet for at least two years from the testing date.

e. Glove fingertip sampling shall be conducted at least annually for all compounding personnel if compounding low and medium risk CSPs and semi-annually if compounding high risk CSPs. When a finger plate result for personnel monitoring after proper incubation exceeds the action limit, a review of hand hygiene and garbing procedures as well as glove and surface disinfection procedures and work practices shall occur.

f. A pressure gauge or velocity meter shall be installed to monitor the pressure differential or airflow between the cleanroom and anteroom and the anteroom and the general pharmacy area. The results shall be reviewed and documented on a daily basis. The pressure between the ISO Class 7 and general pharmacy area shall not be less than 5 pa (0.02-inch water column, w.c.).

21.20.80 Cleaning and Disinfecting the Workspaces.

a. The cleaning and sanitizing of the workspaces shall be done pursuant to written procedures and shall be the responsibility of trained operators, using appropriate disinfecting agents.

b. The direct and contiguous compounding area (DCCA), including ISO Class 5 areas, shall be cleaned and disinfected prior to the beginning of each shift. All items shall be removed from the DCCA and all surfaces shall be cleaned of loose material and residue from spills prior to cleaning.

c. Work surfaces in the ISO Class 7 buffer areas and ISO Class 8 anteroom/areas are cleaned and disinfected at least daily.

d. Dust and debris shall be removed as necessary from the storage areas for compounding ingredients and supplies.

e. Storage shelving shall be disinfected at least monthly. All items shall be removed from the shelving prior to cleaning.

f. The walls and ceilings in the buffer and anteroom areas shall be cleaned and disinfected at least monthly.

g. **Floors in the buffer and anteroom areas shall be mopped daily when no aseptic operations are in progress.**

h. **All cleaning tools, such as wipers, sponges, and mops shall be non-shedding and dedicated to use in the buffer or clean area. Floor mops may be used in both the buffer or clean area and anteroom area, but only in that order. Most wipers shall be discarded after one use. If cleaning tools are reused, their cleanliness shall be maintained by thorough rinsing and disinfection after use and by storing in a clean environment between uses. Trash shall be collected in suitable plastic bags and removed with minimal agitation.**

21.20.90 Personnel Cleansing and Garbing.

a. **Prior to entering the controlled (buffer) area, operators shall remove personal outer garments (such as lab jackets), makeup, and jewelry.**

b. **After donning dedicated shoes or shoe covers, head and facial hair coverings, and face masks, hands and arms shall be thoroughly scrubbed up to the elbow. After drying hands and arms, operators shall properly don non-shedding gowns that fit snugly around the wrists and enclosed at the neck.**

c. **Once inside the clean area, hands shall be cleansed with an antiseptic hand cleanser. Sterile powder-free gloves shall then be donned.**

d. **During protracted compounding activities, personnel shall intermittently resanitize their gloves.**

e. **For low and medium risk compounding: If personnel leave the buffer area, they shall don new hair covers, masks, shoe covers, and gloves prior to reentry. Gowns may be reused during the same compounding session if hung in the anteroom.**

f. **For high risk: If personnel leave the buffer area, they must don new hair covers, masks, shoe covers, gowns and gloves prior to reentry.**

21.21.10 Components.

a. **Compounding personnel shall ascertain that ingredients for CSPs are in compliance with rule 21.00.10(b) and are of the correct identity and appropriate quality using the following information: vendors' labels, labeling, certificates of analysis, direct chemical analysis, and knowledge of compounding facility storage conditions. No expired components may be used in compounding. No component may be used which will expire prior to the beyond-use date of the finished CSP.**

b. **Ingredients used in a compounded preparation shall either originate from FDA-approved sources, if available, or be USP/NF grade substances.**

c. **If neither USP/NF grade substances nor FDA-approved substances are available, or when food, cosmetics, or other substances are, or must be used, the substance shall be of a chemical grade in one of the following categories:**

(1) **Chemically Pure (CP);**

(2) **Analytical Reagent (AR); or**

(3) **American Chemical Society (ACS); or**

(4) **Food Chemical Codex.**

d. **For all ingredients, unless FDA-approved, the pharmacist shall establish purity and stability by obtaining a certificate of analysis from the supplier. The certificate of analysis, when applicable, shall be maintained at the prescription drug outlet for at least two years from the date of preparation.**

e. **A manufactured drug product may be a source of active ingredient. Only manufactured drugs from containers labeled with a lot number and an expiration date are acceptable as a potential source of active ingredients. When compounding with manufactured drug products, the compounder must consider all ingredients present in the drug product relative to the intended use of a compounded preparation.**

f. **Drug preparations that have been withdrawn or removed from the market for safety reasons shall not be compounded. Such preparations may be compounded exclusively for veterinary use provided no documentation exists which indicates that the preparation is unsafe for such use.**

g. **Sterile ingredients and components:**

(1) **A written procedure for physical inspection of ingredients and components prior to compounding shall be followed.**

h. **Non-sterile ingredients and components:**

(1) **If any non-sterile components or ingredients, including containers, devices, and ingredients, are utilized to make the CSP, the product shall be compounded at high risk.**

(2) **If non-USP or non-NF active ingredients, added substances, or excipients are utilized, a certificate of analysis from the supplier of the ingredient shall be maintained at the prescription drug outlet for at least two from the date of preparation.**

(3) **When non-sterile ingredients and components are received at the outlet, their container shall be marked, in indelible pencil or ink, with the date of receipt. In the absence of a supplier's expiration date on the product, the expiration date of the ingredient shall be one-year from the date of receipt, unless either appropriate inspection or testing indicates that the ingredient has retained its purity and quality for use in CSPs.**

(4) **Prior to compounding with non-sterile ingredients and components, the ingredients shall be visually inspected for evidence of deterioration, other types of unacceptable quality and wrong identification.**

i. **Any ingredient regulated by the FDA through an Investigational Review Board (IRB) is exempt from rule 21.21.10 provided the research requirements for the receipt of the ingredient is followed and meets the requirements of CRS 12-42.5-128(2).**

21.21.20 **Equipment.**

a. **Written procedures outlining required equipment, 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 maintenance reports shall be kept on file at the outlet for at least two years from the report date and shall be available for inspection.**

b. Accuracy assessments of automated compounding devices (ACD) shall be conducted daily for each day used. At routine intervals, the pharmacist manager, or his or her designee, shall review these assessments to avoid potentially clinically significant cumulative errors over time. These assessments shall be documented and be maintained and available for inspection at the outlet for at least two years.

21.21.30 Finished Preparation Release Checks and Tests.

a. Physical Inspection

(1) Finished CSPs shall be individually inspected after compounding pursuant to written procedures. Immediately after compounding, and prior to dispensing or distribution, each 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.

b. Compounding Accuracy Checks.

(1) Written procedures for double-checking compounding accuracy shall be followed for every CSP during preparation and immediately prior to release. Outlets which compound CSPs shall have at least the following written procedures for verifying the correct identity and quality of CSPs prior to dispensing or distribution:

(a) Verification of label for accuracy;

(b) Correct identities, purities, and amounts of ingredients have been used; and

(c) Correct fill volumes in CSPs and correct quantities of filled units of the CSPs were obtained.

c. Sterility Testing.

(1) Sterility testing shall be done on the following high risk CSPs:

(a) Batches larger than 25 identical individual single-dose packages (ampules, bags, syringes, vials, etc);

(b) Multiple dose vials for administration to multiple patients;

(c) Product is exposed longer than 12 hours at refrigerator temperatures prior to sterilization; or

(d) Product is exposed longer than 6 hours to temperatures warmer than refrigerator temperature prior to sterilization.

(2) The sterility test shall be compliant with the most current USP/NF Chapter 71 <Sterility Tests>. A method not described in the USP/NF may be used if verification results demonstrate that the alternative is at least as effective and reliable as the USP/NF methods.

(3) When a high risk CSP is dispensed or distributed before receiving the results of the sterility test, there shall be a written procedure requiring daily observation of the incubating test specimens and requiring an immediate

recall if there is any evidence of microbial growth. In addition, the patient and the practitioner of the patient to whom a potentially contaminated CSP was administered shall be notified of the potential risk. Positive sterility results shall prompt a rapid and systematic investigation of aseptic technique, environmental and other sterility assurance controls to identify sources of contamination and correct problems in the methods or processes.

d. Bacterial Endotoxin (Pyrogen) Testing.

(1) Endotoxin testing shall be done on the following high risk CSPs that are to be administered parenterally:

(a) Batches larger than 25 identical individual single-dose packages (ampules, bags, syringes, vials, etc.);

(b) Multiple dose vials for administration to multiple patients;

(c) Product is exposed longer than 12 hours at refrigerator temperatures prior to sterilization; or

(d) Product is exposed longer than 6 hours to temperatures warmer than refrigerator temperature prior to sterilization.

(2) The endotoxin test shall be compliant with the most current USP/NF Chapter 85 <Bacterial Endotoxins Test>. In the absence of a bacterial endotoxins limit in the official monograph or other CSP formula source, the CSP must not exceed the amount of USP/NF Endotoxin Units (EU per hour per kg of body weight) specified for the route of administration.

21.21.40 Storage and Beyond-Use Dating.

a. The temperature of drug storage areas of CSPs shall be monitored and recorded daily, either manually or electronically. Temperature records shall be maintained and be available for inspection for at least two years.

b. Finished CSPs that are not immediately dispensed or administered shall be refrigerated or frozen unless their chemical and physical stability are known to be adversely affected by cold or freezing temperatures.

c. In the absence of sterility testing FOR EACH COMPOUNDED BATCH compliant with the most current USP/NF Chapter 71 <Sterility Tests>, the beyond-use date (before administration) shall not exceed the following:

(1) Low risk CSPs 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**

(2) Low risk CSPs with 12-hour or less BUD:

Room temperature:	**No more than 12 hours**
Refrigerated temperature:	**No more than 12 hours**

Frozen: **Not applicable**

(3) Medium risk CSPs:

Room temperature: **No more than 30 hours**

Refrigerated temperature: **No more than 9 days**

Frozen: **No more than 45 days**

(4) High risk CSPs:

Room temperature: **No more than 24 hours**

Refrigerated temperature: **No more than 3 days**

Frozen: **No more than 45 days**

d. For high risk products, there must be a reliable method for establishing all expiration dates, including sterility. There must be a reliable method for establishing all beyond-use dating. Products maintaining beyond-use dating of greater than thirty (30) days shall have lab testing of product stability and potency.

e. Each outlet shall adhere to manufacturers' instructions for handling and storing of Add-Vantage®, Mini Bag Plus®, Add A Vial®, Add-Ease® products, and any similar products.

21.21.50 Formulation Record.

a. For each CSP, a uniform, readily retrievable formulation record shall be maintained and available for inspection for two years from the date last utilized, documenting:

(1) The name, strength, dosage form, and route of administration of the compounded preparation;

(2) All ingredients and their quantities;

(3) The equipment used to compound the preparation, when appropriate, and mixing instructions;

(4) The beyond use date;

(5) The containers used in dispensing;

(6) Storage requirements; and

(7) Procedures for quality control, if applicable.

21.21.60 Compounding Record.

a. For each CSP prepared, a record shall be maintained and available for inspection for two years on the original order, or on a separate, uniform, readily retrievable record documenting the following:

(1) Name and strength of the compounded preparation;

(2) Formulation record reference for the preparation;

(3) Sources and lot number of each ingredient;

(4) Manufacturer's expiration date of each ingredient, when applicable;

(5) Total number of dosage units compounded;

(6) Name of the person who compounded the preparation;

(7) Name of the pharmacist who approved the preparation;

(8) Batch (lot) number assigned, if multiple units compounded;

(9) Date of preparation;

(10) Beyond use date;

(11) Prescription number(s), if appropriate;

(12) Results of quality control procedures; and

(13) If a high risk product, the record shall also include comparisons of actual with anticipated yields, sterilization methods, and quarantine specifications.

21.21.70 Labeling of CSPs.

a. Labeling of CSPs dispensed pursuant to a prescription order or LTCF chart order shall include at least the following:

(1) All requirements of CRS12-42.5-121;

(2) Batch (lot) number, if appropriate;

(3) Beyond-use date;

(4) If for parenteral administration, the following shall be included:

(a) Name of base solution; and

(b) name and amounts of drugs added.

(5) Storage directions; and

(6) A clear statement that this product was compounded by the pharmacy.

b. Labeling of CSPs dispensed pursuant to a hospital chart order shall include at least the following:

(1) All requirements of CRS 12-42.5-121;

(2) Batch (lot) number, if appropriate;

(3) Beyond-use date;

(4) If for parenteral administration, the following shall be included;

(a) Name of base solution; and

(b) Name and amounts of drugs added; and

(5) Storage directions.

c. Labeling of CSPs distributed to practitioners, ~~or~~ other prescription drug outlets, OR OTHER OUTLETS allowed by law shall include at least the following:

(1) Name of the outlet;

(2) Name and strength of the drug(s);

(3) Total quantity in package;

(4) Quantity of active ingredient in each dosage unit;

(5) Beyond-use date;

(6) Batch (lot) number;

(7) Specific route of administration;

(8) Storage directions;

(9) "Rx only"; and

(10) "This product was compounded by the pharmacy."

d. Labeling of CSPs distributed within hospitals as floor stock shall include at least the following:

(1) Name of the outlet;

(2) Name and strength of the drug(s);

(3) Total quantity in package;

(4) Quantity of active ingredient in each dosage unit;

(5) Beyond-use date;

(6) Batch (lot) number;

(7) Specific route of administration; and

(8) Storage directions.

21.21.80 Maintaining Product Quality and Control After the CSP Leaves the Outlet or Hospital Location.

a. The outlet shall have written policies and procedures that are adhered to which shall ensure the CSP is packaged properly for transit, stored properly during transit, and stored properly at site of administration. Such policies and procedures shall also discuss patient or caregiver training.

21.21.90 Patient Monitoring, Adverse Events Reporting, and Product Recall.

a. **Outlets which compound CSPs shall provide patients and other recipients of CSPs with a way to address their questions and report any concerns that they may have with CSPs and their administration devices.**

b. **The outlet shall have written policies describing specific instructions for receiving, acknowledging, and dating receipts; and for recording, or filing, and evaluating reports of adverse events and of the quality of preparation claimed to be associated with CSPs.**

c. **The pharmacist manager shall report to the Board in writing significant errors related to compounded CSPs such as those that result in serious personal injury or death of a patient.**

d. **If a CSP 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 include at least the following:**

(1) **Product name, strength, dosage form;**

(2) **Reason for recall;**

(3) **Amount of product made;**

(4) **Date made; and**

(5) **Amount of product dispensed or distributed.**

e. **The outlet shall conduct tests, as appropriate, on the recalled product to identify the reason the product was defective. Results of these tests shall be maintained at the outlet for at least two years.**

f. **Adverse event reports and product recall records shall be retained and be available for inspection at the outlet for at least two years.**

21.22.00 **Quality Assurance Program.**

a. **Outlets that make CSPs shall have a formal written quality assurance (QA) program which shall provide a mechanism for monitoring, evaluating, correcting, and improving the activities and processes regarding the compounding of sterile products.**

b. **At a minimum, the written QA program shall include the following:**

(1) **Consideration of all aspects of the preparation, dispensing, and distribution of products, including environmental testing, WORK AREA CLEANING EFFECTIVENESS, validation results, etc;**

(2) **Describe specific monitoring and evaluation activities;**

(3) **Specification of how results are to be reported and evaluated;**

(4) **Identification of appropriate follow-up mechanisms when action limits or thresholds are exceeded; and**

(5) **Delineation of the individuals responsible for each aspect of the QA program.**

21.22.10 Cytotoxic Drug Preparation.

a. Cytotoxic drugs shall be compounded in a vertical flow, Class II biological safety cabinet (BSC) or CACI. Such BSC or CACI shall be placed in an ISO Class 7 area that is physically separated from other preparation areas and is negative pressure to adjacent positive pressure anteroom. If used for other products, the cabinet must be thoroughly cleaned;

b. Appropriate personnel protective equipment (PPE) shall be worn when compounding in a BSC or CACI and when using closed-system vial transfer devices (CSTDs). PPE should include gowns, face masks, eye protection, hair covers, shoe covers or dedicated shoes, double gloving with sterile chemo-type gloves, and compliance with manufacturers' recommendations when using a CACI;

c. Appropriate safety and containment techniques for compounding cytotoxic drugs shall be used in conjunction with the aseptic techniques required for preparing sterile products;

d. Appropriate disposal containers for used needles, syringes, and if applicable, cytotoxic waste from the preparation of chemotherapy agents and infectious waste from patients' homes. Disposal of cytotoxic waste shall comply with all applicable local, state and federal requirements;

e. Written procedures for handling major and minor spills and generated waste of cytotoxic agents must be developed and must be included in the policy and procedure manual; and

f. Prepared doses of cytotoxic drugs must be labeled with proper precautions inside and outside, and shipped in a manner to minimize the risk of accidental rupture of the primary container.

21.22.20 Exemption for Sterile Compounding of Products in Closed or Sealed System.

a. Pharmacists and pharmacies or other outlets where sterile compounding is provided may be exempt from this rule when compounding is restricted to utilizing compounds or products that are contained only in a closed or sealed system and can be transferred or compounded within this self-contained system or topical products that require further transfer or combination in order to achieve a finished product without further modification of the product.

Basis and Purpose: The purpose of the amendments to this rule is to: (1) implement amendments to Part 4 of Title 12, C.R.S. pursuant to HB 14-1283; and (2) increase the frequency both in-state and nonresident pharmacies must report controlled substance dispensing data to the Prescription Drug Monitoring Program from once every two weeks to once daily by providing prescribers and pharmacists with more updated controlled substance prescription dispensing information to help reduce prescription drug abuse in Colorado.

Authority for Promulgation of Rules: Sections 12-42.5-101, 12-42.5-105, 12-42.5-106, 12-42.5-401 through 12-42.5-109, specifically 12-42.5-404(2), and 24-4-103, C.R.S.

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. "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. "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. **"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.**

f. **"PDMP" means the Electronic Prescription Drug Monitoring Program.**

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

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

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

j. **"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.**

23.00.30 Data Submission Timeline.

Every prescription drug outlet must ensure THAT ALL controlled substance dispensing transactions are reported to the PDMP ON A DAILY BASIS BY NO LATER THAN THE OUTLET'S NEXT REGULAR BUSINESS DAY. ~~twice each month on the following schedule:~~

~~**a. For dispensing transactions from the first through the 15th day of each month, data shall be transmitted to the PDMP between the 16th and 25th day of that month.**~~

~~b. For dispensing transactions from the 16th through the last day of the month, data shall be transmitted to the PDMP between the 1st through the 10th day of the subsequent month.~~

~~c. If the prescription drug outlet does not dispense any controlled substances for the reporting period, it must enter a "zero" entry or will be considered non-compliant.~~

23.00.40 Data Submission Format.

Prescription drug outlets shall submit to the PDMP the following data requirements:

a. Identifier (Transmission type identifier), if applicable;

b Bin (Bank Identification Number);

c Version Number (a number to identify the format of the transaction sent or received);

d. Transaction Code;

e. NABP or Drug Enforcement Administration number assigned to pharmacy;

f. Customer ID (number to identify the patient receiving the RX);

g. Zip Code (3 digit US Postal Code identifying the State Code), if applicable;

h. Customer's Birth Date;

i. Sex Code;

j. Date Filled;

k. Prescription Number;

l. New/Refill Number;

m. Metric Quantity;

n. Days Supply;

o. Compound Code;

p. NDC Number of the drug dispensed;

q. Prescriber's Drug Enforcement Administration registration;

r. Drug Enforcement Administration suffix, if applicable;

s. Date RX Written;

t. Number of Refills Authorized;

u. RX Origin Code;

v. Customer Location;

w. Diagnosis Code, if available;

x. Alternate Prescriber #, if applicable;

y. Patient Last Name;

z. Patient First Name;

aa. Patient Street Address;

bb. Patient's state of residence;

cc. Patient's zip code;

dd. Triplicate Serial Number, if appropriate; and

ee. Filler Field to be populated with Payment Type as designated by PDMP vendor.

23.00.50 Data Correction.

~~a.~~ Any errors identified by the PDMP shall be corrected and resubmitted by the prescription drug outlet WITHIN 30 CALENDAR DAYS OF ORIGINAL DISPENSING DATE OF THE AFFECTED PRESCRIPTION(S). ~~on the following schedule:~~

~~1. For dispensing transactions from the 1st through the 15th day of each month, errors shall be corrected no later than the first day of the following month.~~

~~2. For dispensing transactions from the 16th through the 31st of each month, errors shall be corrected no later than the 16th day of the following month.~~

~~b~~A. If errors cannot be corrected, the pharmacy must retain a record in written format detailing the following information for each uncorrected error:

1. Detail of Error Notification highlighting uncorrected error(s); and

2. Detailed reason of why error cannot be corrected.

23.00.60 Patient Notification. Prescription Drug Outlets shall disclose to patients receiving controlled substance prescriptions that their prescription information is being submitted to the PDMP, and that this prescription information may be queried by specific individuals for a limited number of purposes as authorized by statute.

23.00.65 UNSOLICITED REPORTING. IN CONJUNCTION WITH OTHER COLORADO BOARDS WHO REGULATE PRESCRIBING PRACTITIONERS AND APPLICABLE STAKEHOLDERS, THE BOARD SHALL DEVELOP CRITERIA FOR INDICATORS OF MISUSE, ABUSE, AND DIVERSION OF CONTROLLED SUBSTANCES AND, BASED ON THOSE CRITERIA, PROVIDE UNSOLICITED REPORTS OF DISPENSED CONTROLLED SUBSTANCE PRESCRIPTIONS TO THE RESPONSIBLE PRESCRIBING PRACTITIONERS AND DISPENSING PHARMACIES OF CONTROLLED SUBSTANCE(S) DISPENSED TO THE PATIENT FOR PURPOSES OF EDUCATION AND INTERVENTION TO PREVENT AND REDUCE OCCURRENCES OF CONTROLLED SUBSTANCE MISUSE, ABUSE, AND DIVERSION.

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. 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 to whom the pharmacist is providing clinical patient care services;

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

e. Law enforcement officials so long as the information released is specific to an individual patient, ~~or~~ 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;

f. 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.

g. 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

h. 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.

I. 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 AND IMPLEMENTING FEDERAL REGULATIONS, INCLUDING THE REQUIREMENT TO REMOVE ANY IDENTIFYING DATA UNLESS EXEMPTED FROM THE REQUIREMENT.

23.00.80 Research or Education Agreements. The Board may enter into a written agreement to provide data to qualified personnel of a public or private entity for the purpose of bona fide research or education, so long as such information does not identify a recipient, prescriber, or dispenser of a prescription drug. Any public or private entity wishing to enter into or extend such an agreement shall submit a written request to the Board detailing the information it is seeking and the public benefit of such research or education. The Board will act on such request in the normal course of business.

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.