1.00.00 Rules of Professional Conduct.

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

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

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

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

1.00.16 Confidentiality.

a. A pharmacist shall not exhibit, discuss, or reveal the contents of any order or prescription, the therapeutic effect thereof, the nature, extent, or degree of illness suffered by any patient or any medical information furnished by the practitioner with any person other than the patient or his authorized representative, the practitioner or another licensed practitioner then caring for the patient, another pharmacist or intern serving the patient, or a person duly authorized by law or by the patient to receive such information.

b. A pharmacist may disclose patient information to unlicensed assistants, authorized law enforcement personnel, another pharmacist acquiring and maintaining the records, third party entities responsible for payment and any other parties allowed by federal privacy regulations.

c. The pharmacist shall exercise his professional judgment in the release of patient information to a patient or his authorized agent.

1.00.17 A pharmacist or prescription drug outlet shall not pay or offer to pay or infer that payment might be made of any sum of money or other thing of value to a practitioner, health care facility, nursing care or assisted living facility, or any other health care provider or entity as consideration for any referral to, or promotion of, a prescription drug outlet.

1.00.18 Patient Counseling.

a. When the patient seeks advice, or when, in the pharmacist's professional judgment, the best interest of the patient will be served, the pharmacist shall offer to advise the patient regarding the prescription.

b. An employer, employer's agent, employee, pharmacist or prescription drug outlet shall not interfere with the professional judgment of the pharmacist to advise the patient regarding a prescription.

1.00.21 Violation of Board Orders or Negotiated Stipulations or Diversion Program Contracts. It shall be considered unprofessional conduct for a Colorado-licensed pharmacist or intern to violate a lawful Board order or negotiated stipulation issued in result of a formal complaint against the licensee or

to violate a peer health assistance diversion program contract entered into pursuant to Rules 18.02.11 and 18.02.18.

1.00.22 A pharmacist has a professional responsibility to report to the Board in a timely manner any pattern of misconduct in the practice of pharmacy which constitutes a danger to the health, safety or welfare of a patient or the public.

1.00.23 Severability Clause. If any word, clause, sentence, paragraph, or section of these Rules of Professional Conduct shall for any reason be adjudged by any court of competent jurisdiction to be unconstitutional or otherwise invalid, such judgment shall not affect, repeal, or invalidate the remainder thereof, but shall be confined in its operation to the word, clause, sentence, paragraph, section thereof so found to be unconstitutional or otherwise invalid.

2.00.00 Orders.

2.00.10 Receipt of Order.

a. Only a pharmacist or intern may receive and reduce to writing an oral order except for chart orders as provided in CRS 12-22-121(12).

b. An electronically transmitted order (ETO) may be accepted in a PDO for dispensing.

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:

a. The name, initials, or license number of the pharmacist making the final evaluation as required by regulation 3.00.50;

b. The date the order was compounded and dispensed; and

c. In the case of a prescription order, the prescription order serial number.

d. The quantity dispensed if differs from the quantity ordered.

e. In the case of a controlled substance order, the patient address, prescriber address, and prescriber's DEA registration.

2.01.20 Additional Information. The following shall also appear on the prescription order when appropriate:

a. Any change in or clarification of an order shall be documented on the order and shall beat the initials of the responsible pharmacist or intern, the date contacted and the name of the individual conveying such change or clarification.

b. When a substitution is made, the prescription order shall indicate the following:

(1) The names of both the drug prescribed and the drug actually dispensed, as well as the date on which such substitution was initially made.

(2) The prescription order shall also indicate the name of the distributor of the drug dispensed as it appears on the package or the national drug code number.

(3) On an order for a schedule II controlled substance, substitution shall not be deemed to be an alteration of the order.

(4) On subsequent refilling of any prescription order, any change in the name of the distributor or the national drug code number as it appears on the package shall be recorded on the prescription order unless the computer system used at that prescription drug outlet changes only the affected transaction(s) (any computer entry change must not alter previous transaction records).

c. In the case of a chart order, the following information need not necessarily appear on the chart order, provided that such information is recorded on another appropriate, uniformly maintained and readily retrievable permanent record which reflects:

(1) The identity of the pharmacist making the initial interpretation;

(2) The identity of the pharmacist making the final evaluation each time a drug is dispensed, if different from the pharmacist making the initial interpretation;

(3) The quantity dispensed and

(4) The date of dispensing.

(5) Any record of a controlled substance dispensed pursuant to a chart order for an individual patient shall be visually identifiable from records of non-controlled substances.

2.01.30 Responsibility of a Pharmacist in Recording Refills. When a prescription order is refilled, the following information must be recorded on the back of the prescription order, or on the daily computer printout as specified in Regulation 11.00.00, and may be entered by an unlicensed assistant if no interpretation is required: Date refilled and quantity, if different from the quantity shown on the face of the prescription order. If authority to refill is obtained, the name of the individual conveying such authority must be recorded. The entry shall also bear the name, initials or license number of the pharmacist making the final evaluation. This information shall be maintained and available for inspection for a period of two years from the date of any transaction relating to the order unless otherwise required by statute.

2.01.40 Prescription Order Copies. A pharmacist may issue a written copy conspicuously marked “COPY FOR REFERENCE ONLY” to the patient or patient's agent. A pharmacist who issues such a written copy of a prescription order shall place on the original prescription order his/her initials, the date, and an indication that a written copy has been issued. No information regarding authority to refill shall be issued in a written copy.

2.01.50 Transfer of Prescription Orders Between Prescription Drug Outlets.

a. A prescription label or a written copy of a prescription order from another pharmacy may be used for informational purposes only and shall not be considered to be a valid prescription order. A pharmacist who receives such a label or prescription order copy shall either contact the prescribing practitioner for authorization to dispense the prescription, or, alternatively, shall comply with 2.01.52 through 2.01.59.

b. A pharmacist may orally transfer prescription order information for non-controlled substances for the purpose of dispensing a prescription if the information is communicated by one pharmacist to another pharmacist or an intern, or by an intern under the direct supervision of a pharmacist to another pharmacist. The transferring prescription drug outlet must communicate the serial number assigned to the prescription order and the receiving prescription drug outlet must record that serial number.

c. A prescription drug outlet may transfer a prescription order electronically to another

prescription drug outlet for the purpose of dispensing a prescription order.

(1) If the prescription order information is transmitted by facsimile, the transferring pharmacist shall comply with Regulation 2.01.52.

(2) Prescription order information may be transmitted electronically between two compatible computer systems that are capable of complying with the requirements of regulations 2.01.52 and 2.01.53 (1)-(10).

(3) In the case of prescription drug outlets that access and share the same data storage device and that can electronically retrieve all that information, if the original prescription order information is not invalidated, each dispensing prescription drug outlet shall be capable of accessing a transaction record that indicates the following information: (a) date, (b) time, and (c) location from which the prescription was dispensed. If the prescription order is assigned a new prescription number at the receiving pharmacy, the prescription information at the originating pharmacy shall be invalidated.

d. The one-time transfer of original prescription information for a controlled substance listed in schedules III, IV, or V for the purpose of dispensing is permissible between pharmacies. However, pharmacies electronically sharing a real-time, on-line data base may transfer up to the maximum refills permitted by law and the prescriber's authorization. If the prescription order is assigned a new prescription number at the receiving pharmacy, the prescription may be transferred on a one-time basis only.

e. A pharmacist may authorize an unlicensed assistant to electronically transfer an order, for the purpose of redispensing said order, provided that the ETO is between two compatible systems and no changes are made.

2.01.52 The transferring pharmacist shall:

a. Write the word “void” across the face of the original prescription order to make the order invalid;

b. Record on the reverse side of the invalidated prescription order:

(1) His/her name;

(2) The name of the receiving pharmacist or intern;

(3) The name of the receiving prescription drug outlet;

(4) The address and telephone number of the receiving prescription drug outlet; and

(5) The date of the transfer.

(6) In the case of a controlled substance in schedule III through V, the Drug Enforcement Administration registration number of the receiving prescription drug outlet.

c. A pharmacy utilizing a computer for storage and retrieval of information regarding prescription transactions shall be exempt from the requirements of paragraphs (a) and (b) of this regulation if the computer is capable of invalidating the prescription order and retaining as part of the permanent record the information specified in paragraph (b) of this regulation.

2.01.53 The pharmacist receiving the transferred prescription order information shall:

a. Reduce the transferred information to writing or print; write or print the word “transfer” on the face of the transferred prescription order; and provide all information required by law or regulation to be on the prescription order, including:

(1) The date of issue of the original prescription order;

(2) The date of initial compounding and dispensing of the original prescription order;

(3) The number of refills authorized or any limitations placed on the prescription;

(4) The number of valid refills remaining;

(5) The date of the last refill of the original prescription order;

(6) The prescription order number from which the prescription order information was transferred;

(7) The name of the transferring pharmacist or intern;

(8) The name of the transferring prescription drug outlet;

(9) The address and telephone number of the transferring prescription drug outlet;

(10) In the case of a controlled substance in schedules III through V, the DEA number of the transferring prescription drug outlet, and the practitioner's DEA number.

(11) The pharmacist receiving the prescription transfer shall inform the transferring pharmacist of 2.01.52 and shall request the transferring pharmacist to comply with 2.01.52.

2.01.54 The transferring prescription drug outlet shall retain the original prescription order as required by Regulation 14.05.11.

2.01.55 The receiving prescription drug outlet shall retain the transferred prescription order as required by Regulation 14.05.11.

2.01.56 The pharmacist at the receiving prescription drug outlet at the time of the dispensing of the transferred prescription, shall inform me patient that the prescription order is now invalid at the prescription drug outlet from which it was transferred.

2.01.57 (Repealed, effective 8-30-96.)

2.01.58 Nothing in this regulation shall be deemed to permit the transfer of a prescription order for a schedule II controlled substance.

2.01.59 A prescription order for a controlled substance in schedule III through V may be transferred only one time, mat transfer being from the prescription drug outlet where the prescription was originally filled. It shall not be further transferred by, or to, any other prescription drug outlet

2.01.60 A prescription order for a non-controlled prescription drug may be transferred from a prescription drug outlet to another prescription drug outlet as provided in 2.01.50 only so long as there are refills remaining and each prescription drug outlet can establish that a valid refill existed at the time of dispensing.

2.01.70 (Repealed, effective 1/30/99)

2.01.80 When a prescription drug outlet discontinues business and the prescription order files are moved to another prescription drug outlet, those orders shall be considered void and shall not be refilled. However, if the receiving pharmacist can establish that an authorized refill or authorized refills remain on any such order, such authorization may, at the sole discretion of the pharmacist, be used to establish a new order.

a. If the record which reflects the authorized refill or refills is the original prescription order, the serial number of the original prescription order shall be recorded on the new order, and the serial number of the new prescription order shall be recorded on the original order.

b. If the record which reflects the authorized refill or refills is electronic, the pharmacist shall maintain in written or printed form a record which indicates both the serial number of the original prescription order and the serial number of the new prescription order. This record may be made part of the daily printout required by Regulation 11.00.12 if it is routinely recorded in such printout. The refill authorization(s) contained in the original electronic record must be invalidated to prevent further refilling.

c. The files from the prescription drug outlet that has discontinued business may be transferred to another prescription drug outlet under the following conditions:

(1)tb/>The computer or electronic database from the prescription drug outlet that discontinued business is located and will remain at the pharmacy to which it is transferred for at least two years.

(2)tb/>The computer or electronic database must be capable of complying with regulation 2.01.52(c).

3.00.00 Dispensing.

3.00.10 Limitations. Except as provided in CRS 12-22-122(2), no order shall be dispensed or refilled after one year from the date of issue by the practitioner.

3.00.20 Medical Need. No licensee or registrant shall compound, dispense, deliver or distribute any drug to any person in such quantity or in any situation where the licensee or registrant knows or reasonably should know said drug has no recognized medical utility or application. Violation of this rule shall constitute prima facie proof of violation of CRS 12-22-125.

The pharmacist may not dispense a prescription drug or a controlled substance to a practitioner based on an order that does not list a specific patient. A prescription order for “office use” is not a valid order.

3.00.30 Labeling. When a prescription drug is dispensed pursuant to an order, the name of the drug that appears on the container label shall correspond with the identity of the drug contained therein unless otherwise requested by the practitioner.

3.00.40 Expiration Dating. 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.

3.00.50 Final Evaluation. Each time a prescription drug or device is dispensed in a prescription drug outlet, a pharmacist shall make the final evaluation of the transaction. At the time of such final evaluation, the pharmacist shall take whatever action is necessary to ensure that the initial interpretation, container, label, and prescription drug or device dispensed, as well as all records relating to the transaction are complete, accurate, and appropriate.

a. The record or records of each dispensing transaction shall bear the identity of the pharmacist

making the final evaluation, and this pharmacist shall be held responsible and accountable for each dispensing transaction which bears this pharmacist's identity.

b. In the event that the pharmacist making the final evaluation did not make the initial interpretation and does not have access to the order, then the pharmacist making the initial interpretation must be identified in the transaction record as responsible for that initial interpretation.

3.00.60 When a substitution is made on a prescription order, a patient shall be given oral and written notice of this fact at the time such substitution initially occurs, except as provided in CRS 12-22-124. On subsequent refilling of a prescription order, such oral and written notices shall not be required unless, in the professional judgment of the pharmacist, the best interest of the patient will be served by giving such notices.

3.00.70 Responsibility for Unlicensed Assistants. A pharmacist:

a. Shall not at any time supervise the work of more than two unlicensed assistants to assist in the practice of pharmacy as defined in CRS 12-22-102(26)(b). (Refer to Rule 4.00.26 regarding interns.)

b. Shall be responsible for unlicensed assistants and shall at all times strictly comply with CRS 12-22-119(5).

3.00.80 Return or Exchange of Drugs for Dispensing. No outlet shall accept drugs for return or exchange for redispensing after such drugs have been dispensed except in the following situations:

a. An outlet that complies with Regulations 3.00.81 through 3.00.86 may accept drugs for return and redispensing.

b. A hospital prescription drug outlet may accept drugs for redispensing or reissue from all areas of the hospital, provided that the integrity of the product and package are maintained.

c. A drug shall only be returned to the prescription drug outlet from which originally dispensed.

3.00.81 For the purposes of this regulation:

a. “Unit dose package” means a package which contains one pharmaceutical unit.

b. “Unit of issue package” means a package which provides multiple units of doses but separated in a medication card or other specifically designed container.

c. “Unit dose dispensing system” means a drug distribution system which is in a prescription drug outlet or hospital other outlet and uses unit dose packages or unit of issue packages that enable distribution of packaged doses in a manner that preserves the identity of the drug until the time of administration.

d. “Traditional dispensing system” means a drug package system in which individual doses are not packaged in unit dose packages or unit of issue packages.

e. “Single dose package” means a package which contains a quantity of a drug intended for administration as a single dose.

f.tb/>“Customized patient medication package” means a package which contains two or more drugs.

g. “Prepackage” means to prepare a drug in a container in advance of actual, immediate need for dispensing, prior to the receipt of an order. Such packaging may be in a unit dose, single dose or unit of issue package for use in a unit dose dispensing system, or in a container suitable for a traditional dispensing system, or in a customized patient medication package.

h. “Repackage” means to prepare a unit dose, single dose, unit of issue, customized patient medication package or traditional dispensing system package for dispensing pursuant to an existing order.

3.00.82 No prescription drug outlet shall accept a returned drug product for redispensing unless and until the pharmacist manager of the prescription drug outlet has submitted to the Board a set of protocols detailing procedures for such restocking and redispensing, and has received the written approval of such protocols from the Board. Any change to such approved protocols shall be submitted to the Board in writing for approval prior to implementation. Such protocols shall clearly set forth at least the following:

a. Methods of ensuring that deterioration and/or contamination of the product will not occur during delivery to the location, storage at the location, and return to the prescription drug outlet from which dispensed;

b. Methods of prepackaging and/or repackaging with a description of the container system(s), labeling and records to be kept, including examples and/or samples as appropriate.

3.00.83 The following shall not under any circumstances be returned to the prescription drug outlet for redispensing:

a. Any drug declared to be a controlled substance under any state or federal law or regulation except as provided in 3.00.80(b).

b. Any drug dispensed in a traditional dispensing system, as defined in 3.00.81(d).

c. Any drugs dispensed in a customized patient medication package.

d. Any drug not labeled in accordance with 3.01.20 and 3.01.21.

3.00.84 The following are the responsibility of the pharmacist manager of the prescription drug outlet:

a. To ensure that conditions of delivery to, storage at the location, and during the return from the location, are such as to prevent deterioration and/or contamination by any means that would affect the efficacy and/or toxicity of the product.

b. To ensure that:

(1) Control of the drug being returned is known to the pharmacist to have been the responsibility of a person trained and knowledgeable in the storage and administration of drugs, and the drug has not come into the physical possession of the person for whom it was prescribed.

(2) It can be readily determined that entry or attempted entry to the unit dose or unit of issue package has not been made.

(3) The drug labeling or packaging has not been altered or defaced so that identity of the drug and such other information as may be required pursuant to Regulation 3.01.00 is retrievable.

3.00.85 When drugs are returned for redispensing, the following shall apply:

a. Drug products in manufacturer's unit dose or unit of issue packages may be redispensed as often as necessary, provided that the integrity of the product and package are maintained.

b. Drug products which have been prepackaged or repackaged into unit dose or unit of issue packages in the prescription drug outlet may be redispensed one time only, provided that the integrity of the product and the package are maintained.

c. Drug products which have been prepackaged or repackaged into unit of issue packages in the prescription drug outlet may be redispensed one time only and then only in the package in which originally dispensed, except as provided in (e) below. Partially-used unit of issue packages may not be emptied and the drugs removed and repackaged, nor may additional units of medication be added to partially-used unit of issue packages.

d. Drug products which have been prepackaged or repackaged into single dose packages in the prescription drug outlet may be redispensed one time only and then only in the package in which originally dispensed, except as provided in (e) below. Single dose packages may not be emptied and the drugs removed and repackaged.

e. Drug products which have been prepackaged or repackaged into unit of issue packages or single dose packages may be removed from such packages and repackaged, but not prepackaged, for dispensing in a traditional dispensing system.

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

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

b. A written record or a record printable upon request is maintained indicating a return to stock and the date of such return;

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

d. The drug remains under the same ownership from which it was originally dispensed.

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

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

OR

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

3.01.00 Prepackaging and Repackaging

3.01.10

a. In a prescription drug outlet prepackaging and repackaging shall only be done by a pharmacist, or by an intern or an unlicensed assistant under the supervision of a pharmacist. In an other outlet, prepackaging and repackaging may be done by a person not licensed as a pharmacist pursuant to protocols approved by the Board.

b. Such packaged drugs shall only be dispensed or distributed from the premises where prepackaged or repackaged. Such drugs shall only be distributed to a location which is under the same ownership as, or is contractually affiliated with, the premises where prepackaged or repackaged.

c. Any container used for prepackaging or repackaging shall meet compendia requirements.

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

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

b. A suitable expiration date, which shall be not later than the expiration date on the manufacturer's container, or one year from the date the drug is prepackaged or repackaged;

c. The identity of the manufacturer or distributor;

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

e. The date the product was prepackaged or repackaged;

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

g. If a suitable internal record is maintained in the prescription drug outlet or other outlet, the requirements of (c), (d), (e) and (f) may be omitted from the labeling and maintained in such record. An internal lot number shall be assigned and shall appear in the labeling. In a prescription drug outlet the record shall be signed by the pharmacist responsible for each lot prepackaged or repackaged. In an other outlet the record shall be signed by the person specified in the board approved protocol. The record shall be retained for two years from the date of prepackaging or repackaging, unless otherwise required by law or regulation.

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

3.02.00 Compounding.

The purpose of this regulation is to provide information to pharmacists to enhance the pharmacist's ability to compound preparations that 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.

3.02.10 Limitations. No preparation shall be compounded in advance in such quantity as may exceed a 30 day supply or is necessary to accurately compound the preparation. A 30 day supply shall be determined by the average number of dosage units for which prescription orders were received for said preparation during the previous 6 month period.

The preparation shall only be dispensed by the compounding pharmacy pursuant to a valid prescription order or chart order from a practitioner. No such preparation shall be distributed in any other manner.

3.02.20 Formulation Record. For each compounded preparation, a uniform, readily retrievable formulation record shall be maintained, documenting:

a. the name, strength, and dosage form of the preparation compounded;

b. all ingredients and their quantities;

c. the equipment used to prepare the preparation, when appropriate, and mixing instructions;

d. the formulation assigned expiration date;

e. the container used in dispensing;

f. the storage requirements;

g. procedures for quality control.

3.02.30 Compounding Record. For each compounded preparation, a record shall be maintained on the original order, or on a separate, uniform, readily retrievable record documenting:

a. The name and strength of the compounded preparation;

b. The formulation record reference for the preparation;

c. The sources and lot numbers of each ingredient;

d. the manufacturer's expiration date of each ingredient when applicable;

e. The total number of dosage units compounded;

f. The name of the person who prepared the preparation;

g. The name of the pharmacist who approved the preparation;

h. The date of preparation;

i. The assigned internal identification number if applicable;

j. The assigned expiration date which, in the absence of stability information that is applicable to a specific drug and preparation,

(1) For nonaqueous and solid formulations

(a) Where the manufactured drug product is the source of the active ingredient, 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, shall not be greater than 6 months;

(2) For water-containing formulations prepared from ingredients in solid form, shall not be greater than 14 days when stored at cold temperatures;

(3) For all other formulations, shall not be greater than the intended duration of therapy or 30 days, whichever is earlier;

k. The prescription number;

l. The results of quality control procedures.

3.03.00 Customized Patient Medication Packages (Med Paks).

3.03.10 When a unit dose, single dose, unit of issue or customized patient medication package is dispensed pursuant to an order, the prescription shall comply with all requirements of CRS 12-22-123(2). Container requirements of a prescription for the purpose of unit dose systems may be broadened to include trays, bins, carts and locked cabinets or drawers. Additionally, a customized patient medication package shall comply with all the following requirements:

a. Labeling

The patient med pak shall bear a label stating

(1) The name of the patient;

(2) A serial number for the patient med pak itself and a separate identifying serial number for each of the prescription orders for each of the drug products contained therein;

(3) the name, strength, and total quantity of each drug product contained therein;

(4) the directions for use and cautionary statements, if any, contained in the prescription order for each drug product therein;

(5) any storage instructions or cautionary statements;

(6) the name of the prescriber of each drug product therein;

(7) the date of preparation of the patient med pak, the expiration date which may not exceed 60 days from the date of preparation;

(8) the name, address, and telephone number of the dispenser.

b. Record Keeping.

(1) Patient name and address;

(2) The serial number of the prescription order for each drug in product contained therein;

(3) Descriptive information sufficient to allow subsequent preparation of an identical patient med pak;

(4) Date of preparation of the patient med pak and the expiration date assigned;

(5) Any special labeling instructions;

(6) The identity of the pharmacist who prepared the patient med pak.

c. Packaging

(1) Each container shall meet or exceed United States Pharmacopeia standards.

(2) Each container shall be either not reclosable or so designed as to show evidence of having been opened.

4.00.00 Licensing.

4.00.10 Interns. An intern must practice in conformity with the laws, rules, and regulations of the state in which he/she interns.

a. The intern must obtain one thousand five hundred (1,500) hours of internship.

(1) A maximum of one thousand one hundred (1,100) hours may be obtained by participation in a rotation program conducted by an accredited school or college of pharmacy; other internship hours may be obtained by a licensed intern enrolled in, in good standing with, or graduated from an approved school of pharmacy or holding a valid Foreign Pharmacy Graduate Equivalency Committee certificate.

(2) Up to thirty (30) percent of the required hours may be obtained with a drug manufacturer under the supervision of such manufacturer or with a school or college of pharmacy in drug or drug related research activities as provided in CRS 12-22-111(1)(b)(i).

b. An intern, within 10 days after becoming employed or changing location of employment, of preceptor or of residence, shall inform the board, in writing, of the change. Not more than 40 hours per seven (7) consecutive days will be credited toward the internship requirement as stated. The intern will submit all information to the Board when due and as requested. The intern will submit a Work Record and all accompanying evaluations and appropriate pages from the Colorado Intern Manual within 21 days of the termination of the preceptor/intern relationship.

c. An intern who fails to report his/her experience or location of employment or residence as required above, or who is no longer eligible to be licensed as an intern under Regulation 4.00.10(d) and who fails to surrender his/her intern license upon the request of the Board, shall be deemed to be in violation of this regulation. Although he/she may be granted the experience time submitted, administrative action may be instituted to suspend or revoke his/her license to practice as an intern, or to deny his/her license to practice as a pharmacist.

d. A license to practice as an intern may be granted only to a person who has submitted satisfactory evidence that he/she has graduated from, is enrolled in, is in attendance at, or is in good standing with an accredited school or college of pharmacy, or has submitted to the Board a certificate issued by the Foreign Pharmacy Graduate Examination

Commission.

e. A person on suspension from a school or college of pharmacy does not meet the definition of an intern and is not entitled to exercise the privileges of the intern license

f. A person who is in good standing with the school or college of pharmacy, but is not attending, may be licensed as an intern.

4.00.20 Preceptors. A preceptor is a pharmacist or other authorized person training an intern in compliance with the pharmacy laws, rules and regulations of a state and who has been notified in writing by the Board that he/she is deemed qualified to train an intern.

a. A pharmacist preceptor shall have been licensed and in the practice of pharmacy for at least two consecutive years immediately prior to his/her application for preceptor approval.

b. Other than Letters of Admonition, during the five years preceding such application, the preceptor shall not have been found guilty nor been disciplined by a court or board for violation of any law, rule or regulation pertaining to drugs.

c. A preceptor approved by the Board or approved by an accredited school or college of pharmacy within a clinical rotation shall be employed at each location where an intern is engaged in the practice of pharmacy for credit towards satisfaction of the intern requirements.

d. A pharmacist shall directly supervise the practice of pharmacy of an intern and shall be responsible for the actions of such intern that pertain to the practice of pharmacy as defined.

e. A preceptor of record shall be responsible for the overall training program of not more than two interns at the same work time.

f. A pharmacist shall have up to 10 days after accepting an intern to apply to the Board for approval as a preceptor.

g. More than one pharmacist or other authorized person may be approved by the Board as a preceptor at any location.

h. To obtain credit hours, the hours must be obtained by the intern in compliance with a state's internship program. Every intern and every preceptor shall complete the Colorado Intern Training Manual and shall be held jointly responsible for the timely filing of reports and documents.

i. No pharmacist practicing in Colorado shall supervise the practice of pharmacy, as defined, of more than one intern and one unlicensed assistant or of more than two unlicensed assistants, or of more than two interns, at the same work time.

4.01.00 License Transfer. An applicant for license transfer must transfer a license which was issued by another state by examination and which is current and in good standing.

a. The applicant for license transfer shall use the Board designated clearinghouse for license transfer. The applicant must submit the application for license transfer on forms approved by the Board, along with such other documents, fees and requirements as designated by the Board.

b. The applicant for license transfer must have passed a board examination with a score meeting

the Colorado standards at the time of original licensure.

c. Limitations. An applicant for license transfer must pass a board approved jurisprudence examination, which, for the purpose of this regulation, shall be the practical examination. The passing point shall be set at 75 to reflect minimum competence.

d. A person may be denied license transfer if disciplinary action is pending or has been taken by a board, or if the applicant has been convicted of any crime other than traffic violations not involving drugs or alcohol. For the purpose of this regulation disciplinary action shall mean suspension or revocation of license, fines, probationary periods or letters of admonition.

e. License transfer will be granted to those persons who have met all other requirements of this regulation and have been licensed for at least one year or have served an internship meeting the Colorado requirements at the time of original licensure.

f. No temporary license to practice pharmacy in the State of Colorado shall be granted.

4.02.00 Licensure by Examination. The examinations for licensure as a pharmacist shall consist of an academic examination and a jurisprudence examination, each approved by the Board.

a. For licensure by examination the academic examination shall be fairly designed to test the applicant's knowledge of pharmacy and other related subjects. The passing point shall be set at 75 to reflect minimum competence.

b. The candidate for licensure by examination must pass a Board approved jurisprudence examination, which, for the purpose of this regulation, shall be the practical examination. The passing point shall be set at 75 to reflect minimum competence.

c. If an applicant for licensure by examination passes only one of the required examinations, the applicant shall be required to repeat the failed examination. If, after 24 months, the applicant has not passed both required examinations, he shall be required to also repeat the previously passed examination.

d. Score Transfer applicants must complete their licensure within one year from the date the score transfers are received by the Colorado State Board of Pharmacy.

e. If a candidate for licensure fails to appear for a scheduled examination, the fee shall be forfeited. If the candidate later desires to take the examination, he/she shall reapply and pay the current fee.

f. Practice in lieu of internship. One year of practice of pharmacy as a licensed pharmacist in another state may be accepted by the Board in lieu of a Colorado internship, if the candidate is seeking licensure by examination and has completed this year of practice prior to taking the examination.

g. Examination results. Results of the examination for licensure by examination shall be released whether the candidate is eligible for licensure or not. The Board's staff may release licenses to all candidates when all requirements have been met, and the Board shall act on such released licenses at the next scheduled meeting.

4.03.00 Reinstatement of Pharmacist License. A person seeking to reinstate his/her license as a pharmacist shall be required to pay the appropriate fee, to prove 24 hours continuing education in the 24 month period preceding the application date, and to take and pass the approved examinations as specified below prior to the granting of such reinstatement:

a. If the person has not practiced pharmacy as defined in CRS 12-22-102(26)(a) and (b), for at least 400 hours during the year prior to seeking such reinstatement, he/she shall be required to take and pass both the current practice and jurisprudence examinations, each Board approved, to be eligible for reinstatement. The passing point shall be set at 75 to reflect minimum competence.

b. If the person has been practicing pharmacy as defined in CRS 12-22-102(26) for at least 400 hours during the year prior to seeking reinstatement, he/she shall only be required to take and pass the jurisprudence examination. The passing point shall be set at 75 to reflect minimum competence.

4.04.00 Reactivation of Pharmacist License. A person seeking to reactivate his license when his license is inactive shall be required to file an application and demonstrate that he has met the twenty-four hour approved continuing education requirement. Should the person's license have been inactive for a period longer than two years from the date of filing of the application for reactivation, he must also take and pass the current practice examination and the jurisprudence examination prior to reactivation. The passing point shall be set at 75 to reflect minimum competence.

4.05.00 License Changes.

a. **Name change**. The board records shall reflect a name change that has been appropriately reported. When a licensee's name changes, a duplicate license will not be required in the new name. If the licensee wishes a copy of the license with the new name, the licensee shall pay the requisite fee.

b. **Change of employment or address**. All pharmacists shall notify the Board in writing within 30 days of any change of location of employment or change of address.

c. **Change of manager**. A pharmacist shall immediately notify the Board in writing of the date he ceases to be the pharmacist manager of a prescription drug outlet.

4.06.00 Identification of Licensee. A pharmacist shall at all times while on duty wear a badge which is visible to the patient and which shall state at least the title Pharmacist and license number. Interns shall wear a badge labeled intern pharmacist.

5.00.00 Outlets. (Amended, effective 4/30/02)

5.00.10 Registration. The applicant for registration shall obtain the appropriate form as approved by the Board to register an outlet. In the case of an application for a new prescription drug outlet, for a transfer of ownership of a prescription drug outlet, or for the relocation of a prescription drug outlet, the applicant shall submit such additional documentation as the Board may require.

5.00.20 Applications. The Board, or its agent, may require any applicant or manager of an outlet to meet with the Board, or its agent, before the Board takes action on any registration.

5.00.30 No two registered outlets may occupy the same physical space. If there are two (or more) registrants, each must have its own area, separated by floor to ceiling walls, and separate entrances.

5.01.00 Prescription Drug Outlet.

5.01.10 Controlled Substance Inventory.

a. Upon the change of pharmacist manager of a prescription drug outlet, an inventory of all controlled substances shall be taken within seventy-two hours, by the new pharmacist

manager or the new pharmacist manager's designee. The inventory shall be taken either as of the opening or as of the close of business activity on the inventory date and such time and date taken shall be entered on the inventory record.

b. Upon the transfer of ownership of a prescription drug outlet, an inventory of all controlled substances shall be taken by the pharmacist manager or the pharmacist manager's designee. The inventory shall be taken either as of the opening or as of the close of business activity on the inventory date and such time and date taken shall be entered on the inventory record.

5.01.20 Transfer of Ownership. Application to transfer registration of a prescription drug outlet shall be submitted to the Board as provided in CRS 12-22-119, upon transfer of ownership. Transfer of ownership shall be deemed to have occurred;

a. In the event the prescription drug 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.

b. In the event the prescription drug outlet is owned by a partnership, upon sale or transfer of 20 percent or more of any ownership interest.

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

d. Upon incorporation of an existing prescription drug outlet.

5.01.21 In the event a transfer of ownership of a prescription drug outlet occurs, and the principal compounding dispensing area or any satellite compounding dispensing area does not meet the physical requirements of this regulation, the transfer of the registration may be approved, provided that compliance with such requirements shall be accomplished within six months of the approval of the transfer of the registration or by the next prescription drug outlet registration renewal date, whichever time is greater.

5.01.30 For the purposes of this regulation 5.00.00:

a. The term “compounding/dispensing” means and includes prescription drug storage, handling and preparation including, but not limited to, prepackaging, repackaging, compounding and or dispensing pursuant to orders and/or disposal by any other means.

b. The term “compounding dispensing area” means any area in a prescription drug outlet where “compounding dispensing” is performed.

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

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

prior to remodeling or relocation. Satellite compounding dispensing areas at the same location must not be less than 100 continuous square feet and must be approved by the Board prior to use for compounding dispensing.

b. All compounding dispensing areas shall be well-lighted and well-ventilated with clean and sanitary surroundings devoted primarily to compounding dispensing. These areas shall provide necessary protection for drugs, chemicals and devices from deterioration due to light, heat or evaporation and shall be arranged to protect all prescription drugs and devices from pilferage or other unauthorized removal. No areas shall be subject to any condition likely to lead to errors.

c. All counters and similar work surfaces in the compounding dispensing areas shall be a minimum of 24 inches in width. There shall be a minimum of 12 continuous square feet of compounding/dispensing area, and a minimum of 6 continuous square feet of compounding/dispensing area for each person engaged in compounding/dispensing as defined. These counters and surfaces shall be kept free and clear at all times for the purpose of compounding/dispensing. Any computer workstation or other equipment for the preparation of prescription labels and or storage and retrieval of records shall be in addition to the minimum free compounding dispensing area.

    (1) The free floor space behind all compounding dispensing counters or work surfaces shall be not less than 30 inches in width;

    (2) The free floor space between shelf sections shall be not less than 24 inches;

    (3) There shall be sufficient shelf, drawer and/or cabinet space for proper storage of prescription drugs and devices.

d. In the principal compounding/dispensing area there shall be a sink, equipped with running hot and cold water, which is attached to an approved drain, waste and vent system, or to a portable enclosed tank which is emptied as frequently as necessary. Each satellite area shall also be so equipped if appropriate to the compounding/dispensing activities which are or will be performed therein.

e. The following minimum professional and technical equipment shall at all times be located within at least one of the compounding/dispensing areas:

    (1) Pharmaceutical graduates capable of accurately measuring volumes from 1 ml to at least 250 ml

    (2) Spatula

    (3) Ointment slab or ointment pads

    (4) Glassine papers for weighing and compounding

    (5) Suitable containers for various dosage forms

    (6) Prescription balance meeting minimum compendia sensitivity

    (7) Weights: appropriate metric

    (8) Refrigeration meeting the compendia requirements and with an accurate thermometer in the refrigerator

(9) Any other such equipment as may be necessary for the safe compounding and dispensing of drug products.

f. There shall be a professional reference library available in the prescription drug outlet or electronically. If an electronic library is provided, workstations must be provided in a compounding/dispensing area and must be readily available for use by staff, interns and Board personnel. This library shall contain current copies of the following references which shall be maintained and readily available for use by staff and inspection by the Board:

(1) CRS title 12, Article 22, Part 1, the Drug and Druggists Act; Part 3, the Colorado Licensing of Controlled Substances Act; and Part 6, the Pharmacy Peer Health Assistance Diversion Program;

(2) CRS Title 18, Article 18, the Uniform Controlled Substances Act of 1992;

(3) the current rules and regulations of the Board of Pharmacy;

(4) the current edition of 21 Code of Federal Regulations ("CFR") Part 1300 to End containing drug enforcement administration rules relating to controlled substances;

(5) any other references that the pharmacist manager of the prescription drug outlet may deem necessary.

g. If telephone prescription orders are accepted while the compounding/dispensing area is closed, a voice recording device shall be provided to receive them, and they shall be played back by the pharmacist or intern.

h. Written prescription orders and refill requests for prescription orders may be delivered to the prescription drug outlet while the compounding/dispensing areas are closed, provided a slot or drop box is provided for the prescription order or prescription order refill requests.

i. All prescription drug outlets shall maintain an adequate inventory of prescription drugs and shall offer adequate pharmaceutical service to the public they normally serve. Adequate service shall include the compounding of prescriptions generally used whether composed of a single or many ingredients.

j. Every prescription drug outlet shall display in the principal compounding/dispensing area the report of the most recent inspection conducted by the Board or a photocopy of the most recent self-inspection performed by the pharmacist manager using the form provided by the Board, whichever is more recent, and have readily available documents sent or provided by the Board to clarify or assist in the legal operation of the prescription drug outlet.

k. No person other than a pharmacist or intern employed by the prescription drug outlet shall be permitted in the compounding/dispensing area without the consent of the pharmacist in charge of the compounding/dispensing area.

5.01.32 General Requirements for Prescription Drug Outlets That Compound Sterile Products:

a. Minimum Requirements:

(1) The prescription drug outlet shall have a designated area for a laminar flow hood, or it shall have a class 100 clean room as required by General Services

Administration Federal Standard 209(b) as amended, for the preparation of sterile products. If a clean room is installed and utilized, the clean room shall:

(a) Be designed to avoid outside traffic and air flow;

(b) Have non-porous and cleanable surfaces, walls and floors;

(c) Be ventilated in a manner not interfering with laminar flow conditions;

(d) Not be used for bulk storage for supplies and materials.

(2) Equipment:

(a) A laminar flow hood, or clean room as required by General Services Administration Federal Standard 209 (b) as amended, and certified yearly;

(b) A refrigerator, the temperature of which is within the limits specified in the current edition of the United States Pharmacopoeia National Formulary. The temperature shall be monitored and recorded each business day. Prescription Drug Outlets with electronic systems that alert the pharmacist to non-compliant temperatures are exempt from daily recording;

(c) Supplies necessary for sterile product compounding;

(d) A prescription drug outlet involved only in compounding sterile products may request a waiver of 5.01.31(e).

(3) Current References. In addition to the references required by regulation 5.01.31(f), the following are required:

(a) Guide to Parenteral Admixtures or Handbook on Injectable Drugs or other comparable references as determined by the pharmacist manager.

(b) Technical Manual Section VI: Chapter 2, Controlling Occupational Exposure to Hazardous Drugs or ASHP Technical Assistance Bulletin on Handling Cytotoxic and Hazardous Drugs if cytotoxic products are compounded.

b. Other Requirements/Quality Assurance:

(1) Labeling: Each IV admixture unit dispensed must bear a label that complies with CRS 12-22-123, and with the following additions:

(a) Name of base solution;

(b) Name and amount of drug(s) added;

(c) Expiration date of solution based on published data when available or other supporting documentation.

(2) Policy and Procedure Manual: a policy and procedure manual relating to sterile products shall be maintained on a current basis and shall be available for staff use and inspection by the Board. The manual shall include policies and procedures relating to:

(a) Security.

(b) Sanitation.

(c) Drug storage.

(d) Drug delivery.

(e) Drug labeling.

(f) Drug destruction and returns.

(g) Recordkeeping.

(h) Recall procedures.

(i) Duties of the staff.

(j) Sterile compounding techniques.

(k) Patient training.

(3) The prescription drug outlet shall provide telephone accessibility to its patients at all hours.

c. Cytotoxic Drugs: if cytotoxic drugs are prepared:

(1) The prescription drug outlet shall have the reference required in 5.01.32(a)(3)(b) above, and

(2) Such drugs shall be prepared or otherwise handled in accordance with that manual.

5.01.33 The use of any tobacco product in any compounding/dispensing area is hereby prohibited. However, this regulation shall not apply to the compounding, dispensing or use of a drug which has been derived from a tobacco product and which is being used as an adjunct to a smoking cessation program.

5.01.34 Delivery and Temporary Storage of Prescriptions. Upon the request of a patient or an agent of the patient and with the approval of the pharmacist on duty a prescription may be delivered or temporarily stored outside the confines of a compounding/dispensing area The pharmacist manager of the prescription drug outlet shall determine or approve procedures for the storage and security of, the access to, the confidentiality of, and the counseling regarding, prescriptions, including record keeping including recordkeeping.

5.01.40 Minimum Hours of Operation.

a. The principal compounding/dispensing area of a prescription drug outlet shall be open for normal business a minimum of two designated days per week (Monday through Sunday) and at least four continuous hours on each such designated day.

b. In the event that the principal compounding/dispensing area is open less than 32 hours per week, the pharmacist manager shall submit to the Board a written statement of the designated days and hours when the principal compounding/dispensing area will be open for business, and this statement shall be submitted at least 30 days prior to the date on which the hours of operation will be less than 32 hours per week.

5.01.41 Discontinuance.

a. Discontinuance shall mean the permanent cessation of the practice of pharmacy in any prescription drug outlet.

b. Discontinuance shall be deemed to have occurred if the compounding/dispensing area is not open for business the minimum hours specified in 5.01.40(a).

c. Upon the discontinuance of the practice of pharmacy in any prescription drag outlet it shall be the responsibility of the last pharmacist manager of record to remove the prescriptions and/or chart orders to another prescription drug outlet where patrons and/or practitioners are afforded reasonable access to a pharmacist's interpretation of such orders. Such relocation of records shall be made within 72 hours after discontinuance of the practice of pharmacy occurs. If the last pharmacist manager of record fails to relocate the records as required herein, the Board may direct the removal of the records to a suitable location. The last pharmacist manager of record shall make a reasonable effort to inform patrons of the prescription drug outlet of the location of the records.

d. The Board on request shall provide the owner of any prescription drug outlet an instruction sheet applicable to the transaction prior to discontinuing business, or conducting bankruptcy proceedings, or transferring or selling the prescription drug inventory.

5.01.50 Security. In every prescription drug outlet, all compounding/dispensing areas shall comply with this regulation.

a. When any compounding/dispensing area of a prescription drug outlet is occupied by any employee, a pharmacist must be physically present on the premises.

b. In the event a pharmacist is on the premises but absent from a compounding/dispensing area, it is the responsibility of the pharmacist to ensure the proper safeguard of all drugs.

c. If a compounding/dispensing area is continually attended by a pharmacist when other people are in the building, the compounding/dispensing area need not be enclosed. However, if other people are in the building when there is not a pharmacist present, every compounding/dispensing area must be enclosed by a barrier as specified in paragraph (d) below.

d. A prescription drug outlet constituting part of a large establishment may be closed while the balance of the establishment is open for business, provided every compounding/dispensing area is enclosed with a secure floor-to-ceiling physical barrier, which shall be a divider or secure total enclosure, in which any openings shall not be large enough to permit removal of items from the compounding/dispensing area. The barrier must be of weight and strength sufficient to prevent it from being readily lifted, removed, penetrated or bent.

e. All entrances to every compounding/dispensing area shall be secured from unauthorized entry when the pharmacist leaves the building. No one other than a pharmacist shall be permitted to enter any compounding/dispensing area except in extreme emergencies, which shall be defined as a threat to property, public disaster or other catastrophe whereby the public is better served by overlooking the security restrictions of drugs and devices. If any compounding/dispensing area is opened in the absence of a pharmacist the pharmacist manager shall notify the Board of Pharmacy in writing within ten days of the opening. This written notice shall state:

(1) The name of the person authorizing the opening of the compounding/dispensing area

if known;

(2) The name of the person opening the compounding/dispensing area if known; and

(3) A description of the situation requiring opening of the compounding/dispensing area including the date and time of the opening.

f. While the compounding/dispensing area is closed and the rest of the establishment is open, a person on duty in the establishment shall be able to contact a pharmacist in case of emergency.

g. The hours of business of the compounding/dispensing area shall be submitted to the Board in writing.

h. No prescription drug outlet shall avail itself of the privileges of this regulation until the barrier system and other requirements have been acknowledged, subject to final approval by the Board.

i. This paragraph applies only to the compounding/dispensing areas of a hospital which operates a prescription drug outlet pursuant to a certificate of compliance; or which operates a registered prescription drug outlet on the premises of the hospital for the primary purpose of providing pharmaceutical services to the hospital's in-patients; or permits a registered prescription drug outlet to be operated on the premises of the hospital by another business entity for the primary purpose of providing pharmaceutical service to the hospital's in-patients.

(1) In an emergency situation and when a pharmacist is not on the premises of the hospital and administration of a drug to, or use of a device by or on, an in-patient is necessary pursuant to a chart order, and such drug or device is only available from a locked compounding/dispensing area, an authorized registered nurse may enter a locked compounding/dispensing area to obtain the drug or device. In the case of a drug, only pre-labeled packages, such as unit dose or unit-of-use packages, or a pre-labeled container, may be removed from the compounding/dispensing area.

(2) The following information regarding the removal of such drug or device shall be consistently recorded and maintained in a retrievable document: date; time; name, strength and dosage form of drug, and/or name, and size, if applicable, of device; total quantity of drug or device removed; name and location of patient for whose use the drug or device is necessary; name of the practitioner ordering the drug or device; and the initials or signature of the nurse obtaining the drug or device. This document shall be available for inspection by the Board for a period of 2 years. Additionally, the original, duplicate or electronic or mechanical facsimile of the chart order shall be left with the above document by the nurse at the time of obtaining the drug or device.

(3) Any unused portion of a drug or device so removed shall be returned to the compounding dispensing area when a pharmacist is again on the premises. Additional quantities of the drug or device shall be supplied by a pharmacist and properly recorded as required by law and regulation.

5.02.00 Other Outlets.

5.02.10 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-

22-120(1)(e), are stated below.

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.

5.02.11 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, admirustration, compounding, dispensing, and/or distribution, including the retum to the original source, of all prescription drugs and devices, including recalled items. 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 DEA registration number of the prescriber.

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

An other outlet utilizing a computer system to record dispensing transactions shall comply with Regulation 11.00.00.

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.

5.02.12 Revisions to Other Outlet Protocols and/or Formulary. Revisions to other outlet protocols shall be submitted as a complete set in duplicate for approval by the Board or its designee prior to becoming effective.

5.02.13 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.

5.02.14 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.

5.02.15 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.

5.02.20 Other Required Registrations. The other outlet shall obtain such state and/or federal registrations as may be required.

5.02.30 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 regulation 5.02.00. The review shall be documented in writing, signed, and dated by the Consultant Pharmacist.

d. A Consultant Pharmacist shall visit the other outlet a minimum of one time each quarter to ensure compliance with the protocols and all applicable laws, rules, and regulations. The Consultant Pharmacist shall develop a 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 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.

f. 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.

5.02.31 The duties of the Consultant Pharmacist specified in regulation 5.02.30 shall be included in the protocols.

5.02.32 Institutions Operating Other Outlets for Limited Public Welfare Purposes Pursuant to Board-Approved Protocols.

a. Jails which operate registered other outlets. 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 shall be exempt from registration.

b. County Health Departments.

c. Community and Rural Health 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. Hospitals which do not operate a registered prescription drug outlet. For such institutions, dispensing shall be limited as provided in CRS 12-22-121(11).

f. Family Planning Clinics.

5.02.33 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.

6.00.00 Repealed.

7.00.00 Pharmacy Manager Responsibilities. (AMENDED, Effective 1/30/2003)

7.00.10 Reporting Violations. The pharmacist manager of a prescription drug outlet shall report the following violations of the Drugs and Druggists Act:

a. Diversion of substances from the pharmacy.

b. Security breaches within the pharmacy or pharmacy area of the establishment.

c. The unaccountable loss of medications from the pharmacy, whether by theft or unknown means.

d. Any pharmacist working in the pharmacy who is impaired due to the use of alcohol or drugs, or a pharmacist with a mental or physical impairment which affects his ability to perform his job competently.

e. Significant errors related to the practice of pharmacy such as those that result in serious personal injury of death of a patient.

7.00.20 Administrative Reporting Responsibilities:

a. A pharmacist manager shall immediately notify the Board in writing of the date he ceases to be the pharmacist manager of a prescription drug outlet.

b. Upon the change of pharmacist manager of a prescription drug outlet, the new pharmacist manager or the new pharmacist manager's designee shall take an inventory of all controlled substances within seventy-two hours. The inventory shall be taken either as of the opening or as of the close of business activity on the inventory date and such time and date taken shall be entered on the inventory record.

c. Upon the transfer of ownership of a prescription drug outlet, the pharmacist manager or the pharmacist manager's designee shall take an inventory of all controlled substances. The inventory shall be taken either as of the opening or as of the close of business activity on the inventory date and such time and date taken shall be entered on the inventory record.

d. The pharmacist manager shall determine or approve procedures for prescriptions delivered or temporarily stored outside the confines of a compounding/dispensing area at the request of a patient or an agent of the patient. This procedure shall include the storage of, security of, the access to, the confidentiality of, and the counseling regarding, prescriptions and necessary record keeping.

e. Upon the discontinuance of the practice of pharmacy in any prescription drug outlet it shall be the responsibility of the last pharmacist manager of record to remove the prescription and/or chart orders to another prescription drug outlet where patrons and/or practitioners are afforded reasonable access to a pharmacist's interpretation of such orders.

f. The daily printout shall contain all information as required by regulation except that the identity of the pharmacist who makes the final evaluation may appear either on the daily printout or on another separate, uniformly maintained and readily retrievable record. The pharmacist manager shall determine which of the two methods for identifying the responsible pharmacist is more appropriate for the outlet, and only that method for recording such information shall be used. This applies to both prescription order and chart order dispensing.

g. It is the responsibility of the pharmacist manager to ensure that all prescription drug outlet staff are aware that they must be able to print a report of all prescription order or chart order transactions for such period of time as the Board or its inspector(s) may specify, or to 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 prescription drug outlet elects to comply with the latter requirement of providing equipment and/or personnel, the system must also be capable of printing the reports previously described.) Any failure or refusal by the pharmacist 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 regulations.

h. It is the responsibility of the pharmacist manager to maintain records as required by

Regulation 14.00.00.

7.00.30 Compliance of Outlet:

a. The manager of a prescription drug outlet is responsible for the operation of the outlet in compliance with all state and federal laws, rules, and regulations.

8.00.00 Advertising.

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

8.00.20 Prescription Order Forms. No prescription drug outlet shall provide any practitioner with prescription order forms that refer to a pharmacist or prescription drug outlet.

8.00.30 Multiple Names. A prescription drug outlet shall only use, operate or advertise under the name that appears on the current registration issued by the Board of Pharmacy.

8.00.40 Truth in Advertising. No pharmacist or prescription drug outlet shall advertise or allow advertisement that is untrue or misleading in any manner regarding prescription drugs.

9.00.00 Legal Proceedings.

9.00.10 The Board must be immediately notified of the filing of all legal proceedings and/or disciplinary action in another state and within 20 days of the disposition of such proceedings wherein it is alleged that a Board licensee has violated any law or regulation pertaining to drugs or devices.

10.00.00 Emergency Kits.

10.00.10 Application. Nursing homes, home health agencies, hospices, extended care facilities or intermediate care facilities licensed or certified by the Department of Public Health & Environment may maintain an emergency kit. 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 pharmacy to whom the approval was issued. Emergency kits and the contents thereof shall meet the following requirements:

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

a. In the case of an approved facility, only a pharmacist employed by the prescription drug outlet which provides the kit, the consulting pharmacist, and any nurse employed at the facility shall have access.

b. In the case of a certified home health agency or a licensed hospice, only a pharmacist employed by the prescription drug outlet which provides the kit or a nurse employed by the certified home health agency or licensed hospice shall have access.

10.00.30 Categories and Limits. The Board shall establish therapeutic categories for drugs to be placed in the kit.

a. In the case of an approved facility (i.e. nursing homes, intermediate and extended care facilities, etc.) 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. Only an approved facility shall be permitted to have oral dosage forms of drugs in the kit.

b. In the case of a certified home health agency or a licensed hospice, the director of nursing of the certified home health agency or of the licensed hospice, or designee, and a pharmacist employed and designated by the prescription drug outlet providing the kit shall determine the specific drugs to be kept in the kit. A certified home health agency or licensed hospice may not have oral dosage forms of drugs 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.

c. The responsibility for stocking and restocking the emergency drug kit is that of a licensed pharmacist.

10.00.40 Notification. A pharmacy which supplies an emergency drug kit to an approved facility or certified home health agency or licensed hospice 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 an approved facility, or of the designated pharmacist in the case of a certified home health agency or a licensed hospice.

10.00.50 The kit shall be sealed in such a mariner that the seal must be broken to remove a drug. Paper or tape seals are unacceptable.

10.00.51 The following information shall be placed on the outside of the kit and shall be readily visible and up-dated as required: name, address and telephone number of the prescription drug outlet providing the contents of the kit; the date of sealing; 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, in the case of an approved facility, the name of the consulting pharmacist, or, in the case of a certified home health agency or a licensed hospice, the name of the designated pharmacist. A copy of the kit contents shall also be attached to the outside of the kit.

Use of automated storage units must comply with current pharmacy rules and follow the procedures outlined in these regulations, except as provided below:

a. No seal is required on the unit, but a code is required in order to access it;

b. The unit shall be restocked by a licensed pharmacist only at the facility in which it resides.

10.00.60 Inspection. A pharmacist employed by the prescription drug outlet providing the kit shall inspect and inventory the contents of the kit at least annually and within 72 hours after being notified that the seal was broken. Inspection shall be documented by that pharmacist, and such documentation shall be maintained and available for inspection at the prescription drug outlet for a period of two years.

10.00.70 Records. The prescription drug outlet providing the kit shall maintain a separate record of use for each drug placed in the kit, and for each kit provided, which shall state the name and address

of the approved facility, certified home health agency, or licensed hospice; the name and strength of the drug; and the container size and the quantity initially placed in the kit. When a drug is removed for administration the prescription drug outlet shall obtain a prescription 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 Regulation 14.05.11. Additionally, the separate record required for each drug in the kit shall reflect the following information: date and quantity administered; names of both the patient and practitioner; date the drug was replaced in the kit; the quantity of the drug replaced, which shall not exceed the quantity administered or removed for administration; and the prescription order number assigned.

10.00.80 Use. The drugs shall only be administered to patients of the approved facility, certified home health care agency, or licensed hospice pursuant to the order of a practitioner.

10.00.90 Withdrawal of approval. The possession or disposition of the drugs in contravention to these regulations shall result in the Board withdrawing approval of the drugs in the kit and may be deemed to be in violation of CRS 12-22-125.

11.00.00 Records and Recordkeeping. This section is completely rewritten and will be replaced with the update published in July.

12.00.00 Nuclear Pharmacy.

12.00.10 Authorized handling. It is unlawful to receive, possess or transfer radiopharmaceuticals, except in accordance with C.R.S. 12-22-108. It is also unlawful for any person to provide radiopharmaceutical services unless he or she is a nuclear pharmacist acting in accordance with C.R.S. Title 12, Article 22, and the regulations of the State Board of Pharmacy and regulations of the Colorado Department of Health, with the exception of an authorized practitioner for administration to his patients. No person may receive, acquire, possess, use, transfer or dispose of any radioactive material except in accordance with the conditions of any radioactive material license required by the Colorado Department of Health pursuant to C.R.S. 25-11-101 et seq. The requirements of this regulation are in addition to, and not in substitution for, other applicable provisions of regulations of the State Board of Pharmacy and the State Radiation Control Agency.

12.00.20 Definitions.

12.00.21 A “nuclear prescription drug outlet” means a prescription drug outlet which deals with the preparation and delivery of radioactive material as defined in C.R.S. 25-11-101.

12.00.22 “Nuclear pharmacist” means a pharmacist who has received notification by letter from the Board that, based on the evidence submitted, he or she is recognized by the Board as qualified to provide radiopharmaceutical services.

12.00.23 “Radiopharmaceutical service” shall mean, but shall not be limited to, the compounding, dispensing, labeling and delivery of radiopharmaceuticals; the participation in radiopharmaceutical selection and radiopharmaceutical utilization reviews; the proper and safe storage and distribution of radiopharmaceuticals; the maintenance of radiopharmaceutical quality assurance; the responsibility for advising, where necessary or where regulated, of therapeutic values, hazards, and use of radiopharmaceuticals, and the offering or performing of those acts, services, operations or transactions necessary in the conduct, operation, management and control of radiopharmaceuticals.

12.00.24 A “radiopharmaceutical” is any substance defined as a drug in Section 201(g)(1) of the Federal Food, Drug and Cosmetic Act which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or protons and includes any such drug which is intended to be

made radioactive. This definition includes non-radioactive reagent kits and nuclide generators which are intended to be used in the preparation of any such substance but does not include drugs such as carbon-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides.

12.00.25 "Radiopharmaceutical quality assurance" means, but is not limited to, the performance of appropriate chemical, biological and physical tests on radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals, including internal test assessment, authentication of product history and the keeping of proper records.

12.00.26 "Internal test assessment" means, but is not limited to, conducting those tests of quality assurance necessary to ensure the integrity of the test.

12.00.27 "Authentication of product history" means, but is not limited to, identifying the purchasing source, the ultimate fate, and intermediate handling of any component of a radiopharmaceutical.

12.00.28 "Authorized practitioner" means a practitioner authorized by law to possess, use and administer radiopharmaceuticals, acting within the scope of such authority.

12.00.30 Requirements For Nuclear Prescription Drug Outlets. A nuclear prescription drug outlet shall only be managed by a nuclear pharmacist. All personnel performing tasks in the preparation and distribution of radiopharmaceuticals shall be under the direct supervision of a nuclear pharmacist. A nuclear pharmacist shall be in attendance at all times that the nuclear prescription drug outlet is open for business and shall be responsible for all operations of the registered area.

12.00.31 A nuclear prescription drug outlet shall have adequate space, commensurate with the scope of services required and provided. The nuclear prescription drug outlet area shall be separate from the areas for non-radioactive drugs and shall provide a radioactive storage and product decay area, occupying at least 25 square feet of space, separate from and exclusive of the radioactive laboratory, compounding, dispensing, quality assurance and administrative area. A nuclear prescription drug outlet handling radiopharmaceuticals exclusively may be exempted from the general space requirements for prescription drug outlets by obtaining a waiver from the Board. Detailed floor plans shall be submitted to the Board and the State Radiation Control Agency before approval of the registration.

12.00.32 A nuclear prescription drug outlet shall maintain a library commensurate with the level of radiopharmaceutical service to be provided, and shall include state and/or federal regulations governing the use of applicable radioactive materials. A detailed library listing shall be submitted to the Board and the State Radiation Control Agency before approval of the license. The nuclear prescription drug outlet shall maintain current editions of the publications shown on the library listing.

12.00.33 A nuclear prescription drug outlet shall comply with all applicable laws and regulations of federal and state agencies, including those laws and regulations governing non-radioactive drugs.

12.00.34 A nuclear prescription drug outlet shall have adequate equipment commensurate with the scope of radiopharmaceutical services to be provided. A detailed list of equipment and description of use must be submitted to the State Board of Pharmacy and State Radiation Control Agency before approval of the registration. The Board may, for a nuclear prescription drug outlet, and for good cause shown, waive the requirements of regulation 5.01.45

12.00.40 General Requirements For Nuclear Pharmacists. A nuclear pharmacist shall:

12.00.41 Meet minimal standards of training and experience in the handling of radioactive materials in accordance with the requirements of the State Radiation Control Agency;

12.00.42 Be a pharmacist licensed to practice in Colorado;

12.00.43 Submit to the Board either:

a. Certification that he or she, after graduation from a school or college approved by the Board, has completed during a period of not more than twelve consecutive months a minimum of 640 hours of on-the-job training providing radiopharmaceutical services under the supervision of a nuclear pharmacist in a nuclear prescription drug outlet, or

b. Certification that he or she has received a minimum of two hundred (200) contact hours of didactic instruction in radiopharmaceutical service from an accredited school or college of pharmacy.

12.00.44 Upon application to the Board, in affidavit form, and upon the furnishing of such other information as the Board may require, the Board may grant partial or equivalent credit for education and experience gained in programs not sponsored by an accredited school or college of pharmacy if, in the opinion of the Board, the education and experience gained by participants in these programs would provide the same level of competence as participation in a program at an accredited school or college of pharmacy;

12.00.45 Receive a letter of notification from the Board that the evidence submitted meets the requirements of subsections 12.00.41, 12.00.42 and 12.00.43 above and had been accepted by the Board and that, based thereon, the pharmacist is recognized as a nuclear pharmacist.

12.00.50 Nuclear pharmacist. A nuclear pharmacist may distribute radiopharmaceuticals to authorized practitioners. Such distribution shall be documented in the control system.

12.00.51 A nuclear pharmacist may transfer to authorized persons radioactive materials not intended for drug use, in accordance with regulations of the State Radiation Control Agency.

12.00.60 Dispensing. A nuclear prescription drug outlet shall only dispense radiopharmaceuticals which comply with acceptable standards of radiopharmaceutical quality assurance.

12.00.61 Except as provided in 12.00.50, radiopharmaceuticals are to be dispensed only upon an order from an authorized practitioner.

12.00.62 In addition to any labeling requirement of the Board for non-radiopharmaceuticals, the immediate outer container of the radiopharmaceutical to be dispensed shall also be labeled with: (1) the standard radiation symbol; (2) the words “caution--radioactive material”; (3) the name of the radiopharmaceutical; (4) the amount of radioactive material contained, in millicuries or microcuries; (5) if a liquid, the volume in milliliters; (6) the requested calibration time for the amount of radioactive material contained; (7) expiration data, if applicable; (8) specific concentration of radioactivity.

12.00.63 The immediate inner container shall be labeled with: (1) the standard radiation symbol; (2) the words “caution--radioactive material”; (3) the name and address of the nuclear prescription drug outlet; (4) the serial number of the prescription order; (5) the name of the radiopharmaceutical.

12.00.64 The amount of radioactivity shall be determined by radiometric methods for each individual preparation immediately prior to dispensing.

12.00.65 A nuclear prescription drug outlet may redistribute NDA approved radiopharmaceuticals if the prescription drug outlet does not process the radiopharmaceuticals in any manner or violate the product packaging.

12.00.70 Records. In addition to any requirement of the Board for non-radiopharmaceutical prescription orders, the prescription order shall include: (1) address of the authorized practitioner and/or the address where the prescription is to be administered; (2) the name of the radiopharmaceutical; (3) the amount of radioactive materials contained, in millicuries or microcuries; (4) if a liquid, the volume in milliliters; (5) the requested calibration time for the amount of radioactivity contained; and (6) specific concentration of radioactivity.

12.00.71 A nuclear prescription drug outlet shall maintain records of acquisition and distribution of all radiopharmaceuticals in accordance with C.R.S. Title 12, and C.R.S. Title 25.

13.00.00 Declaratory Orders.

13.00.10 Requests. Any person[1] may petition the Board for a declaratory order to terminate controversies or to remove uncertainties as to the applicability to the petitioner of any statutory provision or of any rule or order of the Board.

[1]Refer to existing definition of "person" in APA, rules or statute, if any.

13.00.11 The Board will determine, in its discretion and without notice to petitioner, whether to rule upon any such petition. If the Board determines that it will not rule upon such a petition, the Board shall promptly notify the petitioner of its action and state the reasons for such action.

13.00.12 In determining whether to rule upon a petition filed pursuant to this rule, the Board will consider the following matters, among others:

a. Whether a ruling on the petition will terminate a controversy or remove uncertainties as to the applicability to petitioner of any statutory provision or rule or order of the Board.

b. Whether the petition involves any subject, question or issue which is the subject of a formal or informal matter or investigation currently pending before the Board or a court but not involving any petitioner. Whether the petition seeks a ruling on a moot or hypothetical question or will result in an advisory ruling or opinion.

c. Whether the petitioner has some other adequate legal remedy, other than an action for declaratory relief pursuant to Rule 57 Colorado Rules of Civil Procedure, which will terminate the controversy or remove any uncertainty as to the applicability to the petitioner of the statute, rule or order in question.

13.00.13 Any petition filed pursuant to this rule shall set forth the following:

a. The name and address of the petitioner and whether the petitioner is licensed pursuant to the provisions of C.R.S. 12-22-101, et. seq., as amended. The statute, rule or order to which the petition relates.

b. A concise statement of all of the facts necessary to show the nature of the controversy or uncertainty and the manner in which the statute, rule or order in question applies or potentially applies to the petitioner.

13.00.20 Ruling. If the Board determines that it will rule on the petition, the following procedures apply:

a. The Board may rule upon the petition based solely upon the facts presented in the petition. In such a case: Any ruling of the Board will apply only to the extent of the facts presented in the petition and any amended to the petition.

b. The Board may order the petitioner to file a written brief, memorandum or statement of position. The Board may set the petition, upon due notice to petitioner, for a non-

evidentiary hearing.

c. The Board may dispose of the petition on the sole basis of the matters set forth in the petition.

d. The Board may request the petitioner to submit additional facts, in writing. In such event, such additional facts will be considered as an amendment to the petition.

e. The Board may take administrative notice of facts pursuant to the Administrative Procedure Act (C.R.S. 24-4-105(8)) and may utilize its experience, technical competence and specialized knowledge in the disposition of the petition.

f. If the Board rules upon the petition without a hearing, it shall promptly notify the petitioner of its decision.

g. The Board may, in its discretion, set the petition for hearing, upon due notice to petitioner, for the purpose of obtaining additional facts or information or to determine the truth of any facts set forth in the petition or to hear oral argument on the petition. The notice to the petitioner setting such hearing shall set forth, to the extent known, the factual or other matters into which the Board intends to inquire. For the purpose of such a hearing, to the extent necessary, the petitioner shall have the burden of proving all of the facts stated in the petition, all of the facts necessary to show the nature of the controversy or uncertainty and the manner in which the statute, rule or order in question applies or potentially applies to the petitioner and any other facts the petitioner desires the Board to consider.

13.00.30 Parties. The parties to any proceeding pursuant to this rule shall be the Board and the petitioner. Any other person may seek leave of the Board to intervene in such a proceeding, and leave to intervene will be granted at the sole discretion of the Board. A petition to intervene shall set forth the same matters as required by section 13.00.13 of this rule. Any reference to a "petitioner" in this rule also refers to any person who has been granted leave to intervene by the Board.

13.00.40 Review. Any declaratory order or other order disposing of a petition pursuant to this rule shall constitute agency action subject to judicial review pursuant to C.R.S. 24-4-106.

14.00.00 Repealed.

15.00.00 Wholesalers.

15.00.10 Sanitation.

15.00.11 Adequate sanitary and plumbing facilities shall be installed. These facilities shall be maintained in good repair and shall be regularly cleaned.

15.00.12 All areas of the facility shall be regularly and routinely cleaned. The walls, ceilings, windows and floors of the premises shall be clean and maintained in good repair and order.

15.00.13 The premises shall be free from obnoxious odors.

15.00.14 There shall be adequate pest control.

15.00.15 All personnel shall keep themselves and their attire as clean as possible. Facilities for storage of additional clothing and changing shall be provided as necessary and appropriate.

15.01.00 Storage.

15.01.10> All areas of the outlet shall be well lighted and ventilated. Drugs shall be stored in such a manner as to protect them from possible deterioration due to light, humidity or evaporation. Surrounding environmental conditions shall be such as to prevent contamination from outside sources. There shall be adequate storage space. Products which are not stored on shelving or under special conditions, such as refrigeration, shall not be stored directly on the floor.

15.01.11 Drugs shall be stored at appropriate temperatures according to label requirements. Adequate heating and cooling equipment and controls shall be installed and maintained to ensure proper storage temperatures in all areas where such drugs are stored.

15.01.12 Equipment shall be installed and maintained for storage of products which require storage at other than room temperature. Refrigeration and/or freezer unit temperature(s) shall be monitored each business day and the temperature(s) recorded along with the date, time and initials or signature of the responsible person.

15.01.13 Drugs shall be placed under proper storage conditions as soon as possible after receipt.

15.01.14 The wholesaler shall be responsible that proper storage requirements are met for all drugs during shipment to a purchaser or other person entitled to receive such products.

15.02.00 Security.

15.02.10 Security precautions shall be taken to ensure that access from outside the facility is reduced to a minimum. The entire facility shall be subject to controlled access, and this shall apply both to entrances from outside the facility and to those areas where controlled substances are stored. Adequate lighting shall be provided at the outside perimeter of the premises to reduce the possibility of illegal entry. There shall be appropriate alarm systems to detect unauthorized entry. Such alarm systems shall be both external and centrally monitored with a dedicated line and systems back-up. The systems and the back-up shall be regularly inspected and tested.

15.02.11 One person shall be designated by name or title, in writing, to have ultimate responsibility for security of all keys or other methods of entry into the facility itself and into all limited access areas within the facility. There shall be a list that identifies all persons who are authorized to have access to controlled substances. This information shall be made available to the Board upon request.

15.02.12 Storage areas shall be constructed in such a manner as to reduce the possibility of illegal entry. Controlled substances shall be secured and stored in compliance with all applicable provisions of 21 Code of Federal Regulations sections 1301.71 through 1301.74, which are hereby incorporated by reference. Controlled substances shall be stored in a vault or cage, as appropriate, as soon as possible after receipt. The wholesaler shall take adequate precautions to ensure the security of controlled substances during shipment to a purchaser or other person entitled to receive and possess controlled substances.

15.02.13 Any theft, suspicious loss, or recurring loss of prescription drugs or any loss of controlled substances shall be reported to the Board, along with a description of the loss, cause of the loss and any other appropriate information. Any loss of controlled substances shall also be reported to the appropriate law enforcement agency.

15.02.14 Any computer system used by the wholesaler shall be protected from unauthorized use.

15.03.00 Records.

15.03.10 Records shall be maintained in compliance with Regulation 14.00.00 and this regulation shall be followed for all incoming and outgoing prescription drugs.

15.03.11 All records of receipt, distribution or other disposal of prescription drugs and/or controlled substances shall be available to the Board on request for inspection, copying, verifying or other proper use. If authorization has been granted to maintain certain records centrally at another location, these records shall be made available within two business days (48 hours maximum.) Records kept at an inspection site or other site that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. If recap records are available, the Board may, at its option, utilize them, but the original records must also be produced if requested and shall be considered the document of record in any case.

15.03.12 Wholesale drug distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution of prescription drugs. These records shall include the following information:

a. The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped.

b. The identity and quantity of the drugs received and distributed or disposed: and

c. The dates of receipt and distribution or other disposition of the drugs.

15.04.00 Distribution.

15.04.10 A wholesaler shall only distribute a drug in compliance with C.R.S. 12-22-121(3). A wholesaler shall take such precautions as deemed necessary and appropriate to ensure that a drug or controlled substance is only distributed to a person who may lawfully receive and possess it.

15.05.00 Policies and Procedures.

15.05.10 Wholesale drug distributors shall establish, maintain and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of prescription drugs, including controlled substances, and including policies and procedures for identifying, recording, and reporting destruction, losses or thefts, and for correcting all errors and inaccuracies in inventories. Wholesale drug distributors shall include the following in their written policies and procedures:

a. A procedure whereby the oldest approved stock of a prescription drug product is distributed first. The procedure may permit deviation from this requirement, if such deviation is temporary and is itself, an approved deviation procedure.

b. A procedure to be followed for handling recalls and withdrawals of prescription drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to:

(1) Any legal action initiated at the request of the Food and Drug Administration or other government agency with jurisdiction;

(2) Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

(3) Any action undertaken to promote public health and safety by the replacing of existing merchandise with an improved product or new package design.

c. A procedure to ensure that wholesale drug distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.

d. A procedure to ensure that any outdated, misbranded, adulterated or unsaleable prescription drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation which shall be maintained for 2 years after dispositions of the outdated drugs.

e. Policies and procedures to cover the examination of materials to include the visual inspection of shipping containers for prescription drugs unfit for distribution, prescription drugs which have been damaged in storage or held under improper conditions.

f. Procedures which assure employees possess the necessary education or experience for the position they hold and the job functions they are assigned.

15.05.11 The policies and procedures shall contain a provision for review at least annually, at which time they shall be up-dated as necessary. A record documenting this review shall be kept with the policies and procedures and shall indicate the date of completion of the review and the signature of the responsible person as defined in Regulation 15.07.10.

15.05.12 These policies and procedures and the documentation of the annual review shall be available to the Board on request for review or other proper use.

15.06.00 Unsaleable Drugs.

15.06.10 A procedure to assure that any outdated stock, or any stock with an expiration date that does not allow sufficient time for dispensing by the prescription drug outlet shall be segregated from other stock and shall be prepared for return to the manufacturer or otherwise destroyed, and documented.

15.06.11 Any unsaleable drug shall be segregated in a specific area away from saleable stock. A drug which has been returned to the wholesaler shall be segregated from other stock until it can be determined if the item is saleable and suitable for placement into inventory or is unsaleable.

15.06.12 An unsaleable controlled substance shall be destroyed or otherwise disposed of in compliance with the requirements of the Drug Enforcement Administration and appropriate records shall be kept. In the case of a non-controlled drug which is unsaleable, records shall be kept which contain the same information as required in 14.02.52 (a) through (f) and indicate the disposition of the item. If the item is destroyed, the record shall include the method of destruction.

15.06.13 Prescription drugs returned to a wholesaler shall not be redistributed if the product is misbranded or adulterated and shall be returned to the source or destroyed.

15.07.00 Wholesale Drug Distributor Licensing Requirement.

Every wholesaler distributor as defined who engages in wholesale distributions of prescription drugs must be licensed in accordance with this part before engaging in wholesale distributions of prescription drugs.

15.07.10 A single person shall be designated by name and title who has complete and overall responsibility for the operation of the facility in compliance with all applicable laws, rules and regulations pertaining to drugs. This person's name and title shall be reported to the Board in writing. Any change in name or title of the person having such responsibility shall be reported to the Board in writing within fifteen days of such change unless extended by the Board.

15.07.11 Minimum Required Information for Licensure.

a. The following minimum information shall be required from each wholesale drug distributor as

part of the license described in Section 15.07.00 and as part of any renewal of such license:

(1) The name, full business address, and telephone number of the licensee;

(2) All trade or business names used by the licensee;

(3) Addresses, telephone numbers, and the names of contact persons for all facilities used by the licensee for the storage, handling and distribution of prescription drugs;

(4) The type of ownership or operation (i.e., partnership, corporation, or sole proprietorship); and

(5) The name(s) of the owner and/or operator of the licensee, including:

(a) If a person, the name of the person.

(b) If a partnership, the name of each partner, and the name of the partnership.

(c) If a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the state of incorporation: and

(d) Name of the business entity. If a sole proprietorship, the full name of the sole proprietor and the name of the business entity.

b. Changes in any information in section 15.07.11(a) shall be submitted to the Colorado Board of Pharmacy within ten days thereof.

15.07.12 Minimum Qualifications.

a. The Colorado Board of Pharmacy shall consider, at a minimum, the following factors in reviewing the qualifications of persons described in 15.07.11(e) above who engage in the wholesale distribution of prescription drugs within the state:

(1) Any conviction of the applicant under any federal, state, or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances:

(2) Any felony convictions of the applicant under federal or state laws as provided under the standards of Section 24-5-101, C.R.S.;

(3) The applicant's past experience in the manufacture or distribution of prescription drugs, including controlled substances;

(4) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;

(5) Suspension or revocation by federal, state, or local Government of any license currently or previously held by the applicant for the manufacture, distribution or dispensing of any drugs, including controlled substances;

(6) Compliance with licensing requirements under previously granted license, if any;

(7) Compliance with requirements to maintain and/or make available to the Colorado

Board of Pharmacy or other governmental agency with jurisdiction those records required under the section; and

(8) Any other factors or qualifications the Colorado Board of Pharmacy considers relevant to and consistent with the public health and safety.

b. The Colorado Board of Pharmacy shall have the right to deny a license to an applicant if it determines that the granting of such a license would not be in the public interest under Title 12, C.R.S., and these rules.

15.07.13 Wholesalers shall certify that all staff, employees and personnel have suitable education or experience for the position such staff and employees hold and the job functions they are assigned.

15.08.00 Change of Name or Ownership.

15.08.10 Any change in the name of the business shall be reported to the Board in writing within fifteen days of such change unless extended by the Board.

15.08.11 Any change in ownership shall be reported in writing to the Board within fifteen days of the change and the new owner(s) shall apply for a new registration from the Board and pay the appropriate fee. A change of ownership shall be deemed to have occurred:

a. In the event the owner is a corporation, upon sale or transfer of 20 percent or more of the shares of the corporation to a single individual or entity; or

b. Upon the sale or transfer of any interest in the business of 20 percent or more to a single individual or entity.

17.00.00 Electronic Transfer Order(s) (ETO).

17.00.10 The electronically transmitted order must be transmitted by a practitioner or the agent of a practitioner to a prescription drug outlet.

17.00.20 A prescription drug outlet may transmit a prescription order electronically to another prescription drug outlet for the purpose of dispensing a prescription order.

a. If the prescription order information is transmitted by facsimile, the transferring pharmacist shall comply with Regulation 2.01.52.

b. Prescription order information may be transmitted electronically between two compatible computer systems that are capable of complying with the requirements of regulations 2.01.52 and 2.01.53(1)–(10).

c. In the case of prescription drug outlets that access and utilize a common data base, if the original prescription order information is not invalidated, each dispensing prescription drug outlet shall be capable of accessing a transaction record that indicates each date, time and location from which the prescription was dispensed.

18.00.00 Pharmacy Peer Health Assistance Diversion Program.

18.01.10 Peer Health Assistance Organizations (PHAO)

18.01.11 Eligibility for Awards.

In addition to the provisions of CRS 12-22-603(3)(c)(1) through (VII) a PHAO shall provide for licensees experiencing impaired practice as defined in CRS 12-22-602(2) the following:

a. An initial assessment and interview of licensees who apply to participate in the diversion program.

b. An initial evaluation report for the Rehabilitation Evaluation Committee within 10 working days of a licensee being referred by the REC.

c. Monitoring of the compliance of all licensees with recovery/treatment plan as established between the PHAO and the licensee.

d. Except as provided above, quarterly written reports to the REC for each licensee in the program.

e. Report(s) within 72 hours to the REC regarding any licensee's failure to comply with the contractual/recovery plan.

f. Phone contacts and provide a written notice to the REC within 24 hours or the next working day when any licensee is unsafe to practice with reasonable skill and safety.

g. A current network of treatment programs and support groups for referral of licensees.

h. Other duties as set forth in the contract with the Board of Pharmacy (“Board”).

18.01.12 Compliance Reports. Each PHAO and/or licensee shall provide to the REC compliance reports on the licensee in the diversion program on a quarterly basis. Compliance reports may include summaries of, but shall not be limited to:

a. Records of attendance at all prescribed therapeutic activities including, but not limited to, counseling sessions and group meetings.

b. Records of attendance and performance from the licensee's supervisor/employer.

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 licensee's recovery/treatment plan or licensee's contract with the REC.

18.01.13 Demographic Reports. Each PHAO shall provide to the REC on an annual basis demographic data including but not limited to:

a. Number of pharmacists and interns who are participants in the programs and who receive services from the PHAO.

b. Age and gender of the licensees who are in the program.

c. Practice setting.

d. Number of licensees who are in compliance with their treatment/recovery plan.

e. Number of licensees who are terminated from PHAO services for non-compliance.

f. Number of successful discharges.

18.01.14 Financial Reports. Each peer health assistance organization shall provide to the Board quarterly financial reports explaining how the funds were expended so as to comply with 12-22-604 (3) CRS.

18.01.15 Confidentiality.

18.01.16 Any compliance report submitted by a PHAO to the REC regarding a licensee in the diversion program shall be reported by case number, except as outlined below.

18.01.17 Reports provided to the REC by the PHAO will be maintained in the Board offices in the custody of the Program Administrator.

18.01.18 >Whenever any licensee fails to comply with his/her PHAO treatment/recovery plan such failure will be reported by the PHAO to the REC, which may report such non-compliance to the Board.

18.01.19 When a failure to comply with the PHAO treatment/recovery plan has been reported to the Board, the individual's REC records and reports will no longer be confidential from the Board under this program. Such reports and records shall be subject to the provisions of 24-72-203 CRS. and 24-4-104 CRS.

18.01.20 If a participant successfully completes the program, the participant's records in the possession of the REC shall be maintained for three years and then destroyed. Notice of intent to destroy a licensee's diversion program records shall be sent to the licensee's last known address 30 days prior to destruction.

18.02.10 Participants.

18.02.11 Eligibility. To be eligible for participation in the diversion program, a licensee shall:

a. Be a pharmacist or intern licensed by this state.

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

c. Voluntarily request admission into the program.

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

e. Bear the cost of the program.

f. Cooperate by providing such evaluation and treatment information, disclosure authorizations and releases of liability as may be requested by the REC and/or PHAO.

g. Sign a written agreement with the PHAO to comply with all elements of the diversion program including a recovery plan.

h. Sign a written agreement with the REC to comply with all elements of the diversion program.

18.02.12 Admission Procedures.

18.02.13 Each licensee requesting admission into the diversion program shall submit an application to the REC.

18.02.14 Licensees may self-report to the REC.

18.02.15 Each licensee requesting admission into the diversion program shall be available for an interview with selected members of the REC, upon such request by the committee.

18.02.16 Each licensee admitted will be assigned a case number by the PHAO for purpose of confidential identification during the licensee's participation in the program.

18.02.17 The licensee shall have his/her contract with the REC signed by an authorized representative of the REC. The contract is to be kept in the confidential files of the REC with a copy to the PHAO and the licensee.

18.02.18 The minimum term of any contract between the licensee and the REC shall be three years. The term of the contract may be extended and/or retroactive credit may be given at the discretion of the REC.

18.02.19 The licensee shall have a contract with the PHAO, signed by an authorized representative of the PHAO and others as necessary. The contract shall be kept in the PHAO confidential files with copies provided to authorized parties as needed.

18.02.20 The REC shall make recommendations to the Board for admission or denial of admission into the program, as well as continuation of practice and/or restriction of practice, as appropriate to the licensee, throughout the licensee's participation in the program.

18.02.21 The Board shall specify to the REC, in writing, any grounds for denial of a licensee's admission into the program.

18.02.22 Should the licensee request to practice while participating in the diversion program, such request shall be evaluated by the REC with input from the PHAO, and a recommendation made to the Board.

18.02.23 The Board may permit the continuation of practice, the removal from practice, or may place restrictions on the practice of the licensee as specified in 12-22-125(2)(a)(I) and/or (II)CRS as condition(s) of admission into the program.

18.02.24 If the Board receives a written complaint, that if proven would constitute a violation of 12-22-125(2)(a)(I) and/or (II)CRS, the licensee shall be notified and given 20 days from the date of the notice to respond to the Board.

18.02.25 If the Board has reasonable cause to believe that a licensee is in violation of 12-22-125(2)(a)(I) and/or (II)CRS, the Board may refer a licensee to the REC by formal motion for admission into the program.

18.02.26 If the PHAO reports to the REC that a licensee is unable to practice with reasonable skill and safety, such information and the case number of the licensee shall be disclosed to the Board within twenty-four hours or the next working day.

18.02.27 If the REC receives information from a PHAO, that if proven would constitute a violation of 12-22-125(2)(a)(I) and/or (II)CRS, the licensee named shall be advised by the REC to seek admission into the program within 20 days from the date of the notice. The licensee will notify the

REC of his/her actions.

18.02.28 If no response is received by the REC from the licensee within 20 days from the date of the notice, or the licensee refuses to apply for admission into the program, the REC shall notify the Board and the Board shall proceed with formal disciplinary action.

18.02.29 Successful Discharge from the Diversion Program

a. A licensee shall be considered to have completed the program when he/she has met the following conditions:

(1) Has been in compliance with all of the terms of the contract with the REC and has completed the contractual treatment program.

(2) Shall be available for an interview with two designated members of the REC upon request and reasonable notice.

b. A licensee is considered to have completed the program if he/she transfers his/her license to another state and submits to the jurisdiction of that state's Board of Pharmacy for a diversion program or for discipline, and the other state notifies the Colorado Board of Pharmacy of its action.

18.02.30 Termination of a Licensee from the Diversion Program

A licensee may be terminated from his/her contract with the REC for any of the following reasons:

a. Failure to comply with his/her treatment plan or any terms of the contract with the REC.

b. The licensee has become unsafe to practice with reasonable skill and safety.

c. Transfer to another state and failure to submit to that state's Board of Pharmacy for discipline or admission to a diversion program.

18.03.10 Rehabilitation Evaluation Committee.

18.03.11 Responsibilities. The committee shall be responsible for:

a. Entering into a contract with those licensees who are admitted into the program.

b. Informing each licensee admitted into the program of his/her rights and responsibilities under the program and the possible consequences of non-compliance.

c. Evaluation and recommendation to the Board regarding continuation of a contract between the Board and each PHAO receiving awards from the diversion fund.

d. Reporting to the Board.

e. Corresponding with the licensee regarding Board or REC actions.

f. Reviewing the reports submitted by the PHAO.

g. Notifying the licensee, the Board and the PHAO of the termination of any licensee from the program.

h. Destruction of all confidential material maintained by the REC three years after the licensee's successful completion of the program.

18.03.12 Administration.

18.03.13 The committee shall elect a chairperson and a vice-chairperson.

18.03.14 The Board shall provide adequate clerical support to maintain files, correspondence, and the routine business of the REC.